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Comparative analysis on the effect of the endoscopic versus conventional treatment for pilonidal sinus

A meta-analysis of controlled clinical trials

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Abstract

Background: Pilonidal sinus is a common disease in the sacrococcygeal region. Although many treatments have been described in recent years, the recurrence of each method remains high. Surgeons did not reach a consensus on the preferred approach for pilonidal sinus. We carried out a meta-analysis of controlled clinical trials comparing the outcomes of endoscopic treatment versus conventional treatment for pilonidal sinus disease in this study.

Methods: We performed a systematic literature search, and we used electronic databases such as PubMed/Medline, Embase, and the Cochrane library to search for the relevant literature comparing endoscopic management to other conventional treatments for pilonidal sinus disease. The primary outcome parameters were operative time, recurrence, postoperative complications and pain, and total healing time.

Results: Six studies were included in the review. Endoscopic pilonidal sinus treatment had a lower overall complication rate than the conventional surgery group (risk ratio = 0.33 [0.19–0.58], $P = .0001$) and lower pain score with a weighted mean difference of −2.44 (95% confidence interval: (−3.96) to (−0.92), $I^2 = 99\%$, $P = .002$). There was no significant difference in recurrence (risk ratio = 0.75, 95% confidence interval [0.30–1.90],$P = .55$). Compared to the excision followed by the primary closure technique, the operation time, time to complete wound healing, and satisfaction were similar.

Conclusions: Endoscopic pilonidal sinus treatment is a unique and potential method of sacrococcygeal pilonidal disease treatment. The foremost benefits of this technique are mild postoperative pain, lower complications rate, and return to routine for a shorter time. However, due to the limited number of articles, we need to conduct more rigorous large-sample prospective randomized controlled trials to clarify the efficiency of endoscopic treatment for pilonidal cysts.

Abbreviations: CI = confidence interval, EHSI = en-bloc excision and healing by secondary intention, EPC = excision and primary closure, EPSiT = endoscopic pilonidal sinus treatment, ERAS = enhanced recovery after surgery, NA = Not available, PSD = pilonidal sinus disease, RCT = randomized controlled trial, RR = risk ratio.

Keywords: endoscopic treatment, pilonidal sinus, VAAPS

1. Introduction

Pilonidal sinus disease (PSD) is a widely known inflammatory condition of the gluteal region, with a population incidence of 26 per 100,000. It primarily afflicted males 4 times more than females and it mainly troubled young adults of working age.[1,2] This disease can manifest as an acute pointing abscess or a chronic sinus with intermittent drainage in patients. Whatever the presentation, the infected pilonidal sinus is usually followed by one or more pits in the midline.[3] For symptomatic patients, the onset of the disease can cause significant distress to them. In addition, after surgical excision, a high rate of wound complications leads to prolonged healing time and, as a result, a more extended return to regular activities.[4]

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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According to the studies, surgical resection is the primary treatment of pilonidal disease, and it is the key to preventing the recurrence of PSD. With the development of medical technology, various techniques have been reported to deal with this problem, such as excision with lay open, primary closure after excision, Karydakis procedure, Bascom cleft lift, and Limberg flap. Recurrent disease with its concomitant morbidity remains a concern, and no single therapeutic option has acquired general acceptability.[5–12]

In recent years, people are more and more inclined to minimally invasive surgery. Minero et al[13] introduced a more minimally invasive approach for sacrococcygeal pilonidal disease named Endoscopic Pilonidal Sinus Treatment in 2013 (EPSiT). The authors employed the same video-assisted anal fistula treatment device and technology to treat primary and recurrent pilonidal disease. The idea behind endoscopic pilonidal sinus treatment (EPSiT) is to use a Futuroscope to remove all damaged tissues through a small circular incision endoscopically. It will bring down the surgical morbidity associated with more wide-ranging flap reconstruction.

In this study, we conducted a meta-analysis of controlled clinical trials comparing the outcomes of Endoscopic treatment versus conventional treatment for PSD.

2. Materials and methods

2.1. Search strategy

From inception until February 2022, a comprehensive search of electronic databases such as PubMed, Embase, and the Cochrane library was conducted. We adopted the search terms: (pilonidal sinus) and (endoscopic OR VAAPS OR EPSiT OR minimally invasive). Two reviewers carried out a literature search and review of the articles. In addition, all of the retrieved publications' reference lists were manually reviewed.

