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Efficacy and Durability of Intravenous Ertapenem Therapy for Recalcitrant Hidradenitis Suppurativa

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IMPORTANCE Hidradenitis suppurativa (HS) is a debilitating follicular skin disorder in which bacterial colonization is typical. Oral antibiotic efficacy can be unreliable; however, selective intravenous antibiotics, specifically ertapenem, may provide favorable clinical outcomes.

OBJECTIVE To explore optimal course duration, efficacy, and patient satisfaction associated with intravenous ertapenem for HS.

DESIGN, SETTING, AND PARTICIPANTS This retrospective review of the medical records of 98 patients with HS between 2018 and 2022 measured and evaluated patient outcomes before and after treatment with intravenous ertapenem. Participants were followed up in a telephone survey assessing patient perspectives and satisfaction. All of those included in this study received medical care from the Albert Einstein College of Medicine's Montefiore HS Center.

EXPOSURES Patients were treated with 1 g of ertapenem that was self-administered at home through a peripheral intravenous central catheter using an elastomeric pump for 12 to 16 weeks. Antiandrogens and immunomodulatory biologic therapies initiated prior to ertapenem were maintained throughout the treatment course.

MAIN OUTCOMES AND MEASURES The primary outcomes, encompassing clinical severity (evaluated through the HS Physician Global Assessment score [a 6-point scale ranging from clear to very severe] and a numerical rating scale for pain [an 11-point scale in which a score of 0 indicates no pain and a score of 10 indicates the worst possible pain]) and markers of inflammation (such as leukocytes, erythrocyte sedimentation rate, C-reactive protein, and interleukin-6), were measured at baseline, the midcourse of intravenous ertapenem treatment, at the end of the course, and posttherapy. Bacterial abundance was also examined at these 4 points, and patient satisfaction was assessed during follow-up.

RESULTS A total of 98 patients (mean [SD] age, 35.8 [13.0] years; 61 [62.2%] female) with HS were treated with intravenous ertapenem. The self-reported racial distribution included 3 individuals identifying as Asian (3.1%), 59 as Black/African American (60.2%), 13 as White (13.3%), and 23 as either other or unknown (23.5%). Additionally, 24 participants (24.5%) reported Spanish/Hispanic/Latino ethnicity. The mean (SD) treatment duration spanned 13.1 (4.0) weeks, with posttherapy follow-up occurring after 7.8 (3.6) weeks. From baseline to posttherapy follow-up, significant reductions were found in the mean (SD) HS Physician Global Assessment scores (3.9 [1.0] vs 2.7 [1.2]; $P < .001$) and the numerical rating scale for pain (4.2 [3.3] vs 1.8 [2.7]; $P < .001$), C-reactive protein (5.4 [11.4] vs 2.4 [2.0] mg/dL; $P < .001$), interleukin-6 (25.2 [21.1] vs 13.7 [13.9]; $P < .001$), and leukocytes (11.34 [3.9] vs 10.0 [3.4]; $P < .001$). At follow-up, 76 patients (78.0%) participated in the telephone survey, where 63 (80.3%) reported medium to high satisfaction; further, 69 (90.8%) would recommend ertapenem to other patients.

CONCLUSIONS AND RELEVANCE In this retrospective review of medical records and telephone survey, treating HS with intravenous ertapenem, administered for a mean of 13 weeks, was associated with improvement in clinical and inflammatory markers, as well as heightened patient satisfaction. Nonetheless, this approach should be monitored for the emergence of antimicrobial resistance given a longer than standard treatment course.

