

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endoscopic ablation for a pilonidal sinus

A pilonidal sinus is a small infected cavity under the skin between the buttocks, just above the anus. It commonly contains hairs. It may cause pain and leak blood or pus. In this procedure, an endoscope (a thin flexible tube with a camera on the end) is put into the sinus tract. The hairs and infected tissue are removed and the sinus is cleaned. An electrode is passed through the endoscope to deliver heat, which seals the tissues inside the sinus. The aim is to clean the sinus and encourage healing.

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IP overview: Endoscopic ablation for a pilonidal sinus

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Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in October 2018 and updated in December 2018.

Procedure name

- Endoscopic ablation for a pilonidal sinus

Specialist societies

- Association of Coloproctology of Great Britain and Ireland
- The Royal College of Surgeons
- Association of Surgeons of Great Britain and Ireland (ASGBI).

Description of the procedure

Indications and current treatment

A pilonidal sinus is a small infected tract or a network of interlinking tracts under the skin between the buttocks. The exact cause is unknown but it may be from loose hairs pushing into the skin, combined with friction from clothes. The risk of developing a pilonidal sinus is increased by spending long periods of time sitting down, being overweight, a persistent irritation or injury to the affected area, having a hairy buttock cleft or a family history of the condition. A pilonidal sinus does not usually cause symptoms unless it is infected and an abscess develops causing pain, redness, swelling under the skin and leakage of blood and pus. Treatments include conservative management with regular bathing and keeping the area dry and treatment with antibiotics if the sinus is infected. However, this does not close the sinus tract. Procedures to close the sinus include injecting fibrin glue injection and surgical excision.

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What the procedure involves

Endoscopic ablation of a pilonidal sinus is less invasive than surgery and is usually done as a day case, using spinal or local anaesthesia. With the patient in the prone position, the external opening of the sinus is incised and a fistuloscope is inserted into the sinus tract. A continuous jet of irrigation solution is used, allowing optimal visualisation and assessment of the inside of the sinus. Under direct vision, forceps are used to remove hairs, infected tissue and any debris. Then an electrode is passed through the fistuloscope to cauterise the main sinus tract and any secondary tracts or abscess cavities. Necrotic material is removed using an endobrush and the sinus tract is cleaned using irrigation solution.

Efficacy summary

Complete healing

A systematic review of 8 studies (1 randomised control trial [RCT] and 7 case series) on endoscopic pilonidal sinus treatment (EPSiT) reported complete healing in 3 studies, and 3 other studies reported healing rates of over 88%. In 1 study an increased number of external openings were associated with a higher rate of incomplete wound healing ($p=0.01$).²

A retrospective comparative case series comparing EPSiT ($n=21$) with conventional excision followed by primary closure (EPC, $n=63$) in paediatric patients with chronic sacrococcygeal pilonidal sinus reported that there was no difference in complete healing rates between the groups (100% [19/19] compared with 92% [55/60], $p>0.05$).⁴

A case series of 43 paediatric patients who had pilonidal sinus treated with EPSiT reported complete healing (defined as complete wound closure, no discharge, no pain in the area of surgery both spontaneously or during palpation and no signs of infection/inflammation) after a median of 3 weeks in 88% (38/43) of patients.⁵

Non-healing or recurrence rate

In a systematic review and meta-analysis of 9 studies on endoscopic pilonidal sinus treatment (in 497 patients with sacrococcygeal pilonidal disease [SPD]), the overall failure rate (defined as persistent (non-healing) or post-operative recurrence of SPD) was reported in 8% (40/497) of patients. 4% (20/497) of patients had non-healing pilonidal sinus (defined as persistence of wound discharge or swelling more than 2 months after the procedure) and 4% (20/497) of patients had recurrence of SPD after complete healing of primary wound (diagnosed and reported symptoms of local pain, discharge or swelling at least 4 months after complete healing). The weighted mean failure rate was 6% (95%

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confidence interval [CI] 4% to 9%, $I^2=24%$, $p=0.23$). Failures were managed with repeat endoscopic treatment in 24 patients, surgical excision and primary closure in 3 patients and lotus petal flap construction in 2 patients. Management of persistent or recurrent SPD was not clear in 3 studies.¹

In the systematic review of 8 studies, 3 studies reported no recurrence during follow-up. A recurrence rate of 5% or less was reported in 4 studies.² In a RCT comparing EPSiT with conventional treatment in patients with chronic non-recurrent pilonidal sinus, recurrence (defined as additional occurrence of symptoms after an interval of complete healing) was reported in 4% (3/76) of patients in the EPSiT group compared to 6% (4/69) of patients in the conventional treatment group ($p>0.99$).³

The retrospective comparative case series comparing EPSiT (n=21) with conventional excision followed by primary closure (EPC, n=63) reported that there was no difference in recurrence rates between the groups (10% (2/19) compared with 22% (13/60), $p>0.05$). Time to disease recurrence in both the EPSiT and conventional EPC groups was 83 and 91 days respectively.⁴

In the case series of 43 patients with pilonidal sinus treated with EPSiT, recurrence (defined as persistence of discharge after more than 3 months with either abscess formation, infection or local pain and discomfort) was reported in 12% (5/43) of patients.⁵

In a retrospective comparative analysis of EPSiT (n=40) with standard sinusectomy, the recurrence rate was significantly lower in the EPSiT group compared with the sinusectomy group (7.5% [3/40] versus 25% [10/40], $p=0.035$).⁸

Delayed healing

In the case series of 43 patients with pilonidal sinus treated with EPSiT, delayed healing (defined as wound closure occurring after more than 6 weeks) was reported in 5% (2/43) of patients.⁵

Time to return to work

In the systematic review of 9 studies, the mean time to return to work and normal activities was 2.9 days (range 1.6 to 6 days).¹

In the systematic review of 8 studies, 7 studies reported that patients on average took less than a week off work after EPSiT and, in 1 RCT, patients in the EPSiT group reported significantly less time off work compared with those in the conventional treatment group (1.6 compared with 8.2 days; $p<0.001$). A significant correlation was detected between time off work and pain at 1 week ($p<0.001$) and pain at 1 month ($p<0.001$).^{2,3}

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In a retrospective comparative study comparing EPSiT (n=15) with conventional open repair (n=15) the average time to daily activities was shorter in the EPSiT group compared to conventional group (2.5 compared with 15.4 days, p=0.001).⁶

In a case series of 19 patients with pilonidal sinus treated with EPSiT for pilonidal abscess, all patients returned to activities of daily living within 48 hours.⁷

In the retrospective comparative analysis of EPSiT (n=40) against standard sinusectomy (n=40) no differences were found in time off work (2.01 ± 1.30 days compared with 2.08 ± 1.24 days; p=0.620).⁸

Time to complete healing

In the systematic review of 9 studies, the mean time to complete healing after the procedure was 33 days (range 15 to 75 days).¹

The retrospective comparative case series comparing EPSiT (n=21) with conventional excision followed by primary closure (EPC, n=63) in paediatric patients with chronic sacrococcygeal pilonidal sinus reported that there was no difference in median time to complete healing (28 compared with 37.5 days, p>0.05).⁴

In the retrospective comparative study comparing EPSiT (n=15) with conventional open repair (n=15), the average time to healing was shorter in the EPSiT group compared to conventional treatment group (30 compared with 92 days, p=0.001).⁶

