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Welcome from Co-Chairs

Dear SHSA Colleagues

We have reimagined the way we deliver the Symposium on HS Advances with this virtual conference and believe we have provided an innovative and outstanding learning environment that challenges our understanding about this devastating disease.

The Program Committee, led by Dr. Isabelle Delorme and Dr. Joslyn Kirby, has ensured the program continues to feature the most highly-regarded speakers in the field of HS. SHSA is a unique conference where you will be immersed in all aspects of HS, from epidemiology, clinical features, pathogenesis, as well as the latest medical and surgical treatments. The virtual platform has been custom-built to allow you to connect with colleagues, as well as to provide unparalleled access to sessions, poster presentations and our industry partners. Sessions will be recorded and posted to this site for viewing by SHSA attendees until September 2021!

While we may not be able to gather in person this year, we hope you will use the networking and social media features available on the virtual platform to reconnect with old colleagues and introduce yourselves to new colleagues. Thanks for being part of this virtual experience. And, until we meet again in person: September 2021 in Montreal. See you online!

Sincerely,



Dr. Isabelle Delorme President, CHSF and Co-Chair, SHSA 2020



Dr. Joslyn S. Kirby Co-Chair, SHSA 2020



Dr. Iltefat Hamzavi President, HSF

Planning Committee

Conference Co-Chairs

Isabelle Delorme, MD, President, Canadian Hidradenitis Suppurativa Foundation and Dermatologist, Dr. Isabelle Delorme Inc., Drummondville, QC, Canada

Joslyn S. Kirby, MD, Assoc. Professor and Vice Chair of Education, Depart. of Dermatology, Pennsylvania State, Hershey, PA, USA

Committee Members

Afsaneh Alavi, MD, MSc, FRCPC, Professor, Div. of Dermatology, University of Toronto, Women's College Hospital, Toronto, ON, Canada

Raed Alhusayen, MBBS, MSCE, FRCPC, Assoc. Professor, University of Toronto, Assoc. Scientist, Sunnybrook Research Institute, Dermatology, Sunnybrook Health Sciences Centre, Toronto, ON, Canada

Marc Bourcier, MD, FRCPS, Dermatologist, Durondel CP, Moncton, NB, Canada

Angel Byrd, MD, PhD, Asst. Professor | Adjunct Asst. Professor, Dermatology, Howard University College of Medicine | Johns Hopkins University School of Medicine, Washington, DC, USA

Steven Daveluy, MD, FAAD, Associate Professor and Program Director, Dept of Dermatology, Wayne State University, Detroit, MI, USA

Ralph George, MD, FRCS, Associate Professor, General Surgery, University of Toronto, Medical Director, CIBC Breast Centre, St. Michael's Hospital, Toronto, ON, Canada

Stephanie Goldberg, MD, Assoc. Professor of Surgery, Medical Director VCU ACCESS, Virginia Commonwealth University School of Medicine, Richmond, VA, USA

Sandra Guilbault, Director, Community Lead, Hope for HS, Detroit, MI, USA

Iltefat Hamzavi, MD, FAAD, President HSF, Dermatologist, Department of Dermatology, Henry Ford Hospital and Hamzavi Dermatology, Detroit, MI, USA

Paul Hazen, MD, Case-Western Reserve University School of Medicine, Clinical Associate Professor of Dermatology, Ohio University College of Osteopathic Medicine, Director, Division of Dermatology, Fairview General Hospital, Loraine, OH, USA

Hadar Lev-Tov, MD, MAS, Assistant Professor, Dr. Philip Frost Department of Dermatology and Cutaneous Surgery, University of Miami, Miller School of Medicine, Miami, FL, USA

Michelle Lowes, MB.BS, PhD, Co-Chair SHSA 2019, Physician, The Rockefeller University, New York, NY, USA

Angela Miller, Clinical Research Manager, Department of Dermatology, Henry Ford Health Systems, National Director, HS Foundation, Detroit, MI, USA

Elizabeth O'Brien, MD, Associate Professor, Internal Medicine, McGill University, Senior Staff, Dermatolgoy, Montreal General Hospital, Montreal, QC, Canada

Vincent Piguet, MD, PhD, FRCP (London), Division Director, Dermatology, University of Toronto and Division Head, Dermatology, Women's College Hospital, Toronto, ON, Canada

Se Mang (Simon) Wong, MD, FRCPC, Clinical Associate Professor, Director Undergraduate Education, UBC Department of Dermatology and Skin Science, Vancouver, BC, Canada



Sponsors

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General Information

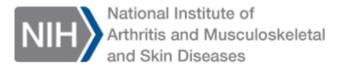
Accreditation

This event is an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification Program of The Royal College of Physicians and Surgeons of Canada, and approved by the Canadian Dermatology Association. You may claim a maximum of 7.5 hours.

Certificate of Attendance

Certificates of Attendance will be emailed to delegates following the conference.

NIAMS Support



Profound thanks to Dr. Ricardo Cibotti and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) for their support of the SHSA meeting and HS research.

Funding for this conference was made possible in part by R13AR077976 from NIAMS. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government



Invited Speakers



Angel Byrd, MD, PhD
Assistant Professor | Adjunct Professor, Depts of Dermatology, Howard
University College of Medicine | Johns Hopkins University School of
Medicine, Washington, DC, USA

Angel was born and raised in Edwards and Jackson, Mississippi. She obtained her BS ('04) from Tougaloo College in Tougaloo, Mississippi and MD ('16), PhD ('14) from Warren Alpert Medical School of Brown University in Providence, Rhode Island. She completed an Ethnic Skin Postdoctoral Fellowship at Johns Hopkins University School of Medicine (JHUSOM) under the direction of Dr. Ginette Okoye. Currently, she is an Assistant Professor at Howard University College of Medicine and Adjunct Assistant Professor at JHUSOM (Departments of Dermatology) where her work centers on the establishment of tissue biobanks to understand the immunopathological mechanisms contributing to ethnic skin diseases, particularly among African-American patients with Hidradenitis Suppurativa.

Her main research focus is elucidating the unreported roles of neutrophils and the innate immunity in the induction of local and systemic immune dysregulation. Angel leads multidisciplinary collaborative projects with the overarching goal of establishing a scientifically-driven approach to treatment options for patients suffering from these debilitating diseases. She has contributed to the scientific literature, given numerous lectures, national/international talks, and has been featured on the *BET 33rd Annual UNCF An Evening of Stars*® international program, recognizing her as one who is "changing the face of science, one mind at a time."

Session 2: Basic & Translational Science Research Forum

Date: Saturday, October 10, 2020

Title: Translational Research – From biobank to bench: Understanding immune dysregulation in hidradenitis

suppurativa

Photo not available

Ricardo Cibotti, PhD

Program Director, Immunobiology and Immune Diseases of Skin Program, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Health, USA

Session 1 : Health Services & Epidemiology
Date: Saturday, October 10, 2020

Title: NIAMS Update



Wayne Gulliver, MD, FRCPC Dermatologist, Memorial University of Newfoundland, St. John's, NF, Canada

A Dermatologist experienced as a clinician, educator, administrator, clinical and basic science researcher. Has been in clinical practice for almost thirty years and has supervised over 250 clinical trials covering many aspects of dermatology with the focus in genetics, psoriasis, wound care, virology and hidradenitis suppurativa. He has more than 100 published papers authored or co-authored, as well as over 200 abstracts authored or co-authored. Professor and Chair of the Discipline of Medicine, Memorial University of Newfoundland (2009-2011), as well as Head of Dermatology, Faculty of Medicine, Memorial University of Newfoundland (1989-present). Adjunct Professor, Henan University of Traditional Chinese Medicine, and Zhengzhou University, Henan, PR China. Chair & Medical Director of NewLab Clinical Research Inc. (1996-2009),

Chief Scientific Officer, NewLab Life Sciences (2009-2011). Former President of Matrixx Cosmetic Laser Clinic, Vice-President of Focus Continuing Education Inc., Vice-President of the Canadian Dermatology Association (1996-1997) and Chair of the organizing committee for the CDA meeting (1996-1997), St. John's, Newfoundland. Former Chief, Division of Dermatology, Eastern Health, St. John's, Newfoundland (1996-2008). Co-founder of Newfound Genomics (a Newfoundland & Labrador based genomics company). Former member of the Governing Council of the National

Research Council (2003-2006); CEO of Advanced Immuni T Inc. (Canada) and Advanced Immuni T Inc. (USA) (2003-2005). Member of the Editorial Board for the Journal of Cutaneous Medicine and Surgery and Medical Editor The Chronicle of Skin & Allergy. Reviewer for Clinical and Experimental Dermatology, the BMJ (British Journal of Dermatology UK) and British Journal of Dermatology. Previous member of the College of Reviewers for the Canada Research Chairs Program (2007-2010), Chair, Newfoundland and Labrador Association of Technology Industries (NATI) (2008/09), Chair and Board Member, Newfoundland and Labrador Science Centre.

Session 4: Clinical Study Design and Outcome Measures

Date: Sunday, October 11, 2020

Title: The Outcome Measure May Vary By the Drug Mechanism of Action and Immune Mediated

Inflammatory Disease Being Treated



Mark Kirchhof, MD, PhD, FRCPC Head, Division of Dermatology, University of Ottawa, Ottawa, ON, Canada

Dr. Mark Kirchhof, MD, PhD, FRCPC obtained his Bachelor of Science in Molecular Biology from McMaster University before joining the MD/PhD program at Western University. His PhD research involved studies of the signalling pathways important to immune system regulation. He then went on to complete his dermatology residency at the University of British Columbia. He was the dermatology education director at Queen's University in Kingston for 3 years, coordinating and leading undergraduate, post-graduate and CME educational activities. He has published over 50 peerreviewed papers and maintains a keen interest in clinical and bench-to-bedside research. He has been invited to speak at local, national and international meetings.

He is now the head of the Division of Dermatology in Ottawa.

Session 3 : Clinical Management
Date : Sunday, October 11, 2020
Title : Treatment Combinations



Haley Naik, MD
Assistant Professor of Dermatology and Director, Hidradenitis Suppurativa Clinic, University of California, San Francisco, CA, USA

Haley Naik is Assistant Professor of Dermatology and Director of the Hidradenitis Suppurativa Clinic and Research Program at the University of California, San Francisco.

She completed medical school and dermatology residency at Harvard Medical School, and went on to complete a postdoctoral clinical research fellowship at the National Institutes of Health and received a Masters of Health Sciences from Duke University.

She established the UCSF Hidradenitis Suppurativa Clinic and Research Program in 2016, and the multi-center Hidradenitis Suppurativa PRospective Observational REgistry and bioSpecimen repoSitory (HS PROGRESS) in 2018. The primary goals of her research are to uncover the mechanisms underlying HS in order to identify novel therapeutic targets, and to better understand the impact of HS on the lives of people who live with this devastating disease.

In her free time, she enjoys puzzles, the beach, and traveling with her husband and 2 delightful daughters.

Session 1: Health Services & Epidemiology
Date: Saturday, October 10, 2020
Title: COVID19 Registry Discussion





Amanda M. Nelson, PhD Assistant Professor of Dermatology, Pennsylvania State University College of Medicine, Hershey, PA, USA

Amanda Nelson, PhD, is an Assistant Professor of Dermatology at the Pennsylvania State University College of Medicine in Hershey, PA. Dr. Nelson received her graduate degree in Molecular Medicine at the Pennsylvania State University College of Medicine where she studied the mechanism of action of isotretinoin in the treatment of acne vulgaris. Dr. Nelson completed two postdoctoral research fellowships in dermatology at Penn State and at Johns Hopkins University where she expanded her expertise in sebaceous glands, hair follicles, skin stem cells and wound healing. Her research interests lie in understanding the pathomechanisms of inflammatory skin diseases (acne, hidradenitis suppurativa) and the impact of the skin microbiome in inflammatory skin disease. Her work is supported by grants from NIH/NIAMS, American Acne and Rosacea Society, Hidradenitis Suppurativa Foundation and the Acne Cure Alliance. Dr. Nelson serves as a reviewer for multiple

journals including the Journal of Investigative Dermatology. Dr. Nelson has authored numerous manuscripts and book chapters on sebaceous glands, hair follicles and wound-healing and currently holds multiple patents related to her work.

Session 2: Basic & Translational Science Research Forum

Date: Saturday, October 10, 2020
Title: Microbiome Research



Christopher Sayed, MD Associate Professor, Dermatology, University of North Carolina at Chapel Hill, Durham, NC, USA

Dr. Sayed is an Associate Professor of Dermatology at the University of North Carolina at Chapel Hill where he also completed his undergraduate, medical school, and residency training. He is Director of the Hidradenitis Suppurativa Clinic at UNC where he focuses on a multidisciplinary approach including medical, laser, and surgical management of HS. He is a directing member of the HS Foundation, serves as medical lead the local chapter of the Hope for HS support group, and co-chaired development of the first North American Clinical Management Guidelines for HS. Current research efforts include roles as an investigator in clinical trials and basic science research exploring the underlying genetic mechanisms of HS.

Session 1: Health Services & Epidemiology

Date: Saturday, October 10, 2020

Title: Making the most out of visits with HS patients



Jerry Tan, MD, FRCPC Dermatologist, Windsor Clinical Research, Windsor, ON, Canada

Dr. Jerry Tan trained in internal medicine at the University of Toronto and in dermatology at University of British Columbia and University of Michigan. His general dermatology and aesthetic practices are in Windsor Ontario Canada. Dr. Tan conducts clinical trials research at Windsor Clinical Research, a clinical trials site in dermatology. Topics in dermatology of research interest include acne, rosacea, hidradenitis suppurativa. Additional interests include outcome measurements and informed shared decision making in dermatology. Dr. Tan's group has developed 3 patient decision aids in dermatology – acne, psoriasis and hidradenitis suppurativa. He currently chairs the working group on clinical practice guidelines of the Canadian Dermatology Association, and co-chairs the rosacea international consensus group (ROSCO) and the acne core outcomes research

network (ACORN). He has authored or co-authored more than 100 peer-reviewed publications.

Session 4: Clinical Study Design and Outcome Measures

Date: Sunday, October 11, 2020

Title: The HS-patient decision aid: practical aspects and future directions



Hessel van der Zee, PhD Dermatologist, Erasmus MC and DermHaven, Rotterdam, The Netherlands

In 2011, Hessel defended his PhD thesis: Hidradenitis suppurativa (HS); Pathogenesis and treatment of hidradenitis suppurativa (HS) at the Erasmus University of Rotterdam (Netherlands). His thesis contained fundamental laboratory research as well as clinical studies. Hereafter, during his training as a dermatologist, he remained active in the field of HS research supervising several PhD students. Since 2016 he works as a dermatologist at the department of dermatology Erasmus MC and DermaHaven in Rotterdam. He set up specialized HS consulting hours integrated research to improve patient care. In his research he has close collaborations with many international HS experts. Furthermore, he is a pro bono medical advisor for the Dutch HS patient foundation and founding member of the European HS foundation as well as the Dutch HS expert group. He participated in national and international HS guidelines. Till 2020, he has published over 70 peer-reviewed international papers.

Session 3: Clinical Management
Date: Sunday, October 11, 2020
Title: HS Clinical Phenotypes



SHSA 2020 Live Sessions Program

Overall Learning Objectives

- To highlight the current research ranging from the burden of the disease to the new treatment
- To discuss the latest innovations, discoveries and new treatment modalities related to HS
- To discuss experiences and unmet needs regarding HS research and management

Session times are noted in Eastern Time

Friday October 9, 2020

9:00 – 5:00	Sponsor Exhibit Profiles Poster Viewing SHSA Abstract Book Connect with fellow attendees	
	Visit at your leisure on the conference virtual platform	
12:00 – 2:00	Meet your Sponsor Reps in the Exhibitor Profiles Sponsor reps will be available at this time in video meeting rooms	
12:00 – 1:00	Patient Chat Room: Welcome Session is open to all Patients and Caregivers. This is an informal discussion	Moderators: Michelle Lowes, Joslyn Kirby
2:00 - 3:00	HCP Chat Room: HS Progress Session is open to all attendees.	Moderators: Michelle Lowes, Haley Naik
3:00 - 4:00	Satellite Symposium: Session is open to all SHSA Attendees.	
4:00 - 5:00	Meet your Sponsor Reps in the Exhibitor Profiles Sponsor reps will be available at this time in video meeting rooms	
4:00 - 5:00	Patient Chat Room: Finding Great HS Care Session is open to all Patients and Caregivers. This is an informal discussion	Moderator: Sandra Guilbault
4:00 - 5:00	HCP Chat Room: Mentorship – becoming an HS Expert Session is open to all new and experienced HS professionals with an interest in mentorship. This is an informal discussion.	Moderators: Steven Daveluy, Stephanie Goldberg

Saturday, October 10, 2020

9:00 – 5:00	Sponsor Exhibit Profiles Poster Presentations SHSA Abstract Book Connect with fellow attendees Visit at your leisure on the conference virtual platform	
9:00 - 10:00	Meet your Sponsor Reps in the Exhibitor Profiles Sponsor reps will be available at this time in video meeting rooms	
9:00 – 10:00	Patient Chat Room: Comorbidities of HS Session is open to all Patients and Caregivers. This is an informal discussion	Moderators: Raed Alhusayen, Isabelle Delorme

10:00 - 12:00	Session 1: Health Services & Epidemiology	Moderator: Joslyn S. Kirby
Learning Object	tives	
To disci	oribe recent data related to the epidemiology and burden of HS cuss HS Covid registry findings we research funding opportunities for HS	
10:00	NIAMS Update	Ricardo Cibotti
10:10	Making the most out of visits with HS patients	Christopher Sayed
10:30	COVID19 Registry Discussion	Haley Naik
10:50	Provider perspectives and practice patterns on the management of hidradenitis suppurativa in pregnancy	Jennifer Hsiao
10:58	Comorbidity screening in HS: evidence-based recommendations from the US and Canadian HSFs	Amit Garg
11:06	Outcomes of Pregnancy, Childbirth, and Pueperium	Surav M. Sakya
11:14	Pregnancy in HS: Patient perspectives and practice gaps	Natalie M. Villa
11:22	Pain severity and management of HS at Emergency Department Visits in the US	Matthew T. Taylor
11:30	Live Panel Q&A	All Presenters
12:00 – 12:30	Stretch Break, Visit the Sponsor Exhibit Profiles Sponsor reps will be available at this time in video meeting rooms	
12:00 – 12:30	Patient Chat Room: Treatment of HS – Medicines and Integrative Session is open to all Patients and Caregivers. This is an informal discussion.	Moderators: Simon Wong, Afsaneh Alavi, Vivian Shi
12:30 – 2:12	Session 2 - Basic & Translational Science Research	Moderator: Simon Wong
Learning Object	tive:	
To disci	cribe recent data related to the bench research pertaining to HS uss cutting edge translational research findings for HS9 ew the perturbations in the microbiome associated with HS	
12:30		
i -	Microbiome Research	Amanda M. Nelson
12:50	Microbiome Research Translational Research – From biobank to bench: Understanding immune dysregulation in hidradenitis suppurativa	Amanda M. Nelson Angel Byrd
12:50 1:10	Translational Research – From biobank to bench: Understanding immune	
	Translational Research – From biobank to bench: Understanding immune dysregulation in hidradenitis suppurativa	Angel Byrd
1:10	Translational Research – From biobank to bench: Understanding immune dysregulation in hidradenitis suppurativa Drug repurposing for hidradenitis suppurativa treatment	Angel Byrd Christos C. Zouboulis
1:10 1:18	Translational Research – From biobank to bench: Understanding immune dysregulation in hidradenitis suppurativa Drug repurposing for hidradenitis suppurativa treatment Immunopathogenesis of HS and Response to Therapy	Angel Byrd Christos C. Zouboulis Margaret M. Lowe
1:10 1:18 1:26	Translational Research – From biobank to bench: Understanding immune dysregulation in hidradenitis suppurativa Drug repurposing for hidradenitis suppurativa treatment Immunopathogenesis of HS and Response to Therapy Localization of Upregulated Proteins in Hidradenitis Suppurativa Expression of antimicrobial peptides in lesional keratinocytes of patients with	Angel Byrd Christos C. Zouboulis Margaret M. Lowe Courtney A. Prestwood



Sunday, October 11, 2020

9:00 – 5:00	Sponsor Exhibit Profiles Poster Presentations SHSA Abstract Book Connect with fellow attendees Visit at your leisure on the conference virtual platform	
9:00 – 10:00	HCP Chat Room: Surgery Session is open to all HCPs interested in Surgery	Moderators: Stephanie Goldberg, Ralph George
9:30 – 10:00	Meet your Sponsor Reps in the Exhibitor Profiles Sponsor reps will be available at this time in video meeting rooms	
9:30 – 10:00	Patient Chat Room: Conversations with Clinicians Session is open to all Patients and Caregivers. This is an informal discussion	Moderators: Elizabeth O'Brien, Afsaneh Alavi, Iltefat Hamzavi
10:00 – 12:00	Session 3 - Clinical Management	Moderator: Isabelle Delorme
To discu	ew the treatment of HS, including multimodality treatment uss research related to HS phenotypes wribe recent data related to the novel HS therapeutics	
10:00	Treatment Combinations	Mark Kirchhof
10:20	HS Clinical Phenotypes	Hessel van der Zee
10:40	Antibiotherapy targeted against hidradenitis suppurativa flora may significantly improve inflammatory bowel disease symptoms	Aude S. Nassif
10:48	Prevalence and Risk Factors for Anemia in a Population with Hidradenitis Suppurativa	Sydney R. Resnik
10:56	A Randomized, Placebo-Controlled, Phase 2 Study of the Janus Kinase 1 Inhibitor INCB054707 for Patients With Moderate-to-Severe Hidradenitis Suppurativa	Afsaneh Alavi
11:04	A Patient Survey of Pain Management Modalities used in Hidradenitis Suppurativa	Jennifer M. Fernandez
11:12	Diet, supplementation, and topical home remedies in HS: is there an adjunctive role?	Annika S. Silfvast- Kaiser
11:20	The Use of Brodalumab in Hidradenitis Suppurativa: Results from Two Open Label Cohort Studies	John W. Frew
11:28	Live Panel Q&A	All Presenters
12:00 – 12:30	Virtual Stretch Break / Visit the Sponsor Exhibit Profiles Sponsor reps will be available at this time in video meeting rooms	
12:00 – 12:30	Patient Chat Room: Treatment of HS Procedures Session is open to all Patients and Caregivers. This is an informal discussion	Moderators: Ralph George, Elizabeth O'Brien

12:30 – 14:20	Session 4 – Clinical Study Design and Outcome Measures	Moderator: Stephanie Goldberg
Learning Object	tive	
	uss research findings for novel HS outcome measures	
	cribe research pertaining to HS disease states and measurement	
To revie	ew aspects of clinical trial design for HS	
12:30	The HS-patient decision aid: practical aspects and future directions	Jerry Tan
12:50	The Outcome Measure May Vary By the Drug Mechanism of Action and Immune Mediated Inflammatory Disease Being Treated	Wayne Gulliver
13:10	Evaluating the responsiveness and score bands of the HiSQOL, a novel HS- specific patient-reported outcome measure	Joslyn S. Kirby
13:18	Novel approach to HS flare measurement using patient-reported outcomes	Joslyn S. Kirby
13:26	Quantifying the Natural Variation in Lesion Counts Over Time in Untreated Hidradenitis Suppurativa: Implications for Outcome Measures and Trial Design	John W. Frew
13:34	Do HS trial participants reflect the HS patient population?	Victoria M. Madray
13:42	Development and validation of an Investigator Global Assessment in HS	Amit Garg
13:50	Live Panel Q&A	All Presenters
14:20 – 14:35	Closing Remarks	Iltefat Hamzavi Joslyn Kirby Isabelle Delorme
	Patient Perspective	Sandra Guilbault
14:35 – 15:05	Meet your Sponsor Reps in the Exhibitor Profiles Sponsor reps will be available at this time in video meeting rooms	
14:35 – 15:05	Patient Chat Room: Thank you and wrap-up Session is open to all Patients and Caregivers. This is an informal discussion	Moderators: Michalle Lowes, Joslyn Kirby



Abstracts

Session 1 – Health Services and Epidemiology

Saturday, October 10, 2020

10:00 - 12:00 ET

10:00 - 10:10 am

NIAMS Update

Ricardo Cibotti, PhD

Program Director, Immunobiology and Immune Diseases of Skin Program, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Health, USA

Summary not available

10:10 - 10:30 am

Making the most out of visits with HS patients

Christopher Sayed, MD

Associate Professor, Dermatology, University of North Carolina at Chapel Hill, Durham, NC, USA

Patients with HS have often faced difficult disease and lengthy diagnostic delays. By the time they reach your office there is a lot to talk about and the need to develop a plan of care. It can often feel difficult to dedicate the time needed to provide counseling and settle on a treatment plan. In this lecture, focus will be placed on how to effectively gather patient history, provide important education, develop a treatment plan, set expectations and plan for short and long term improvement.

Learning objectives:

- Understand how to efficiently gather history while acknowledging challenges that patients have faced
- Provide important education on hidradenitis, its treatment options and expectations for the course of management.
- Understand how to assess extent of disease during the physical exam

10:30 - 10:50 am

COVID-19 Registry Discussion

Haley Naik, MD

Assistant Professor of Dermatology and Director, Hidradenitis Suppurativa Clinic, University of California, San Francisco, CA, USA

Summary not available

10:50 - 10:58 am

Provider Perspectives and Practice Patterns on the Management of Hidradenitis Suppurativa in Pregnancy

Erin K. Collier¹, Kyla Price², Tristan Grogan³, Jennifer Fernandez⁴, Raed Alhusayen⁵, Afsaneh Alavi⁶, Iltefat Hamzavi⁷, Michelle Lowes⁸, Martina Porter⁹, Vivian Y. Shi¹⁰, Jennifer L. Hsiao¹¹

Affiliations:

- ¹David Geffen School of Medicine, University of California, Los Angeles
- ²College of Medicine, University of Illinois, Chicago, IL, USA
- ³Department of Medicine Statistics Core, David Geffen School of Medicine, University of California, Los Angeles, CA, USA ⁴University of Arizona College of Medicine, Tucson, AZ, USA
- ⁵Division of Dermatology and Sunnybrook Research Institute, University of Toronto, ON, Canada
- ⁶Division of Dermatology, Women College Hospital, University of Toronto, Toronto, Canada
- ⁷Department of Dermatology, Henry Ford Hospital, Detroit, MI
- ⁸The Rockefeller University, New York, NY USA
- ⁹Department of Dermatology, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, Massachusetts, USA
- ¹⁰Department of Dermatology, University of Arkansas for Medical Sciences, USA
- ¹¹Division of Dermatology, Department of Medicine, David Geffen School of Medicine, University of California, Los Angeles

Introduction: There is a lack of consensus on the management of HS during pregnancy as well as lack of information on safety of HS therapies during pregnancy.

Methods: An anonymous, web-based questionnaire was distributed to online listservs, including "HS Place" (an online forum for specialty HS providers sponsored by the United States HS Foundation) and the Canadian HS Foundation between March and May 2020.

Results: A total of 49 physician survey respondents participated in the study. Mean number of patients seen per month by survey respondents was 37.1 +/- 35.8 (range 3-200). The majority of respondents (73%) direct an HS specialty clinic. Most participants were comfortable prescribing topical medications (47/49, 96%), systemic antibiotics (37/49, 76%), and biologics (32/49, 65%) and performing office-based procedural interventions (43/49, 88%). 59% of participants reported having prescribed or continued the use of biologics for HS management of pregnant patients. Biologics that were reported to have been prescribed or continued in pregnant HS patients included adalimumab (26/29, 90%), infliximab (12/29, 41%), certolizumab (10/29, 34%), and secukinumab and ustekinumab (both 1/29, 3%). Nearly half of respondents (21/49, 43%) reported that their general approach is to keep a patient on a biologic throughout pregnancy, with 20% (10/49) tending to discontinue biologics in the 3rd trimester, and the remaining 37% (18/49) preferring to stop the biologic earlier.

Conclusion: HS specialists overall feel comfortable with managing pregnant HS patients, however, there exists variation on use of biologics during pregnancy. More data is needed on the safety and efficacy of biologics and of procedural treatments such as laser therapy to treat pregnant HS women. A prospective registry collecting data on HS treatment strategies and outcomes during pregnancy would be beneficial. Future studies on general dermatologist perspectives is warranted to determine comfort levels among non-HS specialists.

Learning Objectives:

- To understand provider comfort in managing pregnant patients with HS
- To investigate HS specialists' practice patterns when caring for pregnant HS patients
- To determine types of biologics used, and timing of use, in treatment of HS in pregnant patients

Takeaway Message:

• Further investigation on safety, efficacy, and optimal timing of use of biologics and procedural treatments such as lasers for HS during pregnancy is warranted.

10:58 - 11:06 am

Comorbidity Screening in Hidradenitis Suppurativa: Evidence-based Recommendations from the US and Canadian Hidradenitis Suppurativa Foundations

Amit Garg¹, Neeta Malviya¹, Andrew Strunk¹, Shari Wright¹, Afsaneh Alavi², Raed Alhusayen²¹, Ali Alikhan³, Steven D. Daveluy⁴, Isabelle Delorme⁵, Noah Goldfarb⁶, Wayne Gulliver⁷, Iltefat Hamzavi⁸, Tarannum Jaleel⁹, Alexa Kimball¹⁰, Joslyn Kirby¹¹, Mark Kirchhof¹², Janice Lester¹, Hadar Lev-Tov¹³, Michelle Lowes¹⁴, Robert Micheletti¹⁵, Lauren A. Orenstein¹⁶, Vincent Piguet¹⁷, Christopher Sayed¹⁸, Jerry Tan¹⁹, Haley Naik²⁰

1. Zucker School of Medicine at Hofstra Northwell, New Hyde Park, NY, USA, 2. Faculty of Medicine, Women College Hospital, University of Toronto, Toronto, YT, Canada, 3. Sutter Medical Foundation, Sacramento, CA, USA, 4. Wayne State University School of Medicine, Detroit, MI, USA, 5. Dr Isabelle Delorme Inc., Drummondville, QC, Canada, 6. Minneapolis VA Health Care System, Minneapolis, MI, USA, 7. Memorial University of Newfoundland, St John's, NL, Canada, 8. Henry Ford Hospital, Detroit, MI, USA, 9. Duke University School of Medicine, Durham, NC, USA, 10. Beth Israel Deaconess Medical Center, Boston, MA, USA, 11. Penn State Milton S Hershey Medical Center, Hershey, PA, USA, 12. University of Ottawa and The Ottawa Hospital, Ottawa, NW, Canada, 13. University of Miami, Miami, FL, USA, 14. Rockefeller University, NYC, NY, USA, 15. University of Pennsylvania, Philadelphia, PA, USA, 16. Emory University School of Medicine, Atlanta, GA, USA, 17. Women's College Hospital, Toronto, ON, Canada, 18. University of North Carolina at Chapel Hill, Durham, NC, USA, 19. University of Western Ontario, Ontario, ON, Canada, 20. University of California, San Francisco, CA, USA, 21. University of Toronto, Toronto, ON, Canada

Importance: Hidradenitis suppurativa (HS) is associated with comorbid conditions that contribute to poor health, impaired quality of life, and increased mortality risk.