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Multimedia
Supplemental content

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Hidradenitis suppurativa (HS) is a chronic disorder of follicular biology, primarily affecting the axillary, inframammary, suprapubic, inguinal, genital, upper inner thigh, perineum, and buttock skin. HS manifests as painful pustules, nodules, abscesses, tunnels, and scarring. The decrease in quality of life is pernicious.[1] In addition to malodor, pain, and medical complications, HS is associated with depressive symptoms, including feelings of hopelessness and low self-esteem.[2]

Advanced HS remains extremely challenging to treat. The current multitiered treatment algorithm combines topical, oral, and intravenous (IV) antibiotics, antiandrogen therapy, and immunomodulators that target mediators of inflammation.[3,4] Surgical deroofing and excision of selected sites may also have great value in recalcitrant cases. No single treatment has proved effective for all patients.[5]

Although oral antibiotics are generally accepted as a core therapeutic approach to HS, much less is known about the efficacy of IV antibiotics, especially ertapenem, a parenteral carbapenem possessing activity against many gram-positive bacteria, gram-negative bacteria, and anaerobic organisms.[6] Since 2015, multiple studies and case reports have demonstrated the efficacy of ertapenem for recalcitrant HS.[7-9] We previously described the efficacy of daily IV ertapenem for 6 weeks in 7 patients with HS experiencing notable remediation of disease that was rapidly lost within 1 month of withdrawal.[10,11] Given these findings, we sought to explore the outcomes of a longer duration of treatment with ertapenem as an adjunct therapy in treating HS.

Key Points

Question What are the optimal course duration, efficacy, and patient satisfaction rates of intravenous ertapenem for hidradenitis suppurativa (HS)?

Findings In this retrospective medical record review of 98 patients with HS, who received intravenous ertapenem treatment over a mean (SD) of 13.1 (4.0) weeks, the HS Physician Global Assessment score, numerical rating scale for pain, C-reactive protein, interleukin-6, and leukocytes significantly decreased.

Meaning Administering intravenous ertapenem for an average of 13 weeks was associated with improvements in clinical and inflammatory markers as well as heightened patient satisfaction; however, this approach to HS therapy should be monitored for the emergence of antimicrobial resistance due to the longer than standard treatment course.

Methods

The Albert Einstein College of Medicine institutional review board approved this retrospective medical record review of 98 patients receiving care at the Montefiore HS Center. All participants provided verbal informed consent to participate prior to the follow-up telephone interviews.

Participants

A proprietary web-based platform (Atlas), developed by the Einstein Center for Health Data Innovations, was used to identify eligible patients and access clinical and health data. All patients with a diagnosis of HS (*International Statistical Classification of Diseases and Related Health Problems, Tenth Revision [ICD-10]* code: L73.2) undergoing intravenous ertapenem therapy at the Montefiore HS Center between January 1, 2018, and July 1, 2022, were eligible. The inclusion criteria for ertapenem therapy included patients with advanced HS (HS Physician Global Assessment [HS-PGA], a 6-point scale ranging from clear to very severe, score of 3 to 5),[12] responding suboptimally to topical and oral antibiotics, antiandrogen(s), and anti-inflammatory therapies. The latter included adalimumab and infliximab, both tumor necrosis factor α inhibitors. Ertapenem was initiated only in the case of intractable HS despite ongoing management with all treatment modalities. Patients who did not have follow-up visits after discontinuing ertapenem were excluded.

Treatment

Treatment with ertapenem (Invanz; Merck, Sharpe and Dohme LLC), 1 g daily, was self-administered at home through a peripheral intravenous central catheter (PICC) using a 100-mL elastomeric pump (Avanos Medical, Inc) for 12 to 16 weeks. Except for oral antibiotics, the majority of treatments that patients were receiving at the baseline visit were continued throughout the course.

Data Collection

Data extracted from the electronic medical record included age, sex, self-identified race (Asian, Black/African American, White, or other/unavailable), self-identified ethnicity (Spanish/Hispanic/Latino or not Spanish/Hispanic/Latino), body mass index, smoking status, and concomitant treatments (topical antibiotics, oral antibiotics, spironolactone, finasteride, oral contraceptives, infliximab, and adalimumab). Additionally, data were extracted regarding disease severity, including HS-PGA (eAppendix 1 in Supplement 1)[12] and numerical rating scale for pain (NRS-Pain) scores, in which a score of 0 indicates no pain and a score of 10 indicates the worst possible pain. Further variables collected from medical records encompassed inflammatory markers (including leukocytes, erythrocyte sedimentation rate, C-reactive protein [CRP], and interleukin-6 [IL-6]), as well as aerobic and anaerobic microbial culture results. Clinical and inflammatory markers were collected at each of 4 visits (visit 1: baseline measurements before ertapenem treatment; visit 2: midcourse corresponding with the sixth scheduled week of ertapenem; visit 3: end-of-course recorded most closely to the last day of treatment; visit 4: posttherapy follow-up recorded 6 to 8 weeks following the end-of-course visit). All participants were invited to complete a telephone interview consisting of 12 standardized questions to assess their perspectives about the therapy (eAppendix 2 in Supplement 1).

