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ORIGINAL SCIENTIFIC REPORT

Global Gender Differences in Pilonidal Sinus Disease: A Random-Effects Meta-Analysis

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Abstract

Background Pilonidal sinus disease (PSD) is traditionally associated with young male patients. While PSD is rare in Asia and Africa, lifestyles are changing considerably throughout the so-called developed world. We question that PSD is an overwhelmingly male disease and that the proportion of women suffering from PSD is worldwide evenly distributed in a homogenous matter.

Methods We analysed the world literature published between 1833 and 2018, expanding on the database created by Stauffer et al. Following correction for gender bias with elimination of men-only and women-only studies, data were processed using random-effects meta-analysis in the technique of DerSimonian and Laird.

Results The share of female pilonidal sinus disease patients analysed from all studies available in the world literature is 21%. There are marked regional differences including South America (39%), North America as well as Australia/New Zealand (29%) and Asia (7%), which are highly significant. These results stand fast even if analysis without gender bias corrections was applied.

Conclusion The share of female patients suffering from PSD is considerable. It is time to think of PSD as a disease of both men and women. Previously unknown, there are significant regional differences worldwide; the reason(s) for the regional differences is still unclear.

Introduction

"Human clinical research suffers from a lack of sex-based reporting and sex-based analysis of the results" is a straightforward Joint Statement made by the Surgery Journal Editors Group. It was not published decades ago, but recently in 2018 [1]. Mansukhani analysed 2347 articles, identified 1668 studies with human participants and concluded that 4.4% of all studies were single-gender studies, with 1.3% with only men and 3.1% with only women. Less than one-third of the studies analysed their data in relation to gender, and less than one-fourth discussed their results in a gender-related manner [2]. Thus, as Lundine urges in her Lancet commentary 2019, gender-related research should be encouraged [3]. Gender bias will by no means easily overcome [4], as it is common and even

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deep rooted even in medical education [5, 6] and influence medical decisions [7]. Not surprisingly, the perception of gender bias is gender dependent [8] and may complicate medical therapy [9].

Pilonidal sinus disease (PSD) is known since 1833. It is popularly associated mainly with young male patients. First described in a man [10], the majority of reports up to World War II were from the military and mostly included men. In fact, some publications didn't even mention women because it was "obvious" that PSD was a "men's disease" [11]. There were few female soldiers serving in fighting troops in the western world, and women with pilonidal sinus disease were largely regarded with curiosity. The times changed, the gender equality movement gathered momentum, and wealth and lifestyles changed considerably throughout the world. In Asia and Africa, PSD remained almost unreported up to now. In contrast, surgeons such as Karydakis of Greece had the impression that PSD was on the rise—male PSD, of course, as female disease was nearly not acknowledged in scientific literature.

Nowadays, it has been proven that the incidence of PSD is increasing [12], with bodyweight increasing in parallel [13].

We previously studied whether pilonidal disease has been increasing worldwide or just regionally, to what extent it has been increasing, and which countries are most affected. To investigate this question, we analysed the world literature between 1833 and 2018, expanding on the database of Stauffer et al. [14]. We now hypothesized that global differences in PSD also exist in relation to gender. Therefore, we aimed to estimate the worldwide gender ratio in pilonidal sinus disease and deduce global gender differences with a stabilized random-effects meta-analysis of our database from there on.

Material and methods

The original strategy used for our literature search and assembly of our database was described previously [14, 15]. In short, the NCBI Medical Subject Heading (MeSH) terms "pilonid*" and ["cyst" AND "dermoid"] were searched for in the Cochrane Central Register of Controlled Trials, Embase, MEDLINE, Ovid, PubMed Central, PubMed, Scopus, as well as several other search engines [14]. Publications from 1833 to 2018 in English, French, German, Italian and Spanish were considered [14]. Reports in other languages were included if definitive treatment strategies were available in an abstract of the languages mentioned. Data were handled with Microsoft Excel (Version 2016, Microsoft Corp., Redmond, WA). Specific surgical approaches described in a report were listed in a row, while columns included citation details (incl. country of origin), follow-up times, number of patients studied, recurrence and study details such as gender, age, body mass index (BMI) and others [14]. Figure 1 displays the PRISMA low diagram based on the PRISMA guidelines, illustrating the search for evidence of pilonidal surgical procedures in women and men since 1833 in the world literature [14].

