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ORIGINAL ARTICLE

Pit excision with fibrin glue closure versus lateralizing flap procedures in the management of pilonidal sinus disease in adolescents: a 14-year cohort study

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Abstract

Introduction Pilonidal sinus disease (PSD) arises in the hair follicles of the gluteal cleft with many cases occurring during adolescence. Early studies of pit excision with fibrin glue closure (PEF), a minimally invasive procedure for the management of chronic PSD, suggest it is safe and effective with similar results to traditional lateralizing flap procedures (LFP), without the need for extensive tissue excision and associated complications. However, these studies lack large sample sizes and prolonged follow-up.

Methodology All children undergoing primary operative procedures for chronic PSD from May 2009 to February 2022 received either a PEF or a LFP. Recurrence and complications rates alongside their demographic and disease severity data were compared using statistical and Kaplan–Meier analyses.

Results Seventy-eight children had 33 primary PEF and 45 primary LFP procedures with a median follow-up of 2.21 and 2.52 years, respectively. Demographic and disease severity indicators were similar between groups ($p > 0.05$). The overall recurrence rate in each cohort was 3% for PEF and 11% for LFP, respectively ($p = 0.2346$). The all-cause repeat intervention rate was 12% and 49% in the PEF and LFP cohorts, respectively ($p = 0.0007$). Kaplan–Meier analysis showed a reduction in the requirement of re-operation in the PEF cohort ($p = 0.0340$). Operative time was significantly decreased in the PEF cohort compared to the LFP cohort ($p < 0.0001$). Wound dehiscence was significantly decreased in the PEF cohort compared to the LFP cohort (3% vs 31%; $p = 0.0026$).

Conclusion This 14-year study is the largest pediatric-focused cohort utilizing PEF to manage PSD and demonstrated clinically relevant decreases in symptom recurrence alongside significantly decreased rates of complications and further surgical intervention compared to traditional LFP techniques. We conclude that PEF is a viable minimally invasive technique in the management of pediatric PSD.

Keywords Pilonidal sinus · Fibrin glue · Children · Operation

Introduction

Pilonidal sinus disease (PSD) arises in the hair follicles of the gluteal cleft with many cases occurring during adolescence [1]. Traditionally, the gold standard operative management of PSD in both adults and children has been lateralizing flap techniques, such as those of Kardayakis [2], Bascom [3], and Limberg [4]. These lateralizing flap procedures (LFP) aim to reconfigure the gluteal cleft following pilonidal pit excision using surgical closure of the wound with a skin flap [5].

Minimally invasive techniques in the management of PSD are relatively recent developments [6] and are emerging as alternatives to traditional LFP. Fibrin glue techniques are a promising example whereby fibrin glue is used to fill an excised pilonidal cavity. This invokes and maintains hemostasis in the wound, as well as promoting wound healing [6]. This is commonly known as pit excision with fibrin glue closure (PEF) [6].

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A 2017 Cochrane review evaluating the use of fibrin glue in the management of PSD in adults showed promising early results [7]. Early evidence suggests that fibrin glue techniques are a safe and effective minimally invasive procedure with similar results to traditional LFP techniques in adolescents, without the need for extensive tissue excision and associated complications [6, 8, 9]. Studies detailing the long-term outcomes of fibrin glue techniques and with larger sample sizes are missing in the literature, especially those focusing on pediatric patients [10].

We have previously published our initial experience using a fibrin glue closure technique (PEF) [6] and now present our findings of a subsequent study examining the outcomes of using PEF in children in comparison to traditional LFP procedures to manage chronic PSD at our institution over a 14-year period.

Methodology

Study design

This is a retrospective comparative cohort study of all children undergoing primary operative procedures for chronic PSD from May 2009 to February 2022 at our institution, identified via the hospital's theater registry. Patients who had previous surgical procedures for chronic PSD were excluded. All patients had a minimum of 12-month follow-up.

This study had two comparative arms each utilizing different primary operative techniques: one using PEF, and the other using traditional lateralizing flap procedures (LFP). The PEF technique was performed as per our previous study [7]. Briefly, the PEF technique has three steps: (1) excision of the pilonidal sinus and pit with a fine blade (#number 65 blade, Swann-Morton, Sheffield), (2) curettage with a cytology brush, ensuring that the entire hair nest is removed, and (3) the cavity is filled with Tisseel™ (Baxter UK, Thetford, UK). Postoperatively, we place a simple dressing and review routinely in the clinic setting. The majority of LFPs were performed as adiposal lateral flaps [11, 12] with the remainder as Bascom flaps [3] or Limberg flaps [4], with similar post-operative follow-up to patients receiving PEF. Two surgeons, who were the only surgeons doing procedures for pilonidal disease at our institution, performed both PEF and LFP procedures. This study followed up all patients from the previous study, except 3 patients (who received LFPs) as we were unable to access this historical data.