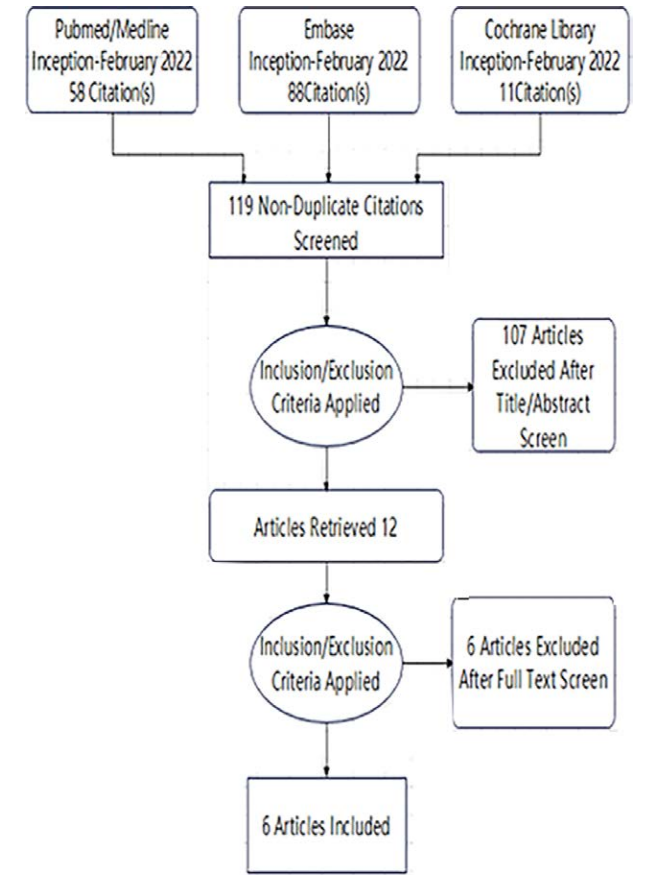

Figure 1. Flow diagram of the search strategy and study selection.

2.2. Eligibility criteria

All studies, whether randomized or nonrandomized that compare the endoscopic versus conventional surgery for the treatment of pilonidal sinus were qualified for inclusion. As for language, we have no restrictions.

We excluded extraneous articles, editorials, letters, cases reports, reviews, single-arm studies, and meta-analyses. We also excluded the articles that did not explicitly report the main results of this review. We included studies with the most comprehensive data for similar literature.[14,15]

2.3. Data extraction

Both investigators did data extraction separately, and the data extraction between them was double-blind. The data extraction of each study was extracted using a unified, standardized statistical table. We extracted the data from each study, including the type, duration, and country of the study; patient characteristics

Figure 2. Summary of review authors' assessments of risk of bias for each Cochrane item and each included study.

such as age, gender distribution, and comorbidities; technical details of the procedure; operation time; VAS pain scores; incidence of recurrence of sacrococcygeal pilonidal disease; complications rate; full healing time, time to everyday life, and length of follow-up.

2.4. Evaluation of literature quality

The modified Jadad scoring system (total score of 7 points, including randomization, double-blind, and follow-up) evaluated the included RCTs' methodological quality. 1 to 3 points were considered low quality, and 4 to 7 points to high quality. The methodological quality of the non-RCT studies was evaluated using the MINORS scale. Scores ≥ 18 were high-quality clinical trials.

2.5. Statistical analysis

Statistical analysis was performed using RevMan version 5.3 software. The risk ratio (RR) and 95% confidence interval (CI) were calculated for each trial result. Heterogeneity between studies was assessed. We defined $I^2 < 50\%$ as less heterogeneity, and $I^2 \geq 50\%$ considered more significant heterogeneity among studies. If $I^2 < 50\%$, we used the fixed model. Otherwise, a random model was used. We used the funnel plot method to evaluate the publication bias of the included literature. The asymmetry of the funnel plot indicated the situation of publication bias, and the more significant the asymmetry, the greater the degree of bias. A *P*-value less than .05 was considered significant.

