Mucosal coaptation technique for early urinary continence after robot-assisted radical prostatectomy: a comparative exploratory study

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Introduction Urinary incontinence is a troublesome complication following radical prostatectomy. Various robot-assisted radical prostatectomy (RARP). We describe our technique (Santosh-PGI) of urethral and urinary bladder mucosa coaptation for early continence following RARP.

Material and methods We performed a prospective comparative study of patients planned for RARP between July 2018 and December 2019 at our centre. A total of 40 patients were enrolled in the study protocol. Following prostatectomy, patients were alternatively assigned into two groups. In one group, urethral and urinary bladder coaptation sutures were placed in a purse string manner using 3-0 Monocryl sutures and none in the another group. All patients underwent standard end to end vesico-urethral anastomosis as described by Van Velthoven. The urinary catheter was removed on day 10 after surgery. All patients were evaluated on day 1, 30 and 90 after catheter removal.

Results The two groups, each with 20 patients, were comparable in terms of age, clinical staging and D’Amico risk classification. The operative time, blood loss and surgical margin positivity were comparable. Following catheter removal, 75% of patients in Group A (Mucosal coaptation) and 50% in Group B (Standard technique) were continent (p = 0.264). At 30 and 90 days, 90% and 95% in Group A and 60% and 80% in Group B reported continence respectively (p-0.078). Four patients in group B reported bothersome incontinence at 90 days follow-up.

Conclusions Urethral and urinary bladder mucosal coaptation is a simple innovative technique for early continence following RARP.

Key Words: urethral mucosal coaptation, robot-assisted radical prostatectomy, prostate cancer, continence

INTRODUCTION

Early urinary incontinence is a bothersome complication following robot-assisted radical prostatectomy (RARP). Although robot assistance has decreased long term incontinence rates as compared to retro-pubic or laparoscopic radical prostatectomy (LRP), it still remains a formidable problem following RARP (up to 30%). To create the vesico-urethral anastomosis, the standard technique of Van Velthoven is used for RARP [1]. Simone et al. reported his simplified technique of vesicourethral anastomosis with a ‘single knot-single running’ suture and suggested excellent outcomes [2]. The various techniques described for the early return of continence are posterior rhabdosphincter reconstruction [3], apical dissection modifications [4], anatomic bladder neck preservation [5] and puboprostatic ligament sparing surgery [6]. It is based on the 3 concepts of preservation, reconstruction and reinforcement so as to maintain the normal anatomical and functional status in the pelvis.
Deficiency of the sphincter mechanism is postulated to be the predominant factor in post-prostatectomy incontinence. A number of studies have explored the change in urodynamic parameters following radical prostatectomy [7]. A reduction in urethral pressure and decrease in functional urethral length leading to sphincter dysfunction is the most pertinent finding. Loss of the elastic properties of the proximal urethral urothelium (zone of coaptation) is another proposed mechanism of post-prostatectomy incontinence. Pelvic floor muscle training is a common practice after RARP as it improves pelvic muscle strength and continence occurs faster when adopted [8]. As ageing is associated with late onset incontinence following radical prostatectomy, one should be counselled for the same [9].

We proposed a novel technique of mucosal coaptation in addition to the routine steps of RARP. We proposed that coaptation of the urethral mucosa in the ‘zone of coaptation’ increases the urethral pressure and augments the sphincter integrity. Furthermore, the coaptation purse-string suture at the bladder neck acts to increase the functional length of the urethra aiding in the early recovery of continence. We evaluated the technique of mucosal coaptation in patients who underwent RARP for localized prostate cancer and compared it with standard RARP.

**MATERIAL AND METHODS**

Patient selection after institutional ethics approval (NK/4839/MD/099), 40 patients with localized prostate cancer underwent RARP between July 2018 and December 2019 at our center by a single surgeon. This was a comparative study whereby patients undergoing RARP were alternatively assigned to two groups: Group A underwent RARP with mucosal coaptation as a modification and patients in Group B underwent standard RARP. The inclusion criteria were patients diagnosed with localized prostate cancer planned for RARP and consenting to participate in the study. Patients not fit for undergoing RARP/ not consenting for RARP patients not compliant with follow-up, patients who had undergone open prostatectomy, transurethral resection of the prostate, pelvic radiation and patients with a history of neurological disease were excluded from the study. The study was conducted in accordance with good clinical practice rules and ethical principles as contained in the declaration of Helsinki. Each patient was provided with a detailed patient information sheet and informed consent was obtained. Operative data such as duration of surgery, blood loss, lymph node dissection, hospital stay, histopathology, surgical margin status and complications were recorded for all of the patients. Foley’s urethral catheter was removed for all of the patients at 10 days following the surgery. Pre and post-operative pelvic floor muscle training is a routine practice for all of the patients who are planned for RARP in our institute.

