Comparison of a magnetic retrieval device vs. flexible cystoscopy for removal of ureteral stents in renal transplant patients: A randomized controlled trial

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Abstract

Introduction: Placement of a ureteral stent at the time of renal transplantation can reduce complications when compared to non-stented anastomoses. Removal by flexible cystoscopy can be associated with discomfort, risk for infection, and high costs. New magnetic stents offer a means of bypassing cystoscopy by use of a magnetic retrieval device. Our objective was to compare clinical and cost-related outcomes of conventional and magnetic stents in patients undergoing deceased donor renal transplantation.

Methods: Patients were randomized to receive either a conventional or a Black-Star® magnetic stent. Clinical, procedural, and cost outcomes were assessed, and the Ureteral Stent Symptom Questionnaire (USSQ) was administered with the stent in situ and after stent removal. All variables were compared between groups.

Results: Forty-one patients were randomized to conventional (n=19) or Black-Star (n=22) stent. The total time for stent removal under cystoscopy was significantly longer compared to Black-Star removal (6.67±2.47 and 4.80±2.21 minutes, respectively, p=0.019). No differences were found in the USSQ domains between groups. Rates of urinary tract infections and surgical complications between groups were similar. Stent removal was well-tolerated in both groups. Black-Star stent use resulted in a cost savings of $304.02 Canadian dollars (CAD) per case.

Conclusions: USSQ scores suggest that stent removal with the Black-Star magnetic stent is as equally well-tolerated as flexible cystoscopy by renal transplant patients. Black-Star stent removal was significantly faster than conventional stents. No differences in discomfort, infection rate, or complication rate were found. Use of the Black-Star stent resulted in an estimated annual savings of $27 360 CAD at our centre.

Introduction

Renal transplantation is the treatment of choice for end-stage renal disease. Intraoperatively, a stent is placed in the transplant ureter between the renal pelvis and the bladder to reduce complications. The advantages of a stented anastomosis include continuous decompression of the ureter, reduced anastomotic tension, less kinking of the ureter, and maintaining a patent lumen against edema or external compression.[1,2] Postoperatively, the use of a ureteral stent has been shown to reduce the incidence of urinary leaks and ureteral stenosis. These complications can contribute to increased patient morbidity, graft loss, and prolonged hospital stay in up to 3–9% of renal transplant cases.[1-4]

The placement of a ureteral stent is not always without side effects. Stents have been associated with an increase in the number and severity of urinary tract infections (UTIs), intermittent hematuria, stent migration, and encrustation of the outer surface of the stent.[5] Removal of a ureteral stent, typically done via flexible cystoscopy, can cause pain and distress for patients. Cystoscopy itself is often associated with discomfort or pain to the patient (38%), transient urinary frequency (15%), urgency (14%), and/or UTI (8%).[6] The Black-Star® double-J ureteral stent with magnetic retrieval device (Urotech, Achenmühle, Germany) was approved by Health Canada in 2017 and offers a means of eliminating the need for flexible cystoscopy for stent removal, which can be done outside of the cystoscopy suite. Magnetic ureteral stents were first proposed nearly 30 years ago;[7] however, patient discomfort and poor magnetization limited their uptake early on. Recent advancements in materials and stent design have since addressed these concerns.[8,9] Using a small biocompatible magnet attached to a polyurethane body (Fig. 1), the Black-Star stent has shown reproducible success in patients post-ureteroscopy without added patient discomfort, while affirming that retrieval is simple procedure (Fig. 2).[10]

The objectives of this study were to evaluate clinical, procedural, and cost-related outcomes relative to the use of the Black-Star stent and retrieval device vs. a traditional ureteral stent with cystoscopy removal in deceased-donor renal transplant patients at a single center. An additional aim was to determine the feasibility of conducting a larger randomized, controlled trial.

Methods

This was a prospective, randomized, controlled trial at a single transplant center in Ontario, Canada. Research ethics board approval was obtained by our affiliated academic institution. All patients meeting inclusion criteria in our transplant center were asked to participate in the study between May 2017 and April 2018. Following the informed consent procedure, patients were randomly allocated to one of two study arms: magnetic ureteral stent (Black-Star) (intervention) or conventional ureteral stent (controls). Once informed consent was gained, randomization was conducted using a random number generator via Research Randomizer® (*www.randomizer.org*) and participants were assigned a unique study identification number. Neither patients nor surgeons were blinded to group allocation. All patient identifiers were removed for analysis and confidentiality was maintained.