3. Results

3.1. Patient and study characteristics

Six studies[14,16–20] were available after the initial screening and were included in the review (Fig. 1). Two studies were carried out in Italy, 1 in the UK, 1 in Poland, 1 in Portugal, and another in Spain. Three prospective studies, 2 retrospective series, and 1 randomized controlled trial were included. The publication bias of the studies was assessed by using the Review Manager program (Rev Manager 5.3) according to the Cochrane tool (Fig. 2). The characteristics of the literature and the outcome of quality appraisal of the trials are shown in Table 1.

This study included 458 patients, 195 of whom received endoscopic treatment, and the remaining patients were treated using other surgical methods. Table 2 shows the specific demographic characteristics and results.

3.2. Operation time

Data on operative time was given in 5 studies. The EPSiT had a considerably longer operation time than conventional surgery, with a weighted mean difference of 11.29 (95 % CI: 3.10 to 19.49, $I^2 = 96\%$, $P = .007$). We divided it into 3 subgroups based on the surgical approaches. There was no significant difference between the EPSiT and the excision followed by the primary closure technique (including the flap technique) ($P = .54$) (Fig. 3).

3.3. Disease recurrence

All trials included details on illness recurrence. The meta-analysis revealed a tendency toward a decreased incidence of recurrent conditions with endoscopic therapy, with a RR of 0.75, although this was not statistically significant ($P = .55$, 95 %CI [0.30–1.90]). Milone[21] advocated that a follow-up period of at least 5 years is the gold standard for assessing the effective recurrence rate of pilonidal sinus. So we ran a subgroup analysis based on follow-up time; both categories with endoscopic treatment had decreased recurrence rates, but the difference was not statistically significant. (follow-up = 5 years: RR = 0.62, 95%CI: 0.19–2.04, $I^2 = 69\%$, $P = .43$; follow-up < 5 years: RR = 0.84, 95%CI: 0.12–5.83, $I^2 = 71\%$, $P = .86$) (Fig. 4).

3.4. Complications

Common complications after both procedures included wound infection (5.14% after EPSiT vs 12.03% after conventional surgery), wound dehiscence (0 vs 4.98%), seroma (0 vs 2.49%), hematoma (1.71 vs 0.83%), bleeding (0 vs 2.49%), granutoma (0 vs 2.07%), infection and dehiscence (0 vs 2.90%), and infection and bleeding (0 vs 0.41%). The EPSiT group had a considerably reduced overall rate of complications than the traditional surgery group (RR = 0.33 [0.19-0.58], $P < .0001$), according to the meta-analysis (Fig. 5).

Table 1

Characteristics of included studies.

Study	Country	Duration	Type	Type of sinus (primary/recurrent/acute)	Endoscopic technique	Conventional surgery	Follow-up (mo)	Study quality
Javed et al	UK	January 2015 to April 2016.	Retrospective	Acute	EPAT(n = 20)	Conventional incision(n = 20)	3-6	15
Milone et al	Italy	March 2011 to August 2013	Prospective	Chronic non-recurrent	VAAPS (n = 40)	Sinusectomy (n = 40)	60	21
Romaniszyn et al	Poland.	2013 to 2018	Prospective	Recurrent	EPSiT (n = 26)	Limberg (n = 34)	27	20
Milone et al	Italy	January 2012 to December 2013.	RCT	Chronic nonrecurrent	VAAPS (n = 76)	Bascom cleft lift treatment (n = 69)	60	5
Sequeira et al	Portugal	January through December 2015 for conventionally treated patients January through December 2016 for EPSiT	Retrospective	Chronic recurrent or nonrecurrent	PEPSiT (n = 21)	Excision followed by primary closure (EPC) (n = 63)	11.9 (EPSiT) 24.7 (EPC)	17
Pérez-Bertólez et al	Spain	January to December 2019	Prospective		PEPSiT (n = 14)	EHSI (n = 23), EPC (n = 12)	14.8	19

EHSI = en-bloc excision and healing by secondary intention, EPSiT = endoscopic pilonidal sinus treatment, RCT = randomized controlled trial.

Table 2

Patient's demographic characteristics and results.