Firstly, we tended to include all studies (Table 1), but to realize that studies including only male patients may lead to a selection bias in the results, as the percentage of female patients is zero by study design. The same is true for the few studies reporting only women. Thus, we excluded all studies reporting only men (n = 155) or only women (n = 8), resulting in 163 studies covering 84.427 patients in total (Table 2).

Statistical analysis

Crude proportions of female patients were calculated as the number of reported females divided by the total number of patients with reported gender for each study, across all studies, and stratified by geographic region. Subsequently, we excluded all studies that only included either men (n = 155) or only women (n = 8), as these studies are evidently subject to selection bias (e.g. studies performed in a military population or case reports). The percentage of females is either 0% or 100% by study design, and these studies thus do not contribute unbiased information to the estimation of the percentage of female patients. Then, the percentage of female patients was pooled across studies with a random-effects meta-analysis using the method of DerSimonian and Laird [16]. Variances were stabilized using the Freeman–Tukey double arcsine transformation, after confirming that back-transformation led to similar estimates as obtained with the exact likelihood approach [17]. Heterogeneity was quantified with the I^2-statistic, and small study bias was assessed with funnel plots [18]. Meta-regression was performed on the logit-transformed proportion to explore the relationship between the decade and region in which the study was performed with female gender. All analyses were performed in STATA 16.0, specifically using the "metaprop_one", "metafunnel" and "metareg" programs.

Results

The search yielded 842 studies, which a total of 104,055 patients in whom the gender was reported. The number of studies reporting PSD has been increasing for four decades, and this increase is seen in different groups of countries.

