



## Original article

## The vicissitudes of open and laparoscopic retropubic urethropexy for stress urinary incontinence in Taiwan: An 11-year nationwide analysis

Pei-Yang Hsu<sup>a</sup>, Cheng-Yu Long<sup>b</sup>, Yu-Tung Huang<sup>c</sup>, Kuan-Hui Huang<sup>d</sup>, Chao-Hsiun Tang<sup>e</sup>, Ming-Ping Wu<sup>f,g,h,\*</sup><sup>a</sup> Department of Obstetrics and Gynecology, National Cheng Kung University Hospital, Tainan, Taiwan<sup>b</sup> Department of Obstetrics and Gynecology, Kaohsiung Municipal Hsiao-Kang Hospital, Kaohsiung Medical University, Kaohsiung, Taiwan<sup>c</sup> Department of Gerontological Care and Management, Chang Gung University of Science and Technology, Taoyuan, Taiwan<sup>d</sup> Division of Gynecology, Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Kaohsiung Medical Center, Chang Gung University College of Medicine, Kaohsiung, Taiwan<sup>e</sup> School of Health Care Administration, Taipei Medical University, and the Gynecology Research Center, Taipei Medical University Hospital, Taipei, Taiwan<sup>f</sup> Division of Urogynecology and Pelvic Floor Reconstruction, Department of Obstetrics and Gynecology, Chi Mei Medical Center, Tainan, Taiwan<sup>g</sup> Department of Obstetrics and Gynecology, College of Medicine, Taipei Medical University, Taipei, Taiwan<sup>h</sup> Center of General Education, Chia Nan University of Pharmacy and Science, Tainan, Taiwan

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## ABSTRACT

**Objective:** To characterize the changing trend and variables of either open or laparoscopic retropubic urethropexy (RPU) in treating female stress urinary incontinence (SUI) in Taiwan.**Materials and methods:** Using the National Health Insurance Research Database (NHIRD), a total of 8977 female patients with SUI during the period between 1997 and 2007 were identified. The differences in distribution of open and laparoscopic RPU in the context of different years, patient age, surgeon age and gender, and hospital accreditation level and ownership were examined using Chi-square tests.**Results:** An upward trend of annual RPU was found between 1997 (377 procedures per year) and 2004 (1060), followed by a downward trend between 2004 and 2007 (705). In the meantime, an upward trend of using laparoscopy for SUI was found between 1997 and 2002 (annual percentage change, APC = 24.86,  $p = 0.001$ ), followed by a downward trend from 2002 to 2007 (APC = -41.88,  $p = 0.001$ ), which was evidenced by joinpoint regression analysis. In year 2007, only 10 laparoscopic RPU procedures were performed. Patient age, surgeon age, hospital accreditation level, and ownership were shown to have statistically significant associations with the types of RPU chosen (all  $p$  values for the Chi-square tests were less than 0.0001). Surgeon gender was not associated with the choices of surgical types ( $p = 0.85$ ). **Conclusion:** The vicissitudes of laparoscopic RPU, with an initial increase followed by a decrease around the year of 2002, happened during the past 11 years in Taiwan. The evolution of the surgical methods for SUI may affect the trend of the choices of RPU approaches significantly. The increased and decreased demands on laparoscopic RPU before and after the emergence of tension-free vaginal tape denote the need for more minimally invasive procedures. Nevertheless, the long-term value of novel surgical modalities for SUI is yet to be defined.

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## Introduction

Stress urinary incontinence (SUI) is a prevalent disease in women, affecting 4–35% according to different epidemiologic definitions.<sup>1</sup> According to the International Continence Society, the

symptoms and signs of SUI are defined as complaints of involuntary loss of urine and the observation of involuntary urinary leakage from the urethra on effort, physical activities, sneezing, or cough.<sup>2</sup> Various surgical options were taken as choices for treating SUI, including injectable therapy, retropubic urethropexy (RPU) or colposuspensions, artificial sphincters, pubovaginal slings, and minimally invasive suburethral slings (MISS).<sup>3</sup> RPU involves stitches placed at tissues close to the bladder neck and proximal urethra and fixed behind the pubic bones (Marshall–Marchetti–Krantz, MMK) or the Cooper ligament (Burch colposuspension).<sup>4</sup>

\* Corresponding author. Division of Urogynecology and Pelvic Floor Reconstruction, Department of Obstetrics and Gynecology, Chi Mei Medical Center, Number 901, Chung-Hwa Road, Yung-Kang, Tainan 710, Taiwan.

