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Original Article

Effectiveness of Kelly Plication Method on Clinical Improvement in Stress Urinary Incontinence Patients

Puspitasari Notohatmodjo[1], Besari Adi Pramono[2], Inu Mulyantoro[3], Herman Kristanto[2], Dewi Astri Purnaningtyas[4], Arufiadi Anityo Mochtar[4], Erwinanto[4]

[1]Obstetric and Gynecology Department, Medical Faculty of Diponegoro University Semarang, Indonesia
[2]Fetomaternal Subdivision, Obstetrics and gynecology Department, Medical Faculty of Diponegoro University / Central General Hospital of Kariadi Semarang, Indonesia
[3]Fertility Subdivision, Obstetrics and gynecology Department, Medical Faculty of Diponegoro University / Central General Hospital of Kariadi Semarang, Indonesia
[4]Urogynecology Subdivision, Obstetrics and gynecology Department, Medical Faculty of Diponegoro University / Central General Hospital of Kariadi Semarang, Indonesia

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Author Affiliation:
Obstetric and Gynecology Department, Medical Faculty of Diponegoro University Semarang, Indonesia

Author Correspondence:
Puspitasari Notohatmodjo
Dr. Sutomo 16 street, Semarang, Central Java 50244, Indonesia

E-mail:
mrs.evilusiana@fk.unsri.ac.id

Abstract

Background : Patients with pelvic organ prolapse (POP) usually present with POP, but stress urinary incontinence (SUI) is also found during history taking and physical examination. As a result, the complaint of SUI is persistent despite POP surgery. Therefore, SUI found along with POP and undergoing surgery can be performed Kelly plication method. The objectives ot this study was to examine the effectiveness of Kelly's plication method on clinical changes and quality of life of patients suffering from SUI.
Methods : A single cohort prospective one-group pretest-posttest design conducted at RSUP Dr. Kariadi Teaching Hospital Semarang involving 31 research subjects. All subjects were measured preoperative IIQ-7 questionnaire and pad test. Then, all subjects will undergo Kelly method surgery. Postoperative evaluation will be conducted 3 months later, including measurement of the IIQ-7 questionnaire and pad test. All data will be analyzed with univariate and bivariate analysis using paired t-test and Wilcoxon test.
Results : The effectiveness rate of Kelly's plication method was 58.06% in this study. Most of the subjects were aged 50–59 (38.7%) years and had experienced menopause (87.1%). Correlation analysis of baseline data on the degree of preoperative SUI showed that the degree of POP correlated SUI. The Pad test and IIQ-7 questionnaire test showed a significant decrease in postoperative measurements in the treatment group ($p < 0.001$ & $p < 0.001$).
Conclusion : Kelly's plication method is effective in treating SUI.

Keywords : stress urinary incontinence, SUI, Kelly plication, pelvic organ prolapse.

INTRODUCTION

According to the definition by the International Continence Society (ICS), urinary incontinence is a complaint of involuntary urine loss that is objectively demonstrable and is a social or hygiene problem.[1,2] Elderly women are most commonly affected by stress urinary incontinence (SUI). In Indonesia, the overall prevalence of urinary incontinence ranges from 23–35%, with stress urinary incontinence accounting for 17.9% of cases.[3,4] Despite often being overlooked by patients and their families, stress urinary incontinence (SUI) can reduce the quality of life and productivity of those affected. Moreover, individuals with SUI may experience external genital irritation or even urinary tract infections as a result of infrequently changing sanitary pads.[5] Although patients with pelvic organ prolapse (POP) typically present with POP-related complaints, stress urinary incontinence (SUI) is often discovered during the medical history and physical examination. Consequently, SUI symptoms may reoccur after POP reconstruction surgery. Occult Stress Urinary Incontinence (OSUI) refers to hidden SUI that occurs after reconstruction in patients with pelvic organ prolapse (POP). The prevalence rate of OSUI in women with severe POP is estimated to range between 27% until 68%.[6]

