



## The Early Results of Male Bulbourethral Sling for Post Radical Prostatectomy Incontinence from June 2010 to August 2011.

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### Abstract

Male Urinary Incontinence following the Radical Prostatectomy can be a devastating complication significantly impacting quality of life. Male sling is one of the surgical treatment option, but data are still lacking.

**Objectives:** To assess the outcomes and adverse events of the bulbourethral sling for treating postprostatectomy urinary incontinence at Siriraj hospital.

**Design, setting and Participants:** We conducted a prospective evaluation on 22 patients treated at Siriraj hospital between June 2010 and August 2011 for male urinary incontinence following radical prostatectomy.

**Intervention:** Placement of bulbourethral sling

**Measurements:** Patients were evaluated by medical history, urinalysis, daily pad use at baseline and during follow up. Intraoperative and postoperative complications, self-evaluation questionnaire assessment were collected. Cure was defined as no pad usage postoperatively and improvement as a reduction in number of pad usage per day.

**Results and Limitations:** The mean operative time was  $109.32 \pm 30.33$  min (range 45-185 min). Mean estimated blood loss was  $199.55 \pm 137.16$  ml. (range 50-600 ml.). Two patients had the estimated blood loss  $\geq 500$  ml. (500 and 600 ml.) due to severe periurethral adhesion. Complications and their incidence included urinary retention 3 cases (13.6%), urethral injury 2 cases (9.1%) and wound infection for 1 case (4.5%). The two patients with intraoperative urethral injury were treated with primary repaired and suprapubic cystostomy, and then sling placement was continued. All patients with urinary retention and wound infection are managed conservatively. After a mean follow up time of 363 days (Median 377 days, range 139-503), 3 patients (13.6%) were cured, 11 patients (50%) were improved and 8 patients (36.3%) were failed.

**Conclusions:** The Outside-In transobturator sling technique is an effective procedure for treatment Postprostatectomy SUI especially in patient with mild to moderate degree. It seems to be safe, with few complications.

**Keywords:** Radical Prostatectomy, Male incontinence, Bulbourethral sling

**Abbreviations:** LRP; Laparoscopic Radical Prostatectomy, EERPE; Endoscopic Extraperitoneum Radical Prostate Extraction, RALP; Robotic Assisted Laparoscopic Radical Prostatectomy

## Introduction

Prostate cancer is the most common cancer in western countries. In 2002, the prevalence of the prostate cancer in Thai elderly men was more than 0.75 percent[19]. At Siriraj hospital, Prostate cancer is the second leading cause of new cancer registration in male[18]. The Siriraj Hospital Tumor Registry in 2008 indicated that there were 564 (6.83% of all primary site) new prostate cancer patients from a total of 8,256 all new cancer patients treated in Siriraj Hospital. These account for the 5<sup>th</sup> most frequently incidence of all cancer patients. Also, it is the 2<sup>nd</sup> most common malignancy in males (14.44%) [Siriraj Cancer Center, 2010]. The prevalence of prostate cancer continues to rise.

Localized prostate cancer can be treated with one or more of several modalities e.g. watchful waiting, Active surveillance, Brachytherapy, Radiation therapy, Radical prostatectomy. Efficacy and complication rates vary widely even within treatment modalities.

When prostate cancer is believed to be localized, Radical Prostatectomy is the one of treatment option available to a patient. It is the curative surgery of a localized prostate cancer, particularly for men with a long life expectancy. It may be performed using a retropubic or perineal incision or by using a laparoscopic or robotic assisted technique.

Stress urinary incontinence (SUI) following prostatectomy is the one of distressing complication. The incidence of this clinical condition ranges between 3% and 45%.[7,10,14,21] Initial management is usually conservative and includes the use of diapers or pads, penile clamps, or various collecting systems (e.g. condom catheter). Mild degrees of SUI in the early postoperative period may be improved by pelvic muscle exercises, physiotherapy, and pharmacotherapy[8].