E-mail address: [mpwu@mail.chimei.org.tw](mailto:mpwu@mail.chimei.org.tw) (M.-P. Wu).

attempting to stabilize the bladder neck in a high retropubic position and correcting urethral hypermobility.<sup>5</sup> This procedure could be done through laparotomy (or open procedure) or laparoscopy with different modification.<sup>6–8</sup>

In the era of minimally invasive surgeries, laparoscopy has been advocated for its shorter recovery time, less blood loss, and less pain compared to traditional open RPU surgeries in the context of similar short-term and long-term outcomes.<sup>9</sup> However, laparoscopy is more costly, time-consuming, and technically difficult. Starting from 1993 when the first series of laparoscopic RPU was published by Liu and Paek,<sup>6</sup> cumulating evidence suggested that RPU performed through laparoscopy is a suitable alternative to open RPU surgery.<sup>10,11</sup> Based on our previous descriptive study regarding the different surgical types for SUI in women in Taiwan,<sup>12</sup> the goal of this study is to describe the changing trend for open and laparoscopic approach for RPU surgery using the nationwide population-based National Health Insurance (NHI) claims data.

## Materials and methods

We studied female patients who had received either open or laparoscopic RPU surgeries for SUI in Taiwan from 1997 to 2007. We used the data from the National Health Insurance Research Database (NHIRD), which is built by the National Health Research Institute (NHRI) in Taiwan. According to our previous study,<sup>12</sup> several variables of interest were incorporated into our study, including the types of diseases (coded according to the International Classification of Diseases, Ninth Revision, Clinical Modification, ICD-9-CM), the codes of surgeries, the patients' characteristics, e.g., age, and the accreditation level and ownership of hospitals where the surgeries were performed. Through the registries of contracted medical facilities and medical personnel, the age and gender of surgeons who were responsible for the surgeries were also identified and entered our analysis. This study strictly followed the data regulations of the Bureau of National Health Insurance (BNHI), and Institutional Review Board approval was waived.

This study is based in part on data from the NHIRD provided by the Bureau of National Health Insurance, Department of Health and managed by the National Health Research Institute of Taiwan. The interpretations and conclusions contained herein do not represent those of the Bureau of National Health Insurance, Department of Health, or the National Health Research Institute.

For analytical purposes, we divided the age of patients into seven 5-year age groups, ranging from younger than 35 years to older than 60 years. The surgeons' ages were also separated into six 5-year age groups, with a range between age younger than 35 years and age older than 55 years. The hospitals are classified either by their ownership or accreditation level. The types of ownerships included private, private not-for-profit hospitals, and government-owned hospitals. The hospitals' accreditation levels, according to the Taiwan Joint Commission on Hospital Accreditation, were classified into medical centers, regional hospitals, and local hospitals. The codes used to identify the surgeries performed for SUI were ICD-9-CM 59.5 for RPU, either MMK or Burch colposuspension. The presence or absence of ICD-9-CM 54.21 (laparoscopy) was used to identify either laparoscopic or open RPU, respectively.

Chi-square tests were used to examine the differences in the distribution of open and laparoscopic RPUs in the context of different variables. The alpha value set of 0.05. A *p* value less than 0.05 was taken as statistically significant. A multiple logistic regression was used to examine the independent effects of each individual variable in choosing an open RPU for SUI. We used joinpoint regression analysis to identify points of significant inflection in trends. The analysis starts with minimum number of inflections (joinpoints), and tests whether one or more additional

joinpoints should be added to the model. In the final model, each joinpoint indicates there was a statistically significant change in trend (either increase or decrease). The annual percentage change (APC) is calculated for the time segments on either side of inflection points. The analyses were performed using the Joinpoint Regression Program (Version 3.4.3 Statistical Research and Applications Branch, National Cancer Institute, Bethesda MD, 2010). The significance of the statistics was determined using *p* < 0.05. All analyses in this study were carried out using SAS System Software for Windows Version 9.01 (SAS institute Inc., Cary, NC).