In the case series of 19 patients with pilonidal sinus treated with EPSiT complete wound healing was achieved within a median of 4 weeks.⁷

Patient satisfaction

In the systematic review of 9 studies, 3 studies (with 113 patients) assessing patient satisfaction reported that 96% (108/113) of patients were completely satisfied with the procedure (ranging from 78 to 97%).¹

In the systematic review of 8 studies, one included RCT reported that patients in the EPSiT group reported higher satisfaction at 1 month and 6 months after surgery (p<0.001) compared to those in the conventional treatment group. 3 other studies which assessed this outcome reported satisfaction rates of 97%, 93% and 78%.^{2, 3}

In the retrospective comparative analysis of EPSiT (n=40) against standard sinusectomy (n=40) no differences were found in satisfaction at 6-month follow-up (8.3 ± 1.2 compared with 8.2 ± 1.3 ; p=0.78).⁸

Mean operation time

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In the systematic review of 9 studies, the mean operation time was 34.7 minutes (range 20 to 45 minutes).¹

In the systematic review of 8 studies, one included RCT showed that the mean operating time was significantly shorter for conventional treatment than for minimally invasive EPSiT (26.5 compared with 42.9 minutes; $p < 0.001$).^{2,3}

In the retrospective comparative case series comparing EPSiT (n=21) with conventional excision followed by primary closure (EPC, n=63), the mean operative time was similar for EPSiT and convention EPC groups (30 compared with 38 minutes, $p > 0.05$).⁴

In the case series of 43 paediatric patients who underwent EPSiT, the mean operative time was 34 minutes.⁵

In the retrospective comparative study comparing EPSiT (n=15) with conventional open repair (n=15), the average operative time was significantly shorter in the EPSiT group compared to conventional treatment group (28.5 compared with 42 minutes, $p = 0.001$).⁶

In the case series of 19 patients with pilonidal sinus treated with EPSiT the mean operative time was 36 minutes.⁷

In the retrospective comparative analysis of EPSiT (n=40) against standard sinusectomy, the mean operative time was less for the sinusectomy group compared with the EPSiT group (30.38 ± 6.23 minutes compared with 44.39 ± 7.76 minutes; $p = 0.001$).⁸

Safety summary

Complication rate

In the systematic review and meta-analysis of 9 studies, 2% (8/85) of patients in 2 studies developed complications after the procedure (range 0% to 11%). Complications included hematoma, infection, persistent discharge, and failure to heal. The weighted mean complication rate was 1.1% (95% CI less than 1% to 2%, $I^2 = 24\%$, $p = 0.22$).¹

In the RCT of 145 patients comparing EPSiT with conventional treatment, the overall complication rate was similar in both groups. There were fewer infections (1% [1/76] compared with 7% [3/69]; $p = 0.10$) in the EPSiT group but this was not statistically significant.³ In the retrospective comparative case series comparing EPSiT (n=21) with conventional EPC (n=63) wound infection rates were lower for EPSiT group compared to conventional treatment group (5% [1/21] compared with 20% [12/63], $p > 0.05$).⁴ Surgical site infection (defined as persistent smelly discharge with pain and redness possibly associated to systemic signs requiring

antibiotic administration) was reported in 1 patient in the case series of 43 patients with pilonidal sinus treated with EPSiT.⁵

The case series of 43 patients with pilonidal sinus treated with EPSiT reported an overall complication rate of 16% (6/43).⁵

In the retrospective comparative analysis of EPSiT (n=40) against standard sinusectomy (n=40), the infection rate showed a trend toward reduction in the EPSiT group compared with standard sinusectomy (12.5% [5/40] compared with 30% [12/40]; p=0.057).⁸

Pain (assessed using a VAS pain scale, ranging from 0 to 10)

In the systematic review of 9 studies, the mean pain score (assessed on a visual analogue scale [VAS]) within the first week after the procedure (reported in 7 studies) was 1.35 ± 0.8 (range 0.5 to 2). 9% (36/416) of patients in 7 studies required intravenous analgesics in the first post-operative day, ranging from 0% to 22% across studies.¹

In the systematic review of 8 studies, 3 studies reported minimal or no pain after 1 week with a VAS score of less than 2. Patients were managed with simple analgesia such as NSAID and paracetamol. In the RCT, patients with pilonidal sinus treated with EPSiT reported less pain after surgery at all follow-up periods (1 hour, 6 hours, 1 day, 1 week and 1 month; p<0.001) compared to those in the conventional treatment group.^{2,3}

In the case series of 43 patients the mean pain score (assessed on a VAS) 6 hours after the procedure was 2. The mean pain score for local anaesthesia was significantly higher (3.2 ± 1.1) when compared to general (0.2 ± 0.4 , p<0.0001) and spinal anaesthesia (2.06 ± 0.6 , p=0.0004) respectively.⁵

In the retrospective comparative study comparing EPSiT (n=15) with conventional open repair (n=15) the average pain score (assessed with a VAS) during the first 48 hours was shorter in the EPSiT group compared to conventional treatment (3.2 compared with 6.8, p=0.001). The average analgesic requirement was also shorter in the EPSiT group (22 compared with 88 hours, p=0.001).⁶

In the case series of 19 patients with pilonidal abscess treated by EPSiT, the median pain score (measured on a VAS) reduced from 7 at baseline to 1 at 6 weeks after the procedure.⁷

In the retrospective comparative analysis of EPSiT (n=40) against standard sinusectomy (n=40), no differences between the groups were found in the pain score at 1 week after surgery (3.71 ± 1.24 compared with 3.76 ± 1.39 ; p=0.883).⁸

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Wound complications

In the retrospective comparative case series comparing EPSiT (n=21) with conventional EPC (n=63) wound complications were lower for the EPSiT group compared to conventional treatment group (11% (2/21) compared with 28% (17/63), $p>0.05$).⁴

Granuloma (in the site of endoscopy, treated with topical silver nitrate administration) was reported in 5% (2/43) of patients in the case series of 43 patients.⁵

Reoperation

Reoperations were reported in 9% (4/43) of patients in the case series of 43 patients.⁵

21% (4/19) of patients needed further surgical intervention for pilonidal disease in the case series of 19 patients. 3 of these patients were from the recurrent pilonidal abscess group and one was from the primary group. 2 of them had excision and 2 needed flap reconstruction and 1 of them developed recurrence following intervention.⁷

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers listed the following anecdotal adverse event: infection. They considered no theoretical adverse events.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to endoscopic ablation for a pilonidal sinus. The following databases were searched, covering the period from their start to 28.12.2018: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the [literature search strategy](#)). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

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The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with pilonidal sinus.
Intervention/test	Endoscopic ablation or endoscopic pilonidal sinus treatment (EPSiT).
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 683 patients from 2 systematic reviews^{1,2}, 1 randomised controlled trial³, 3 retrospective comparative studies^{4,6,8} and 2 case series^{5,7}.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in the [appendix](#).

