Characteristics and treatment pathways in pediatric and adult hidradenitis suppurativa: An examination using real world data

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Background: Hidradenitis suppurativa (HS) is a chronic, debilitating, inflammatory disease. Contemporaneous real-world data can be used to elucidate the clinical treatment of pediatric patients and how treatment strategies compare with adult hidradenitis suppurativa patients.

Objective: The objective of this study is to evaluate clinical and treatment characteristics of pediatric and adult HS patients.

Methods: HS adult and pediatric patients were identified in 3 the United States administrative claims databases during the study period between 2016 to 2021. Patients were required to have 2 diagnostic codes for HS and have at least 365 days of prior observation time to the first HS diagnosis.

Results: Pediatric and adult HS treatments were similar. The proportions of subjects treated with topical and oral antibiotic or oral antibiotic alone or topical medication alone or surgery alone covered 90% of the treated pediatric subjects and 91% of treated adult subjects. The remaining proportion of subjects received other treatment combinations.

Limitations: The databases represent subjects with commercial or government insurance coverage and thus do not necessarily represent the broader US population. The databases do not capture information about medications obtained without insurance.

Conclusions: Although subtle differences exist, this study confirms that topical and systemic therapeutic treatment of HS in adults and adolescents is very similar. (JAAD Int 2023;12:124-32.)

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Data availability statement: The data that support the findings of this study are available to license from IBM and Clinformatics. Data are available from IBM at https://www.ibm.com/products/marketscanresearch-databases, from Clinformatics at https://www.optum.com/business/solutions/life-sciences/real-world-data.html. The use of Clinformatics and CCAE was reviewed by the New England Institutional Review Board and was determined to be exempt from broad Institutional Review Board approval as this project do not qualify as human subject research.

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INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic, recurring, inflammatory skin disease. The prevalence of HS is underdiagnosed as it may be misdiagnosed and coded as abscesses or boils. Inaccuracy of prevalence estimates may be due to differences in study design and varying study populations when using epidemiologic data. US studies that use observational data estimate the prevalence of HS to be less than 1%.[1-3] Age of HS onset typically occurs in the second or third decade of life[4] but can also occur in pediatric patients (aged <18 years), although generally after the onset of puberty.[5] Among adolescents, HS can be associated with significant comorbidities including diabetes, metabolic syndrome, psychiatric disorders, and inflammatory arthritis.[6,7] Pain and bipolar disorders, psychoses, schizophrenia, and suicide occur at higher rates in subjects with HS than in those without HS.[8,9] Several studies have reported associations with smoking and obesity in HS patients.[10]

Current guidelines recommend treatment with topical and/or systemic antibiotics, hormonal interventions, analgesics and, in selected cases, the tumor necrosis factor (TNF) inhibitor monoclonal antibody adalimumab (Food and Drug Administration-approved for pediatric patients ≥12 years of age), and surgical excision.[11-13] More recently, biological therapies have been used to treat HS subjects with moderate to severe disease.[14] HS patients receiving biologic therapies have reported reductions in the count of abscess and nodules, reductions in pain score, and reductions of the impact of HS on daily life.[15] There have been very few adequately powered studies conducted to study the efficacy of biologics in HS subjects[16] and studies using real world data have been limited in studying[17] this recently approved drug class for HS treatment.

Although several HS clinical guidelines are published,[11,15,18,19] few have specific language regarding treatment of pediatric subjects.[11,15,19] The North American clinical management guidelines for treatment recommendation state that the management strategies are similar for pediatric and adult HS populations with the exception of the following: One should avoid the use of tetracyclines in children younger than 9 years and the use of acitretin in female patients during childbearing years.[19]

Studies using observational data to describe pharmacologic treatments and procedures in pediatric HS and similarity of treatments between pediatric and adult HS patients have not been reported. This study leverages data from 3 large real-world US databases to evaluate the clinical characteristics and treatment patterns of pediatric (<18) and adult (≥18 years) HS populations. This work fills a knowledge gap for a population (pediatric) and subject area that is understudied.

CAPSULE SUMMARY

- Treatment patterns are similar in children and adults with HS.
- Among commercially and federally insured hidradenitis suppurativa (HS) patients, access to biologic treatments is low, and use in children appears more limited than adults. Increasing HS patients' access to dermatologists would increase access to biologic therapies and potentially improve outcomes of these patients.