Objective: To provide evidence-based screening recommendations for comorbid conditions linked to HS.

Evidence Review: A series of systematic reviews were performed to summarize evidence on prevalence and incidence of 30 comorbid conditions in HS patients relative to the general population. Recommendation to screen for each comorbidity



were informed by the consistency and quality of existing studies, disease prevalence and magnitude of association with HS, and benefits, harms, and feasibility of screening. Level of evidence and strength of the corresponding screening recommendation for each comorbidity were graded using SORT criteria.

Findings: Screening is recommended for the following comorbidities: acne, dissecting cellulitis of the scalp, pilonidal disease, pyoderma gangrenosum, depression, generalized anxiety disorder, suicide, smoking, substance use disorder, polycystic ovarian syndrome, obesity, dyslipidemia, diabetes mellitus, metabolic syndrome, hypertension, cardiovascular disease, inflammatory bowel disease, spondyloarthritis and sexual dysfunction. It is also recommended to screen Down syndrome patients for HS. Decision to screen for specific comorbidities may vary with patient risk factors. The role of the dermatologist in screening varies according to comorbidity.

Level of evidence and strength of comorbidity screening recommendations in hidradenitis suppurativa

Comorbidity in HS	Level of Evidence	Strength of Recommendation	Is Screening Recommended?*
Acne	II	В	Yes
Dissecting cellulitis of scalp	II	В	Yes
Pilonidal cyst	II	В	Yes
Pyoderma gangrenosum	II	В	Yes, for patients with ulcerations, regardless of IBD status
Depression	II	В	Yes
Anxiety	II	В	Yes
Suicidality	II	В	Yes, for patients who have known psychiatric disease, including substance use, or those who exhibit signs of psychological distress
Tobacco	II	В	Yes
Substance misuse	II	В	Yes, for patients with chronic pain, depression or anxiety
Polycystic ovarian syndrome	II	В	Yes
Obesity	II	В	Yes
Dyslipidemia	II	В	Yes
Diabetes mellitus	II	В	Yes
Metabolic syndrome	II	В	Yes
Hypertension	II	В	Yes
Cardiovascular disease	II	В	Yes
Inflammatory Bowel Disease	II	В	Yes
Spondyloarthritis	II	В	Yes
Sexual dysfunction	II	В	Yes

Trisomy 21	II	В	Yes, screening patients with trisomy 21 for HS	
Thyroid disease			Insufficient evidence	
Non-alcoholic fatty liver disease			Insufficient evidence	
Obstructive sleep apnea			Insufficient evidence	
Renal disease			Insufficient evidence	
Sleep disturbances			Insufficient evidence	
Alzheimer's disease	II	В	No	
Herpes zoster	II	В	No	
Lymphomas	II	В	No	
Psoriasis vulgaris	II	В	No	

Conclusions and Relevance: Dermatologists should support screening efforts to identify comorbid conditions in HS.

Learning Objectives:

- To provide systematic review of comorbidities in HS
- To provide screening recommendations on comorbid conditions in HS

Takeaway Message:

Hidradenitis suppurativa has a high comorbidity burden. Dermatologists may play a role in advancing overall health for patients with HS.

11:06 - 11:14 am

Outcomes of Pregnancy, Childbirth, and the Pueperium in Women with Hidradenitis Suppurativa in the United States

Surav M. Sakya¹, David R. Hallan², Steven A. Maczuga², Joslyn S. Kirby²

1. Penn State College of Medicine, Hershey, PA, USA, 2. Penn State Milton S. Hershey Medical Center, Hershey, PA, USA

Introduction: Most women affected by hidradenitis suppurativa (HS) are of childbearing age. Multiple different factors, including immune, metabolic and hormonal imbalances during pregnancy may change the clinical course of HS. Our retrospective study sought to understand the pregnancy-related outcomes in HS. The objective was to investigate maternal and obstetric outcomes in HS-associated pregnancies in the United States.

Methods & Results: This was a retrospective cohort study that utilized claims-based data from the IBM MarketScan Commercial Claims and Encounters Database from January 2015 to December 2017. Cohorts of women with or without HS were created based on diagnostic (ICD-10) codes. Outcomes during pregnancy, childbirth, and the pueperium were compared between the two cohorts. Outcomes included abortion, pre-eclampsia/ eclampsia, and gestational hypertension, and delivery methods.

Overall, 13,478 women with HS were identified and compared to a random cohort of 67,390 women without HS. Mean age from both cohorts was 25.2 years old. The control group had proportionally higher livebirths than the HS group [3,583 (5.3%) vs. 519 (3.9%); p<0.0001]. The HS group had proportionally more elective terminations than the control group [287 (2.1%) vs. 663 (1.0%); p<0.0001]. Moreover, the HS group had significantly higher proportions of pre-eclampsia/ eclampsia [44 (8.5%) vs. 188 (5.3%); p=0.003] and gestational hypertension [90 (17.3%) vs. 319 (8.9%); p<0.0001]. The control group had a significantly higher probability of vaginal delivery [2,156 (60.2%) vs. 282 (54.3%); p=0.0115], whereas the HS group had a significantly higher probability of cesarean delivery [193 (37.2%) vs. 1,137 (31.7%); p=0.013]. Women with HS had proportionally higher use of topical medications [78 (15.0%) vs. 120 (3.4%); p<0.0001] and oral antibiotics [55 (10.6%) vs.





57 (1.6%); p<0.0001] and significantly higher probability of cutaneous surgeries before delivery [97 (18.7%) vs. 46 (1.3%); p<0.0001].

Conclusions: The results of our study showed that women with HS have an increased probability of complicated maternal and obstetric outcomes. This may be due to the chronic inflammatory processes that underlie HS or differences in health service application for women with HS.

Learning Objectives:

- Investigate the outcomes of pregnancy, childbirth, and the pueperium in women with HS in the United States.
- Compare the pregnancy and abortive outcomes, pre-eclampsia/ eclampsia and gestational hypertension incidence, treatments before delivery and delivery methods between pregnant women with HS and those without HS.
- Review the literature on HS and pregnancy and discuss special considerations and practical recommendations to help HS women with family planning.

Takeaway Message:

This study found that women with HS have an increased probability of complicated maternal and obstetric outcomes, including elective terminations, pre-eclampsia/ eclampsia, gestational hypertension and cesarean deliveries.

11:14 - 11:22 am

Pregnancy in HS: Patient perspectives and practice gaps

Ademide Adelekun¹, Natalie M. Villa², Jennifer L. Hsiao², Robert G. Micheletti³

1. Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA, 2. Division of Dermatology, Department of Medicine, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, USA, 3. Departments of Dermatology and Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

Introduction: Hidradenitis suppurativa (HS) is a chronic inflammatory disease disproportionately affecting women of reproductive age. Study of other inflammatory conditions has shown that they may significantly impact pregnancy outcomes, including pregnancy loss and preterm birth.(1) However, there is a paucity of data regarding the impact of HS on pregnancy, limiting the ability of physicians to comprehensively counsel patients.(2) This study characterizes patient perspectives and practice gaps related to pregnancy and childbirth amongst women with HS.

Methods/Results: Anonymous electronic surveys were distributed to 172 female HS patients, age 18-40. 59 responded (34.3% response rate) with a mean (SD) age of 32 (5.4) years. 29 respondents (49%) reported ever being pregnant, with 17 (59%) reporting their most recent pregnancy was planned.

43 women (73%) reported that HS negatively impacts their sexual health. Nearly half of respondents (49%) believed pregnancy requires discontinuation of all HS medications for safety reasons. One fifth (12/59) believed HS poses risks to the child, including via transmission of HS (8/12, 67%) or infection (7/12, 58%) during vaginal delivery. Most patients reported that they have not received counseling on how HS impacts pregnancy (83%), heritability of HS (80%), sexual health (76%), or the impact of HS medications on pregnancy (71%). A majority (54%) preferred that their doctor provide more counseling on HS and pregnancy.

Conclusions: These findings identify patient concerns regarding the impact of HS on reproductive health, highlighting a practice gap in counseling and reflecting a general paucity of data on HS and pregnancy. Family planning and improved prenatal counseling are relevant to guide decision-making regarding treatment choices, balancing drug safety with disease control in the setting of pregnancy and lactation. Study limitations include response rate, recall bias, and generalizability to non-academic settings.

References:

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- Adelekun AA, Micheletti RG, Hsiao JL. Creation of a Registry to Address Knowledge Gaps in Hidradenitis Suppurativa and Pregnancy. JAMA Dermatol. Published online January 8, 2020. doi:10.1001/jamadermatol.2019.4162

Learning Objectives:

HS patients express significant concerns regarding the impact of HS on pregnancy and childbirth, in addition to a desire to further understand this relationship. Practice gaps identified include the lack of adequate counseling regarding HS and impact

on sexual health and pregnancy; many HS patients perceived a need to discontinue all HS medications during pregnancy and harbored misconceptions about the heritability of HS.

Takeaway Message:

HS patients expressed a desire for increased counseling regarding the impact of HS on sexual health, pregnancy, and childbirth, representing an important clinical practice gap that warrants further study.

11:22 - 11:30 am

Pain severity and management of HS at Emergency Department Visits in the US

Matthew T. Taylor¹, Lauren A. Orenstein², John S. Barbieri³

1. Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA, USA, 2. Department of Dermatology, Emory University School of Medicine, Atlanta, GA, USA, 3. Department of Dermatology, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA, USA

Introduction: Emergency department (ED) utilization is common among patients with hidradenitis suppurativa (HS). Both opioid and antibiotic prescribing are common at ambulatory encounters for HS; however, little is known about prescribing patterns and management of HS at ED visits, specifically.

Methods/Results: We analyzed data from 2006-2017 from the National Hospital Ambulatory Care Survey, which is a nationally-representative sample of visits to EDs in the United States. We identified encounters for HS using *ICD-9-CM* code 705.83 and *ICD-10-CM* code L73.2. We calculated rates of pain severity upon presentation and estimated opioid and antibiotic prescribing at discharge as well as incision and drainage (I&D) procedures among HS visits. For comparison, we also analyzed pain severity and rates of opioid prescribing at visits for atopic dermatitis or psoriasis.

There were an estimated 383,000 ED visits for HS. Severe pain was reported at 69.9% of visits and 40.1% reported 10/10 pain. At discharge, opioids (58.3%; 95% CI: 41.0-73.8) and antibiotics (66.6%; 95% CI: 49.1-80.5) were commonly prescribed. Clindamycin, trimethoprim/sulfamethoxazole, and cephalosporins were the most commonly prescribed antibiotics. I&D was performed at approximately 28.9% (95% CI: 15.5-47.5) of ED visits. In comparison, severe pain (13.9%; 95% CI: 6.6-26.8) and opioid prescribing rates (4.0%; 95% CI: 1.5-10.2) were significantly lower at ED visits for atopic dermatitis and psoriasis. Concomitant diagnoses of cellulitis and abscess were relatively common at visits for HS at a rate of 20.8% (95% CI: 11.2-35.3).

Conclusion: Our findings demonstrate that severe pain is common among patients with HS presenting to the ED and opioids are frequently prescribed. These findings raise concern as HS is associated with long-term opioid utilization. The majority of antibiotic prescribing in the ED setting was for classes not generally recommended for HS, which may be related to misdiagnosis of HS lesions as skin and soft tissue infections. These findings demonstrate that improved management of HS and early referral to dermatology may lead to decreased ED visits and improved quality of life in patients with HS.

Learning Objectives:

- Severe pain is commonly reported at ED visits for HS and opioids are prescribed at high rates upon discharge.
- Antibiotics are frequently prescribed at discharge at ED visits, though most antibiotics prescribed are not in line with current HS guidelines.
- Prescribing patterns and pain severity at ED visits for HS likely reflect poorly managed and underrecognized disease.

Takeaway Message:

Management of HS in the ED is not optimal and may pose unnecessary health risks to patients; early referral to dermatology may limit ED visits and prevent adverse health outcomes.



Session 2 – Basic and Translational Science Research Forum Saturday, October 10, 2020 12:30 – 2:20 ET

12:30 - 12:50 pm

Microbiome Research

Amanda M. Nelson, PhD

Assistant Professor of Dermatology, Pennsylvania State University College of Medicine, Hershey, PA, USA

Learning Objectives:

- To understand how skin microbiome studies in HS are conducted, analyzed and interpreted.
- To review our current understanding the skin microbiome's role in HS psychophysiology

12:50 - 1:10 pm

Translational Research – From biobank to bench: Understanding immune dysregulation in hidradenitis suppurativa

Angel Byrd, MD, PhD

Assistant Professor | Adjunct Professor, Depts of Dermatology, Howard University College of Medicine | Johns Hopkins University School of Medicine, Washington, DC, USA

Although the definitive etiology of Hidradenitis suppurativa (HS) is poorly understood, the underlying theme of contributing mechanisms appears to be progressive and recurrent inflammation. Studies have shown genetic, microbiome, obesity, and smoking correlations, as well as predominance in African American females. Surgical resection of affected areas is often the best responsive treatment. We sought to establish an HS tissue biobank to study the role of the host immune response in HS. Using collected biospecimens we have shown a potential role of macrophage-mediated upregulation of CCL18 and fibroblast-mediated collagen production, which may result in chronic HS lesions. We have also shown neutrophil-mediated immune dysregulation. In chronic HS lesions, neutrophils were the predominant extravasated leukocyte in the dermis. Rupture and neutrophilic inflammation often occurred with neutrophil extracellular trap (NET) formation within HS lesions, and has shown a positive correlation with disease severity. Interestingly, NETs detected in HS lesions were in close proximity to plasmacytoid dendritic cells (CD303), which likely contributed to the type 1 interferon signature. Additionally, plasma cells and IgG were identified in HS lesions. Peptidylarginine deiminases (PADs) 1 to 4 enzymes were detected via immunofluorescence, which mediates citrullination within HS lesions. In summary, immune dysregulation seen in HS is a major component of the disease pathogenesis. Despite studies that have been done to better understand the immunopathological mechanisms, major gaps in our understanding persist. Ex vivo and potential in vivo studies provide promising advances in HS research, which would aid in the identification of cellular crosstalk to enhance the development of targeted treatments to improve patient outcomes.

Learning Objectives:

- Overview of the establishment of an HS biobank
- Understand the immunopathological mechanisms is HS
- 3.Discuss the importance and utility of ex vivo and in vivo studies to advance the field

1:10 - 1:18 pm

Drug repurposing for hidradenitis suppurativa treatment

Christos C. Zouboulis^{1, 2}, André Nogueira da Costa³

1. Departments of Dermatology, Venereology, Allergology and Immunology, Dessau Medical Center, Brandenburg Medical School Theodor Fontane, Dessau, Germany, 2. European Hidradenitis Suppurativa Foundation e.V., Dessau, Germany, 3. Precision Medicine and Biosamples, Oncology R&D, AstraZeneca, Gothenburg, Sweden

Introduction: Hidradenitis suppurativa is a complex, chronic inflammatory disease of unknown etiology. It has, therefore, seen a limited number of therapeutic options coming into the market until now. Discovery of novel actors involved in the aetiopathogenesis of diseases and possible treatment candidate targets through integrated approaches using combined molecular tools has currently gained strong interest in complex diseases. In addition to innovative compounds drug repurposing resulting from alternative druggable therapeutic targets can be deployed in a clinical setting.

Methods/Results: Transcriptome data from public data repositories were preprocessed and analysed using the limma package in R with significantly dysregulated genes identified based on 2-fold change in intensity values, FDR<0.05, and Fisher's exact test (p<0.01). Selected genes were further investigated using Enrichr, integrated network-based cellular signatures (LINCS) direction signature search engine and Drug Gene Interaction Database (DGldb). Transcriptome and LINCS L1000 analysis identified a panel of 26 single-gene perturbations that were proposed as key potential HS molecular mediators. Gene-drug interaction analysis utilizing DGldb confirmed that 15 of the key HS molecular mediators – *AR*, *EGF*, *FGF1*, *GAS6*, *GDNF*, *HGF*, *IFNα*, *IFNγ*, *IGF2*, *IL-1/IL-1α*, *IL-17/IL-17α*, *IL-4*, *IL-6*, *MCSF/CSF1*, *TNF/TNFα* – showed to be known druggable targets. Therapeutic target-therapeutic agent binomials were validated utilizing publicly available transcriptomes from other studies and through current clinical disease management, indicating potential repurposing of registered drugs (Table). Moreover, key molecular mediators were identified, which were not detected in previous studies, such as FGF1, KGF and SCF, with FGF1 proposed as therapeutic targets.

Therapeutic agents associated with more than one key HS molecular mediators identified by Zouboulis et al. J Eur Acad Dermatol Venereol 2020;34:846-61 (GSE137141) and Zouboulis et al. J Eur Acad Dermatol Venereol 2020;[online ahead of print] (GSE144801).

The interaction between the molecular mediator and therapeutic agents is based on publicly available databases and focuses on compounds that have been reported as modulators of a specific gene. FDA approved therapeutic agents are also included.

Molecular mediator	Therapeutic agent identified	Molecular and clinical function	Source supporting mediator- therpeutic agent interaction (byond Pubmed.gov)
GAS6 + IL17/IL17A + TNF/TNFα	GENTAMYCIN	Aminoglycoside mixture - disrupting the ability of the bacteria to construct proteins	NCI
GDNF + IL6 + TNF/TNFα	IBUDILAST	PDE4 inhibitor, TLR4 antagonist – antiinflammatory compound	DrugBank, TTD
AR + TNF/TNFα	SPIRONOLACTONE	Mineral corticosteroid receptor competitive antaonist - potassium-sparing diuretic, antiandrogen	DrugBank, NCI
HGF + IFNy	TRASTUZUMAB	Herceprin 2 receptor monoclonar antibody – Antitumor agent against epithelial tumours	CGI, NCI
HGF + TNF/TNFα	THALIDOMIDE	Piperidindione - Sedative, hypnoticum, immunosuppressive compound	NCI, Tdg Clinical Trial, TEND, DrugBank, TTD
IFNγ + TNF/TNFα	APREMILAST	PDE4 inhibitor – antiinflammatory, immunoregulatory compound	DrugBank
	GLUCOSAMINE	Monosaccharide - Precursor in the biochemical synthesis of glycosylated proteins and lipids	DrugBank
IFNγ + IL6	INTERFERON-α-2b	Synthetic interferon alpha - Antiviral, antitumoral, im-munoregulatory, antiprolif-erative properties	NCI
IL6 + TNF/TNFα	BINIMETINIB	Mitogen-activated protein kinase inhibitor – Antitumoral activities	DrugBank
	MIDOSTAURIN	Tyrosine kinase inhibitor – Antitumoral properties	NCI
	•	•	•

AR: Androgen Receptor; GAS6: Growth Arrest-Specific 6; HGF: Hepatocyte Growth Factor; IFNy: Interferon-y; IL6: Interleukin-6; TNF/TNFa: Tumor Necrosis Factor/Tumor Necrosis Factor-a; Tdg Clinical Trail: The Druggable Genome Clinical Trial; CGI: Cancer Genome Interpreter; CIViC: Clinical Interpretations of Variants in Cancer; TEND: Trends in the exploitation of novel drug targets; TTD: Therapeutic Target Database; NCI: NCI Cancer Gene Index.





Conclusions: Molecular evidence is provided for several anti-inflammatory agents, hormones/antidiabetic compounds, antibiotics and analgesics as prominent repurposing therapeutic agents for patients with active hidradenitis suppurativa.

Learning Objectives:

Alternative druggable therapeutic targets resulting from analysis of publicly available transcriptomes may lead to clinically relevant drug repurposing of existing molecules, already registered in other therapeutic uses.

Takeaway Message:

The combination of translational research data with integrated network-based cellular signatures and drug gene interaction database may provide valuable information of existing molecules with the potential to be introduced in clinical studies for hidradenitis suppurativa treatment.

1:18 - 1:26 pm

Immunopathogenesis of HS and Response to Therapy

Margaret M. Lowe¹, Haley B. Naik¹, Sean Clancy¹, Mariela Pauli¹, Kathleen M. Smith², Yingtao Bi², Robert Dunstan³, Maia Paul¹, Richard Ahn^{4, 1}, Wilson Liao¹, Scott L. Hansen¹, Michael D. Rosenblum¹

1. University of California, San Francisco, San Francisco, CA, USA, 2. AbbVie, Cambridge, MA, USA, 3. AbbVie Bioresearch Center, Worcester, CA, USA, 4. University of California, Los Angeles, Los Angeles, CA, USA

The inflammatory pathways driving hidradenititis suppurativa (HS) are largely unknown. In addition, we have limited understanding of how TNFa blocakde influences HS skin at the cellular and moleular levels. We utilized multi-parameter flow cytometry, mass cytometry (CyTOF), whole tissue RNASequencing and single cell RNASequencing, to comprehensively elucidate the inflammatory pathways in HS skin at both the cellular and molecular levels. Within HS lesional skin, we have identified a bias towards type 1 T cell responses, relatively reduced regulatory T cells (Tregs) and a memory B cell infiltrate in active inflammatory HS lesions that precedes a plasmablast/plasma cell infiltrate in end-stage disease. In addition, we discovered quantitative and qualitative dysfunction of type 2 dendritic cells (cDC2s) in HS skin, including alterations in IL-1 production and signaling. In functional experiments, anti-TNFα reduced B cell activation, but other inflammatory pathways remained elevated. Finally, signatures of higher immune activation in HS skin prior to initiation of anti-TNFα therapy were correlated with poor response. This data provides critical insight into the immunopathogenesis of HS and can serve as a foundation to develop novel treatment strategies for this disease.

Learning Objectives:

- The immune system of hidradenitis suppurativa lesional skin is disrupted across myeloid, B cell, and T cell compartments.
- Increases in Type 1 T cell responses and IL1 production and signaling differentiate HS from psoriasis, another inflammatory skin disease.
- The immune infiltrate of HS skin responds differentially to anti-TNF treatment, with greatest effects observed on B cell activation.

Takeaway Message:

The immune infiltrate of HS skin is polyfactorial; consequentially, separating drivers of disease from pathways increased by ongoing inflammation is difficult. Through comprehensive dissection of alterations in myeloid, B cell, and T cell compartments, we identify Type 1 T cell responses, increased IL1 signaling, and increased memory B cells as features of HS lesional skin that may prove fruitful targets for future clinical trials.

1:26 - 1:34 pm

Localization of Upregulated Proteins in Hidradenitis Suppurativa

Courtney A. Prestwood, Chenlu Zhang, Tamia Harris-Tryon

The University of Texas Southwestern Medical Center, Dallas, TX, USA

Introduction: Hidradenitis Suppurativa (HS) is a chronic debilitating inflammatory skin disease. Histologically, the inflammatory changes of HS are characterized by a perifollicular lymphocytic infiltrate due to follicular occlusion, keratinocyte hyperplasia, and subsequent rupture. These changes then lead to the loss of sebaceous glands and other adnexal structures. Recent transcriptomic studies comparing HS skin to healthy skin controls reveal multiple transcripts that are more abundant in HS skin including *SPRR2B*, *SPRR2C*, psoriasin (*S100A7*), koebnerisin (*S100A7A* or *S100A15*), calgranulin (*S100A12*), Peptidase Inhibitor 3 (*PI3*), *OAS2*, and *OASL*.

Methods/Results: We employed immunohistochemical staining to determine the expression pattern of these proteins in HS skin samples compared to normal controls. All of the transcripts that were more abundant in HS skin by RNA analysis showed a noticeably darker staining pattern by immunohistochemistry compared to normal skin controls. SPRR1B, SPRR2A, OAS2, OASL, and PI3 were all pan positive in HS skin. In normal skin, psoriasin expression is restricted to the distal outer root sheath and suprabasal keratinocytes. However, in HS skin samples psoriasin is expressed in the basal epidermis and throughout the hair follicle. The nonhealing sinus tracts in HS skin show an increased expression of OAS2, psoriasin, koebnerisin, elafin, and OASL, which is a pattern also seen in chronic wounds.

Conclusions: Our findings reveal the antimicrobial and structural proteins that are more abundant in HS skin are expressed at different locations in HS skin compared to control skin. Additionally, the expression pattern of OAS2, psoriasin, koebnerisin, elafin, and OASL in non-healing sinus tracts in HS further highlights the link between chronic wounds and HS. Our findings add to the growing knowledge of the pathological changes associated with HS.

Learning Objectives:

- Understand which antimicrobial and structural proteins are more abundant in HS skin compared to normal skin.
- Describe the protein expression patterns in HS skin and normal skin for the proteins: SPRR1B, SPRR2A, psoriasin (S100A7), koebnerisin (S100A7A or S100A15), calgranulin (S100A12), OAS2, OASL, and Peptidase Inhibitor 3 (PI3, Elafin, SKALP).
- Analyze the ways in which HS is similar to chronic wounds.

Takeaway Message:

Innate immunity and skin barrier proteins are more abundant and expressed more broadly in HS compared to normal skin. Building upon the work of transcriptomic studies, we use immunohistochemistry to identify the expression patterns of innate immunity and skin barrier proteins in HS skin compared to normal skin. With more information being discovered about the pathophysiology of HS, it is important to understand how protein expression changes in this condition.

1:34 - 1:42 pm

Expression of antimicrobial peptides in lesional keratinocytes of patients with HS

<u>Thomas Meyer</u>¹, Schapoor Hessam², Marina Skrygan¹, Maria Bakirtzi¹, Thilo Gambichler¹, Falk G. Bechara¹
1. St. Josef Hospital, Department of Dermatology, Ruhr University Bochum, Bochum, Germany, 2. Katharinen Hospital, Department of Dermatology, Unna, Germany

Introduction: The chronic inflammation in hidradenitis suppurativa (HS), probably results from overactive keratinocytes of the follicular epithelium and the interfollicular epidermis. Up-regulated IL36 production has been shown in HS lesions that may induce production and release of other pro-inflammatory cytokines (i.e. TNFα, IL6, IL8) and antimicrobial peptides (AMPs). This local response, however, appears to be insufficient to control colonization of commensal bacteria, but instead may even be boosted by microbial factors.

Methods, Results: Cultured keratinocytes isolated from lesional skin of 3 HS patients were stimulated for 6, 24, and 48 hours with muramyl-dipeptid (MDP) and Pam₂CSK₄ to simulate bacterial colonization. Gene expression of the following AMPs was analyzed by quantitative RT-PCR: hBD-2, LL37, RNAse 7, psoriasin and SKALP (Elafin). In HS keratinocytes expression of hBD-2 and psoriasin was stimulated with Pam₂CSK₄, but almost no expression was induced by MDP. In contrast, both Pam₂CSK₄ and MDP stimulated expression of hBD-2 and psoriasin in a normal keratinocyte cell line. Expression of RNAse 7 in HS keratinocytes was even higher than of psoriasin and hBD-2, but could not be increased by Pam₂CSK₄ or MDP. Similarly, expression of LL37 and SKALP increased only marginally after stimulation.

Conclusions: In HS keratinocytes expression of hBD-2 und psoriasin is stimulated only with Pam₂CSK₄ but not with MDP. The lack of stimulation with MDP is remarkable, as it represents a constituent of the bacterial cell wall and thus a common pathogen-associated molecular pattern (PAMP). It may be related to the impaired control of commensal bacteria, potentially contributing to the pathogenesis of HS.

Learning Objectives:

- · Mechanisms of chronic inflammation in HS
- Expression of pro-inflammatory cytokines and antimicrobial peptides (AMPs) in HS
- Ability of AMP production in keratinocytes isolated from HS lesions



Takeaway Message:

Insufficient AMP production indicated by the lack of MDP stimulation in vitro may impair control of bacterial colonization in HS and promote chronic inflammation.

Session 3 – Clinical Management Sunday, October 11, 2020 10:00 – 12:00 ET

10:00 - 10:20 am

Treatment Combinations

Mark Kirchhof, MD, PhD, FRCPC

Head, Division of Dermatology, University of Ottawa, Ottawa, ON, Canada

Although a variety of medical and surgical interventions exist for the treatment of hidradenitis suppurativa (HS), it remains a challenging disease to manage because of its variable presentation and unpredictable clinical course. Apart from the combination of clindamycin and rifampin, the success of other combination therapies is largely unknown. The goal of our study was to examine the clinical utility of various combination therapies for the treatment of HS. We conducted a qualitative retrospective chart review of 31 patients with dermatologist-diagnosed HS who were seen at an academic teaching hospital. Although no statistical results are provided because of the small sample size, we have identified several drug combinations that show promising clinical response for patients with HS based on their IHS4 score, such as isotretinoin/spironolactone for mild disease, isotretinoin or doxycycline with adalimumab for moderate disease, and cyclosporine/adalimumab for severe disease. This preliminary work demonstrates that HS treatment with combination therapy appears to be a promising method of disease management.

Learning Objectives:

- Review treatment options for hidradenitis suppurativa
- Explore clinical results of combination therapy for hidradenitis suppurativa
- Formulate potential therapeutic plans for patients with specific hidradenitis suppurativa phenotypes

10:20 - 10:40 am

HS Clinical Phenotypes

Hessel van der Zee, PhD

Dermatologist, Erasmus MC and DermHaven, Rotterdam, The Netherlands

The clinical presentation of HS, regardless of severity, is undeniably heterogeneous. Because of this variety in presentation, different phenotypes are very likely to exist. Identifying these phenotypes could be of clinical relevance since different phenotypes could have variable prognosis and require different treatment strategies.

Learning objectives

- There probably are HS phenotypes independent from severity
- Several phenotypes are proposed
- How to use these phenotypes in daily practice

10:40 - 10:48 am

Antibiotherapy targeted against hidradenitis suppurativa flora may significantly improve inflammatory bowel disease symptoms

Maïa Delage¹, Olivier Join-Lambert², Damien Soudan¹, Léon Maggiori², Yoram Bouhnik¹, Isabelle Nion-Larmurier³, Alain Hovnanian⁴, Xavier Treton¹, <u>Aude S. Nassif</u>⁵

1. CHU Beaujon, Service de Gastro-entérologie, Paris, France, 2. CHU Beaujon, Service de Chirurgie Digestive, Paris, France, 3. CHU St Antoine Service de Gastro-entérologie, Paris, France, 4. Institut Imagine, Laboratoire de Génétique des Maladies Cutanées, Paris, France, 5. Institut Pasteur, Centre Médical, Paris, France

Introduction: Inflammatory bowel diseases (IBD) are associated with hidradenitis suppurativa (HS) in about 5% of cases. Targeted antibiotherapy (TA) may obtain HS remission. Since antibiotherapy usually worsens diarrhea, we feared this strategy might worsen IBD. However, using TA for HS for 10 years, we unexpectedly observed dramatic IBD improvements in patients presenting with HS + IBD.