The management options for patients with SUI can be categorized into non-operative therapy and operative therapy.[7] Non-operative therapy can be further divided into pharmacological and non-pharmacological therapy. Non-pharmacological therapy may include lifestyle modifications such as reducing caffeine intake and weight loss, Kegel exercises to strengthen pelvic floor muscles, or the use of a pessary for patients with SUI.[7] Invasive treatment options for managing SUI include neuromodulation, Kelly plication, Burch colposuspension surgery, the retropubic urethropexy methods such as Raz or Marshall-Marchetti-Krantz, or sling placement surgeries like transobturator tape (TOT) and tension-free transvaginal tape (TVT).[8] In both of these methods, a sling is placed as a substitute for the pubourethral ligaments.[9] These surgical methods are quite expensive and may not be covered by the Indonesian National Health Insurance (Jaminan Kesehatan Nasional or JKN). Therefore, for patients with concurrent stress urinary incontinence and pelvic organ prolapse who undergo surgery, the Kelly plication method is often chosen as it is more cost-effective. The aim of this study is to assess the effectiveness of the Kelly plication method in terms of clinical improvement and quality of life for patients with stress urinary incontinence in Indonesia, addressing the lack of available data on its efficacy.

METHODS

The research was conducted using an observational analytical method with a single cohort prospective design, one-group pretest-posttest. It took place over a period of one year, from December 2021 to December 2022, at the Obstetrics and Gynecology Clinic of Merpati Polyclinic RSUP Dr. Kariadi, a teaching hospital in Semarang. This study obtained ethical clearance from the Medical Research Ethics Commission of the Dr. Kariadi Central General Hospital Semarang with approval number: 948/EC/KEPK-RSDK/2021.

Consecutive sampling of 31 samples who were willing to take part in this research and undergoing surgery were included in this study. Patients with a history of uncontrolled diabetes mellitus, a body mass index (BMI) greater than 40 kg/m^2, pregnancy, malignancies, hormonal estrogen therapy, a history of stroke, smoking, and regular alcohol consumption were excluded as criteria for this research sample.

Subsequently, individuals who were willing to participate in the study, including their readiness to undergo the surgical procedure, were provided with an explanation, research information sheet, and research consent letter outlining the research's conduct, objectives, procedures, benefits, risk, disadvantages and expected outcomes. Patient data include name, date of birth, weight and height, occupation, address, and last education were then retrieved from their medical records, and a validated Indonesian version of the IIQ-7 questionnaire was administered to the patients through a structured interview conducted by the researcher or research assistant. The IIQ-7 questionnaire were a tool to assess life quality and symptom distress for urinary incontinence (UI) in women. Patients were then admitted for preoperative preparation. Following this, the Kelly plication surgical procedure was performed by multiple healthcare professionals as a treatment for UI based on medical indications. Three months post-operation, subjects who had undergone the surgical procedure completed the IIQ-7 questionnaire through a structured interview, and pad tests were conducted both before and after the operation. A three-month analysis were carried out since there should be improvement in complaints and asses the effectiveness of short-term actions.

Univariate analysis was used to present the characteristics of the study subjects by providing the distribution of variables using descriptive statistics such as mean, median, and standard deviation. Tables displayed quantitative data. Paired T-tests were conducted to analyze the pad test and IIQ-7 questionnaire results before and 3 months after the operation. The significance level was set at $p<0.05$. The Wilcoxon test was used for non-normally distributed data.

RESULTS

The total number of patients with stress urinary incontinence who presented at the Obstetrics and Gynecology Clinic of Merpati Polyclinic RSUP Dr. Kariadi during the study duration was 40 patients. Five patients declined to participate in the study, while 2 patients had morbid obesity (BMI >40 kg/m^2), and 2 patients had type 2 diabetes mellitus, leading to their exclusion from the study. This resulted in 31 patients who met the inclusion criteria and provided informed consent to participate in the research.

Characteristics of Study Subjects

The largest age group in the study was between 50–59 years old (n=12, 38.7%), with an average age of 59.58 ± 8.64 years. All research subjects were married, with only 3 subjects having been married twice. A total of 27 subjects (87.1%) involved in the study had experienced menopause, with an average duration of 10.52 years. In this study, all subjects were married, and among them, 22 patients (71.0%) had a history of giving birth more than two times, with vaginal deliveries being the most common (n=30, 96.8%). The majority of the research subjects had a normal BMI (n=14, 45.2%).