MATERIALS AND METHODS

This study describes and characterizes HS patients. We used the Observational Health and Data Sciences and Informatics (OHDSI) ATLAS tool (https://github.com/OHDSI/Atlas) to generate cohorts and conduct the characterization and treatment pathway analyses for this study. (ATLAS is a web based open-source application that provides a unified interface to patient level data and analytics).

Data

We used 3 US observational datasets. Each dataset has unique attributes. The IBM MarketScan Commercial Claims and Encounters Database (CCAE) which contains insurance claims for commercially employed individuals and their dependents and contains subjects less than or equal to the age of 65. The Optum De-Identified Clinformatics Data Mart Database — Socio-Economic Status — (Clinformatics) is a similar database to CCAE except that it includes claims from subjects with Medicare supplemental insurance and thus does not have an upper age threshold. The IBM MarketScan Multi-State Medicaid Database (MDCD) contains claims from subjects covered by Medicaid and is primarily composed of women and children.[20] All databases were

Abbreviations used:

CCAE:	IBM MarketScan Commercial Claims and Encounters Database
Clinformatics:	Optum De-Identified Clinformatics Data Mart Database — Socio-Economic Status
FDA:	Food and drug administration
HS:	hidradenitis suppurativa
IRB:	Institutional Review Board
MDCD:	IBM MarketScan Multi-State Medicaid Database
OHDSI:	Observational Health and Data Sciences and Informatics
TNF:	tumor necrosis factor

standardized to the Observational Medical Outcomes Partnership Common Data Model[21] version 5.3.

Study population

We extracted data for HS patients during the study period January 1, 2016 to December 31, 2021. This study utilized a specific incident HS phenotype algorithm.[22] The algorithm identified newly diagnosed HS subjects and required 2 diagnostic codes for HS (SNOMED codes 59393003 or 69741000). The index date is anchored on the first code for HS and the second code is identified in the 31 to 365 days after the first code. This phenotype algorithm was shown to have high validity (positive predictive value ranging from 83%-95%) and was selected after use of a data driven process to develop and evaluate HS phenotype algorithms.

All subjects were required to have at least 365 days of continuous observation time prior to the first HS qualifying diagnosis (where they then had a second HS diagnosis within 31-365 days after the first diagnosis). Pediatric subjects were defined as subjects with HS and age <18 years at the time of diagnosis, while adults were defined with age ≥18 years at the time of diagnosis.

Analyses

Incidence rate estimates were calculated as patients per 100,000 person-years and stratified by age, sex, and database, and they excluded patients with HS at any time prior to the index date. The analyses were performed using web-based, interactive, OHDSI developed Cohort Diagnostics application - Version 2.2.4 (https://ohdsi.github.io/CohortDiagnostics/) which provides descriptive summaries across various databases. Characterization of the HS cohorts provided demographic and comorbidity information in the 180 days after and 30 days prior to the index HS diagnosis. Measures of absolute standard differences were plotted for each drug prescriptions in the pediatric and adult HS cohorts. Absolute standard differences >0.1 deviating from the 45-degree line indicate differences between the 2 populations. Treatment pathways were generated to illustrate the use of therapies at each line of treatment using the following exposure categories: topical treatments (clindamycin and resorcinol), oral antibiotics (tetracycline, doxycycline, lymecycline, minocycline, amoxicillin, pristinamycin, ceftriaxone, and metronidazole), biologics (adalimumab, infliximab, anakinra, and ustekinumab), and surgical treatments (laser procedures, incision and drainage of abscess, excision of skin and subcutaneous tissue), and acne surgery (eg, marsupialization, opening or removal of multiple milia, comedones, cysts, pustules). Exposures dispensed within 14 days of each other were considered a combination therapy. Pharmacologic treatments were defined at the ingredient level and combination treatments containing those ingredients are included in the pathways analysis.