Statistical Methods

Descriptive statistics for demographics, clinical variables of interest, and concomitant medications were generated for

all 98 patients. Various markers of HS severity were compared using 2-tailed paired *t* tests and independent samples *t* tests where appropriate. Statistical significance was defined as $P < .05$ in any comparison. All statistical analyses were conducted using SPSS software, version 29.0 for Mac (IBM). Figures were generated using Prism software, version 9.5.1 for Mac (GraphPad Software Inc).

Results

Patient Characteristics

Of 98 study participants, the mean (SD) age at baseline was 35.8 (13.0) years, and 61 (62.2%) were female. The self-reported racial distribution included 3 individuals who identified as Asian (3.1%), 59 as Black/African American (60.2%), 13 as White (13.3%), and 23 as either other or unknown (23.5%). Other or unknown indicates that race and ethnicity data were not available. Additionally, 24 participants (24.5%) reported Spanish/Hispanic/Latino ethnicity. Additional patient characteristics, such as body mass index, smoking status, and concomitant therapies, are present in **Table 1**.

Treatment Course

Patients were treated for a mean (SD) of 92.0 (27.9) days (13.1 [4.0] weeks), with posttherapy follow-up taking place after a mean (SD) of 54.4 (25.2) days (7.8 [3.6] weeks) (**Table 2**; eAppendix 3 in Supplement 1). Significant decreases from baseline to posttherapy follow-up were found in mean (SD) values for HS-PGA score (3.9 [1.0] vs 2.7 [1.2]; $P < .001$); NRS-Pain (4.2 [3.3] vs 1.8 [2.7]; $P < .001$), CRP (5.4 [11.4] vs 2.4 [2.0] mg/dL; $P < .001$), IL-6 (25.2 [21.1] vs 13.7 [13.9]; $P < .001$), and leukocytes (11.3 [3.9] vs 10.0 [3.4]; $P < .001$) (Table 2).

Concomitant Medications

The Montefiore HS Center treatment algorithm consists of 3 core therapies: antibiotics (topical and/or oral), antiandrogen therapies (spironolactone, finasteride, and/or oral contraceptive pills), and biologics (adalimumab and infliximab). Overall, 78 participants (80%) in this cohort were receiving 1 or more medications from all core treatment groups at baseline, and 74 (76%) continued this combination (excluding oral antibiotics) during the ertapenem treatment course. A minority of patients did not receive all core therapies because of insurance denial or adverse effects, including intolerance or allergic hypersensitivity.

At the baseline visit, the range of treatments included topical antibiotics (n = 97); oral antibiotics (n = 75); spironolactone (n = 44); finasteride (n = 41); oral contraceptive pills (n = 25); adalimumab (n = 9); and infliximab (n = 78). These therapies were maintained during the course of ertapenem as follows: topical antibiotics (n = 95; 98%); spironolactone (n = 39; 89%); finasteride (n = 22; 90%); oral contraceptive pills (n = 22; 88%); adalimumab (n = 8; 89%); and infliximab (n = 75; 96%).

Of the 78 patients on intravenous infliximab at baseline, the mean (SD) pretreatment duration was 25.3 (15.6) months (eAppendix 4 in Supplement 1). Infliximab dosage varied from 5.0 mg/kg to 12.5 mg/kg, with a mean (SD) dosage of 9.5 (1.6) mg/kg. Infliximab may not have been at maximal dosage prior to the initiation of ertapenem due to intolerance, insurance denial, or an urgent level of disease severity that necessitated more immediate intervention. Of the 9 patients taking 40 mg/wk of adalimumab at baseline, the mean (SD) pretreatment duration spanned 10.3 (11.8) months.

