



Minimally invasive techniques in the management of pilonidal disease

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Abstract

Background Pilonidal sinus disease (PD) is a chronic condition involved in natal cleft. Excision surgery carries equally morbid course of recovery to that of disease itself. Minimally invasive treatments therefore have been developed to minimise morbidity and improve healing rates. This review looks at the literature on effectiveness of endoscopic pilonidal sinus treatment (EPSiT) and compares that of the other minimally invasive techniques in practice.

Methods MEDLINE, EMBASE, Cochrane and CINAHL databases were searched to look at the peer-reviewed articles on minimally invasive treatments on PD. Primary endpoint was to determine complication rates. Data were pooled using random effect model. Heterogeneity among studies was estimated with χ^2 tests. Statistical analysis was performed with Review Manager Version 5.1.2.

Results Out of 371 papers, ten were retrieved for full appraisal. One randomised clinical trial (RCT) and four case series presented retrospective data on EPSiT. Five RCTs were on alternative minimally invasive treatments. Complication rate, return to work, wound healing rate and pain scores were superior in minimally invasive treatments compared to excision surgery. There was no statistically significant difference in complication rate or return to work in EPSiT compared to that of alternate minimally invasive techniques.

Conclusion Minimally invasive treatments of pilonidal disease were found to be safe and effective compared to conventional techniques. It is also demonstrated that EPSiT is a safe alternative with a low short-term complication rate. Further randomised controlled trials are required to more accurately define its effectiveness and closely evaluate the side effect profile.

Keywords Pilonidal sinus · Pilonidal disease · Abscess

Background

Pilonidal sinus disease (PD) can present as an acute abscess or a painful sinus tract with chronic discharge. It is most

commonly seen in the sacro-coccygeal area around the natal cleft. The reported incidence is around 25 per 100,000 with a male to female ratio between 3:1 and 4:1 [1]. There can be considerable impact on quality of life due to pain, amended activities and time off work. The cost of treatments depends on the initial treatment and post-treatment costs, including recurrent disease and re-treatments [2].

PD was first described by Mayo in 1833 and subsequently by Andersson in 1847, although in its current description by Hodges in 1880 [3–5]. The aetiology, once considered congenital, is now understood to be principally acquired [6, 7].

Historically, Lord and Millar suggested a minimally invasive approach with elliptical excision and cavity cleaning with brushes [8, 9]. This was followed by Bascom's method of excision of individual openings and tracts utilising a lateral approach [10]. Karydakos hypothesised that by making the natal cleft an open portal for hair entry by leaving an open wound and by causing defects in a sutured midline wound or with holes from sutures, further sinuses may form [11].

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Minimally invasive approaches include sinotomy, sinusectomy, trephining and more recent advent of video assisted and endoscopic pilonidal sinus treatment (EPSiT). Hair removal has been attributed to aiding prevention of recurrence, with interesting successful advances in this area potentially influencing and supporting minimally invasive treatments in the future [12]. Progression of technology and conservative techniques has led to the development of video-assisted ablation and EPSiT.

Endoscopic pilonidal sinus treatment

Endoscopic treatment of PD was initially described by Meirero in 2013 [13]. The technique utilises a specially designed optical “Fistuloscope” inserted through a small circular incision around the pilonidal sinus opening. There are two parts to the operation, the diagnostic phase and operative phase. During the diagnostic phase, the main tracts are identified with the fistuloscope. Once defined under direct vision, the operative phase can commence. A monopolar electrode is inserted through the fistuloscope to enable electrocautery of the sinus tracts of the affected area. Debridement of the fistula paths and removal of necrotic material is carried out with the endo-brush. At this stage, the causative hair may be identified and removed. Copious concurrent irrigation of the sinus tract with glycine is carried out. Following the procedure, the wound is left open, and the patient is instructed to irrigate the channel daily with saline for 2 weeks. The key distinguishing feature of EPSiT compared to traditional excision is that it is performed under continuous direct vision with a small incision.

This review aims to identify data relating to endoscopic treatment and to allow the comparison of endoscopic treatments with other minimally invasive treatments. This was to allow safety analysis by considering complication rates and to identify benchmark levels for further analysis and comparison to other treatment options.

