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RESEARCH ARTICLE

Gender-specific outcomes in pilonidal sinus disease: Female outcomes after cleft lift surgery in a large prospective Danish cohort

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Abstract

Aim: Pilonidal sinus disease (PSD) is a common condition particularly affecting young men. Females affected by the condition account for about 20% of patients and are rarely mentioned, much less studied specifically. In this study we evaluate the surgical outcomes in a female population following Bascom's cleft lift (BCL) surgery in primary extensive disease, non-healing wounds after previous surgery and recurrent disease in a large Danish cohort from a high-volume centre.

Method: The study is based on a prospective database established at Randers Regional Hospital in 2016. All patients undergoing BCL surgery from June 2016 until October 2022 were included in this study.

Results: In all, 560 patients underwent BCL surgery at our centre during this period. Eighty-eight (15.7%) were women. Only 10 (11.3%) were operated due to primary extensive manifestations. The rest presented with either non-healing wounds after previous surgery (47.7%) or recurrent PSD (41%). Risk of recurrence in female patients was 30% higher than in male patients (risk ratio 1.30, 95% CI 0.79–2.09) and the risk of prolonged healing after BCL surgery was 46% higher in women compared to men (risk ratio 1.46, 95% CI 1.02–2.14).

Conclusion: Female PSD patients may represent a subcategory of patients at higher risk of treatment failure and should be dealt with as such. Initially, few present with the need for extensive surgery. However, given the common occurrence of prolonged healing and recurrence, we recommend a minimal invasive approach when possible.

KEYWORDS

Bascom's cleft lift, cleft lift surgery, female, gender, healing, pilonidal disease, pilonidal sinus, pilonidal sinus disease, recurrence

INTRODUCTION

Pilonidal sinus disease (PSD) is a common condition particularly affecting the young population [1]. Studies have found an overall 5:1

male-to-female ratio, which has remained consistent over time, with an earlier onset of PSD in women [2]. Despite this, female PSD continues to be viewed as a rare occurrence, and few studies have specifically focused on the topic. Pilonidal literature seems to assume

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uniformity, if not in disease manifestation, then at least in treatment response across genders.

Since PSD onset is related to puberty, a time when the body undergoes gender-specific biological changes, it has been suggested that PSD may present differently and follow a different disease course between the sexes. During puberty, both boys and girls experience significant changes in their skin, driven by a surge in sex hormones. In boys, the primary sex hormone responsible for these changes is testosterone, while in girls it is oestrogen. These hormones play multifaceted roles in maintaining the health and function of apocrine-bearing skin by regulating sebaceous gland activity, hair growth, collagen production, wound healing and skin thickness.

In female PSD patients, serum prolactin levels have been found to be elevated [3] and a potential relationship between PSD and polycystic ovarian syndrome has been suggested, possibly mediated by obesity, hyperandrogenism and aberrant hair follicles [4–6]. A recent study comparing disease manifestation between 110 women and 127 men found that men presented with granuloma formation (12% in women vs. 36% in men, $P < 0.001$) and drainage (35% of women vs. 67% of men, $P < 0.001$) more often than women [7]. In this study, 35% of female patients with PSD reported gluteal cleft pain related to menstruation. Upon immunohistochemical examination these women had more fibroblasts with oestrogen receptor expression, which was suggested as a potential mechanism for the gluteal cleft pain [7].

Gender differences aside, PSD is poorly understood and optimal treatment is still debated. However, off-midline closure techniques have become the standard of care in more advanced or complex cases. While the best therapies with the lowest rates of recurrence have been reported in the literature [8], most used therapies still have high recurrence rates and long healing times, leading to dissatisfaction among both patients and clinicians.

The aim of this study was to examine risk of recurrence by stratification based on indication for cleft lift surgery in a large cohort of complex female PSD patients treated with Bascom's cleft lift (BCL) surgery, compared to the male patients in the same cohort. We hypothesized that risk or recurrence differed according to indication and gender.

METHODS

Ethics

The study was performed at the Department of Surgery, Randers Regional Hospital, Denmark. It was conducted in accordance with the Declaration of Helsinki and the database was registered with the Danish Data Protection Agency (1-16-02-353-15).

Subjects

Since 2010, our department has served as a reference centre for complex PSD in the Central Region of Denmark, covering a

What does this paper add to the literature?

