ORIGINAL ARTICLE

Outcome of rolled fortified vaginal flap operation on female patients with intrinsic sphincteric deficiency: 2-year follow-up

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Abstract

Introduction and hypothesis We evaluate the 2-year outcome of the rolled fortified vaginal flap (RFVF) operation for the treatment of stress urinary incontinence (SUI) due to intrinsic sphincteric deficiency (ISD).

Methods A prospective study of 20 women suffering from SUI due to ISD was conducted. All patients were subjected to history-taking, clinical examination, cough stress test, and urodynamics. Symptom severity and quality of life (QoL) were assessed using the Arabic version of the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF). All studied women were followed up for 24 months to detect success rate, any postoperative complications, and reveal changes in the quality of life.

Results Mean age was 53 ± 8 years. Preoperative Valsalva leak point pressure was 50.1 ± 11.3 cmH$_2$O. After a follow-up period of 24 months, only 2 patients (10%) showed mild stress incontinence with mean VLPP 80 ± 3 cm H$_2$O. Postoperative mean maximum flow rate (Q-max) and mean Pdet-Qmax showed no significant difference from the preoperative results ($P = 0.115$ and 0.187 respectively). The quality of life domain of the ICIQ-UI-SF decreased significantly from $73.5 \pm 12.1\%$ (preoperatively) to $2.6 \pm 8.1\%$ (after a 1-year follow-up), $P < 0.001$ and then showed a slight increase to 4.5 ± 10.6 at 24 months' follow-up.

Conclusion The RFVF operation has a success rate of 90% after a 24-month follow-up. It significantly improved the quality of life of women with SUI due to ISD.

Keywords Stress urinary incontinence · Rolled fortified vaginal flap · Quality of life · Urodynamics

Introduction

Stress urinary incontinence (SUI) is the primary type of urinary incontinence reported among younger women, with approximately 50% of urinary incontinence being caused by stress [1]. It is defined as the involuntary loss of urine during coughing, sneezing or physical exertion. The overall prevalence of incontinence tends to increase in young adulthood, with a steady increase seen among elderly women [2, 3]. This problem affects the physical, mental, and sexual aspects of women and causes deprivation of social status and decreases quality of life [4, 5]. In addition, it produces serious economic and psychological problems with feelings of helplessness, depression, and anxiety [6].

In 1980, McGuire et al. [7] recognized the importance of urodynamic evaluation, which highlighted the concept of intrinsic sphincteric deficiency (ISD) as an important factor in the etiology of stress incontinence. McGuire et al. observed that some patients in whom multiple retropubic operations failed had a deficient sphincteric mechanism characterized by an open vesical neck and proximal urethra at rest, with minimal or no urethral descent during stress. This led to the classification of stress incontinence into type I and II (due to urethral hypermobility) and type III (due to ISD).

For types I and II SUI, midurethral tapes are commonly used with a high degree of success and minimal postoperative complications [8]. On the other hand, cases of SUI due to ISD may be treated by bladder neck slings using biological or synthetic materials, injectables, or artificial urinary sphincter [9]. However, the use of synthetic materials carries the risk of erosion and postoperative voiding dysfunction [10]. Moreover, synthetic slings and artificial sphincters are

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expensive and may not be affordable for patients in low-income countries. Thus, the current study was conducted to evaluate the use of the rolled fortified vaginal flap (RFVF) operation in the treatment of SUI due to ISD, addressing its technical feasibility, complications, outcome, and its impact on the quality of life of those women.

Patients and methods

After institutional review board approval, this prospective study was conducted on 20 consecutive female patients suffering from SUI due to ISD as proved by urodynamics. Patients with clinical overactive bladder, neurogenic bladder and/or grade II–IV prolapse according to the Baden–Walker system pelvic organ prolapse (POP) were excluded.

