

SYSTEMATIC REVIEW

Word catheter in women with Bartholin's cysts: a systematic review and meta-analysis

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ABSTRACT

Objective. Our study aims to compare the outcomes of Word catheter and marsupialization as the main treatment modalities in women with Bartholin's cysts or abscesses.

Materials and Methods. An electronic database search was conducted using PubMed, MEDLINE, the Cochrane Library, ClinicalTrials.gov, Embase, and Google Scholar. The date of the last screening was April 20, 2023. Randomised clinical trials (RCTs) and non-randomised clinical trials evaluating the efficacy of the Word catheter compared to marsupialization of Bartholin cysts or abscesses were included.

Results. A total of 671 articles were analyzed. After excluding duplicates and irrelevant reports, five studies were included in the qualitative and quantitative synthesis: one publication was a randomized trial, and four were non-randomized studies, which yielded 756 patients. There was no statistically significant difference between the Word catheter and the marsupialization group (RR = 1.28, 95% CI: 0.84–1.95, P = 0.26) in terms of recurrence rates. The heterogeneity for this comparison was 15%. The results of the three studies show that the duration of the procedure was shorter in the Word catheter group compared to the marsupialization group. Increased pain scores during treatment and post-treatment were more common in the Word catheter group.

Conclusions. Our systematic review and meta-analysis show that there is no statistically significant difference regarding recurrence rates. In addition, marsupialization, compared to the Word catheter, is a more traumatic treatment method with a longer duration and requires general anesthesia and an operating theater. Nevertheless, correct therapeutic management and a personalized approach are important to ensure effective treatment and prevent complications.

Key words

Word catheter, Word balloon, Bartholin gland, Bartholin's cyst, Bartholin's abscess.

INTRODUCTION

Approximately 2% of women of reproductive age have a risk of developing Bartholin's cyst or abscess as a complication at least once in a lifetime [1,2].

The Bartholin's glands are essential organs of the female reproductive system that are active toward puberty. These pea-sized glands are symmetrically located in the posterior aspect of the labia minora and produce secretions of mucus that lubricate the vagina.

Bartholin's cyst is a condition that happens due to obstruction of the distal Bartholin's duct because of inflammation or trauma that causes the accumulation of secretions and cystic dilatation. An abscess develops when infection is a factor in this process [3].

These conditions can today be treated with a wide range of techniques, including simple incision and drainage, marsupialization, a Word catheter, and others.

Bartholin's cyst or abscess treatment methods and technologies are improving and becoming more effective in recent years.

Efficient, cost-effective, and availability are the main requirements for surgical treatment of Bartholin gland pathologies. The possibility of performing the procedure without using general anesthesia [4]. Word catheter is a thin silicone tube ending in a small balloon that is placed, inflated, and fixed in the Bartholin gland (after opening and draining the abscess or cyst) to allow for continued drainage and epithelialization.

It should be noted that reduction of frequencies and recurrence risks are two of the main criteria for the effectiveness of the Word catheter method.

However, there are still a lot of controversies about whether the Word catheter is an effective and safe method for Bartholin's cyst treatment. [24]

Therefore, our study aims to compare the outcomes of Word catheter and marsupialization as the main treatment modalities in women with Bartholin's cysts or abscesses.

MATERIALS AND METHODS

The present systematic review was registered in the PROSPERO international prospective registry of systematic reviews by the National Institute of Health Research (NIHR). Protocol and registration number: PROSPERO 2021 CRD42021291268 [5]

Our systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 guidelines for reporting systematic reviews [6]. Institutional review board (IRB) approval was not requested since the present study is a review. All published research articles written in English were included.

The studies considered were randomized clinical trials (RCTs) and non-randomized clinical trials.

Papers in other languages than English, case reports, pre-clinical studies or reviews, opinion articles, and studies published only in abstract form were excluded.

An electronic database search was conducted using PubMed, MEDLINE, the Cochrane Library, ClinicalTrials.gov, Embase, and Google Scholar. The authors used a combination of the following terms: "Word catheter", "Word Balloon", "Bartholin gland", "Bartholin's cyst", "Bartholin's abscess". The date of the last screening was April 20, 2023.