This study is the largest to examine gender-specific outcomes in pilonidal sinus disease (PSD). We present a large monotherapeutic cohort with a long follow-up showing that female PSD patients are at increased risk of recurrence and prolonged healing compared to men.

catchment area of 1.2 million. Patients are referred in the case of primary extensive manifestation, recurrence after previous elective surgery or non-healing postoperative wounds (>3 months since surgery). These patients are then evaluated for treatment by one of three dedicated PSD surgeons. Primary disease is considered extensive if it is not suited for minimally invasive techniques offered at our centre, primarily pit picking.

Since June 2016, patients undergoing BCL surgery were consecutively registered and followed until complete healing within our database. Smokers were required to abstain from smoking and nicotine for at least 6 weeks before BCL surgery. Postoperatively, patients were followed up in the outpatient clinic at 2 and 12 weeks post-surgery or until complete wound healing. Additional wound care was offered if needed.

In June 2023, a retrospective follow-up was conducted using medical records. In Denmark, all citizens have a unique civil registration number (CPR) linked to electronic patient records nationwide [9]. If a patient was lost to follow-up before complete healing, the date of last contact was noted, and the case was marked as missing. As our department is a reference centre for recurrent and complex PSD, all recurrences are referred to us, minimizing the risk of missing data.

All patients undergoing BCL surgery from June 2016 until October 2022 were included in this study.

Data collection

Study data were collected and managed using REDCap (Research Electronic Data Capture [10, 11]), a secure, web-based software platform designed to support data capture for research studies [11, 12]. Background information such as name, CPR, sex, American Society of Anesthesiologists (ASA) score, comorbidities, smoking habits, body mass index (BMI), disease duration, preoperative symptoms, previous surgeries and indication for current surgery were registered. Surgical details were added on the day of surgery. Follow-up included outpatient appointments at 2 and 12 weeks postoperatively, or until complete healing.

The retrospective follow-up in June 2023 was based on journal entries and included the following retrospective patient's data: date of last contact, time to healing, number of clinical visits postoperatively, recurrence after cleft lift surgery, time of recurrence and if applicable date of repeat surgery. The date of last contact was defined as the date of patient discharge from the outpatient clinic.

Surgical outcomes

The primary aim of this study was to assess recurrence. Recurrence was defined as a new PSD manifestation after complete initial healing. Secondary outcome included time to healing. As patients were followed up in the clinic at 2 and 12 weeks postoperatively, uneventful healing was defined as healing present at the time of the second clinical follow-up (<4 months postoperatively), with the understanding that most patients would have healed before then. If the patients were not healed at the time of second follow-up (3–4 months postoperatively) they were defined as prolonged healing and were followed until complete healing.

Statistical analysis

All statistical analyses and illustrations were conducted in RStudio, version 2023.03.0 [13], and R Software, version 4.3.2 [14]. For surgical outcomes, the risk ratio (RR) with 95% confidence interval was calculated to compare the difference between genders in prolonged healing and recurrence with men as the reference.

Descriptive data are reported as median (interquartile range, IQR) and compared using the Wilcoxon rank sum test, Fisher's exact test, Pearson's chi-squared test or the Kruskal–Wallis rank sum test, as appropriate. A *P* value <0.05 was considered statistically significant. Cumulated incidence proportion plots were used to compare gender and indication-specific recurrence.

RESULTS

Patient characteristics

A total of 568 patients (88 women) underwent BCL surgery between June 2016 and October 2022, with a median follow-up of 48 months (IQR 28; 67). Male and female patients were comparable in terms of age, disease duration, ASA score and BMI. However, the indication for BCL surgery differed significantly (Table 1).

Female patients were comparable across indications for BCL surgery except for a larger proportion of ASA 2 and 3 in the categories of lack of healing and recurrence (Table 2).

TABLE 1 Patient characteristics, comparing male and female patients.

Characteristic	Overall (n = 568) ^a	Female (n = 88) ^a	Male (n = 480) ^a	<i>P</i> value
Age	23 (19, 29)	23 (20, 27)	23 (19, 29)	0.6 ^b
Age at start of symptoms	20 (17, 24)	20 (17, 23)	20 (17, 24)	0.2 ^b
Missing	53	10	43	
ASA score				
1	424 (76%)	59 (69%)	365 (78%)	0.12 ^c
2	120 (22%)	24 (28%)	96 (20%)	
3	12 (2.2%)	3 (3.5%)	9 (1.9%)	
Missing	12	2	10	
BMI	26.3 (23.7, 29.7)	26.3 (22.2, 31.6)	26.3 (23.8, 29.4)	0.8 ^b
Missing	36	7	29	
Smoking habits				
Former smoker (>6 weeks)	168 (30%)	13 (15%)	155 (33%)	<0.001 ^d
Never	336 (61%)	68 (79%)	268 (57%)	
Smoker	49 (8.9%)	5 (5.8%)	44 (9.4%)	
Missing	15	2	13	
Indication for cleft lift				
Extensive manifestation (no previous surgery)	197 (35%)	10 (11%)	187 (39%)	<0.001 ^d
Healing problems after previous surgery	192 (34%)	42 (48%)	150 (31%)	
Recurrence after previous healing	179 (32%)	36 (41%)	143 (30%)	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index.