All patients were subjected to history-taking with objective evaluation using the Arabic version of the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF) to assess the severity of symptoms and the degree of affection of urinary incontinence on the patient's quality of life (QoL; Appendices 1, 2) [11, 12]. This was followed by clinical examination in the form of abdominal examination and vaginal examination to exclude POP. Special tests were used to detect SUI in the form of cough stress test and urodynamics. Following the International Continence Society standards, filling cystometry was performed using a 6-Fr urodynamic catheter to detect the degree of stress incontinence by VLPP starting from a 200-ml bladder capacity, then repeated every 100 ml. Bladder capacity, compliance, sensations and detrusor over-activity were also assessed. Pressure–flow studies were done to detect changes in urinary flow rate, voiding pressure and detrusor pressure at maximum flow (Pdet-Qmax) that may indicate postoperative bladder outlet obstruction [13].

The RFVF procedure was performed for all patients. This new technique was originally developed in our department to use native vaginal tissue for SUI treatment [14]. The procedure can be performed under spinal or general anesthesia in the dorsal lithotomy position. A urethral catheter is inserted to keep the bladder empty at all times. A rectangular anterior vaginal wall flap is fashioned such that the top of the flap is approximately 2 cm below the urethral meatus and the bottom of the flap is extended toward the bladder neck (Fig. 1). The flap is kept attached to the underlying tissue to preserve its blood supply. Cauterization of the superficial epithelial surface of the vaginal flap is done with a coagulating diathermy electrode to avoid dermoid cyst formation. This is followed by placement of two diagonal rows of zero prolene sutures within the flap to reinforce it (Fig. 2). The next step is rolling the flap upon itself, covering the prolene threads and forming a strong
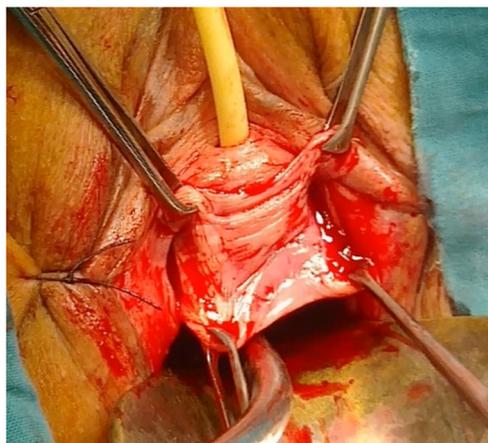

Fig. 1 Fashioning the rectangular anterior vaginal wall flap

cylindrical structure to support the urethra from behind. The rolled flap is now suspended by two threads from either side (Fig. 3) that are passed into the suprapubic region using Stamey needles from above through two abdominal incisions 3 cm from the midline on each side. The two sutures are tied above the rectus sheath without any tension and are tied to each other (Fig. 4).

Follow-up visits were conducted periodically at 6, 12, and 24 months postoperatively and included history taking with questionnaire, clinical examination and urodynamic evaluation. Success was defined as being dry (known from the questionnaire, question 3) at the follow-up visits without complications. Data were fed to the computer using Statistical Package for Social Science (SPSS, version 19). For comparative purposes, paired t test was utilized to compare pre- and post-operative quantitative variables. Friedman test was utilized to compare pre- and post-operative Qol score variables measured more than twice. Appropriate inferential statistics was calculated with a ≤0.05 level of significance.
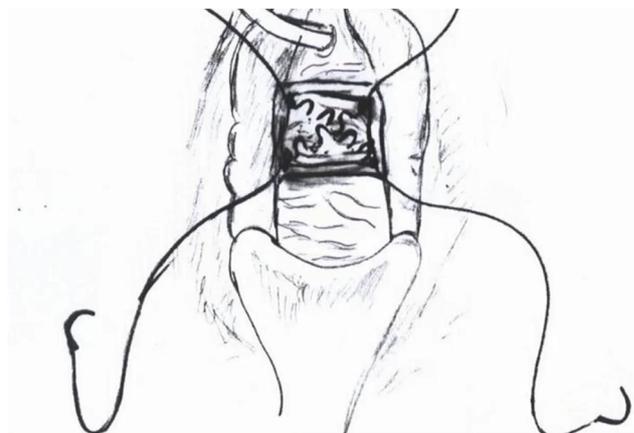

