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Modified Word Catheter and Marsupialization in Women with a Cyst or Abscess of the Bartholin Gland: A randomized clinical trial

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ABSTRACT

Objectives: To compare outcomes of a cyst or abscess of the Bartholin gland after surgical treatment using a modified Word catheter or marsupialization.

Materials and Methods: We conducted a single-center, open-label, randomized controlled trial at Vachira Phuket Hospital, in Thailand. Women presenting with a symptomatic Bartholin gland cyst or abscess were randomly assigned to undergo either modified Word catheter placement, using a Foley catheter, or marsupialization under local anesthesia. Participants were followed-up at 1 week, 4 weeks, 6 months, and 12 months post-procedure. The primary outcome was recurrence within one year. Secondary outcomes included procedural time and perioperative pain. Analyses were performed according to the intention-to-treat principle.

Results: A total of 50 women were enrolled between June 2023 and March 2024. Recurrence occurred in 3 of 25 women (12%) in the modified Word catheter group and in 3 of 24 women (12.5%) in the marsupialization group (relative risk 0.96; 95% confidence interval [CI] 0.21, 4.3; $p = 0.957$). The median procedural time was shorter with modified Word catheter placement (10 minutes; interquartile range [IQR] 8, 12) compared to marsupialization (14.5 minutes; IQR 14, 16; $p < 0.001$). Pain scores during the procedure were lower in the modified Word catheter group (mean ± standard deviation [SD] 4.7 ± 1.2) than in the marsupialization group (mean ± SD 6.6 ± 1.1; $p = 0.001$).

Conclusion: In women with a Bartholin gland cyst or abscess, treatment with a modified Word catheter provides similar recurrence rates to marsupialization, but with shorter procedural time and less perioperative pain.

Keywords: Bartholin abscess, Bartholin cyst, word catheter, marsupialization, recurrence.

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การศึกษาเพื่อเปรียบเทียบประสิทธิภาพในการรักษาโรคถุงน้ำหรือฝีต่อมบาร์โธลิน ด้วยการดัดแปลงใช้สายสวนปัสสาวะเลียนแบบสายสวนเวิร์ด กับการผ่าและเย็บปากถุงน้ำ

สุภาพันธ์ วัฒนเจริญ, ชาญชัย สุประสงค์สิน

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาเปรียบเทียบผลของการใช้สายสวนปัสสาวะเลียนแบบสายสวนเวร์ด(modified Word catheter) กับการผ่าและเย็บปากถุงน้ำ (marsupialization)ในการรักษาโรคถุงน้ำหรือฝีต่อมบาร์โธลิน*

วัสดุและวิธีการ: *การศึกษานี้เป็นการทดลองแบบสุ่มที่ดำเนินการ ณ โรงพยาบาลวชิระภูเก็ต ประเทศไทย ในสตรีที่มีถุงน้ำหรือฝีของต่อมบาร์โธลินที่มีอาการ โดยสุ่มได้รับการรักษาด้วยการใส่ Modified Word catheter (ใช้สายสวนปัสสาวะ Foley catheter) หรือการทำ marsupialization ภายใต้การฉีดยาชาเฉพาะที่ มีการติดตามผลที่ 1 สัปดาห์, 4 สัปดาห์, 6 เดือน และ 12 เดือน ผลลัพธ์หลักคือการกลับเป็นซ้ำภายในหนึ่งปี ผลลัพธ์รอง ได้แก่ เวลาในการทำหัตถการและความเจ็บปวดระหว่างและหลังหัตถการ การวิเคราะห์ข้อมูลใช้หลักการ intention-to-treat*

ผลการศึกษา: *มีผู้เข้าร่วมทั้งหมด 50 คน ระหว่างเดือนมิถุนายน 2566 ถึงมีนาคม 2567 การกลับเป็นซ้ำพบใน 3 รายจาก 25 ราย (ร้อยละ 12) ในกลุ่ม Modified Word catheter และ 3 รายจาก 24 ราย (ร้อยละ 12.5) ในกลุ่ม marsupialization (อัตราส่วนพัทธ์ [RR] 0.96; ช่วงความเชื่อมั่น 95% 0.21, 4.3; p = 0.957) เวลาการทำหัตถการสั้นกว่าชัดเจนในกลุ่ม Modified Word catheter (มัธยฐาน 10 นาที; interquartile range [IQR] 8, 12) เทียบกับ marsupialization (มัธยฐาน 14.5 นาที; IQR 14, 16; p < 0.001) และมีคะแนนความเจ็บปวดขณะทำหัตถการต่ำกว่า (ค่าเฉลี่ย ± ส่วนเบี่ยงเบนมาตรฐาน 4.7 ± 1.2 เปรียบเทียบกับ 6.6 ± 1.1; p = 0.001)*