Table 2 Summary of key efficacy and safety findings on Endoscopic ablation for a pilonidal sinus

Study 1 Emile SH (2018)

Details

Study type	Systematic review and meta-analysis
Country	Italy (6 studies) , UK (1 study), Turkey (1 study) and Singapore (1 study)
Search period	Search period: inception to 2017; Databases searched: PubMed, Medline, Scopus, Embase and Cochrane library and manually screened references of potentially relevant articles.
Study population and number	n=9 studies (n=497 patients with sacrococcygeal pilonidal sinus disease [SPD]) <u>Type of studies:</u> 1 randomised controlled trial (Milone 2016), 6 prospective (Giarratano 2017, Gecim 2017, Meinero 2016, Milone 2014, Milone 2014, Meinero 2011) and 2 retrospective case series (Javed 2016, Chia 2015) <u>Type of SPD:</u> Primary SPD: 73.2% (364/497), history of previous surgery for SPD 26.8% (133/497) Complex SPD with lateral pits: 38% (142/497)
Age and sex	Mean age 24.8 years; male to female ratio of 3.2:1
Study selection criteria	All studies, cohort or comparative studies that assessed the outcome of endoscopic pilonidal sinus treatment were included. No language restrictions applied. Conference abstracts, duplicate reports, editorials, letters, case reports, reviews, meta-analyses, studies with less than 3 patients, those with data overlapping with subsequent studies, those that did not report main outcomes of interest were excluded.
Technique	Video-assisted endoscopic treatment for sacrococcygeal pilonidal sinus disease (EPSiT using Meinero fistuloscope Karl Storz) in 7 studies. 2 studies used 4mm continuous flow operative Bettocchi Office Hysteroscope fistuloscope (Karl Storz). Procedure done as a day case in all studies. 4 studies done under local anaesthesia, 2 used sedation and 1 study used spinal or local anaesthesia. Glycine/Mannitol 1% solution was used for irrigation, necrotic material was removed with an endobrush or Volkmann spoon and light dressing applied. 2 studies had additional treatment after ablation, 1 study (Gecim 2017) injected crystallised phenol crystals inside the sinus and another study (Milone 2014) inserted a Gore Bio –A fistula plug inside the sinus cavity.
Follow-up	Median follow-up across studies was 12 months (ranging from 2.5 to 25 months).
Conflict of interest/source of funding	2 authors are paid consultants and receive royalties from the manufacturer. Others declare no conflicts of interest or financial time.

Analysis

Follow-up issues: short term follow-up.

Study design issues: the review was done according to preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines. Two reviewers checked eligibility for inclusion of articles, assessed methodological quality of studies (using the case series checklist of NICE) and any disagreements were resolved after discussion with a third reviewer. Quality of each study defined as good (score 7-8), fair (4-6) and poor (0-3). The revised grading system of Scottish Intercollegiate guidelines network (SIGN) was used to assess comparative studies (score of <8 indicated poor quality, 8-14 fair quality and >14 good quality). 7 studies were of fair quality and 2 were of good quality (median score in case series was 6). The primary outcomes were incidence of failure (defined as non-healing or persistence post-operative recurrence) and complication rate. Meta-analysis was conducted using openMeta version 12.11.14. Statistical heterogeneity was observed among the studies. Some studies had very small sample sizes. Only 1 comparative study included.

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Study population issues: patients were mainly young male adults with different characteristics across studies, half of the patients were from 1 study (Meinero P 2016). More than half of the studies were from 1 group of authors in 2 centres in Italy.

Other issues: there is some variation in the techniques used in included studies and not standardised.

There is an overlap of studies in the 2 systematic reviews.

Key efficacy and safety findings

Efficacy	Safety																
<p>Number of patients analysed: 9 studies (n=497 patients)</p> <p>Failure of endoscopic treatment</p> <table border="1"> <thead> <tr> <th></th> <th>% (n)</th> </tr> </thead> <tbody> <tr> <td>Overall failure of technique*</td> <td>8.04 (40/497)</td> </tr> <tr> <td>Persistent (non-healing) pilonidal sinus[^]</td> <td>4.02 (20/497) range 0-20%</td> </tr> <tr> <td>Recurrence of SPD after complete healing of primary wound^{^^}</td> <td>4.02 (20/497) range 0 -5.2%</td> </tr> <tr> <td>Weighted mean failure rate</td> <td>6.3% (95% CI 3.6 to 9.1%, I²=23.6%, p=0.23).</td> </tr> </tbody> </table> <p>*defined as persistence (non-healing) or post-operative recurrence of SPD. [^]defined as persistence of wound discharge or swelling more than 2 months after the procedure. ^{^^} diagnosed reported symptoms of local pain, discharge or swelling at least 4 months after complete healing.</p> <p>Failures were managed with redo of endoscopic treatment in 24 patients, surgical excision and primary closure in 3 and lotus petal flap in 2 patients. Management of persistent or recurrent SPD was not clear in 3 studies.</p> <p>Mean operation time: the mean operation time was 34.7±17.7 minutes (range 20-45 minutes).</p> <p>Time to complete healing The mean time to complete healing after the procedure was 32.9±23 days (range 15-75 days).</p> <p>Time to return to work The mean time to return to work and normal activities was 2.9±1.8 days (range 1.6-6 days).</p> <p>Patient satisfaction 3 studies (with 113 patients) assessing patient satisfaction reported that 95.6% (108/113) patients were completely satisfied with the procedure (ranging from 77.7 to 97.4%).</p> <p>Predictors for failure of treatment Variables significantly associated with failure of EPSiT were age (SE=-0.017, p=0.02), and history of previous surgery for SPD (SE=-0.001, p=0.022).</p>		% (n)	Overall failure of technique*	8.04 (40/497)	Persistent (non-healing) pilonidal sinus [^]	4.02 (20/497) range 0-20%	Recurrence of SPD after complete healing of primary wound ^{^^}	4.02 (20/497) range 0 -5.2%	Weighted mean failure rate	6.3% (95% CI 3.6 to 9.1%, I ² =23.6%, p=0.23).	<p>Complications of treatment</p> <table border="1"> <thead> <tr> <th></th> <th>% (n)</th> </tr> </thead> <tbody> <tr> <td>Weighted mean complication rate</td> <td>1.1% (95% CI 0.3 to 2.4%, I²=24.4, p=0.22)</td> </tr> <tr> <td>Complication rate (in 2 studies)</td> <td>1.6 (8/85) Range 0 to 11.1%</td> </tr> </tbody> </table> <p>Complications included hematoma, infection, persistent discharge, and failure to healing.</p> <p>No complications/recurrences reported in combined treatment procedures.</p> <p>Post-operative pain (assessed using VAS scale, ranging from 0 to 10) The mean pain within the first week after the procedure (reported in 7 studies) was 1.35±0.8 (range 0.5 to 2).</p> <p>Percentage of patients needing analgesia 8.6% (36/416) patients in 7 studies required intravenous analgesics in the first post-operative day, ranging from 0 to 22.2% across studies.</p>		% (n)	Weighted mean complication rate	1.1% (95% CI 0.3 to 2.4%, I ² =24.4, p=0.22)	Complication rate (in 2 studies)	1.6 (8/85) Range 0 to 11.1%
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<p>Abbreviations used: CI, confidence interval; EPSiT, endoscopic pilonidal sinus treatment; SE, standard error; SPD, sacrococcygeal pilonidal sinus disease; VAS, visual analogue scale.</p>																	

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Study 2 Tien T (2018)

Details

Study type	Systematic review
Country	Italy, Turkey, Singapore
Search period	Search period: inception to November 2017; Databases searched: Medline, Embase and Cochrane library searched, reference lists of included papers were screened.
Study population and number	n=8 studies (with 477 patients) Type of studies: 1 randomised controlled trial (Milone 2016), 7 case series, mainly prospective (Giarratano 2017, Gecim 2017, Meinero 2016, Milone 2014, Milone 2014, Meinero 2013, Chia 2015)
Age and sex	Not reported
Study selection criteria	All studies (randomised controlled trials to case series) on patients with pilonidal sinus treated with an endoscopic device were included. Conference abstracts, comments, letters were excluded. Papers on the use of endoscopy to treat pilonidal abscess were also excluded.
Technique	Endoscopic treatment for sacrococcygeal pilonidal sinus disease
Follow-up	Varied ((ranging from 2.5 to 25 months)
Conflict of interest/source of funding	Authors declare that they have no conflict of interest.

