Comparison of Removing Double-J Stent With and Without Cystoscopy in Kidney Transplant Patients: A Randomized Clinical Trial

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Purpose: The ureteric stent can be attached to the Foley catheter in kidney transplantation to exclude cystoscopy for its removal. It is rarely practiced in renal transplantation. There has been no randomized trial to evaluate the outcome of this procedure on major urologic complications.

Materials and Methods: One hundred sixty-three kidney transplant patients were randomized into an intervention group in which the stent was attached to the Foley catheter and removed together and a control group in which stent was removed by cystoscopy. In both groups, stents were removed around the 8th post-operative day.

Results: From March 2016 to June 2017, out of 234 kidney transplants performed in our center, one hundred Sixty-three (69.6%) patients met the study inclusion criteria. 91patients (55.8%) were allocated to the intervention group. Mean days before JJ removal for intervention and control groups ("per-protocol" group) were 8.08 ± 1.52 and 8.57 ± 1.58, respectively (P = .09). There was no difference between groups regarding major urologic complications (P = .679). Visual analog scale pain scores were significantly higher in the control group (p = .001). The procedure reduced 63-120 USD from the cost of operation in the intervention group.

Conclusion: In selected kidney transplant patients, attaching stent to the Foley catheter and removing both of them early may be a safe maneuver regarding major urological complications, reduces pain, and eliminates the cost of cystoscopy.

Keywords: cystoscopy; double-J-stent; kidney transplantation; stent; ureteric stenting

INTRODUCTION

With the current adequate immunosuppression, the surgical complications are the significant cause of graft loss after kidney transplants[1]. Urologic complications are associated with significant morbidity, graft loss, and mortality[2]. The urinary anastomosis technique evolution occurred gradually during more than half a century from uretero-ureteral to the ureteroneocystostomy anastomosis, and from Leadbetter-Politano to the Lich-Grégoire[3]. The Lich-Gregoire extravesical technique has reduced these complications[4], has stood the test of time,[5], and it is technically less demanding[6]. Stents which mostly are used in the Lich-Gregoire ureteroneocystostomy[6] technique are still a controversial issue[6]. The benefits of stents are still debated[6] but may include making watertight ureteroneocystostomy anastomosis procedure easier and lowering the chance of kinking[6]. The optimal stent caliber, length, design[6], duration[7], and methods to remove it remain to be determined[6]. There is a considerable amount of research about the stents to address their cost-effectiveness[8,9], their disadvantages regarding urinary tract infections[6], encrustation, reflux[10], obstruction[11], irritation, migrations, a dread complication of "forgotten stents" and the last but not the least, the need for the cystoscopy for their removal[12-16]. Attaching ureteral stent to the Foley catheter and excluding cystoscopic removal of the stent, was first reported in 1988[17]. Although it has not adopted widely, we think that it is a good maneuver making transplant a more comfortable experience for patients. To the best of our knowledge, our study is the first randomized controlled trial which evaluates the major urologic complications (MUC), pain, and costs between regular stent removal through cystoscopy with stent removal through attachment to Foley catheter.

MATERIALS AND METHODS

Study design

We did a randomized controlled trial in patients transplanted at Shahid Labbafinejad Medical Center, Tehran, Iran (a quaternary referral hospital) from March 2016 to June 2017. The Ethics Committee of the Urology and Nephrology Research Center of Shahid Beheshti University of Medical Sciences approved the study protocol (IR.SBMU.UNRC.1395.13). The study has been registered in the Iranian Registry of Clinical Trials (IRCT20100313003547N6). Written informed consent obtained from all participants. The stent of all participants proposed to be removed around the seventh post-op day. In the intervention group, the stent was attached to the Foley catheter by a nylon suture and removed

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Table 1. Etiology of the 71 patients excluded from the study.

Exclusion criteria	Number (%)
Age less than 16 years	23 (32.3)
History of BPH and bladder outlet obstruction	10 (14.0)
Multiple arteries in allograft	6 (8.45)
Neurogenic bladder	6 (8.45)
Surgeon preferred not to included after reperfusion	3 (4.22)
Up-side-down transplant of the right-sided living donor nephrectomy	3 (4.22)
Sever iliac vein adhesion found during surgery	3 (4.22)
Third transplant	3 (4.22)
History of cystoplasty	2 (2.86)
Double ureter in allograft	2 (2.86)
Double ureter and multiple arteries in the allograft	2 (2.86)
Transplant in continent urinary diversion	1 (1.40)
Iatrogenic trauma to the allograft ureter leading to Boari flap procedure	1 (1.40)
History of vesicostomy and Mitrofannoff procedure	1 (1.40)
Others	3 (4.22)

together. In the control group, the stent was removed by flexible or rigid cystoscopy in the operating room.

