Impact of catheter size on pain and continence following robotic prostatectomy

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Introduction: *Continence and catheter related pain following prostatectomy are significant patient concerns, and it is unknown whether catheter size impacts these variables. In this study, patients undergoing prostatectomy were randomized to receive either a 16 French or 20 French catheter to assess the impact of catheter size on postoperative continence and pain.*

Materials and methods: *Patients were prospectively randomized to receive either a 16 French or a 20 French latex catheter at the completion of prostatectomy. Subjects were asked on postoperative day 7 to report their average catheter-related pain and the amount of opioid medication used. International Prostate Symptom Score, Quality of Life score and pads per day were recorded 6 and 12 weeks postoperatively.*

Results: *Fifty-two patients were randomized. Seven were excluded: surgeon catheter preference (3) or withdrawal of consent (4). Demographic and pathologic data did not differ between groups (all $p > 0.20$). Catheter pain scores and postoperative opioid use were not different between groups (all $p > 0.78$). Postoperative subjective urinary symptom scores, and pads per day did not differ between groups at both 6 and 12 weeks (all $p > 0.16$).*

Conclusions: *Catheter size did not impact postoperative urethral and bladder pain or continence prostatectomy. These data suggest that surgeon preference should guide catheter selection between 16-20 French. Future studies might investigate precise intraoperative anastomosis size measurement and the impact of catheter size on pain scores in a nonoperative population.*

Key Words: prostatectomy, catheters, pain, robotic surgery

Introduction

Robotic assisted laparoscopic prostatectomy (RALP) is now the most common surgical approach to prostate cancer.[1] In 2014, over 90% of all radical prostatectomies in the United States were performed robotically; and this figure continues to rise.[2] Well known postoperative sequalae such as urinary incontinence and erectile dysfunction make RALP a frequent target for improvement efforts as it relates to postoperative outcomes.

Continence after RALP is a central perioperative concern. Much debate has occurred as it relates to duration of postoperative urethral stenting (catheter) as a potential impact on ultimate urinary control.[3] During the catheterization interval, urethral and bladder pain are frequently bothersome postoperative complaints.[4] Such catheter related concerns have resulted in urologists seeking technical advancements to decrease anastomotic related complications. Such innovations have included: the Rocco stitch,[5] bladder

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neck preservation[6] and the Retzius sparing approach.[7] In each of these techniques the anastomosis is sewn over a urinary catheter. To avoid catheter related complications, some providers have even advocated the use of a robotically placed suprapubic catheter to improve postoperative pain and potentially improve anastomotic healing.[8] Multiple studies have corroborated that SPT drainage was significantly less bothersome to patients, but that postoperative voiding parameters did not differ.[9-11]

Initially, many surgeons used larger catheters (22 French) to promote an open anastomosis. Ultimately, however, larger catheters were found to be associated with a higher rate of fossa navicularis strictures.[7] As a result, most surgeons now leave an 18 or 20 French (Fr) Foley catheter for approximately 1 week postoperatively.[12] Interestingly, no study has assessed whether catheter size has an impact on continence, postoperative urethral and bladder pain, or long term complication rates such as bladder neck contracture.

In this study, we randomize RALP patients to receive either a 16 Fr or 20 Fr catheter following anastomosis to assess the impact of catheter size on postoperative bladder and urethral pain as our primary outcome. Secondary outcomes were also assessed including urinary continence and long term complications such as bladder neck contracture (BNC). We hypothesize that patients with a smaller catheter will have improved pain scores and less opioid use. In terms of return to continence, we predict that the use of a smaller urethral catheter will decrease flow rates and consequently protect against urinary leakage without higher risk of urinary retention. Similarly, we predict that this group would use fewer pads per day at the 6 and 12 week postoperative visits. In terms of long terms outcomes, we expect to observe a higher risk of BNC in the 16 Fr group given the smaller diameter anastomosis.