Study population

Prior to gaining informed consent, patients were screened for inclusion and exclusion criteria. Inclusion criteria were as follows: 1) patients were at least 18 years of age at the time of recruitment and capable of giving informed consent; and 2) patients were scheduled for deceased-donor renal transplant surgery at our center. Patients were excluded if they were undergoing living-donor renal transplantation, as at our center, live donor recipients receive stents based on surgeon discretion only.

Outcome measures

The primary outcome measure was patient comfort of the stent in situ and after removal using the validated Ureteral Stent Symptom Questionnaire (USSQ), which was developed by the Bristol Urological Institute (Southmead Hospital, Bristol, U.K.).[11] Secondary outcome measures included: 1) stent retrieval time in minutes; 2) infection rate (number of urine culture positive tests with stent in situ and after removal); 3) cost-effectiveness in Canadian dollars (CAD), including cost of disposables, sterilization of instruments, use of cystoscopy suite, and nursing and physician charges (mean cost per procedure); and 4) to determine the feasibility of conducting a larger randomized, controlled trial.

Black-Star stent

The Black-Star stent is designed to allow for easy removal using a magnet attached to the distal end of the stent (Fig. 2). In this study, a 10 cm 4.8 Fr Black-Star stent was used. Removal of the stent was conducted using a 9 Fr, 40 cm retrieval device. The catheter-like retrieval device is composed of soft polyurethane that features a 30° Tiemann tip, which facilitates interaction between the magnetic components of the stent and retrieval device (Fig. 1). This allows the stent to be removed per urethra without the need for cystoscopy. Black-Star stents were provided for this study by Red Leaf Medical, Inc. (Mississauga, ON, Canada).

Data collection and analysis

Prior to surgery, a series of baseline characteristics, including patient demographic information, clinical history, and medical comorbidities, was collected. Intraoperatively, all major and minor complications and any anatomical variants (e.g., number of ureters) were noted. Total surgical time was recorded, as well as any difficulties with placement of the stent or additional operative time due to stent placement.

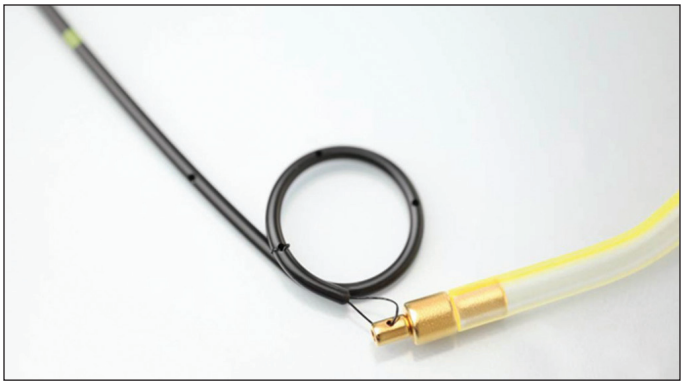

Fig. 1. Black-Star® stent design (Urotech, Achenmühle, Germany).

Fig. 2. Black-Star® magnetic separation design (Red Leaf Medical, Inc., Mississauga, ON, Canada).

All participants were followed from the time of surgery to one week post-stent removal. The USSQ was completed at four weeks post-renal transplantation ("stent in situ" questionnaire) and at one week following stent removal ("post-stent" questionnaire).[11] Both questionnaires are comprised of domains for urinary issues, pain index, general health, work performance, and sexual matters. Each domain can be scored and evaluated separately from the overall USSQ score. The questionnaires also contain a global quality of life score and an option for patients to report any additional problems related to the stent, as well as a space for free-text comments. Details of the validation and scoring of the USSQ are described in Joshi et al.[11]A urinalysis and urine culture were collected one week post-stent removal to assess the rate of UTIs in each group.

Data analysis was conducted using descriptive statistics, Chi-squared tests, and independent samples t-tests for between groups analysis. Statistical significance was set at α=0.05. All analyses were performed using SPSS version 26 (IBM SPSS Statistics, Armonk, New York, U.S.).