Methods

Literature search strategy

The databases of MEDLINE, EMBASE, Cochrane and CINAHL for the period 1950 to April 2017 were searched using a combination of Medical Subject Heading (MeSH) and key words below:

‘randomised controlled trial’, ‘controlled clinical trial’, ‘placebo’, ‘crossover procedure’, ‘double-blind procedure’, ‘single-blind procedure’, ‘randomly’, ‘trial’,

‘groups’, ‘placebo’, ‘pilonidal disease’, ‘pilonidal tract’, ‘pilonidal sinus’, ‘pilonidal’, ‘minimally’, ‘endoscopic’, ‘epsit’, ‘video’, ‘video assisted’, ‘sinusectomy’, ‘trephine’, ‘sinotomy’, ‘laying open’, ‘de-roofing’, ‘excision’, ‘primary closure’, ‘flap’.

Selection criteria

Only peer-reviewed articles published in English were considered. Inclusion criteria were initially confined to RCTs. However, with just one randomised trial on EPSiT identified, this area was expanded to include retrospective reviews of case series. Any case reviews limited to a single case reports were excluded. Key meta-analysis papers on excision surgery were identified as part of the analysis for comparison with data from previous meta-analysis.

Data extraction

Two authors performed the literature search and also reviewed the articles for suitability and extracted the end points. Two authors independently reviewed the studies to assess methodological quality of the trials according to PRISMA guidelines [14] (Fig. 1). Disputes were settled by mutual consent between all authors. Clinical studies were included only where providing a clear description of the operative technique used and transparently presented data on surgical outcome, follow-up, morbidity and recurrence rates.

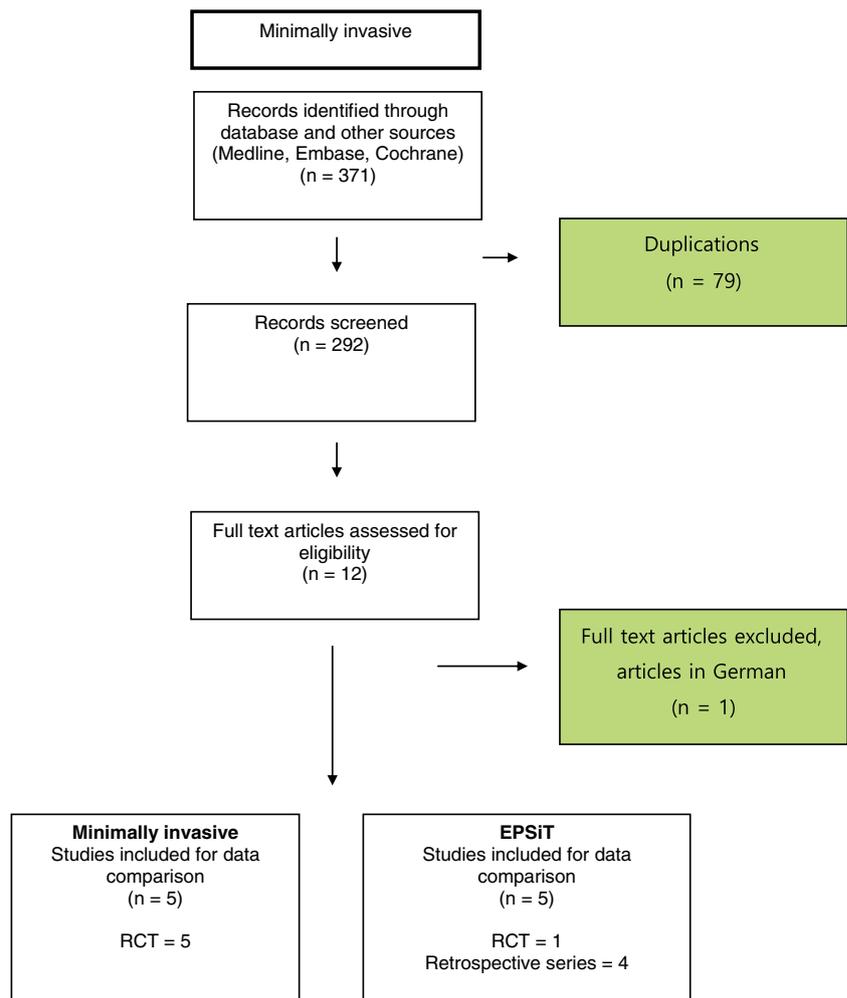
Endpoints

Primary endpoint was to determine complication rate using EPSiT. The secondary endpoints were to determine recurrence rate, return to work (days), wound healing time and pain.