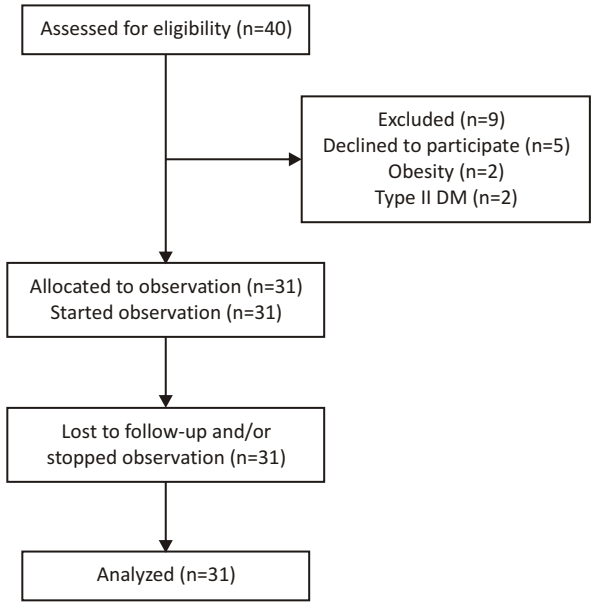

Figure 1. Consort Diagram

TABLE 1
Research Subject Characteristics

Variable		n	%	Mean ± SD	Median (min – max)
Age	40 – 49 years	5	16.1	59.58 ± 8.64	58 (42 – 72)
	50 – 59 years	12	38.7		
	60 – 69 years	10	32.3		
	≥ 70 years	4	12.9		
Parity	1 – 2	9	29.0		
	> 2	22	71.0		
Delivery	Caesar Section	1	3.2		
	Vaginal Birth	30	96.8		
Menopause	No	4	12.9		
	Yes	27	87.1		

TABLE 1. Continued.

Variable		n	%	Mean ± SD	Median (min – max)
Menopause duration				10.52 ± 6.49	10 (2 – 21)
BMI	Underweight	1	3.2		
	Normal	14	45.2		
	Overweight	11	35.5		
	Obesities I	5	16.1		
POP Degree	Mild	5	16.1		
	Severe	26	83.9		
Preoperative SUI	Mild	9	29		
	Moderate	17	54.8		
	Severe	5	16.1		

TABLE 2
Analysis of the Differences in the Characteristics of Study Subjects by Preoperative SUI Severity

Variable		SUI pre op			p
		Mild	Moderate	Severe	
Age	40 – 49 years	2 (22.2)	2 (11.8)	1 (20)	0.817£
	50 – 59 years	3 (33.3)	7 (41.2)	2 (40)	
	60 – 69 years	2 (22.2)	7 (41.2)	1 (20)	
	≥70 years	2 (22.2)	1 (5.9)	1 (20)	
Parity	1 – 2	2 (22.2)	5 (29.4)	2 (40)	0.780£
	>2	7 (77.8)	12 (70.6)	3 (60)	
Delivery	Caesar Section	0 (0)	1 (5.9)	0 (0)	0.653£
	Vaginal Birth	9 (100)	16 (94.1)	5 (100)	
Menopause	No	2 (22.2)	2 (11.8)	0 (0)	0.483£
	Yes	7 (77.8)	15 (88.2)	5 (100)	
Menopause duration		10.4 ± 7.2	11.2 ± 6.5	8.6 ± 6.5	0.770¥
BMI	Underweight	0 (0)	1 (5.9)	0 (0)	0.408£
	Normal	6 (66.7)	5 (29.4)	3 (60)	
	Overweight	1 (11.1)	8 (47.1)	2 (40)	
	Obesities I	2 (22.2)	3 (17.6)	0 (0)	
POP Degree	Mild	4 (44.4)	0 (0)	1 (20)	0.013£*
	Severe	5 (55.6)	17 (100)	4 (80)	

*Significant (p <0.05); £ Chi–Square; ¥ Spearman's Correlation

All study subjects were UI patients with pelvic organ prolapse who underwent pelvic organ reconstruction procedures, including anterior colporrhaphy, simultaneously with the Kelly plication method. Pad test examinations and completion of the IIQ-7 questionnaire were conducted prior to the surgical procedure. Subjects underwent the second evaluation of these examinations three months after the operation.