Study procedures

All cases were performed by one of three transplant surgeons at our center, using the identical surgical approach. After back table preparation of the graft, extraperitoneal access was achieved using a modified Gibson's incision. Reconstruction of the urinary tract was done via urethrovesical anastomosis (Lich-Gregoir technique) using either the Black-Star double-J stent or a conventional 12 cm 4.8 Fr double-J stent. The placement of each stent was performed over a guidewire.

Patients randomized to the conventional stent group were seen in followup for stent removal via flexible cystoscopy at six weeks post-transplant. Removal was conducted by one of two renal transplant fellows at our center. Patients were brought to the cystoscopy suite, where the stents were removed under sterile technique. All patients received local anesthetic in the form of 11 cc Instillagel® (Farco-Pharma GmbH, Cologne, Germany), a lidocaine and chlorhexidine gel administered per urethra prior to insertion of the flexible cystoscope. A flexible stent grasper was inserted through the working port of the cystoscope, allowing the stent to be removed. All cystoscopes were 16.2 Fr size. Time was recorded from when the patient entered the cystoscopy suite until the stent was removed. Patients were asked to state whether the removal was comfortable (yes/no).

Patients randomized to the Black-Star group underwent stent removal in our outpatient transplant clinic by one of two renal transplant fellows, also at six weeks post-transplant. Under sterile technique, patients were given 11 cc Instillagel® local anesthetic followed by insertion of the magnetic retrieval device. This is done blindly and requires contact between the retrieval device and magnetic portion of the stent. Time was recorded from when the patient entered the room until the stent was removed. If a first pass of the retrieval device failed to remove the stent, a second pass was performed. Patients were then asked to state whether the removal was comfortable (yes/no).

Cost analysis

A cost analysis was performed to evaluate the cost per case between the Black-Star and conventional stent. Black-Star costs included the price of the stent and retrieval device, as well as supplies used at the time of removal (Instillagel). Conventional stent costs included the cost of the stent, supplies (drapes, local anesthetic, irrigation, and tubing), processing costs of the flexible cystoscope, surgeon and nursing fees, and facility fees at our cystoscopy center.

Results

A total of 41 patients were recruited and randomized, with 22 patients in the Black-Star group and 19 in the conventional stent group. In the Black-Star group, one patient was admitted to the intensive care unit for an unrelated medical event prior to having their stent removed. This patient's stent was removed at the bedside in the intensive care unit. Additionally, one Black-Star patient required stent removal via flexible cystoscopy after failure to remove the stent using the magnetic retrieval device. This patient had prolonged stent placement due to a postoperative anastomotic leak, which resulted in significant encrustation of the stent. The stent was successfully removed via flexible cystoscopy and the patient's post-stent questionnaire data were not included in the analysis.

Demographic and baseline characteristics are reported in Table 1. There was no significant difference between groups in age, sex, medical comorbidities, or baseline lower urinary tract symptoms. Urinary index scores on the USSQ with stent in situ were not significantly different between groups, with a mean score of 21.48/56 (±5.47) in the Black-Star group and 22.47/56 (±3.89) in the conventional stent group (p=0.515) in the conventional stent group (for the urinary index domain, a lower score indicates fewer symptoms) (Table 2). Analysis of the other domains of the USSQ also showed no significant difference between groups with the stent in situ (Table 2). Mean USSQ scores for the urinary index one week post-stent removal were 21.75/56 (±4.06) in the Black-Star group and 20.64/56 (±4.06) in the conventional stent group (p=0.481). This was consistent for each domain in the post-stent USSQ (Table 2).

The rate of UTIs based on positive urine culture collected one week post-stent removal, were not significantly different between groups, with two positive cultures in the Black-Star group and four in the conventional stent group (p=0.374). Six

Table 1. Patient demographics and medical comorbidities

Variable	Black-Star® stent (n=22)	Conventional stent (n=19)	p
Age, mean (SD)	60.41 (±11.36)	57.16 (±14.96)	0.434
Gender, n (%)			
Male	15 (68.2)	12 (63.2)	0.735
Female	7 (31.8)	7 (36.8)	
Comorbidities, n (%)			
Hypertension	12 (54.5)	9 (47.4)	0.647
Coronary artery disease	5 (22.7)	2 (10.5)	0.301
Diabetes mellitus	7 (31.8)	4 (21.1)	0.438
Asthma	0 (0)	1 (5.3)	0.276
Other	6 (27.3)	3 (15.8)	0.376
Previous LUTS, n (%)			
Urgency	0 (0)	0 (0)	
Frequency	0 (0)	0 (0)	
Dysuria	0 (0)	0 (0)	0.347
Poor stream	1 (4.5)	0 (0)	
Straining	0 (0)	0 (0)	
Sense of incomplete voiding	0 (0)	0 (0)	
Hematuria	0 (0)	0 (0)	
Nocturia	0 (0)	0 (0)	
Incontinence	0 (0)	0 (0)	
Pelvic pain	0 (0)	0 (0)	