To verify all possibly relevant studies, no restrictions or search filters (publication status, type of article, or language of publication) were applied to the search.

The search strategy in the electronic database PubMed was the following: Using the advanced search builder on PUBMED, the following combination of the search terms was conducted: ((Word catheter OR Word balloon OR catheter) AND (Bartholin's cyst OR Bartholin's abscess OR Bartholin gland)).

The search strategy in the electronic database The Cochrane Library was conducted using the following combination of the search terms: ("Word catheter" AND "Bartholin gland" OR "Bartholin's cyst") and in the Google Scholar using the following search term: (Word catheter AND Bartholin's cyst).

Furthermore, the search was conducted using MeSH terms in PubMed (("Bartholin's Glands/surgery"[Mesh] OR "Bartholin's Glands/therapy"[Mesh])) and in The Cochrane Library (MeSH descriptor: [Bartholin's Glands] explode all trees and with qualifier(s): [surgery - SU]).

The authors conducted the search independently (L.O., A.G., P.M.). All articles were re-checked based on their titles and abstracts following the search.

All types of studies were selected, and each potentially relevant study was obtained in full text and assessed for inclusion independently by the authors. In addition, a manual search of references from retrieved articles was carried out to identify additional studies of interest.

The primary outcome was the rate of recurrence of the Bartholin cyst or abscess after a Word catheter or marsupialization. Secondary outcomes included pain after treatment (measured on a 10-point scale) and the duration of the procedure.

The inclusion criteria for the present systematic review were women with Bartholin's cysts or abscesses that require drainage. Furthermore, articles that included adolescents (under 18 years of age), pregnant women, oncological patients, any patients with other types of interventions, and articles in which the Word catheter was not compared with other interventions were excluded.

Quality assessment

A risk-of-bias assessment was performed for each of the included studies using the Cochrane Handbook for systematic reviews of interventions [7]. Four review authors independently assessed the quality of the selected studies. Any discrepancies between the reviewers were resolved by discussion or by consultation with a fifth review author (L.P.).

Following the Cochrane Handbook for Systematic Reviews of Interventions, the RoB 2 tool [8] was used to assess the risk of bias in randomized controlled studies, and ROBINS-I [9] was used for non-randomized studies (prospective controlled, prospective cohort, retrospective studies, and other types of studies). Furthermore, these tools were also used to assess the risk of bias that arises from reporting biases due to missing synthesis results.

Statistical analysis

Regarding the quantitative synthesis, the meta-analysis (forest plot) was performed using RevMan 5.4 (recommended by the Cochrane Society). According to the Cochrane Handbook for Systematic Reviews of Interventions, an I² value of 0 indicates no observed heterogeneity, whereas I² values from 30 to 60% may represent moderate heterogeneity, and I² values from 50% to 90% may represent substantial heterogeneity, and I² values from 75% to 100% represent considerable heterogeneity.

RESULTS

Search results

The initial search of three high-quality databases produced 627 articles: 32 from PubMed, 576 from Google Scholar, and 19 from the Cochrane Library. (Fig.1)

After the MeSH search, 157 reports were identified: 151 from PubMed and 6 from the Cochrane Library.

113 of 784 records were duplicates and, therefore, were excluded. After that, 671 articles were analyzed, 649 of which were excluded by the titles and abstracts.

Therefore, 22 reports were left for full-text screening and analyzed following our inclusion and exclusion criteria.

Fourteen studies [10-23] were review articles or authors' replies and were excluded for these reasons. Furthermore, two studies [24-25] were excluded because there was no comparison of the Word catheter with another intervention method. One study [26] had no published results.

Figure 1. PRISMA flow-diagram 2020.

Additionally, 59 articles were found in the references of the four articles included in the qualitative analyses, and all of them met the eligibility criteria. However, none of these studies was included in the systematic review because they were duplicates of articles that were found earlier.