Participants

Eligible participants were patients 16 years and older listed for renal transplantation in the renal transplant department, which had given written informed consent. The exclusion criteria were benign prostatic hyperplasia causing bladder outlet obstruction, neurogenic bladder, history of urinary diversion, history of surgery in urethra or bladder, repeat transplanations, patients who had a high risk of bleeding after reperfusion and before performing ureteroneocystostomy anastomosis, double

Table 2. demographic characteristics and immunosuppression regimens.

Variables[a]		Modified intention-to-treat group (%)			Per-protocol group (%)		
		Intervention group	Control group	*P* value	Intervention group	Control group	*P* value
Randomiza-tion							
	Per-protocol	73 (80.2)	50 (69.4)	.016	NA	NA	NA
	As-treated	6 (6.6)	1 (1.4)	NA	NA	NA	
	Intention-to-treat	12 (13.2)	21 (29.2)	NA	NA	NA	
Age		43.85 (±15.09)	41.42 (±14.25)	.311	44.66 (±14.39)	37.91 (±13.95)	.013
Sex							
	Male	53 (58.9)	45 (63.4)	.562	46 (63.0)	32 (64.0)	1
	Female	37 (41.1)	26 (36.6)	27 (37.0)	18 (36.0)		
	BMI	24.83 (±4.56)	25.0 (±4.15)	.821	24.93 (±4.07)	24.02 (±4.21)	.505
Etiology							
	DM	18 (19.8)	11 (15.3)	.108	15 (20.5)	6 (12)	.219
	HPT	19 (20.9)	12 (16.7)		14 (19.2)	8 (16)	
	Unknown	15 (16.5)	10 (13.9)		13 (17.8)	8 (16)	
Preemptive		20 (25.3)	15 (22.7)	.717	18 (27.3)	9 (19.1)	.375
Dialysis dura-tion		16.57 ((±22.5)	15.61 (20.17)	.787	14.71 (±20.2)	17.06 (±22.15)	.557
Positive Histo-ry of diabetes		21 (25.9)	12 (17.1)	.238	17 (27)	6 (12.5)	.097
Donor							
	Live	44 (48.4)	31 (43.7)	.332	38 (52.1)	24 (48.0)	.398
	Cadaveric	47 (51.6)	40 (56.3)		35 (47.9)	26 (52.0)	
Previous his-tory of trans-plant							
	No	67 (87.0)	58 (90.5)	.345	54 (87.1)	44 (95.7)	.117
	Yes	10 (13.0)	6 (9.4)		8 (1209)	2 (4.3)	
Donor age		34.1 ((±11.89)	33.91 ((±11.03)	.920	33.83 (±11044)	31.35 (±9.69)	.220
Donor sex							
	Male	65 (78.3)	44 (64.7)	.175	54 (80.6)	32 (66.7)	.234
	Female	17 (20.5)	23 (33.8)		12 (17.9)	15 (66.7)	
Left or right							
	Right kidney	24 (27.3)	22 (32.4)	.596	15 (21.4)	13 (27.1)	.311
	Left kidney	64 (72.7)	46 (67.6)		55 (78.6)	35 (72.9)	
Warm ische-mia time		2.62 ((±3.09)	2.80 ((±3.34)	.799	2.87 (±3.07)	3.33 (±3.45)	.571
Cold ischemia time		117.04 ((±79.07)	112.33 ((±66.01)	.781	103.58 (±69.81)	97.70 (±66.77)	.758
Surgeon's ex-pertise level							
	Senior cosultatn (NS, AB, AT)	35 (39.3)	19(27.5)	.272	27 (37.5)	13 (27.11)	.237
	Jonior consultant (MNS)	12 (13.5)	13 (18.8)	10 (13.9)	12 (25)		
	Surgical fellow	42 (47.2)	37 (53.6)	35 (48.6)	23 (4709)		
Day double J removed		8.93±3.87	11.79±6.69	.001	8.08 (±1.52)	8.57 (±1.58)	.094
Immunosuppression							
	Cyclospor-ine+Mycophenolic acid + Corticoster-oids	33 (53.2)	29 (46.8)	.767	27 (56.3)	21 (43.8)	.745
	Tacro +Mycophenolic acid + Corticosteroids	24 (58.5)	17 (41.5)		19 (63.3)	11 (36.7)	
	Cyclosporine + Si-rolimus + Cortico-steroids	7 (43.8)	9 (56.3)		6 (54.5)	5 (45.5)	
	Tacro + Sirolimus + Corticosteroids	12 (50)	12 (50)		9 (47.4)	10 (56.3)	