When conservative therapies fail to alleviate SUI, patients are usually offered one of the following surgical alternatives: injections of bulking agents[11], artificial urinary sphincter (AUS) placement, or sling insertion.

The artificial urinary sphincter (AUS) implantation has good results in terms of continence and quality of life, particularly on long term evaluation[20]. However, in Thailand, this device is costly and requires the patient to have enough mental capacity to use the device and can fail by cuff erosion, infection.

In 2007, Rehder and Gozzi described an outside-in transobturator sling technique involving the placement of a polypropylene tape under the proximal urethral bulb[17]. Since then, several prospective and retrospective studies have evaluated the outcome of outside-in polypropylene-based transobturator male slings

Male slings are a valid option for treating male stress incontinence. Defidio and associates (2002) reported on 15 patients with post-prostatectomy incontinence who underwent the procedure with a synthetic sling. At a mean follow-up of 5 months (2-9 months), 13 patients (86.6%) are completely cured, and 1/15 patients (6.6%) has a total failure[6].

In this study, we present the early results of a prospective study of a bulbourethral sling for treatment of post radical prostatectomy urinary incontinence

## **Patients and Methods**

### **Preoperative Evaluation**

Between June 2010 and August 2011, Patients who suffered from urinary incontinence after radical prostatectomy were candidates for inclusion in this study.

All patients had undergone an adequate trial of nonsurgical treatment such as Pelvic

Floor Muscle Training without success.

The Ethical Committee of Siriraj Hospital Mahidol University approved the protocol used in this trial. All patients presenting with the following criteria were included: history of laparoscopic radical prostatectomy (Intraperitoneum, Extraperitoneum and Robotic Assisted Laparoscopic Radical Prostatectomy) for treatment of prostate cancer, symptoms of Urinary incontinence assessed by clinical examination, urinalysis for exclude urinary tract infection. These symptoms had persisted for more than one year after adequate trial of non surgical treatment without success. Patients who had active urinary tract infection and history of pelvic radiation were excluded.

Preoperative evaluation included detailed history, Physical Examination, Urinalysis, number of pad usage.

In the postoperative period , incontinence was assessed on the number of pad usage per day. Patient's satisfactions were recorded using non-validated patient questionnaire.

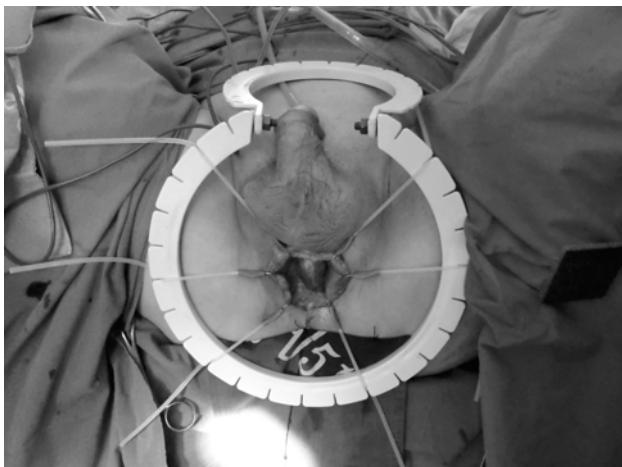
### **Surgical Procedure**

Appropriate Anesthesia was established using general or regional anesthesia. Patient was positioned in dorsal Lithotomy. After that, the urethral catheter (18 Fr Foley catheter) was left in place to drain the urinary bladder. Perioperative Antibiotic drug was administered. It usually was Third generation Cephalosporins.