After excluding duplicates and non-relevant reports, five studies [1,3,4,27,28] were included in the qualitative synthesis. One publication [1] is a randomized study; four [3,4,27,28] are non-randomized studies. (Table 1)

Table 1. General information about the included literature

The first study conducted by JA Kroese et al. aims to evaluate recurrence and pain during and after treatment of Bartholin's cyst or abscess using a Word catheter or marsupialization [1]. Of 162 women with cysts or abscesses, 82 were treated using a balloon catheter and 79 by marsupialization. The primary outcome showed that recurrence of the cyst or abscess needing surgery within 1 year occurred in 10 (12.2%) and 8 (10.3%) women in the Word catheter and marsupialization groups (RR = 1.11; 95% CI 0.64-1.91; P = 0.70), respectively. Secondary outcomes included that recurrence of the cyst or abscess did not need surgery in 1 year in 19 (23%) and 14 (18%) women in the Word catheter and marsupialization groups (RR = 1.2; 95% CI 0.77-1.83; P = 0.41), respectively. In addition, researchers evaluated perioperative pain during and after treatment and measured it on a 1-point scale. The mean pain in the Word balloon catheter group was 4.9/10 and 1.9/10 for marsupialization (P < 0.001). Maximal pain in the Word balloon catheter group was 6.2/10 and 2.0/10 for marsupialization (P < 0.001). Therefore, the Word catheter procedure showed more benefits for Bartholin's cysts or abscesses treatment.

In another retrospective study by Rotem et al. [3] in 215 (67%) patients, Word catheterization was chosen as the treatment of Bartholin gland cysts, and in 106 (33%) patients, marsupialization was chosen. In both groups, the recurrence rates were compared. As a result, these two methods show relatively low frequencies of recurrence (6.7% and 6.3%, p = 0.89). In order to lower the rate of recurrences during the insertion of the Word catheter balloon, it must be in situ until the end of the treatment (2-3 weeks). In conclusion, there is no difference between rehospitalization, clinical characteristics, postoperative complications, and recurrence.

In the prospective intervention study conducted by Z.Haider et al. [4], two ways of treating Bartholin's abscess were compared. 23 of 58 (40%) women were directed for surgical treatment (marsupialization), and 35 of 58 (60%) were directed to the Word catheter insertion procedure. The follow-up for each treatment method continued for 12 months. Out of 35 women with word

catheters, 34 were successfully inserted. Three of them had the word catheter fall during the next 24 hours. Three others—after 1 week—and one—within 11 days. One woman had a recurrence six months after treatment. Thus, 27 patients retained catheters for 4 weeks. This method of treatment has a 97% success rate. Therefore, 24 of 27 women will recommend using a Word catheter as a treatment in the same case. 14 of 23 (60%) women with marsupialization did not recur in the next 6 months.

Boama, V. et al. conducted a cohort study that compared the clinical time gained with the Word balloon catheter and marsupialization as an office procedure [27]. Thirty-five women with Bartholin's cyst and abscess were included in the retrospective audit group of patients ($n = 14$) who were treated by surgical method and the prospective service evaluation group ($n = 21$) who underwent marsupialization ($n = 9$) and Word Catheter ($n = 14$). There were four patients (29%) with cysts and 10 (71%) with abscesses in the retrospective group, and four (19%) had cysts and 17 (81%) had abscesses in the prospective study group. According to the study results, in the retrospective audit group, the mean time for admission to surgery was 9.98 h (range 0.5-33 h), and the mean time for admission to discharge was 24.5 h (7-53 h). In the prospective study group of patients with marsupialization, the mean time for admission to surgery was 16 h (2.5-24 h), and the mean time for admission to discharge was 31 h (9.5-48 h). In the Word catheter group, the mean time for admission to surgery was 20 min (10-40 min), and the mean time for admission to discharge was 40 min (20-90 min).