RESULTS

Incidence of HS was greater in females than in males; it was highest in the 20 to 29-year-old age group in Clinformatics and CCAE and highest in the 30 to 39-year-old age group in MDCD (Results can be viewed interactively at https://data.ohdsi.org/HSPathwaysCohortDiagnostics/). Prevalence per 100,000 population of HS among pediatric (<17 years) and adult (≥18 years) populations by database, year, and sex (Table I) illustrates that overall, the rates are 2 to 4 times higher in adults than in pediatric populations. Among the pediatric females the rates were approximately 5 to 8 times higher than in pediatric males. The rates in pediatric females range from 9.34 (MDCD) in 2021 to 22.84 (MDCD) in 2019 while the rates in pediatric males range from 1.73 (Clinformatics) in 2018 to 4.88 (MDCD) in 2019. The rates in adult females were 2 to 3 times higher than in adult males and ranged from 22.16 (Clinformatics) in 2017 to 64.44 (MDCD) in 2020. The rates in adult males ranged from 7.79 (Clinformatics) in 2016 to 23.43 (MDCD) in 2019.

Characteristics of both pediatric and adult HS subjects were examined. A total of 1894, 2674, and 700 pediatric and 16,121, 11,383, and 9514 adult HS patients were identified (Table II). The proportion of female subjects ranged from 83% to 85% in the pediatric and 74% to 82% in the adult HS cohort. The mean ages ranged from 14.7 to 15.1 (pediatric) and 35.8 to 43.0 (adult) years, across databases. The largest proportion of pediatric HS subjects were in the age category 12 to 17 years (range: 92%-95%). Two databases include race and ethnicity data (MDCD and Clinformatics). Among the pediatric

Table I. Prevalence per 100,000 population of HS among pediatric (<18 years) and adult (≥18 years) populations by database, year, and sex

		Pediatric			Adult		
Database	**Year**	**Males**	**Females**	**Overall**	**Males**	**Females**	**Overall**
CCAE	2016	2.01	16.15	8.92	10.05	28.84	19.95
	2017	3.47	18.72	10.93	9.62	31.35	21.02
	2018	3.46	16.42	9.80	11.36	37.25	24.85
	2019	3.74	16.73	10.10	11.63	39.60	26.15
	2020	4.08	18.67	11.21	12.68	41.49	27.59
	2021	2.69	15.71	9.06	9.76	33.93	22.29
MDCD	2016	4.21	22.49	13.06	24.76	63.71	49.69
	2017	3.21	20.24	11.46	21.25	52.23	41.20
	2018	4.22	22.01	12.82	22.96	56.89	44.69
	2019	4.88	22.84	13.56	23.43	61.17	47.69
	2020	4.18	20.83	12.24	20.81	64.44	48.30
	2021	2.84	9.34	5.99	13.15	36.79	27.91
Clinformatics	2016	1.81	11.50	6.55	7.79	19.93	14.10
	2017	2.28	14.59	8.30	9.41	22.16	16.05
	2018	1.73	16.19	8.80	9.04	24.33	17.03
	2019	2.74	14.22	8.35	10.13	23.98	17.40
	2020	2.25	15.92	8.93	9.25	25.58	17.85
	2021	3.62	13.22	8.31	8.27	22.85	15.96

HS population, the White race category was less common in MDCD (30.1) than Clinformatics (53.7%), Black was more common in MDCD (51.1%) than Clinformatics (17.3), and Asian was the least common (4.1% - only available in Clinformatics). The Hispanic ethnicity category was sparsely population (13%) Clinformatics; 8.8% MDCD. Among the adult HS population, the White race category was less common in MDCD (43.1%) than Clinformatics (59.9%), Black was again more common in MDCD (42.3%) than Clinformatics (19.3%), and Asian was least common (3.4%- only available in Clinformatics). In MDCD the adult HS population was more evenly split between the White and Black race categories than in the pediatric population. Ethnicity data were limited, and Hispanics represented 11.9% of the adult population (Clinformatics) and only 4.1% in MDCD. The median time prior to index varied from 1195 days (Clinformatics) to 1831 days (MDCD) in the pediatric and from 954 days (Clinformatics) to 1215 days (CCAE) in the adult HS cohort. The median time after index varied from 576 days (Clinformatics) to 764 days (MDCD) for the pediatric cohort and from 537 days to 764 days (MDCD) for adult cohort.

Folliculitis was diagnosed in the 180 days prior to and 30 days after the diagnosis of HS in 6% to 7% of adult HS subjects and in 6.6% to 8% of pediatric HS subjects. Acne was diagnosed more in the pediatric (range: 18%-27%) HS subjects than in the adult (range: 8.6%-15%) HS subjects, while pilonidal cyst diagnosis was similar in the pediatric (range: 1.3%-2%) and adult (range: 1.5%-1.7%) groups. Type 2 diabetes, depression, and anxiety was more prevalent in adults (range: 11.2%-20.9%) than in the pediatric (range: 1.1%-3.8%) patients. Obesity was more common in the adult HS cohort (range: 35.7%-5.1%) than in pediatric HS cohort (range: 16.3-17.7).