สรุป: *ในสตรีที่มีถุงน้ำหรือฝีของต่อมบาร์โธลิน การรักษาด้วย Modified Word catheter และ marsupialization ให้ผลการกลับเป็นซ้ำใกล้เคียงกัน โดย Modified Word catheter มีข้อได้เปรียบด้านระยะเวลาหัตถการสั้นกว่าและลดความเจ็บปวดได้ดีกว่า*

คำสำคัญ: *ฝีต่อมบาร์โธลิน, ถุงน้ำต่อมบาร์โธลิน, สายสวนเวร์ด, การผ่าและเย็บปากถุงน้ำ, การเกิดเป็นซ้ำ*

Introduction

A cyst of the Bartholin gland is defined as a swelling filled with mucus at the 4 or 8 o'clock position of the vulva vestibule at the position of the duct of the Bartholin gland. If the same swelling is accompanied by signs of infection or inflammation such as redness, swelling, hotness, or tenderness, it is described as an abscess. Bartholin cysts or abscesses are observed in around 2% of women, generally in their reproductive period[1-3]. Both a cyst and an abscess can cause limitation of activity, and an abscess can also cause extreme pain.

Several treatment modalities exist for Bartholin cysts and abscesses, including needle aspiration, incision and drainage, marsupialization, Word catheter placement, and gland excision. Among these, marsupialization and Word catheter insertion are the most commonly employed techniques. Needle aspiration and simple incision and drainage are associated with high recurrence rates (35–45%), whereas gland excision carries a heightened risk of complications, such as hematoma formation, excessive bleeding, external genital deformity, and scarring[2,3]. The primary challenge in managing Bartholin cysts and abscesses is minimizing recurrence following treatment. Comparative studies have reported recurrence rates ranging from 0–13% for marsupialization and 3–17% for Word catheter placement[1, 2, 4-8]. The WoMan trial[9], a multicenter, open-label, randomized controlled study conducted in the Netherlands, found that both procedures had comparable recurrence rates. However, that study demonstrated that Word catheter placement resulted in lower pain scores within the first 24 hours post-treatment and a shorter procedure duration, suggesting potential advantages over marsupialization.

In Thailand, marsupialization remains the standard treatment for Bartholin cysts or abscesses. However, recurrence rates vary across healthcare institutions, often depending on surgical expertise. Higher recurrence rates are observed when marsupialization is performed by less experienced practitioners[10,11]. Given the potential benefits of Word catheter placement, there is growing interest in exploring use of it as an alternative treatment. Additionally, the Word catheter is less invasive with less pain and can be performed quicker than the marsupialization. The recurrence rate comparison between the Word catheter versus marsupialization is also still debating. However, Word catheters are not readily available in Thailand and are costly to import. To address this limitation, we have adapted the use of a Foley catheter as a drainage device, referring to this technique as the "modified Word catheter" approach. This study aimed to compare the efficacy of the modified Word catheter with marsupialization in the outpatient management of Bartholin cysts or abscesses, with the primary outcome of recurrence rates, procedural time, and patient outcomes.

Materials and Methods

This study was a single-center, open-label, randomized controlled trial (RCT) conducted at Vachira Phuket Hospital in Thailand. The study protocol was approved by the Institutional Review Board of the Vachira Phuket Hospital Research Ethics Committee (VPH REC 006/2023) and registered in the Thai Clinical Trials Registry (TCTR20230608002). Prior to study initiation, all participating practitioners reviewed standardized instructions for performing both the modified Word catheter placement and the marsupialization procedure.

Women were eligible for inclusion in the trial if they presented with a symptomatic Bartholin gland cyst or abscess with fluctuation. A cyst or abscess was considered symptomatic if the patient reported pain or discomfort due to swelling, with or without signs of inflammation, at the 4 or 8 o'clock position of the vulvar vestibule. The diagnosis was confirmed by a gynecologist. Women were excluded if they had contraindications to either procedure (e.g., comorbidities precluding the safe use of local anesthesia), were unable to understand Thai or English, were under 18 years of age, or declined to

participate.