Study	Age (yr)		Male (%)/M:F		Operating time(min)		VAS pain scores			Time of healing (d)			Complications		Recurrence	
	E	C	E	C	E	C	E	C		E	C		E	C	E	C
Javed et al	24	24	NA	NA	38.5 (29–47)	13.5 (11–15)	1 (1–2)	2 (1–3)		16 (14–24)	35 (24.5–42)		NA	NA	0	3
Milone et al	26.49 ± 5.53	25.22 ± 6.04	82.5	75	44.39 ± 7.76	30.38 ± 6.23	1.4 ± 0.41	1.53 ± 0.3		NA	NA		5	12	3	10
Romaniszyn et al	29.03 (20–47)	28.55 (17–60)	24:2	28:6	60 (25–80)	67 (35–95)	NA	NA		42 (31–77)	21 (10–24)		3	9	7	2
Milone et al 2020	25.5 ± 5.9	25.7 ± 5.3	78.9	78.3	42.9 ± 9.8	26.5 ± 8.7	1.65 ± 2.9	4.15 ± 4.9		NA	NA		4	7	18	16
Sequeira et al	15.9	16.3	76.2	71.4	30 (20–90)	38 (17–105)	NA	NA		28 (15–270)	37.5 (11–203)		2	17	2	13
Pérez-Bertólez et al	15.35 (13.73-16.56)	EHSI n = 23 15.86	EPC n = 12 16.17	35.7	57.14	NA	0.5 ± 0.8	EHSI 7.3 ± 2.4	EPC 7 ± 2.0	3.1 ± 0.8	EHSI (Weeks) 14.9 ± 10.5	EPC (Weeks) 6.1 ± 4.6	0	16 7	0	0

Data for the 3 articles (Javed et al/Romaniszyn et al/Sequeira et al) are presented as median, the rest as mean (SD). E = experimental group; C = controlled group; NA = not available; EHSI = en-bloc excision and healing by secondary intention; EPC = excision and primary closure.

3.5. Postoperative pain

Four studies covered data on postoperative pain scores. Meta-analysis revealed that the EPSiT had a significantly lower pain score than conventional surgery, with a weighted mean difference of –2.44 (95%CI: (–3.96) to (–0.92), I^2 = 99%, P = .002) (Fig. 6).

3.6. Full healing time

The study demonstrated no difference between the 2 bunches with a standard mean benefit of –0.57[(–2.55) to 1.41] (P = .57). We also performed subgroup analyses, but the results did not change (Fig. 7).

3.7. Quality of life and patient satisfaction

Only 2 studies reported patient satisfaction, and there was no difference between the 2 procedures (Fig. 8).

3.8. Cost

Only one experiment from Italy reported cost data, and endoscopic treatment was less expensive than other conventional procedures. Most other healthcare systems may not be able to use this finding.

3.9. Study bias

Funnel plots appeared to be no proof of publication inclination in this meta-analysis.

4. Discussion

Pilonidal sinus is a complex disorder that often occurs in young men. Not only does it cause discomfort to the patient, but it also imposes an economic burden on society. In recent years, various methods have been described demonstrating the complexity of treating pilonidal sinus. As for pilonidal abscess, the most effective emergency management is simple incision and drainage. However, surgical treatment of chronic and recurrent diseases remains disputable. Many studies suggested advocating one treatment over another, but the absence of comparison groups or short-term follow-up weakened the studies' credibility. In addition, it reported that the long-term recurrence rates of recurrent pilonidal sinus varied from 10% to 30% after operative intervention.[22,23] It is still a challenge for surgeons. In the last few years, investigators have begun looking for more minimally invasive ways to treat the pilonidal sinus. In 2013, Meinero et al first proposed the endoscopic treatment of pilonidal sinus. Since then, many researchers have conducted prospective or retrospective studies on endoscopic treatment for pilonidal sinus. These studies[24–41] showed that endoscopic therapy was a safe, minimally invasive, and less complicated treatment method, but most were single-arm experiments. Therefore, we need more prospective randomized trials with adequate long-term follow-up to improve the body of evidence.

This study reviewed the outcomes of controlled clinical trials that compared endoscopic treatment to conventional treatment for PSD. The results of this study confirmed that endoscopic treatment provided some benefits indeed.

