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Comparison of Magnetic and Conventional Double-J Stent Following Kidney Transplantation: A Randomized Controlled Trial

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Background. This monocentric, randomized controlled trial aims to compare the outcomes of kidney transplant recipients with magnetic double-J (DJ) stents versus conventional DJ stents. Specifically, we assessed stent-related symptoms, procedural difficulties, pain and duration of removal, and associated costs. **Methods.** A total of 30 patients were randomly assigned to receive either a magnetic DJ (mDJ) stent or a conventional, standard DJ (sDJ) stent during kidney transplantation using the Lich-Gregoir technique. Quality of life was evaluated with the USSQ 7–10 d postoperation. sDJs stents were removed cystoscopically by a urologist while mDJ stents were removed bedside by a transplant surgeon. The duration of removal and procedure-associated pain were documented. Questionnaires for physicians and patients were used to assess peri-interventional experience and issues. Additionally, costs associated with the removal of both stents were analyzed. **Results.** Quality of life showed no differences between the groups. Stent removal was successful in all cases, with no differences in duration of removal ($P = 0.24$) or major issues. Patients reported comparable pain levels during the removal of mDJs ($P = 0.55$) and higher satisfaction, although this was not statistically significant ($P = 0.27$). Cost analysis revealed a reduction of approximately €172 with the use of mDJ. **Conclusions.** The use of mDJ stents in kidney transplantation is a safe alternative associated with comparable pain during removal. Additionally, it offers cost savings and reduces the logistical burden for both patients and hospitals.

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Kidney transplantation (KTx) is the preferred treatment for end-stage renal disease, offering improved quality of life (QoL) and increased life expectancy for patients compared with dialysis.[1] Following ureteroneocystostomy as part of KTx, ensuring proper urine drainage from the transplanted kidney is crucial for graft function and overall patient well-being. To facilitate this and prevent urological complications such as stenosis or leakage, ureteral stents, such as double-J (DJ) stents, are commonly placed during the surgical procedure.[2] Despite their utility in facilitating urine drainage, DJ stents are associated with potential complications. Common complications include DJ migration, stent obstruction, irritative bladder symptoms, hematuria, urinary tract infection, or encrustation.[3]

The traditional method of removing a DJ stent cystoscopically is generally considered safe and effective. However, it can be associated with significant discomfort for patients. The manipulation by grasping and extraction of the stent using forceps can elicit sensations of pressure and pain. As a result, >40% of patients with both rigid and flexible cystoscopy report at least mild pain during the procedure.[4] In some cases, these perceptions may necessitate the use of sedation or anesthesia. This, in turn, carries the risk of anesthesiological complications, is time-consuming, and is associated with high costs.

Alternative to cystoscopy, there are other methods for removing a DJ stent. One method involves using a retrieval string attached to the stent, allowing for its removal without

an invasive procedure. However, this approach requires careful placement to ensure the retrieval string is not inadvertently dislodged.[5] Furthermore, there is the option to secure the DJ stent to a suprapubic catheter, thereby simplifying its removal.[6] A suprapubic catheter, nonetheless, represents an additional source of infection and is associated with both intra- and postoperative complications, such as dislocations and hematuria.[7] Another innovative technique is the use of a magnetic DJ stent, which can be removed using a special retrieval device similar to the bladder catheterization procedure.[8] Taylor and McDougall[9] removed ureteral stents, each supplied with a stainless steel bead secured at its distal end, using a catheter equipped with a magnet at its proximal end. Although cystoscopic removal was not necessary, the size of the retrieval catheter resulted in discomfort.[9] With the introduction of new magnetic stents, the size of the catheter could be further reduced without losing magnetic force.[10]

The primary objective of this prospective, monocentric, randomized controlled trial (RCT) is to compare the outcomes of kidney transplant (KT) recipients who received magnetic DJ stents versus those who received conventional DJ stents. Specifically, we aim to assess DJ stent–associated symptoms and peri-interventional difficulties from the physician's and patient's point of view. Furthermore, we calculated the costs associated with removing the DJ stents in both groups.

MATERIALS AND METHODS

This prospective, randomized, single-center study was conducted at the Medical Centre, University of Freiburg, Germany, from July 2018 to March 2021. Approval from the local Ethics Committee under the number 426/17 and patient consent was obtained.