Case reports:

A 37-year-old female with a 14-year HS history and 5-year severe Crohn's disease (CD) history, unresponsive to infliximab, azathioprine and adalimumab, presented with very erosive fissuring inguino-anal dermatitis lasting for weeks. Unable to properly walk or sit, she was prescribed ertapenem for 3 months: erosive dermatitis completely healed, stool number decreased from 5 liquid/bloody to 2 soft stools/day and abdominal pain disappeared; she gained 7kg.

A 20 year-old male had erosive fissuring dermatitis of anal cleft unresponsive to infliximab + azathioprine for 5 years, with trans-sphinteric CD fistula, constant abdominal cramps and 3-4 bloody stools/day. Ertapenem prescribed for inguinal HS obtained dramatic anal cleft healing, stop of abdominal pain and bloody stools within 6 weeks and HS remission.

A 24 year-old female had CD + HS since the age of 14, with failure of systemic steroids, infliximab, then adalimumab + azathioprine for 7 years; she could hardly walk or cross her legs for the past 5 years. Within 6 weeks of ertapenem, prescribed for severe genito-anal CD+HS, abdominal pain (ileal stenosis) disappeared, she walked and sat normally. Similar dramatic improvements in associated IBD were observed in 12 other HS + CD or ulcerative colitis cases.

Conclusion: TA for HS can improve IBD symptoms. Commensal gut flora has been involved in IBD pathophysiology as well as skin flora in HS. These observations suggest a pathogenic host-microbiome mechanism common to both diseases and that selected IBD resistant to biotherapies may benefit from TA.

Learning Objectives:

- cutaneous signs specific to IBD = erosive fissuring dermatitis of skin folds due to digestive fistula
- efficacy of an antibiotherapy targeted against HS flora in patients presenting with IBD + HS
- tolerance of this strategy in HS+ IBD patients

Takeaway Message:

Antibiotic strategy targeted against lesional HS microbiology can dramatically improve IBD symptoms.

10:48 - 10:56 am

Prevalence and Risk Factors for Anemia in a Population with Hidradenitis Suppurativa

Sydney R. Resnik¹, Emily Geisler¹, Nicolas Reyes¹, Juan Lozano¹, Barry I. Resnik²

1. Florida International University Herbert Wertheim College of Medicine, Miami, FL, USA, 2. Dr. Phillip Frost Department of Dermatology & Cutaneous Surgery, University of Miami Miller School of Medicine, Miami, FL, USA

Introduction: Hidradenitis suppurativa (HS) is a chronic inflammatory disease that presents as nodules and abscesses evolving into scarred plaques in intertriginous areas. HS is associated with many co-morbidities, including anemia of chronic disease. There are few studies reporting on the association between HS and anemia. This study sought to examine the prevalence of anemia among a population of HS patients as well as potential associations between risk factors for HS and development of anemia.

Methods/Results: Records of patients diagnosed with HS in one private practice (BR) were reveiwed by the investigators. The 92-patient cohort was evaluated for multiple data points, including age, gender, and presence of anemia, amongst others. Responses were grouped based on age, gender, ethnicity, body mass index, smoking status, and comorbidities to identify differences between patients with and without anemia. Data was analyzed using STATA to perform descriptive analysis followed by bivariate analysis. The prevalence of anemia in this cohort was 41.3%. Of anemic patients, the majority were men (65.2%), black (60.6%), and never/former smokers (48.6%). There was a statistically significant increase in the odds of developing anemia in HS patients that are men (OR 3.8, 95% CI 1.4-10.1) and Black (OR 3.5, 95% CI 1.3-9.2).

Conclusion: Here we show that the prevalence of anemia in a population of HS patients, being 41.3%, greatly surpasses that of the general U.S. population (~5%). It is clear from these results that anemia is a significant complication for HS patients. Anemia in HS may not be solely explained by the designation 'anemia of chronic disease', as we also find that, unexpectedly, men and Blacks have increased odds of developing anemia. We hope that physicians can recognize the importance of screening all patients with HS for anemia in order to medically optimize treatment for their patients.

Learning Objectives:

- Anemia in HS is much more prevalent than was originally understood
- More efforts are needed in the diagnosis of anemia in the HS population
- Further studies are necessary to better understand the demographics of the HS population most at risk for anemia





Takeaway Message:

Based on the significantly increased prevalence of anemia of chronic disease in the HS population, correcting that anemai may be a valuable adjunct in the treatment of HS.

10:56 - 11:04 am

A Randomized, Placebo-Controlled, Phase 2 Study of the Janus Kinase 1 Inhibitor INCB054707 for Patients With Moderate-to-Severe Hidradenitis Suppurativa *Ricardo*

<u>Afsaneh Alavi</u>^{1, 2}, Iltefat Hamzavi³, Kurt Brown⁴, Leandro L. Santos⁴, Zhaoyin Zhu⁴, Michael D. Howell⁴, Joslyn Kirby⁵

- 1. University of Toronto, Toronto, ON, Canada, 2. York Dermatology and Research Centre, Richmond Hill, ON, Canada, 3. Henry Ford Medical Center, Detroit, MI, USA, 4. Incyte Corporation, Wilmington, DE, USA,
- 5. Penn State Health Milton S. Hershey Medical Center, Hershey, PA, USA

Janus kinase (JAK)-mediated cytokine signaling contributes to local and systemic inflammation in hidradenitis suppurativa (HS). We describe results from a multicenter phase 2 trial of the JAK1 inhibitor INCB054707 in patients with HS.

This was a placebo-controlled, dose-escalation study; patients received INCB054707 once daily (30-, 60-, or 90-mg cohorts) or placebo (3:1 randomization per cohort) for 8 weeks, with a 30-day safety follow-up. Patients aged 18–75 years with moderate-to-severe HS of ≥6-months' duration, lesions present in ≥2 anatomic locations (Hurley stage II/III), and total abscess and inflammatory nodule count of ≥3 were eligible. The primary endpoint was safety and tolerability. Additional endpoints included HS Clinical Response (HiSCR), HS quality of life (HiSQoL), and peripheral blood biomarkers. Thirty-five patients were enrolled (median [range] age, 45.0 [18–64] years; 80% female; 89% white; 71% Hurley stage II at baseline). Nine patients were randomized to placebo and 26 to INCB054707 (30 mg, n=9; 60 mg, n=9; 90 mg, n=8). Overall, 81% of patients receiving INCB054707 had ≥1 treatment-emergent adverse event (TEAE; 12% grade 3, all thrombocytopenia at 90 mg); no discontinuations resulted from TEAEs. More patients receiving 90 mg INCB054707 than placebo had Week 8 HiSCR (88% vs 57%; **Figure**). Mean change from baseline in HiSQoL at Week 8 was greater for patients treated with INCB054707 (range across doses, -28.0 to -39.0) vs placebo (-3.4). Biomarker analysis demonstrated dose-dependent differences in the modulation of inflammatory mediators.

INCB054707 was well tolerated, demonstrated preliminary efficacy, and improved QoL in patients with moderate-to-severe HS.

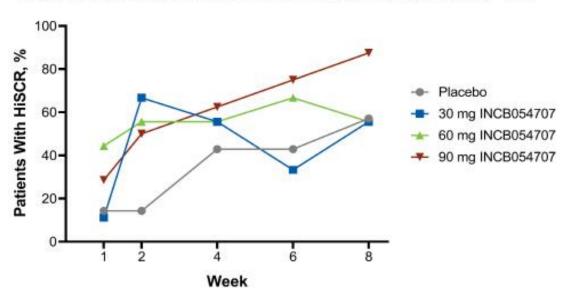


Figure. Proportion of Patients With HiSCR at Each Study Visit

HiSCR, Hidradenitis Suppurativa Clinical Response.

Learning Objectives:

- Provide rationale for the use of Janus kinase (JAK)-1 inhibitors for the treatment of hidradenitis suppurativa (HS)
- Describe clinical efficacy and safety results from a phase 2 study of the JAK1 inhibitor INCB054707 in patients with moderate-to-severe HS
- Summarize patient-reported outcomes related to quality of life following treatment with INCB054707

Takeaway Message:

JAK1 inhibition with INCB054707 was well tolerated and demonstrated preliminary efficacy in improving HS symptoms and quality of life among patients with moderate—to-severe HS.

11:04 - 11:12 am

A Patient Survey of Pain Management Modalities used in Hidradenitis Suppurativa

<u>Jennifer M. Fernandez</u>³, Alyssa M. Thompson³, Mark Borgstrom², Lauren A. Orenstein⁵, Jennifer L. Hsiao⁴, Vivian Y. Shi¹

1. University of Arkansas for Medical Sciences, Little Rock, AR, USA, 2. University Information Technology Services, University of Arizona, Tucson, AZ, USA, 3. University of Arizona College of Medicine Tucson, Tucson, AZ, USA, 4. University of California Los Angeles, Los Angeles, CA, USA, 5. Emory University, Atlanta, GA, USA

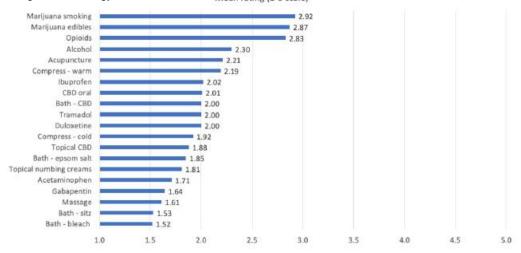
Introduction: Pain is a debilitating symptom and has been reported in the vast majority of hidradenitis suppurativa (HS) patients. Our study aimed to identify pain management therapies used by HS patients and assess patient-perceived effectiveness.

Methods/Results: A web-based anonymous survey was distributed to Facebook HS support groups February-March 2020. Adults (ages 18-75) with HS were asked to indicate which of 20 listed therapies they had used for HS pain. For each therapy, participants were prompted to rate effectiveness: not successful (1), mildly successful (2), moderately successful (3), very successful (4), and extremely successful (5); corresponding numbers were averaged to determine mean effectiveness ratings.

The 438 participants classified themselves as Hurley stage I (8.2%), II (53.4%), and III (38.4%); 93.8% were female. All participants indicated "yes" when asked if they experienced HS pain. The most commonly used pain management methods were warm compresses (82.4%), ibuprofen/naproxen (74.7%), Epsom salt baths (57.8%), cold compresses (45.4%), and acetaminophen (44.7%). Smoking marijuana had the highest mean perceived effectiveness score (2.92±1.10), followed by marijuana edibles (2.87±1.10), and opioids (2.83±0.98). There was no significant difference in perceived effectiveness of opioids compared to marijuana smoking or marijuana edibles (p>0.9999). Effectiveness ratings were lowest for bleach baths (1.52±0.80), sitz baths (1.53±0.56), massage (1.61±0.92), gabapentin (1.64±0.73), and acetaminophen (1.71±0.75). Differences in mean effectiveness ratings by Hurley stage were significant for smoking marijuana (p=0.0229) and acupuncture (p=0.0265) but nonsignificant for the 18 other interventions.

Conclusion: All HS participants in this study reported experiencing pain. However, even the most effective pain treatments for HS are considered by patients to be only moderately effective. Perceived effectiveness of HS pain therapies did not vary by Hurley stage for most therapies, suggesting that other factors aside from Hurley stage may play an important role in devising a pain management strategy.

Mean rating (1-5 scale)





Learning Objectives:

- · Pain is present in all HS patients
- Effectiveness of pain management modalities used for HS pain is suboptimal
- Disease severity does not appear to have a major impact on perceived effectiveness of pain management modalities

Takeaway Message:

Patients with HS may required a multi-modal approach to achieve optimal pain control given limited effectiveness of available pain management methods.

11:12 - 11:20 am

Diet, supplementation, and topical home remedies in HS: is there an adjunctive role?

Annika S. Silfvast-Kaiser¹, Marcus Zaayman¹, So Yeon Paek¹

1. Baylor University Medical Center, Dallas, TX, USA

Introduction: Complementary treatments have long been of considerable interest to the HS patient community and are frequently employed by patients as adjunctive therapy, even after seeking formal treatment by a dermatologist. Dietary elimination, nutritional supplementation, and topical home remedies have all been touted as beneficial; however, formal evidence to support these treatments is limited.

Methods/Results: We evaluated the dietary and weight loss interventions made by a cohort of 46 HS patients in our HS specialty clinic in Dallas, TX. We identified turmeric, vitamin D, and zinc as the most commonly reported beneficial supplements (n= 22, 47.8%). Patient-controlled weight loss was associated with improvement in HS (n = 6, 13.0%). Additionally, two patients who underwent bariatric surgery also reported resultant HS regression. Dairy, alcohol, brewer's yeast, gluten, and nightshade intake were most commonly reported as dietary triggers for worsening HS, and diets eliminating or avoiding these were most commonly employed by patients (n = 16, 34.8%). Topical adjunctive therapies most frequently reported as beneficial were tea tree oil, coconut oil, and epsom salt baths. A larger proportion of our cohort reported current tobacco use (21.74%) and abstaining from alcohol (47.83%) compared to the U.S. population in general.

Conclusion: Hidradenitis suppurativa remains a frustrating disease for patients and clinicians. Evaluation of adjunctive therapies is crucial to potentially increase our understanding of various dietary impacts and home remedies on the pathophysiology of HS.

Learning Objectives:

- Identify the most common complementary treatment measures reported as beneficial by a cohort of 46 HS patients.
- Understand the potential adjunctive role that dietary changes, supplementation, and topical home remedies can play in the improvement of HS.
- Discuss the mechanisms through which adjunctive treatments may be beneficial in HS.

Takeaway Message:

There is a paucity of data regarding the role of diet and home remedies in the treatment of HS as well as a clear deficiency of cohesive information in the formal literature. Data from our cohort suggests potential benefits from supplementation with turmeric, vitamin D, and zinc; weight loss; and avoidance of dairy, alcohol, brewer's yeast, gluten, and nightshade intake. Topical adjunctive therapies that may be considered include tea tree oil, coconut oil, and epsom salt baths.

11:20 - 11:28 am

The Use of Brodalumab in Hidradenitis Suppurativa: Results from Two Open Label Cohort Studies

<u>John W. Frew</u>, Kristina Navrazhina, David Grand, Mary Sullivan-Whalen, Patricia Gilleaudeau, James Krueger Laboratory for Investigative Dermatology, Rockefeller University, New York, NY, USA

Background: Hidradenitis Suppurativa is a debilitating chronic inflammatory disease with Adalimumab the only FDA-approved biologic for the condition. We have conducted two open-label cohort studies at two separate dosages of Brodalumab, an IL-17RA antagonist. Our first study assessed safety, tolerability and clinical response at Weeks 12 and 24 of Brodalumab 210mg/1.5mL subcutaneously every 2 weeks until week 24. The second study examined safety, tolerability and clinical response at Weeks 12 and 24 of Brodalumab 210mg/1.5mL subcutaneously weekly until week 24.

Methods: Both studies were open-label cohort study at a single-center university hospital. Both involved referred samples of 10 participants with moderate-to-severe Hidradenitis Suppurativa and no history of inflammatory bowel disease. All

participants were administered Brodalumab 210mg/1.5mg subcutaneously for 24 weeks. All participants completed the study. Safety was assessed by number of grade 2/3 adverse events associated with Brodalumab. Clinical response was measured using the Hidradenitis Suppurativa Clinical Response (HiSCR) and International Hidradenitis Suppurativa Severity Score (IHS4), along with patient reported outcomes assessing pain, disease severity and quality of life.

Results: 100% participants achieved HISCR at Week 12 in both studies. HiSCR achievement occurred as early as Week 4. Patient reported outcomes and quality of life scores all reduced compared to baseline measurement. Weekly administration of Brodalumab was more effective at reducing draining tunnels in participants with Hurley Stage 3 disease than every-2-week dosing. This may be due to the receptor mediated clearance of Brodalumab in individuals with draining tunnels. Both every-2-weeks and weekly dosing of Brodalumab was well tolerated with no concerning safety issues and rapid improvement in disease activity in these cohorts. In individuals with draining tunnels, weekly dosing of Brodalumab provides a greater level of disease control than every-2-week dosing.

Learning Objectives:

- To understand the role of IL-17RA in HS
- To appreciate the effect of different dosages of Brodalumab upon disease activity
- To identify patient characteristics that may be more suitable for weekly versus 2-weekly dosing in HS.

Takeaway Message:

Brodalumab is an effective treatment for HS with 100% of participants achieving HiSCR. Weekly dosage is more effective for individuals with draining tunnels compared to every-2-week dosing.

Session 4 – Clinical Study Design and Outcome Measures

Sunday, October 11, 2020 12:30 – 2:20 ET

12.30 - 2.20 E1

12:30 – 12:50 pm

The HS-patient decision aid: practical aspects and future directions

Jerry Tan. MD. FRCPC

Dermatologist, Windsor Clinical Research, Windsor, ON, Canada

Over the past 2 years, our group has been developing and evaluating a patient decision aid for hidradenitis suppurativa (HS-PDA). This was performed with input from HS patient representatives from Hope for HS and HS Warriors along with multiple dermatologists from the HS Foundation and authors of the North American clinical practice guidelines for HS.

Along with expert guidance from their physicians, the objective of the HS patient decision aid (HS-PDA) is to help patients make informed treatment decisions. In a randomized controlled trial, we have shown that it increases patient knowledge of HS and its treatment options, increases preparedness for decision making, and reduces decisional conflict. The HS-PDA is now freely available online at www.informed-decisions.org

In this presentation, I will present practical aspects of using the HS-PDA in consultations, in person and virtual. My intention is to transfer oversight of the HS-PDA to an organization for HS that is focused on improving patient care and outcomes. My hope is that this will be an evergreen instrument that is continually edited and updated with new evidence. This symposium presents a timely opportunity to do so annually.

12:50 - 1:10 pm

The Outcome Measure May Vary By the Drug Mechanism of Action and Immune Mediated Inflammatory Disease Being Treated

Wayne Gulliver, MD, FRCPC

Dermatologist, Memorial University of Newfoundland, St. John's, NF, Canada

As we are aware patients may present with more than one immune mediated inflammatory disease. We present a case of a 60-year old lady who has psoriasis, psoriatic arthritis, Crohn's disease, HS, bipolar disease and hypothyroidism. She has failed multiple biologics. In patients such as this we must understand the immunopathogenesis in order to choose the best target to treat the many components of her disease. We know that PsO, PsA, CD and HS have complex immunopathogenesis which include TNF- α, IL12/23, IL23, IL17 and IL1. When it comes to PsO and PsA targeting any of



these cytokines may be helpful. As we are aware the pathogenesis of CD is even more complex and targeting some of the cytokines will improve the disease while CD may be exacerbated by targeting cytokines such as IL17. When it comes to HS, TNF-α, IL1β, IL17 and IL12/23 are all over-expressed in the skin lesions of HS as there is a deficiency in IL22 and paradoxical increase in the expression of the anti-inflammatory IL10. Another important consideration when selecting a drug is the pharmacokinetics and pharmacodynamics of the biologic, i.e. when it comes to the use of adalimumab in Crohn's disease, rheumatoid arthritis, PsA and HS serum levels are very similar but response rates are different and range between 50 and 80%. So based on the immunopathogenesis the available data including some head-to-head studies, we are able to present comparative efficacies and available cytokine strategies in chronic autoinflammatory disorders, thus allowing us to choose a cytokine-directed therapy that would most benefit the patient with multiple chronic autoinflammatory disorders.

Learning Objectives:

- Understand the causes of HS, PsO, PsA and Crohn's
- Understand the factors that contribute to their development and treatment response
- Review the immunopathogenesis, etiology and therapeutic response to biologic therapy in HS, PsO, PsA and Crohn's disease

1:10 - 1:18 pm

Evaluating the responsiveness and score bands of the HiSQOL, a novel HS-specific patient-reported outcome measure

<u>Joslyn S. Kirby</u>¹, Melissa Butt¹, Ankita Sinharoy¹, Linnea Thorlacius², Bente Villumsen³, John Ingram⁴, Amit Garg⁵, Jerry Tan⁶, Gregor B. Jemec²

1. Penn State University, Hershey, PA, USA, 2. Department of Dermatology, Zealand University Hospital, Roskilde, Denmark, 3. The Patients' Association HS Denmark, Copenhagen, Denmark, 4. Cardiff University, University Hospital of Wales,, Cardiff, United Kingdom, 5. Donald and Barbara Zucker School of Medicine at Hofstra Northwell, New Hyde Park, NY, USA, 6. Department of Medicine, University of Western Ontario, Windsor, ON, Canada

Introduction: Health-related quality of life (HRQoL) assessment is an important outcome measure in HS clinical trials. To be clinically useful, HRQoL measurement instruments must have demonstrated validity, reliability and responsiveness to change. The HiSQOL is an HS-specific tool and has established validity and reliability. The aim of this study was to assess the HiSQOL's responsiveness to change using a distribution-based approach.

Methods & Results: A distribution-based approach was used to understand the responsiveness of the HiSQOL by identifying the magnitude of score change over time. We used a paired samples t test to assess whether the DLQI could detect change that occurred. Distribution-based methods were used to detect the magnitude of that change in the HiSQOL scores: Effect size (ES) was calculated as a ratio of the mean HiSQOL score difference/standard deviation [SD] at the first assessment scores. An ES of 0.2 is considered small, 0.5 moderate and 0.8 large. The standardized response mean (SRM) was calculated as the ratio of the mean HiSQOL score difference/SD of the difference.

Overall, 224 US patients with mean age 39 (SD13) years and 87% female (female = 195; male = 29) completed the HiSQOL at two timepoints. The mean HiSQOL score at time 1 was 27.9 (SD16.5). The paired samples t test showed that the HiSQOL was responsive to change with a mean change of 3.0 (SD6.2) (p<.0001). Two distribution-based methods were used: the ES of the HiSQOL change score was 0.18 while the SRM was 0.5, both indicating a small effect. Participants were divided into 4 categories: those having experienced small, moderate, large ES to suggest HiSQOL score interpretations. The mean corresponding change in HiSQOL scores were 3.5 (SD=0.5, SRM=0.55), 8.3 (SD=0.5, SRM=1.34), and 13.3 (SD=0.6, SRM=2.14), respectively. These are significantly different (p=.0009).

Conclusions: To our knowledge, this is the first study to investigate the responsiveness of the HiSQOL. This preliminary study suggests score bands for the HiSQOL, but has methodological limitations. Future studies will use the longitudinal trial data and anchor-based methods to determine the minimal important difference and confirm the score interpretations suggested here.

Learning Objectives:

- Explain disctribution-based approaches to evaluate responsiveness in outcome measures.
- Explore the responsiveness of the HISQOL.
- Describe the first score bands proposed for the HiSQOL to label small, moderate, and large score changes.

Takeaway Message:

Our study found that the HiSQOL was responsive and score changes of 4, 9, and 13 can be used as the initial basis for small, moderate, and large score changes for this novel HS-specific patient-report outcome that assess changes in health-related quality of life.

1:18 - 1:26 pm

Novel approach to HS flare measurement using patient-reported outcomes

<u>Joslyn S. Kirby</u>, Ankita Sinharoy, Melissa Butt *Penn State University, Hershey, PA, USA*

Introduction: Hidradenitis Suppurativa (HS) has a chronic course and superimposed flares. Flare is primarily defined by changes in clinician-reported outcomes; however the reliability and validity may be imprecise. Patient-reported outcomes (PROs), such as the Dermatology Life Quality Index (DLQI) and Hidradenitis Suppurativa Quality of Life (HiSQOL) scales may be able to quantify flare and have not been investigated.

Methods/Results: We conducted a single-center, prospective, longitudinal cohort study of 13 adults with HS. Participants completed an online survey each week for seven consecutive weeks. Participants self-reported whether they had a flare in the 7 days prior then completed the DLQI, HiSQOL, and numerical rating scale (NRS) for average pain. All instruments have a 7-day recall period. Participants were paid for their participation. The sensitivity and specificity of the PROs to identify HS flare was evaluated by constructing receiver operating characteristic (ROC) curves and the area under the curve (AUC) was estimated. The Youden J statistic, the sum of the sensitivity and 1-specificity, was also calculated. An ANCOVA model was used to make comparisons while adjusting for individuals.

Table 1 shows the demographic characteristics of the participants, who contributed weekly data, with only one missing week from one participant. All participants had at least one flare during the study period. PRO scores were significantly higher during flare. The HiSQOL Symptom Subscale (AUC=0.92) and HiSQOL Total score (AUC=0.88) had the highest sensitivity and specificity (Youden J =0.71 and 0.61, respectively (Figure).

Results

- 13/13 participants contributed weekly data and 100% had at least one flare during the study period.
 - · One missing week from one participant
- PRO scores were significantly higher during flare.

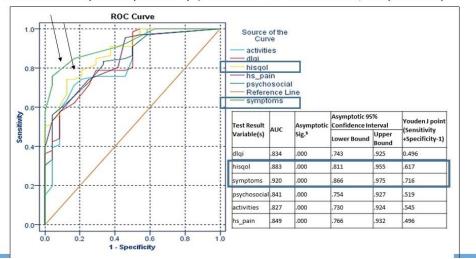
Age	33.8 (SD 7.1)
Female	11 (84.6%)
Ethnicity	330
Hispanic/Latino	0 (0%)
Non-Hispanic/Latino	13 (100%)
Race	
Asian or Pacific Islander	0 (0%)
Black (including African or Afro- Caribbean)	1 (7.7%)
White/ Caucasian	11 (84.6%)
Two or More	1 (7.7%)

Table 2. Differences in PRO scores during flares				
	Flare	No Flare		
	Mean (SD)	Mean (SD)	p-value*	
NRS Pain	5.6 (1.88)	2.2 (2.27)	<0.001	
HiSQOL, Total	37.8 (16.51)	13.0 (12.42)	0.001	
HiSQOL, Symptoms	9.6 (4.03)	3.0 (2.42)	<0.001	
HiSQOL, Activity	16.7 (8.27)	6.1 (6.78)	0.01	
HiSQOL, Psychosocial	11.5 (6.11)	3.9 (4.25)	0.01	
DLQI	14.8 (7.02)	6.0 (5.49)	<0.001	
*ANCOVA model with adjustment for individuals				



Results:

The HiSQOL Symptom Subscale (AUC=0.92) and HiSQOL Total score (AUC=0.88) had the highest sensitivity and specificity (Youden J = 0.71 and 0.61, respectively.



Conclusions: This pilot study shows that the HiSQOL is superior to the NRS for pain to assess HS flare. Currently, PROs are not typically used to define or assess HS flares. This approach draws upon successful strategies used in other chronic inflammatory diseases with flares. We plan to more extensively study the validity, sensitivity, and specificity of PROs to assess HS flare.

Learning Objectives:

- Describe the use of patient-reported outcomes to detect flare in other inflammatory conditions.
- Describe the use of patient-reported outcomes to detect hidradenitis flare.
- Describe the performance of patient-reported outcomes to detect hidradenitis flare.

Takeaway Message:

This pilot study shows the HiSQOL is superior to the NRS for pain and DLQI to detect HS flare. While these measures are not typically used to define or assess HS flares, this approach is used successfully in other chronic inflammatory diseases with flares.

1:26 - 1:34 pm

Quantifying the Natural Variation in Lesion Counts Over Time in Untreated Hidradenitis Suppurativa: Implications for Outcome Measures and Trial Design

John W. Frew¹, Caroline Jiang², Neha Singh², Roger Vaughan², James Krueger¹

1. Laboratory for Investigative Dermatology, Rockefeller University, New York, NY, USA, 2. Department of Biostatistics, Rockefeller University, New York, NY, USA

Background: Hidradenitis suppurativa demonstrates high placebo response rates in clinical trials which are contributed to by the type of outcome measures used, the inter-rater reliability of counting lesions and the natural variability of lesions as an inherent part of the disease process. No quantification of the natural variability of lesion counts in untreated disease has been undertaken which would aid in the design of future clinical trials.

Methods: De-identified individual patient data from the placebo arms of the PIONEER studies were analysed and measurements of variability examined within-subject coefficient of variance (CV), coefficient of variance quartiles (CVq), z-scores and median absolute deviation (MAD). Variability was stratified by disease associated variables (Hurley stage, BMI category, sex, nicotine use, family history) and body site.

Results: CVq was calculated as 33% and 40% of the median AN count in PIONEER 1 and 2, respectively. The 75thpercentile extended to 78% of the median AN count with MAD of 1 lesion (IQR 1-3 lesions). Within-subject variation was greater for sub-epidermal structures such as abscesses and tunnels compared to nodules. Variation was greater for axillary and groin

sites compared to other body sites. Hurley stage 2 participants had significantly greater within-subject variation than Hurley stage 3.

Discussion: Interpretation of within-subject variation data suggests natural disease variation accounts for a large proportion of placebo response rates in clinical trials. Either elevation of clinically significant change to>75% reduction in AN count, inclusion of participants only with baseline AN count>7, or abandoning lesion counts as outcome measures in clinical trials are options to integrate the natural variation of disease activity into HS clinical trial design.

Conclusion: The within-subject variability of lesion counts in untreated HS is greater than previously appreciated. This has profound effects for outcome measures and the conduct of future clinical trials in HS.

Learning Objectives:

- To appreciate that natural variability in lesion counts in HS exists
- To understand the quantification of lesion count variability in HS
- To understand the implications of lesion count variability for clinical trial outcomes and design.

Takeaway Message:

Counting Lesions in HS clinical trials requires elevating the minimum baseline lesion count to 7 or above, including only severe patients, or eliminating counting lesions altogether.

1:34 - 1:42 pm

Do HS trial participants reflect the HS patient population?

<u>Victoria M. Madray</u>¹, JaBreia F. James¹, Mia S. White², Samar Hasan³, Joslyn S. Kirby⁴, Lauren A. Orenstein⁵, John R. Ingram³

1. Medical College of Georgia, Augusta, GA, USA, 2. Emory University, Atlanta, GA, USA, 3. Cardiff University, Cardiff, United Kingdom, 4. Penn State Milton S. Hershey Medical Center, Hershey, PA, USA, 5. Emory University School of Medicine, Atlanta, GA, USA

Introduction: Despite higher disease prevalence among patients with skin of color, a recent review highlighted low representation of racial and ethnic minorities in hidradenitis suppurativa (HS) clinical trials. This systematic review aims to evaluate published HS clinical trials' representation of the patients affected by this disease as well as hardships imposed by clinical trial participation.

Methods, **Results**: HS clinical trials were systematically searched in PubMed, Embase, Cochrane Central, and Web of Science databases. Randomized controlled trials published in peer reviewed literature were included. Studies with fewer than 10 participants were excluded. Title and abstract screening and data extraction were completed by two independent reviewers, with disagreements resolved by a third.

Of the 78 references yielded, 22 studies met inclusion criteria (1592 participants). Trial participants were predominantly white (793/1051, 75.5%) and female (1126/1560, 72.1%), with mean age of 35.6 years old. Nearly all trial participants had Hurley Stage II (492/921, 53.4%) or Hurley Stage III (384/921, 41.7%) disease. Many trials excluded patients with HS that was too severe (7/22), HS that was too mild (13/22), pregnancy (17/22), breastfeeding (11/22), and HIV infection (10/22). Additionally, trial participation imposed hardships on individuals with HS, including prolonged wash out periods from other HS therapies, long periods in the study's placebo arm, and exclusion for taking analgesics prior to randomization.