The most significant benefits of endoscopic therapy were minimal postoperative pain, a lower rate of complications, and return to routine for a shorter time. In our outcomes, only 5.14% of patients who accepted the endoscopic treatment suffered from wound infection, and the rate was lower than other conventional treatments. Thus, the postoperative healing time might be shortened. The findings agreed that endoscopic treatment was associated with a lower occurrence rate in terms of other complications. Other studies have shown a significant difference in infection rates between endoscopic treatment and

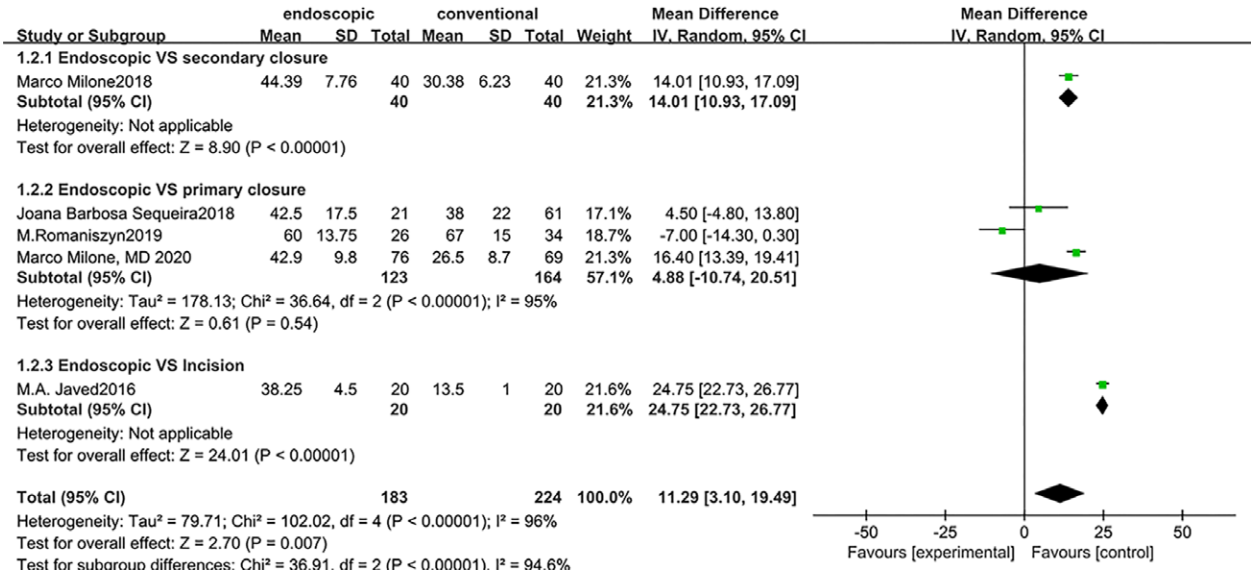

Figure 3. Forest plots of operative time in subgroup analysis by different surgical methods using a random-effect model. Each square represents the individual study's mean score with a 95% CI indicated by the horizontal line. CI = confidence interval.

