The Global Hidradenitis Suppurativa Atlas (GHiSA) Methodology Combining Global Proportions in a Pooled Analysis

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Short Title: Methodology of GHiSA global prevalence studies

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Abstract

Data concerning the global burden of Hidradenitis Suppurativa (HS) are limited. Reported prevalence estimates varies between 0.0003% and 4.1%, and data from various geographical regions are missing. Previously reported prevalence rates have been limited by the methodological approach and source of data. This has resulted in great heterogenicity as prevalence data from physician diagnosed cases poorly match those of self-reported disease.

The Global Hidradenitis Suppurativa Atlas (GHiSA) introduces an innovative approach to determining the global prevalence of HS. This approach involves using a previously validated questionnaire to screen apparently healthy adults accompanying a patient to a non-dermatological out-patient clinic visit in a hospital. The screening questionnaire is combined with a physician-based in-person validation of the participants who screen positive. Ten percent of the screen-negative participants are also clinically assessed to verify their status. The GHiSA Global Prevalence studies are currently running simultaneously in more than 61+ countries (78 centers) across six continents (Africa, Europe, Australia, North America, South America, Asia). The novel standardization of the Global Prevalence studies conducted through GHiSA enables direct international comparisons, which were previously not possible due to substantial heterogeneity in past HS prevalence studies.

A short Abstract should summarize the main points and reflect the content of the article. It should be written in a clear and concise way and be unstructured. Abbreviations used in the main text may be introduced and used. Use neither bibliographic references nor references to figures or tables in the Abstract.

Please refer to the Author Guidelines for more information about the maximum accepted word count of the Abstract in your chosen journal. Where no specific word count is provided, an abstract of between 200-400 words is permitted.

Introduction

Hidradenitis Suppurativa (HS) is a painful and scarring skin disease clinically identified by recurrent inflammatory nodules, sinus tracts and/scarring in the inverse regions of the body occurring more than 2-3 x/ 6 months. To qualify for the diagnosis of HS, all three components need to be met (1). A large proportion of patients show persistent or progressive disease over time. (2) This makes the diagnostic delay of HS is a global concern, as the time from the onset of symptoms to final diagnosis has been reported to be around 7.2 – 10.2 years. (3) This number is significantly higher than the 1.6 years experienced by patients with psoriasis (4). The global delay in diagnosis is partly due to a lack of awareness and recognition by healthcare professionals (5, 6). Furthermore, it is widely acknowledged that there is a continued unmet need for treatment in HS in spite of recent advances. It is speculated that these factors form a mutually supportive negative pathway to the detriment of patients with the disease.

Furthermore, knowledge concerning the global burden of the disease is limited (7). Systematic data on global disease prevalence are conflicting, as it has been reported with a wide variation (0.0003% to 4.1%) (7, 8) A meta-analysis by Jfri et al (7) reported the global prevalence to be 0.4%. However, the reported prevalence needs to be interpreted with caution, as most of the available prevalence data on HS originate from Europe, the US and Australia. Data from large parts of the world are therefore scarce or non-existent.

Past methods to assess the prevalence of HS include register-based studies focusing mostly on medical records or diagnostic codes, validated diagnostic questionnaires resulting in self-reported diagnosis, and in-person validation (7, 8). The heterogeneity in study design, screened population, sampling procedure, and methods to diagnose HS make direct comparisons between various regions/countries very challenging. Studying geographical

variations in disease prevalence is important and may provide clues and inputs for further investigations into etiology, risk factors, and resource allocation (9, 10).

The Global Hidradenitis Suppurativa Atlas (GHiSA) (https://ghisa.org) introduces an innovative approach to determining the global epidemiology of HS. The methodology follows the approach previously invented and validated by Vinding et al and Esmann et al (11, 12). The invented screening questionnaire has a high sensitivity/specificity and has previously been validated in Denmark, Singapore, Greenland, and Ghana (13-16).