A comparison of standardized differences between the pediatric and adult HS drug prescriptions for 3 datasets at 0 to 365 days after the index diagnosis date are shown in Fig 1. Differences in the standardized difference of the mean greater than 0.1 are considered imbalanced.[23] Points closest to the diagonal indicate similar proportions between cohorts; points farther from the diagonal indicate more disparate proportions. The plots compare the prescribed drugs in the HS adult and pediatric subjects and illustrate that overall treatments are similar with a few notable differences. Clindamycin and clindamycin combination therapies are more often prescribed to the pediatric than adult population; conversely, acetaminophen is more often prescribed for adults compared to children.

Pediatric and adult HS treatments were similar with the proportions of subjects treated with topical and oral antibiotic or oral antibiotic alone or topical alone or surgery alone covering 92% to 95% of the pediatric subjects and 90% to 93% of adult subjects (Fig 2 and Table III). The remaining proportion of

Table II. Selected characteristics of adult and pediatric HS subjects

	Adult			Pediatric		
	CCAE (*n = 16121)	MDCD (*n = 11383)	Clinformatics (*n = 9514)	CCAE (*n = 1894)	MDCD (*n = 2674)	Clinformatics (*n = 700)
% Female	78.0	82.4	73.9	83.5	82.8	85.3
Mean age ± SD (years)	36.5 ± 12.4	35.8 ± 12.7	43.0 ± 16.4	15.1 ± 1.9	14.7 ± 2.1	15.0 ± 1.9
Age groups (%)						
0-3	—	—	—	<1	<1	—
4-6	—	—	—	—	<1	<1
7-11	—	—	—	5.5	8.4	6.0
12-17	—	—	—	94.5	91.4	93.9
18-64	99.8	97.7	86.7	—	—	—
>65	<1	2.3	13.3	—	—	—
†Race (%)						
White	—	43.1	59.9	—	30.1	53.7
Black or African American	—	42.3	19.3	—	51.1	17.3
Asian	—		3.4	—		4.1
†Ethnicity (%)						
Non hispanic	—		82.7	—		75.2
Hispanic	—	4.1	11.9	—	8.8	13.3
Median time prior to index date (days)	1167	1215	954	1583	1831	622
Median time after index date (days)	567	694	537	661	764	576
‡Select clinical characteristics (%)						
§Obesity	35.7	45.1	39.5	16.3	30.6	17.7
Type 1 diabetes mellitus	1.0	2.4	2.0	<1	1.2	<1
Type 2 diabetes mellitus	11.2	19.9	20.9	1.1	3.8	1.3
Depression	12.8	25.3	16.7	9.8	11.1	9.9
Anxiety	17.3	29.3	20.4	12.0	12.2	12.7
Cellulitis	8.9	13.4	10.8	6.9	10.5	7.6
Pilonidal cyst	1.5	1.7	1.5	2.0	1.6	1.3
Acne	14.6	8.6	12.3	27.1	17.7	27.3
Folliculitis	6.1	6.4	6.9	7.5	6.8	6.6
Furuncle	5.7	5.9	6.2	6.7	6.4	6.1
Crohn's disease	1.5	1.5	1.7	<1	<1	<1
Ulcerative colitis	<1	<1	<1	<1	<1	<1
Arthropathies						
Rheumatoid arthritis	1.5	1.7	2.6	<1	<1	<1
Psoriatic arthritis	<1	<1	<1	<1	<1	<1
Ankylosing spondylitis	<1	<1	<1	<1	<1	<1

*Indicates the total number of subjects with HS identified using the phenotype algorithm requiring two HS diagnostic codes.
†Race and ethnicity data is unavailable for CCAE; race and ethnicity data in MDCD and Clinformatics has misclassification bias.
‡Assessed in the 180 days prior and 30 days post index.
§Assessed in the 365 days prior to index.