Karabük, E. et al. [28] published a retrospective study in 2022 that included 196 patients treated with either a Word catheter (64 (32.7%)) or marsupialization (132 (67.3%)). In the marsupialization group, bartholin gland cysts were diagnosed in 104 (78.8%) and abscesses in 28 (21.2%) patients, while in the Word-catheter group, cysts were diagnosed in 47 (73.4%) patients and abscesses in 17 (26.6%) ($p=0.404$). Postoperative complications occurred in 7 (5.3%) patients in the marsupialization group and 2 (3.1%) patients in the Word catheter group ($p=0.495$). All complications were related to postoperative infections. Recurrence occurred in 11 patients (8.3%) in the marsupialization group and 12 patients in the Word catheter group (18.8%) ($p=0.034$). The recurrence interval was 7.27 ± 6.46 months for the marsupialization group and 5.58 ± 3.34 months for the Word catheter group.

Thus, based on the data from the studies included in the qualitative synthesis, the Word-catheter method for treating bartholin gland cysts or abscesses demonstrated greater benefits in three of the studies [1,4,27].

According to the Cochrane Handbook, three reviewers (L.O., A.G., and P.M.) assessed the risk of bias in each of the studies using RoB 2 for randomized control trials and ROBINS-I for nonrandomized trials. Any disagreements were resolved by discussion with the fourth author (L.P.).

Visualization tools were created by the ROBVIS app [29]. This app created 'traffic light' graphs of domain-level judgments for each result and weighted bar graphs of the distribution of risk-of-bias judgments within each bias domain.

Based on these tools, randomized controlled trials had some concerns, while nonrandomized trials had a moderate risk of bias. (Figs. 2, 3)

Figure 2. RoB2.0 tool for randomized trials—traffic light plot

Figure 3. ROBINS-I for non-randomized trials: traffic light plot

Five studies were included in quantitative synthesis (meta-analysis), yielding 756 patients to estimate recurrence rates. However, there was no statistically significant difference between the Word catheter and marsupialization groups ($RR = 1.28$, 95% CI: 0.84–1.95, $P = 0.26$). Therefore, the heterogeneity for this comparison was 15%. (Fig.4)

Figure 4. Meta-analysis of recurrence rates between two groups

Mean pain scores and duration of the procedure

Three studies [1,27,28] show that the mean operation time, clinical time gained from admission to insertion of the Word balloon catheter, and time from randomization to treatment were shorter in the Word catheter group compared to the Marsupialization group.

In the publication by Kroese et al. [1], pain was measured on a 10-point visual analog scale. Pain was assessed three days and one week after treatment. The maximum and mean pain, according to the scale, were higher in the Word catheter group. In the first 24 hours after treatment, 33% of Word catheter group patients used analgesics, compared with 74% in the marsupialization group ($P < 0.001$).

Rotem et al. [3] found no statistically significant differences in the assessment of postprocedural pain: in the Word catheter group, 2 patients had complaints of pain (1.0%), in the marsupialization group, no complaints were detected (0.0%).

In the publication by Haider et al. [4], patients completed a questionnaire (with daily pain scores from 0 to 10) and were followed up for 6 months. One week after treatment, five patients had complaints of mild discomfort (pain score 2-3 out of 10) that did not require analgesia. Four patients reported mild discomfort (pain score 2-3 out of 10) from sitting for one week. One patient reported moderate discomfort (pain score 5 out of 10) and a persistent sensation of swelling of the labium. After withdrawing 2 mL of water from the catheter, this discomfort subsided.

In the publication by Boama et al. [27], it was reported that in the Word catheter group, 7 patients (57%) found the procedure highly acceptable, another 7 (58%) would repeat the procedure in case of recurrence, and 12 (100%) would recommend the procedure to family and friends.

In the publication by Emine Karabuk et al. [28], patients' satisfaction was assessed with a postoperative 5-point visual analogue scale (VAS), where 1 point is poor/very difficult; 2- sufficient/moderately difficult; 3- medium/ average difficulty; 4 - good/easy; and 5, excellent/very easy. VAS scores (score: 4 min:1 /max:5) in the marsupialization group were significantly better than those in the Word catheter group (score: 3 min: 1 /max: 5) ($p < 0.001$). In the marsupialization group, dissatisfaction was due to recurrence in 4 out of 12 (33.3%) and pain in 8 out of 12 (66.7%) patients. In the Word catheter group, reasons for dissatisfaction were treatment duration in 8 patients (61.5%), recurrence in 4 (30.8%), and pain in 1 (7.7%) ($p = 0.001$).