TABLE 3
Results of the Wilcoxon test for the pad test

Pad Test (gram)	Mean ± SD	Median (min – max)	p
Preoperative	25.56 ± 18.24	19.20 (3,00 – 63.00)	<0.001‡*
3 months postoperatively	3.73 ± 2.84	3.20 (0,30 – 11.30)	

*Significant; ‡Wilcoxon-test (p <0.05)

TABLE 4
Results of the paired t-test for the IIQ-7 questionnaire

IIQ-7 Questionnare (score)	Mean ± SD	Median (min – max)	p
Preoperative	53.75 ± 21.02	57.10 (14.28 – 95.23)	<0.001+*
3 months postoperatively	10.60 ± 10.04	9.52 (0.00 – 38.09)	

+Paired t-test (p <0.05); *Significant

TABLE 5
Effectiveness of the Kelly Plication Method

Preoperative	Postoperative				Total
	Severe	Moderate	Mild	Fully-Recovered	
Severe	0	1	0	4	5
Moderate	0	0	10	7	17
Mild	0	0	2	7	9
Total	0	1	12	18	31

The degree of POP has an influence on the severity of UI (p=0.013), whereas age, parity, mode of delivery, menopause, and BMI do not have a significant impact on the occurrence of UI.

Pad Test

According to the pad test examination, the median value before treatment was 25,56 ± 18,24, with a range of 0,03 to 11,30 after treatment. The Wilcoxon test was employed because the research data did not follow a normal distribution. The results indicate a significant difference in the mean values of the pad test before and three months after Kelly plication. The study assessed the therapy's success based on daily pad usage. Therapy was considered successful if patients did not use pads six months after the operation. The Kelly plication group exhibited a significant decrease in the number of pads used before and after the surgery.It was found that there was a significant decrease in pad test results before the operation compared to 3 months after the operation, with a difference of 21.83 ± 15.4 grams.

IIQ-7 Questionnare

To assess quality of life scores, the IIQ-7 questionnaire was utilized. The mean score on the questionnaire before Kelly plication was 53.75 ± 21.02, while the score 3 months after the operation was 10.60 ± 10.04. A paired t-test was employed to assess significance due to the normally distributed data in the study. The results of the paired t-test show a statistically significant difference in the mean scores of the IIQ-7 questionnaire when comparing before and three months after the Kelly plication procedure.

Kelly Plication Effectiveness

At the outset of the study, 31 subjects were experiencing UI. Following the Kelly plication procedure, clinical evaluation was continued, with a pad test indicator performed three months after the surgery, revealing that 13 patients still experienced UI. Consequently, the success rate of Kelly plication in UI patients was 58.06%.

The study assessed the therapy's success based on daily pad usage. Therapy was considered successful if

patients did not use pads six months after the operation. The Kelly plication group exhibited a significant decrease in the number of pads used before and after the surgery, namely, 1.92 ± 0.95 vs. 0.4 ± 0.12 (p=0.001).[18] Similar to this study, it was found that there was a significant decrease in pad test results before the operation compared to 3 months after the operation, with a difference of 21.83 ± 15.4 grams.

DISCUSSION

The Kelly plication method is a surgical procedure for the correction of anterior vaginal defects, aiming to reinforce the pubovesical fascia around the bladder neck and proximal urethra to provide necessary support and aid in the mechanism of urethral sphincter closure, thereby preventing urinary leakage. This study represents an observational analytical study with a pre-test and post-test design within a single group, prospectively conducted on 31 SUI patients concurrently diagnosed with POP, who presented at the Obstetrics and Gynecology Clinic of Merpati Polyclinic RSUP Dr. Kariadi, Semarang. All subjects in the study underwent pelvic organ prolapse reconstruction surgery along with Kelly plication.