Materials and methods

Patients scheduled to undergo RALP were approached during their preoperative clinic visit by either a surgeon, resident physician or study coordinator to offer study enrollment (ClinicalTrials.gov NCT04098809). Patients were excluded if they met any of the following criteria: filled a prescription for opioid medications in the last 2 months, known latex allergy, history of pelvic radiation or a pre-operative plan for > 15 day catheter, Figure 1. Additionally, patients with a significant deviation from the normal operative protocol such as bladder neck reconstruction, conversion to open surgery, or

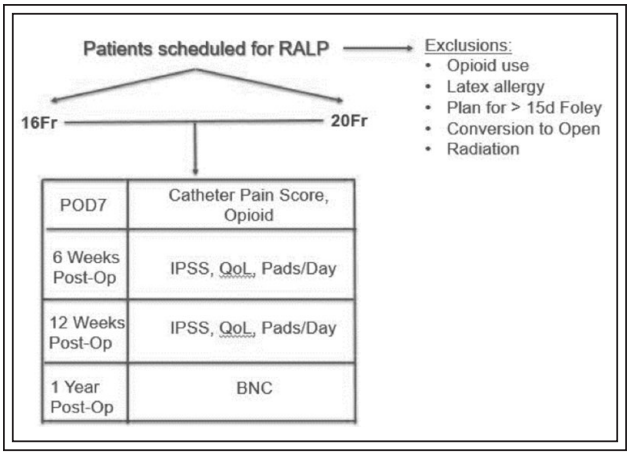

Figure 1. Consort diagram.

major postoperative complications such as pulmonary embolism, myocardial infarction, stroke, or other complications that are unrelated to study intervention were excluded from data analysis and further data collection. Patients were not excluded on the basis of preoperative oncologic parameters such as high risk disease.

We performed a pilot study of 25 patients to assess catheter related pain after transurethral resection of the prostate. Using this data, we calculated an average and standard deviation for catheter related pain of 3.2 and 2.45 respectively on a 10-point scale. In order to detect a difference in pain score of 0.6 between groups, at a power of 80% and alpha of 5%, we determined 44 patients should be included. Predicting a dropout rate of 20%, we planned to enroll 55 patients to ensure 44 patients with full participation.

Subjects meeting study criteria and willing to participate were randomized 1:1 prospectively to receive either a 16 Fr of 20 Fr latex catheter at the completion of prostatectomy. Subjects were not blinded with respect to their catheter size. All prostatectomies were performed robotically by one of three surgeons at our institution. All surgeons preformed the anastomosis with a running 2-0 Monocryl suture following a single interrupted 6 o'clock 2-0 Vicryl suture. One of the three surgeons routinely performed a Rocco stitch while the other two did not.

Preoperative demographics and operative data were recorded. Catheters remained in place for 7-14 days prior to removal. Subjects were asked on postoperative day 7 to indicate their average catheter pain and miliequivalents of opiates used. This length of time was selected because it ensured all patients still had their catheter in place at the time of the

questionnaire. The form included a validated[13] visual analog scale (0-10) for pain scores. Subjects reported opioid use by number of tabs taken. This was later converted to milliequivalents for data analysis. IPSS/QoL scores and pads/day were recorded at 6 and 12 weeks postoperatively. Additionally, long term complications such as BNC or re-operation were assessed at 1 year. Analysis of variance (ANOVA) was performed to compare variables between groups and statistical significance was defined as $p > 0.05$.