Methods/Design

The Methods/Design section should clearly list and describe the method, technique or procedure, with an emphasis on the novel aspects

The prospective GHiSA study is designed as a series of descriptive cross-sectional studies across 61 countries/six continents. The diagnosis of HS is as previously mentioned based on three mandatory clinical criteria (17). These clear clinical criteria enable screening through a questionnaire. One of such has previously been created and validated by Vinding and Esmann et al (11, 12). The questionnaire consists of two simple questions: i) *'Have you had outbreaks of boils during the last 6 months' and ii) 'Have you for the past 6 months had 2 or more boils/abscesses in any of the below locations with five different location options [axilla, groin, genitals, under the breasts and other locations (not specified), e.g., perianal, neck and abdomen]' (11).*

The GHiSA methodological approach relies on the above mentioned questionnaire as modified by Vinding et al (11), but distinguishes itself by the recruitment process of the

participants, target process, and subsequent validation, whereby it achieves an estimate of HS in a cohort representative of the background population from where the sample is drawn.

The source population is apparently healthy adults (> 18 years of age) accompanying a patient undergoing care in an internal medicine, surgery, ophthalmology, ear-nose -and throat, pediatric, family medicine, or rheumatology outpatient clinic at a hospital. The department of dermatology is excluded as a possible recruitment site. This is due to high risk of bias as a genetic component of the disease has been revealed, and as most accompanying persons tend to be family members (18, 19). All apparently healthy accompanying adults, who are willing to participate, are eligible for inclusion. This novel target population allows a random sample from the general population to be screened. Vulnerable populations including pregnant women, and patients who are not able to consent to participation, e.g., unconscious, minors (<18 years of age), psychiatric patients, previously included participants are also excluded. Consequently, the source population described above should adequately reflect the target population of apparently healthy adults serviced by the hospital that constitute the local recruitment center.

Consecutive apparently healthy adults are invited to answer a screening questionnaire until the desired sample size is attained. The screening questionnaire will prior to study initiation be translated into the appropriate local language. For centers to represent a unique reporting unit, and for the findings to reach substantial power, every center will seek to enroll 1000 individuals, with a sample size of 500 being the minimum (Fig. 1); pragmatically evaluated to represent a reasonable precision around the individual proportion estimate. Furthermore, socio-demographic data will be obtained using a supplementary questionnaire, as it will allow for further sub-analyses. Those who screen positive for HS will be clinically examined by an HS experienced physician to clinically verify presence of any self-reported disease and to make the final diagnosis. In addition, in order to gauge the diagnostic accuracy

of the screening questionnaire (the calculated sensitivity, specificity, positive predictive value, and negative predictive value), the axilla of 10% of the screen negatives will randomly be examined for signs of HS. Clinical photographs will also be taken following informed consent. The screening questionnaire (11) will serve as the index test, and the clinical evaluation by a physician will serve as the reference standard. All data will be collected anonymously. The data will be typed into an excel spreadsheet twice by two independent investigators for quality control.

The primary objective is to estimate the point-prevalence of HS in a series of populations sampled from all the participating countries; the point-prevalence of HS is as estimated n_{HS} / N_{Total} (i.e., the ratio between number of HS cases and the sample size). Secondary objectives include the diagnostic accuracy of the screening questionnaire. The contextual impact of sociodemographic data: sex, age, ethnicity, body mass index (BMI), and smoking status, will also be explored.

The global prevalence will be based on the collected (and reported) individual local proportions. When combining proportions in a proportional meta-analysis, there is at least one important issue based on the fact that prevalence data will always fall between the values of zero and one, which is important when considering the pooling of proportional data in a proportional meta-analysis. The 95% confidence limits will likely fall outside of the established zero to one range; this may impact on the readability and presentation of the pooled data as a forest-plot (20). We will apply a logit transformation to solve the problem of confidence interval estimates falling outside the zero to one. While performing a proportional meta-analysis using a fixed-effect model is possible, the assumptions supporting this model is questionable. Thus, the primary proportional meta-analysis model will be performed using a random-effects model with 95% CIs, as well as the 95% prediction interval. Once the meta-analysis has been performed on the transformed proportions, a back-transformation will be applied.

Discussion/Conclusion

The Discussion/Conclusion should provide an evaluation of the method, technique or procedure, and there should be a clear discussion of the implications, significance, and novelty of the method presented.

Disease prevalence influences diagnostic acumen in any given consultation, and this in turn affects patient care. Accurate disease prevalence data furthermore helps policymakers and healthcare professionals to correctly allocate and prioritize resources. This may in turn lead to a more comprehensive public health planning. (21, 22) Accurate prevalence data can furthermore support global awareness, which may inspire additional investigations into the disease.

