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Endoscopic techniques for the treatment of pilonidal sinus disease - a mini-review

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ABSTRACT

Background

Pilonidal sinus disease affects many individuals in the UK and is associated with chronicity, pain and recurrence. It has a negative impact on the individual's quality of life and daily functioning and places a significant burden on the UK's healthcare service. Traditionally, treatment has involved excision and healing by primary or secondary intention; however, recent advances in surgical techniques have led to the development of endoscopic and video assisted treatments.

Aim

This paper evaluates the current research surrounding the endoscopic treatment of pilonidal sinus disease, with particular reference to patient benefits and harm.

Methods

A Medline search of endoscopic/video-assisted and pilonidal sinus disease in adults was undertaken. There was minimal level 1 evidence, due to the recent nature of the treatment's development, therefore levels 1–3 were reviewed.

Findings

Patients generally experience less pain and a quicker return to normal functioning following endoscopic treatment; however, this approach does not appear to improve recurrence rates and may only be replicable in uncomplicated pilonidal disease.

Implications for clinical practice

Endoscopic treatments appear to be an interesting new technique for the treatment of simple pilonidal disease; however, further work is required to identify a technique that also addresses recurrence rates.

INTRODUCTION

Pilonidal sinus disease (PSD), a term derived from Latin meaning 'nest of hairs', was first described in 1833 by Herbert Mayo.[1] Although its pathophysiology has been subject of historical debate[2], current consensus suggests it is an inflammatory condition caused by hair within the natal cleft that is embedded in the surrounding skin, leading to inflammation and oedema that can continue to develop into an abscess or track further, creating a network of sinuses and fistulae.[3,4] Confounding this issue is the impact of locality, with the natal cleft being a warm, moist environment populated by both aerobic and anaerobic bacteria that exacerbate inflammation and lead to chronic infection.[5,6]

It is generally agreed that PSD is an acquired condition more commonly affecting young males. Obesity, increased hair volume, poor hygiene and Mediterranean ethnicity appear to be risk factors for developing the disease.4 With an increasing incidence globally, PSD places a significant financial burden on many international healthcare systems.[7] Furthermore, the nature of PSD is that of a chronic, recurrent and painful disease, often requiring multiple surgical in-

terventions; it has a significant negative impact on patient quality of life (QOL).[8] A recent study has identified stark contrasts in the international management of PSD, with countries such as Germany, Turkey, Italy and the US using many different techniques and experiencing a wide range of recurrence rates dependant on surgical technique.[8] Classically speaking, the surgical technique of excision followed by healing through either primary or secondary intention has been widely used in the UK to treat chronic PSD.[9] Despite multiple surgical techniques being developed, there is no gold-standard treatment, and best practices remain ambiguous.[4] A Cochrane review concluded that each surgical treatment has its own potential benefits and drawbacks, but no consensus has been reached concerning which approach leads to better patient outcomes.[10]

Surgical intervention is often complicated by wound infection, recurrence, pain and prolonged hospital stays, which ultimately impact patient outcomes.[11,12] Standard excision and healing by secondary intention has widely reported recurrence rates between 0 and 57%.[13] Wound healing (WH) following this therapy is generally achieved between 1.5 and 3 months, though follow-up is often poor and leads to the incidence of incomplete WH that is not thoroughly reported.[13] A recent systematic review by Grabowski et al. identified a slight trend moving towards minimally invasive techniques, due to favourable patient outcomes when compared to excision.[14] One such emerging technique is the use of endoscopic ablation, first described in 2014 by Meinero et al.[15] Under spinal or local anaesthetic, endoscopic techniques (ETs) using a fistuloscope is introduced through a small excision (~5mm), allowing a clear visualisation of the inflamed tissues. The hair and debris are removed, tissues are ablated and the tract is left unpacked, but covered with a simple dressing. A series of research trials has subsequently been undertaken to identify the potential benefits and drawbacks associated with ETs versus excision and healing by primary or secondary closure. The present study examines the potential benefits and drawbacks associated with patients undergoing ET for PSD.