LUTS: lower urinary tract symptoms; SD: standard deviation.

patients in the conventional stent group reported discomfort at the time of stent removal compared to two patients in the Black-Star group (p=0.213). The Black-Star stents required significantly less time for removal compared to the conventional stents. Mean time for stent removal with the Black-Star magnetic retrieval device was 4.80±2.21 minutes compared to 6.67±2.47 minutes for conventional stent removal with flexible cystoscopy (p=0.019). Upfront costs for the Black-Star stent were higher than the conventional ureteral stent (Table 3). The use of the Black-Star stent resulted in a cost savings by avoiding the need for a postoperative flexible cystoscopy. The estimated cost of a single conventional stent removal with flexible cystoscopy at our center was $429.28 CAD. When this is accounted for, the Black-Star stent resulted in cost savings of $304.02 CAD per case.

Discussion

Flexible cystoscopy has been associated with patient discomfort, pain, and anxiety, particularly among younger men.[12-14] Several studies have evaluated methods of reducing patient distress at the time of flexible cystoscopy.[15,16] Modifications to ureteral stents have been developed with the aim of eliminating the need for cystoscopy altogether. Recent advancements include magnetic ureteral stents that do not require cystoscopy for their removal, and biodegradable stents that require no removal at all.[17-19] Our study adds to the published data on the Black-Star magnetic ureteral stent as a well-tolerated alternative to conventional ureteral stents;[17-20]

Table 2. Mean USSQ scores with stent in situ and 1week post-stent removal

	Black-Star® mean (SD)	Conventional mean (SD)	p
Urinary index score, stent in situ	21.48 (5.47)	22.47 (3.89)	0.515
Urinary index score, one week post-stent removal	21.75 (5.33)	20.64 (4.06)	0.481
Global score, stent in situ	3.58 (1.64)	3.21 (1.23)	0.439
Global score, one week post-stent removal	3.60 (1.72)	4.20 (1.01)	0.255
General health score, stent in situ	11.29 (3.79)	13.50 (4.53)	0.138
General health score, one week post-stent removal	11.71 (4.71)	13.06 (4.49)	0.398
Pain index score, stent in situ	1.75 (3.74)	1.68 (4.42)	0.960
Pain index score, one week post-stent removal	3.00 (5.47)	2.33 (6.83)	0.331

SD: standard deviation; USSQ: Ureteral Stent Symptom Questionnaire.

however, our study further contributes to the literature base, as the use of these stents were within the deceased-donor renal transplantation setting.

Existing published data have focused primarily on the use of magnetic stents among pediatric and post-ureteroscopy patients.[17,21,22] In our study, deceased-donor renal transplantation patients tolerated the Black-Star stent without any major complications. Intraoperative reports indicated that the Black-Star stents were easily placed, with no increase in operative times. All deceased-donor renal transplantation patients at our center receive a ureteral stent at the time of surgery and many of them undergo preoperative evaluation of their lower urinary tract with cystoscopy. This allowed many patients to compare their experience with a magnetic stent retrieval device to their prior experience with flexible cystoscopy. The superior location of the stent within the bladder of transplant patients (compared to the usual location of a native ureteral orifice) did not cause any difficulty with removal. We were not able to demonstrate any significant differences in patient comfort with stent removal via a magnetic retrieval device compared to flexible cystoscopy. This is not consistent with previously studies,