The primary objective of the study was to evaluate the continence rate following RARP in the two groups. Continence was defined as use of zero to one pad per day. At times, patients use one diaper/24 hours for the fear of incontinence or because of leakage of a few drops upon exertion. These patients were considered continent. Mild to moderate incontinence was defined as the use of 2 pads/24 hours and severe incontinence was defined as the use of more than 2 pads/24 hours. The patients were asked to follow-up at 24 hours following catheter removal, day 30 and day 90 to assess urinary incontinence.

**Surgical technique**

The DaVinci Si system was utilized for performing RARP using 5 ports (two 12 mm ports-camera and assistant; two 8 mm robotic ports; one 5 mm laparoscopic port). Pelvic docking was performed for all of the cases and the patient was laid in a Trendelenburg position. The anterior approach via the retzius space as described by Menon et al. [10] was utilized for RARP in all of the patients. Nerve sparing was offered wherever feasible depending on the location of the tumor and the stage of the disease. Maximal urethral length was preserved with meticulous dissection at the apex of the prostate, preserving as much length of the urethra as possible. The Rocco stitch was used to approximate the remnant Denonvillier’s fascia, posterior detrusor and posterior rhabdosphincter in all of the cases.

In Group A, the patients underwent our modified technique which is described here. After apical dissection and transection of the urethra as mentioned above, a 3-0 poliglecaprone (Monocryl™) suture was used to create a purse string suture along the urethra involving the seromuscular layers only. Special care is taken so as to avoid including the urethral mucosa in the sutures. Next, the bladder neck was reconstructed and plicated in a purse-string manner using 3-0 poliglecaprone (Monocryl™) sutures. It is essential to avoid ureteric orifices while constructing the bladder neck. The vesico-urethral anastomosis was then completed with a mucosa-to-mucosa approximation using barbed V-lok sutures. After completion of the vesico-urethral anastomosis, the purse-string sutures over the urethra and the bladder neck were tied to each other over the 18 Fr catheter, resulting in an increase in the urethral pressure as well as an increase in the functional urethral length (Figures 1, 2).
Statistical analysis

Data was entered and evaluated using SPSS software version 23 (IBM, Armonk, NY, USA). Categorical variables were expressed as frequency tables and continuous variables were described as mean ± standard deviation, median and range. Categorical data were compared utilizing Pearson’s Chi-square test and Fischer’s exact test. Continuous variables were evaluated using Mann-Whitney U test and unpaired student’s t-test. Statistical significance was considered with a p-value of ≤0.05.

RESULTS

Both groups were comparable in terms of age, D’Amico classification and clinical staging. The mean age of the study groups were 66.9 ±5.73 years and high-risk prostate cancer constituted the most common group of patients undergoing RARP, accounting for 42.5% of the patients (Table 1). The operative time, blood loss and surgical margin positivity rate were comparable across both groups (Table 1). The catheter was removed on postoperative day 10 for all of the patients and continence rate was evaluated on 1-day after catheter removal, day 30 and day 90. There was no drop out from the study. Fifteen patients (75%) in Group A were continent on day 1 following catheter removal whereas 10 patients in Group B remained continent at the same time interval (p = 0.264) (Table 2). There was an improvement in continence in both groups over time. The number of patients achieving continence at 90 days increased to 19 (95%) in Group A and 16 (80%) in Group B (p = 0.323). At 30 days following catheter removal, 90% of patients in Group A were continent as compared to 60% in Group B. However, the difference between the 2 groups did not reach significance (0.078). None of the patients in Group A suffered from severe incontinence at the last follow-up. Four patients in Group B remained incontinent at 90 days following catheter removal (3 moderate; 1 severe). On univariate analysis, none of the variables such as age, body mass index, comorbidities, clinical staging, lymph node dissection, positive surgical margin and post-operative complication were predictors of urinary incontinence.

DISCUSSION

The present exploratory study demonstrates improved continence with the technical modification

Figure 1. Schematic diagram showing A. Completion of prostatectomy; B. Purse-string suture application in proximal urethra and bladder neck; C. End-to-end vesico-urethral anastomosis performed using barbed double arm suture in continuous fashion; D. Tightening of purse-string sutures.
of mucosal coaptation in patients undergoing RARP. The coaptation of the urethra and the bladder neck offered by this method influences 3 mechanisms: 1. urethral mucosal coaptation and restoration of zone of coaptation, 2. increase in urethral pressure augmenting sphincter integrity and 3. bladder neck coaptation leading to increase in functional urethral length. Seventy-five percent and 90% of patient undergoing mucosal coaptation remained continent as opposed to 50% and 60% of patients undergoing standard RARP at day 1- and day 30 post catheter removal, respectively.