METHODS

The articles included in this work were obtained through a Medline search conducted in November 2021. The search was based on the key themes identified using the PICO search tool. The categories used were 'pilonidal sinus', 'endoscopic', 'video-assisted' or 'minimally invasive surgical techniques'. Only studies using adults were selected, and only Level I evidence was reviewed. This search returned one randomised controlled trial (RCT). The scope was then widened to include Level 3 evidence, and 19 results were retrieved and reviewed for inclusion.

Endoscopic Pilonidal Sinus Treatment (EPSiT)

Meinero et al. conducted an initial prospective study using 11 adult patients with PSD.[15] There were no exclusion criteria, and all patients were given a prophylactic dose of antibiotics prior to surgery, which may have had consequences for post-surgical infection rates and is not routinely used in excisional techniques10; this could have affected the study's validity.

Though the results of the study are difficult to generalise, due to the small sample size, Meinero et al.[15] suggested that EPSiT could allow a surgeon to achieve better visibility, and therefore a more precise removal of infected tissue, alongside the creation of a substantially smaller wound. This was evidenced by a recurrence rate of 0% at six months, indicating that all infected tissue was successfully removed, although there is growing consensus that follow-up should be undertaken for five years in patients with PSD, due to longitudinal recurrence.[16] Complete WH was achieved in all patients at one month; by comparison, a review by Iesalnieks and Ommer found longer healing times, between 1.5 and 3 months, in patients who underwent excision and secondary healing.[13] Meinero et al. noted that there were no significant complications in this patient group, however no definition of 'complications' was provided, therefore this observation is difficult to substantiate.[15] Pain was described as either low or nil up to two weeks post-operatively, and there was no requirement for further antibiotic therapy, indicating no incidence of post-operative infection; however, this was not implicitly stated. Due to the limitations of study, including its sample size, lack of comparative control, short follow-up time and flaws in the study design, the potential harms and benefits of using EPSiT cannot be widely agreed and may have been subject to reporting and selection bias, as is found in studies that have not been randomised.[17] However, this study did provide an interesting basis for a subsequent RCT conducted by Milone et al.[18]

Video-assisted ablation of pilonidal sinus

In their RCT, Milone et al.[18] explored the safety and

efficacy of a similar ET, video-assisted ablation of pilonidal sinus (VAAPS), versus a Bascom cleft lift, a commonly used procedure involving excision and off-midline flap construction to facilitate primary healing.[19] The primary outcome of this study was time to return to work (TtRTW), which had not been reported in Meinero et al.'s[15] study and may be a direct reflection of the secondary outcomes of pain, infection and recurrence rates, as well as patient satisfaction. A larger cohort (n=145) was used with a ratio of male to female participants of 78.9% to 21.1%, indicating an accurate representation of gender consistent with known risk factors, as male gender is a risk factor for developing PSD[4], strengthening this study's validity. Analyses were undertaken using intention to treat, and no participants were lost to follow up, which suggests that there was no bias associated with participant withdrawal post-randomisation.

In contrast to Meinero et al.'s[15] study, antibiotics were only given in the event of pre-intervention inflammation and surgery then delayed to mitigate the risk of affecting post-surgical infection rates; however, the identification of inflammation can be subjective and readers were not provided with details of how this was assessed, or what antibiotic therapy was provided. Milone et al.[18] also provided their exclusion criteria, which included the presence of co-morbidities, thereby improving validity, given that some co-morbidities, such as diabetes and auto-immune disease, are known to affect WH and increased infection risk.[20]

Despite a reduction in the number of recorded post-operative infections for those undergoing VAAPS versus the Bascom lift (n=1 and n=5, respectively), there was no statistically significant difference in overall likelihood of harm between the surgical techniques ($p>0.05$). The recurrence rate at one year was similar in both studies (VAAPS=3, Bascom=4); however, although previous studies have identified that the majority of recurrences happen within one year of surgery[5], they have been found to occur up to 22 years post-surgery.[16] Though a 22-year follow-up would be impractical, this does suggest that a one-year follow up may not be an accurate representation of the true recurrence. Doll suggested that a five-year follow up should be standard.[16]