Table 1. Patient Demographics and Concomitant Medications

Characteristic	No. (%)
Total participants, No.	98
Age, mean (SD), y	35.8 (13.0)
Sex	
Male	37 (37.8)
Female	61 (62.2)
Self-reported race	
Asian	3 (3.1)
Black/African American	59 (60.2)
White	13 (13.3)
Other or unknown[a]	23 (23.5)
Self-reported ethnicity	
Spanish/Hispanic/Latino	24 (24.5)
BMI, mean (SD)	33.2 (8.9)
Smoking status	
Never smoker	66 (67.3)
Previous smoker	18 (18.4)
Current smoker	14 (14.3)
Concomitant therapies	
Topical antibiotics	97 (99.0)
Spironolactone	44 (44.9)
Finasteride	31 (31.6)
Oral contraceptive pill	25 (25.5)
Infliximab	78 (79.6)
Adalimumab	9 (9.2)
Ertapenem treatment duration, mean (SD), wk	13.1 (4.0)

Abbreviation: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared.

[a] Other or unknown indicates that the data were unavailable.

Disease Severity

HS-PGA and NRS-Pain scores were recorded during visits at baseline, midcourse, end-of-course, and posttherapy follow-up (Table 2). Both disease severity variables improved significantly at midcourse, end-of-course, and follow-up visits when compared with baseline (**Figure 1**A and B).

Inflammatory Markers

Laboratory markers of inflammation were recorded at baseline, midcourse, end-of-course, and posttherapy follow-up (Table 2). Leukocytes, CRP, and IL-6 were significantly reduced during the ertapenem course and the follow-up at a mean (SD) of 54.4 (25.2) days after therapy compared with baseline (Figure 1C, D, E, and F). Although erythrocyte sedimentation rate was significantly decreased at midcourse, the

Table 2. Clinical Markers of Severity and Inflammation Stratified by Visit

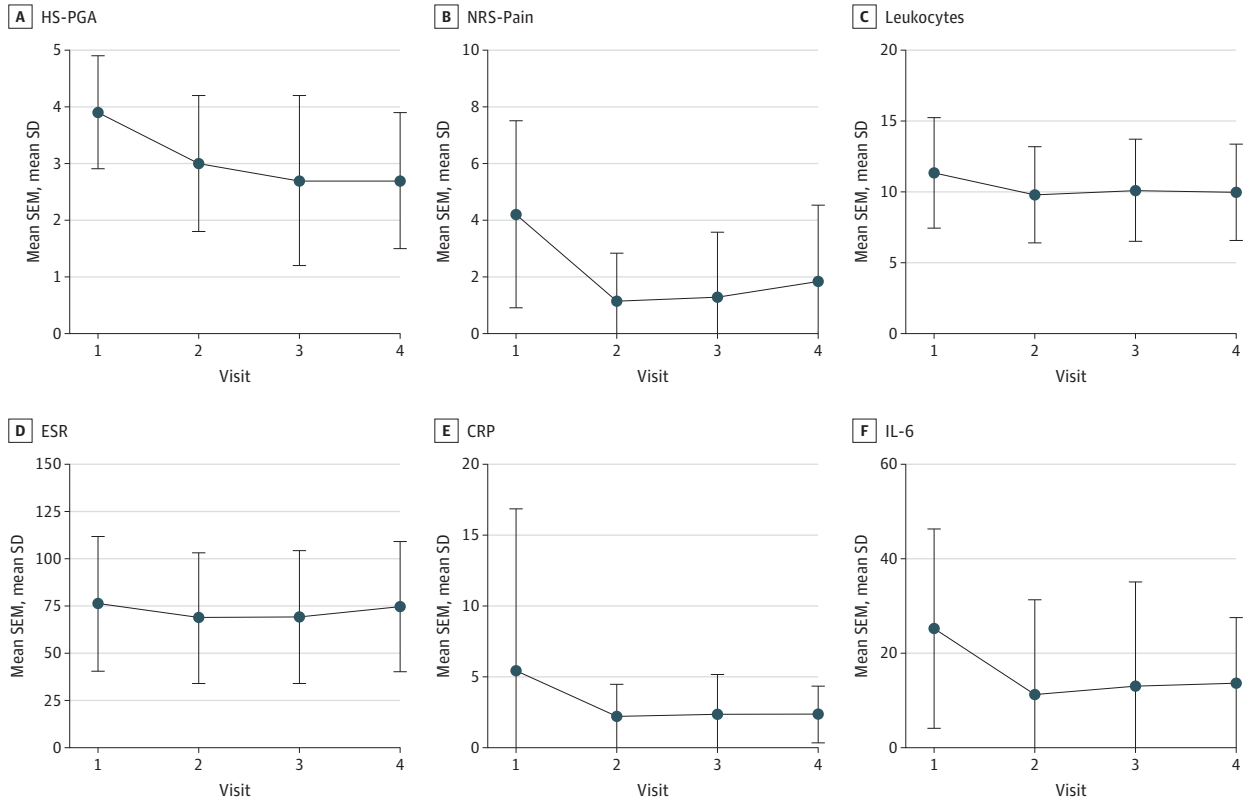
Variable	Mean (SD)			
	Baseline	Midcourse (48.6 [23.8] d)	End of course (92.0 [27.9] d)	Posttherapy (54.4 [25.2] d after therapy)
HS-PGA	3.9 (1.0)	3.0 (1.2)[a]	2.7 (1.5)[a]	2.7 (1.2)[a]
NRS-Pain	4.2 (3.3)	1.1 (1.7)[a]	1.3 (2.3)[a]	1.8 (2.7)[a]
Leukocytes	11.3 (3.9)	9.8 (3.4)[a]	10.1 (3.6)[a]	10.0 (3.4)[a]
ESR	76.3 (35.7)	68.7 (34.6)[b]	69.2 (35.1)	74.7 (34.5)
CRP	5.5 (11.4)	2.2 (2.3)[a]	2.4 (2.8)[a]	2.4 (2.0)[a]
IL-6	25.2 (21.1)	11.3 (20.0)[a]	12.9 (22.2)[a]	13.7 (13.9)[a]

