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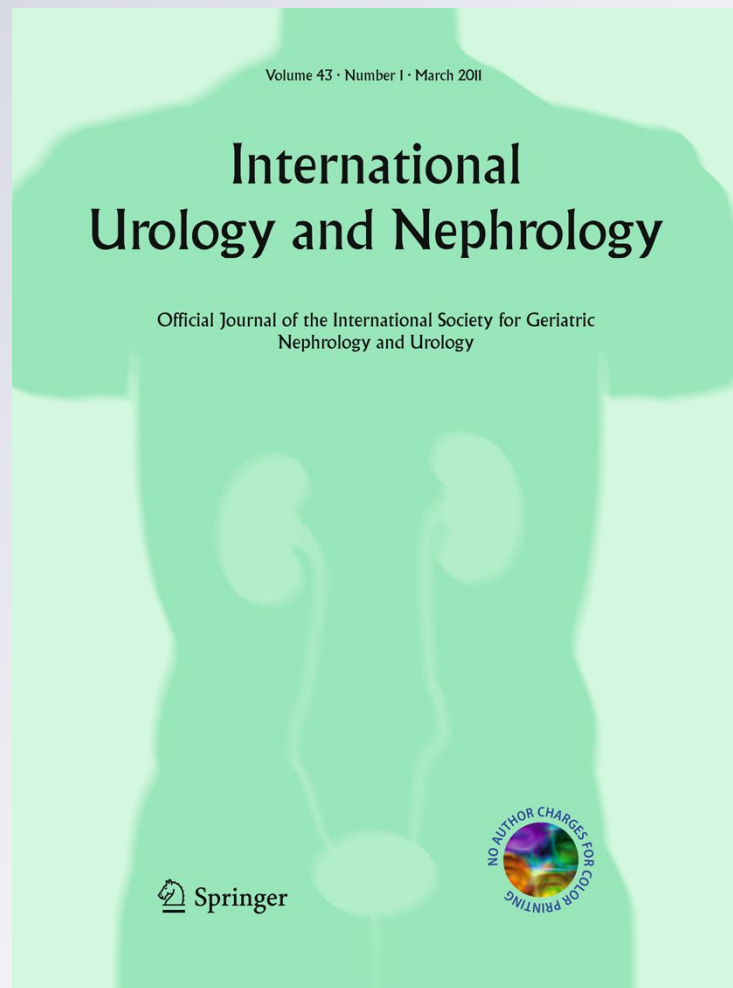
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Decreasing operative time and incontinence rates in patients treated with radical cystectomy and urethral diversion: a prospective randomized trial using a new suturing device (CAPIO)

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Abstract

Purpose Radical cystectomy and orthotopic urinary diversion has been associated with significant long surgery time and postoperative urinary incontinence. We undertook a prospective randomized study to investigate the potential decrease in surgery time and improvement in the continence rate using a new suturing device compared with the traditional suture ligation, which is used for urethro-ileal anastomosis after radical cystectomy and orthotopic diversion for invasive bladder carcinoma.

Materials and methods Between April 2005 and March 2010, 50 consecutive patients (37 men and 13 women) were recruited for the study. They were all subjected to radical cystectomy and W ileal neobladder orthotopic diversion by two senior surgeons. They were divided and randomized into two equal groups according to the methods of urethro-ileal anastomosis. The preoperative characteristics of both groups were equally distributed. One group underwent urethro-ileal anastomosis by the CAPIO suturing device, and the other group subjected to the usual stitches by needle holder. Operative and early postoperative

parameters were assessed. We followed the patients for 6 months postoperatively.

Results The preoperative parameters of the two groups were equally distributed with no statistically significant difference in any parameter. There were no intraoperative deaths. The mean time spent for urethro-ileal anastomosis in CAPIO group was 10.2 ± 1.4 min versus 19.6 ± 2.4 min, which was statistically significant (P value = 0.0001). Also, the mean blood loss was less in the CAPIO group (P value 0.05). As regard the early postoperative follow-up, the postoperative continence rate was significantly better in the CAPIO group than in the classic suturing group.