Based on these findings, increased pain scores were more common in the Word catheter group, both during and after treatment.

Mean pain scores and operation time are presented in Table 2.

Table 2. Mean pain scores and operation time

DISCUSSION

Main findings

An abscess or cyst of the Bartholin's gland, as previously assumed, is a problem for the medical community and all women due to the frequency of the diseases [1, 2]. However, treatment methods have many disadvantages, complications, and recurrences. Therefore, there is a question about various treatment methods and their features for making a treatment with minimal consequences for patients. The National Institute for Health and Care Excellence [30] published guidelines providing a portion of the evidence for the safety and efficacy of Word catheters. According to the guidelines, balloon catheter placement can be used as a surgical treatment for persistent and symptomatic cysts or abscesses. However, the method of insertion of the Word catheter has not been sufficiently studied, and NICE experts have unanswered questions

regarding the complications and disadvantages of this procedure, in particular infection, bleeding, recurrence of abscesses, etc. [30].

Our systematic review and meta-analysis suggest that there is no statistically significant difference in recurrence rates.

Furthermore, according to the qualitative synthesis, when contrasting marsupialization with the Word catheter, the former emerges as a more invasive approach, demanding an extended duration, general anesthesia, and the utilization of an operating theater. Additionally, heightened pain scores were more prevalent in the Word catheter group, both during and after treatment.

Strengths and limitations

The strengths of this systematic review include its comprehensive search strategy, methodological design, and statistical analysis.

Regarding the limitations of our study, our meta-analysis included studies with a high risk of bias. Finally, there are studies with an unequal number of patients in the control and treatment samples among the clinical trials included in our review. We believe that samples must be homogeneous and objective in order to produce reliable results. Another limitation of our systematic review is the lack of quantitative data for meta-analyses on secondary endpoints, as the number of studies is small and there is a risk of high heterogeneity due to differences between groups.

Although our meta-analysis did not show statistically significant differences in recurrences between surgical marsupialization and Word catheter treatment, the second has advantages, including clinical time gained, minimally invasiveness, avoidance of general anesthesia, and the ability to reduce the need for hospital beds and operating theatre time. Also, more well-conducted prospective and randomized trials are needed to assess the advantages and disadvantages of Word catheter use and surgery.

Interpretation and comparison with other literature

We have found studies that demonstrate advantages in terms of time management, cost, and simplicity of the procedure. Unfortunately, the design of these studies did not follow our review protocol, and we were unable to include them. In Applications for Clinical Practice and Simulation [31], the authors also consider that Word catheter placement is appropriate in urgent care. Satisfactory results were shown in the Reif study [24]: balloon treatment was successful in 26/30 cases (87%), recurrence occurred in only 1/26 cases (3.8%), and costs were several times lower compared to marsupialization.

We also found a study that suggested that the benefits of a Word catheter are simplicity of insertion, adjustment, and removal. In the review of the management of Bartholin's gland [17], written by J. Pundir and B. J. Auld, one of the main benefits is fast epithelialization wound healing since the catheter creates a new artificial duct of the gland. In addition, the use of local anesthesia only and the absence of the need for stitches give an advantage over other methods when general anesthesia is undesirable, for example, during pregnancy. To compare other treatments, blood loss is minimal and pain is less severe. As for recurrence, it was noted that only 2 of the 68 were subsequently successfully treated with the same method. A possible disadvantage is the difficulty of keeping the catheter in the correct place for a certain amount of time [17]. The disadvantages of marsupialization are hematoma, prolonged healing, cicatrization, and dyspareunia due to scarring [32].

According to the literature, surgical methods are preferred in the treatment of vulvar diseases [33]. The main long-term goals include preserving women's quality of life and physical and

psychological well-being. Consequently, the most important issues for further research are the reduction of risks and recurrence of vulvar diseases and the postoperative restoration of sexual activity based on the elimination of pain, discomfort, and dyspareunia [33–35].