Abbreviations: CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; HS-PGA, Hidradenitis Suppurativa Physician Global Assessment; IL-6, interleukin-6; NRS-Pain, numerical rating scale for pain.

[a] $P < .001$ when compared to baseline.

[b] $P < .05$.

Figure 1. Severity and Inflammatory Markers at Various Points During Course of Disease and Treatment



Patients received intravenous treatment with ertapenem over a mean (SD) of 13.1 (4.0) weeks. A and B, On average, the values for both disease severity variables (Hidradenitis Suppurativa Physician Global Assessment [HS-PGA] and numerical rating scale for pain [NRS-Pain]) improved significantly at midcourse (represented by 2), end of course (3), and follow-up visits (4), compared with baseline measurements (1). C-F, Additionally, the values for leukocytes, C-reactive protein (CRP), and interleukin-6 (IL-6) were significantly reduced during the ertapenem course and follow-up compared with baseline. Although erythrocyte sedimentation rate (ESR) was significantly decreased at midcourse, the end-of-course and follow-up visits did not reach statistical significance.

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Bacterial Culture Results

Swab bacterial culture results from actively draining sites were recorded for each corresponding visit as shown in eAppendix 5 in Supplement 1. All samples were analyzed for both aerobic and anaerobic cultures. Notably, several species such as *Enterococcus faecalis, Bacteroides ovatus,* and *Prevotella bivia* did not clear by the end-of-course or posttherapy follow-up. Clearance of cultivable bacteria was defined by the absence of growth on subsequent cultures or the absence of exudate on subsequent visits.

Ten of the 98 patients had no microbial growth from draining HS lesions at baseline. There were no significant differences in parameters of HS severity comparing subgroups with negative and positive results from cultures, respectively. Age and sex were similar between the 2 subgroups.

Posttreatment Surgery

Eight patients underwent plastic surgery for HS within 7 (mean [SD], 3.88 [2.36]) months of the end of ertapenem therapy. Two

patients underwent plastic surgery for HS during the course of treatment with ertapenem.