subjects were treated with other treatment combinations. The most utilized first line treatments in the pediatric HS cohort is a topical treatment and oral antibiotic combination (range 36.6%-38.6% of treated cohort) and was utilized in 24.9% to 30.3% of the adult HS treated cohort (Table III). Topical treatments alone and surgical treatments are used less frequently in pediatric (topical treatment range: 11.1%-11.4%; surgical treatments range: 6.2%-7.6%) compared to adult (topical treatment range: 13.3%-14.6%; surgical treatments range: 9.3%-15.1%) HS subjects. The most prescribed first line treatment in adults was an oral antibiotic alone (range: 33.4%-36.4% treated cohort) and was used in 28.3% to 30.8% of the treated pediatric cohort. Children were found to use an oral antibiotic in combination with a topical at a slightly higher rate than adults (CCAE: 38.6% (pediatric) vs 30.3% (adult); MDCD: 36.6% vs 24.9%; Clinformatics: 38.6% vs 26.4%). This is not surprising given that

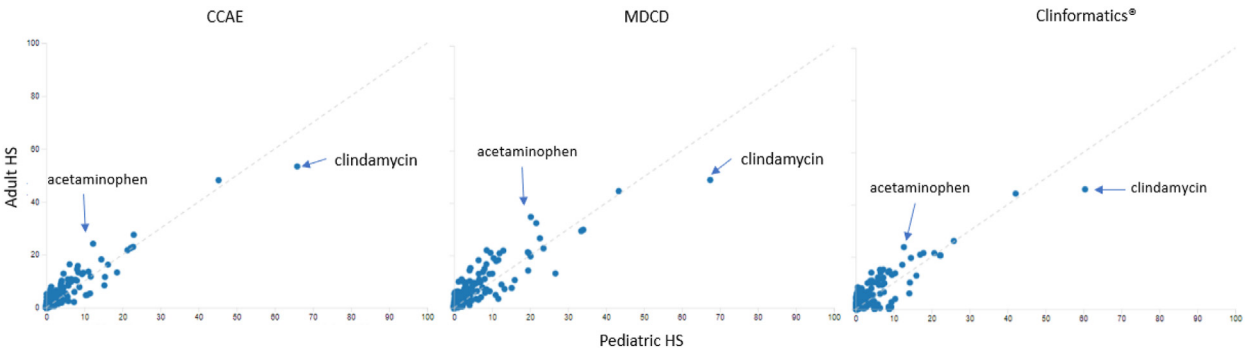

Fig 1. Comparison between the adult and pediatric HS subjects of drug prescriptions in the 365 days after first diagnosis for 3 selected datasets. Points closest to the diagonal indicate similar proportions between the comparators; points farther from the diagonal indicate more disparate proportions.