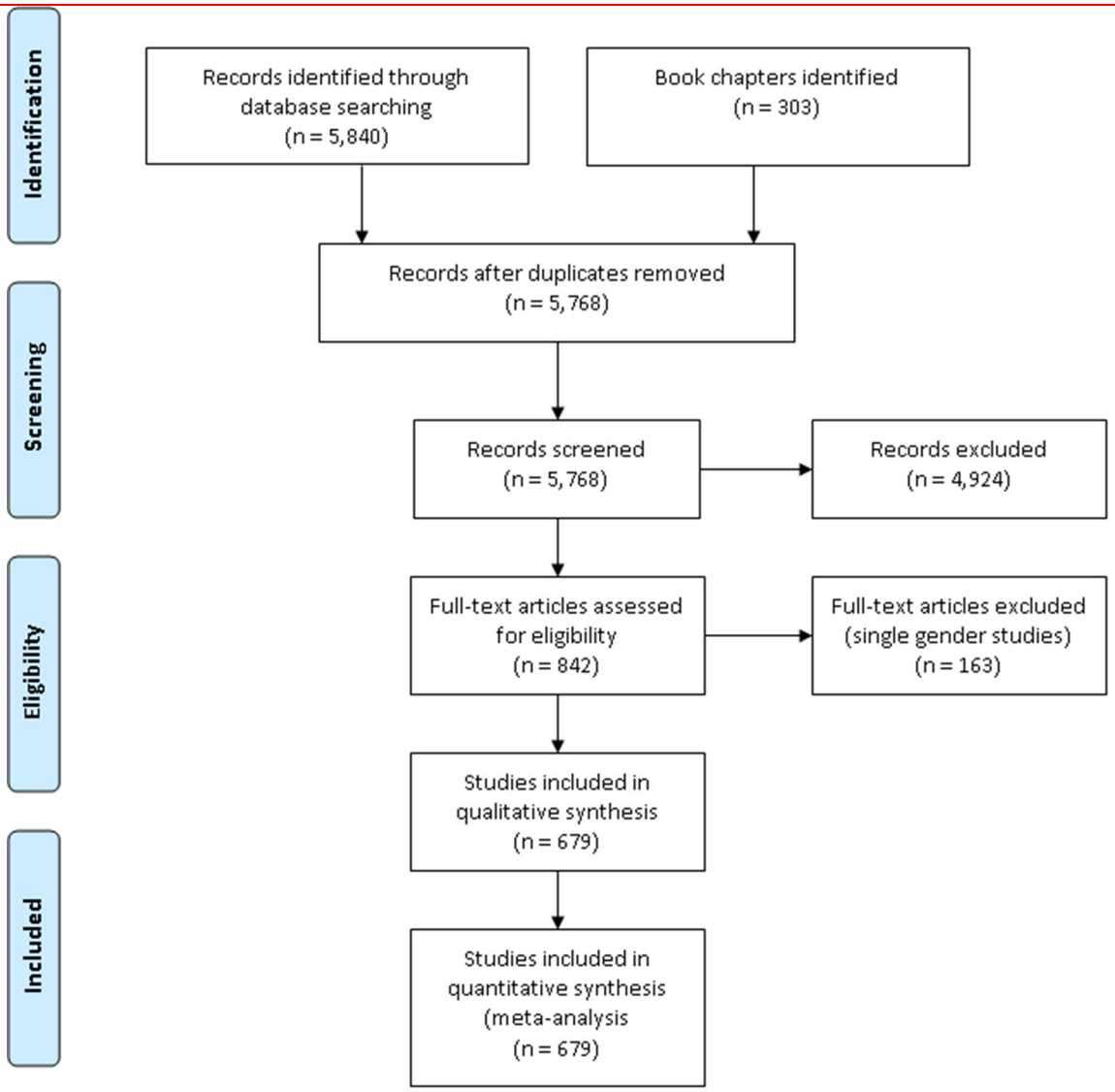

Fig. 1 Flow diagram based on the PRISMA guidelines, illustrating the search for evidence regarding pilonidal surgical procedures in women and men since 1833 in the world literature [14]

Analysis of the world literature showed that most of the patients in publications on PSD come from the Mediterranean region (Table 1 and 2). This region comprises Italy, Turkey, Greece, Israel and Spain. Groups of countries as Northern America, Northern Europe and the Indo-Arab region do differ in the number of PSD patients between the 1940s and now (Fig. 2), but their number of PSD cases published per decade generally stays below 6,000. Asia reported the lowest PSD numbers, whereas the Indo-Arab region has shown an increase in published PSD research since the 1980s. The Mediterranean region reported more than all other regions combined, approaching 15,000 patients published within this last decade.

Analysing all patients from 1833 up to now, the lion's share of patients is reported from Mediterranean countries, with Turkey and Italy heading the field. The largest countries contributing were Turkey (23,998 patients) and Italy (16,088). In Italy, 26% of the patients were women, whereas in Turkey the share of females was 13%.

Using the forest plot method, only summaries and overall estimates of subgroups (regions) are depicted, as there are too many studies for a full forest plot (Fig. 3). Please note that potentially biased single-gender-only studies are excluded. It is noteworthy that the results from Table 2 and the forest plot do differ, which is due to the methods used. The table contains raw data, summarized by

Table 1 All patients with known gender, by region; all studies included

Region	Total studies	Studies with only males	Total patients	Total of male patients	Total of female patients	% of female patients
Asia	14	10	96	91	5	5.21
Australia & New Zealand	11	2	925	613	312	33.73
Indo-Arabia	101	13	9,584	7,837	1,747	18.23
Mediterranean	334	53	55,693	46,392	9,301	16.70
Northern Europe	219	24	21,928	17,866	4,062	18.52
North America	142	52	14,473	12,245	2,228	15.39
South America	21	1	1,356	825	531	39.16
Total	842	155	104,055	85,869	18,186	17.48

Table 2 All patients with known gender, by region; all studies with male and female patients included; not including only-male and only-female studies to reduce selection bias

Region	Total studies	Studies with only males	Total patients	Total of male patients	Total of female patients	% of female patients
Asia	4	0	52	47	5	9.62
Australia + NZ	9	0	923	611	312	33.80
Indo-Arabia	87	0	9,453	7,708	1,745	18.46
Mediterranean	281	0	45,040	35,739	9,301	20.65
Northern Europe	194	0	19,570	15,510	4060	20.75
North America	84	0	8,034	5,813	2,221	27.65
South America	20	0	1,355	824	531	39.19
Total	679	0	84,427	66,252	18,175	21.53

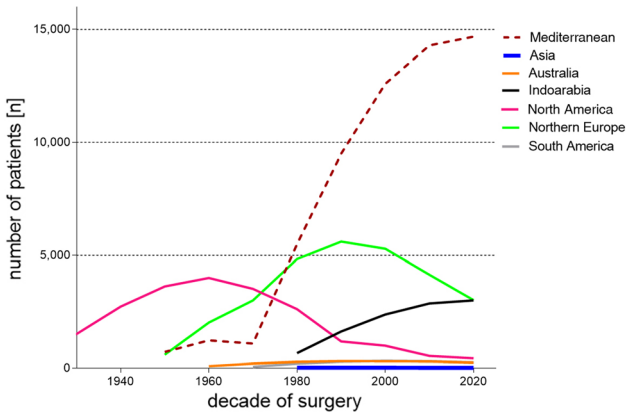

Fig. 2 Number of PSD patients from different world regions (smoothed decades)

region and divided by gender, while the forest plot is compiled by random-effects meta-analysis [19].

