Supplementary material to article by Luis Salvador-Rodriguez "Neoadjuvant Biologic Therapy in the Surgical Management of Patients with Hidradenitis Suppurativa: A Cohort Study"

Appendix S1.

SUPPLEMENTARY MATERIALS AND METHODS

Study design

A prospective cohort study was conducted from February 2017 through March 2020. It included patients with HS who underwent excision and healing by secondary intention at the HS clinic of Hospital Universitario Virgen de las Nieves (HUVN), Granada, Spain. The study comprised 2 cohorts: one cohort underwent surgery plus neoadjuvant biologic treatment (biologic cohort) and the other underwent surgery alone (non-biologic cohort). Assignment to the cohorts was based solely on clinical criteria related to the severity of the disease and the complexity of its management. The clinical criterion for biologic treatment in our centre is the presence of moderate-to-severe HS that does not respond to systemic antibiotics according to current guidelines. Patients who received biologic treatment did not discontinue it before the surgery and did not change their existing treatment regimen.

Use of antibiotic treatment was recorded for both cohorts. Data regarding doxycycline, 100 mg twice a day, clindamycin, 300 mg twice a day, alone or in combination with rifampicin, 300 mg twice a day, as well as any other oral antibiotic prescribed with the intention of treating HS were gathered. Pre-surgical antibiotic treatment was recorded when antibiotics were prescribed 12 weeks or less prior to surgery, while post-surgical antibiotic treatment included all those antibiotics given within the 24 weeks of followup after surgery.

Inclusion criteria

Inclusion criteria were: (i) the presence of moderate-to-severe HS in candidates for surgical excision and healing by secondary intention of axillary or inguinal-genital areas, with draining fistulas/ sinus tracts/subcutaneous tunnels and minimal or no inflammatory activity for ≥ 12 weeks); (ii) projected skin area for excision of \geq 15 cm²; and (*iii*) informed consent to participation in the study.

Exclusion criteria

Exclusion criteria were: receipt of surgical procedures other than excision and healing by secondary intention; and, in the biologic cohort, receipt of biologic treatment for less than 16 weeks before surgery.

Ethics statement

This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Institutional Review Board of the hospital (01-HSURG1901).

Main variable of interest

Recurrence. Recurrence was defined as the appearance of HS lesions (inflammatory nodules, abscesses or sinus tracts) on or within 1 cm of the surgical scar.

Other variables of interest

Surgical wound infection. Defined as the presence of purulent drainage in the wound, with or without microbiological confirmation or microorganism isolation in wound exudate or tissue samples, accompanied by pain, inflammation, ervthema, and/or heat requiring topical or systemic antibiotic treatment.

Bleeding emergency. Defined as bleeding not resolved by continuous gentle pressure and requiring surgical exploration.

Episode of bad odour. Defined as a visit to the emergency department due to bad odour, with no signs of infection, which was resolved by washing with antiseptic solution and required no topical or oral antibiotics.

Time to complete healing. Defined as the time required for the healing of the entire wound area, with no need for further medical care.

Clinical, socio-demographic, and biometric variables were recorded by clinical interview, physical examination, and cutaneous ultrasound using a 7-15 MHz linear probe in B mode (myLab7 Esaote Spa, Genoa, Italy). Hurley staging was used to assess structural damage and the International Hidradenitis Suppurativa Severity Score System (IHS4) to evaluate inflammatory activity. Pain was evaluating using a numerical rating scale (NRS) for pain, with scores ranging from 0 (no pain) to 10 (maximum pain).

Sample size

A sample size of 54 subjects was calculated to detect differences \geq 30% in the rate of recurrence at week 24, with an alpha error of 5% and a power of 80%.

Statistical analysis

Descriptive statistics were used to evaluate the characteristics of the sample, and the Kolmogorov-Smirnov test was applied to check the normality of variable distributions. Continuous variables were expressed as means (SD) or medians (25th-75th percentile) and qualitative variables as absolute and relative frequency distributions. The χ^2 test or Fisher's exact test, as appropriate, were used to compare nominal variables, and the Student's t-test or Wilcoxon-Mann-Whitney test were used to compare between nominal and continuous data. Simple linear regression was performed to compare between continuous variables. The ß coefficient and SD were used to predict the log odds of the dependent variable. Multivariate logistic regression analyses were carried out to identify the factors associated with bleeding emergency and time to complete healing. Epidemiological and statistical criteria were used to model the selection of variables. The effect of each exploratory variable in the model and its significance were studied. Variables were kept in the model when they improved the model fit and adequacy (based on likelihood ratio criteria and significance of the variable) and excluded when they did not. The model was checked for pair-wise interaction between covariates. Potential confounding covariates were defined as a change in the significance of the parameters in the model or by a change in their value of \geq 30%. Statistical significance was defined as a 2-tailed *p*-value < 0.05. JMP version 14.1.0 (SAS Institute, NC, USA) was used for statistical analyses.

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