The majority of the patients suffering from urinary incontinence following radical prostatectomy regain continence within the first year. The advent of robotic surgery has led to an improvement in 12-month urinary continence following radical prostatectomy as compared to open and laparoscopic radical prostatectomy [11]. Despite the advances made in this regard, early urinary incontinence remains a formidable problem for surgeons and patients alike. Young age (≤67 years), organ confined tumor (≤T2 disease) and lower prostate weight have been proposed as predictors of early return of continence following RARP [12]. Chiancone et al reported his retrospective analysis of RARP patients and concluded that prostatic volume, clinical stage pT3, pelvic lymph node dissection and the Rocco stitch are the significant determinants of continence in the early stage while body mass index and early post-operative pelvic floor motor therapy (PFMT) are factors influencing late continence [13]. The mean of age patients in both groups was <70 years in the present study. The incidence of organ confined tumor and prostate volume in both of the groups was comparable across (Table 1). Membranous urethral length and bladder neck width have been associated with early return of continence following RARP in studies utilizing preoperative magnetic resonance imaging (MRI) to study these parameters [14]. Though these parameters were not studied in the present exploratory study, principles involved in the technique of mucosal coaptation led to the increase in the functional urethral length and narrowing of the bladder neck, hence improving early continence rates. Bilateral nerve preservation [15] and intrafascial nerve-sparing [16] have been associated with improved continence following surgery, although contrasting evidence also exists. Nerve-spar-
ing was not offered in 42.5% of the patients in this study as they had high-risk disease.

Multiple technical modifications have been devised to improve post-prostatectomy incontinence. Reconstruction of the posterior rhabdo-sphincter (Rocco stitch) is a widely adapted technique which provides firm support to the urethral sphincter complex posteriorly and allows for better approximation of the vesicourethral anastomosis, reducing tension on the anastomosis [17]. Rocco et al. [3] demonstrated a significant improvement in continence at 3 days and 30 days following catheter removal in a comparative study comprising of 62 patients undergoing laparoscopic radical prostatectomy. The excellent results of this technique have been replicated in RARP as well [18]. Both of the groups in our study also underwent Rocco’s stitch prior to vesico-urethral anastomosis. The addition of anterior reconstruction [19] and retropubic suspension [20] have also demonstrated early return to continence following RARP. Total reconstruction of the vesicourethral junction, a novel but technically demanding technique described by Tewari et al. [21] demonstrated excellent results but has not been replicated thereafter. Walsh et al. [22] demonstrated earlier return of continence with intussusception of the bladder neck in retropubic radical prostatectomy. Taking cue from this technique, Lee et al. [23] demonstrated earlier return of continence with plication anteriorly only as compared to that described by Walsh [22]. Our technique of purse-string sutures on the bladder neck is similar to that described by Swami et al. [24], achieving apposition without tension. However, the purse-string suture in the urethra and at the bladder neck is tightened after the vesicourethral anastomosis is completed. Multiple techniques have focused on the vesicourethral junction, but urethral coaptation as in our technique has not been described in available literature. It shall be of particular value in apical tumors where conservation of urethral length and the ‘zone of coaptation’ thereof may not be feasible.

The retzius-sparing RARP allows for preservation of the anatomical support of the bladder as well as the Santorini plexus and puboprostatic ligaments [25]. This technique has demonstrated superior continence outcomes in various studies. However, one caveat associated with this technique is the higher rate of positive surgical margins, especially in high-risk disease. Moreover, it is associated with a longer learning curve [26]. The conventional anterior approach [27] was used in the present study and there were no positive surgical margins in the present study in either of the groups.

There are several reports which suggest that neurovascular bundle (NVB) preservation minimizes incontinence, however it is difficult to mitigate NVB.