Conclusions CAPIO as a new suturing device significantly shortened the time needed to achieve the urethro-ileal anastomosis with better early postoperative continence rate. It makes urethral stump accessible at any time during surgery. It also enables surgeons to do anastomosis at any time after cystectomy with any number of sutures.

Keywords Urethra · Suture · Device · Cystectomy · Bladder · Orthotopic · Diversion

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Introduction

Conventionally, open radical cystectomy and orthotopic neobladder (ONB) is considered to be a gold-standard treatment for non-metastatic muscle-invasive bladder cancer. Radical cystectomy has been viewed

as a challenging surgical procedure, with a mortality rate of 1–3% and morbidity rate of 25–45% [1]. Hence, with careful attention to detail in surgical technique, continuous modifications of surgical technique will help to limit the morbidity and mortality from radical cystectomy. This major surgery is done transperitoneally with vertical midline incision extending above the umbilicus [2, 3]. The step of neobladder urethral anastomosis is considered an important and critical step in urethro-ileal anastomosis without angulations and mucosa-to-mucosa realignment. Many surgeons tried various methods to achieve a good and patent anastomosis; they usually used 4–8 stitches. However, in some obese patients and patients with deep pelvis, it is too difficult and tedious to make all these stitches. Many surgeons prefer to take all of the urethral stitches immediately after cystectomy before urethral stump retraction. Others created a special device to be passed in the urethra to stretch it and make it accessible for the sutures. We used the CAPIO (device manufactured by Boston Scientific to suture the prolene mesh to the sacrospinous ligament) to make 6 stitches to the urethral stump at any time of the operation after radical cystectomy and orthotopic diversion.

Patients and methods

Between April 2005 and March 2010, a total of 50 patients with invasive bladder carcinoma (Stage T2, T3 of transitional cell carcinoma; TCC or squamous cell carcinoma; SqCC type) were eligible for radical cystectomy and orthotopic diversion. They were prospectively allocated and randomized for urethro-ileal anastomosis by either CAPIO device (Fig. 1) or the classic stitching using only the needle holder and perineal compression.

Technique

After radical cystectomy and preparation of the ileal pouch, from the terminal ileum mad, a urethral catheter was passed through the urethra to identify its lumen in the pelvis. In the CAPIO group, we loaded the CAPIO device by a suitable stitch (2-0 vicryl sutures) using a Debaquey forceps in the left hand to stretch and support the urethral stump. CAPIO was

applied by the right hand from inside the urethral lumen 7–10 mm from the urethral edge so the stitch could be applied from inside out (Fig. 2). Urethral lumen admitted the CAPIO head in all cases. After firing the needle of the device, CAPIO was withdrawn having the needle after it has passed in the urethra for a good grip and length. CAPIO was taken off the needle, which was cut leaving only the stitch hanging the urethral stump. CAPIO was loaded by another 2-0 vicryl stitch for further stitch. We started with the lateral stitches first then we went to the posterior ones and lastly the anterior stitches. We used 6 anastomotic stitches in all patients at 1, 3, 5, 7, 9, and 11 o'clock positions Fig. 3. After finishing the design of the stitches, we started suturing the pouch by loading another regular needle and started to tighten the stitches under vision in rows; lateral to posterior and the last is the anterior one. We calculated the time of urethro-ileal anastomosis for each group using a stop watch. We tested water tightness by injecting saline into the urethra. In the first postoperative days, the neobladder was irrigated and actively aspirated using 50 ml saline, 3 times daily to remove mucus debris. urethro-intestinal anastomosis was stented