Outcome measures and statistical analysis

We utilized a triple-metric methodology for our outcomes to assess procedure success. The primary outcome measure was "overall recurrence" rate at the end of follow-up, with recurrence being defined as the documented recurrence of symptoms outside of the initial healing period following treatment. The secondary outcomes were the "initial procedure recurrence" and "all-cause repeat intervention" rates. Initial procedure recurrence is defined as the documented recurrence of symptoms that required repeat procedures after the initial procedure for chronic PSD, excluding those precipitated by surgical complications. All-cause repeat intervention rate is defined as the need for further intervention following the primary procedure for any cause; for example, this may be recurrence requiring further treatment or procedures to manage subsequent complications. As such, any wound infections, wound dehiscence, or other surgical complications were also recorded.

Disease severity was compared between surgical techniques using the number of pilonidal pits and the presence of an abscess as proxies. Patients' demographic data for age at operation, gender, weight, and body mass index (BMI) were also compared between cohorts. Follow-up was considered to finish once a patient's transition to adult care services was documented, or if this was not documented, once they reached 16 years of age (when transition to adult care would be expected).

This study was reviewed and approved by the hospital Clinical Audit and Effectiveness Committee. Data is presented as percentages or median (range). Statistical comparison was performed using a Mann–Whitney *U* test for continuous non-parametric variables and a Fisher's exact test for categorical data, alongside Kaplan–Meier survival curve analysis with Log rank testing for survival analyses (GraphPad Prism version 9.2.0 for MacOS, GraphPad Software, San Diego, California USA). A p value of < 0.05 was regarded as significant.

Results

Overview and demographics

Seventy-eight children (56% male) were identified as having primary surgical procedures for chronic pilonidal sinus disease, of which 33 had primary PEF and 45 had primary LFP. The median length of follow-up was 2.21 (1.00–5.82) and 2.52 (1.21–5.54) years for PEF and LFP, respectively. A diagram of patient and procedure distribution can be seen in Fig. 1. There were no significant differences in demographic and disease severity data between PEF and LFP cohorts ($p > 0.05$, all variables; see Table 1).

Recurrence of symptoms and survival analysis

The overall recurrence rate in each cohort was 3% for PEF and 11% for LFP, respectively ($p = 0.2346$), with

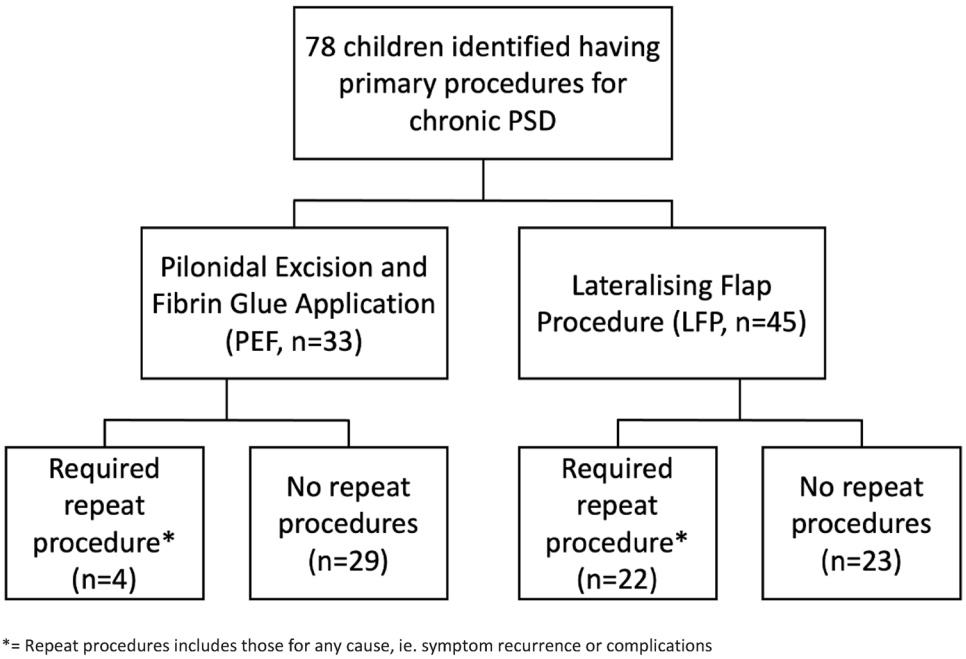

Fig. 1 Flowchart diagram of patient and procedure distribution *Repeat procedures includes those for any cause, i.e., symptom recurrence or complications