The estimated overall female share in non-single-gender studies in the world PSD literature is 21% (95% CI: 20–23%), with a marked heterogeneity across studies ($I^2 = 92.8\%$, $p < 0.001$). This may at least in part be explained by marked regional differences in the percentage of female patients, with South America's percentage of women with around 40%, and North America as well as Australia/New Zealand at around 29% (Fig. 3). The published data weight (which is the impact of the subgroup on the world data set) of the Mediterranean region is around 42.8%, depicting a below-average female share of 18.9%. While Asian women's share is lowest with 7.4%, their data weight is below 1%, as PSD is rare in the Asian region. Meta-regression confirms that the endpoint "region" is significantly associated with the percentage of women

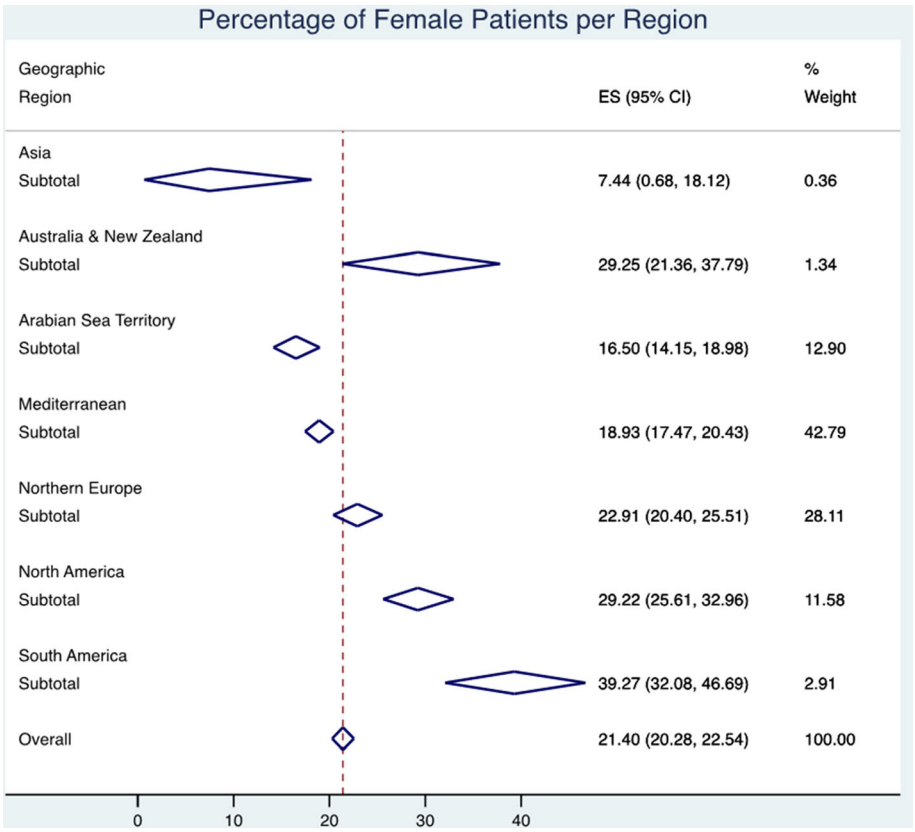

Fig. 3 Forest plot of gender and region (potentially biased single-gender studies are excluded)

($p < 0.001$). To our best knowledge, there are no PSD reports from Africa.

The funnel plot showed no marked asymmetry and provides no evidence for a small study bias. In this context, the study size does not correlate with the proportion of women (data not shown).

Discussion

The incidence of PSD is increasing, and despite manifold industrial and socioeconomic developments over the past five decades, the proportion of female PSD patients has been stable at 21% worldwide. Nevertheless, our data show that there are marked and significant differences between world regions, and that these differences persist even if single-gender studies are excluded to avoid selection or reporting bias.

The Mediterranean countries have contributed a large proportion of the publications about PSD within the last 4 decades. Nevertheless, they show a lower proportion of women with PSD than Northern Europe. (The European ratio is just above world average.) This illustrates that the large body of publications coming from the Mediterranean region do not elevate the female share, as suspected before. Asia and Africa cannot be reliably commented on, as Asian publications on PSD are rare [20], with Chijiwa reporting on few males only from the Japanese Defence Force. PSD publications from Africa are non-existing; only few and mostly anecdotal case reports from PSD in black men in America are available so far [21–24].