Interestingly, the only metric associated with an increased risk of complications was the distance of the wound from the midline, implying that a sinus location >2cm from midline had an overall impact on likelihood of complication, regardless of which surgery was performed. An earlier work by Milone et al. explored the incidence of complications in relation to the distance of the wound from the midline and found that >2cm distance from midline led to a greater risk of complications, and differing surgical techniques were shown to be more or less effective, depending on location of the sinus.[21] This has clinical significance and suggests that the surgical technique used should be tailored to the patient's presentation to achieve the best outcome, rather than developing one technique to treat all cases of PSD, as concluded in the Cochrane review.[10]

One statistically significant outcome was the TtRTW, which was assessed through the criteria of having no pain and returning to normal duties. TtRTW was significantly reduced in the VAAPS group (1.6 days vs 8.2 days), and there appears to be a positive Pearson's correlation graph between pain at one month and TtRTW, though readers were not provided with the correlation coefficient. The presence of pain was measured routinely using a pain scale of 1–10, a scale commonly used to assess acute post-operative pain. However, this can be criticised for being non-descriptive and one-dimensional, as pain may fluctuate or patients may describe types of pain differently[22]; therefore, the use of a more qualitative approach may have provided greater insight into the participants' QOL. Pain scores were found to be significantly lower in the VAAPS group, in comparison to the control group, both immediately after the procedure and at multiple points up to one month post-surgery ($p<0.001$ at each point). Overall patient satisfaction was higher in the VAAPS group ($p<0.001$) at one and six months, indicating that the low pain levels and reduced time off work were accurately recorded, though there may have been a risk of bias associated with the non-blinding of this RCT, and participants may have been responding more favourably to the new technique.[23] As noted previously, Doll[16] suggested that follow up for PSD patients should be for a minimum of five years, thus further longitudinal study is required to ascertain true levels of recurrence and patient satisfaction.

What is not explored in this study is the time to achieve complete WH. It is possible that this is due to the minimal size of excision in the VAAPS procedure; however, this is not implicitly stated. Furthermore, the criteria for this study excluded patients with re-

current disease who had previously undergone surgery. It could be conceived that the group of patients in Milone et al.'s[18] study had simple PSD, rather than complex PSD, which is often associated with frequent recurrence[4], and it would be interesting to explore the efficacy of ETs in patients with complex and recurrent disease. Overall, the study by Milone et al.[18] suggests that, whilst the risk of patient harm is similar to other techniques, the low pain levels and quicker TtRTW contribute to overall patient satisfaction and make this technique an interesting topic for further longitudinal study.

Long-term recurrence

In acknowledgement of the need for longitudinal reporting, Milone et al. later undertook a five-year follow up exploring long-term recurrence rates, patient satisfaction, cosmetic appearance and cost-effectiveness.[24] Four patients from the original study were lost to follow up and excluded from the study, accounting for 3% of the study population. The number of participants lost was equal across both study arms, thereby maintaining validity. Higher patient satisfaction was maintained in the VAAPS group (8.9 versus 7.8, $p<0.001$), which was assessed by an independent, blinded observer using a simple Patient Satisfaction Scale between 1–10; however, no further information on the scale is provided, thus limiting the reliability of this measure, which may have been subject to response bias. The observer also conducted a cosmetic assessment using the validated Wound Evaluation Scale[25] and was blinded to the treatment modalities; a score of 6 out of 6 (6/6) was optimal. The study reports that VAAPS was associated with better cosmetic outcomes in comparison to the control ($p<0.001$); however, on analysis of the statistics, VAAPS scored 0.7/6 versus 3.0/6 which, though it may have been a reporting error, is ambiguous.