Currently, GHiSA Global Prevalence studies are running simultaneously in 61 countries and 78 centers spread across six continents (Africa, Europe, Australia, North America, South America, Asia). The screening questionnaire was previously validated in Denmark, Ghana ,Singapore and Greenland (11, 14-16) and the studies indicated a high diagnostic power. The sensitivity and specificity of the screening questionnaire was reported to be 0.9 & 0.97 in the study by Vinding et al (Denmark, prevalence: 2.10%), 1 & 0.89 in the larger follow up study by Hagan et al (Ghana, prevalence: 0.67%), and 1 & 0.66 in the study by Botvid et al (Greenland, prevalence: 3.2%)). Prevalence rates found in these studies were similar to reported rates in Europe and Australia (8, 23). The prevalence rate of HS in Ghana is of special interest, as speculations of racial differences with African Americans having higher rates of the disease have been raised in the US (24, 25).

The target population of apparently healthy adults accompanying patients to the outpatient clinic of a hospital enables a simple random sampling of the general population. The exclusion of pregnant participants due to ethical concerns may bias the true prevalence and should therefore be considered as a limitation. Selection bias should also be considered as a limitation of this study. However, the in-person validation of the screen-positive participants

prevents a skewed prevalence estimate due to the high number of false positives. The somewhat high number of false positives in Greenland (27/490) and Ghana (16/1476) (and consequently the low to moderate positive predictive value) have so far been the strongest critique (26). However, it is important to underscore that the sampling method employed under GHiSA does not enrich the prevalence as it relies on random sampling through apparently *healthy accompanying persons* not through patients. Participant thus range from grandparents accompanying grandchildren to the pediatrics department to grandchildren accompanying grandparents to the ophthalmology department. Furthermore, while the positive predictive value of any test relies on the prevalence of the disease in the sample population, that does not preclude the usage of the test in establishing the disease prevalence in the given population. It simply requires a failsafe i.e., a way to distinguish between false and true positives. The in-person validation provides such a failsafe. Finally, no false negatives have been reported so far. This supports the usage of the questionnaire as a screening tool.

Additionally, the questionnaire also collects basic data concerning risk factors such as smoking and body mass index. This data is important to include in the interpretation of the calculated prevalence. The simple setup of this innovative method is inviting, as participating centers/countries without large national registries or with limited resources can still participate and provide valuable information. Since prevalence data is missing from the majority of the world, (7) the data from the GHiSA Global Prevalence Studies should be considered as a reference point. Finally, the uniformity of the Global Prevalence studies conducted through GHiSA enables direct international comparisons.

Statements

All papers must contain the following statements after the main body of the text and before the reference list:

Acknowledgement (optional)

Statement of Ethics

Not relevant

Conflict of Interest Statement

RC, RKA, CEM, HHVDZ, BV, PUI, JB, SMN, GV: has no conflicts of interest to declare.

FB:?

DB: UCB Nordic has paid for congress participation. Has received teaching honoraria from UCB Nordic.

JRI: receives a stipend as Editor-in-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate. He is a consultant for Abbvie, Boehringer Ingelheim, ChemoCentryx, Citryll, Novartis and UCB Pharma and has served on advisory boards for Insmed, Kymera Therapeutics and Viela Bio. He is co-copyright holder of HiSQOL, Investigator Global Assessment and Patient Global Assessment instruments for HS. His department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments.

DMLS: has received honoraria as a consultant for advisory board meetings by AbbVie, Janssen, Sanofi, LeoPharma, Novartis and as a speaker and/or received grants from the following companies: Abbvie, Janssen, Novartis, Sanofi, Jamjoom Pharma and Leo Pharma during the last 3 years.
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Author Contributions

DB: conceptualization, literature review, manuscript write up and manuscript review

RC, GBEJ: conceptualization and drafted and/or critically revised the work

RKA, GV, CEM, SMN, DMLS, NSC, HHVDZ, CCZ, FB, BV, AA, PUI, IHH, JJR, HBN, AG, JB drafted and/or critically revised the work

Data Availability Statement

Not relevant

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Figure Legends

Fig. 1. Sample size (per individual center).