TABLE 1. **Demographics**

		16 Fr catheter (n = 24)	**20 Fr catheter (n = 21)**	**Total (n = 45)**	**p value**
Age – Mean (SD)	Mean (SD)	63.17 (7.01)	62.57 (5.95)	62.89 (6.47)	0.762
Body mass index	Mean (SD)	27.77 (3.25)	27.02 (3.33)	27.42 (3.27)	0.446
Prior abdominal surgery					0.096
No		14 (58.3%)	17 (81.0%)	31 (68.9%)	
Yes		10 (41.7%)	3 (14.3%)	13 (28.9%)	
Chronic pain					1.000
No		23 (95.8%)	20 (95.2%)	43 (95.6%)	
Yes		1 (4.2%)	1 (4.8%)	2 (4.4%)	
Previous TURP					1.000
No		23 (95.8%)	21 (100.0%)	44 (97.8%)	
Yes		1 (4.2%)	0 (0.0%)	1 (2.2%)	
AUASS	Mean (SD)	9.24 (6.09)	10.00 (5.78)	9.59 (5.88)	0.692
Baseline QoL	Mean (SD)	1.65 (1.27)	2.11 (1.18)	1.89 (1.23)	0.271
IIEF	Mean (SD)	18.85 (6.83)	17.39 (7.57)	18.16 (7.13)	0.536
Stage					0.812
T2 N0		6 (25.0%)	4 (19.0%)	10 (22.2%)	
T2 NX		5 (20.8%)	6 (28.6%)	11 (24.4%)	
T2c N0		1 (4.2%)	1 (4.8%)	2 (4.4%)	
T3a N0		9 (37.5%)	10 (47.6%)	19 (42.2%)	
T3b N0		2 (8.3%)	0 (0.0%)	2 (4.4%)	
T3b N1		1 (4.2%)	0 (0.0%)	1 (2.2%)	
Gleason score					0.629
6		7 (29.2%)	7 (33.3%)	14 (31.1%)	
7		17 (70.8%)	13 (61.9%)	30 (66.7%)	
8		0 (0.0%)	1 (4.8%)	1 (2.2%)	
Extracapsular extension					1.000
No		12 (50.0%)	11 (52.4%)	23 (51.1%)	
Yes		12 (50.0%)	10 (47.6%)	22 (48.9%)	
Seminal vesical invasion					0.236
No		21 (87.5%)	21 (100.0%)	42 (93.3%)	
Yes		3 (12.5%)	0 (0.0%)	3 (6.7%)	
Pelvic lymph node dissection					1.000
No		5 (20.8%)	5 (23.8%)	10 (22.2%)	
Yes		19 (79.2%)	16 (76.2%)	35 (77.8%)	
Weight (g)	Mean (SD)	69.53 (35.92)	54.30 (14.79)	62.42 (28.86)	0.077
Operative time	Mean (SD)	186.4 (54.6)	171.4 (32.3)	179.4 (45.7)	0.277

TURP = transurethral resection of the prostate; AUASS = AUA symptom score; QoL = quality of life; IIEF = International Index of Erectile Function

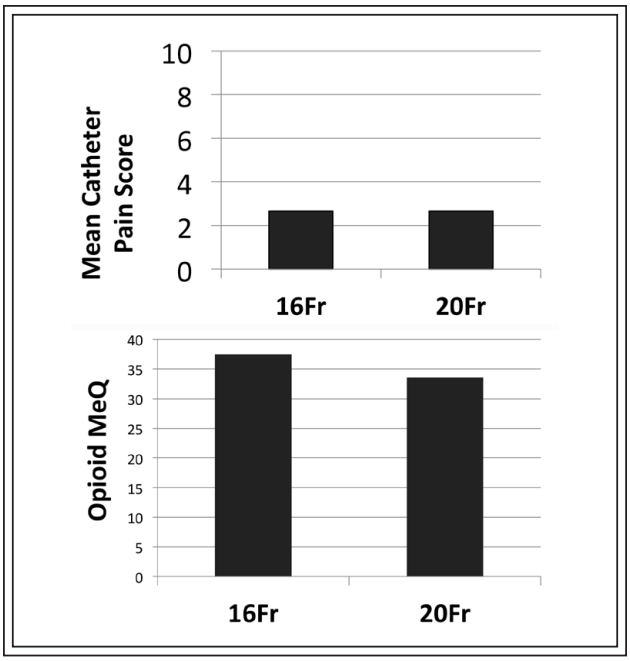

Figure 2a. Mean catheter pain score and opioid use did not differ between groups.

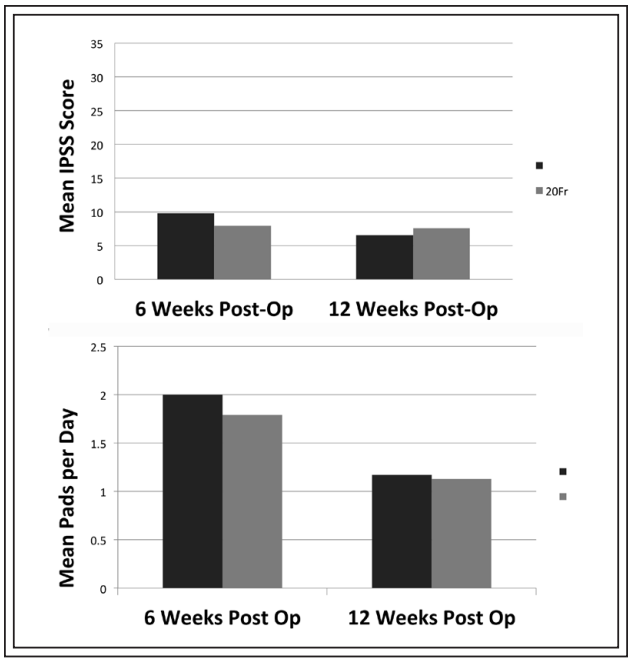

Figure 2b. IPSS score and pads per did not differ between groups at 6 and 12 weeks.