Adverse Events

Adverse events associated with intravenous ertapenem therapy and PICC line use were uncommon. Of the 98 patients, 8 (8.2%) had diarrhea, 5 (5.1%) had nausea, 2 (2.0%) had headaches, 1 (1.0%) had candidiasis, and 1 (1.0%) had multiple episodes of syncope. Drugs like ondansetron, loperamide, and fluconazole were used to alleviate these symptoms. Nine patients (9.2%) required a PICC line replacement because of accidental dislodgement or blockage of fluid flow. Seven patients (7.1%) had dermatitis related to adhesives that anchored the PICC line. Two patients (2.0%) had PICC line–associated infections treated with a replacement. No patients stopped therapy because of any of these adverse effects.

Patient Satisfaction

Of the 98 patients in this study, 76 (77.6%) participated in the phone survey; 22 (22.4%) were not reachable. Questions and responses are shown in eAppendix 2 in Supplement 1. Of those surveyed, 63 patients (80.3%) were satisfied or very satisfied with ertapenem therapy. When respondents were asked if they would be willing to receive another course of therapy, 60 (78.9%) responded affirmatively; furthermore, 69 (90.8%) would recommend ertapenem to other patients.

Clinical Images

The photographs depict skin areas affected by HS before treatment (**Figure 2**A and C) and after 12 to 16 weeks of intravenous ertapenem (Figure 2B and D). Additional clinical images are provided in eAppendix 6 in Supplement 1.

Discussion

In the present study, we report amplified efficacy and durability of intravenous ertapenem administered for 12 to 16 weeks in a large, diverse cohort of patients that had plateaued (ie, ongoing inflammation and drainage) or were unresponsive and deteriorating while undergoing core therapies. The findings from this study are similar to those found by others.[7,13] However, we strengthen these findings with quantitative inflammatory markers that, to our knowledge, have not been previously reported. Although leukocytes, CRP, and IL-6 are not validated markers of disease activity in HS, quantitative trends over time have helped guide treatment decisions when visual inspection during a visit may not represent the patient's everyday experience (ie, outside of a flare). In our experience, these quantitative markers generally align with disease severity.[14]

Although the management of HS has advanced substantially in the last 2 decades, treatment remains imprecise, drawing on wide-ranging antimicrobial, antiandrogen, and anti-inflammatory drugs, as well as multidisciplinary input from plastic, bariatric, head and neck, urologic, and colorectal surgery clinicians, as well as specialists in nutrition, pain management, psychology, and psychiatry.[3-5] In a study of 30 patients by Join-Lambert et al,[7] IV ertapenem was identified in 2016 as an outpatient therapy with uniquely positive outcomes in participants with advanced, recalcitrant HS. This finding was confirmed by Braunberger et al,[9] who reported decreases in HS severity and improved quality of life in 36 patients.

In 2019, we reported short-lived efficacy after 6 weeks of ertapenem for refractory HS; this duration is the current standard of care recommended in the North American treatment guidelines for HS.[11,15] Recurrent disease activity and pain severity within 4 weeks of discontinuing ertapenem led us to explore the durability of HS remissions after longer treatment intervals. Rigorously tracking metrics that reflect disease severity (HS-PGA and NRS-Pain scores), inflammatory markers (erythrocyte sedimentation rate, CRP, and IL-6), and bacterial cultures (aerobic and anaerobic) at the end-of-course and follow-up periods of 6 to 8 weeks for each patient ultimately led us to standardize our duration of ertapenem treatment at 12 to 16 weeks; however, certain patients were extended to periods as long as 24 weeks if they continued to show steady improvement.

The majority of patients in the cohort were receiving the most aggressive therapies available at baseline (especially biologic immunomodulators), and these baseline therapies were continued during ertapenem. Considering these facts, we believe this combination is needed to maximize both the efficacy of ertapenem and durability of remission after treatment in patients with refractory HS.