A vertical incision was made at the perineum approximately 2-3 cm. in length inferior to penoscrotal junction. Dissection is continued through Colles' fascia and the underlying bulbocavernous muscle. Sharp dissection is continued until the spongiosal bulb has been freely dissected. The perineal body is identified. The adductor longus tendon and the inferior pubic ramus are identified. Insertion is performed just lateral to the inferior pubic ramus. On either side of the urethral bulb, a triangular space. The inferior layer of the median perineal aponeurosis, which is located in depth of this space, is carefully dissected. Metzenbaum scissors are used to open up the inferior layer of the median perineal aponeurosis in the anterior portion of the triangular space, just lateral to the bulb. The guide is inserted through the scissors-initiated dissection path with a 45 angle relative to the urethral sagittal plane. The passer is slipped along the gutter of the guide so as to pass through to the skin site. Then the guide is removed. This maneuver brings the mesh in place.

The mesh is checked at this point to ensure that twisting has not occurred. Subsequently, the opposite passer is placed in a similar manner and

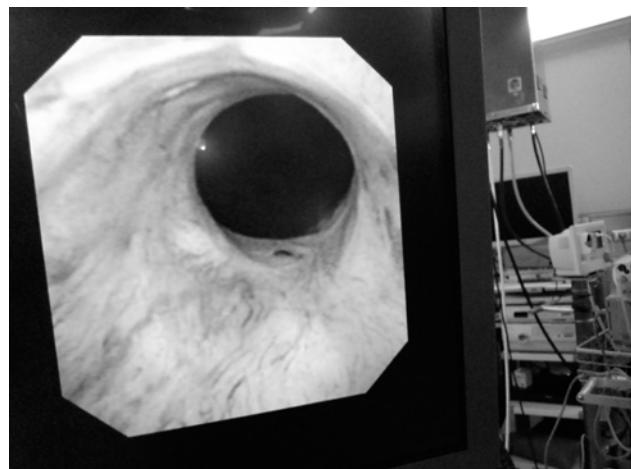
the sling is pulled into place. In addition to this, to prevent the Urethral erosion, we apply the Bovine Pericardial tissue (Lyoplant) to interpose between the synthetic sling and periurethral tissue. The central mesh anchor is sutured into place, with the posterior aspect fixed to the spongiosal tissue. Tensioning of the sling is now performed, by pulling the mesh arms such that the bulb of the corpus spongiosum is brought cephalad by the sling. Cystourethroscopy is performed to rule out urethral or bladder injury. The mesh arms are cut below skin level and skin incisions are closed.



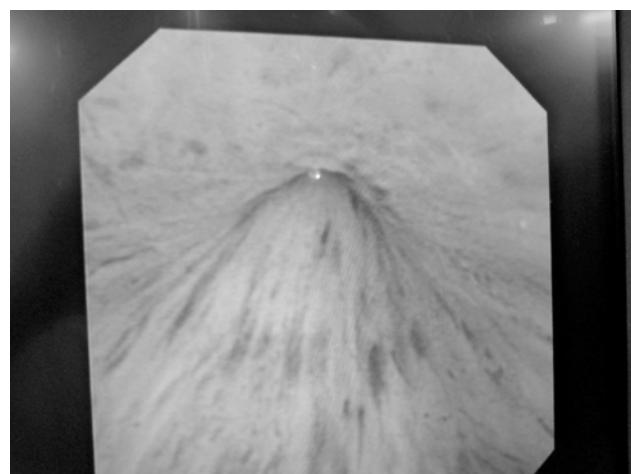
**Fig. 1** Perineal incision with exposure of Corpus spongiosum.



**Fig. 2** Male sling was placed



**Fig. 3** Cystoscopic appearance before tensioning



**Fig. 4** Endoscopic appearance after tensioning.

### 2.3 Perioperative and Postoperative Evaluation

Perioperative information was recorded. Urethral catheter was left in place for 72-96 hours. After the catheter was removed, the patient was discharged if he could void, but in case of urinary retention, the patients were recatheterized and left for 2 weeks. Other immediate postoperative complications were also recorded during the hospital stay of the patients.

Follow up evaluation included Physical Examination, Urinalysis and all patients were also asked to self-evaluate their satisfaction with the treatment.

Postoperative complications were recorded e.g. bladder or urethral injury, hematoma, wound infection, bleeding, acute urinary retention.