Eligible women were counseled by their physician or by a dedicated research nurse in the outpatient care unit. After written informed consent had been obtained, a web-based program using a 3x2 random block design with variable block size randomly allocated the women to either a modified Word catheter or marsupialization treatment. Due to the nature of the interventions, it was not possible to mask participants or physicians.

Both interventions were performed immediately in the outpatient unit (procedure room).

Modified Word Catheter (Fig. 1)

The Word catheter is a 5.5 cm long, 15-French silicone device featuring a 3 cm balloon.

For the modified Word catheter, we utilized a No. 14 Foley catheter. Preparation involved trimming the tip of the Foley catheter distal to the balloon prior to use.

The procedure was performed under local anesthesia by a gynecologist (SW) or a resident (CS). A small incision was made over the cyst, followed by the placement of the catheter. The balloon was inflated with 10 mL of sterile water, and the catheter was then tied at 5–6 cm above the balloon and trimmed accordingly. The catheter remained in situ until the follow-up appointment after four weeks or until it fell out. In the latter case, the treating physician provided further management guidance to the patient.

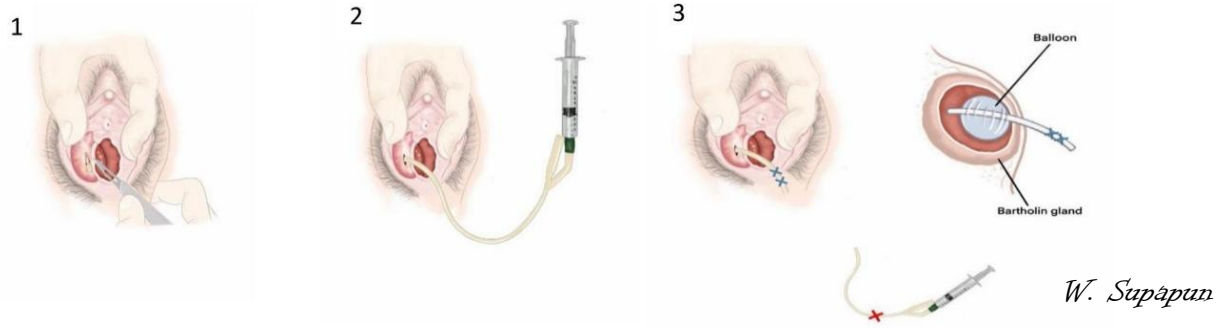

Fig. 1. Illustration of Modified Word catheter procedure.

Marsupialization[3] (Fig. 2)

The marsupialization procedure was performed under local anesthesia by a gynecologist (SW) or a resident (CS). A 1.5 – 3 cm. incision was made over the cyst, after which the cyst wall was everted and approximated to the edge of the vestibular mucosa with interrupted sutures. After 4 weeks, a routine check-up was scheduled.

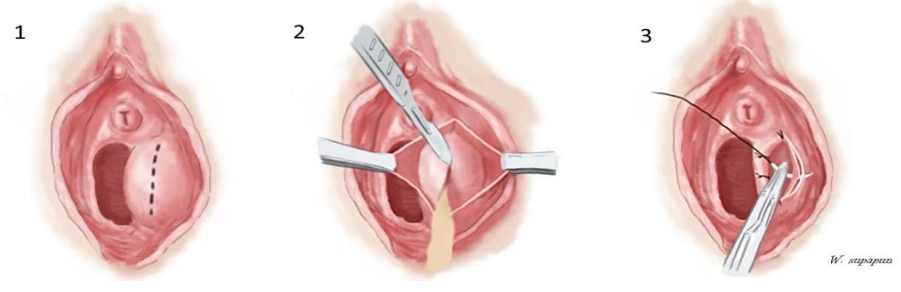

Fig. 2. Illustration of marsupialization procedure.

After obtaining informed consent, participants were interviewed and baseline data were recorded, including age, weight, height, underlying medical conditions, size and location of the Bartholin gland mass, and history of previous Bartholin gland cysts or abscesses. Following treatment and prior to hospital discharge, pain scores during the procedure were assessed and documented. Procedural details, such as the size and location of the mass and the procedural time, were also recorded using a standardized case record form.

