Impact of Stents on Urological Complications and Health Care Expenditure in Renal Transplant Recipients: Results of a Prospective, Randomized Clinical Trial

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Purpose: We performed a randomized, prospective trial to compare the incidence of early urological complications and health care expenditures in renal transplant recipients with or without ureteral stenting.

Materials and Methods: Patients receiving a renal transplant at a single center were randomized preoperatively to undergo Double-J® stent or no-stent ureterovesical anastomosis from November 1998 to October 2001. Early urological mechanical complications were recorded, including urinary leakage or obstruction, or urinary tract infections within 3 months of transplantation. Direct health care costs associated with stenting, urological complications and urinary tract infection management were also collected.

Results: A total of 201 patients were randomized to a stent (112) and a no-stent (89) group. In the no-stent group 11 patients received a stent due to intraoperative findings and were excluded from study. At 3 months there were significantly more cases of urinary leakage (8.9% vs 0.9%, $p < 0.008$) and ureteral obstruction (7.7 % vs 0%, $p < 0.004$) in the no-stent than in the stent group. Mean time of stent removal was 74.3 days. A significant increase in urinary tract infections was observed when stent was left greater than 30 days after transplantation compared to the rate in the no-stent group ($p < 0.02$). An additional cost of £151 per patient was incurred in the no-stent group vs the stent group.

Conclusions: Using a ureteral stent at renal transplantation significantly decreases the early urinary complications of urine leakage and obstruction. However, there is a significant increase in urinary tract infections, primarily beyond 30 days after transplantation. Stent removal within 4 weeks of insertion appears advisable.

Key Words: kidney transplantation, ureter, stents, postoperative complications, cost-benefit analysis

Urological mechanical complications have historically contributed significantly to morbidity and mortality following renal transplantation[1] but they have become less frequent in the last 2 decades.[2–5] Urological complication rates between 0.22% and 14.1% were reported[5,6] but definitions varied and an accurate assessment of the incidence is difficult. At our center a 1995 audit of the records of 148 patients who received a renal transplant and in whom stents were not inserted routinely revealed a urological complication rate of approximately 15% (unpublished data).

Randomized trials evaluating the impact of stents are inconclusive (table 1).[5,7–11] However, stenting does not appear to affect long-term graft or patient survival.[12] A recent review confirmed the benefit of stenting for preventing major urological complications, although it pointed out the need for evaluating quality of life and economic issues.[13]

In this prospective, randomized, 3-month trial we assessed the impact of the routine use of Double-J ureteral stents in renal transplantation on the incidence of early urological mechanical complications and UTIs. Health care costs associated with routine ureteral stent use were also evaluated.

METHODS

Study Design and Performance

Patients undergoing renal transplantation at our center between November 1998 and October 2001 were invited to participate in the study. Pediatric recipients younger than 18 years were excluded, as were patients with urinary diversion, recipients of more than 1 previous transplant and those known to have an abnormal lower urinary tract. Randomization was done preoperatively by the sealed envelope technique. For patients randomized to receive no stent the protocol allowed a stent to be inserted if the ureter/bladder appearance was compromised during surgery. Such patients were then excluded from analysis. Detailed informed consent was obtained from all patients following approval from the local ethics committee.

Surgical Technique

All recipients underwent extravesical onlay ureteroneocystostomy using 4-zero absorbable continuous suture, which was performed by a consultant or resident under consultant supervision. All living donor nephrectomies were done by an open technique. In patients randomized to receive a stent a 6Fr 16 cm Double-J stent was inserted during anastomosis. The urethral catheter was removed at 5 days.

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Study received local ethics committee approval.
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TABLE 1. *Randomized trials of ureteral stents in kidney transplant recipients*

References	No. Pts	Stenting Duration	Significant Increase With Stenting	
			Urinary Complications	UTIs
Pleass et al[10]	300	3 Mos	Yes	No
Bassiri et al[9]	77	54 Days	No	Yes
Benoit et al[8]	194	1 Mo	Yes	No
Kumar et al[5]	100	1 Mo	Yes	No
Dominguez et al[7]	280	7–10 Days	No	No
Osman et al[11]	100	14 Days	No	Yes

The original plan was to remove all stents at 4 to 6 weeks. The stent was removed as a day surgery procedure with the patient under local anesthesia using a flexible cystoscope or under general anesthesia when combined with dialysis catheter removal.