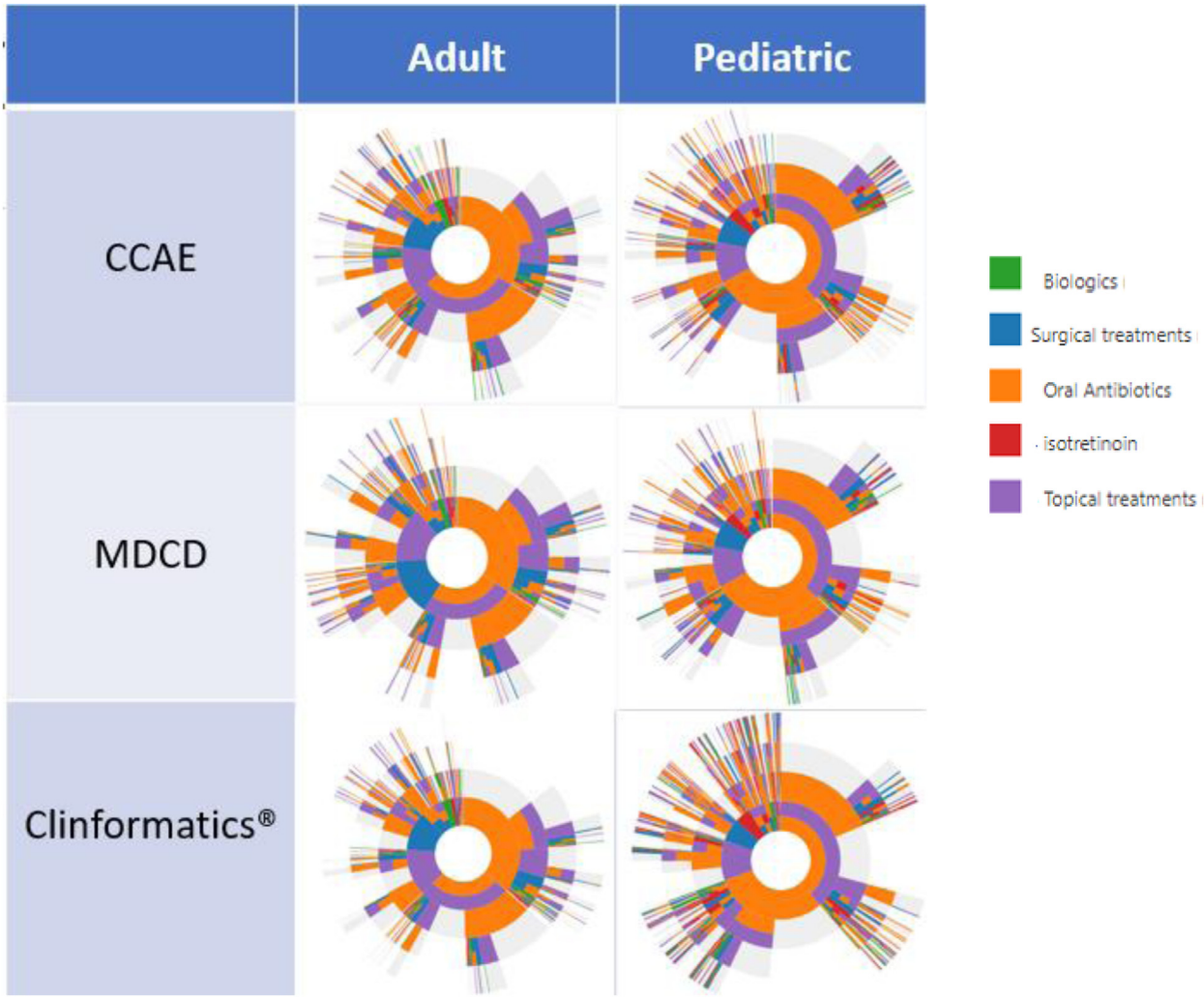

Fig 2. Treatment pathways for adult and pediatric HS subjects (treatments are post HS diagnosis; *innermost circle* indicates *first line* treatments; *next circle* indicates *second line* treatments, etc.)

Table III. Percentage of first line treatments for adults and pediatric HS subjects by database

Database	Treatment	Adult	Pediatric
CCAE	Topical treatments (Clindamycin, Resorcinol)	13.4	11.2
	Oral Antibiotics	33.4	28.3
	Biologics (infliximab, adalimumab, anakinra, ustekinumab)	2.4	1.1
	Surgical treatments (Laser treatment on skin, excisions, unroofing)	9.3	7.3
	Isotretinoin	1.4	3.3
	Oral Antibiotics and topical treatments (Clindamycin, Resorcinol)	30.3	38.6
MDCD	Topical treatments (Clindamycin, Resorcinol)	14.6	11.4
	Oral Antibiotics	34.2	30
	Biologics (infliximab, adalimumab, anakinra, ustekinumab)	1.6	1.3
	Surgical treatments (Laser treatment on skin, excisions, unroofing)	15.1	7.6
	Isotretinoin	0.8	2.9
	Oral Antibiotics and topical treatments (Clindamycin, Resorcinol)	24.9	36.6
Clinformatics	Topical treatments (Clindamycin, Resorcinol)	13.3	11.1
	Oral Antibiotics	36.4	30.8
	Biologics (infliximab, adalimumab, anakinra, ustekinumab)	2.5	1.1
	Surgical treatments (Laser treatment on skin, excisions, unroofing)	11.1	6.2
	Isotretinoin	1.1	4.2
	Oral Antibiotics and topical treatments (Clindamycin, Resorcinol)	26.4	38.6

topical clindamycin combination products are used more frequently in pediatric patients compared to adults and is a common treatment of acne (which is more common in adolescents). Additionally, while the use of surgical procedures (pediatric range: 6.2%-7.6%; adult range: 9.3%-15.1%); and biologics (pediatric range: 1.1%-1.3%; adult range: 1.6%-2.5%) is infrequent in both children and adults, its use in children appears more limited. If subjects don't have a treatment that is included in this analysis, such as an over-the-counter nonprescribed medication, or if they leave the observation period or database, they will not be included in the pathway analysis.