Table 3. Description of the patients included in the "as-treated" group

Reason for meeting the exclusion criteria	Number
Age less than 16 years	3
Multiple arteries in allograft	3
Neurogenic bladder	1

ureter, or multiple arteries in the allograft, and any injuries to the vessels or ureter during retrieval (**Table 1**).

Randomization

The patients were randomly allocated (1:1) to either attaching the stent to the Foley catheter or not attaching them during transplant. A computerized randomization list in blocks of five in random order was created. Numbered dark pockets containing the study groups (attached or not attached) were prepared and sealed accordingly. After reperfusion, if the surgeon did not have any contraindication for allocating the patients, randomization to the intervention or the control groups was done. There was no blinding.

Procedures

The technique of Lich-Gregoire extravesical anastomosis has been described elsewhere[12,18]. The anastomosis was done using 5/0 polyglactin suture. The Foley catheter was attached to the stent with 3/0 nylon stitch, which was passed through the distal end of the stent and the distal drainage eye of the catheter. All patients received Cotrimoxazole for six months.

Outcomes

The primary outcome was a urinary leak or a ureteric obstruction treated with intervention and was defined as major urologic complications (MUC). Secondary outcomes were pain experienced by the patients during stent removal and the reduction of the cost of kidney transplantation. The data were collected by completing a questionnaire.

Statistical analysis

The primary analysis was targeted to the "modified intention-to-treat" group, although we did the "per-protocol" analysis for cases with no significant protocol violations as well. Pearson's chi-squared test, Fisher's exact test, Independent-samples *T*-test, One-way ANOVA were used for analysis. Non-parametric Mann-Whitney U test was used for visual analog score analysis. Throughout, we reported two-sided p values. A *P* value of less than 0.05 was considered significant. We used SPSS software (version 22.0) for the statistical analysis.

RESULTS

From March 2016 to June 2017, two hundred thirty-four patients, mean age 40.11 ± 17.06 (6-77) years; 121 (51.7%) from deceased donors, were transplanted in our department; Seventy-one patients did not meet the inclusion criteria (Table 1). One hundred sixty-three patients were randomly allocated to either an intervention group (n = 91) or control group (n = 72) (Figure 1). There were no differences in demographic characteristics between the two groups (**Table 2**). Mean time to stent removal in the intervention and control groups were 8.93±3.87(CI95%: 8.09-9.77), and 11.79 ± 6.69 (CI95%: 10.07-13.50), respectively (*P* = .001). One hundred twenty-three patients whose stent were removed early from six to fifteen post-op days were considered as protocol cases and analyzed as a "per-protocol" group. Thirty-three patients violated the protocol significantly and were analyzed as an "intention-to-treat" group (**Table 3**). In 16/163 (9.8%) patients, the catheter was removed after 15th post-op day by the decision of the in-charge surgeon because of their post-op condition such as delay graft function. In 33 patients who substantially broke the protocol, the mean ureteric stent removal day in intervention and control groups was 12.75 and 22.38 days (*P* = .008), respectively. Seven randomized patients were considered "as-treated" group because they should not have been included in the study (**Table 4**). The sum of "intention-to-treat," "as-treated," and "per-protocol" groups were defined as 163 cases of the "modified intention-to-treat" group. Because from March 2016 to January 2017, attaching the stent to catheter was satisfactory in adults, from January 2017, NS and MNS were attaching the ureteric stent to the Foley catheter in all of their pediatric transplantations. These caused the residents in our department to consider three children as included in the study by mistake, and the parents of three pediatric patients aged 8, 14, and 15 years, were asked to give the informed consent and were randomized inadvertently to the intervention group. One of these three cases, an eight years old girl, developed urinary leakage after stent removal on the 7th post-op day and underwent ureteroneocystostomy three days later. Six patients in the "per-protocol" group had their catheter removed on the six post-op day. 3/91 (3.2%) patients had accidental stent dislodgement due to malfunction of the balloon of the Foley catheter, (two on the third and one case on the fifth post-op day), and none of them developed MUC, although one of them developed lymphocele.