Statistical analysis

Standard descriptive statistics (reported as means with 95% confidence intervals) were used to summarise demographic and baseline data of the recruited patients from all eligible studies. Meta-analysis of reported outcomes when reported was performed on—complication rate and recurrence rate. Relative risk or mean difference was used as a summary statistic.

Heterogeneity among studies was estimated with χ^2 tests, which was reported as the I^2 statistics to estimate the percentage of total variation across studies, due to heterogeneity rather than chance. Dependent heterogeneity was determined by use of a fixed-effect or random effect model. All statistical analysis was conducted with Review Manager Version 5.1.2 (Cochrane Collaboration, Software Update, Oxford, United Kingdom).

Fig. 1 PRISMA flowchart—literature search

Results

Out of 371 potentially relevant papers identified and screened, ten papers were retrieved for full critical appraisal with six clinical trials included in the review. One RCT and four case series presented retrospective data on video-assisted ablation and endoscopic treatment, as summarised in Table 1 [13, 16–19]. Five RCTs on alternative minimally invasive treatments (sinusectomy or sinotomy) were identified to enable comparison with excision treatment of complication and recurrence rates and to identify baseline results to compare this novel treatment modality in Table 2 [20–24]. Two published articles, Testini and Fazeli, were identified as being appropriate for comparison [25, 26]. Due to the retrospective case series not having a control group or randomisation, meta-analysis was not applied to this data set.

Study characteristics

Sample sizes in the trials ranged from 9 to 144 participants, with a total patient number of 820 in the clinical trials. A total

of 142 EPSiT patients were included with 76 of these in a clinical trial, as summarised in Table 1.

Characteristics of surgical intervention

Five of the eight trials compared the minimally invasive techniques of sinusectomy or sinotomy with excision treatment [20–24], one clinical trial compared EPSiT with excision treatment [19] and two compared open healing with primary closure after excision treatment and was used for comparison [25, 26]. Four papers were identified presenting retrospective case series data with no control group and included due to the limited number of published clinical trials on EPSiT ($n = 1$) [15–18].

Complication rate

Five studies reported complication rates [19–22, 24]. Mohamed et al. in 2005 [23] reported only on blood loss so was not included in the complication analysis. The proportion meta-analysis

Table 1 Literature on EPSiT

	Meinero 2014	Milone 2014	Chia 2015	Gasloli 2015	Milone 2016	Total
Interventions	EPSiT	Video Assisted Ablation	EPSiT	EPSiT	EPSiT VS BASCOM LIFT	
Study type	RCS - no control	RCS - no control	RCS - no control	RCS - no control	RCT	
No. of cases	11	27	9	19	76	142
Wound healing time (months)	1	0.5	1.5	NR	NR	
Recurrence rate	0/11 (0%)	1/27 (4%)	1/9 (11%)	1/19 (5%)	3/76 (4%)	6/142 (4%)
Complication rate	0/11 (0%)	1/27 (4%)	3/9 (33%)	0/19 (0%)	4/76 (5%)	8/142 (6%)
Time to return to work (days)	3.5	3	5	1	1.6 mean [1.7 SD] vs 8.2 [3.9] days $P < .001$	
Median follow-up (months)	6 (1–9)	12	2.5 (1–5)	3	12	
Length of stay	Day case	NR	None required prolonged stay	Same or next day	NR	
Pain (VAS)	1.9	0.5–1.1	NR	2.8	1.3 (1.3) at 1 week	

NR not reported, RCS retrospective case series

plot is shown in Fig. 2. Data were pooled using a random-effect model. Heterogeneity of $I^2 = 35\%$ was calculated, and overall RR of 0.59 (0.16–1.70) favoured a minimally invasive method, comprising sinusectomy, sinotomy or EPSiT, compared to excision treatment \pm local flap. The single randomised trial comparing EPSiT demonstrated a 5% complication rate, and comparison of complication rate for the EPSiT data set including retrospective data (total 8/142, 6%) directly with sinusectomy and sinotomy data (8/235, 3.4%) failed to show a significant result when compared using Chi-squared test.