Thus, the correct and appropriate therapeutic management of vulvar diseases has an important role in ensuring effective treatment, preventing complications, and improving the quality of life of women.

A personalized treatment allows the individual characteristics of each patient to be considered, which leads to optimal results [33].

It is also a necessary addition that practitioners should be proficient in both methods of treating cysts or abscesses of the Bartholin's gland. In addition, we cannot state exactly which method is preferable; therefore, when choosing a procedure, it is necessary to take into account the choice of the patient.

As a result, we need better studies with an appropriate design, criteria, a large number of patients, and a straightforward questionnaire of the period after catheters are placed in patients. Thus, more in-depth information will be obtained about this method of treating Bartholin's gland cyst. It is necessary to collect data on the follow-up period of the Word catheter procedure after one year and beyond.

CONCLUSIONS

Our systematic review and meta-analysis show that there is no statistically significant difference regarding recurrence rates. In addition, marsupialization, compared to the Word catheter, is a more traumatic treatment method with a longer duration and requires general anesthesia and an operating theater. Moreover, increased pain scores during treatment and post-treatment were more common in the Word catheter group. Therefore, both of these methods can currently be used accordingly. Nevertheless, correct therapeutic management of vulvar diseases is important to provide effective treatment and prevent complications. Therefore, an individualized approach is important, which allows treatment to be tailored to the specific needs of each woman, improving not only the effectiveness of therapy but also her tolerance. It also facilitates a fuller understanding of symptoms and their impact on the patient's quality of life. However, we need more evidence and long-term follow-up to answer all the questions in detail.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

L.P. - conceptualization; methodology, writing – review and editing

L.O. - conceptualization; methodology, writing – review and editing

A.G. - methodology; writing – original draft

P.M. - methodology; writing – original draft

J.A. - methodology; writing – original draft

A.U. - conceptualization; methodology

A.I. - conceptualization; methodology

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Study registration

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Disclosure of interests

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Ethical approval

N/A.

Informed consent

N/A.

Data sharing

Data are available under reasonable request to the corresponding author.

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Table 1. General information of the included literature

Study (first author)	Study type	Disease	Patients	Intervention	Comparison	Outcomes
Kroese et al. [1]	Randomized Controlled Trial	Bartholin's cyst and abscess	161 women: • Word catheter (n=82) • Marsupialization (n=79)	Word catheter	Marsupialization	<p>Recurrence of the cyst or abscess needing surgery within 1 year:</p> <ul style="list-style-type: none"> • Word catheter - 10/82 (12.2%), • Marsupialization 8/78 (10.3%) • P-value = 0.698 <p>Recurrence of the cyst or abscess within 1 year with or without treatment:</p> <ul style="list-style-type: none"> • Word catheter - 19/82 (23.2%) • Marsupialization – 14/78 (17.9%) • P-value = 0.414
Rotem et al. [3]	Retrospective cohort database study	Bartholin's cyst and abscess	321 women: • Word catheter (n=215) • Marsupialization (n=106)	Word catheter	Marsupialization	<p>Recurrence of a cyst or abscess:</p> <ul style="list-style-type: none"> • Word catheter - 7/215 (6.7%) • Marsupialization - 13/106 (6.3%) • P=0.83 <p>Bleeding/bleeding/itching</p> <ul style="list-style-type: none"> • Word catheter - 7/215 (6.7%) • Marsupialization - 13/106 (6.3%) • P=0.83
Haider et al. [4]	Prospective intervention study	Bartholin's cyst and abscess	58 women: • Word catheter (n=23) • Marsupialization (n=35)	Word catheter	Marsupialization	<p>One patient relapsed 6 months after treatment. The abscess resolved in 34 of 35 (97%) patients. Fourteen women who underwent marsupialization were followed up for 6 months, and none of them showed recurrence</p> <p>The P-value for statistical significance was not stated.</p>
Boama et al. [27]	Cohort study	Bartholin's cyst and abscess	35 patients: • Marsupialization (n = 14) - retrospective audit group) Marsupialization (n = 9) - prospective service evaluation group • Word Catheter (n = 12) - prospective service	Word catheter	Marsupialization	<p>Reduction of clinically significant time gained of Word catheter intervention compared to marsupialization under general anesthetic.</p> <p>1) Mean admission to surgery interval (range):</p> <ul style="list-style-type: none"> • Marsupialization - retrospective audit group - 9.98 h (0.5–33 h) • Marsupialization - prospective service evaluation group - 16 h (2.5–24 h) • Word Catheter - prospective service evaluation group - 20 min (10–40 min) <p>2) Mean admission to discharge interval (range)</p> <ul style="list-style-type: none"> • Marsupialization - retrospective audit group - 24.5 h (7–53 h)