The peak incidence of UI in women occurs at the age of 50. In this study, the mean age of women experiencing UI was 59.58 ± 8.64 years, with the youngest being 49 years old and the oldest being 72 years old. The majority of UI cases occurred in the age group of 50–59 years (n = 12, 38.7%). In this study, age did not have a significant influence on the occurrence of UI, consistent with a study conducted in Taiyuan.[10] Findings from a study conducted in Saudi Arabia indicate that UI occurs most frequently in the age range of 50–59 years.[11] The results of this study differ from research conducted on 236 Indian women, which reported that age influences the prevalence of UI in women, with 60% of UI cases occurring in the age group above 50 years.[12] This study found that 87% of the patients had experienced menopause with an average duration of menopause of 10.52 ± 6.49 years, although it did not have a statistically significant impact on the occurrence of UI. These results can be explained by the article by Gabriela, where SUI in menopausal patients is not influenced by the duration of menopause, but mainly by the number of pregnancy and births, the baby's birth weight, the patient's BMI, and the patient's chronic conditions.[13]

In this study, 22 subjects (71.0%) had a parity status of more than 2 times, while 9 subjects (29.0%) had a parity status of 1 or 2 times. However, the results of this study were not statistically significant. These results are supported by previous meta-analysis study by Zhou that concluded higher parity has a more significant effect on overall UI, but it all depends on the chronic condition of each patient. The article found that pregnancy and childbirth, especially in multiparous women, were correlated with an increased prevalence of UI. It is known that women who gave birth 1, 2, and more than 3 times had a risk of 1.43 [95% CI: 0.90–2.28; I2=81.4%; n=4], 1.50 (95% CI: 1.02–2.20; I2= 82.5%; n=4), and 1.58 (95% CI: 1.22–2.03; I2=70.1%; n=7), respectively. The study found that having a parity status of more than 2 had the potential to increase the risk of UI compared to nulliparity.[10,14] There is a possibility that this is due to trauma that occurs to the connective tissue or pelvic floor muscles during the childbirth process, which can disrupt bladder function. Based on this hypothesis, the method of childbirth also influences the risk of UI. It was found that cesarean section delivery did not correlate with the risk of UI, whereas vaginal delivery with instrumentation doubled the risk of UI compared to cesarean section delivery. Only 1 subject (29.0%) had a history of cesarean section delivery, and 30 subjects (96.8%) had a history of vaginal delivery, aligning with the characteristics of the study subjects' data.[15,16]

Before the Kelly plication procedure, all study subjects underwent a pad test. This test can be used to determine whether there are changes in incontinence before and after the Kelly plication. The results of the pad test before the surgery had an average of 25.56 ± 18.24 grams, with the smallest result being 3 grams and the highest 63 grams. This wide range of results was influenced by the severity of pelvic organ prolapse (POP) present, where severe POP, namely, stage 3 and stage 4, had significance in increasing the occurrence of UI (p=0.013). The association between POP and UI is based on the shared pathophysiology between the two, involving damage to the ligaments in the pelvic area, as well as similarities in intrinsic predisposing factors such as genetics, race, menopause, and extrinsic predisposing factors including obstetric history, prior pelvic surgeries, obesity, and underlying comorbid diseases.[17]

To assess the effectiveness of the surgery, a repeat pad test examination was conducted during the three-month post-Kelly plication follow-up visit. The results of the pad test at three months post-Kelly plication were lower than those obtained before the surgery. This three-month observation serves as a short-term follow-up. In addition to assessing effectiveness, this short-term observation within a three-month timeframe is performed to evaluate the safety of the procedure and to identify any adverse events associated with the Kelly plication method.[18] A study conducted in Brazil observed the effects of vaginal hysterectomy with the addition of Kelly plication compared to the addition of TOT in POP patients with UI.