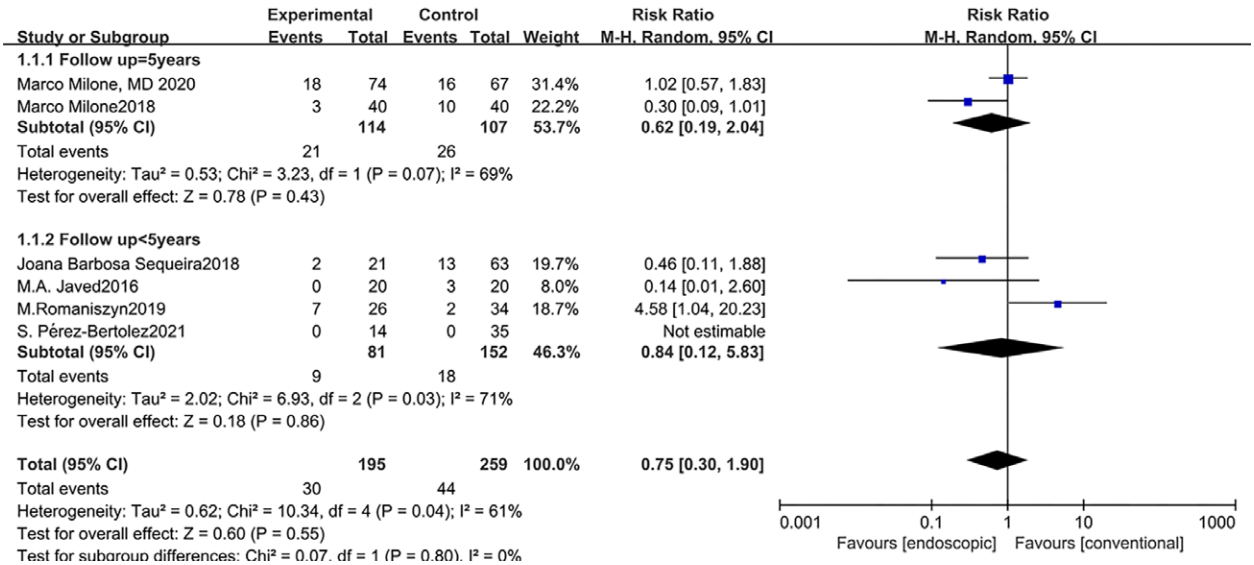

Figure 4. Forest plots of recurrent rate in subgroup analysis by the length of follow-up using a random-effect model. Each square represents the individual study's mean score with a 95% CI indicated by the horizontal line. CI = confidence interval.

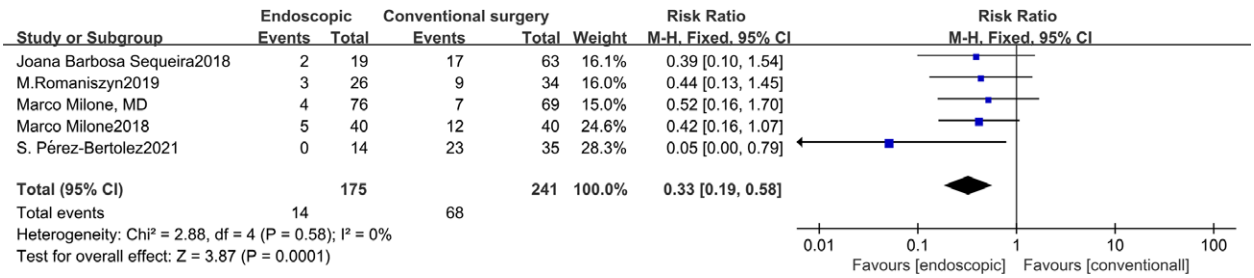

Figure 5. Forest plots of complications using a fixed-effect model. Each square represents the individual study's mean score with a 95% CI indicated by the horizontal line. CI = confidence interval.

conventional therapies. Endoscopic treatments may be a promising intervention based on our findings, as they showed lower rates of complications.

Nowadays, many surgeons recommend using off-midline primary closure with different flap techniques because they are more likely to improve patient outcomes. Based on this point,

we performed the subgroup analysis according to the different techniques and compared the outcomes of endoscopic therapy with the primary closure technique (including the flap technique). In our results, the operative time was shorter in conventional techniques. However, we found no significant difference in operative time when the subgroup analysis was performed. We discovered no substantial difference between endoscopic treatment and conventional surgery in terms of recurrences, but there was a tendency toward fewer recurrences in favor of endoscopic treatment. Only 6 comparative studies cannot demonstrate the advantages of endoscopic therapy. Due to the lack of randomized prospective studies comparing the endoscopic technique to conventional treatment, it is impossible to rule in favor of any of these surgical methods.

Patients who had EPSiT could return to work faster than those who received primary closure or the open laying approach. This procedure also resulted in lower pain scores than previous methods. It also reduced the number of dressings required following surgery. Extrapolating, we can assume that sick leave expenses are lower in the case of endoscopy than in the case of other treatments. It could be beneficial to the general public's health.

4.1. The limitations in our study

Although the quality of the literature included in this paper is high, the total number of literature is 6, and the number of literature and the sample size of some literature is small, which limits the strength of the demonstration of the results of this systematic review. More trials, particularly randomized trials, comparing endoscopic pilonidal sinus therapy to other conventional techniques are needed to assess surgical results with adequate follow-up. Moreover, to make more valid conclusions about the EPSiT's effectiveness and safety.

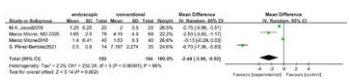

Figure 6. Forest plots of postoperative pain score using a random-effect model. Each square represents the individual study's mean score with a 95% CI indicated by the horizontal line. CI = confidence interval.