Recurrence rate

Six studies reported recurrence rates [19–24]. The proportion meta-analysis plot is shown in Fig. 3. Data were pooled using a random-effect model. Heterogeneity of $I^2 = 20\%$ was calculated, and overall RR of 0.35 (0.17–0.74) favoured a less invasive method, comprising sinusectomy, sinotomy or EPSiT, compared to excision treatment \pm local flap. The single randomised trial comparing EPSiT demonstrated a 4% recurrence rate and comparing recurrence rate for the EPSiT data set including retrospective data (total 6/142, 4%) directly with sinusectomy and sinotomy data (16/213, 7.5%) failed to show a significant result when compared using Chi-squared test.

Return to work (days)

Two studies reported as mean \pm SD [19, 21], and two as median with range [20, 24]. Milone et al. [19], comparing EPSiT with excision treatment, found a significant difference ($P < 0.001$) of a mean of 1.6 days (1.7 SD) vs 8.2 days (3.9 SD), respectively. Karakayali et al. [21], comparing unroofing

and marsupialization with excision, found a significant difference ($P < 0.001$) of a mean of 11.2 days (5.8 SD) vs 17.9 days (9.3 SD), respectively. Gencosmanoglu et al. [20], comparing modified lay open with excision, found a significant difference ($P < 0.001$) of a median of 3 (2–8) days vs 21 (14–63) days. Nordon et al. [24] failed to show a significant result. Study heterogeneity meant results could not be pooled, but three of the four trials found significantly different results favouring minimally invasive treatment with the EPSiT data set demonstrating a mean return to work of 1 to 5 days vs 3, 11 and 18 days for the alternative minimally invasive treatments.

Wound healing time

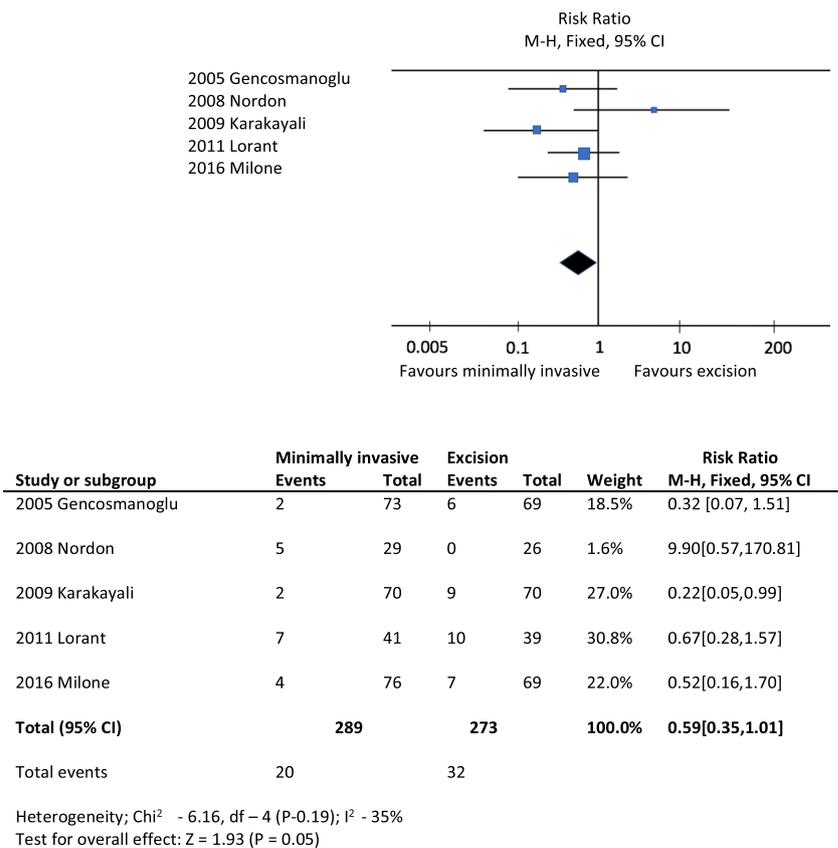
Five studies reported wound healing time [19–21, 23, 24]. This was defined by McCallum et al. [27] as full epithelialisation over the wound. One of these [23] presented the data, as a three-dimensional graph without defining whether mean or median data was displayed, so is not discussed any further. Two papers presented median data [20, 24]. The first [20] 7 (3–16) weeks, for lay open techniques compared with 2 [2–9] weeks for excision and primary closure; the second [24] presented imprecise data stating the majority of wounds (24 of 29 simple Bascom's and 21 of 26 Bascom's cleft) healing by removal of sutures at 10 to 13 days. Though further data was published on the remaining cases, the lack of clarity on the majority of patients means it shall not be discussed further. Two papers presented mean and SD data [19, 24]. Unroofing and marsupialisation demonstrated slower healing (43.8 mean 20.9 SD, days) compared to excision and flap closure (23.7 mean 11.2 SD, days). The EPSiT paper also presented mean (SD), of 1.6 (1.7) days vs 8.2 (3.9) days for the Bascom cleft lift procedure. Heterogeneity meant results could not be pooled.