#### 2.4 Definitions used

The patients were classified as cured if they were using no pad. The urinary incontinence was considered improve when daily pad use were decreased compare preoperatively and postoperatively. All other cases were defined as failed.

#### 2.5 Statistical analyses

All data were collected on data sheets, transferred to a database and analyzed with SPSS. Data are presented as mean + SD with ranges in parentheses.

## Results

### Baseline characteristics of the patients

A prospective evaluation was conducted on patients treated for SUI from June 2010 to August 2011 in one institution. All patients presenting the following criteria were included: history of prostate surgery for prostate cancer, symptoms of SUI assessed by clinical examination. Informed consent was obtained from all patients before entering the study. Baseline characteristics of the patients are summarized in Table 1.

### Perioperative Data

Surgery was performed under spinal anesthesia for all patients. The sling procedure was carried out independently of the patient's size and weight in all case subjects.

The mean operative time was  $109.32 \pm 30.33$  min (range 45-185 min). Mean estimated blood loss was  $199.55 \pm 137.16$  ml. (range 50-600 ml.). Two patients had the estimated blood loss  $\geq 500$  ml. (500 and 600 ml.) due to severe periurethral adhesion.

Complications and their incidence are listed in Table 2 and included Urinary retention 3 cases

(13.6%), Urethral injury 2 cases (9.1%) and wound infection for 1 case (4.5%). The two patients with intraoperative urethral injury were treated with primary repaired with suprapubic cystostomy and sling placement was continued. All patients with urinary retention and wound infection are managed conservatively.

**Table 1** Baseline Characteristics of the patients.

Variables	
Age	$69.32 \pm 5.72$ (57-78)
BMI	$23.99 \pm 2.40$ (19.42-30.12)
Time interval between onset of SUI and sling procedure	$755.36 \pm 260.62$ (420-1281)
Mean Follow up time, days	$363 \pm 103.08$ (139-503)
Type of operation	
LRP*	3 (13.6%)
EERPE**	10 (45.5%)
RALP***	
No of pad used/day	9 (40.9%)
1 pad /day	2 (9.1%)
2-3 pads /day	8 (36.4%)
4-5 pads /day	9 (40.9%)
>5 pads /day	3 (13.6%)

\* LRP; Laparoscopic Radical Prostatectomy

\*\* EERPE; Endoscopic Extraperitoneum Radical Prostate Extraction

\*\*\* RALP; Robotic Assisted Laparoscopic Radical Prostatectomy

**Table 2** Perioperative Data

Variables	
Operative time, min	$109.32 \pm 30.33$ (45-185)
Blood loss, ml	$199.55 \pm 137.16$ (50-600)
complications (%)	
none	16 (72.8%)
Urinary retention	3 (13.6%)
Urethral injury	2 (9.1%)
wound infection	1 (4.5%)

After a mean follow up time of 363 days (Median 377 days, range 139-503), 3 patients (13.6%) were cured, 11 patients (50%) were improved and 8 patients (36.3%) were failed.

### Satisfaction

The 18.2% of patients (4/22) were much more better, 36.4% (8/22) were better, 27.3% (6/22) were equal and 18.2% (4/22) were failed

The patient satisfaction were summarized in Figure 5.