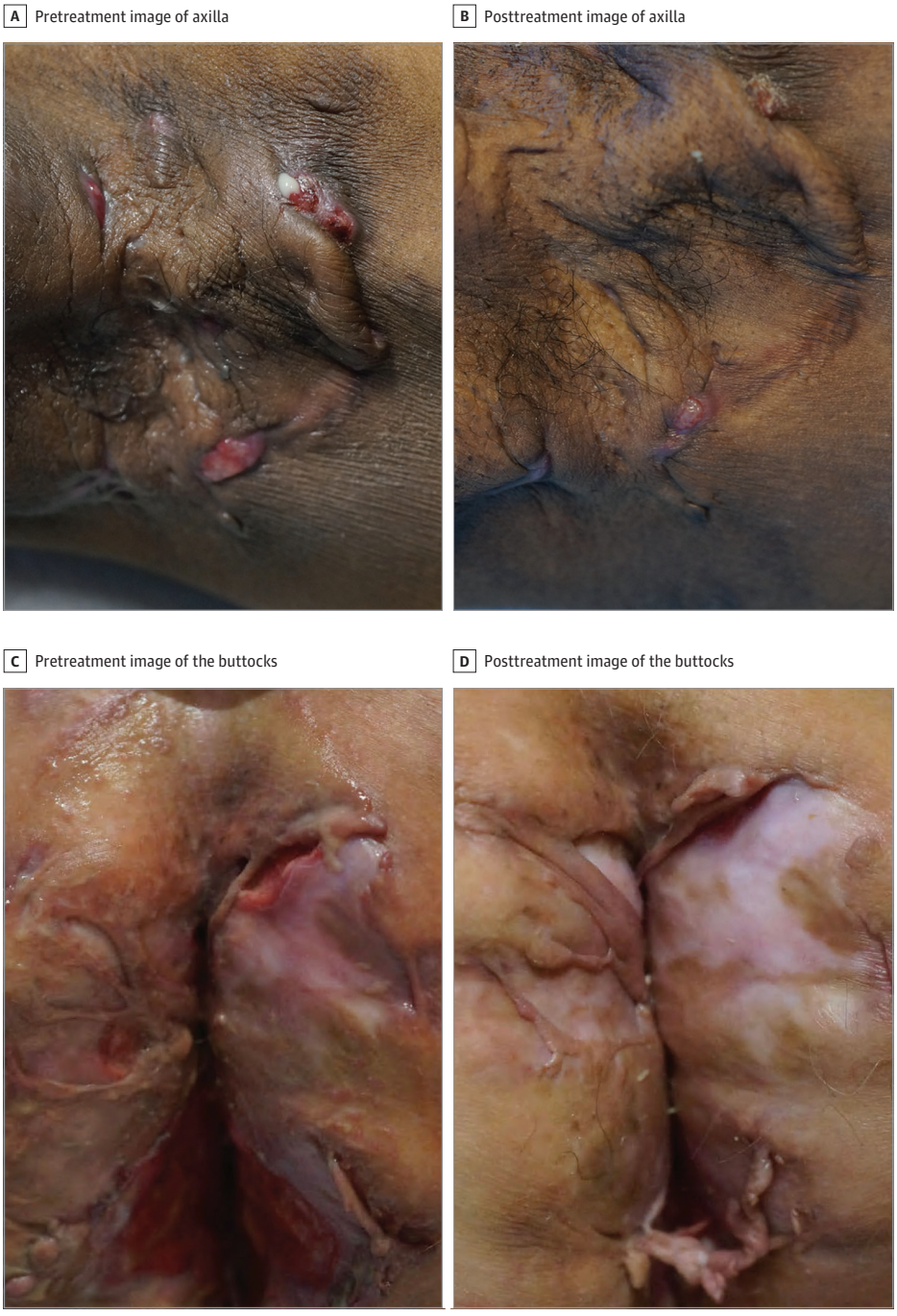
In the HS cohort, IV ertapenem for a mean (SD) of 13.1 (4.0) weeks was associated with substantial declines in both disease severity scores and inflammatory markers. Continued remediation of disease was documented for a mean (SD) of 54.4 (25.2) days, demonstrating both sustained efficacy and durability of response when compared to the immediate recurrence of disease previously after a shorter course of 6 weeks.[10] These findings suggest a course of 12 to 16 weeks of ertapenem may be appropriate as a new standard length of therapy in HS patients, which is at least twice the current recommendation of North American treatment guidelines.[15]

Several patients received longer than 12 weeks of therapy. Extending the ertapenem duration for these patients was primarily rooted in subjective patient reports of ongoing improvement. When these improvements had plateaued, ertapenem was discontinued.