## Results

All female patients with SUI who underwent either open or laparoscopic RPU surgeries were identified during the period between 1997 and 2007 in Taiwan. Patients with incomplete information were excluded from our analysis, leaving a total of 8977 female patients as our study population. The amounts of RPU procedures, including both open and laparoscopic surgeries, and the changing trends of these procedures were shown in Fig. 1. We found that the use of RPU almost tripled from 1997 to 2002 (377 procedures per year to 989 per year), and then shrunk rapidly from 1060 procedures per year in 2004 to 705 in 2007. The significance of increase and decrease were evidenced by joinpoint test (*p* = 0.005). The proportion of laparoscopic RPU gradually increased over the years from 1997 to 2002 (APC = 24.86, *p* = 0.001), but decreased dramatically from year 2003 till 2007 (APC = −41.88, *p* = 0.001). In year 2007, only 10 laparoscopic RPU procedures were performed.

The surgical types of RPU, either through open or laparoscopy, were stratified according to patient age (Fig. 2), and surgeon age and gender (Fig. 3). Patients age 45–49 years and those 60 years or older were the two age groups receiving most RPU surgeries, with total RPUs of 2095 and 2293, respectively. There were statistically significant differences in the distribution of types of surgeries chosen for SUI in patients of different age groups (Chi square 172.489; *p* < 0.001). Patients younger than 50 years attempted more laparoscopic RPU than those age 50 years or older. A rising trend in the proportion of open RPU surgeries was observed as patients got older.

Ages of surgeons performing the RPU procedure were associated with different types of RPU surgeries. The Chi-square test for the proportions of open and laparoscopic RPU performed by surgeons of different age groups was 149.439 (*p* < 0.001). Surgeons younger than 45 years tended to choose more laparoscopic than open RPUs (Fig. 3). The surgeons' gender was not significantly associated with the types of RPU chosen (Chi-square 0.034; *p* = 0.854).

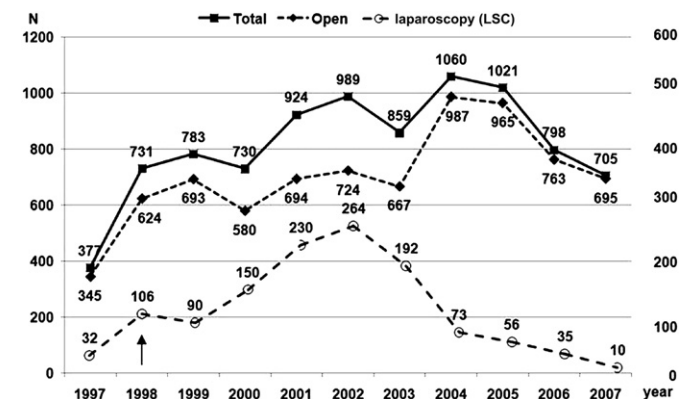
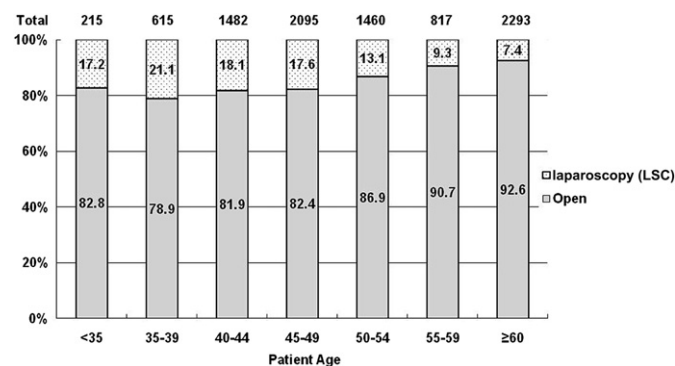


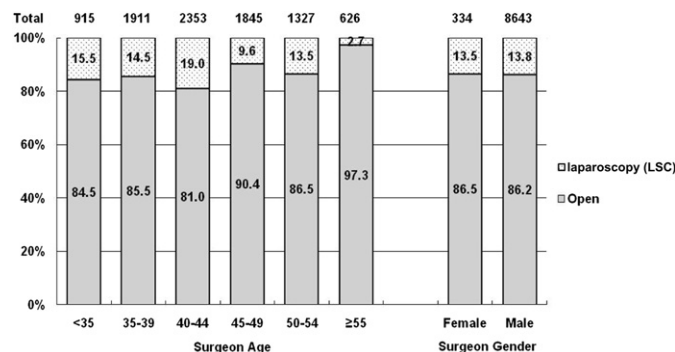
Fig. 1. The changing trends in surgical procedures for retropubic urethropexy in Taiwan, 1997–2007. The arrow indicates the time point of emergence and formal launch in Taiwan. TVT became covered by the NHI in 2005.