Analysis

Follow-up issues: short follow-up in many studies.

Study design issues: review was conducted in accordance to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines. Two independent reviewers selected studies, extracted data and any disagreement was resolved by consensus. Qualitative analysis was done. Some studies had very small sample sizes. Only 1 comparative study included. Quality of the studies was not assessed.

Study population issues: Half of the patients were from 1 study (Meinero P 2016). More than half of the studies were from 1 group of authors in 2 centres in Italy.

Other issues: there is some variation in the techniques used in included studies and not standardised. 2 studies (Gecim 2017, Milone 2014) modified the original technique by Meinero 2013.

There is an overlap of studies between the 2 systematic reviews

Key efficacy and safety findings

Efficacy	Safety
<p>Number of patients analysed: 477</p> <p>Healing rate Complete healing was reported in 3 studies, and 3 other studies reported healing rates of over 88%. In one study an increased number of external openings were associated with a higher rate of incomplete wound healing (p=0.01).</p> <p>Recurrence 3 studies reported that no recurrence occurred during follow-up. A recurrence rate of 5% or less was reported in 4 studies.</p> <p>Time off work and return to work and daily activities (7 studies) Patients on average took less than a week off work after EPSiT and in one RCT, patients who had EPSiT were also shown to go back to work earlier than patients who underwent conventional treatment (p<0.001).</p> <p>Patient satisfaction In the RCT, patients in the EPSiT group expressed higher satisfaction at 1 month and 6 months after surgery (p<0.001). 3 other studies which assessed this outcome reported satisfaction rates of 97, 93 and 78%.</p> <p>Mean operating time One RCT showed that the operating time for conventional treatment was significantly shorter than for minimally invasive EPSiT (26.5 [8.7] versus 42.9 [9.8]; p<0.001).</p>	<p>No infections reported.</p> <p>Pain (measured using 0-10 VAS in 5 studies) 3 studies reported minimal or no pain after one week with a VAS score of less than 2. Patients were managed with simple analgesia such as NSAID and paracetamol. In the RCT, patients with pilonidal sinus treated with EPSiT had less pain than conventional management of pilonidal sinus (p<0.001).</p>
<p>Abbreviations used: EPSiT, endoscopic pilonidal sinus treatment; NSAID, non-steroidal anti-inflammatory drug; RCT, randomised controlled trial; VAS, visual analogue scale;</p>	

Study 3 Milone M (2016)

Details

Study type	Randomised controlled trial
Country	Italy (single centre)
Recruitment period	2012 to 2013
Patient population and number	n= 145 patients with chronic non-recurrent pilonidal sinus 76 video-assisted ablation of pilonidal sinus (VAAPS) versus 69 conventional treatment (Bascom cleft lift procedure) <u>Complex disease</u> : VAAPS 73% (56/76); conventional treatment 75% (52/69)
Age and sex	Mean age: VAAPS group 25.5 years; conventional treatment group 25.7 years Sex: VAAPS group 79% (60/76) male, conventional treatment group 78% (54/69) male
Patient selection criteria	Inclusion criteria: patients with chronic non-recurrent sacrococcygeal pilonidal sinus identified at an outpatient clinic, not previously treated by incision or drainage for the presence of an abscess, indication for surgery, inflammation in the surrounding tissues controlled with antibiotics. Exclusion criteria: Inability to consent to participate in study, acute pilonidal disease (presence of an abscess, recurrent disease and the presence of comorbidity).
Technique	All procedures were done in an outpatient setting under local anaesthesia. Video-assisted ablation of pilonidal sinus (VAAPS) a new endoscopic treatment done by one surgeon. Bascom cleft lift procedures done by expert surgeons according to validated criteria. This included narrow excision of the pilonidal orifices combined with a laterally placed parallel incision for debridement of the cavity. Instructions at discharge included improvement of local hygiene and regular removal of hairs by shaving or the use of depilatory cream for 6 weeks.
Follow-up	12 months
Conflict of interest/source of funding	None reported

Analysis

Follow-up issues: short term follow-up, follow-up rate was 100% at 1 year.

Study design issues: small sample size, patients were randomised using computer based randomisation with sealed envelopes. Primary outcome was time off work.

Study population issues: the 2 groups were similar in baseline characteristics (sex, age, obesity, smoking status and sinus characteristics). The mean distance from the most lateral orifice to the midline was similar in the VAAPS and conventional treatment groups (2.7±0.6 versus 2.6±0.7cm, p=0.80).

Other issues: this study has already been included in the systematic reviews.

Key efficacy and safety findings

Efficacy	Safety																							
<p>Number of patients analysed: 145 (76 VAAPS versus 69 conventional treatment)</p> <p>Time off work</p> <p>Patients in the VAAPS group reported significantly less time off work compared with those in the conventional treatment group (1.6±1.7 versus 8.2±3.9 days; p<0.001). A significant correlation was detected between time off work and pain at 1 week (p<0.001) and pain at 1 month (p<0.001).</p> <p>Satisfaction scores (on a VAS representing their health status)</p> <p>Patients in the VAAPS group reported higher satisfaction at 1 month and 6 months after surgery (p<0.01 for all) compared to those in the conventional treatment group.</p> <p>Pain (measured using VAS scores 0 to 10, 0 for no pain and 10 for severe pain)</p> <p>Patients in the VAAPS group reported less pain after surgery at all follow-up periods (1 hour, 6 hours, 1 day, 1 week and 1 months; p<0.001) compared to those in the conventional treatment group.</p> <p>Operative time</p> <p>The mean operative time was less for the conventional treatment than for the VAAPS treatment (26.5±8.7 versus 42.9±9.8; p<0.001).</p> <p>Recurrence</p> <table border="1" data-bbox="110 867 967 1020"> <thead> <tr> <th></th> <th>VAAPS</th> <th>Conventional treatment</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>Recurrence (additional occurrence of symptoms after an interval of complete healing)</td> <td>3.9 (3/76)</td> <td>5.8 (4/69)</td> <td>>0.99</td> </tr> </tbody> </table>		VAAPS	Conventional treatment	P value	Recurrence (additional occurrence of symptoms after an interval of complete healing)	3.9 (3/76)	5.8 (4/69)	>0.99	<p>Adverse events</p> <table border="1" data-bbox="987 275 1510 659"> <thead> <tr> <th></th> <th>VAAPS</th> <th>Conventional treatment</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>Wound infection (redness and oedema of skin and or discharge)</td> <td>1.3 (1/76)</td> <td>7.2 (3/69)</td> <td>0.10</td> </tr> <tr> <td>Hematoma</td> <td>3.9 (3/76)</td> <td>2.9 (2/69)</td> <td>>0.99</td> </tr> </tbody> </table> <p>The overall complication rate was similar in both groups.</p> <p>The distance of the lateral orifice from midline greater than 2.5 cm was found to be associated with an increased risk of post-operative complications (hazard ratio 9.62; 95% CI 2.05 to 45.25, p=0.004).</p>					VAAPS	Conventional treatment	P value	Wound infection (redness and oedema of skin and or discharge)	1.3 (1/76)	7.2 (3/69)	0.10	Hematoma	3.9 (3/76)	2.9 (2/69)	>0.99
	VAAPS	Conventional treatment	P value																					
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Hematoma	3.9 (3/76)	2.9 (2/69)	>0.99																					
Abbreviations used: CI, confidence interval; RCT, randomised controlled trial; VAS, visual analogue scale; VAAPS, video-assisted ablation of pilonidal sinus.																								