Table 2 Literature on minimally invasive methods

Interventions	Gencos manoglu 2005		Mohamed		Norton		Karakayali 2009		Lorant 2011	
	S	E+C	S	E+C	BS	BC	S	E+C	S	E+C
No. of cases	142		83		55		140		80	
Wound healing time	7(3–16)	2(2–9)	18	9	4 weeks (3–35)	NR	43.8 mean (Range 15–122)	23.7 mean (Range 14–96)	NR	NR
Rate of recurrence	1/73 (1.4%)	12/69 (17.4%)	1/29	3	2/24 (8%)	0/26 (0%)	0/70 (0%)	1/70 (1.4%)	1/41	4/39
Complication rate	2/73 (2.7%)	6/69 (13%)	NR	NR	5/29 (18%)	0/26 (0%)	2/70 (2.9%)	9/70 (12.9%)	7/41 (17.1%)	10/39 (25.6%)
Time to return to work median	3 (2–8)	21 (4–16)	NR	NR	2 week (1–16)	2 week (0.5–4)	11.2 mean (Range 5–35)	17.9 mean (Range 2–46)	NR	NR
Clac mean	4									
Median follow-up (months)	47 (24–69)		15		36 (6–48)		15 (12–26)		12 months	
Mean	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Length of stay	NR	NR	20.30 (3) 15–25	Mean SD range 90.2 (3.6) 85–95	70.8 (3.2) 65–75	NR	1.3 mean (Range 1–3)	1.6 mean (Range 1–5)	NR	nR
Pain (VAS)	NR	NR	NR	NR	NR	NR	1 week 6.1 mean	4.4 mean 1.9 SD	12.7 (from 70) (range 0–51)	14.1 (0–59)

S sinusectomy/sinotomy, E + C excision + closure, E + O excision and open healing, BS Bascom’s simple, BC Bascom’s cleft

Fig. 2 Complication rate



Pain

Three papers presented data on pain levels [19, 21, 22]. Pain levels on the visual analogue scale for unroofing and marsupialisation were 6.1 mean 1.7 SD at 1 week, compared to 4.4 mean 1.9 SD for excision and primary closure [22] and a mean of 14 (range 0–59) for lay open compared with 12.7 (range 0–51) for excision and primary closure [21, 22]. The EPSiT paper displayed results in a bar graph, concluding patients in the EPSiT group expressed less pain at 1 h, 6 h, 1 day, 1 week and 1-month post-surgery, all with statistical significance [19].