Results

Fifty-two patients were randomized. Seven patients were excluded: surgeon's specific catheter preference (3); withdrawal of consent (4). The surgeon's catheter related preference was secondary to unanticipated significant bladder neck reconstruction. After exclusion, 45 patients were included in the analysis, 21 (20 Fr) and 24 (16 Fr) per group. Baseline demographic data including age, body mass index (BMI), IPSS, chronic pain, prior prostate surgery and IIEF did not differ between groups (all $p > 0.10$). Additionally, pathologic parameters including stage, Gleason score, extracapsular extension (ECE), seminal vesical invasion (SVI), pelvic lymph node dissection (PLND), specimen weight (g), and operative time did not differ between groups (all $p > 0.20$), Table 1.

Catheter associated urethral and bladder pain scores, Figure 2a, and postoperative opioid use (mEq), Figure 2b, were not different between groups (all $p > 0.78$). Postoperative IPSS, QoL, and pads per day did not differ

TABLE 2. **Continence and pain outcomes**

		16 Fr catheter (n = 24)	20 Fr catheter (n = 21)	Total (n = 45)	p value
Catheter pain score	Mean (SD)	2.67 (1.61)	2.67 (1.68)	2.67 (1.62)	1.000
Home postop opioid use (tabs)	Mean (SD)	5.00 (5.68)	4.48 (5.75)	4.76 (5.65)	0.760
Home opioid use (meq)	Mean (SD)	37.50 (42.60)	33.57 (43.12)	35.67 (42.40)	0.760
IPSS score week 6	Mean (SD)	9.81 (4.25)	7.95 (4.04)	8.88 (4.20)	0.155
QoL score week 6	Mean (SD)	3.00 (1.30)	2.95 (1.72)	2.98 (1.51)	0.920
Pads per day week 6	Mean (SD)	2.00 (1.50)	1.79 (1.32)	1.89 (1.39)	0.657
IPSS score week 12	Mean (SD)	6.52 (4.75)	7.59 (4.39)	7.00 (4.56)	0.482
QoL score week 12	Mean (SD)	2.24 (1.30)	2.29 (1.05)	2.26 (1.18)	0.886
Pads per day week 12	Mean (SD)	1.17 (1.46)	1.13 (0.96)	1.15 (1.21)	0.925

between groups at both 6 and 12 weeks (all $p > 0.16$), Table 2. With respect to long term sequelae, one patient experienced a bladder neck contracture at 1 year (20 Fr) ($p = 0.28$) and bladder neck reconstruction was equally distributed between groups. There were no major complications such as re-operation, sepsis, and abscess or fistula formation in either group.

Discussion

The approach to radical prostatectomy has been an area of rapid evolution over the past two decades. Specifically, the wide implementation of the robotic approach in addition to enhanced recovery after surgery (ERAS) protocols have been instrumental in improving convalescence and postoperative pain control.[14]

In the present study, we assess the relationship between catheter size and postoperative bladder and urethral pain. This has not been previously described for RALP. Limiting postoperative pain and narcotic use has become a focus in the United States since the opioid epidemic was widely recognized.[15] Furthermore, decreased pain and shorter hospital stay are two of the most commonly cited advantages of robotic prostatectomy.[16] We sought to investigate if changing postoperative catheter size would impact these parameters. Contrary to anecdotal patient experience of increased pain with larger catheters, we observed no difference in pain scores or opioid use between groups. One explanation for this finding is that a 4 Fr difference in catheter size is not clinically perceptible to the patient. More likely is that the abdominal/pelvic pain associated with the procedure was more bothersome than the catheter and therefore diminished the effect of the difference in catheter size.