Fig. 2 Placement of two diagonal rows of zero prolene sutures within the flap
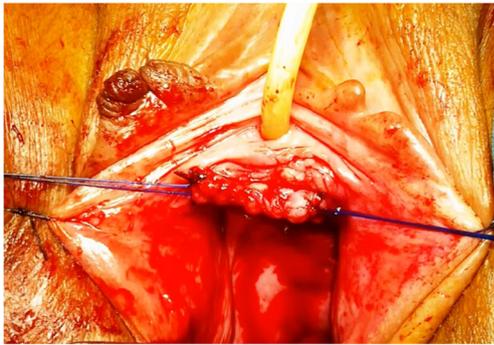
Fig. 3 Rolling the flap and suspension by two threads from either side

Results

The ages of the women studied ranged from 40 to 58 years, with a mean of 53 ± 8 years. Gravidity ranged from 1 to 8, with a mean of 3.8 ± 1.8, whereas parity ranged from 1 to 6 with a mean of 2.8 ± 1.1. All the women studied had at least one normal delivery, whereas three of them underwent cesarean section. One woman had a previous failed vaginal tape and another one had undergone total hysterectomy.

Preoperatively, all the patients had severe incontinence, as indicated by their high score in questions 3 and 4 of the ICIQ-SF questionnaire. By examination, all women studied had a positive cough test. Women with positive urethral hypermobility constituted 45% [9] of the women studied. Preoperative urodynamic examination revealed that Valsalva leak point pressure (VLPP) ranged from 20 to 58 cm H_2O with a mean of 50.05 ± 8.2 cm H_2O. Postoperatively, the success rate was 90% at 2 years' follow-up based on our definition of clinical success (women who were dry at follow-up with negative VLPP

Fig. 4 The two sutures are passed and tied above the rectus sheath

and no major complications; Table 1). SUI was observed in three cases (15%) immediately postoperatively; one of them could be corrected successfully by suprapubic suture adjustment under local anesthesia. The other two patients (10%) still had SUI at 24 months' follow-up, but with a mild degree (scored 1–2 in question 3 and 2 in question 4 of the ICIQ-SF questionnaire) and higher VLPP (80 ± 3 cm H2O) than before surgery.

As regards postoperative complications, transient retention of urine was observed immediately postoperatively in only one woman (5%) and was relieved by a temporary urethral catheter inserted for 5 days, whereas no women suffered such symptoms during the whole period of follow-up ($p = 0.007$). Four cases (20%) suffered from mild urinary obstructive symptoms at the 6-month follow-up as known from the IPSS (<8). This number decreased to just only two cases (10%) after 12 months of follow-up.

Postoperative urodynamic evaluation revealed no significant changes in the mean maximum flow rate (Qmax). It decreased slightly from 23.1 ± 4.6 ml/s preoperatively to 22.2 ± 3.5 ml/s, 21 ± 3.4 ml/s and 19.1 ± 2.2 ml/s at 6 months, 12 months, and 24 months postoperatively respectively ($p = 0.115$). Similarly, Pdet-Qmax showed non-significant changes postoperatively, as the women studied had a mean of 30.85 ± 4.04 cm H_2O at the 6-month follow up and 33.17 ± 3.88 cm H_2O at the 24-month follow-up compared with 28.1 ± 3.2 cm H_2O preoperatively ($p = 0.187$; Table 1).

The QoL domain of the ICIQ-UI-SF score (question 5) showed a significant improvement from a mean percentage score of $73.5 \pm 12.1\%$ preoperatively to $2.6 \pm 8.09\%$ at the 6-month and 12-month follow-up ($p < 0.001$), then showed little increase to 4.5 ± 10.6 at the 24-month follow-up (Table 1).