^aMedian (interquartile range), *n* (%).

^bWilcoxon rank sum test.

^cFisher's exact test.

^dPearson's chi-squared test.

TABLE 2 Female patient characteristics examined by indication for cleft lift surgery.

Characteristic	Overall (n = 88)	Extensive manifestation (no previous surgery) (n = 10) ^a	Healing problems after previous surgery (n = 42) ^a	Recurrence after previous healing (n = 36) ^a	P value
Age	23 (20, 27)	19 (17, 23)	21 (20, 27)	24 (20, 28)	0.15 ^b
Age at start of symptoms	19.5 (16.6, 22.9)	17.6 (15.5, 18.4)	19.3 (17.2, 22.0)	20.8 (17.4, 23.6)	0.2 ^b
Missing	10	1	4	5	
ASA score					0.041 ^c
1	59 (69%)	9 (90%)	26 (63%)	24 (69%)	
2	24 (28%)	0 (0%)	15 (37%)	9 (26%)	
3	3 (3.5%)	1 (10%)	0 (0%)	2 (5.7%)	
Missing	2	0	1	1	
BMI	26.3 (22.2, 31.6)	24.3 (22.0, 31.1)	25.4 (22.5, 32.0)	27.1 (23.4, 31.5)	0.8 ^b
Missing	7	0	3	4	
Smoking habits					0.6 ^c
Former smoker (>6 weeks)	13 (15%)	1 (10%)	4 (9.8%)	8 (23%)	
Never	68 (79%)	9 (90%)	34 (83%)	25 (71%)	
Smoker	5 (5.8%)	0 (0%)	3 (7.3%)	2 (5.7%)	
Missing	2	0	1	1	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index.

^aMedian (interquartile range), n (%).

^bKruskal–Wallis rank sum test.

^cFisher's exact test.

Surgical outcomes

Despite significantly fewer female patients being previous or current smokers, a significantly larger proportion of female patients experienced prolonged healing after BCL surgery (Table 3). Female patients had a 46% higher risk of developing prolonged healing after BCL surgery compared to male patients (RR 1.46, 95% CI 1.02–2.09, $P=0.044$). Additionally, female patients had a 30% higher risk of recurrence compared to male patients (18% vs. 14%, RR 1.30, 95% CI 0.79–2.14, $P=0.3$), with these recurrences occurring earlier (Table 3 and Figure 1).

Among female patients undergoing BCL surgery due to primary extensive manifestation ($n=10$), 30% experienced recurrence during follow-up after a median of 4 months (IQR 4; 7). This was substantially higher than in the groups operated due to lack of healing ($n=42$, 19%) after a median of 6 months (IQR 4; 9), or previous recurrence after elective surgery ($n=36$, 16%) after a median of 24 months (IQR 5; 26) (Figure 2A).

Interestingly, this pattern was not observed in male patients, where the best outcomes were seen in the group with primary extensive manifestation, showing a 12% recurrence rate 5 years post-surgery (Figure 2B).

Subgroup analysis

Females who experienced recurrence after BCL surgery were more likely to be comorbid (13% ASA 3 vs. 1.4% ASA 3 in the

non-recurrence group). Although not statistically significant, female patients who developed recurrence had a higher BMI (29.4 vs. 25.8 in the non-recurrence group) and a significantly larger proportion were active smokers (20% vs. 2.8%, $P=0.04$) (Table S1).

DISCUSSION

To our knowledge, this is the largest series of female PSD patients treated with BCL surgery presented to date. In fact, we encountered difficulties identifying any studies specifically reporting surgical PSD outcomes in female patients. We were able to compare female patients with a male cohort treated over the same period and subdivide them by indication for surgery, revealing that female patients are at an increased risk for prolonged healing and perhaps also recurrence compared to male patients.