Immunosuppression and Antibiotics

According to the protocol at our unit all patients were initiated on calcineurin inhibitor monotherapy unless there was a specific reason to use triple immunosuppression. All patients received a single intravenous dose of 1.2 gm co-amoxiclave if they were not allergic to penicillin, 1,000 mg methylprednisolone intravenously and 20 gm mannitol. All patients received 480 mg co-trimoxazole if not allergic for 6 months as prophylaxis against Pneumocystis carinii.

Monitoring and Management of Complications

Immediate postoperative care included daily measurement of renal biochemistry and full blood count. Ultrasonography, radioisotope scan or biopsy were done when clinically indicated. Urine was sent for culture at the time of catheter removal and as clinically indicated (midstream urine). All episodes of urinary leakage, obstruction, UTI, stent related problems and graft rejection were recorded.

Early urological mechanical complications were defined as urinary leakage or obstruction occurring within the first 3 months after transplantation. Urine leakage was defined as drainage or accumulation of urine around the graft or in the operative wound. Obstruction was defined as impaired renal transplant function with an ultrasound finding of pelvicaliceal dilatation. Antegrade nephrostogram was done to confirm the level of obstruction. UTI was defined as urine growth of greater than 10^5 organisms per ml or urine greater than 100 white blood cells per high power microscopic field in the presence of fever and/or urinary symptoms with graft dysfunction due to no other causes.

Health Care Costs

Direct health care costs associated with stenting, investigation and management of all urological mechanical complications and UTIs were recorded. They included costs related to stent insertion, removal, management of urinary leakages, obstruction or UTIs, ie radiological investigations and interventions, antibiotic therapy, surgical intervention and the cost of hospital stay related to UTIs, urinary leakage or obstruction. Standard costs were obtained from the relevant hospital departments, such as pharmacy, theater, laboratory, radiology, etc. Patient notes were reviewed individually and costs were allocated accordingly per patient.

Statistical Analysis

All analyses were based on the per protocol population. Univariate analyses of risk factors for urological complications and separately UTIs were performed from 2×2 contingency tables with significant differences evaluated by the chi-square or Fisher exact test. For urological complications the evaluated risk factors were mean recipient and donor age, gender, donor type, acute rejection, number of arteries, cold ischemic time and diabetes. For UTIs the risk factors examined were mean recipient age, gender, donor type, cold ischemia time, acute rejection and urological complications. Because there was only 1 mechanical complication in the stent group, univariate analysis of risk factors for complications was performed based on the total study population instead of on each treatment group separately. The OR and CI were calculated and $p < 0.05$ was considered significant. EPI Info™ 6 and SPSS®, version 9.0 statistical software was used.

RESULTS

Of 426 patients receiving a renal transplant at our center during November 1998 to October 2001, 201 (47%) consented to enter the trial. A total of 112 patients were randomized to receive a Double-J stent and 89 were randomized to receive no stent. The trial was initially designed to recruit 200 patients randomized at a 1:1 ratio. Randomization was done in batches of 50 patients. However, at the time of analysis it appeared that there had been an inadvertent clerical error, resulting in unequal numbers in the 2 groups. After obtaining statistical advice it was believed that this would not produce biased results. Following randomization a stent was inserted in 11 patients in the no-stent group due to intraoperative findings. These patients were excluded from analysis, such that the per protocol population comprised 190 patients, including 112 with a stent and 78 without a stent.

The treatment groups were similar in terms of recipient and donor demographics, etc (table 2). Significantly more patients in the no-stent group received a kidney from a living donor and acute rejection was more frequent in the stented than in the no-stent group (53% vs 36%).

There were no deaths during the 3-month study. There were 10 graft failures in the stent group and 3 in the no-stent group (8.0% vs 3.8%, not significant). No graft losses were due to urological complications.

Six cases of urinary obstruction occurred in the no-stent group vs none in the stent group (7.7% vs 0%, $p < 0.004$, table 3). In 3 cases obstruction was managed by PCN plus

TABLE 2. *Patient demographics and characteristics*

	Stent	No Stent	p Value
No. pts	112	78	
Mean recipient age (range)	43 (16–68)	43 (19–67)	Not significant
No. men (%)	63 (56)	53 (68)	Not significant
Mean donor age (range)	45 (8–68)	42 (9–71)	Not significant
No. cadaveric donor (%)	106 (95)	64 (82)	<0.005
No. previous transplant (%)	24 (21)	16 (21)	Not significant
Median hrs cold ischemia time (range)	19 (1–42)	22 (1–42)	Not significant
No. multiple renal arteries (%)	24 (21)	16 (21)	Not significant
No. acute rejection (%)	59 (53)	28 (36)	<0.02