### Discussion

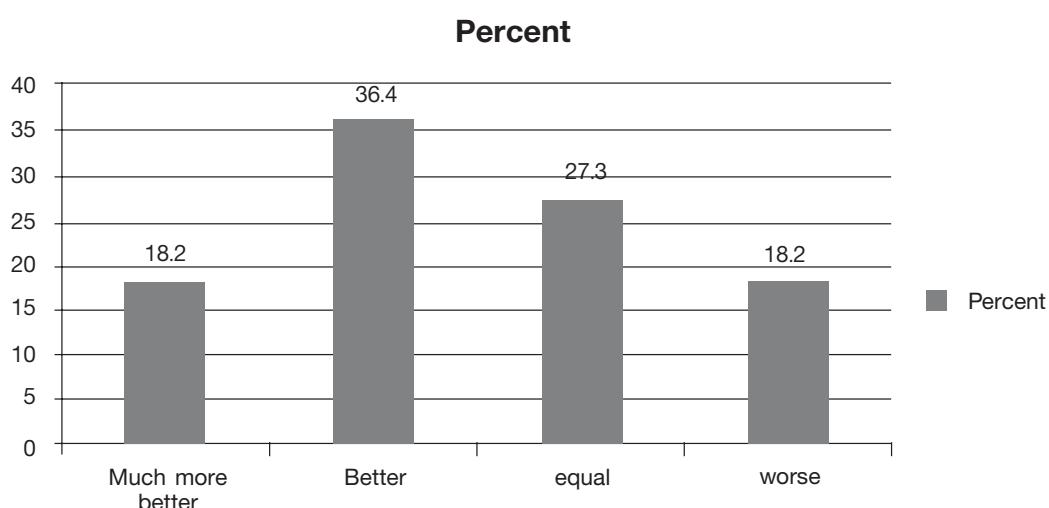
After the success of this approach to cure women's SUI with highly satisfactory results.[12] Male sling procedure has been described as a new option to treat male incontinence postprostatectomy.

The AUS is the best long-term surgical treatment with consistently high patient-satisfaction rates (75-94%) and it has represented, until today, the gold standard by which other surgical management must be compared.[1,9] However, the complexity of the mechanical device, the need of manual dexterity to manipulate the scrotal pump, and revision rates of

more than 20% at 5 years have spurred interest in alternative surgical procedures.[2] Periurethral bulking agents, while minimally invasive, have generally been proven to be ineffective.[16] In the last few years, several techniques for performing a bulbo-urethral sling operation have been described.[13,15]

In this study, we have presented the early experience in performing the Outside - In approach male sling procedure including 22 patients with mean follow up time >6 months. This study was designed to reflect clinical experience as precisely as possible. All patients suffered from postprostatectomy urinary incontinence.

From the study of Jean-Nicolas Cornu in 2009,[3] at median follow up 13 months. The overall success rate was of 80% (including cured and improved patients). And from the study of Rehder and Gozzi, at the 6 weeks postoperatively, Cure rate achieved was 40% and improved rate was 30%. [17] When compare with our study, their results were superior to our results. This is possibly because the number of patient that included in our study were insufficient. Furthermore, the poor results obtained in our series can be explained by the fact that majority of patients



**Fig. 5** Patient satisfaction

in our study were moderate to severe incontinence (54.5% of patients in our study used at least 4 pads/day preoperatively, whereas almost all patients in the study of Cornu[3] were mild to moderate incontinence only. As we know, The Artificial Urinary Sphincter has emerged as the gold standard for the treatment of severe postprostatectomy incontinence, but Artificial sphincters are available at high costs in the developing countries which make their use limited. Furthermore, manual dexterity is required to operate the device. So this device is difficult to use especially in the elderly. So, we decided to perform male sling in these patients to relieve their suffering.

For the postoperative complication in our study, Urethral injury had been occurred in 2 patients (9.1%) due to severe periurethral adhesion. All were managed with Primary repaired with Suprapubic cystostomy. One patient had a postoperative wound infection and 2 patients had acute urinary retention after the urethral catheter removal. All of them were managed conservatively.

The overall complication rate in our study is 27.2 %. It is higher than other study. This is because of our limited experience. This study represent the first twenty two cases of male sling procedure in our center. We believe that, the overall success rate and complication will be better when we gain more experience.

## Conclusion

The Outside -In transobturator sling technique is an effective procedure for treatment Postprostatectomy SUI. It seems to be safe, with few complications. Especially, in the patients with mild to moderate SUI. Patients with severe Postprostatectomy SUI may not be suitable candidates for this sling procedure. Clearly, larger scale studies with longer follow-up are now needed to confirm these findings. For our study, More experience of the surgical team is needed to achieve the better results.

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