Conclusions: This systematic review demonstrates key patient groups which have been historically underrepresented in HS clinical trials. To ensure HS therapies benefit all affected patients, efforts should be made to provide opportunities for inclusion of underrepresented groups. Pragmatic HS studies with shorter washout and placebo treatment periods are needed to reduce the burden of trial participation, capture a more representative patient group, and assess outcomes in a more realistic treatment setting.

Learning Objectives:

- To identify patient groups that are underrepresented in HS clinical trials.
- To recognize burdens commonly imposed by HS trial participation.

Takeaway Message:

Individuals with skin of color, males, and those with Hurley stage I disease are underrepresented in HS clinical trials. HS trials with pragmatic designs are needed to reduce the burden of clinical trial participation and assess outcomes in real world settings.



1:42 - 1:50 pm

Development and validation of an Investigator Global Assessment in HS

Amit Garq¹, Katherine Kim², Naijun Chen², Weihua Gao², Carla Zema³

1. Donald and Barbara Zucker School of Medicine, New Hyde Park, NY, USA, 2. AbbVie, North Chicago, IL, USA, 3. Zema Consulting, Madison, AL, USA

Introduction: Investigator global assessment (IGA) is a domain in HISTORIC's core outcome set and it is the preferred FDA endpoint for dermatology trials.[1] However, IGA does not exist in HS. This study developed and initially validated an HS IGA

Methods/Results: Data from two replicate phase 3 RCTs (PIONEER I and II) evaluating HS treatment were used to develop a draft conceptual framework of a simplified IGA. PIONEER I dataset was used for development. PIONEER II was used for initial validation.

All possible combinations of abscesses, fistulas (draining and non-draining), nodules (inflammatory and non-inflammatory) (AFN), and anatomical regions were explored in multiple multi-variate models to identify variables of importance. The rpart Score R package was used to build classification and regression trees for ordinal responses for the initial framework.[2] Correlations with QoL measures and agreement with HS-PGA were examined, and responsiveness was compared to HiSCR. This iterative process included clinical input for content validity and to balance feasibility.

An IGA with 4 categories and 2 regions (upper and lower body) and AFN combined counts emerged from initial modeling, but it was not shown to be responsive. The final IGA that was validated and shown to be responsive is a 6-pt scale with combined AFN counts in the upper or lower body of 0=0-1; 1=2-5; 2=6-10; 3=11-15; 4=15-20; 5=>20.

Conclusions: A simplified, validated IGA to measure treatment response in HS trials is feasible. Further validation in an external dataset is needed for use in drug development for HS patients.

[1] Thorlacius L, Ingram JR, Villumsen B, et al. A core domain set for hidradenitis suppurativa trial outcomes: an international Delphi process. *Br J Dermatol.* 2018;179(3):642-650.

[2] Galimberti G., Soffritti G., Di Maso M. 2012 Classification Trees for Ordinal Responses in R: The rpart Score Package. Journal of Statistical Software, 47(10), 1-25.

Learning Objectives:

- To describe the need for an HS IGA.
- To describe the development of a simplified IGA for use in HS trials and clinical practice.

Takeaway Message:

A simplified IGA may be implemented to measure treatment response in HS trials as well as clinical practice.

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P2.10	Trial Management During the COVID-19 Pandemic: Lessons Learned from Phase 3 Extension Study of Secukinumab in Patients with Moderate-to-Severe Hidradenitis Suppurativa	Alexa B. Kimball
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Poster	Title	Presenting Author		
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P3.02	Hidradenitis Suppurativa and Chromosomal Abnormalities	Monica Shah		
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P3.04	Squamous Cell Carcinoma Arising in Hidradenitis Suppurativa: A Case Series	Sepideh Ashrafzadeh		
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P4.07	Patient Perspectives on COVID-19 and Hidradenitis Suppurativa in Spring 2020	Kyla N. Price		
P4.08	Patients' Experience With Hidradenitis Suppurativa Care and Treatment: Results from the Hidradenitis Suppurativa Patient Experience Survey	Rachael Manion		
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P4.10	The Impact of Body Mass Index Upon the Efficacy of Adalimumab in Hidradenitis Suppurativa	John W. Frew		
P4.11	Trends in The Management of Hidradenitis Suppurativa in The Middle East Region: a Systematic Review	Mehran Karvar		
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P4.13	Characterization of Pediatric Patients with Hidradenitis Suppuritiva and Implications for Development of Clinical Trials Eligibility Criteria	Helen Bui		
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	P5 – Therapy Including Surgical, Medical, and Complementary			
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P5.02	Surgical Management of Hurley Grade III Hidradenitis Suppurativa Using ECM Graft	Abigail Chaffin		
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Poster Abstracts

P1: Basic and Translational Research

P1.01 Molecular Disease Signatures of Hidradenitis Suppurativa Derived from Highthroughput RNA Sequencing

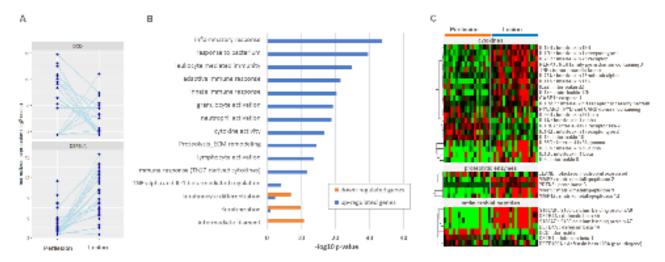
Johannes Freudenberg², Zhi Liu¹, Jennifer Singh², Elizabeth Thomas², Christopher Traini², Deepak Rajpal², Christopher Sayed¹

1. UNC Dermatology, Chapel Hill, NC, USA, 2. GSK Research and Development, Collegeville, PA, USA

Background: Few studies have characterized the transcriptomic profile of affected and unaffected skin in hidradenitis suppurativa.

Methods: Patient-derived RNA from lesional and matching perilesional skin biopsies for 20 patients were used to identify an expression-based hidradenitis suppurativa disease signature. This was followed by differential expression and pathway enrichment analyses.

Results: We established an RNA-Seq based hidradenitis suppurativa expression disease signature and found it largely concordant with an earlier microarray-based study. We confirmed known aspects of the underlying disease biology including known immune response pathways, differential regulation of antimicrobial peptides, and complement activation. We further characterize the extent of changes in the complement cascade in hidradenitis lesions and highlight a signature that implicates host response to bacteria in disease pathogenesis.



Conclusions: Changes in the transcriptome of lesional skin in this cohort of hidradenitis suppurativa patients is consistent with smaller previously reported populations. The findings further support the significance of immune dysregulation, in particular with regard to bacterial response mechanisms.

Learning Objectives:

- Recognize the common inflammatory pathways that are activated in HS
- Understand the role of complement activation in HS pathogenesis
- Recognize inflammatory cytokines that play a role in HS inflammation and their potential roles as therapeutic targets

Takeaway Message:

A number of inflammatory response pathways are upregulated in HS and suggest known and potential therapeutic targets



P1.02 Combined Transcriptomic and Immunohistochemical Analysis Unveils IL-17 Pathway Engagement in Hidradenitis Suppurativa Lesions

Christian Loesche, Lukas Roth, Grazyna Wieczorek, Frank Kolbinger

Novartis Institutes for BioMedical Research, Basel, Switzerland

Introduction: Hidradenitis suppurativa (HS) is a chronic, debilitating, inflammatory skin disease with poorly understood pathophysiology with high unmet medical need for effective and safe treatments. Pathway knowledge outside tumour necrosis factor (TNF)- α and interleukin (IL)-1 β is limited and an in-depth unbiased analysis of cell types and signaling cascades will help to dissect the underlying mechanisms and causes of the disease.

Methods and Results: Lesional and non-lesional skin from surgical discards of patients with HS, Hurley stage II or III, were analysed. Global gene expression (Affymetrix microarrays) was analysed in 19 lesional and 12 non-lesional HS biopsies, and 8 biopsies from healthy volunteers; hematoxylin and eosin staining and immunohistochemistry was performed on adjacent tissue. Hierarchical clustering of the RNA transcript data grouped the HS and healthy volunteers' biopsies into lesional, peri-lesional, and non-lesional/healthy groups, confirmed by histology. The global transcriptomics dataset was analysed for cell type-specific transcript signatures and IL-17 pathway signature using published and in-house signatures. Cell types identified in lesions included neutrophils, macrophages, B-cells, and various T-cell subsets like Th1 and Th17 cells. IL-17A signaling signatures derived from various cell types (keratinocytes, fibroblasts, whole skin) showed a significant increase in lesional samples, suggesting IL-17A pathway engagement. Unbiased analysis of differentially expressed genes between the groups identified the canonical IL-17A pathway and various members of the IL-17 ligand/receptor family as upstream regulators. This transcriptional data was supported by histopathology revealing severe mixed inflammatory infiltrates of mainly macrophages, neutrophils, T and B cells, and plasma cells in the lesional biopsies. Immunohistochemistry showed expression of IL-17A in T cells and neutrophils. In addition, β-defensin 2 and S100A7A were both found in areas mirroring psoriasiform epidermal hyperplasia.

Conclusions: HS lesions show clear IL-17A pathway engagements on several levels. Inhibition of IL-17A signaling could be beneficial for HS patients.

Learning Objectives:

• To investigate pathway engagement of IL-17A and relevant cell types in HS lesions

Takeaway Message:

- Hidradenitis suppurativa (HS) is an inflammatory skin disease with lesional infiltrates of diverse cell types (neutrophils, macrophages, T-cells and B-Cells), including Th17 cells
- HS lesions show presence of IL-17A expressing cells and upregulation of IL-17A associated gene signatures indicating that inhibition of IL-17A could be beneficial for HS patients

P1.04 Hidradenitis Suppurativa and Comorbid Disorders: an Immunohistochemical Real-world Approach

<u>Katarzyna P. Kaleta</u>¹, Georgios Nikolakis¹, Amir M. Hossini¹, Ottfried Balthasar², Daifallah Almansouri¹, Aristedes Vaiopoulos¹, Juergen Knolle², Anna Bogusławska³, Anna Wojas-Pelc⁴, Christos C. Zouboulis¹

1. Departments of Dermatology, Venereology, Allergology and Immunology, Dessau Medical Center, Brandenburg Medical School Theodore Fontane, Dessau, Germany, 2. Institute of Pathology, Dessau Medical Center, Dessau, Germany, 3. Department of Paediatric and Adolescence Endocrinology, Paediatric Institute, Jagiellonian University Medical College, Krakow, Poland, 4. Department of Dermatology, Jagiellonian University Medical College, Krakow, Poland

The major comorbid disorders associated with the occurrence or the aggravation of Hidradenitis suppurativa are obesity and smoking. Numerous efforts to dissociate these factors led to controversial results, since obesity and smoking often co-occur in the same person and family members. For these reasons, we conducted a study to assess the importance of metabolic disorders/obesity, smoking/environmental toxins, and inflammation in HS by utilizing the differential expression of major relevant protein markers in lesional skin of obese/smoking vs. non-obese/non-smoking HS patients.

Lesional skin specimens deriving from two groups of HS patients (BMI> 30 and smokers, n=12 vs. BMI<30 and non-smokers, n=10) were stained with antibodies raised against irisin, PPARγ, and IGF-1R, which correlate with metabolic disorders/obesity, EGFR and AhR, associated with smoking, and IL-17, IL-17R, and S100A8, as markers of inflammation. The intensity of the staining was analyzed for each antibody and expressed as median with interquartile range.

Expression of irisin, PPARγ, and IGF-1R was found significantly upregulated in the non-obese/non-smoking group. EGFR was slightly decreased in the obese/smoking patients, who expressed higher IL-17R levels than non-obese/ non-smoking patients. The in situ expression of AhR, IL-17, and S100A8 was similar in the two groups.

Learning Objectives:

- The fact that the studied patients did not have a manifesting metabolic disease indicates that skin changes could be
 more "sensitive" to tissue hormone levels than to serum ones and can serve as a sensitive marker prophesizing severe
 obese-related metabolic changes.
- 2Although not all inflammation markers were differently expressed between patients of the studied groups, IL-17R
 expression was stronger in obese/smokers, which might indicate the requirement of biologic treatment dose adaptation
 to body weight/smoking.
- Increased lesional S100A8 serves as biomarker of HS, independently from smoking status and BMI.

Takeaway Message:

In the selected real-world setting, metabolic disorders/obesity-related markers exhibited marked differential expression, while smoking-associated markers a limited one, suggesting a primary role of metabolic disorders/obesity in the pathogenesis of the disease. Based on molecular findings tobacco smoking might contribute less to HS than previously suspected.

P1.06 Complement Activation and C5aR1 Elevation in Hidradenitis Suppurativa Patient Lesions

<u>Chris Li</u>¹, Aatman Shah², Karen Ebsworth¹, Carolyn Dunlap¹, James Kilgour², Kathleen Sullivan¹, Israel Charo¹, Kavita Sarin², Thomas Schall¹

1. ChemoCentryx, Mountain View, CA, USA, 2. Dermatology, Stanford University Medical Center, Palo Alto, CA, USA

Complement dysregulation, neutrophil migration and activation have been implicated in the pathogenesis of hidradenitis suppurativa (HS), a chronic, inflammatory skin disease, characterized by neutrophil-rich inflammatory nodules and pus-filled abscesses. It is hypothesized that the complement pathway plays a significant role in neutrophil recruitment and subsequent inflammation in HS. The complement 5a receptor 1 (C5aR1) is a major driver of the pro-inflammatory functions of complement activation, providing a rationale for C5aR1 as a therapeutic target for this disease. Avacopan, a potent and specific inhibitor of human C5aR1, is currently being evaluated in a phase 2 clinical trial for HS.

To improve our understanding of the inflammatory processes underlying HS and the role of C5aR1, the presence of C5aR1 and other complement or inflammatory factors were assessed in the plasma and skin of HS patients. In the plasma, complement factors were measured by ELISA in both HS patients and healthy donors. In HS lesional and perilesional skin biopsies, the gene expression of complement and inflammatory factors were measured, and selected complement factors were also examined by immunohistochemistry (IHC).

Decreased levels of C3a and C5b-9 (the membrane attack complex), and increases in CFH and Bb proteins were observed in the plasma samples from HS patients, as compared to healthy donors. Gene expression of C5aR1 and S100A7 were significantly increased in lesional versus perilesional skin biopsies, with a number of other complement factors also trending towards increased expression in lesional skin. Complement activation markers (C5b-9, C3d and C4d) were also elevated in lesional skin biopsies from a subset of patients as evidenced by IHC, as compared to perilesional regions from the same patients.

These data are consistent with systemic dysregulation of complement in HS patients, potentially resulting in activation of other inflammatory pathways. In this context, the elevation of C5aR1 within HS lesions strengthens the rationale for clinical studies to assess the efficacy of avacopan in HS.

Learning Objectives:

- Pathogenesis of HS
- Complement dysregulation in HS
- Potential use of therapeutics that target complement pathway in HS

Takeaway Message:

Systemic dysregulation of complement and elevation of C5aR1 within lesions are observed in HS patients. These findings strengthen the rationale for clinical studies to assess the efficacy of a C5aR1 inhibitor in HS.



P1.07 Improving Understanding of Hidradenitis Suppurativa Through Deep Clinical Phenotyping and Molecular Profiling

<u>Samuel DePrimo</u>¹, Jun Min¹, Taher Sathaliya¹, Xuejun Liu¹, Michelle Lowes³, Afsaneh Alavi², Ernesto Muñoz-Elias¹

1. Janssen Research & Development, LLC, La Jolla, CA, USA, 2. Division of Dermatology, University of Toronto and Women's College Hospital, Toronto, ON, Canada, 3. The Rockefeller University, New York, NY, USA

Hidradenitis Suppurativa (HS) is a chronic, debilitating skin disease presenting with recurrent heterogeneous lesions, including inflammatory nodules, abscesses, comedomes, and deep dermal tunnels. Disease progression results in characteristic scarring in regions such as axilla, groin and inframammary regions due to irreversible tissue damage. It has been proposed that skin changes start from hair follicles with subsequent involvement of innate and adaptive immune system. Despite the profound negative impact on quality of life, molecular characterization of HS tissues is limited to date. We conducted a study aiming to better characterize molecular and cellular signatures of patients with HS and to define biomarkers by studying cutaneous morphological variants (including nodules, tunnels, abscesses); wound exudates which may have high inflammatory contents; serum; and PBMCs. Here we present results from analysis of lesional, perilesional, and nonlesional skin biopsies from 30 mild, moderate, or severe patients as defined by PGA-HS and Hurley staging. Differential gene expression analysis of RNA-sequencing data revealed 3027 upregulated and 2627 downregulated genes in lesional compared to nonlesional samples. Amongst the differentially expressed genes were innate and adaptive immune cells signatures, including Th1, Th2, Th17 cells, monocytes and neutrophils, as well as anti-microbial and anti-inflammatory signatures, TLRs and S100 family genes. Gene Set Variance Analysis (GSVA) revealed enrichment of complement, TNFα, IL1α/β, IL36, and IL23/IL17 pathway signatures in lesions. Also observed was high enrichment of B cell signatures and immunoglobulin genes in lesional skin, which is unexpected for a disease not considered to be B cell driven. Transcriptionally, no robust difference in nodular lesions from patients with mild vs moderate disease was found. Inflammatory and transcriptional changes in perilesional skin varied across patients and were generally minimal compared to lesional skin, suggesting that peri-lesional skin may not be a faithful surrogate of lesional inflammatory changes.

Learning Objectives:

- To better characterize molecular and cellular signatures of patients with HS and to define biomarkers by studying cutaneous morphological variants (including nodules, tunnels, abscesses)
- To assess the transcriptomic profile differences between nonlesional, perilesional, and lesional skins
- To evaluate molecular differences between disease severity stages

Takeaway Message:

We describe a translational study to improve disease understanding of HS by better characterizing molecular and cellular signatures and here present initial results from gene expression profiling of skin biopsies, representing morphological variants and different disease severity stages.

P2: Clinical Research

P2.01 Intravenous Ertapenem for Refractory Hidradenitis Suppurativa

Kayla M. Babbush, Avigdor Nosrati, Mondana H. Ghias, Kristen P. Pacific, Tyler M. Andriano, Steven R. Cohen Albert Einstein College of Medicine, Bronx, NY, USA

Introduction: Ertapenem, an intravenous (IV) broad-spectrum antibiotic, has been used off-label for refractory hidradenitis suppurativa (HS). Previous studies have reported significant improvement in quality of life, pain, and amount of drainage for HS patients treated with intravenous (IV) ertapenem. Others have documented a significant reduction in white blood cells, polymorphonuclear neutrophils, and CRP with six weeks of therapy.

Methods: We conducted a retrospective chart review of all patients receiving care at the Montefiore HS Treatment Center who initiated and completed at least six weeks of IV ertapenem therapy. A total of 27 patients received 1 gram (500 mg renally dosed) of IV ertapenem daily for 42 days. Demographic information and an inventory of previously failed therapies were obtained from the medical record. Disease severity (HS-Physician Global Assessment [HS-PGA]; Numerical Rating Scale [NRS] pain scores) and serum inflammatory markers (erythrocyte sedimentation rate [ESR], c-reactive protein [CRP], interleukin-6 [IL-6], tumor necrosis factor-alpha [TNF-a]), were assessed at baseline (week 0) and at the follow-up visit (approximately week 6).

Results: The mean age of this cohort was 35.7 ± 11.2 years, including 19 females (70.4%). Diverse ethnic and racial backgrounds were represented. All patients were Hurley Stage III. At follow-up visits, there were significant decreases in HS-PGA scores (p=0.0001), NRS pain scores (p=0.0002), and levels of inflammation, quantified by ESR (p=0.0017) and CRP (p=0.0134). Although there were substantial reductions in IL-6 and TNF-a, the differences were not statistically significant.

Conclusion: This study adds to the existing literature that demonstrates the utility of ertapenem for refractory HS. Defining the optimal duration of therapy is essential to avoid disease recurrent disease, as well as antibiotic resistance.

Learning Objectives:

- Intravenous ertapenem is an effective treatment option for refractory hidradenitis suppurativa.
- Significant reductions in disease severity (HS-PGA), Numerical Rating Scale pain scores, and inflammatory markers support the use of intravenous ertapenem therapy.

Takeaway Message:

The dramatic improvement seen in both clinical and laboratory markers of HS disease severity supports the utility of ertapenem as an effective and well-tolerated option for refractory HS.

P2.02 Physical Flare Symptoms in Hidradenitis Suppurativa

<u>Jennifer M. Fernandez</u>², Alyssa M. Thompson², Joslyn S. Kirby³, Jennifer L. Hsiao⁴, Vivian Y. Shi¹

1. University of Arkansas for Medical Sciences, Little Rock, AR, USA, 2. University of Arizona College of Medicine Tucson, Tucson, AZ, USA, 3. Penn State Health Milton S. Hershey Medical Center, Hershey, PA, USA, 4. University of California Los Angeles, Los Angeles, CA, USA

Introduction: Despite frequent use of the term "flare" by providers and patients, the physical symptoms associated with hidradenitis suppurativa (HS) flares have not been clearly elucidated. A previous qualitative study reported four major themes for HS flare: physical symptoms, emotional symptoms, worsening from prior state of HS activity, and functional impact. Herein we explored patient-reported physical symptoms of HS flares.

Methods/Results: An anonymous online survey was distributed to HS support groups on Facebook from February to March 2020. Participants ages 18-75 with HS were asked to self-report Hurley stage based on text descriptions, select all symptoms they experienced during an HS flare from the list provided (pain, drainage, itch, bleeding, and increased number of new lesions), and then to identify the symptom they believe was most defining of their flares. A chi-squared test was used to evaluate associations (significance level p<0.05).

The survey was completed by 438 participants (93.8% female and 6.2% male) who classified themselves as Hurley stage I (8.2%), II (53.4%), and III (38.4%). The most commonly reported flare symptom was pain (98.9% of participants), followed by itch (81.1%), bleeding (78.8%), increased number of new lesions (66.7%), and other (7.1%). Pain was the most defining flare symptom for 78.8% of participants, followed by drainage (12.8%), itch (3.2%), increased lesion count (2.7%), bleeding (0.5%), and other (2.1%). We found no significant association between symptoms reported during flares and gender or smoking status.

Conclusion: Pain is considered by patients to be the most important physical symptom associated with HS flares. Further investigation of other aspects of flare, such as emotional symptoms, as well as defining severity of flare, can lead to a meaningful treatment outcome measure for clinical trials and routine care.

Sources

• Sarfo A, Butt M, Kirby JS. Periodic worsening, or flare, in hidradenitis suppurativa: the perspective of people with hidradenitis. *Br J Dermatol.* 2020;182(1):218-219. doi:10.1111/bjd.18210

Learning Objectives:

- Patients feel that pain is the most defining symptom of flares in hidradenitis suppurativa (HS)
- HS patients commonly experience pain, drainage, itch, bleeding, and an increased number of new lesions
- The appearance or worsening of HS symptoms may indicate a flare

Takeaway Message:

Patients with hidradenitis suppurativa may require specialized symptom management during flares, particularly for pain.





P2.03 Intralesional Anti-Biofilm Therapy for Acute Tunnels in Patients with Hidradenitis Suppurativa

Maximillian A. Weigelt, Hadar Lev-Tov

Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery, University of Miami - Miller School of Medicine, Miami, FL, USA

Introduction: Current treatment options for Hidradenitis Suppurativa (HS) are unsatisfactory, partially due to incomplete understanding of the disease. The role of biofilms and bacteria in the pathogenesis of HS is becoming increasingly recognized, therefore targeting biofilms may be an effective therapeutic strategy for HS. Herein the authors propose a novel biofilm-targeted procedure for the treatment of HS tunnels using an antibiofilm surfactant wound gel (ABWG).

Methods/Results: This is a retrospective chart review of patients who were treated with ABWG for HS tunnels between December 2019 and March 2020 at a university hospital medical center outpatient dermatology clinic. Three patients from age 24-34 years (mean 27.66 years) were identified and included. After a punch incision, ABWG was injected into HS tunnels using a modified blunt-needle syringe setup. Patients were provided with additional pre-loaded syringes to continue self-injections at home. The primary outcome measure was healing of the tunnels as determined by the physician. Secondary outcome measures included patient's perceived healing speed and changes in lesional pain. Two out of three (66%) of patients demonstrated good healing response – the third patient underwent mechanical trauma to the treated lesion which may have affected the outcome. Two out of three (66%) of patients reported faster perceived healing time and decreased lesional pain. 100% of patients found the procedure easy to self-administer at home. No significant adverse events were reported.



Conclusion: In conclusion, biofilm-based treatment approaches have the potential to improve outcomes for acute flares in patients with hidradenitis suppurativa. Here we report the application of ABWG into HS tunnels as a safe, simple, and low-risk intervention to improve wound healing outcomes. Larger, controlled trials are needed.

Learning Objectives:

- The need for novel treatment modalities for Hidradenitis Suppurativa cannot be understated.
- Biofilms play a role in the pathogenesis of Hidradenitis Suppurativa
- Applying anti-biofilm wound gel into HS tunnels is a safe, simple and low-risk patient-centered intervention.

Takeaway Message:

Biofilm-based treatment approaches have the potential to improve clinical outcomes for acute flares in patients with Hidradenitis Suppurativa

P2.04 Characterizing Perimenstrual Flares of Hidradenitis Suppurativa

Erin K. Collier¹, Kyla Price², Tristan Grogan³, Haley Naik⁴, Vivian Shi⁵, Jennifer Hsiao⁶

1. David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, USA, 2. College of Medicine, University of Illinois, Chicago, Chicago, IL, USA, 3. Department of Medicine Statistics Core, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, USA, 4. Department of Dermatology, University of California San Francisco, San Francisco, CA, USA, 5. Department of Dermatology, University of Arkansas for Medical Sciences, Little Rock, CA, USA, 6. Division of Dermatology, Department of Medicine, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, USA

Introduction: There is a paucity of data characterizing perimenstrual HS flares and the consistency with which they occur. Herein, we aim to describe the temporal pattern of perimenstrual HS flares, association with perimenstrual acne flares, and also explore factors associated with perimenstrual HS flares.

Methods: An anonymous web-based questionnaire was distributed to various HS support groups on Facebook in May 2020. Inclusion criteria for the study were adult women with self-reported HS who report having menstrual cycles. Statistical analyses were performed using IBM SPSS V25 and p-values<0.05 were considered statistically significant.

Results: A total of 283 female participants completed the survey. The majority (176/282, 62.4%) of participants reported HS worsening with menses, with 86.9% (153/176) noting that flares occur 'always' or 'often.' Most (138/175, 78.9%) respondents reported that their HS flared in the week preceding their menses versus during (33/175, 18.9%) or after (4/175, 2.3%) menses. The rate of perimenstrual acne flares is 83.1% for those with perimenstrual HS flares and 16.9% for those without perimenstrual HS flares (p=0.027). There is also a significant positive correlation between the temporal worsening of perimenstrual flares of HS and acne. Furthermore, women who report pre-menstrual HS flares also tended to report pre-menstrual acne flares (Spearman correlation 0.60, p<0.001). Perimenstrual HS flares were more likely in participants with a family history of HS than those without (49.6% v 28.2%, p=0.019); no differences were seen based on race, HS disease severity, BMI, or positive history of acne or PCOS.

Patient characteristics	n (%)
Age	
At time of survey, mean +/- SD (range), y (n=283)	35.0 +/- 8 (18-54)
At menarche, mean +/- SD (range), y (n=282)	12.1 +/- 1.6 (8-17)
At HS symptom onset, mean +/- SD (range), y (n=280)	18.3 +/- 8.0 (4-48)
BMI, mean +/- SD (range), (n=282)	34.6 +/- 8.5 (17.4-64.6)
Country of residence (n=279)	
United States	201 (72.0%)
United Kingdom	36 (12.9%)
Canada	18 (6.4%)
Australia	9 (3.2%)
Puerto Rico	4 (1.4%)
Malaysia	2 (0.7%)
Other*	9 (3.2%)
Race/ethnicity (n=283)	



White/Caucasian	199 (70.3%)
Black/African descent	30 (10.6%)
Hispanic/Latino	28 (9.9%)
Mixed or Multi-racial	15 (5.3%)
Asian/Pacific Islander	6 (2.1%)
Other	5 (1.8%)
History of PCOS (n=283)	63 (22.3%)
History of acne (n=283)	128 (45.2%)
HS severity (n=282)	
Hurley stage I	15 (5.3%)
Hurley stage 2	155 (54.8%)
Hurley stage 3	112 (39.7%)
HS symptoms in relation to menarche (n=279)	
Prior to menarche	37 (13.3%)
Same age as menarche	22 (7.9%)
After menarche	220 (78.9%)
Family history of HS (n=283)	
Yes	91 (31.2%)
No	112 (39.6%)
Do not know	80 (28.3%)
Body parts affected by HS (n=283)	
Groin/genitals	258 (91.2%)
Axillae	217 (76.7%)
Buttocks	191 (67.5%)
Breast/inframammary	158 (55.8%)
Behind ears	44 (15.5%)
Posterior neck	38 (13.4%)
Scalp	26 (9.2%)
Other	79 (27.9%)
Duration of menstrual cycle (n=281)	
Less than 21 days	15 (5.3%)

21-35 days	193 (68.7%)
More than 35 days	6 (2.1%)
Too irregular to say	67 (23.8%)
HS gets worse with period (n=282)	
Yes	176 (62.4%)
No	52 (18.4%)
Do not know	54 (19.1%)
How frequently does your HS get worse with your periods? (n=176)	
Always	96 (54.5%)
Often	57 (32.4%)
Sometimes	23 (13.1%)
HS usually gets worse (n=175)	
In the week before my period	138 (78.9%)
During my period	33 (18.9%)
In the week after my period ends	4 (2.3%)
Does acne get worse with period (n=127)	
Yes	91 (71.7%)
No	21 (16.5%)
Do not know	15 (11.8%)
Acne usually gets worse (n=91)	
In the week before my period	64 (70.3%)
During my period	27 (29.7%)
In the week after my period ends	0 (0.0%)

Conclusion: Peri-menstrual HS flares predominantly and consistently occur during the week prior to menses, supporting a potential role for sex hormones in HS symptoms. Additional investigation is warranted to further elucidate the role of sex hormones in HS pathogenesis and to explore treatments to mitigate menstrual HS flares.

Learning Objectives:

- To characterize the temporal pattern of HS perimenstrual flares
- To identify factors associated with perimenstrual HS flares
- To investigate the association of HS perimenstrual flares with acne menstrual flares

Takeaway Message:

• Physicians should inquire about pre-menstrual HS flares in all their female HS patients of child-bearing age and consider offering hormonal therapies such as combined oral contraceptive pill or spironolactone to help ameliorate symptoms.