It might be thought that variations in women's level of health awareness lead to differences in the number of women seeking surgical therapy for PSD in various countries. This cannot be seen in our data, where Italy with 30% of PSD patients being women is above average, where women are said to be health-, fashion- and self-conscious. Northern European women, which are said to be equally self-determined and self-standing, only "achieve" a 23% share. The same is true for Israel where the female share is 20% despite women being on an equal footing with men in terms of rights and duties in their society. In Israel, military service is mandatory for women, and the percentage of women in Moshe Gips' 2008 study with 1,358 patients was 15.7% [25], so it was not elevated despite high frequency of military female enrolment. In numerous countries, women have gained access to the military, where PSD is reported to be common [26–28].

In contrast, in a survey of 19,013 candidates aged 17–28 years who applied to be students in Turkey, Duman

2017 found that 6% of all PSD patients were female, which is a factor of 5 times lower than our results [27]. In some reports the prevalence of PSD seems to be remarkably higher in the military [12, 26], a finding that is reflected to a greater extent in our data than in Duman's [27]. Epidemiologically speaking, although women are catching up with men with regard to drinking and smoking habits [29], none of these lifestyle changes have been proven to increase the PSD incidence or recurrence rate in the short or long term, as seen in large epidemiological studies in Minnesota 1960 and Turkey recently in 2016, which present even lower shares of 25% [30] and 6% [31] of asymptomatic females. Although it is known that smoking may impair wound healing, this could not be shown in a larger German study on PSD, analysing smoking and wound healing in 534 soldiers. Sievert et al. did not find any influence of smoking on wound healing and recurrence rate in their recent study from 2013 [29]. But a smoking effect on primary PSD incidence was not investigated and thus cannot be ruled out, at least not as a co-effect, if one allows the thoughts that primary disease and secondary disease are generated by two different mechanisms.

Is there a difference in awareness on the part of the doctors treating women with PSD? Is the incidence in women locally under- or over reported? In light of the fact that the countries reporting women with PSD have functioning health systems providing equal access and care for male and female patients, up to now there is limited evidence in the medical literature to support this postulate.

Our study, based on a large database exceeding 100,000 patients, has some inherent limitations. These are closely linked to the diversity of publications and mother tongues present in the world. We were not able to fully analyse publications written in languages other than English, Spanish, French and German. And we are sure that there is some literature outside of the electronic research area that we investigated. Nevertheless, as we were able to assess the large body of research in the world literature on PSD, there is no evidence that the literature we didn't assess is markedly different. Furthermore, if it would differ, because of its paucity it is most unlikely to have a major effect on the volume of evidence already presented and analysed so far.

Second, it might be argued that in our world-spanning literature analysis the heterogeneity is too high to allow a meaningful estimate of the percentage of women, and that we are comparing unlike measures ("apples to oranges"), as studies are too different from each other. However, there is no other way to estimate the percentage of women than using the available studies, and heterogeneity is well applied as long as it reflects real differences between studies that can be explored or discussed (such as regional differences).

In fact, we do not know much about the inclusion and exclusion criteria of the individual studies published, and differences in the number of women with PSD might also simply reflect differences in sampling rather than "true" differences. Firstly, we chose to focus on therapeutic pilonidal sinus studies. Intervention by a doctor was decided to be the most convincing criterion that a pilonidal sinus was present [32], knowing that we would neglect the ever asymptomatic pilonidal sinus which does not need therapy—but this group is small [33]. We are aware that embryological studies, neonatal surveys and epidemiological overviews are not present in our study, but embryological, neonatal and prepuberty pits and their incidence have little in common with adult pilonidal disease.

We did address a potential pitfall of gender-related study bias. The potential danger of this type of selection bias that was evident through the, for example, military men-only studies was discussed and eliminated through including only mixed-gender studies.