One of the instruments used to assess the quality of life of patients following urinary incontinence surgery is the IIQ-7 questionnaire. In a study involving the treatment of UI patients who underwent anterior colporrhaphy with the addition of Kelly plication,

a reduction in IIQ-7 scores was observed before [median 5 (1–10)] and 13.5 years after the procedure [median 0 (0–1)] (p=0.0435).[20] Similar results were also found in another study involving patients with a BMI less than 30 and those with a BMI greater than 30 who underwent mid-urethral sling techniques such as TVT or TOT. In both obese and non-obese women, the IIQ-7 scores decreased before the surgery and 12 months after the surgery (0.0, 95% CI 0.0–4.8 versus 0.0, 95% CI 0.0–14.3, p= 0.033).[21]

The results of the pad test evaluation conducted within 60 minutes indicate that patients are considered cured if the pad test result is less than 3 grams. This study reported a success rate of 58.06% for the Kelly plication procedure. The success rate reported in this study is notably lower in comparison to earlier literature, which indicated therapy success rates of approximately 80% at the three-month evaluation, 63% at the one-year evaluation, and 37% at the five-year evaluation following surgery. The results of this study highlight a lower success rate for the Kelly plication procedure in the short term. However, it's important to note that this research only had a three-month follow-up period. Therefore, longer-term symptom monitoring is needed to assess the effectiveness of Kelly plication in clinical outcomes for UTI patients. Another limitation of this study is that it included only one group of subjects who underwent Kelly plication, without a control or comparative group with other surgical procedures like TVT, TOT, and TVT-O. Despite these limitations, it's noteworthy that significant improvements in patients' quality of life and positive outcomes in the pad test results were observed, contrasting with historical literature. These results indicate that the low success rate value is mainly caused by the shorter follow-up time compared to previous studies, where there is no 1 years and 5 years follow up. This is supported by the value of quality of life and pad test results which are not inferior to previous research. It is essential to interpret these findings in the context of the evolving landscape of UI management and to consider factors contributing to this discrepancy. Further research with extended follow-up periods and larger, diverse subject populations may provide a more comprehensive understanding of the long-term efficacy of the Kelly plication method in UI patients. These findings underscore the importance of ongoing research to refine treatment strategies and optimize outcomes for UI patients.[22] Another study comparing Kelly plication and TOT reported a success rate of 64% for the Kelly plication six months after the procedure, in contrast to a success rate of 68% for TOT.[19]

Limitations

This study had a limited three-month follow-up period, necessitating the monitoring of symptoms in both the medium term (between 3–12 months post-operation) and the long term (beyond 12 months) to assess potential reductions in the effectiveness of the Kelly plication method on clinical changes in UI patients. Another limitation of this research is its exclusive focus on a single group of subjects undergoing Kelly plication, without a comparative group subjected to alternative surgical procedures such as TVT, TOT, and TVT-O. Furthermore, the distribution of subjects across the various severity levels of UI within this study was not uniform.

Nonetheless, the strength of this study lies in its attempt to quantitatively analyze the effectiveness of the Kelly plication method based on urinary pad test results and qualitatively based on the IIQ-7 questionnaire. These findings contribute to the scientific discourse by shedding light on the potential benefits of the Kelly plication method in managing UI associated with pelvic organ prolapse. It is essential to acknowledge and consider these limitations in the context of the study's contributions to our understanding of UI management. Further research with extended follow-up periods and larger, more diverse subject populations may provide additional insights into the comparative effectiveness of various surgical interventions for UI.

CONCLUSION

Based on the findings of this study, it can be concluded that the Kelly plication method effectively reduces urinary incontinence (UI) symptoms in patients, leading to a significant improvement in the mean results of urinary pad tests and a higher reported quality of life among the subjects. The success rate of the Kelly method in improving the condition of UI in this study was 58.06%. This research focuses on the effectiveness of the Kelly plication method in patients who underwent concurrent prolapse surgery. It examines the substantial reduction in urinary incontinence symptoms and the concurrent improvement in the quality of life among these specific patient populations. The findings highlight the potential of the Kelly method as a viable treatment option for UI associated with pelvic organ prolapse, offering valuable insights to the field of urology with implications for clinical practice and patient care in this specific context.

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