P2.05 Anti-androgen Therapy in HS: Finasteride as an Alternative to Spironolactone

<u>Kayla M. Babbush</u>, Mondana H. Ghias, Tyler M. Andriano, Steven R. Cohen *Albert Einstein College of Medicine, Bronx, NY, USA*

Introduction: There is a strong female predominance in hidradenitis suppurativa (HS), and it is widely accepted that sex hormones play a significant role in disease pathophysiology. Although this mechanism is poorly understood, hormone modifying therapy, specifically spironolactone, has become a standard of care due to anti-androgen effects. Alternatively, a small number of studies have reported that finasteride may be used as an androgen antagonist in women. We report finasteride therapy in a cohort of women with HS.

Methods: We conducted an IRB-approved retrospective chart review and telephone survey of all female HS patients, 18-years or older, who were prescribed finasteride by a single provider at Albert Einstein College of Medicine - Montefiore HS Center, between January 2018 and June 2020. The telephone survey was conducted to assess the perceived response to finasteride and inquire about the presence of adverse effects.

Results: Of 30 patients in this study, the mean age was 41.3 ± 15.2 years. Hurley stage documentation included 7 (23.3%) stage I, 8 (26.7%) stage II, and 15 (50.0%) stage III. The primary reasons for initiating finasteride therapy related to contraindications associated with the use of spironolactone, lack of a positive response, and/or poor tolerability. Of 12 patients who participated in a telephone interview, most (83.3%) reported a willingness to take finasteride again or continue with therapy if clinically indicated. Five patients (41.7%) reported overall satisfaction with finasteride; four were neutral about satisfaction (33.3%) and three were dissatisfied (25.0%). No patients reported worsening disease while on finasteride, and only one patient (8.3%) indicated a reduction in quality of life. When asked about side effects, 75.0% (n=9) reported no side effects from the medication. Three patients reported side effects that included nausea, menstrual irregularities, and reduction in libido/sexual dysfunction.

Conclusion: Our study suggests that finasteride may be used as anti-androgen therapy for female patients who have contraindications to or cannot tolerate spironolactone.

Learning Objectives:

- Finasteride, an androgen antagonist, has a role in hidradenitis suppurativa therapy for females with renal disease or another contraindication(s) to spironolactone, lack of clinical responsiveness, or poor tolerability.
- A majority of our cohort experienced no side effects with finasteride and would be willing to continue with therapy if clinically indicated.

Takeaway Message:

There are numerous reasons for initiating finasteride in women including contraindications to spironolactone or failure of spironolactone therapy. Our findings demonstrate finasteride is well accepted as a hormone modifying therapy for females with hidradenitis suppurativa.

P2.06 Patient Perspectives on Telemedicine for Hidradenitis Suppurativa

<u>Tyler M. Andriano</u>, Kayla M. Babbush, Avigdor Nosrati, Gabrielle Benesh, Steven R. Cohen *Albert Einstein College of Medicine, Bronx, NY, USA*

Introduction: During the COVID-19 pandemic, most dermatologic visits were transitioned to telemedicine. While telemedicine studies for both dermatologic and non-dermatologic visits have demonstrated overall satisfaction, this modality has not been evaluated for the management of hidradenitis suppurativa (HS).

Methods: We conducted retrospective chart reviews and telephone surveys of patients under the care of one provider at the Albert Einstein College of Medicine-Montefiore HS Center who had a telemedicine visit between March and May 2020. Demographic and clinical information were obtained from the medical record. Phone surveys were administered to evaluate patient perspectives about technical feasibility, satisfaction, and overall utility of telemedicine visits for HS.

Results: The average age of participants (n=45) was 35 ± 13 , and the majority (87%) were female. Average HS-PGA at live visit prior to telemedicine appointment was 2.9 ± 1.5 . Overall satisfaction with telemedicine was positive, with 32 participants (71%) reporting extreme satisfaction or satisfaction. Forty participants (89%) reported visits were extremely important or important. The majority rated the technology positively, with 32 (71%) reporting it as extremely easy or easy to use. Telemedicine was ranked superior to in-person office visits with regards to time getting to visit by 32 (71%). When comparing telemedicine and in-person office visits, 26 (58%) patients reported no difference regarding the personal connection they felt

with their clinician, and nearly half (22 [49%]) reported no difference in finding a convenient visit time. Concerning the amount of time spent with clinician, 16 (36%) ranked in-person visits better, 10 (22%) ranked telemedicine better, and 18 (40%) ranked them as the same. The willingness to incorporate telemedicine visits for HS follow-ups was high (27 [60%]). Additionally, 5 (11%) reported improvement in HS management using telemedicine; 28 (62%) reported no change. During the period of observation, 16 (36%) patients required in-person management of acute flares (painful inflammatory nodules, abscesses, draining sinus tracts).

Conclusion: Our findings demonstrate an overall positive response to telemedicine in the management of HS.

Learning Objectives:

- Patients report satisfaction, ease, and convenience of telemedicine visits in the management of HS.
- The majority of patients did not feel that telemedicine sacrificed visit quality or efficacy and would be willing to incorporate telemedicine visits for HS follow ups.

Takeaway Message:

The overall positive response suggests that telemedicine can be a valuable adjunct in the management of patients with HS, allowing for expanded access to providers and truncated in-person visit times.

P2.08 Hydroxychloroguine for the Treatment of Hidradenitis Suppurativa

Elena Gonzalez Brant¹, Oleg Akilov²

1. Beth Israel Lahey Health, Burlington, MA, USA, 2. University of Pittsburgh, Pittsburgh, PA, USA

Introduction: Hidradenitis suppurativa (HS) is a debilitating disease involving the development of painful draining nodules and sinus tracts in intertriginous areas. Elevated levels of the inflammatory cytokines IL-12, IL-17, IL-23, TNF α , IL-10 and IL-1 β have been found in patients with HS. Hydroxychloroquine has a well-studied safety profile, can modulate inflammatory markers known to be associated with HS, improves lipid metabolism and glucose, and decreases risk of cardiovascular disease, all factors known to be associated with HS-related morbidity.

Methods/Results: Sequential patients with HS presenting to the University of Pittsburgh department of dermatology were treated with hydroxychloroquine 200mg twice daily for 6 months. Patients were evaluated at baseline, 3 and 6 months by Sartorius scoring and a Dermatology Life Quality Index (DLQI) survey. Comparisons were made using a two-sided t test with a p value<0.05 for statistical significance.

A total of 17 patients enrolled in the trial. 14 were lost to follow up by 6 months. The average age of patients enrolled was 39 and 82% were female. 82% of those enrolled were caucasian and 18% were black.

There was a significant decline in DLQI from baseline to 3 months, from 13.1 to 4.4 (p=0.018), but change from baseline to 6 months was not significant (14.7 to 6 (p=0.21)). The mean Sartorius score decreased a significant amount from baseline to 6 months (N=3) from 23.3 to 17.7 (p=0.042). No long term side effects were associated with treatment with hydroxychloroguine.

Conclusions: The cost and shortage of treatments for HS are a tremendous barrier to disease management. Hydroxychloroquine is a widely available and inexpensive treatment with low toxicity. Although this was a small clinical trial, patients did see improvement in DLQI and Sartorius scores. Our results suggest that a larger study is required to establish the true benefit of hydroxychloroquine in HS.

Learning Objectives:

- Consider the benefits of old medications for new purposes
- Consider hydroxychloroquine as a treatment option for hidradenitis suppurativa.
- A larger study is needed to determine the true value of this treatment

Takeaway Message:

Hidradenitis is a debilitating disease with a need for additional treatment options. Hydroxychloroquine is widely available, has a well-studied safety profile, and has shown benefit as a hidradenitis treatment in our small study.



P2.09 Study Design and Baseline Characteristics of Phase 3 Studies of Secukinumab (SUNSHINE and SUNRISE) in Patients with Moderate-to-Severe Hidradenitis Suppurativa

Alexa B. Kimball¹, Alice Gottlieb², Afsaneh Alavi³, Ziad Reguiai⁴, Elisa Muscianisi⁵, Deborah Keefe⁵, Rafal Mazur⁶, Anna Stefanska⁷, Ruquan You⁸, Lorenz Uhlmann⁶, Xiaoling Wei⁸, Gregor B. Jemec⁹

1. Harvard Medical School and Clinical Laboratory for Epidemiology and Applied Research in Skin (CLEARS), Department of Dermatology, Beth Israel Deaconess Medical Center, Boston, MA, USA, 2. Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY, USA, 3. Department of Medicine, Division of Dermatology, University of Toronto, Toronto, ON, Canada, 4. Dermatology Department, Polyclinique Courlancy, Reims, France, 5. Novartis Pharmaceuticals Corporation,, East Hanover, NJ, USA, 6. Novartis Pharma AG, Basel, Switzerland, 7. Novartis Ireland Ltd, Dublin, Ireland, 8. China Novartis Institutes for BioMedical Research, Shanghai, China, 9. Department of Dermatology, Zeeland University Hospital, Health Sciences Faculty, University of Copenhagen, Roskilde, Denmark

Hidradenitis suppurativa (HS) is a chronic, recurrent, painful, inflammatory skin condition with upregulation of IL-17A associated gene signatures and hyper production of IL-17A. IL-17A is known to have a pathogenic role in several dermatosis due to its ability to induce hyperproliferation of keratinocytes and promoting inflammation, indicating that inhibition of IL-17A could be beneficial for HS patients. Secukinumab is a fully human monoclonal anti-IL-17A antibody which has shown efficacy and safety in psoriasis. Here, we report the study design and baseline characteristics of core studies of secukinumab in HS.

Methods and Results: SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) are twin Phase 3, randomized, double-blind, parallel group, placebo-controlled studies assessing the efficacy and safety of secukinumab 300mg Q4W or Q2W in approximately 471 patients (per study) with moderate-to-severe HS (**Figure**). The primary objective is to demonstrate the superiority of secukinumab vs. placebo at Week 16 with respect to HiSCR. At the time of development of abstract, 203 (43.1%) and 166 (35.2%) patients completed treatment period 1, in SUNSHINE and SUNRISE respectively. In both studies, the mean age of patients was about 37 years, predominantly female (>57%) with a mean weight of 94 kg (**Table**). The vast majority of patients were currently smoking (>57%).

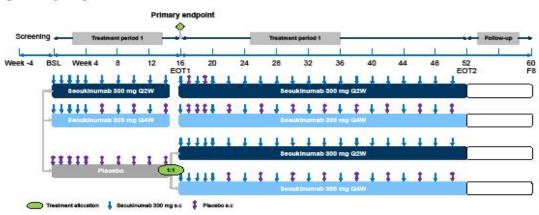


Figure. Study design of the core studies

BSL, baseline; EOT1/EOT2: end of treatment period 1/2; PS, end of 5-week follow-up period; Q2W, every two weeks; Q4W, every four weeks

Table. Baseline demographics and disease characteristics (randomized analysis set)

Characteristic	SUNSHINE (N=203)	SUNRISE (N=166)		
Age (years), mean (SD)	37.2 (12.03)	37.1 (12.09)		
Female, n (%)	116 (57.1)	97 (58.4)		
Weight (kg), mean (SD)	91.71 (23.82)	96.36 (23.60)		
Weight (kg), n (%)				
<90	102 (50.2)	76 (45.8)		
≥90	101 (49.8)	90 (54.2)		
Current antibiotic use, n (%)				
Yes	34 (16.7)	27 (16.3)		
No	169 (83.3)	139 (83.7)		
Smoking status, n (%)				
Never	51 (25.1)	47 (28.3)		
Current	117 (57.6)	96 (57.8)		
Former	35 (17.2)	23 (13.9)		
Disease duration (months), mean (SD)	96.31 (101.94)(n=202)	91.76 (94.77) (n=165)		
Inflammatory nodules, mean (SD)	10.44 (7.89)	10.01 (7.89)		
Abscesses, mean (SD)	2.92 (3.75)	3.73 (5.20)		
Draining fistulas, mean (SD)	2.69 (3.18)	2.78 (3.58)		
Skin pain (NRS), mean (SD)	4.59 (2.54) (n=191)	4.66 (2.38) (n=146)		

Conclusion: The SUNNY trials are the first attempt to evaluate the efficacy and safety of the selective blockage of IL-17A in a Phase 3 development plan in HS. The baseline analysis of study population provides us with a deeper understanding of the population characteristics of HS patients.

Learning Objectives:

- To describe the study design of two Phase 3 studies of secukinumab in patients with moderate-to-severe hidradenitis suppurativa
- To describe the baseline demographics of the study population

Takeaway Message:

The two identically designed trials SUNSHINE and SUNRISE will assess the short- and long-term efficacy and safety of two subcutaneous secukinumab 300 mg dose regimens in patients with moderate to severe hidradenitis suppurativa. The population enrolled is representative of a moderate-to-severe population in different ethnicities and covering multiple geographies.



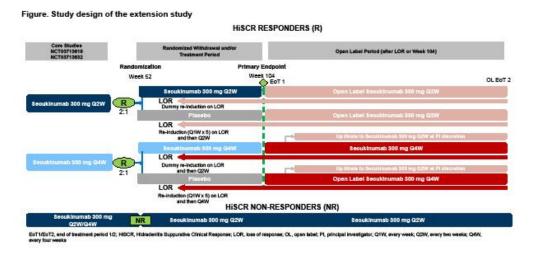
P2.10 Trial Management During the COVID-19 Pandemic: Lessons Learned from Phase 3 Extension Study of Secukinumab in Patients with Moderate-to-Severe Hidradenitis Suppurativa

<u>Alexa B. Kimball</u>¹, Alice Gottlieb², Afsaneh Alavi³, Ziad Reguiai⁴, Rafal Mazur⁵, Elisa Muscianisi⁶, Deborah Keefe⁶, Angela Llobet Martinez⁵, Xiaoling Wei⁷, Lorenz Uhlmann⁵, Gregor B. Jemec⁸

1. Harvard Medical School and Clinical Laboratory for Epidemiology and Applied Research in Skin (CLEARS), Department of Dermatology, Beth Israel Deaconess Medical Center, Boston, MA, USA, 2. Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY, USA, 3. Department of Medicine, Division of Dermatology, University of Toronto, Toronto, ON, Canada, 4. Dermatology Department, Polyclinique Courlancy, Reims, France, 5. Novartis Pharma AG, Basel, Switzerland, 6. Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, 7. China Novartis Institutes for BioMedical Research, Shanghai, China, 8. Department of Dermatology, Zeeland University Hospital, Health Sciences Faculty, University of Copenhagen, Roskilde, Denmark

Introduction: The long-term, 4-year extension study (NCT04179175) of core Phase 3 SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) trials was designed to evaluate the maintenance of clinical response in patients with hidradenitis suppurativa (HS) in either continuous or interrupted therapy with secukinumab. The study opened for enrollment in March 2020. Here, we report the study design and impact of COVID-19 pandemic on study management.

Methods and Results: The study includes 2 periods: (A) 52-week, double-blind, parallel-group, randomized withdrawal, (B) open-label, active-treatment (upto 3 years). In total, 745 patients with moderate-to-severe HS are expected to enter extension study and 336 patients will be randomized based on HiSCR50 response at Week52 of the core studies. Responder patients will be re-randomized to active treatment or placebo, while non-responder patients will continue to an open-label Q2W regimen (Figure). Responder patients will be switched to the open-label treatment with secukinumab 300 mg (Q2W or Q4W) after experiencing loss of response or after 52weeks of treatment in the extension study. COVID-19 pandemic disrupted trial management, burdening: (A) sites, asked to prioritize COVID-related activities or impeded from running clinical trials; (B) patients, quarantined or unable to follow study procedures or attend visits; (C) monitors, limited in activating or visiting sites; (D) potential impact on data collection. To mitigate the impact, Novartis interrupted the core but not the extension enrollment, and amended the program rapidly including home delivery of drug and pregnancy tests, remote safety collection and monitoring. At the time of submission, 51 patients are successfully rolled-over and one discontinued due to an unrelated AE.



Conclusion: Patients were prepared to enter a long-term extension study and sites implemented rapidly the remote/at home changes. This approach ensured continuity of treatment and ability to roll-over for patients. The study was successfully initiated despite COVID-19 pandemic with no new safety signal identified.

Learning Objectives:

- To describe the initiation of a long-term extension study during the COVID-19 pandemic
- To describe the transition of patients from the core phase III trials, SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) to the extension phase during lockdown
- To describe the impact of the COVID 19 pandemic on this trial and the relative remediation plan
- To underscore the relevance of collaboration across the several stakeholders engaged in the management of patients in trials

Takeaway Message:

- The extension trial was disrupted due to COVID-19 pandemic. Nevertheless, pragmatic approaches helped to mitigate some of the challenges posed by the pandemic
- The management of trials requires the commitment and the collaboration of several stakeholders, and is it possible with
 a close communication between sites and industry. Investigators play a critical role in ensuring patient's enrollment and
 safety monitoring, and a fast pragmatic response from the sponsor is required to provide flexible solutions and prompt
 updates

P2.11 Excellent Response to Treatment in Hidradenitis Suppurativa Patient Treated with Guselkumab

Wayne Gulliver^{1, 2}, Susanne Gulliver², Michelle Penney²

1. Faculty of Medicine, Memorial University of Newfoundland, St. John's, NL, Canada, 2. Newlab Clinical Research Inc., St. John's, NL, Canada

Hidradenitis suppurativa (HS) is a chronic, recurrent, and devastating inflammatory skin disorder characterized by painful nodules and draining sinus tracts with consequent scarring. Patients with HS are often undertreated as there are inadequate effective therapies available. Biologic agents are promising therapeutic options used in the management of many inflammatory conditions, more recently including the treatment of HS.

This report describes a 53 year old Canadian male with a long-standing history of HS, Hurley stage III. Despite receiving numerous traditional treatments, the patient continued to present with multiple inflammatory and/or draining lesions and pain. After failing adalimumab, ustekinumab, and infliximab, the patient was treated with 100mg of guselkumab at 0, 4, and 8 weeks with exceptional and rapid response from 32 inflammatory and/or draining lesions at baseline, to a single active lesion at week 12. To our knowledge, this is the first reported Canadian HS patient treated with guselkumab.

Learning Objectives:

- Appreciate the challenges faced by patients and their treating physicians compounded by lack of effective treatment options.
- Understand the utility of biologic agents in the treatment of HS.
- Recognize the importance of patient quality of life when deciding clinical management.

Takeaway Message:

Guselkumab may be a promising treatment option for the clinical management of HS patients who have failed prior intervention, including multiple biologic agents.

P2.12 The Characterization of Hidradenitis Suppurativa as Defined by Differences in Age Groups

Maria del Mar Melendez Gonzalez¹, Christopher Sayed²

1. Universidad Central del Caribe, Bayamon, PR, USA, 2. University of North Carolina School of Medicine, Department of Dermatology, Chapel Hill, NC, USA

Introduction: Hidradenitis suppurativa (HS) commonly begins during adolescence and young adulthood, but as a chronic inflammatory skin disease, its presentation and sequelae can modify with age. By analyzing a patient cohort divided in age groups and its characteristics, we can obtain a better understanding of these changes.

Methods/Results: For this retrospective cohort study of 706 HS patients from a single outpatient academic dermatology clinic, data collection was via interviews and electronic medical record reviews. There were four defined age groups as follows:<18 years old, 18-39 years old, 40-59 years old, and 60+ years old. Variables were analyzed in the cohort (n= 706) and within each age group. Some of the variables of interest include age of onset, age of diagnosis, delay in diagnosis, Hurley stages, phenotypes, lesion location, and comorbidities.

Older age at time of enrollment was linked to increasing mean age of onset, diagnosis and delay in diagnosis. Hurley stage 2 was most common in minors and young adults, while middle and older aged adults were stage 3. Distinct patterns of lesion locations were observed in each age group. Older age was also linked to a higher proportion of conglobata, syndromic, and scarring folliculitis phenotype. Comorbidities burden also increased with age, specifically depression, hypertension and type 2 diabetes. PCOS peaked at 18-39 and went on a decreasing trend with age and IBD having its highest percentage in the middle age group.



Conclusions: The presentation of HS disease characteristics through age groups has presented the opportunity to study trends on how lesion location changes with age, how phenotype defining characteristics can correlate to age, how delay in diagnosis can influence incidence among age groups and how comorbidities are associated with patient age. Understanding HS presentation variability with age can have a significant impact on disease management.

Learning Objectives:

- Recognizing population characteristics of a cohort of HS patients through age groups.
- Understand how increasing patient age relates to comorbidity risk.
- Recognize how patient phenotype may change with increasing age.

Takeaway Message:

Hidradenitis suppurativa disease presentation has modified features depending on a patient's age group.

P2.13 Evaluation of Analytical and Clinical Validity of Doppler Ultrasound-Based Biomarkers in Hidradenitis Suppurativa

John W. Frew¹, David Grand², Kristina Navrazhina¹, James Krueger¹

1. Laboratory for Investigative Dermatology, Rockefeller University, New York, NY, USA, 2. Albert Einstein College of Medicine, New York, NY, USA

Introduction: Hidradenitis suppurativa (HS) is a chronic recurrent inflammatory skin disease which currently lacks validated image-based biomarkers. We studied the analytical and clinical validity of candidate sonographic biomarkers in HS with the intention of establishing the most valid candidate biomarker for future clinical and investigational use.

Methods: Ethics approval for this study was granted by the institutional review board of Rockefeller University, which involved performing 10-22 MHz GE LogicQ ultrasonography and obtaining matching skin biopsies in 22 patients with moderate-to-severe HS.

Results: Sonographic measures of epidermal thickness and dermal tunnel diameter strongly correlate with matched histology (R^2 = 0.8247 and 0.8401 respectively) but correlate poorly with VAS pain (R^2 = 0.0936 and 0.211 respectively). Clinical and analytical validity of dermal tunnel diameter changes when stratifying for draining vs. non-draining tunnels. Power Doppler intensity demonstrates strong correlation with VAS pain (R^2 = 0.673) as well as numerous molecular markers of inflammatory activity, including degree of dermal CD3+ cell (R^2 = 0.4025) and CD11c+ (R^2 = 0.3515) cell infiltration. We introduced candidate non-invasive sonographic biomarkers that correlate to clinical and molecular aspects of disease activity in HS.

Learning Objectives:

- Introduce candidate sonographic biomarkers of HS disease activity.
- Establish the analytical and clinical validity of sonographic biomarkers by correlating biomarker measurements to established clinical and molecular markers of HS disease activity.

Takeaway Message:

Epidermal thickness and dermal tunnel diameter demonstrate analytical validity but lack clinical validity. Power Doppler intensity demonstrates both analytical and clinical validity, suggesting its utility as a non-invasive imaging-based biomarker of HS disease activity.

P2.14 Dermal Tunnels Influence Time to Clinical Response and Family History Influences Time to Loss of Clinical Response in Adalimumab-Treated Hidradenitis Suppurativa

<u>John W. Frew</u>¹, Neha Singh², Caroline Jiang², Kristina Navrazhina¹, Roger Vaughan², James Krueger¹

1. Laboratory for Investigative Dermatology, Rockefeller University, New York, NY, USA, 2. Department of Biostatistics, Rockefeller University, New York, NY, USA

Background: Clinical response in hidradenitis suppurativa (HS) is most commonly assessed using the Hidradenitis Suppurativa Clinical Response (HiSCR). Dermal tunnels, increased BMI, smoking and antibiotic use significantly decrease the odds of achieving HISCR. However, there is little data exploring if clinical features are also associated with length of time to achieve clinical response; and/or time to lose clinical response.

Objectives: To explore whether variables associated with achieving HiSCR are associated with time to achieve HiSCR and time to loss of HiSCR in HS patients treated with PIONEER OLE Adalimumab 40mg weekly.

Methods:Time to event analyses were performed to estimate time to achieve HiSCR and time to loss of HiSCR. The log rank test was used to compare cumulative incidence curves for *a priori*patient and disease associated factors. Cox regression analysis was performed to compare time to event outcomes in the presence of *a priori*variables.All statistical analysis was completed in R version 3.5.3.

Results: Presence of dermal tunnels significantly increased the time to achieve HiSCR (median 32.6 vs. 14.3 weeks, p=0.021) and the hazard ratio was significant after controlling for patient and disease factors (HR=0.70, 95%Cl=0.51-0.96, p=0.03). A positive family history of HS significantly decreased the time to loss of HiSCR (median 11.4 vs. 18 weeks, p=0.00079) and remained significant in Cox regression analysis (HR=2.01, 95%Cl=1.40-2.88, p=0.0001).

Conclusions: The presence of dermal tunnels significantly influences the odds of achieving HiSCR as well as the time to achieve HiSCR, while family history influences time to loss of HiSCR.

Learning Objectives:

- To understand the existing data regarding length of time to achieve and lose HiSCR responses.
- To understand the influence of disease and patient associated variables in altering the time to achieve and lose HiSCR response.
- To appreciate the implications that differential disease response may have in terms of identifying novel, clinically relevant disease subtypes.

Takeaway Message:

The presence of dermal tunnels significantly increases the time to achieve clinical response with Adalimumab therapy as measured by Hidradenitis Suppurativa Clinical Response (HiSCR). A positive family history of HS significantly decreases the time to loss of HiSCR during Adalimumab therapy. The presence of dermal tunnels and positive family history of HS remain significant in cox regression analysis after accounting for other patient and disease associated factors.

P2.15 Preliminary Clinical Experience with a Novel Acrylic Film Dressing for Hidradenitis Suppurativa Wounds

Maximillian A. Weigelt, Hadar Lev-Tov

Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery, University of Miami - Miller School of Medicine, Miami, FL, USA

Hidradenitis suppurativa (HS) is a chronic, relapsing-remitting inflammatory disease characterized by nodules, abscesses and sinus tracts with scarring, primarily in intertriginous areas. The exudate, odor and pain caused by HS wounds exert significant negative effects on patients' quality of life. These effects have the potential to be assuaged by good wound dressings, however data supporting the optimal choice of dressing for HS is limited. Here the authors present an experience with a novel absorbent clear acrylic film dressing (ACFD) for the treatment of HS wounds. Researchers retrospectively reviewed the charts of 9 patients treated with the ACFD at outpatient Dermatology and Wound Care clinics between September 2019 and January 2020 to understand patients' comments on fit, comfort, irritation, pain, exudate and desire to continue using the dressing. 100% of patients reported that the ACFD was comfortable and fit well in a variety of anatomical locations. 88.8% of patients reported that the ACFD handled exudate well. 88.8% of patients expressed their desire to continue using the ACFD. Clinicians and patients also appreciated the transparent design of the dressing. The preliminary clinical experience with this dressing demonstrates its potential to improve the quality of life in patients with HS. Importantly, this heterogenous sample represents well the wide variety of HS lesion types and anatomical locations with 100% of patients nonetheless reporting good fit and comfort of the dressing. Further exploration of these results by controlled prospective studies are needed.



Table 1: Demographics, Lesion Characteristics, and Patient-Centered Outcomes of Nine Patients Treated with ACFD for HS lesions (Mod – Moderate. Y – Yes. N – No.). * two wounds in the same patient

Case	Age	Gender	Hurley Stage	Smoking Status	Lesion Type	Lesion Location	Level of Exudate	Comfort/ Fit	Irritation	Pain	Handled Exudate
1	67	F	III	Never	Mixed Plaque	Buttock	Mod	Y	N	Decreased	Y
2	46	М	I	Current	Nodule	Axilla	Low	Y	N	No change	Y
3	26	F	III	Never	Sinus Tract	Axilla	Low	Υ	Y	Decreased	Y
4	28	F	III	Ex	Nodule	Groin	Mod	Y	N	No change	Y
5	19	F	=	Never	Nodule	Inner Thigh	Low	Y	N	Decreased	N
6	25	F	I	Never	Nodule	Axilla	Low	Y	N	No change	Y
7	39	F	III	Ex	Post-Surgical	Groin	Low	Y	N	Decreased	Y
8	41	М	III	Current	Ulcerative Plaque	Buttock	Mod	Υ	N	No change	Y
9*	35	F	III	Never	Mixed Plaque	Axilla	Mod	Υ	N	No change	Y
9*	35	F	III	Never	Mixed Plaque	Groin	Mod	Y	N	No change	Y



Learning Objectives:

- Selection of an appropriate dressing is an important part of the routine care of patients with hidradenitis suppurativa.
- Evidence for optimal dressing choice in hidradenitis suppurativa is limited
- This novel clear acrylic film dressing fits in a variety of anatomic locations, handles exudate well, and is generally well-liked by patients.

Takeaway Message:

This novel clear acrylic film dressing, in conjunction with adequate systemic therapies, has the potential to improve quality of life in patients with Hidradenitis Suppurativa.

P2.16 Anti-TNF Antibodies in Hidradenitis Suppurativa: a Systematic Review

Justin D. Lu¹, Milica Milakovic², Vincent Piguet^{3, 4}, Afsaneh Alavi^{3, 4}

1. Michael G. DeGroote School of Medicine, McMaster University, Hamilton, ON, Canada, 2. Faculty of Medicine, University of Toronto, Toronto, ON, Canada, 3. Division of Dermatology, Women's College Hospital, Toronto, ON, Canada, 4. Department of Medicine, University of Toronto, Toronto, ON, Canada

Introduction: Hidradenitis suppurativa (HS) is a chronic inflammatory condition which affects apocrine gland-rich skin. Promising biologic treatments are under investigation for HS; however, no systematic review has explored the immunogenicity of biologics for HS. As such, we systematically reviewed the frequency, clinical efficacy, safety, and adverse events associated with anti-drug antibody development of biologics for patients with HS.

Methods: A systematic search was conducted on MEDLINE and Embase from inception to May 2020. The search terms were ('hidradenitis suppurativa' OR 'acne inversa') AND ('immunogenicity', OR 'anti-drug antibodies' OR 'antibodies'). We recorded the biologic, frequency, clinical efficacy, safety, and adverse events associated with anti-drug antibody development.

Results: Five articles were included (two RCTs, one cohort, one case-series, one case control). The method of measuring anti-drug-antibodies was reported for only one study. The pooled frequency of anti-drug antibodies is approximately 8.6% (7.4-10.7%) for adalimumab and 50% (46.7-100%) for infliximab, though there was considerable uncertainty around these estimates due to unclear methods of measuring anti-drug antibodies and different patient populations. Patients with immunogenicity had reduced clinical efficacy for both adalimumab and infliximab and the safety profile was similar.