			evaluation group			<ul style="list-style-type: none"> • Marsupialization - prospective service evaluation group - 31 h (9.5–48 h) • Word Catheter - prospective service evaluation group - 40 min (20–90 min)
Karabuk et al. [28]	Retrospective cohort study	Bartholin's cyst and abscess	196 women: <ul style="list-style-type: none"> • Word catheter (n=64) • Marsupialization (n=132) 	Word catheter	Marsupialization	Recurrence rate: <ul style="list-style-type: none"> • Word catheter - 12 (18.8%) • Marsupialization - 11 (8.3%) • P=0.034 Mean operative time: <ul style="list-style-type: none"> • Word catheter - 15.85±2.88 min. • Marsupialization - 21.67±4.87 min. • P=0.001 Postoperative complications: <ul style="list-style-type: none"> • Word catheter - 2 (3.1%) • Marsupialization - 7 (5.3%) • P=0.495

Table 2. Mean pain scores and operation time

Study (first author)	Pain scores and patient satisfaction	Clinical time
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Kroese et al. [1]	<p>Average pain during treatment:</p> <ul style="list-style-type: none"> • Word catheter - 4.9 (3.0) • Marsupialization – 1.9 (2.9) • P-value – <0.001 <p>Maximum pain during treatment:</p> <ul style="list-style-type: none"> • Word catheter - 6.2 (2.8) • Marsupialization – 2.0 (3.4) • P-value – <0.001 <p>Mean pain scores before treatment:</p> <ul style="list-style-type: none"> • Word catheter - 5.9/10 • Marsupialization – 5.3/10 <p>One week after treatment:</p> <ul style="list-style-type: none"> • Word catheter - 1.5/10 • Marsupialization – 1.3/10 • P = 0.58 	Median time from randomisation to treatment was 3 hours shorter for the Word catheter than for marsupialisation.
Rotem et al. [3]	<p>Postprocedural pain:</p> <ul style="list-style-type: none"> • Word catheter application 2 (1.0%) • Marsupialization 0 (0.0%) 	-
Haider et al. [4]	<p>At one week:</p> <ul style="list-style-type: none"> • Word catheter - mild discomfort (pain scores 2–3 out of 10) 	-
Boama et al. [27]	<p>Postprocedural pain:</p> <ul style="list-style-type: none"> • Word catheter application - only one patient reported pain and discomfort at home over the 4 week period. • Marsupialization- Patient satisfaction data was not sought 	The mean clinical time gained from admission to insertion of Word balloon catheter is 15 h and 40 min.
Karabuk et al. [28]	<p>Patients were not satisfied due to the pain in Word catheter group (8 out of 12 (66.7%)) and recurrence in Marsupialization group (4 out of 12 (33.3%))</p> <p>The visual analogue scale (VAS) scores:</p> <ul style="list-style-type: none"> • Word catheter - score: 3, min: 1 max: 5 • Marsupialization - score: 4 min:1 max:5 • P <0.001 	The mean operation time was shorter in the Word catheter group (15.85±2.88 min), compared to the Marsupialization group (21.67±4.87 min) (p=0.001).

Figure 1. PRISMA flow-diagram 2020.