Discussion

The goal of treatment for ISD is to correct incontinence without creating outlet obstruction. Management of ISD generally falls into one of three categories: urethral bulking agents, slings or artificial urinary sphincter. The pubovaginal sling remains the gold standard therapy for the surgical candidate with a long-term success rate of up to 95% [9]. The transvaginal tape (TVT) procedure has become one of the most popular techniques for treating SUI because of its ease and effectiveness. A published series with a long follow-up duration showed good continence rates after the TVT procedure [15]. However, there is a controversy about the long-term efficacy of the TVT procedure in women with ISD. Doo et al. reported 5-year follow-up results of 31 patients with VLPP below 60 cm H_2O. Cure rates were 51.6% and the success rate of the ISD group was significantly lower [16]. Paick et al. also reported a significantly low success rate in the group below

Table 1 Preoperative and postoperative urodynamic and questionnaire results

	Preoperative	6 months (postoperatively)	12 months (postoperatively)	24 months (postoperatively)	*p* value
VLLP (cm H2O)					
X ± SD	50.05 ± 8.2	Negative (90%)	Negative (90%)	Negative (90%)	<0.001*
Median	53.50				
Q-max					
X ± SD	23.1± 4.6	22.23 ± 3.5	21.61 ± 3.4	19.1± 2.2	0.115
Median	23.5	22.70	21.65	20.5	
Pdet-Qmax					
X ± SD	28.1 ± 3.2	30.85 ± 4.04	32.3 ± 1.7	33.17 ± 3.88	0.187
Median	29.6	31.0	32.8	33.9	
ICIQ-UI (% score)					
X ± SD	73.57 ± 12.01	2.62 ± 8.09	2.62 ± 8.09	4.5 ± 10.6	<0.001*
Median	71.43	3.5	3.5	7.1	

*Significant

60 cmH$_2$O compared with the group above 60 cm H$_2$O (82% vs 93.1%, $p = 0.013$) [17]. In our series, the RFVF procedure showed a 90% success rate at 2 years' follow-up, which is comparable with the gold standard pubovaginal slings (95%). However, an even longer follow-up period of a larger group of patients is needed.

Postoperative bladder outlet obstruction is a crucial problem after anti-incontinence surgery. In our study, only one patient had transient postoperative retention and 20% suffered from obstructive urinary symptoms 6 months following surgery, which decreased to only 10% later on. This reflects the low incidence of obstruction after RFVF operation. For the gold standard bladder neck sling operation, the reported incidence of postoperative obstruction reached up 30% [9].

One of the advantages of RFVF is the cost-effectiveness of the technique, as it uses local tissues rather than external commercial devices such as the synthetic slings or artificial sphincter, which are rather expensive. This is very important in low-income countries where the cost of the operation plays a role in decision-making. Another advantage is the zero incidence of vaginal erosion or bladder perforation, as there is no synthetic foreign material used. On the other hand, all other modalities that use synthetic material carry the risk of urethral, vaginal or bladder erosion. It is reported to be 3–5% after midurethral tapes and 4–6% after artificial urinary sphincter [18, 19].

Incontinence is considered as the main factor affecting quality of life of women following surgery. Measuring QoL using different instruments poses some challenges, namely: which is the better tool for assessing patient-oriented outcomes? The ICIQ, used in the current study, is a brief 3-scored and 1-unscored self-diagnostic item that assesses the prevalence, frequency, and volume of leakage and impact on QoL. The ICIQ demonstrates good construct validity and reliability and a high correlation with the Sandvik severity index [20].

This study offered a unique opportunity to prospectively compare quality of life for 24 months postoperatively. In this study, the QoL domain of the ICIQ score improved from 73.57 ± 12.015% (preoperatively) to 2.62 ± 8.098% (6-month follow-up; $p < 0.001$) and then remained at the same score by the 12-month follow-up, then showed a small increase at the 24-month follow-up (4.5± 9.3). Data from this study are consistent with previous findings that QoL after SUI surgery is observed after a variety of surgical approaches, including Burch retropubic urethropexy, traditional sling operations, and mid-urethral slings. Most reports support roughly a 70–80% improvement that is sustained over time [21, 22].

Strengths of this study include the prospective design of the trial, the use of urodynamic evaluation, and condition-specific measures of QoL at the 6-, 12-, and 24-month follow-up. However, limitations of this study include the lack of a control arm for a randomized controlled study and the small number of patients included. Also, a longer duration of follow-up would better demonstrate the sustainability of the observed success and improvement in the quality of life.