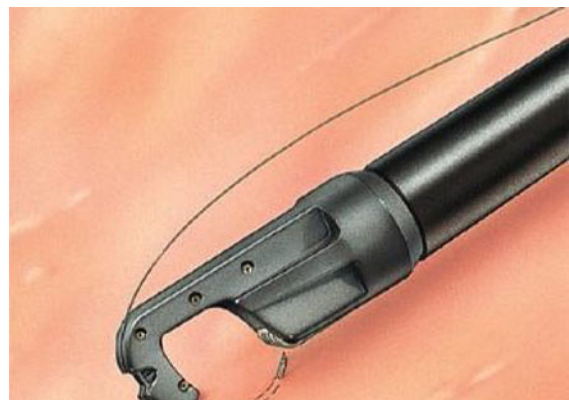


Fig. 1 CAPIO head loaded with its needle



Fig. 2 CAPIO needle fired

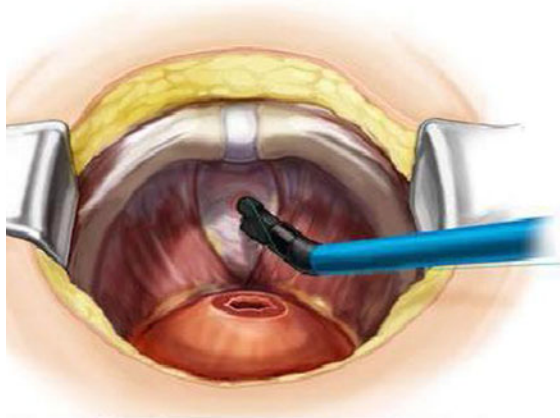


Fig. 3 CAPIO head admitted in the urethral lumen

intra-operatively for at least 14 days. Urethral catheter was left inside for 21 days till urethra-pouchogram was done and removed if no leakage. The two methods were compared regarding the time of surgery, the amount of blood lost and postoperative urethral leakage, fistula occurrence, voiding pattern and timing of early continence. Patients were followed up

biweekly for the first 3 months and at 6 months postoperatively. Statistical analysis was done using the SPSS (Statistical Program for Social Sciences) program. As the data were not normally distributed, the groups were compared using Kruskal–Wallis analysis and Spearman correlation test for numerical variables. Chi-square test was used for categorical ones. A two-tailed *P* value of <0.05 was accepted as statistically significant.

Results

The preoperative data of both groups were comparable; Table 1 shows the preoperative characteristics of both groups. The groups were equivalent in terms of demographic and clinical variables, indicating that randomization produced two comparable groups (Table 1). The randomly divided groups did not differ significantly in age, tumor stage, histopathologic type or preoperative hematocrit. Mean time required for the cystectomy was in favor of CAPIO group (208 min) versus the classic needle holder group (221 min). Also,

Table 1 Characteristics of the studied population

Parameters	CAPIO group <i>N</i> = 25	Classic needle holder group <i>n</i> = 25
Age		
Mean ± SD (year)*	50.0833 ± 9.3340	49.2800 ± 7.1852
Significance and risk	<i>t</i> = 0.338, <i>Df</i> : 47 and <i>P</i> = 0.737	
Sex No. (%)		
Male; 37	16	21
Female; 13	9	4
Significance and risk	Pearson $\chi^2 = 1.92$, <i>P</i> = 0.158 OR = 0.49 at 95% confidence limits [0.09–2.47]	
Tumor staging		
T3 N0M0; 40	21	19
T2 N0M0; 10	4	6
Significance and risk	Pearson $\chi^2 = 0.92$, <i>P</i> = 0.333 OR = 1.66 at 95% confidence limits [0.34–8.46]	
Tumor histopathology		
Sq. cell carcinoma	16	18
Trans. cell carcinoma	9	7
Significance and risk	Pearson $\chi^2 = 0.36$, <i>P</i> = 0.548 OR = 0.69 at 95% confidence limits [0.18–2.67]	
Mean % preop. hematocrit	39.6	40.2
Significance and risk	Pearson $\chi^2 = 0.73$, <i>P</i> = 0.268 OR = 1.32 at 95% confidence limits [0.25–0.88]	