5. Conclusions

Endoscopic pilonidal sinus treatment is a unique and potential method of SPD treatment. The foremost benefits of this technique are slight postoperative pain, lower complications rate, and return to routine for a shorter time. However, due to the limited number of articles, we need to conduct more rigorous large-sample prospective randomized controlled trials to clarify the efficiency of endoscopic treatment for pilonidal cysts.

Author contributions

Conceptualization: Guangyao Dai, Wen Chen, Mingxiang Wang.
Data curation: Sihan Chen, Xian Zhao, Jie Zhang, Chengpeng Yang.
Formal analysis: Sihan Chen, Peng Liu, Xin Xu.
Methodology: Sihan Chen, Guangyao Dai, Peng Liu, Liwei Wang.
Project administration: Guangyao Dai.
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Software: Sihan Chen, Xian Zhao, Chengpeng Yang.
Supervision: Guangyao Dai.
Validation: Guangyao Dai.
Visualization: Sihan Chen.
Writing – original draft: Sihan Chen, Peng Liu, Dian Zhang.
Writing – review & editing: Peng Liu, Sihan Chen.

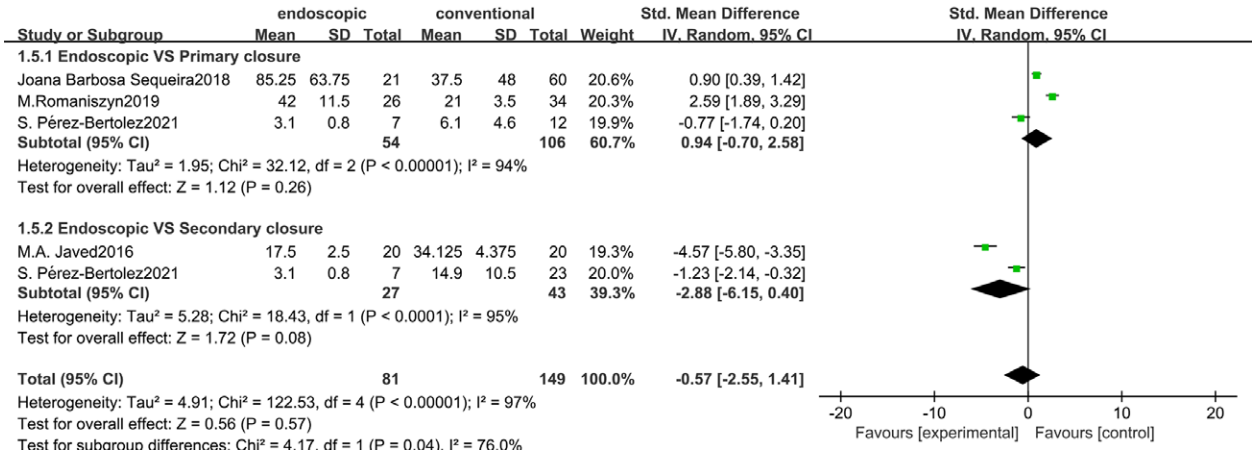

Figure 7. Forest plots of full healing time in subgroup analysis by different surgical methods using a random-effect model. Each square represents the individual study's mean score with a 95% CI indicated by the horizontal line. CI = confidence interval.

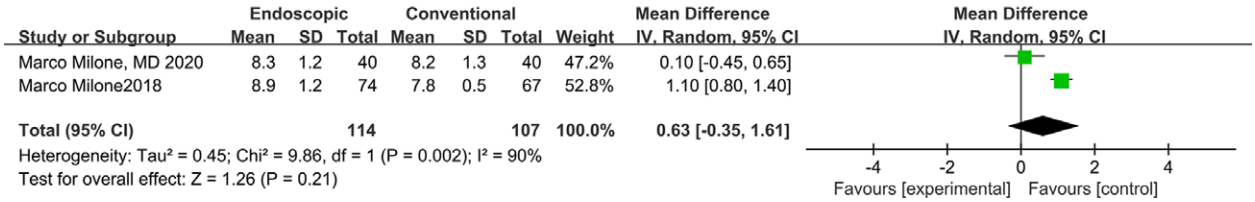

Figure 8. Forest plots of satisfaction using a random-effect model. Each square represents the individual study's mean score with a 95% CI indicated by the horizontal line. CI = confidence interval.

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