Study 4 Sequeira JB (2018)

Details

Study type	Comparative case series
Country	Portugal (single centre)
Recruitment period	2015 to 2016
Patient population and number	n= 84 paediatric patients with chronic sacrococcygeal pilonidal sinus (SPS) treated with either endoscopic pilonidal sinus treatment (EPSiT, n=21) or conventional excision followed by primary closure (EPC, n=63) <u>No previous surgery</u> : 82% (69/84).
Age and sex	Median age: 16.18 years (range 12 to 17.9 years); median weight 65 kg. Sex: 73% (61/84) male
Patient selection criteria	Patients with less than 18 years presenting with chronic recurrent or non-recurrent sacrococcygeal pilonidal sinus disease submitted to either EPSiT or total excision followed by primary closure (EPC) during the course of a 12-month period in a paediatric hospital. Patients were selected for EPSiT according to surgeon's preference and surgical equipment availability. Recurrent SPS or SPS with multiple fistulas were preferably assigned to EPSiT. Patients presenting with acute pilonidal abscess were given antibiotic treatment and submitted to the procedure after resolution of the inflammation.
Technique	All procedures were done under local anaesthesia with sedation in an inpatient setting (and discharged next day). EPSiT procedures were performed by a single trained paediatric surgeon whereas conventional EPC with non-absorbable polypropylene suture was performed by 13 paediatric surgeons. At the end of the procedures a compression dressing was applied. At discharge all patients were given instructions about changing dressing daily, local hygiene and hair removal after wound epithelialisation. EPC patients were recommended 15 days rest lying down in ventral or lateral decubitus. EPSiT patients were given no restriction to daily activity. Post-operative assessments and follow-up was done as planned.
Follow-up	EPSiT group: median 11.9 months (range 4.6 to 16.2 months); EPC group; median 24.7 months (range 19.4 to 31.1 months).
Conflict of interest/source of funding	None reported

Analysis

Follow-up issues: 5 patients (2 cases in EPSiT group and 3 in EPC group) were lost to follow-up in early post-operative period. Overall follow-up time was different for both groups.

Study design issues: retrospective analysis with difference in sample sizes between the groups. Demographic and clinical data were collected from clinical records and surgeons report and compared between the groups. Primary outcome was complete wound healing.

Study population issues: paediatric population, there was no significant differences between EPSiT and EPC groups regarding age and gender ($p>0.05$).

Other issues:

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Key efficacy and safety findings

Efficacy				Safety			
Number of patients analysed: 84 (21 EPSiT versus 63 conventional EPC treatment)				Adverse events			
	EPSiT (n=21)	Conventional EPC treatment (n=63)	P value		EPSiT (n=21)	Conventional EPC treatment (n=63)	P value
Median operative time (range), minutes	30 (20 to 90)	38 (17 to 105)*	>0.05	Wound complications	10.5 (2/21)	28.3 (17/63)	>0.05
Complete healing rate %	100 (19/19)	91.7 (55/60)^	>0.05	Wound infection rate	5.2 (1/21)	20 (12/63)	>0.05
Median time to complete healing (range), days	28 (15 to 270)	37.5 (11 to 203)^	>0.05	Wound dehiscence	-	13.3	>0.05
Recurrence rate %	9.5 (2/19)**	21.7 (13/60)^	>0.05	Bleeding (on day 2, redone EPSiT with cauterisation and used haemostatic powder)	1		
Time to disease recurrence, days	83	91					
^Data from 60 patients; *data from 61 patients. **resubmitted to EPSiT, with complete wound healing at follow-up.							
Abbreviations used: CI, confidence interval; EPSiT, endoscopic pilonidal sinus treatment; RCT, randomised controlled trial; VAS, visual analogue scale							

Study 5 Pini Prato PA (2018)

Details

Study type	Case series
Country	Italy (4 centres)
Recruitment period	2015 to 2017 (21 months)
Patient population and number	n= 43 patients with pilonidal sinus disease (PSD) <u>Pre-operative history:</u> pre-operative surgery 14% (6/43); pre-operative imaging 32% (14/43) <u>PSD type:</u> with chronic discharge 88% (38/43), and abscess with or without fistulation 12% (5/43). <u>Fistula tract:</u> midline fistulas 77% (33/43) and lateral fistulas 23% (10/43). <u>Recurrences after pre-operative surgery:</u> 6
Age and sex	Mean age 15 years, 53% (20/43) male, mean BMI 23±3.5
Patient selection criteria	<u>Inclusion criteria:</u> patients younger than 18 years of age, pilonidal disease with chronic discharge, inflammation or abscess, surgeon trained in EPSiT technique. <u>Exclusion criteria:</u> patients older than 18 years of age, follow-up shorter than 3 months, immunocompromised patients with a high likelihood of persistence or recurrence, refusal of parents to sign informed consent.
Technique	Endoscopic pilonidal sinus treatment (EPSiT) procedure was done by trained paediatric surgeons according to technique described by Meinero 2014. Some surgeons used minor modifications such as 'continuous jet of saline solution instead of glycine-mannitol to ensure clear vision, avoiding use endobrush and using a stool to obtain a better ergonomics during the procedure'. EPSiT has been performed either as an outpatient or as a day case procedure. Anaesthesia was general with intubation in 11 patients, spinal in 17, local in 12 and blended in 3. Antibiotic prophylaxis was given in 29 patients. Patients were followed up on a regular basis. Long-term follow-up was done after a median 4 months (2-16 months).
Follow-up	Median 4 months (range 3 to 16 months)
Conflict of interest/source of funding	One author Meinero is a consultant for the manufacturer and patented and invented the fistuloscope used. All others declare that they have no conflicts of interest.

Analysis

Follow-up issues: short follow-up

Study design issues: small study conducted in 4 paediatric surgery units. Demographic, diagnostic, procedure and clinical data were collected prospectively and retrospectively analysed. Key outcomes assessed were recurrence, delayed healing, infection and success.

Study population issues: Two patients had comorbidities: brainstem tumour and congenital heart malformation.

Other issues: this study included data from 1 centre of 15 patients that has been published separately (Esposito 2018 added to table 2).