Recurrence

Recurrence rates for off-midline closure techniques such as BCL surgery vary widely. However, the rates presented in this study, particularly among women, seem higher than expected compared to international literature [8]. Female gender as a risk factor for recurrence has previously been suggested [15–17]. When examining patients overall, we observed the expected trend. Those patients who have previously experienced surgical failure (recurrence or lack of healing) are

TABLE 3 Surgical outcomes compared between genders.

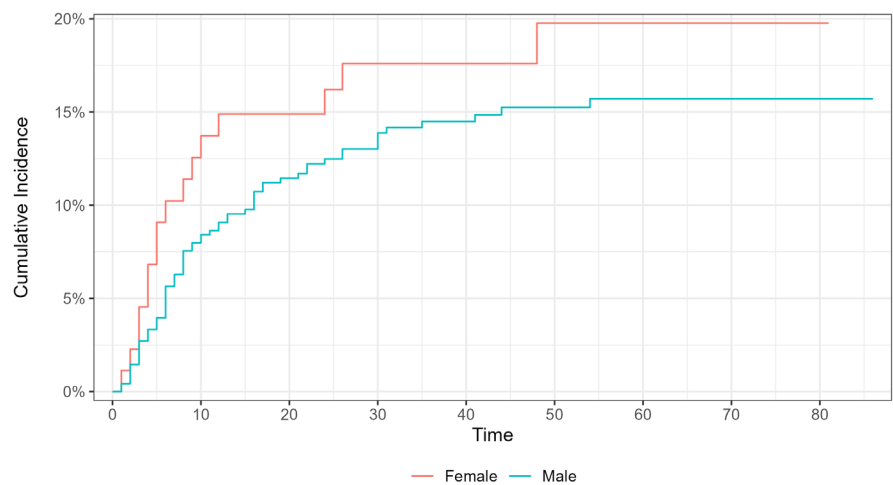
Characteristic	Overall (n = 568) ^a	Female (n = 88) ^a	Male (n = 480) ¹	RR (95% CI) ^b	P value
Follow-up (months)	48 (28, 67)	50 (33, 67)	47 (27, 67)		0.5 ^c
Healing					
Primary healing	412 (76%)	57 (68%)	355 (78%)		0.044 ^d
Prolonged healing	127 (24%)	27 (32%)	100 (22%)	1.46 (1.02–2.09)	
Missing	29	4	25		
Time to complete healing (months)	3.00 (3.00, 4.00)	3.00 (3.00, 5.00)	3.00 (3.00, 4.00)		0.2 ^c
Missing	29	4	25		
Clinical contacts	6.0 (5.0, 8.0)	6.0 (5.0, 8.0)	6.0 (5.0, 8.0)		0.5 ^c
Missing	62	10	52		
Recurrence after cleft lift	83 (15%)	16 (18%)	67 (14%)	1.30 (0.79–2.14)	0.3 ^d
Time to recurrence (months)	8 (4, 16)	6 (4, 11)	8 (5, 17)		0.3 ^c

^aMedian (interquartile range), n (%).

^bRisk ratio with 95% confidence interval and male as reference with value 1.

^cWilcoxon rank sum test.

^dPearson's chi-squared test.

FIGURE 1 Cumulative incidence plot of recurrence in female (red) versus male (blue) patients. The y-axis shows the cumulative proportion of patients with recurrence; the x-axis shows time in months.

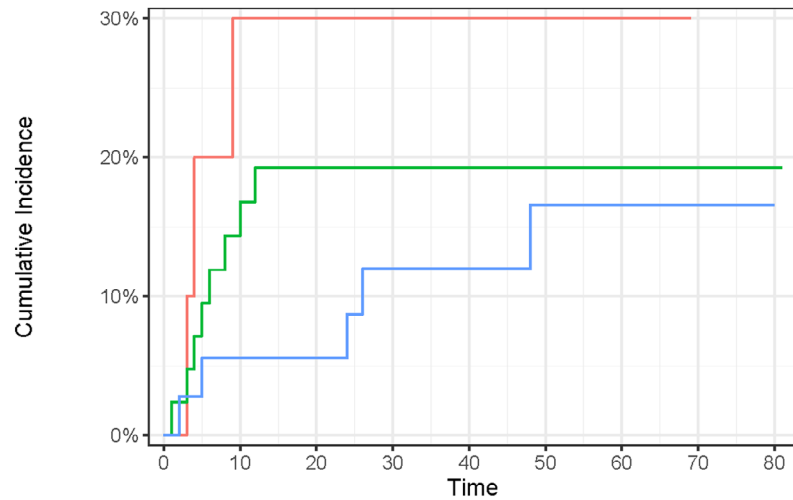
	Female					Male				
At Risk	88	75	66	54	48	37	27	13	3	
Events	0	12	13	15	15	16	16	16	16	
At Risk	480	422	352	304	248	198	145	90	32	
Events	0	40	53	62	64	66	67	67	67	

at an increased risk of repeat recurrence after BCL surgery, whereas patients with primary extensive manifestation have the best prognosis. However, the opposite seems to be true for female patients. The substantial risk of failure is reflected in the fact that 89% of this female cohort underwent BCL surgery due to either lack of healing after elective

surgery or recurrent PSD. This finding cannot be explained by age, disease duration, ASA score or BMI as these factors were similar.