Table 1. Anti-drug antibody (ADA) findings for biologic treatments for hidradenitis suppurativa

Author (year)	Biologic	Freq of ADAs	Average ADA concertation	ADA+ vs. ADA- clinical efficacy	ADA+ adverse events	Biologic concentrations in ADA+ vs ADA-	ADA+ patient characteristics
Kimball et al. (2012)	Adalimumab	16/149 (10.7%)	N/A	12.5% (n=2/16) vs. 21.8% (n=29/133) clinical response rate at week 52	N/A	Mean serum adalimumab concentrations were lower in ADA+ patients vs. ADA- patients	N/A
Liu et al. (2018)	Adalimumab	20/269 (7.4%)	N/A	N/A	Rate of any adverse event and infections were similar between ADA+ and ADA-	Mean serum adalimumab concentrations were lower in ADA+ patients vs. ADA- patients	HLA-DQB1*05, HLA-DRB1*01, and HLA-DRB1*07 were less prevalent in ADA+ than ADA- subjects HLA-DRB1*03 and HLA-DRB1*011 were more abundant in ADA+ than ADA- subjects



Lesage et al. (2012)	Infliximab	1/1 (100%)	N/A	Hurley score for ADA+ (n=1): 1 (baseline was 3) ADA- (n=7): 1 (baseline was 2.3)	1 ADA+ patient developed urticaria, polyarthralgia, fever, and chills	N/A	41 year old male, no family history of HS, smoker, 26 years of HS (continuous recurrences)
van Rappard et al. (2011)	Infliximab	3/5 (60%)	1111 AU/mL	2/3 ADA+ patients had either recurrence of HS or poor response to infliximab	3/3 ADA+ patients developed polyarticular arthritis	N/A	Mean age 52.7, no history of arthritis, high ESR at baseline (86.7 mm/hr), all developed polyarticular arthritis
Wang & Micheletti (2020)	Infliximab	7/15 (46.7%)	N/A	5/7 ADA+ patients required rescue MTX after poor response to infliximab	N/A	N/A	No differences in age, sex, or infliximab dose between ADA+ and ADA- patients.

N/A, not available; ADA, anti-drug antibody; EW, every week; EOW, every other week; HS, hidradenitis suppurativa; MTX, methotrexate

Conclusions: The frequency of anti-drug antibodies is significantly lower for adalimumab than infliximab. However, standardized criteria should be established in the reporting of immunogenicity. Clinicians should also be aware of immunogenicity when dealing with patients with suboptimal response to biologics. Further studies are required regarding the strategies that can prevent or reverse immunogenicity.

Learning Objectives:

- To recognize pharmacokinetic, pharmacodynamic, and immunogenic failures.
- To review anti-drug antibodies and their frequencies for hidradenitis suppurativa.
- To understand the methods of measuring anti-drug antibodies and the need for standardized criteria in reporting immunogenicity in clinical trials.

Takeaway Message:

- We identified the pooled frequency of anti-drug antibodies is approximately 8.6% (7.4-10.7%) for adalimumab and 50% (46.7-100%) for infliximab
- There were unclear methods of measuring anti-drug antibodies as well as different patient populations and standardized criteria should be established in the reporting of immunogenicity in clinical trials

P2.17 Hidradenitis Suppurativa Area and Severity Index Revised (HASI-R): Revised Tool and Psychometric Assessment

Noah I. Goldfarb^{1, 2}, Michelle A. Lowes³, Melissa Butt⁴, Tonya King⁴, Afsaneh Alavi^{5, 6}, Joslyn S. Kriby⁴

- 1. University of Minnesota, Minneapolis, MN, USA, 2. Minneapolis VA Medical Center, Minneapolis, MN, USA,
- 3. Rockefeller University, New York, NY, USA, 4. Penn State Health Milton S. Hershey Medical Center, Hershey, PA, USA,
- 5. Women's College Hospital, Toronto, ON, Canada, 6. University of Toronoto, Toronto, ON, Canada

Introduction: The Core Outcome Set for HS recommends assessment of location, lesion counts, and surface area. However, the majority of outcome measures rely on lesions counts that have low reliability, and do not assess surface area. Two tools, the original hidradenitis suppurativa area and severity index (HASI) and severity and area score for hidradenitis (SASH) were recently proposed, based on combining signs of inflammation and body surface area (BSA). These tools demonstrated good reliability with strong correlation with existing measures, but lacked tunnel assessment. The two groups which created the original HASI and SASH, combined the tools into the current HASI revised (HASI-R), which adds an assessment for tunnels. The objective of this study was to assess the reliability and validity of the HASI-R.

Methods/Results: The measurement properties of the HASI-R were evaluated in a one-day session that included 20 raters, and 15 HS patients. Each rater evaluated all participants and evaluated one participant twice (at random). After the session, raters were asked their preferences regarding the various HS severity assessment tools. The HASI-R had moderate interrater reliability (ICC = 0.60) and was higher than other HS measures. All lesion counts had poor inter-rater reliability. HASI-R had the highest intrarater reliability (ICC = 0.91). The HASI-R demonstrated strong convergent construct validity with the IHS4 (r = 0.81 [0.77-0.85]) and known groups validity, with significant differences in mean HASI scores across IHS4 severity groups. The HASI-R was the most preferred tool by all raters.

Conclusions: The HASI-R appears to be a promising instrument for capturing HS severity with moderate inter-rater reliability and excellent intra-rater reliability. It also appears to be the most preferred method of HS severity assessment by clinicians.

Learning Objectives:

- Lesion counts have poor inter-rater reliability
- The HASI-R has moderate inter-rater reliability (ICC = 0.60), and excellent intrarater reliability (ICC = 0.91), higher than
 other HS measures evaluated.
- The HASI-R shows strong convergent construct validity with the IHS4 (r = 0.81 [0.77-0.85]) and known groups validity, with significant differences in mean HASI-R scores across IHS4 severity groups.

Takeaway Message:

The HASI-R is a promising clinician-reported disease activity measure for assessing HS extent and severity

P2.18 Clinical Predictors of Pain Severity in Hidradenitis Suppurativa

Mark Jedrzejczak¹, Lauren A. Orenstein²

1. Emory School of Medicine, Atlanta, GA, USA, 2. Department of Dermatology, Emory University School of Medicine, Atlanta, GA, USA

Introduction: Pain dramatically reduces quality of life among patients with hidradenitis suppurativa (HS), yet little is known about clinical predictors of HS pain severity.

Methods and Results: We conducted a retrospective cross-sectional analysis of patients seen at the Emory HS Clinic between 1/1/2019 and 6/18/2020. The primary outcome was one-week pain severity measured by the Numerical Rating Scale (NRS). Exposure variables included patient demographics, Hurley stage, Skindex-16 score, patient global assessment of disease severity (PtGA), and PHQ-9 depression and GAD-7 anxiety screening scores. Comparisons were made using the Independent Samples T-test and analysis of variance. Multivariable simple linear regression was also performed. Among 151 included patients, the average one week NRS pain score was 4.29 (SD: 2.98). The patients were predominantly female (113/151) with a mean age of 35.7 (SD: 12.6); over half of patients identified as African American (78/151). No significant differences in pain severity by age, sex, race, smoking, alcohol use, or race were observed. Patients who screened positive for depression (30%) or anxiety (32%) had significantly higher pain scores at 6.0 (3.0) and 5.8 (3.0) compared to negative depression 3.4 (2.7) or anxiety 3.5 (2.7) screens (p<0.001). A multivariable linear regression that adjusted for patient age, sex, race, Hurley stage, Skindex-16 domains, and PtGA, explained 58.2% of the variance in pain severity. Patient reported pain increased significantly by 0.793 (95% CI: 0.374-1.212) for each additional point on the PtGA.



Conclusion: Patient perception of HS disease severity is correlated with pain severity. Those who screened positive for mood disorders reported more physical pain. Although limited by information bias, mental health screenings, pain scores, and quality of life measurements may help identify patients who require careful pain management in the setting of an ongoing opioid crisis.

Learning Objectives:

- Describe the demographic, social, and clinical characteristics of HS patients experiencing HS pain in the Emory HS Clinic
- Detect differences in reported NRS pain scores by HS patient characteristics
- Analyze the relationship between HS patient factors and one week average NRS pain scores

Takeaway Message:

Clinical and patient factors such as comorbid mental health conditions and the perception of disease severity may contribute to the pain experience by patients with hidradenitis suppurativa.

P2.19 Bridging the Diversity Gap: an Examination of African American Participation in Hidradenitis Suppurativa Clinical Trials

<u>Chidubem A. Okeke</u>¹, Jessica D. Perry¹, Faith C. Simmonds², Azure B. Erskine², William D. Shipman³, Janyla A. Seltzer¹, Marcus R. Andrews⁴, Arjun D. Saini⁵, Taylor A. Cole⁶, Jamilah A. Perkins⁷, Jane Otado¹, John Kwagyan¹, Cassandra I. Collins⁸, Ginette A. Okoye⁹, Angel S. Byrd⁹

1. Howard University College of Medicine, Wahsington, DC, USA, 2. Howard University, Washington, DC, USA, 3. Yale-New Haven Hospital, New Haven, CT, USA, 4. Department of Health Behaviors and Health Education, University of Michigan, Ann Arbor, MI, USA, 5. Department of Dermatology, Howard University Hospital, Washington, DC, USA, 6. Charles R. Drew/UCLA Medical Education Program, Los Angeles, CA, USA, 7. Meharry Medical College, Nashville, TN, USA, 8. University of Miami Miller School of Medicine, Miami, FL, USA, 9. Department of Dermatology, Howard University College of Medicine, Wahsington, DC, USA

Introduction: Hidradenitis suppurativa (HS) is characterized by painful nodules, sinus tracts and scarring that generally arise in African Americans (AA); however, this population is minimally represented in clinical trials. Therefore, data is not available for this population as potential beneficial treatments are being developed. We hypothesized that the disparity in enrollment could be related to the demographics of the US cities in which the trials were conducted.

Methods, **Results**: We identified 13 HS clinical trials that occurred either exclusively in the US or in both US and Europe. Racial demographics were obtained through the 2010 US Census Bureau and compared against each of the 96 clinical trial sites that occurred in the US. Almost half of HS clinical trial sites (49%) were located in zip codes with moderate (12.6 - 49.9%) to high (over 50%) AA populations, whereas 43.8% were located in areas with low (0 - 12.5%) AA populations. In addition, we identified physician and patient perspectives that potentially hindered AA enrollment in HS clinical trials.

Conclusion: AA patients with HS are poorly represented in HS clinical trials despite the diversity in clinical trial site demographics. This disparity hinders our complete understanding of the disease and its impact on different populations. Future studies will investigate how to alleviate specific barriers experienced by HS patients to help improve AA recruitment and patient outcomes.

Learning Objectives:

- Discuss the racial disparity in HS clinical trials.
- Analyze the impact of racial demographics on African American enrollment in HS clinical trials.
- Identify the factors influencing the apparent disparity in African American enrollment in HS clinical trials.

Takeaway Message:

African American patients with HS are poorly represented in HS clinical trials despite the diversity in clinical trial site demographics.

P2.20 Evaluate Cutaneous and Circulating Inflammatory Biomarkers for a Novel IRAK4-Targeted Therapeutic in Hidradenitis Suppurativa

Afsaneh Alavi¹, Sara Chavoshi¹, Veronica Campbell², Alice McDonald², Anthony Slavin², Nello Mainolfi², Jared Gollob²

1. York Dermatology Clinic and Research Center, Toronto, ON, Canada, 2. Kymera Therapeutics, Boston, MA, USA Introduction: IRAK4 is a component of the myddosome involved in innate immune activation by interleukin-1 (IL-1) family cytokines and toll-like receptor (TLR) ligands. Kymera is developing potent and selective, orally administered small molecule IRAK4 protein degraders for the treatment of TLR/IL-1 receptor (IL-1R)-driven inflammatory and autoimmune diseases, including hidradenitis suppurativa (HS) and atopic dermatitis (AD). To understand the role of IRAK4 in the pathogenesis of HS and AD and set the stage for trials of IRAK4 degraders, we initiated a non-interventional study in these patients to evaluate IRAK4 levels in the blood and both normal and diseased skin and its relationship to inflammatory biomarkers and disease stage.

Methods: The study is designed to enroll up to 30 HS patients with mild, moderate and severe disease and up to 10 AD patients with moderate and severe disease at a single center (York Dermatology Clinic and Research Center). Eligible patients may not be on biologics or other immunosuppressive therapies. Patient participation in the study consists of a single visit to the clinic for evaluation of disease status, skin biopsies (taken from lesional, peri-lesional and normal skin), blood draws and collection of medical history. IRAK4 levels and levels of proinflammatory cytokines, chemokines and acute phase reactants are measured in skin and blood. Blood is also treated *ex vivo* to determine the effects of Kymera's IRAK4 degrader on IRAK4 levels and on the production of proinflammatory cytokines and chemokines.

Results/Conclusions: The study was initiated on May 28, 2020; 30 HS and 2 AD patients have been enrolled as of July 27, 2020. Interim data on the first 14 HS patients show IRAK4 knockdown across all mononuclear immune cell subsets following *ex vivo* degrader treatment of whole blood. We will present additional data on IRAK4 expression in blood and skin as well as inflammatory biomarkers.

Learning Objectives:

- To discuss the role of IRAK4 in the pathogenesis of HS and AD
- To present the first data on IRAK4 knockdown following exvivo degarder treatment in the blood of patients with HS
- To set the stage for trials of IRAK4 degraders as a potential therapeutic option for HS

Takeaway Message:

The study shows that IRAK4 knockdown across all mononuclear immune cell subsets following *ex vivo* degrader treatment of whole blood in patients with HS

P3: Comorbidities and Complications

P3.01 Hidradenitis Suppurativa and Down Syndrome: a Systematic Review and Metaanalysis

Megan Lam¹, Charis Lai², Nouf Almuhanna^{3, 4}, Raed Alhusayen^{4, 5}

1. Michael G. DeGroote School of Medicine, McMaster University, Hamilton, ON, Canada, 2. Faculty of Science, University of Western Ontario, London, ON, Canada, 3. King Fahd Medical City, Riyadh, Saudi Arabia, 4. Department of Medicine, University of Toronto, Toronto, ON, Canada, 5. Division of Dermatology, Sunnybrook Health Sciences Centre, Toronto, ON, Canada

Introduction: Hidradenitis Suppurativa (HS), characterized by inflammatory nodules, sinus tracts, and abscesses, has been linked to several factors, including immune dysfunction and obesity, which are thought to contribute to its development. Several follicular disorders have also been associated with Down Syndrome, a common chromosomal disorder, including HS, although studies on this topic are limited. Thus, we conducted this systematic review and meta-analysis to characterize HS in Down Syndrome patients, and to further examine the association between HS and DS compared to HS patients without DS

Methods: We systematically searched MEDLINE, Embase, Web of Science, and CENTRAL electronic databases from date of conception to Feb 2020. Random effects meta-analyses were performed analyzing (i) HS characteristics between DS and non-DS participants, and (ii) prevalence or association between HS and DS compared to non-DS individuals.



Results: 11 studies were included in this systematic review, with a total of 354 participants presenting with both HS and DS. Pooled analysis of mean differences between DS and non-DS participants presenting with HS found a significantly younger age of HS symptom onset for DS patients (6.24; 95% CI, -10.01 – -2.24). A meta-analysis examining the association between HS and DS found a significantly increased likelihood of HS in DS patients (OR 9.61; 95% CI, 5.70-16.20).

Conclusions: Our findings suggest an association between HS and DS, with DS patients suffering from an earlier onset of HS symptoms compared to non-DS patients.

Learning Objectives:

- To characterize the presentation and onset of HS in Down Syndrome patients
- To highlight an association between Down Syndrome and HS and quantify increased risk for HS in patients with Down Syndrome
- To increase understanding of the pathogenesis and genetic factors associated with an increased risk of HS

Takeaway Message:

- Our findings suggest that Down Syndrome patients have a significantly higher likelihood of presenting with HS.
- Down Syndrome patients generally present with HS symptoms at a significantly younger age than non-Down Syndrome patients.

P3.02 Hidradenitis Suppurativa and Chromosomal Abnormalities

Monica Shah¹, Muskaan Sachdeva¹, Maria Melendez-Gonzalez², Vincent Piguet^{3, 4}, Christopher Sayed⁵

1. Faculty of Medicine, University of Toronto, Toronto, ON, Canada, 2. Universidad Central del Caribe, Bayamón, Puerto Rico, 3. Division of Dermatology, Department of Medicine, University of Toronto, Toronto, ON, Canada, 4. Division of Dermatology, Department of Medicine, Women's College Hospital, Toronto, ON, Canada, 5. University of North Carolina, Department of Dermatology, Chapel Hill, NC, USA

Background: Hidradenitis suppurativa (HS) is a chronic inflammatory follicular disorder that involves painful nodules, abscesses, and tunnels of intertriginous sites. Although the etiology has not been fully elucidated, recent studies have highlighted its association with chromosomal abnormalities. We present a rare case of HS in a patient with Trisomy 1q;13 and systematically summarize the association between HS and chromosomal abnormalities.

Methods, Results: A search was conducted using MEDLINE and EMBASE in OVID database. Original studies reporting HS among human subjects with chromosomal abnormalities were included. Patient demographics, disease symptomology, clinical features and treatment histories were extracted and summarized. Thirteen studies describing 428 cases met the inclusion criteria. Of the 13 articles, 9 studies reported patients with HS and Down syndrome (DS), 1 article investigated HS and Smith-Magenis syndrome (SMS), and 3 articles analyzed HS and Patau syndrome (PS). While increased prevalence of HS was found in populations with DS, with suggested mechanisms involving amyloid precursor protein cleavage product, keratinocyte proliferation and follicular plugging, the associations between HS and both SMS and PS remain inconclusive due to limited studies with small sample size.

Conclusions: Although evidence suggests that the genetic regulation of chromosome 21 may be implicated in the association between HS and DS, this association may be confounded by additional factors that increase the risk of HS. Further research with larger sample sizes must be conducted to strengthen our understanding of the association between HS and chromosomal abnormalities.

Learning Objectives:

- Examine the current field of research studying the association between HS with chromosomal abnormalities
- Explore the age and sex-specific prevalence of HS among patients with DS
- Stimulate earlier diagnosis, through increased awareness of HS in individuals with chromosomal abnormalities

Takeaway Message:

This systematic review aims to enhance our understanding of hidradenitis suppurativa (HS) in populations with chromosomal abnormalities. While current literature reveals a high prevalence of HS within the Down syndrome population, a significant gap in the literature exists in examining the association between HS and other chromosomal disorders. This review prompts the need for further research to explore the genetic mechanisms that may link HS with chromosomal disorders, and risk factors such as diet and lifestyle that may play a role in the etiology and pathogenesis.

P3.03 Incidence, Prevalence and Predictors of Inflammatory Arthritis in Patients with Hidradenitis Suppurativa: A Systematic Review and Meta-analysis

<u>Nardin Hanna</u>¹, Orli Silverberg², Michael Reaume¹, Dafna Gladman³, Mark Davis⁴, Vincent Piguet^{2, 5}, Afsaneh Alavi^{2, 5}

1. University of Ottawa, Faculty of Medicine, Ottawa ON, Canada, Ottawa, ON, Canada, 2. University of Toronto, Faculty of Medicine, Toronto ON, Canada, Toronto, ON, Canada, 3. Krembil Research Institute, Toronto Western Hospital, Toronto ON, Canada, Toronto, ON, Canada, 4. Division of Clinical Dermatology, Mayo Clinic, Rochester MN, USA, Rochester, MN, USA, 5. Division of Dermatology, Department of Medicine, Women's College Hospital, Toronto ON, Canada, Toronto, ON, Canada

Introduction: An increasing amount of evidence has emerged which suggests that HS is associated with comorbid inflammatory arthritis and spondyloarthropathies. Despite evidence of an association, the risk for developing inflammatory arthritis in HS patients is not well described. This study aims to identify the incidence, prevalence, risk, and predictors of inflammatory arthritis in HS patients.

Methods: The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines were followed. A comprehensive literature search was developed and conducted in CINAHL, Embase and Medline from the date of inception to February 14, 2020. 474 nonduplicate articles were independently screened by two reviewers. Data extraction was then performed by the consensus of two reviewers. Pooled incidence, prevalence and risk data were meta-analyzed using a random effects model. Predictors of inflammatory arthritis were not meta-analyzed due to heterogeneity of outcomes.

Results: The overall incidence of inflammatory arthritis was relatively high: ankylosing spondylitis (0.53/1000; 95%Cl 0.34-0.82), psoriatic arthritis (0.84/1000; 95%Cl 0.37-1.89), and rheumatoid arthritis (5.28/1000; 95%Cl 4.81-5.78). The prevalence of inflammatory arthritis was also high: total inflammatory arthritis (1.91%; 95%Cl 0.58-6.12); spondyloarthropathy (4.23%; 95%Cl 0.60-24.49); rheumatoid arthritis (1.34%; 95%Cl 0.48-3.73). A meta-analysis of the risk of inflammatory arthritis identified that the risk of total inflammatory arthritis, spondyloarthritis, ankylosing spondylitis (p=0.002), psoriatic arthritis (p<0.001), and rheumatoid arthritis (p<0.001) was increased in patients with HS. There was evidence to suggest that patients with severe HS or elevated CRP, or patients taking Infliximab or Adalimumab may be at greater risk for specific subtypes of inflammatory arthritis. However, further data is needed to confirm these associations.

Conclusion: The high incidence, prevalence and risk of inflammatory arthritis within HS patients highlights the need for increased awareness and interdisciplinary partnership within the specialities of rheumatology and dermatology. Considering the underdiagnosis of HS, an increased awareness of this disease in rheumatology can help to facilitate timely referrals and decrease the diagnostic delay associated with HS.

Learning Objectives:

- Recognize that there is a relatively high incidence and prevalence of inflammatory arthritis and its subtypes in patients
 with HS. There is also an increased risk of total inflammatory arthritis, spondyloarthropathy including ankylosing
 spondylitis, rheumatoid arthritis, and psoriatic arthritis in patients with HS.
- Recognize the role of skin disease severity and the use of various biological therapies in increasing the likelihood of inflammatory arthritis in patients with HS.
- Identify the high comorbidity burden and of HS and understand the importance of empathetic, holistic and interdisciplinary care in treating this complicated condition.

Takeaway Message:

Clinicians should be aware of the risk associated with developing inflammatory arthritis in patients with HS, which is critical to facilitating early diagnosis and treatment of this comorbidity. Patients with HS should be thoroughly assessed for inflammatory rheumatological diseases when presenting with articular complaints. Clinicians may also consider proactive screening for inflammatory arthritis in patients with moderate to severe HS. Finally, clinicians should also appreciate the substantial physical and psychological impact of this condition on patients, and address this in their practice.



P3.04 Squamous Cell Carcinoma Arising in Hidradenitis Suppurativa: A Case Series

Sepideh Ashrafzadeh¹, Maryam Asgari²

1. Harvard Medical School, Boston, MA, USA, 2. Department of Dermatology, Massachusetts General Hospital, Boston, MA, USA

Introduction: Hidradenitis suppurativa (HS) is a chronic inflammatory disorder that primarily affects apocrine gland-bearing skin. To date, studies on cutaneous squamous cell carcinoma (SCC) that arise in sites of HS have been limited. We aimed to characterize the clinical characteristics and outcomes of patients with HS who develop SCC.

Methods/Results: We performed a retrospective review of all patients with at least one International Classification of Disease, 9th or 10th Revision code for HS and SCC in our institutional database of seven hospitals (Partners Healthcare, 2000-2019). All HS and SCC diagnosis codes were verified by reviewing electronic medical records for descriptions of characteristic HS lesions arising within relevant anatomic sites and pathology reports confirming SCC. Among 156 patients with both HS and SCC, 12 (7.7%) patients developed SCC in sites affected by HS. Of the 12 patients, 6 (50%) were male; 10 (83.3%) were White, 1 (8.3%) was Black, and 1 (8.3%) was Hispanic; 11 (91.7%) were current or former smokers; and 5 (42%) were diagnosed with depression. The mean age (SD) of HS diagnosis was 33.0 (17.4) years (range 16-62), and the mean age (SD) of SCC co-occurrence was 50.2 (19.0) years. SCCs were most commonly located in the vulva (n=5) and buttocks (n=4), and less-often the upper mid-back (n=1), posterior neck (n=1), and inner thigh (n=1). Human papillomavirus (HPV) infection was noted in only 1 (8.3%) SCC. Of five patients who had died, SCC was cited as the cause of death for 3 (60%) patients (all in men; two White, one Black). Interestingly, one patient developed HPV-negative vulvar SCC one year prior to developing HS in the region.

Conclusions: Our results suggest that although development of SCC in sites of HS occur in both men and women, mortality may primarily affect men. SCC co-occurrence with HS affects all races and is seldom associated with HPV infection. The single case where SCC developed prior to HS may have been coincidental or may suggest underlying inflammation due to subclinical HS or a possible shared mechanistic etiology between HS and SCC.

Learning Objectives:

- Cutaneous squamous cell carcinomas can arise in sites of hidradenitis suppurativa in both men and women and across different races.
- Cutaneous squamous cell carcinomas that arise in sites of hidradenitis suppurativa are associated with high mortality.
- Although human papillomavirus infection may be involved in the pathogenesis of the some squamous cell carcinomas
 that develop in sites of hidradenitis suppurativa, most of these squamous cell carcinomas may be due to chronic
 inflammation from hidradenitis suppurativa and/or other shared mechanistic pathways that are shared between the two
 diseases.

Takeaway Message:

Clinicians should monitor sites affected by hidradenitis suppurativa for potential development of squamous cell carcinoma, which is associated with high mortality.

P3.05 Hidradenitis Suppurativa and Major Adverse Cardiac Events: A Systematic Review and Meta-Analysis

Heidi O. Li¹, Adrian Bailey¹, Marcus G. Tan², Mark G. Kirchhof²

1. University of Ottawa, Faculty of Medicine, Ottawa, ON, Canada, 2. The Ottawa Hospital, Division of Dermatology, Ottawa, ON, Canada

Introduction: Hidradenitis suppurativa (HS) has been associated with several cardiac risk factors. However, the association between HS and major adverse cardiac events (MACEs) remains unclear, as the current evidence is contradictory. Furthermore, this association has not been systematically evaluated across diverse racial and ethnic populations. This study aims to resolve this discrepancy and knowledge gap through a systematic review and meta-analysis of the literature.

Methods: A systematic search of the MEDLINE, Cochrane Central Register of Controlled Trials, and Embase databases yielded 175 records from inception to March 4th, 2020. All English-language full-text retrospective cohort, cross-sectional, and case-control studies comparing the incidence, odds, or risk of cerebrovascular accident (CVA), myocardial infarction (MI), and cardiac associated mortality (CAM) in adult populations (≥18 years) with and without HS were included. The random-effects model and generic inverse variance method were used to pool the risk ratios (RR) for cohort studies and odds ratios for case-control studies. The Newcastle-Ottawa scale was used to determine the quality of included studies.

Results: Three cohort studies and three case-control studies for a total of 68,652 unique patients with HS were included. The studies represented multiple ethnicities, with the inclusion of African American patients in one study and a predominantly Asian study population in another. Four studies were of good-quality, one study was of fair-quality, and one study was of poor-quality. The meta-analysis of the cohort studies found significant associations of HS with CVA (RR 1.22, 95% CI 1.14-1.31, P<0.001) with I²=0% and an increased risk of MI (P=0.02). One cohort study also reported an increased risk of CAM (RR 1.95, 95% CI 1.42-2.67, P<0.001). These findings were supported by the case-control studies.

Conclusions: The current evidence supports an association between HS and MACEs, particularly CVA, MI and CAM. Patients with HS should receive appropriate counselling for modifiable cardiac risk factors, early screening, and prompt cardiology consultation when presenting with cardiac symptoms.

Learning Objectives:

- Evaluate the current evidence on the association between hidradenitis suppurativa and major adverse cardiac events.
- Recognize the cardiac comorbidities associated with hidradenitis suppurativa.
- Consider closer surveillance and early screening for cardiac risk factors for patients with hidradenitis suppurativa.

Takeaway Message:

Patients with hidradenitis suppurativa should receive appropriate counselling for modifiable cardiac risk factors, early screening, and prompt cardiology consultation when presenting with cardiac symptoms.

P3.06 Association of Hidradenitis Suppurativa with Inflammatory Arthritis: a Systematic Review and Meta-analysis

Nouf Almuhanna^{1, 2}, Alexandra Finstad³, Raed Alhusayen²

1. King Fahad Medical City, Riyadh, Saudi Arabia, 2. University of Toronto, Toronto, ON, Canada, 3. University of Ottawa, Ottawa, ON, Canada

Introduction: Hidradenitis suppurativa (HS) is an inflammatory disease associated with several comorbidities such as cardiovascular diseases, diabetes, and inflammatory bowel disease. Several studies report a high prevalence of inflammatory arthritis among HS patients. Therefore, we aimed to study the association between HS and inflammatory arthritis.

Methods: This systemic review and meta-analysis were conducted in accordance with PRISMA guidelines, to identify the association between HS and inflammatory arthritis, spondyloarthritis (SA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS). Random effects model was used to calculate pooled crude odds ratio (OR).

Results: Six studies were included in the analysis, with 185 179 HS patients and 299 702 controls. Pooled analysis illustrated a significantly increased risk of inflammatory arthritis in HS patients compared to control (OR 3.29, 95% CI 1.65-6.5, $I^2 = 99\%$). There was also a significant association between HS and RA, which demonstrated a statistically significant (OR of 1.22, 95% CI 1.09-1.38, $I^2 = 49\%$), and between HS and AS (OR of 1.53,95% CI 1.24-1.87, $I^2 = 0\%$). However, pooled analysis showed no statistically significant association between HS and SA (OR of 1.38, 95% CI 0.94-2.03, $I^2 = 78\%$).

Conclusion: Our findings show that HS patients have a 3-fold increased risk for inflammatory arthritis. Among the subtypes of inflammatory arthritis, HS patients are specifically at higher risk for RA and AS. There was no statistically significant association between HS and SA; this indicates that HS is associated with AS rather than the other types of SA, such as psoriatic arthritis.

References

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Learning Objectives:

- To identify the association between HS and inflammatory arthritis.
- To identify the association between HS and subtypes of inflammatory arthritis: rheumatoid arthritis, spondyloarthritis and ankylosing spondylitis.
- To recognize early signs of arthritis in HS patients.





Takeaway Message:

Recognition of this association by dermatologists will help with early detection, diagnosis, and treatment which can prevent further progression and complications.

P3.07 Ustekinumab Induced Myositis: a Case Series

Nneamaka C. Ezekwe¹, Josee Smith², Aunna Pourang¹, Iltefat Hamzavi¹

1. Department of Dermatology, Henry Ford Health Systems, Detroit, MI, USA, 2. School of Medicine, Wayne State University, Detroit, MI, USA

Introduction: Ustekinumab (UST) is a monoclonal antibody that blocks cytokines IL-12 and IL- 23, disrupting the immune and inflammatory cascade, that has been approved by the Food and Drug Administration (FDA) for the treatment of moderate to severe psoriasis, psoriatic arthritis, Crohn's Disease, and ulcerative colitis. Off-label use of UST has shown promising results as an alternative treatment for moderate to severe hidradenitis suppurativa (HS) in patients who have failed to respond to or unable to tolerate adalimumab, the only FDA approved treatment for HS.Common side effects of UST include fatigue, diarrhea, injection site reactions and infections, with upper respiratory infections being the most common. Previously, myositis has not been reported as an adverse effect of UST. We present two patients with poorly controlled HS who experienced new onset myositis shortly after beginning treatment with UST.

Methods, **Results**: This is a case series and review of the current literature of adverse effects of UST. To our knowledge, this is the first report of UST- induced myositis.