IP overview: Endoscopic ablation for a pilonidal sinus

Key efficacy and safety findings

Efficacy		Safety	
Number of patients analysed: 43		Complications	
Procedure and clinical outcomes of EPSiT			% (n)
Mean length of procedure, minutes	34±7.2	Overall complication rate	16 (6/43)
Length of hospital stay, hours	24 (range 12 to 72)	Granuloma (in the site of endoscopy, treated with topical silver nitrate administration)	5 (2/43)
Complete healing after a median of 3 weeks (range 2 to 6 weeks)** % (n)	88% (38/43)	Reoperation	9 (4/43)
Recurrence* % (n)	12 % (5/43)	Surgical site infection~ (this patient did not receive antibiotic prophylaxis preoperatively)	2 (1/43)
Delayed healing^ % (n)	5% (2/43)	~defined as persistent smelly discharge with pain and redness possibly associated to systemic signs requiring antibiotic administration.	
*defined as persistence of discharge after more than 3 months with either abscess formation, infection or local pain and discomfort.		Post-operative pain (measured using the VAS pain scale)	
^defined as wound closure occurring after more than 6 weeks		Mean VAS score was 2 ± 1.4 at 6 hours after the procedure.	
**defined as complete wound closure, no discharge, no pain in the area of surgery either spontaneously or during palpation, no signs of infection/inflammation.		The mean VAS score for local anaesthesia was significantly higher (3.2 ± 1.1) when compared to general (0.2 ± 0.4, p<0.0001) and spinal anaesthesia (2.06 ± 0.6, p=0.0004) respectively.	
Abbreviations used: EPSiT, endoscopic pilonidal sinus treatment; VAS, visual analogue scale			

Study 6 Esposito C (2018)

Details

Study type	Comparative case series
Country	Italy (1 centre)
Recruitment period	Not reported
Patient population and number	n= 30 paediatric patients with pilonidal sinus fistulas EPSiT (n=15) versus conventional open repair (n=15)
Age and sex	Average age 16 years (range 13-18 years), 60% (9/15) male
Patient selection criteria	Paediatric patients with pilonidal sinus fistulas operated using EPSiT over an 18 month period.
Technique	<p>Paediatric endoscopic pilonidal sinus treatment (PEPSiT) procedure:</p> <p>Patients are given a specific type of subarachnoid spinal anaesthesia and antibiotic prophylaxis. Premedication was given to obtain light sedation. In patients with an active infection or abscess, antibiotic therapy is usually given to clear the infection and after 1-3 weeks the procedure is performed.</p> <p>Patient is then placed in prone position and the technique done as described by Meinero 2014 (a fistuloscope, endoscopic forceps and a monopolar electrode used to remove hairs and heal the fistula). Surgeons used minor modifications such as 'continuous jet of saline solution instead of glycine-mannitol to ensure clear vision, avoiding use endobrush and using a stool to obtain a better ergonomomy during the procedure'.</p> <p>Instructions were given on daily wound care (applying antiseptic lotion and a silver sulfadiazine spray for 3 weeks) and antibiotics for 5 days. Postoperatively hair removal was done with shaving until wound healing and then with laser. Four cases were redo-procedures, for recurrence of disease after open excision repair.</p> <p>In OPEN group a wide excision of the fistula tract until the bone and a primary closure of the wound were performed.</p>
Follow-up	Mean 6 months (range 1-18 months)
Conflict of interest/source of funding	No competing financial interests.

Analysis

Follow-up issues: short follow-up by clinical examinations at 1 and 2 weeks and then at regular follow-up intervals (1, 3, 6, 12 and 18 months).

Study design issues: small study conducted in 1 paediatric surgery unit. Study group outcomes were compared with outcomes of 15 patients who had classic open excision in the same centre.

Other issues: data from this study has been included in Pini Prato 2018 added to table 2.

Key efficacy and safety findings

Efficacy				Safety			
Number of patients analysed: 15				Post-operative complications			
Procedure and clinical outcomes							
	PEPSiT (n=15)	Classic open excision (n=15)	P value		PEPSiT (n=15)	Classic open excision (n=15)	P value
Average operative time, minutes	28.5 (range 26-41)	42	0.001	Bleeding	0	1	0.001
Average VAS pain score during first 48 hours	3.2 (range 2-5)	6.8	0.001	Recurrence	0	13.3% (2/15)	0.001
Average analgesic requirement, hours	22	88	0.001				
Average hospital stay, hours	28 (range 22-48)	76	0.001				
Average time to full daily activities, days	2.5 (range 1-4)	15.4	0.001				
Average healing time, days	30	92	0.001				
Patient satisfaction	100%	NR					
Abbreviations used: NR, not reported; PEPSiT, paediatric endoscopic pilonidal sinus treatment; VAS, visual analogue scale.							

Study 7 Jain Y (2017)

Details

Study type	Case series
Country	UK
Recruitment period	2015 to 2016
Patient population and number	n=19 patients with pilonidal abscess <u>Type of pilonidal abscess</u> : primary 52% (10/19); recurrent 48% (9/19) <u>Median duration of symptoms</u> : 4 days (range 27 to 31 days) <u>Median abscess size</u> : 4 cm (range 4 to 5 cm) <u>American Society of Anaesthesiologists (ASA) grade</u> : 1 (range 1-1)
Age and sex	Median age 24 years (range 22-25 years), 52% (10/19) male, Median BMI 28 (range 27–31);
Patient selection criteria	Patients undergoing Endoscopic pilonidal abscess treatment (EPAT between January 2015 and March 2016.
Technique	EPAT is done under general anaesthesia with the patient in lateral or prone position. This involves making a small incision at the point of maximum fluctuance, draining the pus and a thorough washout of the abscess cavity followed by ablation of the cavity under direct vision using a fistuloscope. A small dressing is applied to the wound. Patients were advised to self-irrigate the wound with saline twice daily.
Follow-up	Median 10.5 months (range 6-12 months)
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: short follow-up; patients were initially examined after 2 weeks with subsequent follow-up at 3 and 6 months.

Study design issues: small study conducted in 1 unit by two surgeons. Demographic, pre-operative and post-operative data were collected prospectively and analysed. Key outcomes assessed were efficacy within 6 weeks, duration of wound healing, post-operative pain, need for analgesia and time to return to usual daily activities.

Key efficacy and safety findings

Efficacy		Safety	
Number of patients analysed: 19		Complications	
Procedural and clinical outcomes		Pain (measured on a VAS pain scale)	
Median operative time, minutes	36 (range 29-47)		
Discharge within 24 hours	73% (14/19)	Pre-operative	Post-operative
Time to complete wound healing, weeks	Median 4 weeks (range 3.5 -6 weeks)	Median VAS pain score	7 (range 6-7)
Return to activities of daily life within 48 hours	100%		1 (range 1-2)
Readmission within 6 weeks for further surgery	0	Further surgery during follow-up	
Need for post-operative antibiotics	0	21% (4/19) of patients needed further surgical intervention for pilonidal disease. 3 of these patients were from recurrent pilonidal abscess group and one was a primary group. 2 of them had excision and 2 needed flap reconstruction and 1 of them developed recurrence following intervention.	
Abbreviations used: VAS, visual analogue scale			

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Study 8 Milone M (2018)

Details

Study type	Comparative study (propensity score matched analysis)
Country	Italy (single centre)
Recruitment period	2011 to 2013
Patient population and number	n=80 patients with pilonidal sinus disease (40 video assisted ablation of pilonidal sinus [VAAPS] versus 40 standard sinusectomy) Complex disease: VAAPS 67.5% (27/40), sinusectomy 60% (24/40)
Age and sex	mean age -VAAPS: 26.49 years; Sinusectomy 25.22 years 75-825 male
Patient selection criteria	Patients with chronic non-recurrent sacrococcygeal pilonidal sinus identified at an outpatient clinical evaluation, those with an indication for surgery and with signs of inflammation treated with antibiotics, with a follow-up of at least 5 years were included. Patients previously treated by incision and drainage for the presence of an abscess, those with acute pilonidal disease and the presence of any comorbidity and inability to consent to participate in study were excluded.
Technique	Video-assisted ablation of pilonidal sinus (VAAPS) was done by one surgeon only. Standard sinusectomy was performed by expert surgeons. Orifices of the sinus were probed, methylene blue injected to mark subcutaneous tract, after that orifices and sinuses were excised and after haemostasis the wounds were left open for secondary wound healing. Both procedures were done under local anaesthesia, all patients examined during follow-up after day 1, 1 week, 1 month, 6 months and every year thereafter.
Follow-up	5 years
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: complete follow-up.