5/163 (3%) cases, including 3/91 (3.2%) in the intervention and 2/72 (2.81%) in the control group underwent ureteroneocystostomy after transplant. 4/163 (2.4%) cases had a urinary leakage, which was resolved by short term percutaneous drainage. One of these four cases was treated by both a percutaneous nephrostomy along with percutaneous drainage. There was no significant difference between the intervention and control

Table 4. Description of the patients analyzed as "Intention-to-treat" group.

Reasons for violation of the protocol	Numbers
Foley catheter came out accidentally before the six post-op day	3
The in-charge surgeon preferred to delay removal for a reason like a delay graft function, rejection,	16
Arterial/venous thrombosis or severe rejection leading to graft nephrectomy	5
Postoperative hemorrhage and exploration for hematoma evacuation	4
High output drain due to urinary leak and lymphocele	2
Severe hyponatremia and convulsion	1
The patient expired before removing the catheter	1
Nonfunctioning graft due to arterial thrombosis	1
Total	33

Table 5. Outcomes comparison between intervention and control group.

Vairables[a]	Modified intention-to-treat group			Per-protocol group		
	Intervention group	Control group	*P* value	Intervention group	Control group	*P* value
Stent dislodgement	3 (3.8)	0	.252	0	0	
Urinary leak	6 (8.0)	2 (4.1)	.477	4 (4.1)	2 (4.8)	1
Lymphocele	1 (1.3)	1 (1.7)	1	0	0	
Ureteroneocystostomy	3 (3.3)	2 (2.8)	.849	2 (2.7)	1 (2.0)	1
Drain for collection	3 (3.4)	1 (1.4)	.627	3 (4.1)	1 (2.0)	0.645
Nephrostomy for hydronephrosis	1 (1.1)	0	1	1 (1.4)	0	1
Major urologic complications	5 (5.5)	3 (4.2)	.679	5 (6.8)	2 (4.0)	0.7
Visual analoge scaleb score	.35 (IQR.6)	4 (IQR 6.35)	.000	4 (IQR .7)	3 (IQR 6.2)	.001
Follow up	283 ± 132	296 ± 131	.545	299.7 (±126.8)	319.9 (±124.3)	0.393
Mean creatinine one year after transplant	1.30 ± .46	1.22 ± .37	.247	1.29 (±.44)	1.22 (±.38)	0.411

[a] Continuous variables were compared by independent samples *t*-test
[b] Continuous variables were compared by MannWhitney *U* test

groups regarding the MUC (**Table 5**). The cost of cystoscopy with and without general anesthesia was 120 and 63 USDs respectively, which was eliminated in the intervention group.

DISCUSSION

To our knowledge, this is the only randomized study in which the attachment of the ureteric stents to Foley catheters versus cystoscopy removal of ureteral catheters were compared in early stent removal groups. 5/163 (3%) patients had ureteroneocystostomy, and 4/163 (2.4%) patients had leakage which was resolved by insertion of a percutaneous drain with or without a nephrostomy.

MUC in our previous study of 100 KT patients in whom urethral catheter was attached to ureteral stent and removed together three weeks after transplantation was 4% (one stenosis and three fistulas)[12]. Patel et al.[19], in a randomized trial conducted at six transplant centers in the UK, studied 205 patients aged 2 to 57 years old. Cases were randomized to early removal arm, in which stent was attached to the Foley catheter and were both removed at the 5th post-op day and a late removal arm, in which stent was removed at six weeks with cystoscopy. 3/80 cases (3.75%) in early removal group and 1/126 (0.79%) in late removal group; (P = 0.36) had ureteroneocystostomy[19]. Stent complications occurred in 27.3% and 10% in late and early stent removal groups, respectively; (P = .387). Urinary tract infection in the early and late groups occurred in 7.6%