Conclusion

The RFVF operation is a safe and cheap procedure for the treatment of female ISD. It carries a high success rate and leads to improvement of the patients' quality of life after a 2-year follow-up.

Compliance with ethical standards

Conflicts of interest None.

Appendix 1

ICIQ-UI Short Form

CONFIDENTIAL

Initial number

DAY MONTH YEAR
Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth:

DAY MONTH YEAR

2 Are you (tick one): Female ☐ Male ☐

3 How often do you leak urine? (Tick one box)

never ☐	0
about once a week or less often ☐	1
two or three times a week ☐	2
about once a day ☐	3
several times a day ☐	4
all the time ☐	5

4 We would like to know how much urine you think leaks.
How much urine do you usually leak (whether you wear protection or not)?
(Tick one box)

none ☐	0
a small amount ☐	2
a moderate amount ☐	4
a large amount ☐	6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

    0   1   2   3   4   5   6   7   8   9   10
not at all   a great deal

ICIQ score: sum scores 3+4+5 ☐ ☐

6 When does urine leak? (Please tick all that apply to you)

never – urine does not leak	☐
leaks before you can get to the toilet	☐
leaks when you cough or sneeze	☐
leaks when you are asleep	☐
leaks when you are physically active/exercising	☐
leaks when you have finished urinating and are dressed	☐
leaks for no obvious reason	☐
leaks all the time	☐

Thank you very much for answering these questions.

Appendix 2

ICIQ-UI Short Form (Arabic)

سري

الرقم الأصلي

اليوم الشهر السنة

تاريخ اليوم

يعاني عديداً من الناس، في بعض الأحيان، من مشكلة التسرب البولي. نحاول هنا تحديد عدد الأشخاص الذين يعانون من مشكلة التسرب البولي ومعرفة إلى أي مدى تؤثر هذه المشكلة عليهم. سوف نكون ممتنين جداً لكم إجابتكم على الأسئلة التالية مع الأخذ في نظر الاعتبار حالتكم العامة في الأسابيع الأربع الماضية.

1. تاريخ الميلاد

اليوم الشهر السنة

2. الجنس

ذكر أنثى

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3. ما هو معدل حدوث التسرب البولي منك؟ (أشر (✓) على مربع واحد فقط)

0	لا يحدث أبداً
1	حوالي مرة في الأسبوع أو أقل
2	من مرتين إلى ثلاث مرات أسبوعياً
3	حوالي مرة يومياً
4	عدة مرات في اليوم
5	في كل الأوقات

---

4. نود معرفة كمية البول المتسرب منك حسب تقديرك.

ما هي كمية البول المتسربة منك عادة أثناء التسرب البولي (سواء استخدمت وسيلة للوقاية أم لا) ؟

0	لا يوجد
2	كمية صغيرة
4	كمية متوسطة
6	كمية كبيرة

---

5. بشكل عام، إلى أي مدى تؤثر مشكلة التسرب البولي على حياتك اليومية؟

ضع دائرة حول الرقم المناسب مع ملاحظة أن (0) تعني أنها لا تؤثر مطلقاً وأن (10) تعني أنها تؤثر إلى مدى كبير

0   1   2   3   4   5   6   7   8   9   10

لا تؤثر   تؤثر إلى مدى كبير

مطلقاً

نتيجة ICIQ : إجمع نقاط 5+4+3

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6. متى يحدث التسرب البولي؟ (رجاءً أشر (✓) على جميع الحالات التي تنطبق عليك)

	لا أعاني أبداً من مشكلة التسرب البولي
	يحدث التسرب البولي قبل الوصول إلى دورة المياه
	يحدث التسرب البولي عند السعال أو العطس
	يحدث التسرب البولي أثناء النوم
	يحدث التسرب البولي مع الحركات الجسدية النشيطة و أثناء ممارسة الرياضة
	يحدث التسرب البولي بعد التبول وارتداء الملابس
	يحدث التسرب البولي بدون سبب واضح
	يحدث التسرب البولي في كل الأوقات

مع جزيل الشكر   لإجابتكم على هذه الأسئلة

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