Conclusion: These two cases demonstrate the unexpected development of UST-induced myositis in HS patients. A proposed mechanism by which UST induces myositis could be related to the overexpression of IL-12 and IL-23 cytokine release secondary to UST's receptor blockade. IL-12 has been shown to be pro-inflammatory and can initiate IL-32 production, a cytokine that has been shown to be overexpressed in HS.3 II-32 induces IFNy and IL-17, precursors to TH1 and TH17 helper cells which has been implicated in autoimmune myositis, most notably dermatomyositis and polymyositis. As the use of UST increases due to its efficacy in the management of many chronic inflammatory diseases, it is important for prescribers to consider the potential risk of drug-induced myositis. Long-term clinical surveillance is needed to evaluate the significance and frequency of this occurrence.

Learning Objectives:

- Ustekinumab can induce myositis, which has not previously been associated as an adverse side effect of drug.
- As the use of UST increases due to its efficacy in the management of many chronic inflammatory diseases, it is important for prescribers to consider the potential risk of drug-induced myositis. 3
- Long-term clinical surveillance of UST is needed to evaluate the significance and frequency of this occurrence.

Takeaway Message:

As therapies like Ustekinumab gain popularity, it is important to be aware of potential adverse effects and publish more evidence on the safety and tolerability of these therapies.

P4: Epidemiology and Health Services Research

P4.01 Hidradenitis Suppurativa (Acne Inversa): A Bibliometric Analysis

Surav M. Sakva¹, David R. Hallan¹, Sage Gee¹, Monica Rizk¹, Justin Brooke¹, Joslyn S. Kirby²

1. Penn State College of Medicine, Hershey, PA, USA, 2. Penn State Milton S Hershey Medical Center, Hershey, PA, USA

Introduction: Hidradenitis suppurativa (HS) is one of the most important dermatologic diseases with unmet needs. Patients experience diagnostic and therapeutic delays, in addition, misinformation about the pathogenesis is rampant. This study sought to conduct a novel bibliometric analysis of HS publications to understand the characteristics of the most influential studies in the HS research landscape. The objective was to identify and analyze the top 100 most cited articles on HS using bibliometric analysis.

Methods & Results: Searches within Scopus and Web of Science were conducted on May 14th, 2020 using the search terms "Hidradenitis Suppurativa" and "Acne Inversa." All non-original articles were excluded. Data from each database were combined, duplicates removed, and the top 100 articles identified. The study topic and study design was determined by consensus of five abstractors. Analysis was performed using R-studio, Bibliometrix, and Microsoft Excel.

The top 100 most cited articles on HS were published between 1982 and 2017. The 100 articles had an average of 128.3 citations overall and 10.58 per year. The top research topic was treatment (40 out of 100 articles), and there were 9 randomized controlled trials. 2011 had the highest number of publications (9). The top 100 cited articles had 86 first corresponding authors from 14 countries. These articles were published in 27 journals. The top journal was the British Journal of Dermatology (BJD). The top two prolific countries were the United States and Denmark. Moreover, the country with most outside country collaborations was Denmark (10 countries).

Conclusions: The results of our study showed that HS research is steadily growing with greatest support from the BJD. There is a focus on treatments in HS research with the USA and European countries leading the way. However, greater worldwide research of HS is needed.

Learning Objectives:

- Identify the top 100 cited HS publications, leading authors, and most prolific countries and institutions.
- Understand the characteristics of the most influential studies in the HS research landscape.
- Describe the growth of HS research and provide an overview of the potential gaps where further research is necessary in HS.

Takeaway Message:

To our knowledge, this is the first worldwide bibliometric study on HS. Our study found that HS research has experienced notable growth in the last five years. The prominent focus of HS research are biological treatments and studies on the reduction of quality of life as demonstrated by the top cited articles. Inter-country collaboration was abundant and encouraged.

P4.02 Access to Surgical Interventions for Hidradenitis Suppurativa

Alexandra Finstad¹, Alex Lee¹, Ralph George^{2, 3}, Raed Alhusayen^{4, 5}

1. Faculty of Medicine, University of Ottawa, Ottawa, ON, Canada, 2. Division of General Surgery, Department of Surgery, University of Toronto, Toronto, ON, Canada, 3. Department of Surgery, CIBC Breast Centre, St. Michael's Hospital, Toronto, ON, Canada, 4. Division of Dermatology, Department of Medicine, Sunnybrook Health Sciences Centre, Toronto, ON, Canada, 5. Division of Dermatology, Department of Medicine, University of Toronto, Toronto, ON, Canada

Introduction: Hidradenitis suppurativa (HS) is a painful, inflammatory cutaneous disorder that confers significant distress to patients. Although a variety of treatment options have been proposed, surgery remains the only potential curative intervention. Unfortunately, the diagnosis of HS is often made after a significant delay, limiting access to treatment. Access to surgery is further influenced by the presence of surgical expertise and competition over operating room time. To inform improvements in HS care, patterns in HS surgery were assessed.

Methods/Results: A retrospective population-based analysis was performed on Ontario Health Insurance Plan (OHIP) billing claims for HS surgery across 10 years. The top five billing specialties, presented in order, were analyzed including general surgery, plastic surgery, obstetrics and gynaecology, urology, and dermatology. The annual number of claims showed an overall increasing trend ranging between 4.9-5.8 claims per 100,000 population, while the number of providers showed a decreasing trend ranging between 1.9-1.7 per 100,000 population. The number of general and plastic surgeons treating HS per 100,000 ranged between 1.1-1.3 and 0.5-0.6, respectively. The mean number of procedures performed annually per physician rose from 2.8 to 3.1 across the study period. Plastic surgeons performed more procedures per physician than general surgeons, ranging between 4.0-4.5 compared to 2.3-2.8. In rural areas, general surgeons performed the majority of surgeries (65.8%), while in urban areas surgeries were more equally performed by general surgeons (50.4%) and plastic surgeons (48.1%). Of HS surgery claims, 25.7-35.9% were provided by a physician residing in a different geographic area than the patient receiving care.

Conclusion: Overall, there were no significant improvements in access to HS surgery across the study period. Moreover, the number of providers decreased despite the increasing number of claims, suggesting a trend towards narrowing scopes of practice for surgeons. Accordingly, approximately one-third of patients received care away from home.

Learning Objectives:

- Evaluate patient access to HS surgery.
- Identify the primary providers of HS surgery.
- Investigate trends in geographic distribution between patients and providers.





Takeaway Message:

System barriers across the continuum of HS diagnosis and management must be evaluated to improve access to surgical care for HS patients.

P4.03 Hidradenitis Suppurativa and Socioeconomic Status: A Systematic Review and Meta-Analysis

Heidi O. Li¹, Adrian Bailey¹, Sophia Colantonio²

1. University of Ottawa, Faculty of Medicine, Ottawa, ON, Canada, 2. The Ottawa Hospital, Division of Dermatology, Ottawa, ON, Canada

Introduction: There is conflicting evidence in the literature regarding the association between hidradenitis suppurativa (HS) and low socioeconomic status (SES), with studies reporting a strong association, a modest association, or no association. Furthermore, this association has not been assessed across different populations, ethnicities, or healthcare systems. This study aims to resolve this discrepancy and knowledge gap through a systematic review and meta-analysis of the literature.

Methods: A search of PubMed and Embase yielded 26 articles from inception to April 3rd, 2020. All English-language full-text retrospective cohort, cross-sectional, and case-control studies comparing SES of adult populations with and without HS were included. The risk of bias was assessed using the Newcastle-Ottawa scale. The meta-analysis was conducted with the generic inverse variance method and random-effects model. Studies adjusting or accounting for confounding variables were analysed separately from unadjusted studies.

Results: Seven studies encompassing diverse populations from five countries with a total of 49,968 participants were included. Five studies were rated good quality, while two studies were rated fair quality as they were unadjusted or prone to selection bias. A total of six studies were included in the meta-analysis. HS was significantly associated with low SES in the pooled analysis of unadjusted and adjusted studies (P<0.0001), although the size of association was unable to be determined due to substantial heterogeneity (I²>50%). One study did not find a significant distribution of SES across different categories of HS severity. Another study controlling for comorbidities known to be associated with HS, specifically obesity and smoking, found a large association of HS and low SES in their unadjusted analysis (OR=1.85) but a modest association of HS and low SES in their adjusted analysis (OR=1.13).

Conclusion: The evidence to date supports an association of HS and low SES and its applicability across global populations. We recommend clinicians to recognize the association of HS and low SES, especially when taking into account the costs of medication and barriers to treatment and to consider the HS specific comorbidities that may be contributing to this association in the management of patients with HS.

Learning Objectives:

- Evaluate the current evidence on the association between hidradenitis suppurativa and low socioeconomic status.
- Explore the directionality of the association between hidradenitis suppurativa and low socioeconomic status and list potential contributing factors.
- Recognize that the association between hidradenitis suppurativa and low socioeconomic status is not dependent on hidradenitis suppurativa severity.

Takeaway Message:

We recommend clinicians to recognize the severity-independent association of hidradenitis suppurativa and low socioeconomic status when managing patients with hidradenitis suppurativa.

P4.04 Characterizing a Cohort of Hidradenitis Suppurativa Patients with Developmental and Intellectual Disorders

Avigdor Nosrati, Kayla M. Babbush, Tyler M. Andriano, Gabrielle Benesh, Steven R. Cohen Albert Einstein College of Medicine, Bronx, NY, USA

Introduction: Hidradenitis suppurativa (HS) is a chronic inflammatory skin disorder characterized by painful pustules, nodules, abscesses, and sinus tracts. Investigators have reported substantial associations between HS and developmental and intellectual disorders. However, a better understanding of this unique patient population is warranted to improve their medical management and quality of life.

Methods: An IRB-approved retrospective chart review of hidradenitis suppurativa (HS) patients treated at the Albert Einstein College of Medicine-Montefiore HS Center with diagnoses of concurrent intellectual and developmental disabilities identified 13 individuals. Demographics, disease severity, comorbidities, BMI, family history, and HS therapy were documented.

Results: Average age at initial visit was 22.8 ± 6.25 years ranging from 15 to 33; BMI was 34.5 ± 7.3 kg/m²; and, 10 (77%) were female. Three patients identified as Black or African American (23%) and ten as other (77%). Ethnically, eight (62%) patients identified as Spanish, Hispanic, or Latino.

Intellectual and developmental disorders in this cohort consisted of five patients (39%) with trisomy 21(ICD-10:Q90.9), four (31%) with a learning disorder (ICD-10:F81.9), two (15%) with an unspecified intellectual disability, one (8%) with trisomy 13 (ICD-10:Q91.7), and one (8%) with infantile cerebral palsy (ICD-10:G81.9).

Average Hurley stage was 1.82 ± 0.83 . Anatomical regions of involvement included the axillae (85%), inframammary region (42%), and equal numbers with groin, inguinal, and buttocks disease (25% each). Eight patients (31%) reported a family history of HS. Other skin conditions included cystic acne, seborrheic dermatitis, eczema, rash, pilonidal cyst, and acanthosis nigricans. Comorbidities include obesity, PCOS, asthma, multiple sclerosis, type 1 diabetes mellitus, attention deficit hyperactivity disorder, depression, bipolar disease, and epilepsy. Therapies included topical antibiotics (92%), oral antibiotics (77%), anti-hormonals (62%), infliximab (38%) intralesional triamcinolone (23%), and isotretinoin (8%).

Conclusion: To our knowledge, this is the only detailed examination of demographic and diagnostic characteristics, as well as the spectrum of therapies employed in a cohort of HS patients with intellectual and developmental disabilities.

Learning Objectives:

- In order to effectively treat HS patients with intellectual and developmental disabilities, a better understanding of this cohort as a whole is necessary.
- Our findings indicate that aggressive treatment modalities, including multiple antibiotic regimens anti-androgen
 combinations (spironolactone or finasteride and oral contraceptives), oral retinoids, and infliximab have an important
 role in the treatment of HS patients with intellectual and developmental disabilities.

Takeaway Message:

HS patients with developmental and intellectual disabilities have unique comorbidities that may account for increased frequency and severity of disease. Despite the practical challenges, it is clear that this population benefits greatly by management with the full range of aggressive HS treatment modalities.

P4.05 British Association of Dermatologists (BAD) National Audit on the management of Hidradenitis Suppurativa (HS)

Samar B. Hasan, John R. Ingram

Dermatology Department, Cardiff University, Cardiff, United Kingdom

In 2019 the BAD published the first UK guidelines for management of HS. This audit evaluates the current management of HS in the UK against the audit standards set in the guidelines.

All members of BAD were invited to participate by auditing five consecutive HS patients between January and May 2020. There were 82 respondents from across the UK with a total number of 406 patients. Documentation of baseline disease using Hurley staging was done in 75% and disease severity using a recognized tool in 56% of patients. Measuring the impact of the disease using quality of life questionnaires and pain measurement was recorded in approximately 50% of patients. The guidelines recommend that all patients be provided with patient information leaflet (PIL), have regular checking of BMI, smoking status and screening for cardiovascular risk factors and mental health problems. In our audit, 41% documented PIL provision. Around 75% documented smoking status but only one-third of smokers were referred to smoking cessation services. BMI was documented in one-quarter of patients and 23% of those with a BMI greater than 35 kg/m2 were referred for weight management. 40%, 25% and 57% of patients were screened for depression, anxiety and cardiovascular risk factors respectively. Our results show that 30% of patients had undergone surgery, of whom 75% had documentation of preoperative discussion. Around 50% had received adalimumab with documentation of baseline severity in 77%, Hurley stage in 68% and contraindication or failure to respond to conventional systemic therapy in 72% of patients. The guidelines recommend discontinuing adalimumab when there is less than 25% reduction in lesion count and there was documentation of following this guidance in 44% of patients.



The audit results show there is a need to improve documentation in most areas especially screening for conditions associated with HS.

Learning Objectives:

- Emphasizing documentation of disease severity using validated tools and screening for important comorbidities like mental health disease and cardiovascular disease annually.
- All patients must have their BMI and smoking status checked at each clinic visit and referred as needed.
- Importance of having a thorough preoperative discussion with an expert to prepare the patients for the long postoperative healing process.

Takeaway Message:

The management of HS patients must be done within a multidisciplinary team in a holistic manner.

P4.06 Hidradenitis Suppurativa in East and Southeast Asian Populations: A Systematic Review and Meta-Analysis

Rvan Gotesman¹, Charles Choi², Afsaneh Alavi³

1. Faculty of Medicine, University of Ottawa, Ottawa, ON, Canada, 2. Faculty Of Medicine, University of British Columbia, Vancouver, BC, Canada, 3. Department of Medicine (Dermatology), University of Toronto, Toronto, ON, Canada

Introduction: Hidradenitis suppurativa (HS) is a chronic, inflammatory skin condition that presents with recurrent inflammatory nodules that form in apocrine bearing skin. Most HS studies have focused on Western populations, though a few have examined HS in Asian patients. We conducted the first systematic review and meta-analysis to characterize the epidemiology of East and Southeast Asian patients with HS.

Methods, **Results**: We conducted a comprehensive literature search for case-series, cross-sectional and observational studies investigating HS in East and Southeast Asian populations. MEDLINE and EMBASE databases were searched and 2 reviewers independently assessed each study for inclusion. Data was extracted from 10 relevant studies and a random effects model was used for the meta-analysis. The pooled proportion of male HS patients was 0.66 (95%CI=0.60–0.72). In terms of severity, the pooled proportion of patients with Hurley Stage I was 0.38 (95%CI=0.20-0.56), 0.42 (95%CI=0.34-0.49) had Hurley Stage II and 0.25 (95%CI=0.10-0.39) had Hurley Stage III. The pooled proportion of HS patients with lesions in the axilla was 0.52 (95%CI=0.33–0.72) and in the gluteal region was 0.48 (95%CI=0.38–0.57). In addition, the proportion of HS patients with a positive family history of HS was 0.05 (95%CI=0.02–0.08).

Conclusions: We report the most up-to-date characterization of HS in East and Southeast Asian populations. Of note, the majority of patients were male, the reverse of what is seen in Western cohorts. Asian patients with HS tend to develop lesions in the axilla and the buttock, whereas Westerners tend to develop HS in the axilla and the groin. Hurley stage I and II were the most common, similar to Western cohorts. These results will hopefully lead to more effective care for Asian patients with HS and improve understanding for how the disease may manifest.

Learning Objectives:

- To learn the sex-distribution patterns of HS patients in East and Southeast Asian populations.
- To learn the distribution of mild, moderate and severe forms of disease in HS patients in East and Southeast Asian
 populations.
- To learn the body distribution patterns of lesions in HS patients in East and Southeast Asian populations.

Takeaway Message:

A systematic review and meta-analysis demonstrated that hidradenitis suppurativa has a unique presentation in East and Southeast Asian populations that is distinct from Western patients.

P4.07 Patient Perspectives on COVID-19 and Hidradenitis Suppurativa in Spring 2020

Kvla N. Price¹, Erin K. Collier², Tristan Grogan³, Jennifer L. Hsiao⁴, Vivian Y. Shi⁵

1. University of Illinois College of Medicine, Chicago, IL, USA, 2. David Geffen School of Medicine, University of California, Los Angeles, CA, USA, 3. Department of Medicine Statistics Core, David Geffen School of Medicine, University of California, Los Angeles, CA, USA, 4. Division of Dermatology, Department of Medicine, David Geffen School of Medicine, University of California, Los Angeles, CA, USA, 5. Department of Dermatology, University of Arkansas for Medical Sciences, Little Rock, AR, USA

Introduction: The purpose of this study is to assess the impact of COVID-19 on the healthcare and lifestyle of patients with hidradenitis suppurativa (HS).

Methods: An anonymous survey was distributed to the Facebook pages of HS support groups in May 2020. Respondents self-reported their Hurley staging using a provided description. The relationship between patient characteristics and Likert scale survey questions was assessed using Spearman's correlation coefficient. P<0.05 were considered statistically significant.

Results: A total of 335 respondents participated (mean age 37.4 [SD 10.0] years; 326 women [97.3%]). More than half of respondents (160/275, 58.2%) reported that they were able to reach a dermatologist during the pandemic (Figure 1). Meanwhile, over half of respondents (171/334, 51.2%) reported avoiding the emergency room/urgent care for HS flares since the pandemic began. Almost half of respondents (150/305, 49.2%) agreed that they were worried having HS increases their risk for infection.

The majority of respondents (205/335, 61.2%) reported more frequent HS flares since the pandemic started and nearly half reported weight gain. About a third (122/335, 36.4%) of respondents reported current tobacco use, of which 62.3% (76/122) reported no change, 23.0% (28/122) reported an increase, and 14.8% (18/122) reported a decrease in usage.

Overall, 42.3% (77/182) of respondents disagreed that telemedicine provides equally effective care compared to in-person visits. Respondents with higher Hurley stages were significantly more likely to disagree that telemedicine is equally effective as in-person visits (Spearman correlation -0.14, p=0.013) and that their concerns were adequately addressed by their dermatologist during the pandemic (Spearman correlation -0.17, p=0.002).

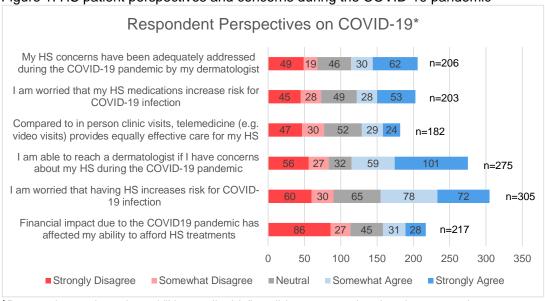


Figure 1. HS patient perspectives and concerns during the COVID-19 pandemic

Conclusion: The COVID-19 pandemic has impacted accessibility, quality of care, and driven lifestyle changes for HS patients. Continued efforts are warranted to understand the impact and adapt care (improve telehealth, shared decision-making, patient education, etc.) to meet unique HS patient needs during this challenging time.

Learning Objectives:

• To understand the impact of the COVID-19 pandemic on the accessibility and quality of HS patient care

^{*}Respondents who selected "Not applicable" or did not respond to the above questions were excluded.



- To investigate lifestyle changes among HS patients in response to the COVID-19 pandemic
- To guide clinical decisions for improved patient care and outcomes during the COVID-19 pandemic

Takeaway Message:

As the COVID-19 pandemic progresses, continuous effort is needed to understand the impacts of COVID-19 on HS
patients and to develop methods for addressing unique patient needs during this challenging and rapidly evolving time.

P4.08 Patients' Experience With Hidradenitis Suppurativa Care and Treatment: Results from the Hidradenitis Suppurativa Patient Experience Survey

Rachael Manion¹, Ilya Mukovozov², Jennifer Pereira³, Stephanie Carter⁴, Raed Alhusayen⁵

1. Canadian Skin Patient Alliance, Ottawa, ON, Canada, 2. University of British Columbia, Vancouver, BC, Canada, 3. JRL Research & Consulting Inc., Toronto, ON, Canada, 4. HS Heroes, Toronto, ON, Canada, 5. Sunnybrook Research Institute, University of Toronto, Toronto, ON, Canada

Introduction: HS is a devastating skin condition, characterized by recurrent nodules and abscesses in skin folds, affecting up to 4% of the population. A comprehensive examination of the patient experience was undertaken to to improve access and care for individuals with HS.

Methods: In January and February 2020, we conducted an online survey of individuals with HS. To disseminate the survey, HS patient advocacy groups, physician groups, and social media groups were engaged. Survey questions included: time to diagnosis, number of healthcare encounters, disease-related costs, and impact on work, school, personal life and intimacy. This report is an update to a 2017 baseline report.

Results: A total of 537 surveys were received, of which 73 were from Canada. The average age was 38 years with a range of 14 to 73 years. Median time from symptom onset to HS diagnosis was 7 years for Canadian respondents. During this prediagnosis period, 97% of respondents visited a family physician or walk-in clinic regarding symptoms, and 48% made 10 or more visits. More than half made at least one trip to the emergency room, and 16% visited the emergency room 10 or more times. Of the Canadian respondents, 83% received at least 1 misdiagnosis, and an average of 3 misdiagnoses. Only 24% of respondents reported satisfaction with the healthcare system during the pre-diagnosis period, rising to 41% when asked about current satisfaction with the system. Only 11% of all respondents consider their pain to be very well-controlled.

Learning Objectives:

- To provide an overview of the patient experience for people living with hidradenitis suppurativa (HS) in Canada and around the world.
- To compare results from 2020 with baseline report in 2017 of the patient experience in Canada and the USA.
- To share recommendations on improving the HS patient experience in Canada.

Takeaway Message:

Diagnoses are being made more quickly than previously reported in 2017. However, patients are still frustrated by the lack of support for their condition and effective treatment options for HS, and the significant psychosocial impacts of their symptoms.

P4.09 Unmet Needs and Struggles With HS From the Patient Perspective

Heather Lapidus Glassner, Elizabeth Luce

MyHealthTeams, San Francisco, CA, USA

Introduction: Social listening research was undertaken among people living with hidradenitis suppurativa (HS) who are members of myHSteam.[1] The goals were to understand patients' struggles with HS along their journey -- from recognizing symptoms and attaining diagnosis, to subsequent treatment, and the impact on quality of life.

Methods: myHSteam has over 11,000 members who are HS patients or caregivers. Select keywords from dialogue were analyzed using data from January 2019 to June 2020. Additionally, an in-depth analysis on all posts, comments, questions and answers for 174 patients were analyzed to identify key trends.

Results: In the analyzed patient cohort, ninety-six percent are women and fifty-five percent ages 30 to 49. Sixty-one percent are from the United States and twenty-six percent from the United Kingdom. Almost all have severe HS (multiple reoccurring boils, tracts, and pain).

Patients reported symptoms including boils and abscesses, both of which can cause inordinate pain, leak fluid, and smell. For many, the path to diagnosis is long and involves multiple doctors and appointments. Reticence to bring symptoms to healthcare providers, combined with misdiagnoses, contribute to delayed diagnosis, disease progression, and declining quality of life. Some have been shamed by doctors (e.g., called "unhygienic").

Few patients report successfully managing HS. They seek treatments that work, often cycling through them with limited success. They look for help to control flares.

As a result of the arduous patient journey, there is a significant impact on quality of life. Daily activities can become challenging. Appearance and self-esteem are affected, with many reporting anxiety, depression, and withdrawing from relationships. Patients seek networks such as myHSteam to ask and offer advice and find others with similar experiences.

Conclusions: Given the complexity of the patient journey and impact on quality of life, recognizing key challenges from the patient perspective is critical to bringing greater awareness and understanding among healthcare providers who treat patients with HS.

[1] Work was done in partnership with UCB.

Learning Objectives:

- Identify the experience of attaining an HS diagnosis from the patient perspective.
- Identify the needs of patients to better manage HS symptoms and flares, including experiences with treatments.
- Understand the impact HS has on patients' quality of life.

Takeaway Message:

Missed opportunities for earlier diagnosis add to patients' burden with HS. After diagnosis, they struggle to manage HS from a treatment and quality of life perspective. Recognizing patients' key challenges is critical to bringing greater awareness and understanding among healthcare providers who treat patients with HS.

P4.10 The Impact of Body Mass Index Upon the Efficacy of Adalimumab in Hidradenitis Suppurativa

John W. Frew¹, Neha Singh², Caroline Jiang², Roger Vaughan², James Krueger¹

1. Laboratory for Investigative Dermatology, Rockefeller University, New York, NY, USA, 2. Department of Biostatistics, Rockefeller University, New York, NY, USA

Background: Elevated Body Mass Index (BMI) in Hidradenitis Suppurativa (HS) is associated with decreased response to Adalimumab therapy. It has been proposed that BMI may segregate distinct HS disease subtypes. It remains unresolved whether the relationship between BMI and treatment response is linear or if a threshold BMI exists above which increased dosages may provide clinical benefit.

Methods: Individual patient data from 578 PIONEER Phase 3 participants were analyzed. BMI was calculated as a continuous variable as well as a categorical variable in line with standardized BMI categories. Descriptive, multivariable regression analysis and receiver operating characteristic (ROC) curves were calculated to assess the relationship between BMI and clinical outcome measures. All analysis was conducted in R v3.5.3.

Results: BMI was only a significant covariate in PIONEER 2. Participants in the overweight and obese BMI category had reduced odds (58% and 67% respectively) of achieving HiSCR (OR=0.42 (95%CI -0.19,0.91) p=0.03), (OR=0.33 (95%CI 0.16,0.67) p=0.002) compared to participants with BMI<25. Reduction in AN count and IHS4 score was not significantly associated. ROC analysis did not reveal any cut off value predictive of treatment outcome. No correlation between BMI and baseline disease activity or covariate interactions were identified.

Conclusions: Elevated BMI reduces odds of achieving HiSCR. No significant association was observed between BMI and reduction in continuous measures of disease activity (AN Count and IHS4 change). These findings suggest BMI may only be a significant covariate in the setting of lower baseline disease activity, supporting the concept of disease heterogeneity and differential therapeutic response to Adalimumab.

Learning Objectives:

- To Appreciate previous reports of BMI impacting HS disease activity
- To Understand the relationship between BMI, disease activity and therapeutic success with Adalimumab in HS.
- To identify directions for future work to unravel the role of BMI in the pathogenesis of HS





Takeaway Message:

Elevated BMI reduced the risk of achieving HiSCR, but this may be a product of the HiSCR outcome measure. BMI plays a significant role in the setting of lower disease activity suggesting disease heterogeneity.

P4.11 Trends in The Management of Hidradenitis Suppurativa in The Middle East Region: a Systematic Review

Mehran Karvar¹, Adriana C. Panayi¹, Afsaneh Alavi², Zahra Baziar³, Dennis P. Orgill¹

1. Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA, 2. Women's College Hospital, University of Toronto, Toronto, ON, Canada, 3. Shiraz University of Medical Sciences, Shiraz, Iran

Introduction: There is no universal consensus on the management of Hidradenitis Suppurativa (HS). Current available guidelines are from western countries which may be of limited use in other parts of the world. In this study we sought to identify the differences of HS management in the Middle East (ME) region compared with the West.

Methods, **Results**: A systematic literature review was performed to identify all studies in HS management from experts in the ME from database inception to June 2020 using PubMed, EMBASE, and Cochrane databases. Only original articles published in English language were included. Guidelines from western countries were used for comparison. Fifty four eligible studies comprising 7649 HS patients from the ME region, and nine guidelines from the West were included. In the ME, sex ratio is different with men reported to be affected in a higher rate than in the West. Screening for comorbidities for ME-associated disorders such as Familial Mediterranean Fever is necessary in patients in the ME. Recommended antibiotic regimens are different in some countries in the ME and the experts in the ME tend to be more procedure intensive than experts in the West.

Conclusions: Establishing a guideline for HS management in the ME is recommended to address unique considerations in the countries in this region.

Learning Objectives:

- To demonstrate unique clinical features of hidradenitis suppurativa (HS) in the Middle East (ME) region.
- To determine approaches to the management of HS in the ME.
- To identify differences between management of HS in the ME and the West.

Takeaway Message:

- More men suffer from hidradenitis suppurativa (HS) in the Middle East (ME) than in the West.
- HS may be associated with unique comorbidities in the ME such as Familial Mediterranean Fever.
- Recommended antibiotic regimen in the treatment of HS can differ in the ME from the West.
- Several factors may render medical therapies less effective in the ME, leading to more procedure intensive approaches
 in HS management in the ME than in the West.

P4.12 Hidradenitis Supparativa Impact on Parents: a Claims-based Study of Parents of Adolescents with HS

Jay Yang, Joslyn S. Kirby

Penn State College of Medicine, Hershey, PA, USA

Hidradenitis supparativa is a chronic skin condition that causes painful lumps and nodules to form on the body, mainly affecting apocrine gland-rich areas such as the groin and axilla. While the negative impacts of an HS diagnosis on the patients themselves have been well-documented, less is known about how an HS diagnosis affects the patient's family members. Thus, our study looks at the impact of an HS diagnosis on an adolescent's parents, including mental-health issues and work-related disruptions.

De-identified data were obtained from the IBM MarketScan Commercial Claims database, a database that contains a wide array of medical claims data for over 265 million patients. This retrospective claims analysis included data sampled from 01/01/2015 to 12/31/2017. A total of 3,428 families with adolescents with HS were identified and 17,140 randomly-selected age-/sex-matched adolescents and their families (5:1 ratio) were used as controls.

Of the 3,428 adolescents with HS (18.3% men and 81.7% women), 21.5% had parents who either already had been or were diagnosed with depression following their child's diagnosis of HS, compared to 19.6% of control families (P=0.00888). In addition, 6.3% of HS parents experienced a change in employment status, compared to only 5.2% of control parents

(P=0.00983). HS parents also experienced a slightly higher rate of anxiety than controls (26.43% vs 25.87%), although this difference was not significant (P=0.495).

We found that parents of adolescents afflicted by HS are significantly more likely to either have or be diagnosed with depression than unaffected parents. This disparity is mainly seen in parents under the age of 55. In addition, parents of adolescents afflicted by HS are significantly more likely to experience a change in employment status than unaffected parents. HS is a disease that affects not only the quality of life of the patient but also the patient's family members, and more attention should be given to the mental health of these parents.