DISCUSSION

Limited research exists examining real-world pharmacologic treatment patterns and therapeutic procedures for adult and pediatric HS patients. Prior research examining the treatment of patients has been limited to cross sectional studies[24] while others lacked information regarding the type of treatments that were received by patients.[25] A recent publication[17] reported similar findings to this study using 2 of the 3 claims' databases.

Our study leveraged 3 large real-world databases to understand pediatric and adult HS patients' disease characteristics and treatment patterns. The current study utilized prescription and medical claims data from 2 commercially insured patient populations representing a broad cross-section of the US population, including a portion of those receiving Medicaid a government sponsored health plan. Among the pediatric cohort <18 years, HS disease was primarily identified in patients ≥12 years of age. Our results show the drugs prescribed at index to 365 days after the index HS diagnosis are similar in children and adults. The treatment pathway results illustrate slight variation between pediatric and adult HS patients when examining groupings of drugs and procedures. The first line treatments or innermost circle of the pathway show 65% of the adults and 53% of pediatric cohort received a monotherapy, while the remaining proportion of subjects received a combination therapy. Among the treatments examined in this study the use of biologics was infrequent in both pediatric and adult HS patients. Among the HS patients using biologics, use was highest in the 2 commercial claims databases (CCAE and Clinformatics) and lower in MDCD. Reporting the frequency of use of biologics in the real-world is an important addition to the knowledge space. Overall, our data demonstrate that the treatment patterns for HS are similar between adult and pediatric patients which, agrees with recent guidelines.[19]

An algorithm that identifies patients with two HS diagnosis codes was used and the algorithm is shown to have high validity in the databases utilized in this study (positive predictive value ranging from 83%-95%).[22] Comorbid conditions were identified via the requirement of a single diagnosis code, which maximized the sensitivity for capturing these conditions. This study fills a knowledge gap by providing details on the real-world pharmacotherapy treatment practices and comparing adults and children.

Similar to other retrospective epidemiologic database studies, there are limitations. These limitations include: (1) over the counter drug exposures are not captured in the databases, and (2) claims coding can be distorted by the requirement to code medical care for reimbursement. Indications for drug exposures are not known definitively, and data are captured only when a patient seeks care and there is a medical code associated with the reason the patient sought medical care. Individuals who lack or have insufficient medical insurance could be underrepresented in the data; therefore, the total patient population will be larger. These numbers describe the populations captured by these respective databases, and care should be taken when generalizing findings to the broader US population. Lastly this study is unable to assess HS disease severity as there is no specific diagnostic code for diagnosing moderate to severe disease in the databases utilized, therefore this is a limitation.

A strength of this study was inclusion of biologic treatments in addition to other pharmacotherapies. Biologics have recently been introduced for treatment of HS[14] but have not been widely reported in claims-based research of treatment patterns. In this study and another recent claims data based study[17] the prevalence of use of biologics is very low. The low use of biologics may be attributable to patient factors including limited access to specialists with expertise in HS and the use of biologics, hesitancy regarding injections or side effects, lack of trust in medical providers, delayed diagnosis, and previous experience with ineffective treatments. Patients may need to pay high out-of-pocket costs to cover their treatments or rely on patient assistance programs as providers may not reimburse the cost of the biologics. The novelty of this study is that it increases the knowledge base regarding how often these options are utilized in the real-world and increases the understanding of how HS is contemporaneously treated. Future research of HS treatment patterns as, additional biologic use data as well as other newly approved treatments become available, may describe the impact of these therapies on treatment decisions, and potentially outcomes.

Our study examines multiple US claims data sources with substantial populations of pediatric HS patients. Our study is retrospective and utilizes claims data that are not subject to volunteer bias. We analyzed multiple databases that capture different (though potentially overlapping) populations (CCAE and Clinformatics: commercial, employer-supplemented insurance coverage; MDCD: government-sponsored insurance coverage). These analyses support that HS treatment patterns are similar between adolescents and adults and this work fills a current knowledge gap for a population and subject matter that is understudied.

Input on study design provided by Emily Brouwer PhD. Review and approval of the work provided by Anna Sheahan PhD.

Conflict of interest

Drs Hardin, Makadia, Black, and DeKlotz are employees of Janssen Research & Development, LLC, and may own stock and/or stock options. The work on this study was part of their employment. Drs Lara-Corrales, Diaz, and Kirby report no conflicts of interest.

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