One week after treatment, participants were scheduled for an outpatient follow-up visit. During this visit, pain scores on days 1, 2, 3, and 7 post-treatment were recorded, along with the type and quantity of analgesics used. At four weeks post-treatment, wound healing was assessed during a further follow-up visit. At six months, participants were followed-up either in person or by telephone to assess for recurrence. A final follow-up was conducted via telephone at 12 months to evaluate any recurrence of the Bartholin gland cyst or abscess.

The primary outcome was the recurrence of a symptomatic Bartholin gland cyst or abscess requiring treatment within one year of follow-up on the ipsilateral side, confirmed as a clinical diagnosis by a gynecologist (SW). Secondary outcomes included operative time as recorded in the operative notes, pain score during procedure, and peri-operative pain scores assessed at 24 hours, 3 days, and 1 week after treatment. Pain was measured using standardized pain questionnaires.

Based on the results from the WoMan trial conducted by Kroese et al[9], which was an randomized controlled trial, no significant difference was observed in recurrence rates between the Word catheter and marsupialization treatments. Given that the intervention used in the present study follows a similar therapeutic principle to the Word catheter, the researchers adopted a different statistically significant outcome from the WoMan trial—post-treatment analgesic use—as the reference for calculating the sample size.

According to the WoMan trial, the rate of post-treatment analgesic use was 33% in the Word catheter group and 74% in the marsupialization group. We needed to randomize 25 women (two groups of 80% power; two-sided test, alpha error 5%, beta error 20%, and 10% dropout rate).

Statistical analysis was conducted based on the intention-to-treat principle. Differences in dichotomous outcomes were analyzed using the chi-square test or Fisher's exact test when expected frequencies fell below five. Continuous variables were tested for normal distribution. In the case of normal distribution, we compared means of the variables using a t-test, while non-normally distributed variables were analyzed using the Mann–Whitney U test for univariate comparisons. Primary and secondary outcomes were compared by calculating relative risks (RRs) or mean differences, along with their 95% confidence intervals (CIs). Kaplan–Meier survival curves were used to illustrate the time to recurrence of a cyst or abscess requiring surgery within one year of follow-up, and differences between groups were assessed using the log-rank test.

Women lost to follow-up were excluded from the primary analysis. A sensitivity analysis was performed to assess the potential impact of missing data on study conclusions. All statistical analyses were conducted using SPSS, version 22.0. A p value of < 0.05 was considered statistically significant.

Results

Between June 2023 and March 2024, 50 women gave informed consent for randomization and were allocated to either treatment by modified Word catheter (n = 25) or marsupialization (n = 25). One patient in the marsupialization group was lost to follow-up. Therefore, we analyzed the data of 25 women randomized for modified Word catheter and 24 women randomized for marsupialization (Fig. 3).

Baseline characteristics of the two groups were comparable as shown in Table 1. The number of women with a previous ipsilateral cyst or

abscess of Bartholin was 4 (16%) in the modified Word catheter group compared to 8 (33%) in the marsupialization group. Before treatment, the mean pain score was 7.64/10 in women allocated to a modified Word catheter and 7.58/10 in women allocated to marsupialization.

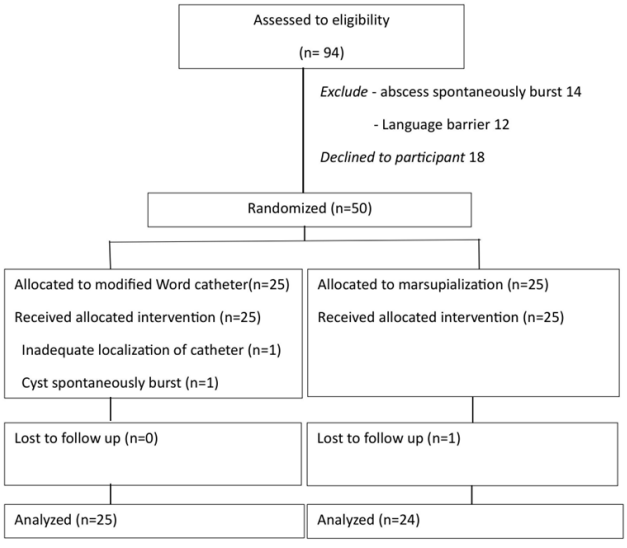

Fig. 3. Flow chart of participants recruitment.

Table 1. Baseline characteristics of women allocated to modified Word catheter or marsupialization for treatment of Bartholin gland cyst or abscess.