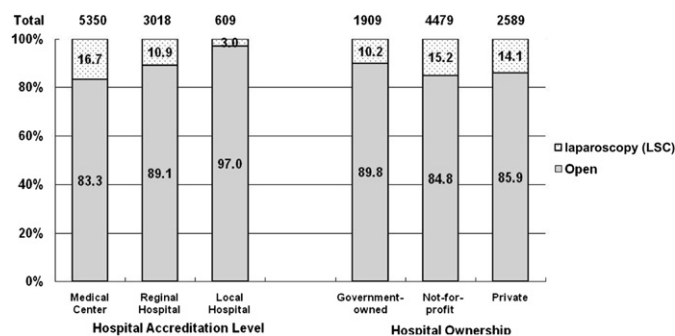
**Fig. 2.** Types of surgery for RPU in Taiwan according to patient age, 1997–2007. The Chi-square test was used to examine the association between the distribution of open and laparoscopic RPU and of patients' age (172.489,  $p < 0.001$ ).

The types of RPU were further analyzed according to the accreditation levels and ownerships of the hospitals (Fig. 4). Medical centers held the highest amount of RPU surgeries with a total number of 5350, compared to 3018 in regional hospitals and 609 in local hospitals. A statistically significant difference was found in the distributions of performing laparoscopic RPU surgeries in hospitals of different accreditation levels (Chi-square 118.064;  $p < 0.001$ ). Higher percentages of open RPUs were delivered in local and regional hospitals compared to the percentage in medical centers. As for the ownership of hospitals, government-owned hospitals tended to have fewer laparoscopic RPUs than the not-for-profit or private for-profit hospitals (Chi-square 27.812;  $p < 0.001$ ).

Results from the multiple logistic regression analysis were given in Table 1. Older patients (55 years or older) had a lesser chance of receiving a laparoscopic RPU than younger patients (younger than 35 years), with an odds ratio (OR) of 0.51 and 95% confidence interval (CI) of 0.33–0.78 ( $p = 0.002$ ) in those 55–59 years; an OR of 0.41 and 95% CI of 0.28–0.61 ( $p < 0.001$ ) in those 60 years or older. Older surgeons (45 years and older) were less likely to perform laparoscopic RPU than younger surgeons (OR 0.48, 95% CI 0.38–0.62,  $p < 0.001$  in the age group of 45–49 years; OR 0.15, 95% CI: 0.09–0.26,  $p < 0.001$  in age group of 55 years and older). Female surgeons did not have a greater chance of performing an open RPU compared to male surgeons (OR 1.00, 95% CI 0.71–1.39,  $p = 0.980$ ). As for hospital accreditation, there was a lower rate of laparoscopic RPU performed in regional hospitals and local hospitals (OR 0.54, 95% CI 0.47–0.63,  $p < 0.001$ , and 0.14, 95% CI 0.09–0.23,  $p < 0.001$ ,



**Fig. 3.** Types of surgery for RPU in Taiwan according to surgeons' age and gender, 1997–2007. The Chi-square test was used to examine the association between the distribution of open and laparoscopic RPU and of surgeon age (149.439  $p < 0.001$ ) (left panel), and gender (0.034,  $p = 0.854$ ) (right panel).



**Fig. 4.** Types of surgery for RPU in Taiwan according to hospital accreditation level and ownership, 1997–2007. The Chi-square test was used to examine the association between the distribution of open and laparoscopic RPU and of hospital accreditation levels (118.064,  $p < 0.001$ ) (left panel), and hospital ownership (27.812,  $p < 0.00201$ ) (right panel), respectively.

respectively). As for hospital ownership, there was a greater likelihood of laparoscopic RPU being performed in both not-for-profit (OR 1.33, 95% CI 1.11–1.59,  $p = 0.002$ ) and private hospitals (OR 1.73, 95% CI 1.41–2.11,  $p < 0.001$ ) compared to government-owned hospitals.