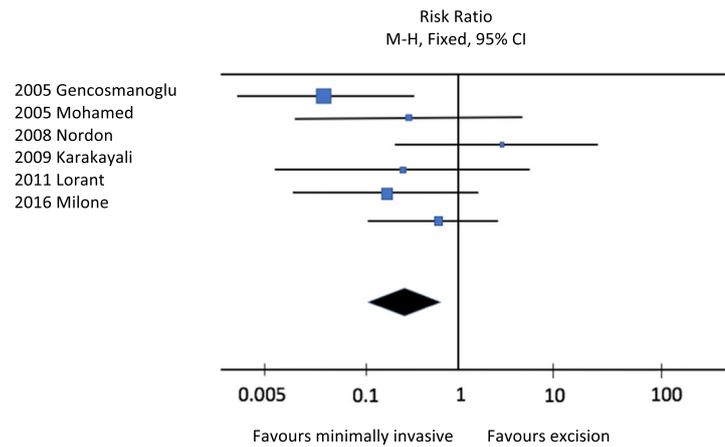
Discussion

With this review, we set out to establish that the complication rate of minimally invasive treatments was comparable to that of excision surgery. The previous literature has been assessed with data from both retrospective and RCTs. The major issue with the published data relates to the retrospective nature being subjected to selection bias, and the clinical trial being potentially biased as being funded by the manufacturer of the endoscopic device.

The meta-analysis (Table 2) comparing sinusectomy or sinotomy with en-bloc excision and primary closure has provided mixed results [20–24]. Varied results for return to work were found, with complication rates not proving to be significantly different. Rate of recurrence was not significant compared to open excision, but favoured conservative approaches compared to primary closure. A conservative approach gave improved post-operative pain compared to both open and primarily closed excisions. Although favourable results have been noted in some aspects of conservative approaches, the standard of care remains excision surgery. The issue remains that the reconstructive procedures that flatten the natal cleft can cause a cosmetic deformity deemed unacceptable to patients.

There is little published data about the potential difference in disease process associated with PD in women. The classical pattern of a male with a hairy natal cleft and back is not always seen in affected females. A research team in Turkey investigated the potential causation between serum hormones and PD, concluding that raised serum prolactin levels were found in women but not in men. The prolactin level in females with PD was significantly higher than those of females in the control group without PD ($P < 0.05$). There was no statistically significant difference in the male group

Fig. 3 Recurrence rate



Study or subgroup	Minimally invasive		Excision		Weight	Risk Ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total		
2005 Gencosmanoglu	1	73	12	69	48.4%	0.08 [0.01, 0.59]
2005 Mohamed	1	26	3	28	11.3%	0.36[0.04, 3.24]
2008 Nordon	2	24	0	26	1.9%	5.40[0.27,107.09]
2009 Karakayali	0	70	1	70	5.9%	0.33[0.01,8.04]
2011 Lorant	1	41	4	39	16.1%	0.24 [0.03,2.04]
2016 Milone	3	76	4	69	16.4%	0.68[0.16,2.94]
Total (95% CI)		310	301		100.0%	0.35[0.17,0.74]
Total events	8		24			

Heterogeneity: Chi² = 6.25, df = 5 (P=0.28); I² = 20%
 Test for overall effect: Z = 2.77 (P = 0.006)

[28]. The paper suggests a possible endocrine difference in females with the disease.

Previous data from meta-analysis has demonstrated the advantages of conservative surgery. This is in keeping with guidelines published by the Italian Society of Colorectal Surgery who concluded that minimally invasive techniques should be considered in treatment of pilonidal disease [29]. Advantages include shorter operative time and time to discharge with impact on resource management in both primary and secondary care. Another area of potential interest is use of laser hair removal as an adjunct to treat recurrent or even primary PD.

This novel minimally invasive approach demonstrates a progression of conservative techniques that has initially proven superior to both excision and other conservative methods, the promising early results and ease of application has stimulated interest in EPSiT.

Conclusion

MITs in treatment of PD were found to be safe and effective compared with conventional techniques. It is demonstrated at this stage that EPSiT is safe, with a low short-term

complication rate, comparable to published results. The literature presented one clinical trial comparing EPSiT with excision, and four retrospective case series. Follow-up for 1 year is likely to prove representative of overall recurrence, with Gips et al. in 2008 reporting a disease-free probability estimate at 1 year of 93.5% [30]. Further randomised controlled high-powered trials are required to more accurately define its effectiveness and closely evaluate the side effect profile, especially on long-term follow-up.

Compliance with ethical standard

Conflict of interest The authors declare that they have no conflict of interest.

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