But even now, there could be still a residual pitfall with respect to gender:

Pilonidal sinus, especially the asymptomatic form, is often discovered if patients are examined when they have applied for military or police duty. In the past many aspirant soldiers and police men had to be operated for PSD, even if the sinus itself was asymptomatic. If they were not operated on, they were not felt fit for the police or army service. So, it might be postulated that women might have more (asymptomatic) PSD (than men), and therefore, the numbers of women that were operated on (because of symptoms) was lower in this study. Speaking against this is that Gips, as cited before, reports that female share is 15.7% in Israel [25], and Obedman mentions Franckowiak and his unpublished thesis with a study made among 31,497 asymptomatic Minnesota University students where he found 365 males and 24 females with pilonidal sinus, thus giving a female share of 16.2% [30]. Franckowiak´s dissertation is not available at the university; but in a publication in DCR 2 years later he stated that from 354 patients operated on the male/female ratio was 3:1 (25%) [34], so m/f ratio varies, but within a certain restricted range, and obviously varies to both sides, as (here) the female surgical share is higher than the epidemiological share. Duman 2016 examines $n = 19{,}013$ candidates aged between 17 and 28 years who applied to be students or officials of the Turkish state's schools and institutions. 5.9% of PSD patients recognized were female [31]. This documents that there is a zone of uncertainty that is hard to avoid at this point.

Of course medical conditions for applicants for police service, army or firefighters are not equal but differ from country to country. A higher rate of surgeries would be expected in the rich countries, as northern America and

northern Europe, but less in Southern America. This is not reflected in the forest plot, but may be indeed a potential source of smaller potential bias.

Although selection bias is an omnipresent danger for any international and retrospective study like the one presented, this statistical approaches seems to be the most thorough statistical approach to estimate the proportion of women with PSD.

Other factors potentially involved, but not corrected for, are to be acknowledged. Body hair in the region of the trunk is present more often in PSD patients and is seen as a risk factor for development of pilonidal sinus disease [35, 36], which may differ regionally. Furthermore, patients with PCOS (polycystic ovary syndrome) and hirsutism are seen more often in the Mediterranean region. PCOS patients have shown higher levels of free testosterone and an elevated BMI [37]. While BMI has been largely suspected to be a PSD cofactor, this has not been proven convincingly up to now. However, BMI, insulin resistance and PCOS do seem to interact in a way that is not yet fully understood [38, 39]. In our study, Mediterranean female share is below average, which contradicts a larger PCOS influence here.

Testosterone is a key hormone in male puberty and may play a crucial role in PSD occurrence early, at around the age of 15 [13]. Earlier puberty (menarche) in women [40], combined with unchanged onset time of puberty in men, would result in an earlier increase in female PSD, but also an earlier decrease in female PSD, as incidence drops with ongoing age [13]. Thus, earlier menarche paralleling same age puberty in men would not increase the extent of female PSD over time. It would neither increase the female-to-male ratio, if subsumed over all ages.

In familiar pilonidal disease, we see more extensive disease with earlier recurrence and higher recurrence rate [41]. A higher female PSD caseload would theoretically be possible if earlier in life onset of female PSD would be linked to earlier recurrence and higher recurrence rate, as observed in familiar disease. This link between earlier menarche and earlier and increased recurrent female disease has not been proven nor disproven yet.

It has been proven that increased wealth is linked to earlier menarche [40], which may be linked to earlier PSD presence [42–44]. Nevertheless, in a successful society, wealth should increase and health should improve in both men and women simultaneously, and the incidence of PSD should increase in both sexes in parallel, not distorting the female–male relation.

Interestingly, axial hair force strength has been identified as stronger in PSD patients as compared to their matched pairs in a recent German study [45]. Unpublished data of this study indicate that men's axial hair force is 2.5 times stronger than that of women. Male-to-female axial hair force differences have not been tested systematically in patients at all, and neither compared both gender patients from different countries. The axial hair force strength potentially opens the door to explain gender differences as well as regional differences in pilonidal differences, as published 2019 [15]. Nevertheless, the aforementioned study incorporated a limited number of patients and healthy population of one northern European country only. International and gender-related axial hair force differences still have to be shed light on and are subject of an ongoing study just started.

Although the first female PSD patient was reported early in 1880 by Hodges [46], female PSD patients were perceived as a rarity since. Our current research shows that between 9% of Asian and 39% of Southern American PSD patients published are women, with a worldwide average of 21%. Pilonidal sinus is a disease of both genders with important cofactors differing between men and women not yet identified. Hair strength factors may play a pivotal role mirrored in these regional geographical differences now found in this data. These reasons are still to be unravelled.

Researchers from around the world are invited to participate in this international study group.

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Author contributions PS, DD, MML and MD performed statistical analysis and calculations. PS, MML, VKS, DD and MD contributed to manuscript editing and interpretation of data. PS, DD, VKS, MML and MD were involved in manuscript writing and critical reviewing. PS, MD, DD and MML designed the graphics. MD and DD performed data acquisition.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflicts of interest.

Human and animal rights This article does not contain any studies with human participants, human samples or live vertebrates.

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