Learning Objectives:

- Explore the incidence of mental-health related issues among parents of adolescents with HS.
- Identify work-related disruptions that parents of adolescents with HS face.
- Explore ways in which parents of adolescents with HS can receive additional support as needed.

Takeaway Message:

HS is a disease that affects not only the quality of life of the patient but also the patient's family members, especially in regards to depression and work-related disruptions, and thus increasing attention should be given to the mental health of these parents.

P4.13 Characterization of Pediatric Patients with Hidradenitis Suppuritiva and Implications for Development of Clinical Trials Eligibility Criteria

Helen Bui, Christopher Saved

University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Introduction: Hidradenitis Suppuritiva (HS) often develops in adolescence, but there are limited studies of HS in pediatric patients. The large majority of medication trials have excluded patients<18 years, which will hinder FDA-approval for pediatric patients. Frequently used inclusion/exclusion criteria in adult trials may create major barriers to inclusion for pediatric patients due to the unique characteristics of this group that are typically early in their disease course. We will examine clinical trial inclusion/exclusion criteria in recent and ongoing clinical trials, characterize a cohort of pediatric patients in our HS registry and discuss the implications for development of clinical trials in this group.

Methods/Results: Using a registry of prospectively collected data, a cohort of about 60 pediatric patients age<18 and about 700 adults from a subspecialty HS clinic at the University of North Carolina Chapel Hill was identified. Data on disease course, physical exam findings, and demographic information were collected. Mean abscess/nodule (AN) counts in the pediatric cohort was 1.95 compared to 4.98 in adults, with the large majority of pediatric patients having Hurley stage I or II disease. Only 5 patients were under 60kg, and only 5 and 16 patients had AN counts of ≥5 and ≥3, respectively.

Conclusion: In the context of developing future clinical trials for pediatric HS patients it is imperative to consider how their baseline characteristics will impact recruitment and disease assessment. Frequently used current trial inclusion criteria such as requiring AN count ≥5 would severely limit the ability of adolescent patients to participate. Early intervention and cessation of progression is immensely important and clinical trials should aim to include younger patients with lower disease severity. Tools to assess disease progression and response to treatment specifically for the pediatric population are also essential.

Learning Objectives:

- Understand the demographic makeup of a cohort of pediatric patients with hidradenitis suppurative in the southeast United States.
- Understand the differences in disease and patient characteristics based on age.
- Recognize the implications of pediatric HS patient characteristics on development of clinical trials to study this population.

Takeaway Message:

Despite the need for early intervention, pediatric HS patients are usually excluded from clinical trials, and currently used clinical trial inclusion/exclusion criteria would likely be ill-suited for use in pediatric populations based on the characteristics of our registry cohort.



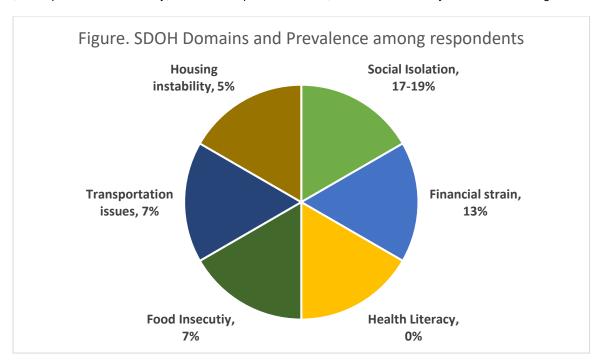
P4.14 Social Determinants of Health impacts for People with Hidradenitis Suppurativa

Ankita Sinharov, Melissa Butt, Joslyn S. Kirby

Penn State University, Hershey, PA, USA

Introduction: Hidradenitis Suppurativa (HS) has been shown to impact work productivity and is associated with lower socioeconomic status (SES). These economic and social influences on health are considered social determinants of health (SDOH). The objective of this study was to evaluate six SDOH domains for people with HS at our center.

Methods & Results: A cross-sectional survey study was conducted among the HS patients, based on ICD9/10 code in the Penn State EHR. Data was collected using REDCap survey software. SDH data was collected for six domains. Overall, 154 people responded, 121 responses (78.6%) were complete and analyzed. The majority of respondents were white (85.71%), female (88.33%), and had an annual income of less than \$50,000 while working full-time (60.0%). Of note, 25.8% were unemployed and not seeking employment. Of SDOH domains, the highest prevalence of endorsement was in social concerns with 17-19% of respondents feeling left-out or isolated. None reported health literacy concerns. Financial strain was reported by 13%, 7% reported food insecurity, 7% had transportation issues, and 5% had difficulty with stable housing.



Conclusion: This study gives an insight the economic and social challenges encountered by people with HS. It is crucial for clinicians to be aware of SDOH domains and their potential to impact people's ability to manage their HS. Social isolation was most frequent; however, financial strain and transportation issues may be critical barriers to people receiving care, medications, or undergoing procedures. There are opportunities to identify these barriers in practice, engage resources to support the patient, and evaluate the holistic effects on disease outcome.

Learning Objectives:

- Discuss the role of social and economic factors on health.
- Review the literature related to socioeconomic status for people with HS.
- Describe the prevalence of six domain of socioeconomic determinants among a cohort of people with HS.

Takeaway Message:

This study shows people with HS encounter economic and social challenges that have the potential to impact their ability to manage their HS. Social isolation was most frequent; however, financial strain and transportation issues may be critical barriers to people receiving care, medications, or undergoing procedures.

P4.15 Expert Management of HS Pain: a Survey Study

Mark Jedrzeiczak¹, John R. Ingram², Michelle A. Lowes³, Haley Naik⁴, Anne Marie McKenzie-Brown¹, Suephy Chen⁵, Lauren A. Orenstein⁵

1. Emory School of Medicine, Atlanta, GA, USA, 2. Department of Dermatology and Wound Healing, Division of Infection and Immunity, Cardiff University, Cardiff, United Kingdom, 3. The Rockefeller University, New York, NY, USA, 4. Department of Dermatology, University of California, San Francisco, San Francisco, CA, USA, 5. Department of Dermatology, Emory University School of Medicine, Atlanta, GA, USA

Introduction: Pain is the most important cause of disability and quality of life impairment in hidradenitis suppurativa (HS). Little evidence exists to guide HS pain management, and HS experts' approach to managing HS pain remains poorly characterized. This study aimed to describe HS experts' attitudes and practices surrounding pain management.

Methods, Results: In this cross-sectional study, a 38-item survey was anonymously distributed to HS experts by email. Participants were board-certified dermatologists with at least 1 HS patient encounter in the prior 6 months. Among the 56 respondents, 49 dermatologists from 15 countries met inclusion criteria. The estimated response rate was 56/234. Most respondents (46/49) self-identified as HS experts. Although all participants strongly agreed (44/49) or agreed (5/49) that pain greatly impacts HS patients' quality of life, only 9/49 agreed or strongly agreed that HS guidelines on pain are sufficient in practice. Most participants asked their patients about HS pain at every visit (27/49) or most visits (10/49). The most common pain measurement instruments were the numerical rating scale (NRS) and visual analog scale (VAS), although 11/49 did not measure pain. For acute HS pain, the most commonly used analgesics were acetaminophen, intralesional triamcinolone, and nonsteroidal anti-inflammatory drugs (NSAIDs). For chronic HS pain, respondents also frequently prescribed gabapentin. Short opioid courses were considered appropriate by 18/49 respondents for acute HS pain and 26/49 for post-operative HS pain. The most frequently cited barriers to managing HS pain included lack of knowledge or experience in prescribing pain medications (30/49) and concern about medications' habit-forming potential (30/49). Only 30/49 correctly recognized cognitive behavioral therapy as an effective treatment for chronic pain.

Conclusion: HS expert's management of HS pain varies widely, possibly due to weak evidence and sparse guidelines. Dermatologist education about pharmacologic and non-pharmacologic pain management may promote safe treatment of HS pain.

Learning Objectives:

- Describe HS expert's attitudes, knowledge, and practices regarding HS pain.
- Discover barriers to managing pain commonly cited by HS experts.
- Compare the frequency of both pharmacologic and non-pharmacologic methods commonly recommended or prescribed for acute, chronic, and post-operative HS pain.

Takeaway Message:

Although there is consensus that it is very important to address HS pain, there is great variation in expert management of HS pain.

P4.16 Delay in Diagnosis, Severity of Disease, and Dermatology Visits in Black and White Hidradenitis Suppurativa Patients in Southeast Wisconsin

Caden Ulschmid¹, Linda Serrano¹, Gretchen M. Roth¹, Olayemi Sokumbi²

1. Medical College of Wisconsin, Milwaukee, WI, USA, 2. Mayo Clinic, Jacksonville, FL, USA

Hidradenitis suppurativa (HS) is an inflammatory skin condition that disproportionately affects black patients. In this study we assess delay in diagnosis, severity/stage of disease, and management of HS by a dermatologist in both black and white HS patient populations.

We searched the Medical College of Wisconsin and Froedtert Health i2b2 electronic data warehouse, including over 1.3 million patients in Southeast Wisconsin, for patients with an HS diagnosis and ≥3 encounters for HS using ICD9 705.83 and ICD10 L73.2 codes. To date, 453 patients have been characterized by retrospective chart review. Patients without an encounter in which they were treated for HS were excluded.

50.6% (229) of patients were black, 46.8% (212) were white, 2.4% (11) were other, and 1 patient lacked data. Age at initial presentation was documented in 340 black or white patients with a mean age of 27.86 (n=183) for black and 31.33 (n=157) for white patients. Of 309 patients with documentation of both year of symptom onset and year of diagnosis, the mean delay



in diagnosis was 3.95 years (n=163) for black and 3.46 years (n=146) for white patients. 172 black or white patients had documentation of disease severity/stage. 27.4% (26) of black patients had Hurley I as the worst documented stage, 28.4% (27) Hurley II, and 44.2% (42) Hurley III. 39.0% (30) of white patients had Hurley I as the worst documented stage, 35.1% (27) Hurley II, and 26.0% (20) Hurley III. 44.1% (101/229) of black patients had seen dermatology for management of HS, compared to 60.7% (128/211) of white patients.

Our data suggest black patients have a greater delay in time to diagnosis, more severe disease, and are less likely to receive care from a dermatologist for HS treatment than their white counterparts. These potential differences must be further assessed, and the underlying causes explored.

Learning Objectives:

- Understand the racial distribution of HS patients in Southeast WiscsonsinUnderstand the racial disparities in disease severity in HS patients in Southeast Wisconsin
- Review racial disparities in delay in diagnosis and care by a dermatologist for HS patients in Southeast Wisconsin

Takeaway Message:

Black patients in Southeast Wisconsin experience multiple disparities in HS care including time to diagnosis, disease severity, and treatment by a dermatologist.

P5: Therapy Including Surgical, Medical and Complementary

P5.01 Use of Infliximab vs. Infliximab-abda in Patients with Hidradenitis Suppurativa

Linnea L. Westerkam¹, Kelly J. Tackett^{1, 3}, Christopher Sayed^{1, 2}

1. University of North Carolina School of Medicine, Chapel Hill, NC, USA, 2. University of North Carolina Department of Dermatology, Chapel Hill, NC, USA, 3. University of North Carolina Gillings School of Public Health, Chapel Hill, NC, USA

Introduction: Recent studies have described the effectiveness of infliximab (Remicade) for the treatment of hidradenitis suppurativa (HS) and it is frequently used off-label in clinical practice. Cost saving biosimilar alternatives have recently become available, though no data currently exists on their safety and efficacy for treating HS. In order to address this, a retrospective cohort study was done to evaluate the efficacy and safety of the infliximab biosimilar, infliximab-abda (Renflexis), compared to infliximab in the treatment of HS.

Methods: The study population included patients who met the clinical criteria for HS and were seen at the University of North Carolina in Chapel Hill. Patients started on infliximab or infliximab-abda were clinically tracked beginning at the time of drug initiation using the electronic medical record system. Demographics, lab values, medication regimen, past and concomitant treatments, and clinical findings including AN and sinus counts and patient reported outcomes were collected via chart review. These categories were compared before and after the use of infliximab or the biosimilar. Primary endpoint of HiSCR and multiple secondary endpoints were recorded at the most recent assessment following at least 10 weeks of treatment. The infliximab and infliximab-abda treatment groups consisted of 20 and 14 patients, respectively.

Results: Statistical analysis is underway but initial findings indicate similar population characteristics across both treatment groups. The infliximab and infliximab-abda HiSCR rates were similar, with a 60% and 71% response rate, respectively. The secondary endpoint of DLQI improved similarly by 5.1 for infliximab and 6.6 points for infliximab-abda. Another secondary endpoint, IHS4, improved by 12.9 and 14.5 points for the infliximab and infliximab-abda treatment groups, respectively.

Conclusions: Preliminary data indicates similar improvement in primary and secondary outcome measures in patients treated with infliximab and infliximab-abda. Infliximab-abda is likely a valuable treatment option for hidradenitis suppurativa, though additional studies are warranted given our small sample sizes.

Learning Objectives:

- Understand how biosimilars are unique from reference products
- Become familiar with biosimilar treatment options for infliximab
- Recognize the potential role for treatment of HS with biosimilar infliximab

Takeaway Message:

Preliminary data indicates similar improvement in primary and secondary outcome measures in patients treated with infliximab and infliximab-abda. Infliximab-abda is likely a valuable treatment option for hidradenitis suppurativa, though additional studies are warranted given our small sample sizes.

P5.02 Surgical Management of Hurley Grade III Hidradenitis Suppurativa Using ECM Graft

Abigail Chaffin¹, Marie-Claire Buckley²

1. Tulane University, New Orleans, LA, USA, 2. University of Minnesota Medical School, Minneapolis, MN, USA

Introduction: Wide excision and flap reconstruction is a common strategy for surgical intervention of Hidradenitis Suppurativa (HS), however the complication rates (24%) and recurrence rates (20.1%) remain relatively high, possibly due to the poor quality of the underlying tissues, potential for dead space and/or poor vascularity of the tissues [1]. To address this an ECM was evaluated as part of surgical reconstruction of Grade III HS. The ECM graft serves as a bioscaffold for soft repair and contains many proteins found in human soft tissue [2, 3], is anti-inflammatory [4, 5], stimulates angiogenesis [3], and undergoes complete remodelling [3, 6].

Methods: This case series included the surgical reconstruction of six patients (n=8 defects) with axilla HS lesions using two methods. Either wide excision and placement of the ECM graft under a fasciocutaneous flap (n=5 defects), or as a dermal substitute (n=3 defects).

Results: When used as an implant to stabilize the tissue flap, no dehiscence of the primary closure occurred. Where the ECM graft was used as a dermal replacement the graft granulated in 2-3 weeks and the defects closed either via secondary intention (n=1 defect), or placement of a STSG (n=2 defects). None of the cohort had post-surgical complications or recurrence in the follow-up period, 1-7 months.



Participant, Age, Comorbidities	HS Diagnosis	Location	Surgical Management	Time of last follow-up
Male, 29	2 years (Hurley Grade III)	Right axilla	Resected into deep subcutane-ous fat layer	Minor complications at 1 week – resolved week 2
Deep Vein Throm-bosis			down to fascia	
(DVT)			ECM graft ap-plied as	
			dermal substitute	
			 Paraffin gauze dressing, 	9+ months
			then NPWT applied	
			 Closed via sec-ondary 	No further complications



			intention • Granulated at 4 weeks • ~80% epitheli-alized at 6 weeks	No recurrence
Female, 31	5 years (Hurley Grade III)	Right axilla	Partial axillary resection ECM graft placement Fasciocutneous flap reconstruction lodoform suture packing GV/MB foam plus with alginate secondary dressing Fully healed at 3 weeks	10+ months No complications No recurrence
Female, 26 HIV	5 years (Hurley Grade III)	Right axilla	Entire hair-bearing axillary resection ECM graft placement Fasciocutaneous flap reconstruction lodoform suture packing GV/MB foam plus with alginate secondary dressing Fully healed at 3 months	Minor complications at week 3 – resolved week 6 8+ months No further complications No recurrence
Male, 39 Uncontrolled diabetes Smoker HGB A1c 12.6	Bilateral Hurley Grade III	Right and left axilla	Wide resection down to fascia ECM graft applied as dermal substitute NPWT Fully granulated at 3 weeks STSG at 22 weeks, 100% graft take at 23 weeks	5+ months No complications No recurrence
Female, 37 Gout	Hurley Grade III	Right axilla	Entire hair-bearing axillary resection ECM graft placement Fasciocutaneous flap reconstruction lodoform suture packing GV/MB foam plus with alginate secondary dressing Fully healed at 3 months	4+ months No complications No recurrence

10 years, Bilateral Hurley Grade III	Right and left axilla	Entire hair-bearing axillary resection	1 month
		 ECM graft placement Fasciocutaneous flap	No complications
		reconstruction Iodoform suture packing GV/MB foam plus with alginate secondary dressing Fully healed at 1 month	No recurrence

Conclusions: This limited case series provides preliminary insights into the surgical management of grade III HS using an ECM graft to reduce complications.

Learning Objectives:

- Understand the function of extracellular matrix bioscaffolds in soft tissue repair especially as it relates to the pathophysciology of HS
- Learn the surgical deployment of ECM grafts in complex surgical reconstruction of HS tips and tricks to reduce complication rates
- Understand long-term patient outcomes using ECM graft as part of complex reconstruction of Grade III HS

Takeaway Message:

- Modern regenerative medicine has provided advanced solutions for soft tissue repair and reconstruction. These technologies augment the bodies natural ability to heal.
- Reconstruction of Grade III HS presents complex challenges that modern ECM grafts can help overcome potentially reducing complication rates

P5.03 Golimumab for the Treatment of Hidradenitis Suppurativa in Patients with Previous Tumor Necrosis Factor-alpha Treatment Failure

Maria del Mar Melendez Gonzalez¹, Judy Hamad², Christopher Sayed³

1. Universidad Central del Caribe School of Medicine, Bayamon, PR, USA, 2. University of North Carolina School of Medicine, Chapel Hill, NC, USA, 3. University of North Carolina School of Medicine, Department of Dermatology, Chapel Hill, NC, USA

Introduction: TNF- α inhibitors are recommended for moderate to severe HS.¹ Golimumab is a TNF- α inhibitor with higher affinity to protein receptors than adalimumab during preclinical studies². Use of golimumab has been reported in two patients with ulcerative colitis and HS with mixed results, at typical dosing for ulcerative colitis.

Methods/Results: Seventeen patients prescribed golimumab, typically at a dose of the higher of 2mg/kg or 200mg at week 0, 2, and then every 4 weeks, were identified through medical record tracking lists and fourteen met the inclusion criteria. Hidradenitis suppurativa clinical response (HiSCR) after 10 weeks was the primary outcome. Eleven of fourteen patients had data available for HiSCR analysis; of which 5 were responders and 6 nonresponders. All had previously received adalimumab, and 10/11 had received infliximab. Secondary outcome measures of change in IHS4 and DLQI trended toward improvement within the groups, but fell slightly short of statistical significance. Mean change in IHS4 was found significantly different between the cohort with responders having a decrease in mean IHS4 and DLQI scores, no change in pain scores, and an increase in Hct, though only IHS4 improvement met statistical significance.

Conclusions: 45% of treated patients achieved HiSCR response, comparable to adalimumab's 41.8% and 58.9% response rate during PIONEER I and II, respectively, which featured biologic-naïve patients³. Trends towards DLQI and IHS4 score improvement were also noted across the cohort, which was limited by its small sample size. Golimumab may be a reasonable treatment option in patients recalcitrant to other TNF inhibitors.

Learning Objectives:

- The study of golimumab as a treatment option for severe recalcitrant HS.
- The study of golimumab in HS patients with previous TNF-alpha treatment failures.
- The use of secondary outcome measures to assess treatment response to golimumab.





Takeaway Message:

Golimumab should be considered as a treatment option in HS patients with severe recalcitrant disease with previous TNF-alpha treatment failures.

P5.04 A Retrospective Analysis of the Duration of Long-Term Oral Antibiotic Use for the Treatment of Hidradenitis Suppurativa

Sarah Kitts¹, Ramon Govea¹, Steven Maczuga², Joslyn Kirby²

1. Pennsylvania State College of Medicine, Hershey, PA, USA, 2. Penn State Health, Milton S Hershey Medical Center, Hershey, PA, USA

Introduction: Hidradenitis suppurativa (HS) is a chronic skin condition that results in painful inflammatory lesions, often in intertriginous body sites. Oral antibiotics are a mainstay of treatment; however, the duration of use in clinical studies is typically 12-16 weeks. It is possible that longer durations are used in clinical care. This study aimed to investigate the duration of long-term oral antibiotic use for the treatment of HS.

Methods/Results: The MarketScan® database was queried for patients with a diagnosis of HS from January 1, 2005 through December 31, 2014 using ICD-9 codes. Antibiotic use and duration was determined using National Drug Codes. Courses ≥30 days were included. Prescriptions occurring within<30 days of each other were considered part of 1 longer course. Combination therapies were labeled by the class that comprised the majority. Multiple therapy included courses without a majority. Overall, 9,293 people with HS were identified; partial results are reported on 2,936 HS patients with 3875 courses ≥30 days. The mean duration of treatment was 75 days. The majority of courses were 30 days [48%, n=1870] followed by 31-90 days [35%, n=1391]. Few were greater that 91 days [17%, n=614]. 30 day courses of tetracyclines were the most frequently prescribed [27%, n=1033]. Single agent therapy [70%, n=2729] was more common than combination [24%, n=911] and multiple therapy (6%, n=236).

Conclusion: Our results show the majority of oral antibiotic courses have a duration less than 90 days consistent with antibiotic stewardship found in guidelines for other dermatologic conditions. Limitations of the study include lack of data regarding patient adherence or information on HS severity and clinical outcomes. Additionally, the cumulative effect of courses<30 days was not assessed. Further research is needed to investigate the clinical outcomes associated with length of use, determine optimal duration, and assess effects on antibiotic resistance.

Learning Objectives:

- Examine the duration of long-term oral antibiotic use in hidradenitis suppurativa
- Compare the duration of use to current guidelines
- Investigate the use of combination antibiotics in long-term treatment of hidradenitis suppurativa

Takeaway Message:

The majority of longterm oral antibiotic courses do not exceed three months and are consistent with antibiotic stewardship guidelines.

P5.05 Systemic Steroids May Reveal or Worsen Hidradenitis Suppurativa

Maïa Delage¹, Olivier Join-Lambert², Sandrine Perol³, Thi Lam¹, Karima Amazzough⁴, Geneviève Plu-Bureau³, Aude S. Nassif¹

1. Institut Pasteur, Paris, France, 2. Centre Hospitalo-universitaire de Caen, Caen, France, 3. Hopital Cochin- Port-Royal, Paris, France, 4. Hopital Necker-enfants Malades, Paris, France

Introduction: Few studies reported benefits from systemic steroids (SS) in hidradenitis suppurativa (HS), always combined with other molecules, questioning their role in patients' improvement.

On the contrary, for 13 years, in our HS cohort, we observed constant worsening of patients or treatment failure under SS. Therefore, we selected instructive cases to illustrate this potential SS triggering role.

Case reports:

A 23-year-old female presented with Hurley III necrosis of both axillae. She reported early HS with many treatment failures and finally a 6-month course of SS alone, ending with bilateral axillary skin necrosis and 40 kg weight gain. A sleeve with 40kg loss failed on HS, subsequently cured with combined targeted antibiotics (TA) and wide excision. A 50 year-old female with Hurley I inguinal lesions since puberty reported many previous treatment failures including one month of SS at age of

36, resulting into bilateral axillary necrosis and subsequent emergency wide excision.

A 43 year-old female presented with Hurley III granulomatous mastitis (GM) in both breasts lasting for 18 months, after failure of SS + methotrexate + adalimumab prescribed for GM, cured with TA and SS+ immune suppressors stop.

A 50-year-old pharmacist, with no previous HS history, auto-treated her chronic urticaria with 2 steroid injections and immediately developed high blood pressure and axillary HS, incised in emergency; 6 months later, because of urticaria relapse, 2 new steroid injections induced HS relapse.

A 32-year-old female with previous Hurley I disease, in remission under cotrimoxazole for 2 years, underwent facial palsy and took oral prednisolone for 10 days. On the eleventh day, she relapsed from bilateral groin HS.

Conclusions: In Mahé's kidney transplant cohort under SS and immune-suppressors, HS prevalence was 12% instead of usual 1%, questioning immune suppressors role.

In individuals predisposed to HS, SS may reveal or induce HS flares.

Learning Objectives:

- Know whether systemic steroids are beneficial in HS
- Know that skin necrosis can occur with systemic steroids
- Know that the worsening usually occurs after treatment is stopped or during when it is prolonged

Takeaway Message:

Systemic steroids may worsen and induce HS flares

P5.07 The Use of Biologics in Pediatric Patients with Hidradenitis Suppurativa: a Systematic Review

Muskaan Sachdeva¹, Khalad Maliyar¹, Asfandyar Mufti², Afsaneh Alavi²

1. University of Toronto, Faculty of Medicine, Toronto, ON, Canada, 2. Division of Dermatology, Department of Medicine, Women's College Hospital, Toronto, ON, Canada

Background: The Food and Drug Administration (FDA) and European Union (EU) have recently approved biologics for pediatric patients with Hidradenitis Suppurativa (HS). However, no reviews or clinical trials have analyzed the effectiveness and safety data of biologic use specifically in pediatric patients with HS. The objective of this systematic review is to identify and summarize the outcomes of biologic therapy in pediatric patients with HS.

Methods: MEDLINE and EMBASE databases were used to conduct the search on June 29th, 2020. Search keywords included variations of hidradenitis suppurativa, biologic and pediatric population. A total of 49 articles were screened, 30 articles underwent a full text screen, and 11 articles that met the inclusion criteria were included.

Results: The 11 included studies comprised of 12 patients, with the mean age of 13.8 years. The females to males ratio was 2:1, with females accounting for 66.7% (n=8/12) of cases and males accounting for 33.3% (n=4/12). The average duration of HS prior to biologic initiation was 3.6 years, with majority of them being Hurley Stage III. The 12 pediatric cases with HS used a total of 13 biologics: 84.6% used anti-TNF alpha (i.e. adalimumab n=5, infliximab n=3, etanercept n=1, and not specified n=2), 7.7% used anti-IL-12/23 (i.e. ustekinumab n=1), and 7.7% used anti-IL-1 (i.e. anakinra n=1) biologics. Of the 12 patients, 58.3% (n=7/12) experienced complete resolution and 41.7% (n=5/12) experienced partial resolution. The resolution period between biologic initiation and complete or partial resolution of HS lesions ranged from 10 days to 11.5 months (mean: 6.2 months). No adverse events were reported in the studies.

Conclusion: Although TNF alpha inhibitors were the most common biologics used for HS in pediatric cases with results showing partial or complete resolution of the lesions, large-scale trials specific to pediatric patients with HS are needed to confirm these findings.

Learning Objectives:

- Investigate the effectiveness of biologic use for HS in pediatric population through the summarization and analysis of quantitative data in current literature.
- Identify and understand trends among biologics used for HS pediatric cases, based on mechanism and resolution outcome data.
- Recognize the important need for large scale trials specific to the pediatric population with HS.



Takeaway Message:

TNF alpha inhibitors are found to be the most common biologics used for HS in pediatric cases with results showing partial or complete resolution of the lesions; however, large-scale trials specific to pediatric patients with HS are needed to confirm these findings.

P5.08 Hidradenitis Suppurativa in Female-to-male Transgender Patients after Initiation of Testosterone Therapy

Michele Buonomo¹, Matthew D. Mansh², Deborah Thorp³, Noah Goldfarb^{4, 5}

1. University of Minnesota Medical School, Minneapolis, MN, USA, 2. University of Minnesota, Department of Dermatology, Minneapolis, MN, USA, 3. Park Nicollet Health Services, Department of Obstetrics and Gynecology, St. Louis Park, MN, USA, 4. University of Minnesota, Departments of Medicine and Dermatology, Minneapolis, MN, USA, 5. Minneapolis VA Medical Center, Departments of Medicine and Dermatology, Minneapolis, MN, USA

Introduction: Transgender individuals are a growing patient population with unique dermatologic needs. Masculinizing hormone therapy (MHT) represents a common therapeutic intervention for transgender men (female-to-male) and other gender diverse individuals. While MHT has been associated with adverse cutaneous effects including acne vulgaris and androgenic alopecia, there have been no reported cases of hidradenitis suppurativa (HS) in this population. Herein we present two patients, one that developed HS and one with worsening HS symptoms after initiating MHT.

Cases: Case 1 is a 30-year-old transgender man that developed Hurley stage II HS shortly after his IM testosterone dose was increased from 100mg/week to 140mg/week. Case 2 is a 40-year-old transgender man with a history of Hurley II HS that experienced repeated disease flares after administering IM testosterone 60mg/week. Both patients failed conventional therapies, but responded well to a dose reduction in IM testosterone while maintaining their desired secondary sex characteristics. Case 2 was able to increase back to consistent 60mg/week T with the addition of oral finasteride.

Conclusion: MHT is considered medically necessary in treating gender dysphoria, but may result in unwanted dermatologic side effects. While the pathophysiology of HS is not fully understood, androgens have been suggested to play a role. Our cases demonstrate HS may develop or worsen among patients receiving MHT. Dose adjustments to testosterone and adjunctive finasteride may help patients manage their HS, but need to be balanced with the gender-affirming goals of MHT.

Learning Objectives:

- Describe how HS may develop or worsen in transgender individuals receiving masculinizing hormone therapy (MHT).
- Understand the unique, population-specific considerations when treating HS in transgender men.
- Develop a greater understanding of the dermatologic needs of transgender individuals to promote best practices for culturally competent and affirming care.

Takeaway Message:

Transgender individuals receiving masculinizing hormone therapy (MHT) may develop undesirable side effects such as hidradenitis suppurativa. While MHT is considered medically necessary in treating gender dysphoria, dose adjustments to testosterone and adjunctive finasteride may be of benefit to control HS symptoms.

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Kaleta, Katarzyna P.	No conflicts to disclose
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Kirby, Joslyn S.	AbbVie: Speaker, Consultant, Advisory Board Consultant: ChemoCentryx, Incyte, UCB, Novartis	
Kirchhof, Mark	Speaker: Janssen, Leo Pharma, Novartis, Pfizer, UCB, Sanofi Genzyme Advisory Board, Consultant: Eli Lilly, Janssen, Leo Pharma, Novartis Pfizer, UCB, Sanofi Genzyme	
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Lev-Tov, Hadar	Founder, own stock: Learnskin.com Clinical Trials: BSN Medical, Medline, Molnyke, Pfizer, Tissue Tech, UCB Consultant: NextScience, Pfizer	
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Shah, Monica	No conflicts to disclose	
Silfvast-Kaiser, Annika S.	No conflicts to disclose	
Tan, Jerry	Consulting: Almirall, Bausch, Boots/Walgreens, Botanix, Cipher, Galderma, Novartis, Promius, Sun, Vichy Advisory Board Member: Almirall, Bausch, Galderma, Promius, Sun, Vichy Speaker: Galderma, Pfizer, Vichy Investigator: Bausch, Incyte, UCB	
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