### Table 1. Clinico-demographic details of the patients in the two groups

| Variables                      | Group A (Urethral Mucosal Coaptation RARP) | Group B (Standard RARP) | p-value |
|-------------------------------|-------------------------------------------|-------------------------|---------|
| Age (mean ±SD; years)         | 65.7 ±5.5                                 | 68.25 ±5.95             | 0.176   |
| Presentation                  |                                           |                         |         |
| Symptomatic                   | 16 (80%)                                  | 15 (75%)                | 0.705   |
| Incidental                    | 4 (20%)                                   | 5 (25%)                 |         |
| Smoking                       |                                           |                         | 0.113   |
| Yes                           | 7 (35%)                                   | 12 (60%)                |         |
| No                            | 13 (65%)                                  | 8 (40%)                 |         |
| Comorbidities                 |                                           |                         | 0.113   |
| Yes                           | 10 (50%)                                  | 11 (55%)                |         |
| No                            | 10 (50%)                                  | 9 (45%)                 |         |
| D’Amico Classification        |                                           |                         | 0.45    |
| Low-risk                      | 8 (40%)                                   | 5 (25%)                 |         |
| Intermediate-risk             | 5 (25%)                                   | 5 (25%)                 |         |
| High-risk                     | 7 (35%)                                   | 10 (50%)                |         |
| T1c staging                   |                                           |                         | 0.549   |
| T2                            | 16 (80%)                                  | 18 (90%)                |         |
| T3                            | 4 (20%)                                   | 2 (10%)                 |         |
| Prostate volume (ml)          | 54.8 ±18.6                                 | 56.9 ±23.4              | 0.755   |
| Operative time (min)          | 134.5 ±11.6                                | 138.3 ±9.8              | 0.264   |
| Blood loss                    | 134 ±39.4                                 | 133.3 ±48.9             | 0.958   |
| Nerve sparing                 |                                           |                         | 0.525   |
| Yes                           | 12 (60%)                                  | 10 (50%)                |         |
| No                            | 8 (40%)                                   | 10 (50%)                |         |
| pT staging                    |                                           |                         | 0.780   |
| pT2                           | 10 (50%)                                  | 9 (45%)                 |         |
| pT3a                          | 5 (25%)                                   | 7 (35%)                 |         |
| pT3b                          | 5 (25%)                                   | 4 (20%)                 |         |
| Lymph node involvement        |                                           |                         | 0.677   |
| Yes                           | 3 (15%)                                   | 4 (20%)                 |         |
| No                            | 17 (85%)                                  | 16 (80%)                |         |
| Positive surgical margins     | 0                                         | 0                       | 1.0     |
| Hospital stay (days)          | 4 ±0.9                                    | 4.35 ±1.2               | 0.313   |

RARP – robot-assisted radical prostatectomy; SD – standard deviation

### Table 2. Postoperative continence following surgery

| Degree of Incontinence | Group A | Group B | p value |
|------------------------|---------|---------|---------|
| 24 hours post catheter removal |
| No incontinence        | 15 (75%) | 10 (50%) |         |
| Moderate incontinence  | 3 (15%)  | 6 (30%)  | 0.264   |
| Severe incontinence    | 2 (10%)  | 4 (20%)  |         |
| 30 days post catheter removal |
| No incontinence        | 18 (90%) | 12 (60%) |         |
| Moderate Incontinence  | 1 (5%)   | 6 (30%)  | 0.078   |
| Severe Incontinence    | 1 (5%)   | 2 (10%)  |         |
| 90 days post catheter removal |
| No Incontinence        | 19 (95%) | 16 (80%) |         |
| Moderate incontinence  | 1 (5%)   | 3 (15%)  | 0.323   |
| Severe incontinence    | 0        | 1 (5%)   |         |
manipulation in high-risk and advanced cases. Amniotic and umbilical cord (UC) tissues have been used in a wide variety of clinical applications to reduce inflammation and promote regenerative healing. Ahmed et al. reported that an umbilical cord allograft used as a nerve wrap around the NVB resulted in early continence at 1, 3 and 12 months in his retrospective analysis of 200 patients [28]. Krol et al. reported that the use umbilical cord allografts appear to offer an advantage in terms of a faster return to continence as well as potency [29].

The present study demonstrates earlier return of continence utilizing the technique of mucosal coaptation. This study is the first technique described in order to recreate the ‘zone of coaptation’, apart from preservation of maximal urethral length. Robotic assistance aids in meticulous dissection as well as precise placement of sutures, avoiding the mucosal layer while placing purse-string sutures in the urethra. One may raise concerns over urethral narrowing and stricture following placement of this suture. However, ensuring avoidance of the mucosa and using early absorbing sutures like poliglecaprone shall help avoid the formation of stricture. Albeit the present study has a short follow-up of 3 months, none of the patients in Group A experienced symptoms suggestive of urethral stricture or decrease in urinary flow. The present study has a few limitations. Firstly, it is a non-randomized comparative exploratory study consisting of a small number of cases in each arm. The small sample size accounts for the nonsignificant difference between the two groups. Secondly, only short-term outcomes are reported. However, the technique aims at reducing the incidence of early incontinence and hence, a short-term follow-up focusing on early incontinence was decided for the present study. Thirdly, a significant proportion of patients enrolled in both arms were high-risk and hence did not undergo nerve-preservation.

CONCLUSIONS

Mucosal coaptation is a simple technique leading to the early return of continence as compared to standard RARP. Robotic assistance aids in the execution of this novel technique, especially sparing the mucosa in the urethral purse-string sutures. Randomized multi-center studies with larger cases and longer follow-up are needed to confirm the reproducibility and outcomes of this technique.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

STATEMENT OF ETHICS

Institute ethics committee clearance taken. Ref. no NK/3880/MS/148

AUTHOR CONTRIBUTIONS:

SK and KP – initial concept, design, draft. PS – collection of data, AC – revision of manuscript, SK, PG – critical comments. All authors read the manuscript and contributed equally.

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