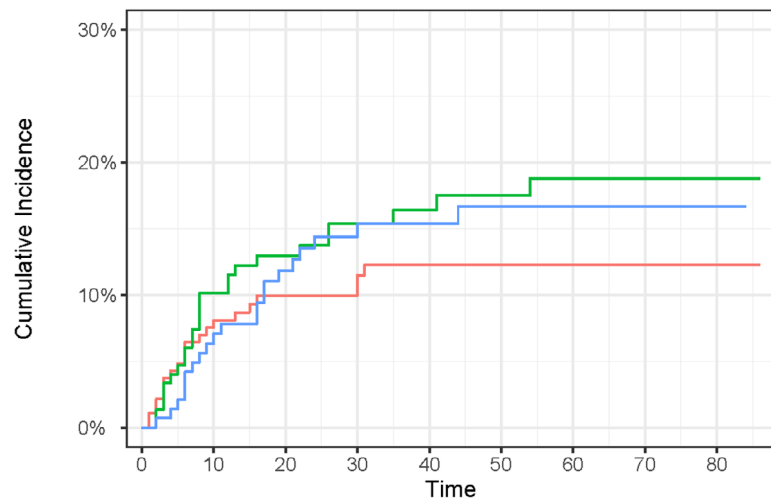
However, although this is a large cohort, women with recurrence represent relatively small numbers and point estimates are subject to great insecurity. As such, the 30% higher risk of recurrence

(A)



	0	10	20	30	40	50	60	70	80
Extensive manifestation (no previous surgery)	10	7	5	5	4	2	2	0	0
Healing problems after previous surgery	42	35	30	24	21	17	15	9	2
Recurrence after previous healing	36	33	31	25	23	18	10	4	1
Events									
Extensive manifestation (no previous surgery)	0	3	3	3	3	3	3	3	3
Healing problems after previous surgery	0	7	8	8	8	8	8	8	8
Recurrence after previous healing	0	2	2	4	4	5	5	5	5

(B)



	0	10	20	30	40	50	60	70	80
Extensive manifestation (no previous surgery)	187	166	134	118	94	71	50	26	8
Healing problems after previous surgery	150	128	114	99	77	67	55	44	18
Recurrence after previous healing	143	128	104	87	77	60	40	20	6
Events									
Extensive manifestation (no previous surgery)	0	15	18	20	21	21	21	21	21
Healing problems after previous surgery	0	15	19	22	23	24	25	25	25
Recurrence after previous healing	0	10	16	20	20	21	21	21	21

FIGURE 2 (A) Cumulative incidence plot of recurrence in female patients ($n=88$) compared by indication: red, primary extensive manifestation; green, lack of healing; blue, recurrence. The y-axis shows the cumulative proportion of patients with recurrence; the x-axis shows time in months. (B) Cumulative incidence plot of recurrence in male patients ($n=480$) compared by indication: red, primary extensive manifestation; green, lack of healing; blue, recurrence. The y-axis shows the cumulative proportion of patients with recurrence; the x-axis shows time in months.

compared to male patients is statistically insignificant and should be interpreted as a trend.

We observed that female recurrences occurred earlier, which has been observed in other studies as well [17]. It is noteworthy that recurrences are less frequent and occur much later compared to both primary extensive PSD and non-healing wounds after elective surgery. This may be due to recurrences representing less widespread disease.

Among female patients, those who developed recurrence were more comorbid, heavier and more prone to smoking compared to those who did not develop PSD recurrence. Whether or not smoking is a risk factor for recurrence remains conflicted, as some studies find smoking to increase risk of recurrence [18] while others find it does not affect surgical outcome [19]. Compared to male patients, we found a significantly larger proportion of never-smokers among female patients. A limitation of this observation is that smoking status and history is based solely on information provided by the patient. When motivated for surgery, there is a substantial risk of incorrect information on the matter. Despite this, we still observed a 30% increased risk of recurrence among women.