Study design issues: Propensity score analysis was done to exclude any bias related to allocation of patients into groups. Data from a small sample group was analysed retrospectively.

Population issues: patients in the 2 groups were similar in terms of sex, age, BMI, smoking status and complexity of sinus.

Key efficacy and safety findings

Efficacy				Safety			
Number of patients analysed: 80				Complications			
Procedural and clinical outcomes							
	VAAPS (n=40)	Standard sinusectomy (n=40)	P value		VAAPS	Standard sinusectomy	P value
Median operative time (minutes)	44.39 +/- 7.76	30.38 +/- 6.23	0.001	Pain score 1 day after surgery	3.71 +/- 1.24	3.76 +/- 1.39	0.883
Recurrence rate %	7.5 (3/40)	25 (10/40)	0.035	Pain score 1 week from surgery	1.40±0.41	1.53±0.30	0.106
Satisfaction at 6 months (points)	8.3 +/- 1.2	8.2 +/- 1.3	0.78	Infection (%)	12.5 (5/40)	30 (12/40)	0.057
Time off from work (days)	2.01 +/- 1.30	2.08 +/- 1.24	0.769				
Mean recurrence time over follow-up (months)	45.33±10.21	44±8.98					
Abbreviations used: VAAPS, video-assisted ablation of pilonidal sinus;							

Validity and generalisability of the studies

- EPSiT is the name given to the procedure to treat pilonidal sinus with the VAAFT equipment.
- Only 1 randomised controlled trial and 3 retrospective comparative analyses compared EPSiT with conventional treatments. The remaining studies were small case series. Half of the studies in the systematic reviews were from 1 study group and there is an overlap of studies between the 2 systematic reviews included in the overview.
- There is some evidence of the use of the procedure in paediatric patients.
- Only 2 studies were from UK.
- The long-term outcome of the procedure is unclear.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

There is currently no NICE guidance related to this procedure.

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Two Specialist Advisor Questionnaires for endoscopic ablation for a pilonidal sinus were submitted and can be found on the [NICE website](#).

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 1 company who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- [NCT02222298](#) Video Assisted Ablation of Pilonidal Sinus versus Conventional Treatment. Prospective study of 300 patients; completion date November 2015; location: Italy.
- [NCT01963273](#) Video Assisted Ablation of Pilonidal Sinus. Evaluation of safety and efficacy of a minimally invasive technique. Prospective study of 200 patients; status: unknown; completion date December 2015. Location: Italy.

References

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7. Jain Y, Javed MA, Singh S et al (2017). Endoscopic pilonidal abscess treatment: a novel approach for the treatment of pilonidal abscess. *Ann R Coll Surg Engl*; 99: 134–136.
8. Milone M, Velotti N et al (2018). Video-assisted ablation of pilonidal sinus (VAAPS) versus sinusectomy for treatment of chronic pilonidal sinus disease: a comparative study. *Updates in Surgery* (12) 12.

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	28/12/2018	Issue 12 of 12, December 2018
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	28/12/2018	Issue 12 of 12, December 2018
HTA database (CRD website)	28/12/2018	n/a
MEDLINE (Ovid)	28/12/2018	1946 to December 27, 2018
MEDLINE In-Process (Ovid) & MEDLINE Epubs ahead of print (Ovid)	28/12/2018	December 27, 2018
EMBASE (Ovid)	28/12/2018	1974 to 2018 Week 52

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

- 1 Pilonidal Sinus/
- 2 ((pilonidal* or sacrococcygeal or coccygeal or natal cleft) adj4 (sinus* or cyst* or abscess* or infect* or disease*)).tw.
- 3 1 or 2
- 4 Video-Assisted Surgery/
- 5 ((video-assist* or (video* adj2 assist*)) adj2 (ablat* or surg* or tech* or treat* or therap* or device*)).tw.
- 6 (video-telescope* or video telescope*).tw.
- 7 (unipolar-electrode* or unipolar electrode*).tw.
- 8 ((Fistula* or endoscop*) adj2 (brush* or forcep*)).tw.
- 9 fistuloscop*.tw.
- 10 (Endoscop* adj4 ablat*).tw.
- 11 *Endoscopy/mt

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- 12 (EPSiT or "E.P.Si.T.").tw.
- 13 (endoscop* adj2 pilonidal adj2 sinus* adj2 treat*).tw.
- 14 VAAPS.tw.
- 15 "Video-assisted ablation of pilonidal sinus".tw.
- 16 Video* assist* anal fistula* treat*.tw.
- 17 VAAFT.tw.
- 18 or/4-17
- 19 3 and 18
- 20 limit 19 to ed=20180628-20181231

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Chia CL, Tay VW and Mantoo SK (2015). Endoscopic pilonidal sinus treatment in the Asian population. Surgical Laparoscopy, Endoscopy & Percutaneous Techniques (25) 3 e95-7.	Retrospective review N=9 patients with pilonidal sinus disease treated with EPSiT Follow-up; 2.5 months	The median age was 24 years (range, 16 to 41 y). The median duration of follow-up was 2.5 months (range, 1 to 5 mo). Median duration of sinus healing is 6 weeks (range, 2 to 7 wk). One patient had pain despite sinus healing. Satisfaction rate was 78% (7/9).	Included in study 1 in table 2.
Esposito, C., Escolino, M et al (2018). Pediatric endoscopic pilonidal sinus treatment (pepsit), a revolutionary technique to adopt in children with pilonidal sinus fistulas: A comparative study with classic open repair. Journal of Laparoendoscopic and Advanced Surgical Techniques (28 (7)) A28-A29.	Comparative case series N=30 patients with non-infected pilonidal sinus disease G1: 15 had PEPSIT G2: 15 had convention open excision surgery. Follow-up: mean 6 months (range 1-18 months)	The average length of surgery was significantly shorter in G1 compared to G2 (28.5 min vs 42 min, p = 0.001). The average pain score evaluated using VAS pain scale during the first 48 postoperative hours was significantly better in G1 compared to G2 (3.2 vs 6.8, p = 0.001). The average analgesic requirement was significantly shorter in G1 compared to G2 (22 hours vs 88 hours, p = 0.001) and so was also the average hospital stay length (28 hours vs 76 hours, p = 0.001). No postoperative complication occurred in G1 whereas a bleeding requiring operative hemostasis was recorded in one G2 patient (6.6%) (IIIb Clavien-Dindo). Two recurrences of pilonidal disease were reported in G2 (13.3%). The average healing time was significantly shorter in G1 compared to G2 (30 days vs 92 days, p = 0.001) and the average time to full daily activities was significantly shorter in G1 patients compared to G2 ones (2.5 days vs 15.4 days, p = 0.001).	Multiple publication
Gecim IE, Goktug UU, Celasin H and Balci D (2016). Video-assisted treatment of pilonidal disease, using a combination of diathermy ablation and phenol application. BMJ Case Reports (13) 13.	Case report N=1 Video-assisted diathermy ablation (VADA) and crystallised phenol application (CPA) for sacrococcygeal pilonidal disease (SPD).	First case in the literature that has been treated by combining CPA and VADA. The patient healed within less than a month, with no need for professional wound care, and was free of recurrence at 2-year follow-up	Combination treatment