## Discussion

RPU is a well-known procedure for treating SUI. Our study offers the observation that the use of RPU increased rapidly from years 1997 to 2004, and then shrunk dramatically from year 2004 to 2007. In a report in a Cochrane Database Systems review, which included 46 trials and a total of 4738 women, open retropubic colposuspension surgery is an effective method for treating SUI, especially in the long term. The overall continence rate in the first year of treatment is approximately 85–90%. After 5-year follow-up, approximately 70% of patients remained continent.<sup>13</sup> In addition, open RPU surgery has a failure rate lower than that of conservative treatment, anticholinergic treatment, and anterior colporrhaphy. Such benefit was maintained over time.<sup>13</sup>

**Table 1**  
Multivariate logistic regression analysis for predicting use of laparoscopy for retropubic urethropexy.

		Odds ratio	95% CI	p
Patient age (yr)	<35	Reference		
	35–39	1.27	0.84–1.91	0.263
	40–44	1.03	0.70–1.52	0.873
	45–49	1.02	0.70–1.49	0.931
	50–54	0.74	0.50–1.09	0.130
	55–59	0.51	0.33–0.78	0.002
	≥60	0.41	0.28–0.61	<0.001
Surgeon age (yr)	<35	Reference		
	35–39	0.93	0.74–1.17	0.556
	40–44	1.06	0.85–1.32	0.612
	45–49	0.48	0.38–0.62	<0.001
	50–54	0.87	0.68–1.11	0.268
	≥55	0.15	0.09–0.26	<0.001
Surgeon gender	Male	Reference		
	Female	1.00	0.71–1.39	0.980
Hospital accreditation	Medical center	Reference		
	Regional hospital	0.54	0.47–0.63	<0.001
	Local hospital	0.14	0.09–0.23	<0.001
Hospital ownership	Government	Reference		
	Not-for-profit	1.33	1.11–1.59	0.002
	Private	1.73	1.41–2.11	<0.001

R-square = 0.099.  
CI = confidence interval.

Laparoscopic colposuspension was one of the first minimal access operations in treating females with SUI, with the presumed advantages over traditional Burch colposuspension of avoiding major incisions, shorter hospital stay, and quicker return to normal activities.<sup>10</sup> Over the past two decades, starting from the development of laparoscopic colposuspension,<sup>6–8</sup> their popularity increased as similar treatment outcomes could be achieved through minimally invasive procedures.<sup>10,14</sup> Patient-reported failure rates in short, medium, and long-term follow-up showed no significant difference between open and laparoscopic colposuspension, but confidence intervals were wide.<sup>13</sup> In a meta-analysis of nine studies, laparoscopic and open colposuspension had similar subjective cure rates for SUI.<sup>15</sup> Nevertheless, there was some evidence of poorer objective outcomes within 18 months after the laparoscopic colposuspension surgery (80.4% vs. 95.6%,  $p = 0.044$ ).<sup>16</sup> Laparoscopic colposuspension, in comparison with open colposuspension, was shown to have a lower perioperative complication rate, less intraoperative blood loss, less postoperative pain, shorter hospital stay, quicker return to normal activities, and shorter duration of catheterization use. No significant difference was observed for postoperative urgency, voiding dysfunction, or *de novo* detrusor overactivity. However, longer operating time and higher short-term cost were observed in laparoscopic colposuspension.<sup>15</sup>

Laparoscopic colposuspension is more difficult in techniques than open RPU, thus requiring a higher standard of surgical experiences and surgical skills. A variety of approaches and methods could be used. As for the number of paravaginal sutures, significantly higher subjective and objective (dry on pad test) 1-year cure rates were found for women who received two sutures for colposuspension compared with one suture in one trial (89% vs. 65% and 83% vs. 58%, respectively).<sup>10</sup> Suture materials for laparoscopic colposuspension were also discussed. Two studies compared sutures with mesh and staples and suggested a favorable outcome by using the sutures, although the results were not statistically significant.<sup>10</sup>