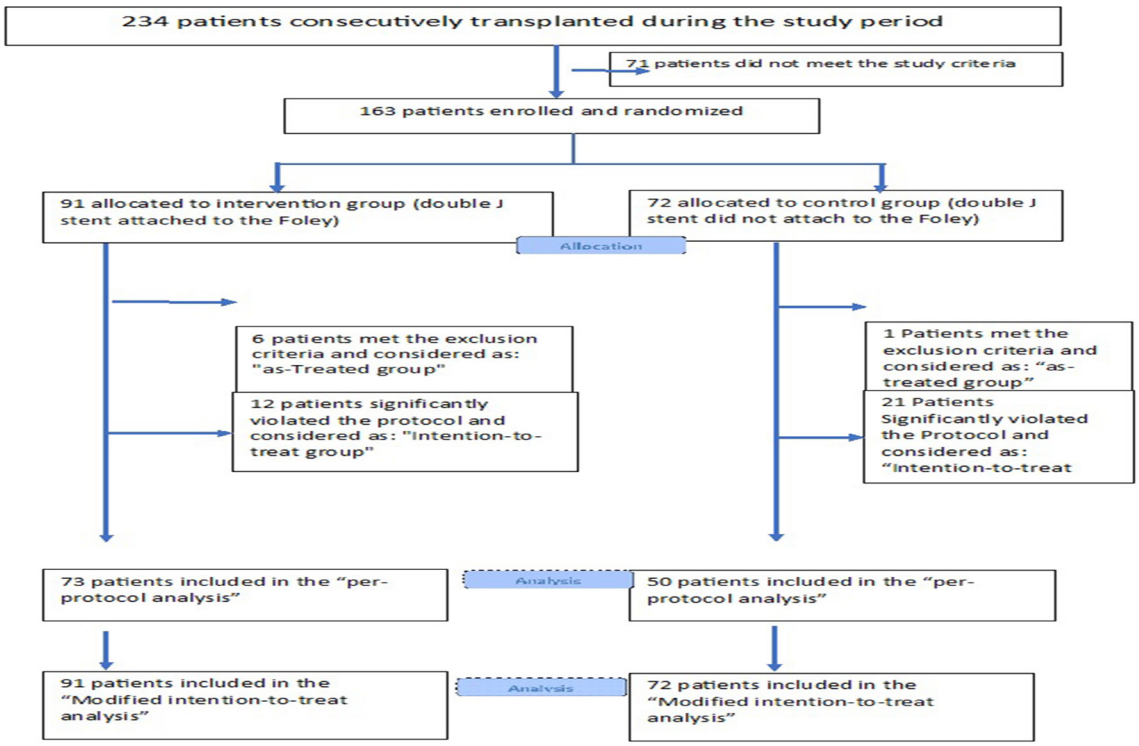

Figure 1. Trial profile.

and 24.6%, respectively; (P = .004). 37 (18%) patients were ≤ 16 years, and there was no ureteroneocystostomy in any[19] patient. In 11 patients, the surgeon was not able to attach the stent to the urethral catheter because it was a little bit challenging task[19]. We also acknowledge that finding the catheter and extracting it through a small incision of bladder mucosa is challenging. One of the authors' recommendations (NS) for this issue is to push the bladder downward so that the superior bladder wall approaches to the floor of the bladder. By this maneuver, the tip of the Foley catheter could be grabbed quickly and smoothly by the surgeon.

In a retrospective study (2007-2009) in the UK[20] on 127 transplantation comparison was made between 48 cases, which their ureteric stents were removed on the 5th post-op day with 79 cases in which their stents removed 6-8 weeks postoperatively by flexible cystoscopy. UTI occurred in early and late removal groups in 25% and 44% (P = .03), respectively. MUC in early and late removal groups were 4% and 7% (P = 1), respectively.

The preliminary result of an ongoing randomized trial comparing early with late stent removal in adults (ISRCTN51276329) has revealed that MUC has not increased in the early group (Mr. Kourosh Saeb-Parsy. Addenbrooke's Hospital (UK), November 2018, email response).

Sansalone et al.[21], in 590 consecutive transplanted patients, attached the 7 or 8 Fr silicone ureteral stent to the Foley catheter and removed both together at mean duration of ten days[8-14]. Urinary leakage and stenosis occurred in 0.3% and 1.5% respectively[21].

In 1998, the simple technique of attaching the ureteric stent to the Foley catheter was reported for the first time by Morris-Stiff (a surgical research fellow) et al.[22] In fifteen (eight men) patients, mean age 48 years, they have attached the stent to a Foley catheter and removed both at the mean eight post-op day. None of them developed MUC or sepsis. The authors conclude the method as a useful maneuver to be used in renal transplantation. Authors state that they had not invented, but they have reported this technique in the surgical literature[22].