* Independent *t*-test was used to elucidate significant differences

none of the CAPIO group patients have postoperative leakage at 3 weeks, whereas 2 patients in the classic needle holder group had prolonged leakage with delayed catheter removal. The mean time for urethroileal anastomosis in CAPIO group was 10.2 ± 1.4 min versus 19.6 ± 2.4 min, which was statistically significant (Levein's test $F = 6,26$ P value 0.016), and independent t test was used to elucidate significant differences. Estimated risk for odd's ratio (OR) at 95% confidence limits (CL) was determined to be 10.6–8.3 $t = 16.6$ $Df = 47$ (P value 0.0001) (Table 2). Voiding pattern and continence were evaluated with a standardized questionnaire during scheduled follow-up visits postoperatively. Continence was defined as good when the patient is completely dry, satisfactory when the patient used only 1 pad during the day or evening and poor where more than 1 pad was used during the

day or evening. Good daytime and nighttime continence was reported in the first month postoperatively: in the CAPIO group 22 (88%) daytime continence and 19 (76%) nighttime continence patients. In the classic group, good daytime and was reported by 20 (80%) patients and good nighttime continence was reported by 17 (68%) patients. By the end of third month, 23 (92%) patients had good daytime and nighttime continence in the CAPIO group, and 21 (84%) patients in the other group. Only two patients (8%) in the CAPIO group had nighttime incontinence, where they used only one pad at night. On the other hand, in the classic needle holder group, one patient (4%) developed chronic retention and managed by clean intermittent catheterizations, and 3 patients (12%) had poor nighttime continence, where the patients used to have more than two pads at night.

Table 2 Intraoperative data of both the CAPIO and classic groups

Item	Suture type	Mean	SD	SE
Operative time (min)	Capio gp.	208.5833	22.4265	4.5778
	Classic gp.	221.8000	34.0000	6.8000
Blood loss (ml)	Capio gp.	422.9167	188.8058	38.5398
	Classic gp.	538.0000	220.4541	44.0908
Stop watch time (min)	Capio gp.	10.2083	1.38247	0.28220
	Classic gp.	19.6400	2.43036	0.48607

Independent samples test

Parameters	Levene's test for equality of variances		t test for equality of means						
	F	Sig.	t	Df^a	Sig. ^a	Mean difference	SE difference	95% CI ^a	
								Lower limit	Upper limit
Operation time (min)									
Equal variances assumed	5.999	0.018	-1.599	47	0.116	-13.2167	8.2649	-29.8434	3.414
Not assumed			-1.612	41.738	0.114	-13.2167	8.1973	-29.7626	3.330
Blood loss (ml)									
Equal variances assumed	1.836	0.182	-1.959	47	0.056	-115.0833	58.7483	-233.2697	3.130
Not assumed			-1.965	46.413	0.055	-115.0833	58.5604	-232.9310	2.820
Stop watch timing									
Equal variances assumed	6.263	0.016	-16.603	47	0.000	-9.43167	0.56807	-10.57447	-8.28886
Not assumed			-16.781	38.358	0.000	-9.43167	0.56205	-10.56913	-8.29420