One aspect that was not previously explored in Meinero et al.'s[15] initial study was that mean total expense for the procedure, dressings and time off work was significantly less using VAAPS than the control (€784.21 vs €1384.17 respectively, $p<0.001$), which provides promising clinical significance, given the growing financial burden of wound care.[26] However, Romaniszyn et al.[27] argued that the initial cost of ET training and the purchasing of specialist equipment may affect the initial cost-effectiveness. Finally, the recurrence rate between VAAPS and the Bascom lift was found to be similar between the treatments (n=18 vs n=16 respectively, $p=0.95$), supporting the findings by Meinero et al.[15] and Milone et al.[18], which suggested that ET for PSD does not improve recurrence rates when compared to alternative treatments.

DISCUSSION

Due to the recent interest in this topic, multiple prospective trials have been undertaken, since Milone et al.[18], though results from these have limited relevance in clinical practice, due to their study design and sample size. Of note, Romaniszyn et al.[27] explored the long-term outcomes of EPSiT versus the Limberg flap technique used in more complex cases of PSD (n=62) and concluded that, overall, EPSiT was less successful in complex PSD with three or more pits (57.7% successful vs 94.1%), with 'success' defined as no further recurrence at follow-up (median 27 months). However, the likelihood of complications was significantly less using EPSiT versus the flap procedure (11.5% vs 26.5%), indicating that it may be a safer alternative to flap treatment. In contrast to this, Gulcu and Ozturk published results indicating recurrence rates of 1.2% in a retrospective study of 86 patients with PSD undergoing EPSiT and no incidences of complication.[28] However, in support of Romaniszyn et al.[27], Gulcu and Ozturk[28] also found that PSD patients with three or more pits experienced a high rate of treatment failure (n=5/6); despite this, a qualitative assessment of patient satisfaction indicated an improvement in QOL factors, including return to physical duties and self-perception.

As there is currently no gold-standard treatment for PSD, experts' opinions suggest that treatment should be in response to the presentation of PSD, rather than conforming to one gold-standard treatment.[10,15,29] Furthermore, RCTs evaluating ET versus other techniques will naturally differ, due to the lack of a gold-standard control, meaning that direct comparisons of studies are challenging, as each control arm is undergoing a different treatment. There is a growing call for the development of a standard classification system for PSD[28,30], and it could be hypothesised that such a classification system would support the development of an agreed treatment pathway dependent on the presentation of PSD, with each stage of classification requiring a different surgical approach to reduce the risk of harm to patients, reduce their risk of recurrence and ensure a satisfactory patient outcome.[15] It appears from current evidence that ETs for PSD are most effective in cases of simple PSD and areas associated with shorter return to normal function, higher patient satisfaction, low risk of complications ▶

and post-operative pain and general cost-effectiveness.[18,24] However, ETs may not be appropriate for cases of complex PSD[27] and do not reduce recurrence in comparison to other techniques.[24]

CONCLUSION

There have been no RCTs published since Milone et al.'s[18] work and, without further RCTs, it is difficult to evaluate the true benefits and harms associated with ETs for PSD. Based on a review of the current evidence, ETs appear to offer improved patient satisfaction and a quicker return to normal functioning, alongside significant financial benefits[18,24], though the initial financial outlay should be noted.[27] However, these findings are only generalisable to simple cases of PSD with fewer than three pits; more complex cases appear to have better outcomes with different techniques. It can be concluded that ETs for simple PSD appear to be beneficial in reducing the risk of patient harm, such as infection[15,27], and providing good patient satisfaction and quick recovery.[18,24]

Implications for practice and further study

The findings of this review have identified that, though endoscopic treatments may be a suitable alternative for simple cases of PSD, further research is required to identify a treatment that also reduces recurrence rates. It may also be of interest to develop a standardised classification system for PSD, as doing so may help to differentiate between treatment arms and guide a clinician and patient towards a mutually agreeable and effective surgical therapy. ■

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