While subjective assessments of pain are notoriously difficult, IPSS and QoL scores for urinary symptoms are well validated.[17] In our RALP population, IPSS and QoL scores had a baseline of 9.6 and 1.9 respectively which is consistent with prior literature.[18] As expected, both these measures increased 6 weeks postoperatively compared to preoperatively but decreased again as anticipated by 12 weeks. The same improvement from 6 to 12 weeks was observed across the cohort in the objective measure of pads per day.

Robotic surgery also has allowed for new approaches toward continence preservation. Bladder neck sparing and imbrication have shown success in improving continence.[6] However, there have also been concerns regarding potential ischemia leading to BNC.[19] More recently, the Retzius sparing approach has become more widely utilized given expedited return to continence and some reports of superior nerve sparing.[7] One would expect that with each of these techniques, the circumference of the anastomosis to be a critical aspect of the continence mechanism. Interestingly, this has not been widely studied.

In this study, by randomizing patients to different sized catheters, we anticipated a possible impact on final anastomotic circumference. Based on well described properties of fluid dynamics,[20] we predicted that this anastomotic circumference difference would lead to changes in volumetric flow and therefore postoperative continence. Urinary flow rates act according to Poiselle's law, and several studies have evaluated this property within urology.[21,22] Poiselle's law of fluid dynamics demonstrates that fluid velocity is dependent on viscosity of the fluid and the length and diameter of the channel. With respect to radius, fluid velocity is directly proportional to radius to the fourth power, meaning a larger radius results in exponentially more robust flow. Relating this back to a measurement familiar to urologists, a 4 Fr difference in catheter size (16 versus 20 for example) represents over a 2-fold difference in volumetric flow rate. It is unknown at what circumference difference fluid velocity changes are clinically noticeable in a vesicourethral anastomosis, but it has been described that urinary flow rates decrease with tighter circumference urethral strictures.[20] Interestingly, we found that in all measures of continence, final catheter size did not make a clinically significant difference.

As mentioned previously, there have been a variety of other techniques described to improve continence with mixed results. For example, a meta-analysis performed by Heesakers et al reported on the various attempts to impact continence.[23] In this analysis, the Rocco stitch, bladder neck sparing, and laxity of posterior support had inconsistent results. Only anterior fixation had consistent impact on continence across multiple studies. Given this wide variation across studies regarding continence preserving techniques, we should remain cautious in concluding that catheter size differential has no impact on continence. Further studies to corroborate this finding may be warranted.

In addition to objective measures of continence, subjective data also provides an important window into the patient experience. Prior studies have suggested that for subjective continence outcomes in men, the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), and the postoperative Patient Global Impression of Improvement (PGI-I) score may be superior measures to the IPSS assessment.[18] This would be a paradigm shift in our practice as the IPSS is traditionally used as the pre and postoperative assessment tool for prostatectomy.

Another important reported improvement with robotic prostatectomy compared to open is reduced rates of bladder neck contracture.[16] Reported rates of BNC for contemporary large cohort robotic prostatectomy series is 1.1%.[19] Here, we report one patient with BNC out of 45. Longer follow up may be required to capture further development of BNC at 2-5 years.

The strengths of this study include its prospective randomized design, multiple surgeons and measurement of both subjective and objective outcomes. Limitations include lack of blinding to catheter size, limited follow up duration and relatively small cohort size. Anecdotally, it is surprising that catheter pain scores did not differ between 20 Fr and 16 Fr catheters. Latex catheters were used for all patients to standardize catheter stiffness. Therefore, future studies should consider prospectively measuring catheter pain difference in a non-surgery cohort. Additionally, future studies might consider measuring the anastomosis circumference intra-operatively and postoperatively with Bougie dilators to obtain an exact circumference. In our study, the intraoperative catheter for urethral visualization was the same in both groups (18 Fr) and therefore final postoperative catheter may have not impacted final anastomosis circumference.

Conclusions

Catheter size impacted neither bladder and urethral pain nor urinary continence up to 12 weeks after RALP. These data suggest that surgeon preference may guide catheter selection between 16-20 Fr in RALP. There was no difference in BNC at 1 year to suggest any increased risk with smaller catheter size. In future studies it would be interesting to assess if pain differs based on catheter size in nonoperative patients. Additionally, the size of catheter used intra-operatively to sew the anastomosis may play a larger role than the postoperative catheter. Accurate measurement of the anastomosis circumference intraoperatively may help to clarify this impact. □

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