Table 1 Demographic and disease severity data for the PEF and LFP cohorts

Variables	PEF cohort ($n=33$)	LFP cohort ($n=45$)	Statistical significance (p value)
Median age (years; range)	15 (12–17)	15 (12–17)	>0.05
Gender (% male)	58%	56%	>0.05
Median weight (kg; range)	71 (53–136)	74 (50–105)	>0.05
Median BMI (range)	25 (18–39)*	26 (18–43)*	>0.05
Median number of pits (range)	3 (1–7)	2 (0–5)	>0.05
Presence of an abscess (% present)	36%	20%	>0.05

*BMI was able to be calculated for 82% and 69% of PEF and LFP patients, respectively, due to missing data

a median time to recurrence after primary procedure of 0.62 years for PEF vs. 0.27 years for LFP ($p=0.0012$). Patients undergoing primary PEF experienced initial procedure recurrence in 16% of cases compared to 33% of primary LFP patients ($p=0.1142$). The all-cause repeat intervention rate in the primary PEF cohort was 12% ($n=4$) compared to 49% ($n=22$) in the primary LFP cohort ($p=0.0007$).

Kaplan–Meier analysis with Log rank comparative testing for symptom recurrence at the 1 year and end of follow-up timepoints was non-significantly different between cohorts (both $p>0.05$; Fig. 2a and b). The rate of repeat surgery was significantly different at both 1 year and end of follow-up, showing a reduced probability requiring re-operation in the PEF cohort ($p=0.0402$ and $p=0.0340$, respectively; Fig. 2c and d).

Complications and additional data

Operative time was significantly decreased in the PEF cohort compared to the LFP cohort [21 min (15–30) vs. 65 min (31–90); $p<0.0001$). Wound infection was observed in 6% ($n=2$) and 9% ($n=4$) of patients for primary PEF and LFP, respectively ($p>0.05$). Three patients required exploration under anesthesia and washouts for wound infections in the LFP cohort, while the remainder of the wound infections recorded were successfully managed with oral antibiotics. Wound dehiscence was significantly decreased in the primary PEF cohort compared to the primary LFP cohort [3% ($n=1$) vs 31% ($n=14$); $p=0.0026$]. The single dehiscence in the PEF cohort and 6 in the LFP cohort did not require intervention; however, 8 patients required repeat procedures to correct wound