	Modified Word catheter (n = 25)	Marsupialization (n = 25)	p value
Age (years), mean (SD)	38.75 (11.53)	35.88 (11.96)	0.397
BMI (kg/m^2), mean (SD)	24.13 (5.14)	22.98 (3.40)	0.406
Underlying, n (%)			0.747
No	18 (72.0)	19 (76.0)	
Yes	7 (28.0)	6 (24.0)	
Hypertension	6 (24.0)	1 (4.0)	0.098
SLE	0 (0.0)	1 (4.0)	0.312
Dyslipidemia	2 (8.0)	2 (8.0)	1.000
Other	2 (8.0)	3 (12.0)	0.637
Smoking, n (%)			0.508
No	18 (72.0)	20 (80.0)	0.508
Yes	7 (28.0)	5 (20.0)	
History of cyst/abscess of Bartholin gland, n (%)			0.185
No	21 (84.0)	17 (68.0)	
Yes, ipsilateral	4 (16.0)	8 (32.0)	
Pain score before treatment (0-10), mean (SD)	7.64 (1.96)	7.60 (1.89)	0.976

BMI: body mass index, n (%): number and percentage, SD: standard deviation, SLE: systemic lupus erythematosus

Of the 25 women randomized to the modified Word catheter group, 23 underwent catheter placement. In one case, placement was unsuccessful, and in another, the abscess ruptured spontaneously

prior to the procedure. Both of these patients were subsequently converted to a marsupialization procedure. In two women, the catheter was removed within the first week due to discomfort. The catheter dislodged spontaneously in two women between 2–7 days, in one woman after 2 weeks, and in two women between 3-4 weeks. At the 4-week follow-up, 16 women (64%) still had the catheter in situ.

All 25 women randomized to the marsupialization group underwent the procedure. One participant was lost to follow-up one week after treatment. Her data were included in the analysis of baseline characteristics, pre-procedural pain scores, procedural time, and perioperative pain scores, but were excluded from the recurrence analysis.

Out of the 50 randomized women, none were lost to follow-up in the modified Word catheter group compared to one in the marsupialization group. The recurrence of the cyst or abscess requiring treatment within one year of follow-up occurred in 3 (12.0%) women in the modified Word catheter group and 3 (12.5%) women in the marsupialization group (RR 0.96; 95% CI 0.21, 4.30; p = 0.957) (Table 2). The median time for recurrence of the cyst or abscess requiring treatment was 6 months after the modified Word catheter and 5 months after marsupialization (p = 0.513). The Kaplan-Meier curve for the time to recurrence of the cyst or abscess needing treatment is shown in Fig. 4. (log-rank test, p = 0.839)

Table 2. Outcomes of women allocated to modified Word catheter or marsupialization for treatment of Bartholin gland cyst or abscess.

Outcomes	Modified Word catheter	Marsupialization	Relative risk or mean difference (95% CI)	p value
Primary outcomes	(n=25)	(n=24)		
Recurrence of the cyst or abscess needing surgery within 1 year	3 (12.0%)	3 (12.5%)	0.96* (0.21 to 4.30)	0.957
Median time to recurrence (months)	6.0	5.0	-	0.513
Secondary outcomes	(n=25)	(n=25)		
Procedure time, median (IQR)	10 (8-12)	15 (14-16)	-	< 0.001
Average pain during treatment, mean (SD)	4.7 (1.8)	6.7 (1.9)	-2.0 (-3.0 to -1.0)	< 0.001
Pain after treatment, mean (SD)				
1 day after treatment	3.8 (1.2)	4.8 (1.5)	- 1.0 (-1.7 to -0.2)	0.024
2 days after treatment	3.6 (1.0)	3.9 (1.4)	- 0.3 (-0.9 to 0.5)	0.624
3 days after treatment	2.3 (0.8)	2.9 (1.6)	- 0.6 (-1.3 to 0.1)	0.074
1 week after treatment	1.1 (1.0)	0.7 (1.0)	0.4 (-0.2 to 0.9)	0.160

* Relative risk
IQR: interquartile range, SD: standard deviation

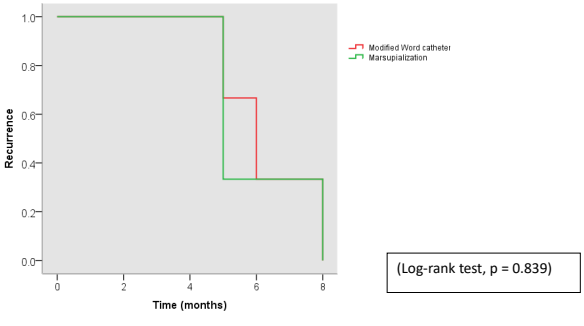

Fig. 4. Kaplan-Meier curves for time to recurrence of the Bartholin cyst or abscess after treatment.