Although it was not the intention of this study, the review of patient records identified that 10 study participants with surgically accessible HS elected to undergo plastic surgery, using ertapenem therapy as a bridge to this more definitive treatment modality.

Significantly improved HS outcomes in the absence of cultivable bacterial growth appear paradoxical. A possible mechanism of IV ertapenem may involve its effect on uncultivable bacteria that escape detection in aerobic and anaerobic cultures, rendering false-negative results. At this time, we are unable to validate this hypothesis with conventional culture-based methods.[16] This suggests that microbial cultures offer a limited form of guidance in clinical decision-making. The findings of the current study underscore the value of ertape-

Figure 2. Clinical Images



The photographs depict skin areas affected by hidradenitis suppurativa before treatment (A and C) and after 12 to 16 weeks of intravenous ertapenem (B and D). All patients photographed provided written permission.

nem treatment when debilitating HS is refractory to other conventional modalities, independent of culture results. The definite mechanism of ertapenem efficacy in HS remains elusive.

Several bacterial species were cleared at midcourse (*Actinomyces turicensis* and *P bivia*) but returned during subsequent visits. This is most likely due to nondraining disease at the midcourse visit; however, this finding was observed only in these species. Future studies analyzing culture data and resistant organisms in patients who undergo repeated courses of ertapenem therapy are needed.

The telephone survey in this study revealed substantial improvements in all subjective parameters of disease during and after ertapenem therapy. Although 76.3% of survey respondents had minor flares after an average of 6 weeks of therapy, nearly 80% of patients expressed satisfaction and willingness to undergo further therapy. Moreover, 90.8% of respondents would recommend therapy to other patients living with HS.

Overall, IV ertapenem therapy was well tolerated. Patient-reported adverse effects of nausea, diarrhea, headaches, candidiasis, and syncope were minimal and did not interrupt therapy.

Strengths and Limitations

Despite study limitations that include a single-institution population, lack of a control group, incongruent follow-up times, and a retrospective design, these findings demonstrate the efficacy and durability associated with extended courses of ertapenem therapy for HS, in a larger cohort of patients than has been previously reported. Additionally, compared with baseline, HS-PGA scores at each visit did not meet the clinically meaningful threshold of a 2-point decrease that serves as a standard in the literature. Furthermore, the post hoc telephone interview results are limited by potential recall bias. Because patients receiving ertapenem without a follow-up visit were excluded, the possibility remains that these patients did not experience long-lasting benefits and were not captured in this study. Nonetheless, high subjective satisfaction paired with a statistically significant 1.2-point decrease in HS-PGA from baseline to posttherapy follow-up suggests this treatment approach may have substantial efficacy. Treatment of HS with IV ertapenem for approximately 13 weeks was associated with improvements in clinical and inflammatory markers. Overall positive subjective responses among telephone survey participants affirmed its valuable remediation of advanced HS.

Conclusions

The use of antibiotics continues to play a complementary role in the management of HS as new immunomodulator therapies are developed.[3] Larger, prospective, randomized clinical trials are needed to further optimize ertapenem dosing and duration, to evaluate the coadministration of other therapies, and to develop strategies for maintaining therapeutic outcomes.

ARTICLE INFORMATION

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Concept and design: Nosrati, Torpey, Benesh, Andriano, Campton, Cohen.
Acquisition, analysis, or interpretation of data: Nosrati, Ch'en, Torpey, Shokrian, Ball, Benesh, Andriano, Zhu, Heibel, Hosgood, Cohen.
Drafting of the manuscript: Nosrati, Ch'en, Torpey, Shokrian, Zhu, Hosgood, Cohen.
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Supervision: Torpey, Andriano, Hosgood, Campton, Cohen.

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