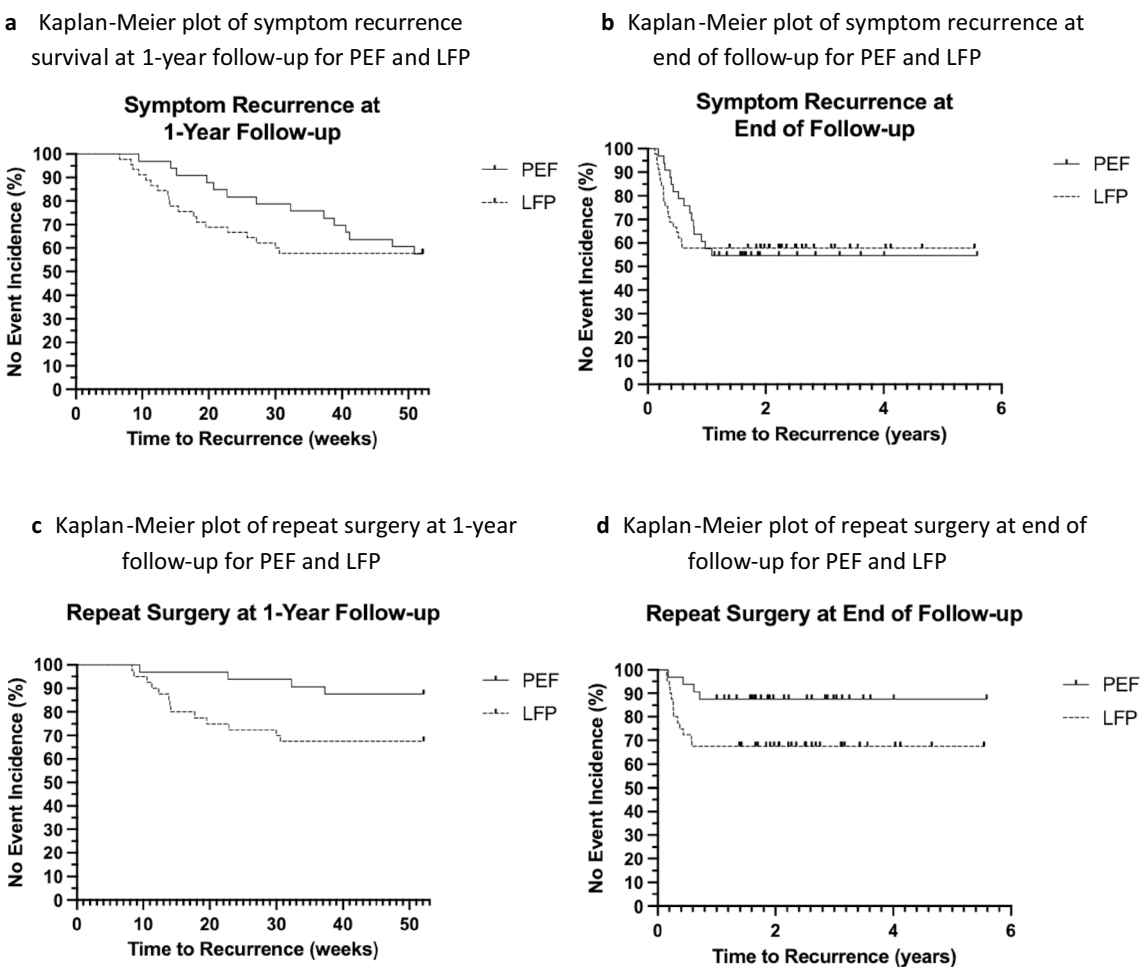

Fig. 2 Kaplan–Meier plots of symptom recurrence and surgical recurrence at 1 year and end of follow-up for PEF and LFP

dehiscence within the LFP cohort. No other complications were recorded.

Discussion

This 14-year comparative cohort study found similar overall and initial procedure recurrence rates for PEF and LFP, with trends suggesting improvements in recurrence with PEF, over the relatively long follow-up for pediatric pilonidal studies. The significantly decreased incidence of wound dehiscence in the PEF cohort compared to the LFP cohort is very promising [3% ($n=1$) vs 31% ($n=14$); $p=0.0026$].

Recurrence is an important issue in the management of PSD and is very common with 19% of all surgeries for PSD in Switzerland and Austria being repeat procedures [13]. Previous studies have shown primary recurrence rates of 15–26% for LFP [6, 14] and 6–17% for fibrin glue techniques [6, 8, 9] in pediatric patients. For comparison, a recurrence rate of 0.2% has been achieved with Bascom and Kardayakis LFP procedures in adults [15], suggesting an increased level of complexity in the management of pediatric patients. The overall recurrence rates observed in this study are slightly decreased compared to those reported for pediatric patients in the literature (3% and 11% for PEF and LFP, respectively, in this study) over a longer follow-up.

In this study, we utilized a clear definition of recurrence and our 3 distinct metrics to assess outcomes (overall recurrence, initial procedure recurrence and all-cause repeat intervention rates) to be transparent and allow the best assessment of morbidity and treatment success. In contrast, many studies in the literature utilize definitions of overall recurrence/cure rate that allow patients to have repeat procedures for recurrence and yet exclude recurrence as an outcome if the patient is eventually disease free at the end of the follow-up period [6, 8, 9, 16–23]. Though useful, this does not provide the full context of outcomes and can be misleading. Our outcome metrics give more context and detail, allowing clinicians the information to better counsel patients around their likelihood of symptom recurrence and the procedure's

success, while also enabling better comparison between studies in the literature; as such, we believe this triple-metric methodology should be adopted as the standard.