In our study, we found a trend of increased proportion in laparoscopic RPU use from 1997 to 2002, which was followed by a marked decrease after year 2002 and remained low over the next few years. Several possible reasons could lead to this phenomenon. First, the existence and popularity of MISS may affect the choice of RPU.<sup>17</sup> MISS started with the first time the tension-free vaginal tape (TVT) (Gynecare, Ethicon Inc, Summerville, NJ) was introduced in 1996.<sup>18</sup> MISS was formally launched in Taiwan in 1998,<sup>19,20</sup> when the urogynecologists or female urologists gradually accumulated experiences in this procedure. Afterward, the transobturator MISS, as the second generation of MISS, was introduced in 2001,<sup>21</sup> which was launched in Taiwan in 2004. The objective success rates of treatment were 80.8% and 77.7% in the retropubic sling group and transobturator-sling group, respectively.<sup>22</sup> There is growing evidence indicating that TVT may be an appropriate alternative for RPU surgeries. According to a meta-analysis pooling eight studies to compare the efficacy of laparoscopic RPU and MISS, no significant differences in reported subjective cure rates of the two procedures were found (relative risk [RR] 1.12, 95% CI 0.98–1.29). Nevertheless, MISS procedures did provide a significantly higher objective cure rate at 18 months (RR 1.16, 95% CI 1.07–1.25).<sup>10,15</sup> In addition, a significantly longer surgical time, longer hospital stay, and slower return to normal activities were found for patients who underwent laparoscopic colposuspension rather than MISS procedures.<sup>10</sup>

Second, surgeons in Taiwan practicing the laparoscopic surgeries tended to be younger in this study (Fig. 3) and our previous studies.<sup>12,23</sup> Young surgeons are willing to learn and perform the laparoscopic RPU, and are also likely to be the same cohort who would like to acquire a new surgical modality such as TVT for treating SUI. Because laparoscopic RPU and TVT share the

nature of minimal invasion, it is not hard to imagine that TVT would prevail over laparoscopic RPU for its even shorter surgical time and hospital stay. Third, the insurance coverage of retropubic and transobturator MISS may further facilitate the promotion of MISS. The medical services that are not covered by the NHI are paid by the patients as out-of-pocket expenses in Taiwan.<sup>24</sup> Therefore, whether one treatment is covered by the NHI may become an important consideration for deciding which treatment is chosen. Before 2005, the commercially available TVT procedural kits were not reimbursed by the NHI. After 2005, as TVT became covered by the NHI, the cost effect may drive both the surgeons and patients toward this minimally invasive surgery and to abandon the technically difficult laparoscopic RPU.

Patient age was significantly associated with type of surgery received in our study. Older patients received more open than laparoscopic RPU (Fig. 2). Although it has been advocated that older age is not a contraindication for laparoscopic surgery,<sup>25</sup> some adverse outcomes, including prolonged duration of surgery and longer postoperative hospitalization stay, were reported in the older patients who underwent laparoscopic surgeries in comparison with those who had laparotomies.<sup>26</sup> In addition, cosmetic outcome may be of less concern in older age groups. These factors may contribute to the higher proportion of laparoscopic RPU surgeries in younger patients.

Our data suggested that laparoscopic RPUs are performed more often in medical centers than in regional or local hospitals. This phenomenon indicated that the patients' choices for types of surgeries were associated with hospitals they attended and, in turn, the surgeons consulted for SUI. This result was not surprising because medical centers in Taiwan hold abundant resources in both personnel and facilities. Surgeons with the ability to perform the laparoscopic RPU procedure are clustered mainly in the hospitals with higher accreditation levels. Patients consulting with these surgeons would have the choice to receive RPUs either laparoscopically or through laparotomy, and laparoscopic RPUs may become their final selection after thorough consideration.

Some limitations of this study must be mentioned while interpreting our study results. First, we could not acquire the urodynamic study results into our inclusion criteria due to the unavailability of these data. Second, the exact methods for colposuspension, e.g., the MMK procedure or the Burch colposuspension, suture, or staple with mesh, cannot be separated in our study. Despite these limitations, our study did provide a nationwide, long-term, and population-based descriptive analysis that clearly illustrated the evolution of treatment choices for SUI.

In summary, the changing trend of the approaches for RPU marked the evolving surgical methods for treating SUI. The increased and decreased demands on laparoscopic RPU before and after the emergence of MISS denote the need for more minimally invasive procedures. Nevertheless, traditional RPU surgeries should not be abandoned before the long-term outcomes of novel surgical modalities for SUI are well established.

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