^a Df degrees of freedom, CI confidence interval of the difference

Discussion

Although in the last decade the robotic radical cystectomy and laparoscopic diversion became an important development in the field of oncologic urologic surgery, still the classic open surgical approach is a golden standard, especially in big teaching hospitals. In addition, the cost of open surgery is low compared to the robotic laparoscopic surgery. However, prolonged surgery time and significant blood loss are very important concerns regarding the safety of the surgical procedure in this group of patients. Moreover, urinary leakage and urinary continence are among the most important early postoperative complications of open surgical interventions. Removal of bladder neck and adjacent short segment of the urethra is beneficial for the patient from ontological point of view as well as volitional voiding [4], hence the importance of easier techniques to do a urethro-ileal anastomosis. We used the device manufactured by Boston Scientific to suture the prolene mesh to the sacrospinous ligament and compared the results with those of the classical needle holder method. We noticed a statistical difference during urethral realignments. Our total mean operative time was approximately 3.4 h for cystectomy, pelvic lymph node dissection and urinary diversion in the CAPIO group, while it was 3.6 h in the classic needle holder group. We calculated the time spent for urethro-ileal anastomosis in both groups and found that the time was significantly shorter while using the CAPIO device (10.2 min versus 19.6, P value 0.0001). This time is shorter than some of the historical cystectomy series where mean operative time was around 6 h [5]. Also, regarding the early postoperative leakage in the first 4 weeks, we did not encounter this complication in the CAPIO group on ascending cystography compared with 8% extravasations in classic needle holder group. The reported incidence by Ali Eldin et al. [6] on 192 patients offered radical cystectomy, and orthotopic diversion was 1.6%, which is low compared to the results showed by our patients. Interestingly, none of our patients in the CAPIO group developed urethro-ileal stricture; however, one patient 4% in other group developed urethro-ileal stricture and chronic retention. The incidence in our series is 4% in accordance with the literature, reporting a stricture rate in patients with an ileal neobladder between 2.7 and 8.8% [7].

Sacco et al. [8] reported an overall anastomotic stricture rate of 4.5%, but the stricture rate in incontinent patients was 33.8%. Chao and Mayo noted that anastomotic strictures were an important factor in the etiology of sphincter weakness, and that excessive scarring at the anastomosis may extend distally into the sphincter, impairing the closure mechanism provided by vascular and elastic tissue in the submucosa [9]. Myers emphasized the importance of maximizing the length of the urethral stump to achieve good urinary control and recommended several maneuvers [10]. He cautioned that too many sutures in the urethral stump can foreshorten the length of the stump. We believe this new suturing device may overcome these challenging difficulties and help in the preservation of continence mechanism. Neovesico urethral anastomotic strictures are one of the most important complications after cystectomy and orthotopic diversion.

Good daytime and nighttime continence rate was 92% in the CAPIO group versus 84% in the classic needle holder group, by the end the 3rd month. Estimated risk for OR at 95% CL was determined to be 2.19 at confidence limits 0.3–19.51 (chi-square 0.76; P value 0.384). Although the P value that denotes the significant difference between the two groups is 0.384, the estimated risk for the classic needle holder group is high by 19% (odd's ratio 2.19 at confidence interval 0.3–19.51). Careful preparation at the apex of the prostate and meticulous sphincter management during surgery are also of utmost importance for high postoperative continence rates [11].

In most series, the early postoperative minor complications are around 25–30% and most of these complications are not life threatening, such as paralytic ileus, wound-related complications, urinary leakage and sepsis [12, 13]. With the modification of surgical techniques, we can reduce these perioperative complications, whereas reduction in the duration of surgery, decreasing blood loss and hospital stay will play some roles. The pelvis of the obese patient can be less accessible, making cystectomy and orthotopic diversion more difficult. A short and thick mesentery can undermine the ability to create a watertight neovesicourethral anastomosis during neobladder formation. This new suturing device (CAPIO) makes the deep pelvis in obese patient easily accessible.

We believe this device may help in reducing the duration of surgery especially in deep pelvis of obese

patients and suggest its extended use in the urethral anastomosis after radical prostatectomy and in high perineal approach to minimize surgical possible complications.

Conclusion

In this randomized prospective study of radical cystectomy and orthotopic urethral diversion, CAPIO as a new suturing device significantly shortened the time needed to achieve the urethro-ileal anastomosis with better early postoperative continence rate. It makes urethral stump accessible at any time during surgery. It also enable surgeon to do the anastomosis at any time after cystectomy with any number of sutures. Also, this device may help transperineal urethral realignment for stricture urethra.

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