Obesity has never been specifically examined as a risk factor for developing PSD; however, several studies identify increased BMI as a risk factor for developing recurrence [19–21]. Across genders we did not observe any difference in BMI. It may simply be that risk factors differ among genders.

Prolonged healing

The markedly increased risk of prolonged healing in female patients with PSD was unexpected. Unfortunately, lack of healing is not an uncommon situation. A recent UK-based multi-centre study reported—across the multiple therapies applied—that 25% of patients had not healed their surgical wounds at 6 months' follow-up, and among unhealed patients after excisional surgery 12% had still not returned to normal activity [22]. However, this study did not examine gender-specific differences.

Female patients with PSD in this study smoked (previously and currently) significantly less than their male counterparts and yet had a 46% increased risk of prolonged healing. On comparing women who achieved primary healing with those with prolonged healing, no difference in smoking habits was found.

Gender-based approach

Traditionally, medical research and treatment approaches have largely been gender-neutral, assuming uniformity in disease manifestation and treatment response across genders. However, our data show that female patients with PSD have a 30% increased risk of developing recurrent PSD and a 46% increased risk of developing prolonged healing after BCL surgery compared to male patients. Whether this finding is specific to BCL or off-midline procedures remains to be studied. However, in a review of a historical cohort of 3407 soldiers treated

with the Gips minimal surgery technique, the relative risk of recurrence was found to be double among women ($n=653$) [17]. This suggests the need for a gender-specific approach in the management of PSD. Based on these data, excisional surgery in female PSD patients should be reserved for only a small group of patients, where other options are no longer available. Further, as 89% of patients included in this study presented with advanced PSD after a surgical failure/recurrence, it seems intuitive that female patients should be treated by dedicated specialists at index surgery to decrease surgical burden caused by poor technique or lack of routine as is so often the case [23].

Strengths and limitations

Our study benefits significantly from a large population size within a monotherapeutic treatment framework. We do acknowledge that the size of the female population is still relatively small, limiting the generalizability of conclusions. The rigorous categorization of patients enables us to examine subcategories individually, even though the number of patients in the primary extensive manifestation group is quite small. Another key strength is the elimination of recall bias, as our study establishes the temporal sequence between exposure and outcome without requiring participants to recollect past information. Data collection was conducted prospectively at baseline, ensuring the accuracy and reliability of the information.

However, our study also has several limitations. First, being a single-centre study, it reflects an 'in my hands' experience, meaning that our setup and patient selection might not be directly comparable to other settings. Additionally, determining the exact postoperative time to healing has been challenging, as patients may have healed before their scheduled outpatient clinic visits at 2 weeks and 3 months post-surgery. The prospective design also means that some patients may have been lost to long-term follow-up if they moved outside of Denmark, potentially missing some recurrence events for those treated elsewhere. This loss to follow-up could impact the validity and precision of our results. Nevertheless, due to diminishing recurrence rates over long-term follow-up, we estimate the number of missed recurrences to be minor, as movements within Denmark are fully captured by our health data registry. Our approach holds a risk of false positive results; however, with a CI of 95% we consider the risk minor. Finally, the relatively small size of the female pilonidal patient group limited our ability to perform detailed subcategorization.

CONCLUSION

In this study, we identified a new at-risk category: female PSD patients should be handled with care. Our study shows that female patients with advanced PSD have an increased risk for prolonged healing and perhaps also recurrence after BCL surgery compared to male PSD patients. The differences cannot be attributed to age, disease duration or BMI. Surprisingly, the prognosis is worse when undergoing surgery due to primary extensive manifestation. Extensive

surgery should be reserved for the few cases where no other options are available, and index surgery should preferably be conducted by a dedicated specialist surgeon.

AUTHOR CONTRIBUTIONS

I. K. Faurischou: Formal analysis; validation; writing – original draft; writing – review and editing. **J. L. Ankersen J:** Investigation; resources; validation; writing – review and editing. **Pedersen N:** Investigation; resources; validation; writing – review and editing. **M. J. Sørensen:** Conceptualization; investigation; writing – review and editing. **M. L. Friis:** Conceptualization, investigation; writing – review and editing. **A. G. Pedersen:** Conceptualization; investigation; writing – review and editing. **D. Doll:** Conceptualization, resources, validation, writing – review and editing. **S. Haas:** Conceptualization; methodology; investigation; resources; validation; writing – original draft; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

The author(s) have no affiliations or financial involvement with any organization or entity with financial interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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