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources

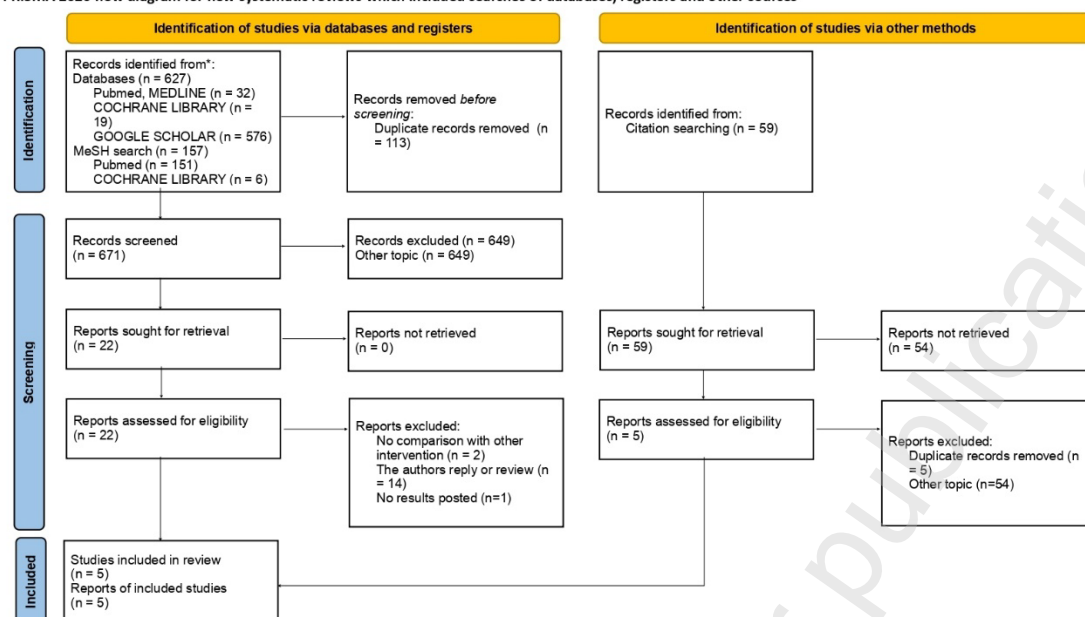



Figure 2. RoB2.0 tool for randomized trials - traffic light plot.

		Risk of bias domains					
		D1	D2	D3	D4	D5	Overall
Study	Kroese et al. 2016						

Domains:

D1: Bias arising from the randomization process.


D2: Bias due to deviations from intended intervention.

D3: Bias due to missing outcome data.

D4: Bias in measurement of the outcome.

D5: Bias in selection of the reported result.

Judgement

 Some concerns

 Low

Figure 3. ROBINS-I for non-randomized trials - traffic light plot.

		Risk of bias domains							
		D1	D2	D3	D4	D5	D6	D7	Overall
Study	Rotem, 2021	<div>-</div>	<div>-</div>	<div>-</div>	<div>+</div>	<div>+</div>	<div>+</div>	<div>+</div>	<div>-</div>
	Haider, 2007	<div>-</div>	<div>-</div>	<div>-</div>	<div>-</div>	<div>+</div>	<div>-</div>	<div>-</div>	<div>-</div>
	Boama, 2016	<div>-</div>	<div>-</div>	<div>-</div>	<div>-</div>	<div>+</div>	<div>-</div>	<div>-</div>	<div>-</div>
	Karabuk, 2022	<div>-</div>	<div>+</div>	<div>-</div>	<div>+</div>	<div>+</div>	<div>+</div>	<div>+</div>	<div>-</div>

Domains:

D1: Bias due to confounding.

D2: Bias due to selection of participants.

D3: Bias in classification of interventions.

D4: Bias due to deviations from intended interventions.

D5: Bias due to missing data.

D6: Bias in measurement of outcomes.

D7: Bias in selection of the reported result.

Judgement

- Moderate

+ Low

Figure 4. Meta-analysis of recurrence rates between two groups