A median time to symptom recurrence of 0.62 years and 0.27 years ($p=0.0012$) for PEF and LFP, respectively, alongside the plots shown in Fig. 2, demonstrate that after a single procedure PEF lasts significantly longer than LFP before symptoms recur, in addition to fewer recurrences overall. This study has an overall median follow-up of over 2.5 years, with some patients with over 5 years, which is longer than that of other pediatric PSD studies utilizing fibrin glue techniques [9]. Despite this, a limitation of this study and many pediatric pilonidal studies is that patient follow-up does not continue into adulthood hindering interpretation of long-term outcomes. To this end, we have made the deliberate choice to report an overall recurrence rate rather than using terminology such as "cure rate" despite often being used synonymously in the literature, as we do not wish to extrapolate beyond the extent of our data. While it is known that the risk of PSD recurrence increases with time [15], all but one of the recurrences observed after primary procedure occurred within 1 year. Symptom recurrence after more than a few years after treatment may be the emergence of new discrete disease in the original region, rather than recurrence of the original disease following treatment. The few patients in this study who experienced long-term recurrence either transitioned to adult care teams in the region, or underwent extensive debridement and repair in collaboration with our plastic surgery colleagues, as in the case of 2 patients. Anecdotally, patients who underwent PEF continue to have good outcomes into adulthood.

Wound dehiscence was a common complication in the LFP cohort (31%), while all complications were rare in the PEF cohort resulting in a significantly decreased all-cause repeat intervention rate. This demonstrates clear and clinically significant benefits for patients when using the PEF technique. The all-cause repeat intervention rate is lower than the recurrence rate for the PEF cohort because while some patients experienced symptom recurrence, their symptoms were mild and resolved spontaneously without further intervention. This was not the case in the LFP cohort, and repeat intervention due to complications, e.g., wound dehiscence was much higher in the LFP cohort. Additional benefits were demonstrated with substantially reduced operative times with PEF than LFP, confirming similar findings in the literature [6, 8]. Previous work has also demonstrated that PEF can easily be performed as a day-case procedure and even solely under local anesthetic [6]. Moreover, fibrin glue closure has been shown to allow an earlier return to normal activities in 3 days [8], compared to 10–15 days for primary closure techniques [24]. Only 68% of children were found to be back to normal activities at 2 months following Bascom LFP procedures [25]. Minimally invasive treatments of PSD have been shown to improve quality of life more than other methods [26] and subsequently patients significantly prefer them to more extensive traditional procedures [9].

Alternative minimally invasive treatments of PSD to PEF exist with a limited, but growing, evidence base. Examples include injection of phenol solution, endoscopic pilonidal sinus treatment (EPSiT) and laser hair depilation. In comparison to other minimally invasive options, we have demonstrated lower overall recurrence and similar complication rates following PEF [16–23]. Direct comparison between studies, however, is difficult given the lack of transparent and precise definitions of recurrence outcomes in the literature. There is substantial scope for future work such as multicenter randomized controlled trials as well as exploration of the use of phenol injection/hair depilation as adjuncts to PEF/endoscopic procedures to identify the ideal minimally invasive treatment regime. At present, work is underway at our institution to organize a prospective trial comparing PEF and LFP.

The limitations of this study include a small sample size compared to adult studies, as well as its retrospective methodology. PSD has a wide spectrum of disease severity which can include complex cavities and their associated complications which means a perfect direct comparison of severity between patients is near impossible. Despite being a known risk factor for PSD [28], the degree of hirsutism was not compared between cohorts as this information was not reliably documented in a fashion enabling this. This study compared a single PEF technique to LFP techniques that were not the same for all patients. While this may influence direct comparison, the various LFP techniques have been shown to perform similarly [6, 14, 15].

Covering a span of nearly 14 years, this study is the largest pediatric-focused cohort utilizing fibrin glue to manage PSD with the longest follow-up, to the best of our knowledge [6, 8, 9, 27, 29, 30]. We have demonstrated clinically relevant decreases in symptom recurrence alongside significantly decreased rates of complications and further surgical intervention using fibrin glue techniques, compared to traditional LFP techniques. We believe LFP in the pediatric population should be saved for severe or refractory disease, when minimally invasive treatment of recurrent PSD is felt to be inappropriate or fails.

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Author contributions All authors made substantial contributions to the conceptualisation and design of the work. WG acquired and interpreted the data. All authors were involved in data interpretation. WG wrote the main manuscript test and prepared all tables/figures. All authors were involved in critical revision of the work and approve the work to be published.

Data availability All figures, tables and data included in this manuscript that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request. Data are located in controlled access data storage at Sheffield Childrens' Hospital NHS Foundation Trust. The corresponding author can be contacted to request the data: Richard Lindley (Consultant Paediatric Surgeon at Sheffield Children's Hospital) at Richard.lindley1@nhs.net, with backup contact details of William Giles at williamaegiles@gmail.com.

Declarations

Competing interests The authors declare no competing interests.

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