IP overview: Endoscopic ablation for a pilonidal sinus

<p>Gecim IE, Goktug U U. and Celasin H (2017). Endoscopic Pilonidal Sinus Treatment Combined With Crystalized Phenol Application May Prevent Recurrence. <i>Diseases of the Colon & Rectum</i> (60) 4 405-407.</p>	<p>Prospective cohort study n=23 patients underwent video-assisted diathermy ablation of the sinus cavity and the application of phenol crystals for pilonidal disease. Patients were followed up for 18 to 24 months (mean, 22.00+/-1.88 mo).</p>	<p>Patients discharged on same day. There was no or minimal post-operative pain (mean visual analogue scale score, 1.40+/-0.95). Mean operation time was 20.43+/-6.19 minutes, and the median return-to-work duration was 2.00 days (mean, 3.03+/-2.95 d). No serious complications or rehospitalization were observed. No primary failure to heal or recurrence was observed.</p>	<p>Combination treatment</p>
<p>Giarratano, G., Toscana, C et al (2017). Endoscopic Pilonidal Sinus Treatment: Long-Term Results of a Prospective Series. <i>Journal of the Society of Laparoendoscopic Surgeons</i> (21) 3.</p>	<p>Case series N=68 patients had a primary sacrococcygeal pilonidal sinus, and 9 had recurrent pilonidal sinus; all had EPSiT Follow-up (median follow-up was 25 (range, 17-40) months.</p>	<p>Median operative time was 18 (range, 12-30) minutes. The median hospital stay was 6.5 (range, 5-9) hours, and the median time to return to work was 5 days. Median healing time was 26 (range, 15-45) days. There were no major or minor complications. Six patients experienced recurrence. The overall satisfaction rate was 97%.</p>	<p>Included in study 1 in table 2.</p>
<p>Isik A, Idiz O and Firat D (2016). Novel Approaches in Pilonidal Sinus Treatment. <i>Prague Medical Report</i> (117) 4 145-152.</p>	<p>Review</p>	<p>In the presented review, modalities in pilonidal sinus treatment in the light of current information in the literature are evaluated.</p>	<p>Review</p>
<p>Fowler H, Javed MA et al (2017). Comparison of conventional Incision and drainage for pilonidal abscess versus novel Endoscopic Pilonidal Abscess Treatment (EPAT). <i>Colorectal Disease</i> (19 (Supplement 4)) 10.</p>	<p>Retrospective comparative study N=40 patients undergoing incision and drainage (I&D, 20) versus EPAT (n=20) Follow-up 10.5 months</p>	<p>There was a significant difference in the median duration of complete wound healing (days) [EPAT; 16 (14-24), I&D; 28 (21-35) P-value < 0.05], return to work (weeks) [EPAT; 2.5 (2-4), I&D; 4 (2-7) P-value < 0.05], need for district nurse reviews [EPAT; 8/20 (40%), I&D 20/20 (100%), P-value < 0.05] and post-operative pain scores [EPAT; 1 (1-2), I&D 2 (1-3), P-value, 0.05] favouring the EPAT group. None of the patients required any further treatments in the follow-up period.</p>	<p>Included in study 1 in table 2.</p>

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<p>Korenkov, M (2018). Surgical Treatment for Pilonidal Sinus Disease. Surgical Technology International (32) 105-108 06 01.</p>	<p>Case series</p> <p>N=4 patients with pilonidal sinus disease (1 with abscess) had video-assisted subcutaneous destruction of the sinus tract (VADST) as well as the long-term vessel-loop drainage of the wound channel (DST)</p>	<p>Procedure steps included widening of pilonidal pits with mosquito and/or Pean clamps, the subcutaneous destroying of the sinus tract, lifting the skin in a natal cleft with a curette, removing the hair with a Pean clamp and a subcutaneous vessel-loop drainage.</p> <p>The patients with simple forms of PSD had no adverse events during the first 8 weeks postoperatively. The patient with an acute abscess formation developed a purulent inflammation that required a wide local excision with an open-wound healing. Due to the very small number of patients in this report, we were not able to assess this technique properly.</p>	<p>Larger studies included in table 2.</p>
<p>Meinero P, Mori L and Gasloli G (2014). Endoscopic pilonidal sinus treatment (E.P.Si.T). Techniques in. Coloproctology (18) 4 389-92.</p>	<p>Case series</p> <p>N=11 patients with pilonidal disease treated with EPSiT</p> <p>Follow-up 6 months</p>	<p>There were no significant complications. The pain experienced during the post-operative period was minimal. At 1 month postoperatively, the external opening(s) were closed in all patients and there were no cases of recurrence at a median follow-up of 6 months. All patients were admitted and discharged on the same day and commenced work again after a mean time period of 4 days. Aesthetic results were excellent.</p>	<p>Included in study 1 in table 2.</p>
<p>Meinero P, Staz, A et al (2016). Endoscopic pilonidal sinus treatment: a prospective multicentre trial. Colorectal Disease (18) 5 O164-70.</p>	<p>Case series</p> <p>N=250 patients with chronic PD treated with EPSiT</p> <p>Follow-up 12 months</p>	<p>The complete wound healing rate was 94.8%, and the mean complete wound healing time was 26.7 +/- 10.4 days. The incomplete healing rate (5.2%) was significantly related to the number of external openings (P = 0.01). There was no difference in the failure rate when EPSiT was performed as the first-line treatment for PD or when it was used after unsuccessful procedures (P = n.s.). Recurrence occurred in 12 cases (5%). The QoL significantly increased from pre-operative levels 15 days after the EPSiT procedure (45.3 vs 7.9; P < 0.0001).</p>	<p>Included in study 1 in table 2.</p>

Milone M, Bianco P, Musella M and Milone F (2014). A technical modification of video-assisted ablation for recurrent pilonidal sinus. <i>Colorectal Disease</i> (16) 11 O404-6.	N=4 recurrent complex pilonidal sinus treated by VAAPS plus plug positioning	All were successfully treated by this new approach. No difficulties in inserting the plug were identified. Complete healing was achieved in all cases. No infection or recurrence was reported during a limited follow-up.	Included in study 1 in table 2.
Milone M, Musella M et al (2014). Video-assisted ablation of pilonidal sinus: a new minimally invasive treatment--a pilot study. <i>Surgery</i> (155) 3 562-6.	Case series N=27 patients with primary sacrococcygeal pilonidal sinus treated with EPSiT Follow-up 12 months	All procedures were successful, with complete ablation of the sinus cavity. No infection and only 1 recurrence were recorded during the follow-up (1 year) with an immediate return to work and normal activities. In addition, patient satisfaction and aesthetic appearance were high.	Included in study 1 in table 2.