Women who underwent the modified Word catheter procedure had a procedural time ranging 8 to 12 minutes, with a median time of 10 minutes. In comparison, the marsupialization group had procedural times ranging from 14 to 16 minutes with a median time of 14.5 minutes ($p < 0.001$).

Pain questionnaires were returned by all 50 women who participated in the study. Supporting information displays perioperative pain scores, measured on a 10-points scale, for women allocated to each group. The average pain experienced during the placement of the modified Word catheter was 4.7 out of 10, compared to 6.6 out of 10 for marsupialization ($p = 0.001$). Mean pain scores in the days following treatment can be found in Table 2. One week after treatment, the mean pain scores for the modified Word catheter and marsupialization groups were 1.1 out of 10 and 0.7 out of 10, respectively ($p = 0.179$).

In a sensitivity analysis, the assumption that one woman lost follow-up in the marsupialization group had a recurrence event did not affect our results (data not shown).

Discussion

Marsupialization is still the standard treatment for Bartholin cysts or abscesses in Thailand. In our study, the recurrence rate after marsupialization was 12.5%, which was consistent with the range reported in the literature (0 –13%)[1, 2, 4-8], although it may be considered relatively high. When analyzing factors related to recurrence, we discovered that the type of anesthesia administered during the procedure could impact the results. Specifically, local anesthesia was linked to a higher recurrence rate, while general or spinal anesthesia seemed to decrease the chances of recurrence[7, 8].

In previous studies, recurrence rates with catheter drainage using the commercial Word catheter have been reported to range from 2.7% to 17.4%[1, 2, 4-8]. In our study, we utilized a modified approach by using a Foley catheter, which is functionally equivalent to the Word catheter, for drainage. The recurrence rate observed in the modified Word catheter group (12%) was similar to the rates reported for the standard Word catheter.

At the one-year follow-up, the recurrence rates were 12% in the modified Word catheter group and 12.5% in the marsupialization group. These results closely resembled those of the WoMAN trial[9], which reported one-year recurrence rates of 12% for the standard Word catheter and 10% for marsupialization. To our knowledge, our study is the first RCT to directly compare the modified Word catheter with marsupialization. Given the similar recurrence outcomes, we concluded that the modified Word catheter demonstrated comparable efficacy to the standard Word catheter in the management of Bartholin cysts or abscesses.

Regarding other outcomes, the median procedural duration was 4.5 minutes shorter for the modified Word catheter compared to marsupialization. This suggested that the modified Word catheter was easier to handle. Similar findings have been reported in several studies comparing the procedural difficulty scores between Word catheterization and marsupialization[12-15].

In addition to its ease of application, our study found that the average pain experienced during treatment was lower in the modified Word catheter group compared to the marsupialization group. This finding contrasted with the WoMan trial[9], which reported higher mean pain scores during treatment in the Word catheter group compared to the marsupialization group (4.9/10 vs 1.9/10, respectively; $p < 0.001$). The discrepancy may be attributed to differences in analgesic methods: in our study, local anesthesia was used for both groups, whereas in the WoMan trial, local anesthesia was administered for the catheter group and general or spinal anesthesia for the marsupialization group.

In the context of managing Bartholin's cyst or abscess on an outpatient basis, we believe that using local anesthesia is preferable. Our findings suggested that using the modified Word catheter results in greater patient tolerance of pain in these situations.

There were some limitations in this study. First,

this study was conducted as an open-labelled RCT as these procedures were unable to perform blindly. Second, subjective evaluation was evaluated and should be interpreted cautiously. Finally, sample size was quite small. Even though it met with the sample size calculation, this calculation was performed based on analgesic use, not the recurrent rate. Further larger RCTs may be needed to confirm the results of this study.

Conclusion

Both modified Word catheter placement and marsupialization yielded comparable 1-year recurrence rates for the treatment of symptomatic Bartholin gland cysts or abscesses. However, the modified Word catheter offered advantages in terms of patient tolerance, faster symptom relief, and lower procedural costs, supporting its use as the preferred first-line outpatient intervention.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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