Baxbi, k.[23] (a consultant urological surgeon) wrote a remarkable letter to the journal and criticized the authors' conclusion as follow: " authors describe a method of suturing the distal end of a ureteric stent to the tip of the urethral catheter at the time of ureteric anastomosis and say that they cannot find this technique described in the surgical literature. Perhaps the reason for the latter is that orthodox urological teaching has long been that this is bad practice. The reason is that if the urethral catheter is, or has to be, removed very early in the postoperative period, the ureteric stent inevitably comes with it. The catheter may block with clots (admittedly rare after transplantation) and have to be changed; a faulty balloon may deflate so that the catheter 'falls out while the bed is being changed,' and it is not unknown for a confused patient to remove the urethral catheter with the balloon intact[23]." The comments by Bixbi are a real and annoying concern for every transplant surgeon. In 3/92 (3.26%) of our patients, the catheter came out for the faulty balloon, and none of them developed MUC. All of them were re-catheterized, and the catheter removed from 7th to 10th post-op day, although one of them developed lymphocele. Patel et al[19]. reported catheter and the ureteric stent attached to it were dropped out before the fifth post-op day in 2/79 (2.53%) cases, which is in concordance to our study.

Parapiboon et al.[24], in a randomized study of 74 patients, assessed the MUC and UTI in two groups in which the stents were removed either on the median of 8 or 15 days. UTI and MUC in the eight days and 15 days were 40.5% vs. 72.9%; (P = .004) and 2 cases vs. 4 case; (P = .39) respectively(24).

Taghizadeh et al.[25] reported the result of a prospective study randomizing 43 cases to a cystoscopic stent removal group at four post-op week and another 43 patients to the attachment of Foley to the ureteric stent group removed at seventh post-op day. The UTI and Urinary leak in early and late removal groups were not significantly different[25].

Impressing innovations in KT have reported for omitting the cystoscopy, the unwanted procedure imposed by the use of the stent[26,27]. As an exciting innovation, the magnetic-tipped stent was first introduced by Macaluso et al. in 1989[28] and was developed mainly to decrease additional costs associated with stent removal. Pain measurement by Visual analog scale method in our study showed that cystoscopic stent removal was significantly more painful than removal by pulling the Foley catheter, which is attached to the stent. In a study of the pain at stent removal in the USA, 68 patients who underwent ureteroscopy for urolithiasis were randomized to stent removal by office cystoscopy or the removal by pulling an attached string. The pain score was lower in the cystoscopic removal as compared to removing it by pulling the string, although the difference was not significant[29].

There are some shortcomings in our research. First, the data provided is from a single center with center-specific patients, treatment protocol, and a financial perspective. We have excluded 23 children from our study, although no evidence shows a younger age of the recipient is a more significant risk factor for MUCs. We did not study the UTI in our trial. Although both groups in our study had an equal indwelling stent time, i.e., eight days, but its measurement could reveal the effect of cystoscopy on the occurrence of UTI in transplanted patients. Insertion of the stent is easy but will add a procedure of cystoscopy to the KT, for its removal. Cystoscopy after kidney transplant unquestionably increases the risk of UTI. There are reports of urosepsis in the transplanted immunocompromised patients after cystoscopy[30]. Our study has an insufficient sample size. However, ours is the most extensive reported series of its sort. Moreover, the study was not able to blind the surgeons or patients regarding the allocation.

Notwithstanding the previously mentioned shortcomings, we could analyze the primary outcome in the intention-to-treat subgroup and compare it with the per-protocol group. Our randomized clinical study presents a shred of clear evidence regarding the rate of MUCs occurring with the early stent removal strategy in 163 patients. MUC is the critical concerns of surgeons wishing to remove the stent early by attaching the ureteric stent to the Foley catheter. The attaching ureteric stent to the Foley catheter is not practiced widely and not a well-acknowledged strategy in KT, although it is an easy-to-do maneuver. It is clear from our trial that this is a safe and economical procedure with less pain for the patients in regards to omitting the cystoscopy for the stent removal.

CONCLUSIONS

In selected kidney transplant patients, attaching the Foley catheter to the stent and removing both of them early may be a safe maneuver regarding the major urological complications, reduces pain, and eliminates the cost of cystoscopy.

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