Table 3. Cost-analysis of Black-Star® and conventional stents per case

	Black-Star® costs ($CAD)	Conventional stent costs ($CAD)
Cost of stent	183.96	64.85
Flexible cystoscopy (total cost including materials and fees)	–	429.28
Outpatient in-clinic stent removal (supplies)	6.15	–
Total cost	190.11	495.13
Difference	304.02	

which showed that the Black-Star stent was preferred to flexible cystoscopy with respect to patient comfort during the removal.[17,20] Rasseweiler et al found that patients who had a Black-Star stent placed following ureterorenoscopy reported significantly less pain at the time of removal compared to those with a conventional stent using a visual analog scale.[17] Likewise, O'Connell et al found that among patients who underwent a prior cystoscopy, 71% preferred the magnetic retrieval device of the Black-Star stent.[20] Our study's patients responded to the yes/no question, "Was stent retrieval comfortable?" to assess discomfort at the time of stent removal. We feel that this binary question limited our ability to detect more subtle differences in patient discomfort and/or distress at the time of stent removal between groups. The use of a visual analog scale, as reported in other Black-Star studies, may have yielded more useful and consistent results and will be considered in future research.

Although the Black-Star stent was well-tolerated in our study, there are important considerations for patient selection. One patient in the Black-Star group required removal of their stent via flexible cystoscopy, which was delayed well beyond the six-week mark due to an anastomotic urine leak. As a result of stent encrustation, we were unable to remove the Black-Star using its retrieval device. As this is a rare complication, we feel that the Black-Star stent remains a viable option for deceased-donor renal transplantation patients, as the majority will have their stent removed before significant encrustation occurs. In addition to stent encrustation, the presence of a large median lobe has been reported as a barrier to removal using the magnetic retrieval device.[17] This may be a preoperative consideration for stent selection in patients with a documented occlusive median lobe.

By eliminating flexible cystoscopy, we have shown that in deceased-donor renal transplant patients, magnetic ureteral stents can be removed in less time with decreased costs when compared to conventional stent removal with flexible cystoscopy. In our study, time was recorded from when patients entered the room to the time of stent removal. The removal time for conventional stents included the turnover and instrument preparation factors unique to the cystoscopy suite, while the Black-Star removal was conducted in an outpatient clinic room. However, in observing the significant time differences between the conventional and Black-Star removal (6.67±2.47 and 4.80±2.21 minutes, respectively, p=0.019), it is important to consider the overall time saved by bypassing the cystoscopy suite for magnetic stent removalThe cost savings observed in our study are consistent with previous reports, which had estimated savings of €100–810 (approximately $155–1245 CAD).[17,20] Despite a higher upfront cost of the Black-Star vs. a conventional stent ($119 vs. $64.85 CAD, respectively), the use of the Black-Star stent resulted in considerable cost savings by avoiding the physician, nursing, and processing fees of a flexible cystoscopy (Table 3). At our center, the use of the Black-Star stent in all deceased-donor renal transplantation alone would generate an annual cost savings of approximately $27 360 CAD.

Our study is limited by its small sample size. However, this study confirms the feasibility of conducting a larger randomized, controlled trial to analyze clinical and cost-related differences between the use of conventional and Black-Star magnetic stents in deceased-donor renal transplantation patients. The addition of a visual analog scale or Likert-type pain scale at the time of stent removal may increase the ability to more accurately detect differences in pain and discomfort with flexible cystoscopy compared to the use of a magnetic retrieval device. Furthermore, UTIs were estimated based on culture results alone and were not confirmed by patient symptoms. This may have led to some asymptomatic bacteriuria being labeled as a UTI. Given the low overall rate of culture positive results, we feel this is unlikely to have changed our results.

Conclusions

The Black-Star magnetic stent and retrieval device offers an alternative to conventional ureteral stents in deceased-donor renal transplantation patients. In our study, the Black-Star stent was well-tolerated, with no increase in major complications or patient discomfort when compared to the conventional stent. Despite its higher upfront costs, the use of the Black-Star stent and retrieval device has the potential to offer considerable cost savings over conventional stents by eliminating the need for postoperative cystoscopy. Further study with larger, multicenter, randomized, controlled trials should be conducted to determine the clinical and monetary value of using magnetic stents, such as the Black-Star, vs. conventional ureteral stents in renal transplant patients. It is important to note that during the course of this study, the Black-Star double-J ureteral stent with magnetic retrieval device (Urotech, Achenmühle, Germany), which was approved for use in Canada in 2017, was widely available and used. However, in early 2020, its distribution was discontinued in Canada, although it is still available in other world markets.

Competing interests: Dr. Kapoor has been an advisory board member for and participated in clinical trials supported by Amgen, Astellas, GSK, Janssen, Novartis, Pfizer, and Sanofi. The remaining authors report no competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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