A total of 31 patients undergoing KTx at our institution were screened for eligibility. Inclusion criteria comprised adult patients (age 18 y or older and 65 y or younger) undergoing primary living KTx with placement of a ureteral stent. Exclusion criteria encompassed previous renal transplant recipients, patients in acute medical emergencies, and the inability to provide informed consent. Eligible patients were randomly assigned in a 1:1 ratio to receive either a magnetic DJ stent (mDJ, intervention) or a conventional, standard stent (sDJ, control) based on ABO compatibility and sex. Neither the surgeon nor the patient was blinded regarding group assignment. KTx were performed by 2 experienced transplant surgeons. Ureteral stent placement was performed intraoperatively following ureteroneocystostomy (Lich-Gregoir technique). Removal of mDJ was conducted at the bedside by a transplant surgeon or experienced transplant nurse between days 10 and 14 after transplantation. In case of a medical condition requiring longer DJ placement, removal of the mDJ was performed during an outpatient visit. Alternatively, the sDJ was removed cystoscopically by urologists in an operating room during the same period (Figure 1). In all cases, a local anesthetic was applied before removing the DJ stent (Farco-Pharma GmbH, Cologne, Germany). The timing started when the doctor entered the room and ended after the DJ was removed.

ABO-incompatible KT recipients received rituximab (375 mg/m²) 30 d before transplantation, followed by tacrolimus (12–15 ng/mL), mycophenolate mofetil (2 g/d), and prednisone (30 mg/d) starting 7 d preoperatively. Basiliximab

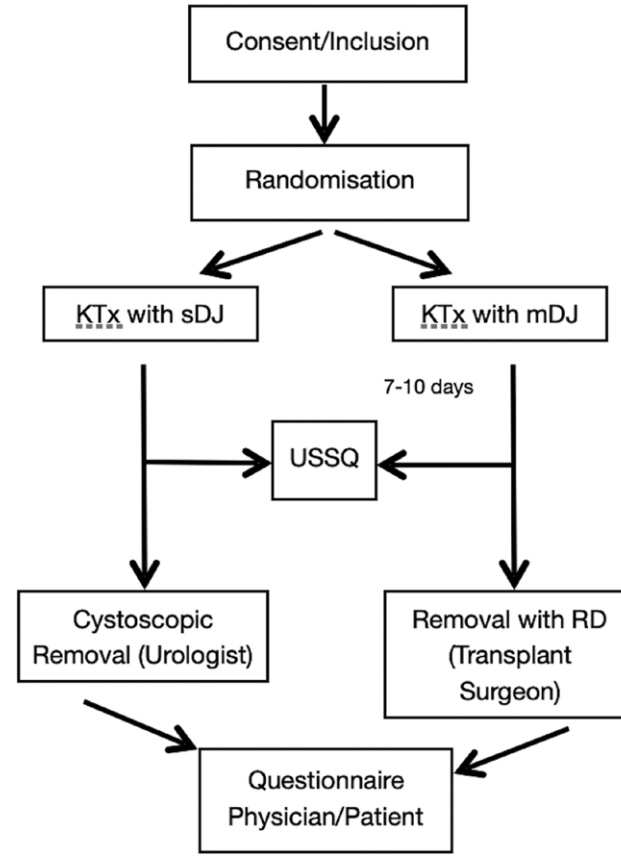

FIGURE 1. Study design. Following consent, participants were randomly assigned to either receiving a sDJ stent during KTx or a mDJ stent. After 7–10 d, quality of life was evaluated using the USSQ. Conventional stents were removed cystoscopically in the urology outpatient clinic by an urologist. mDJ stents were removed using the magnetic RD by a transplant surgeon/nurse, either in the intermediate care unit or as an outpatient procedure. Subsequently, stent removal was evaluated by both physician and patient. DJ, double-J; KTx, kidney transplantation; mDJ, magnetic DJ; RD, retrieval device; sDJ, standard DJ; USSQ, Ureteral Stent Symptom Questionnaire.

(20 mg) was administered on the day of surgery and postoperative day 4. Prednisone was tapered from 500 mg at surgery to 15 mg by discharge at around day 14. Tacrolimus targets were reduced to 6–12 ng/mL on day 7. Prophylaxis included valganciclovir (3 mo), trimethoprim/sulfamethoxazole (6 mo), and fluconazole (28 d).

ABO-compatible KT recipients received similar basiliximab induction therapy. Prednisone was tapered from 250 mg at surgery to 125 mg on day 1, 50 mg on day 2, and 15 mg at discharge. Tacrolimus (8–12 ng/mL), mycophenolate mofetil (2 g/d), and maintenance immunosuppression were identical to ABOi-KT. Prophylaxis included fluconazole (28 d), trimethoprim/sulfamethoxazole (6 mo), and valganciclovir (3 mo for high/intermediate-risk cases).

The magnetic ureteral DJ stent, produced by UROTECH GmbH in Achenmühle, Germany, under the trademark Black Star, is made of polyurethane and incorporates a magnet affixed to its distal end via a string. These stents adhere to a standard diameter of 6 Fr and a length of 22 cm, mirroring the specifications of conventional DJ stents that we used for the sDJ group. The retrieval device, made from soft polyurethane, features a magnetic tip at its extremity (Figure 2).

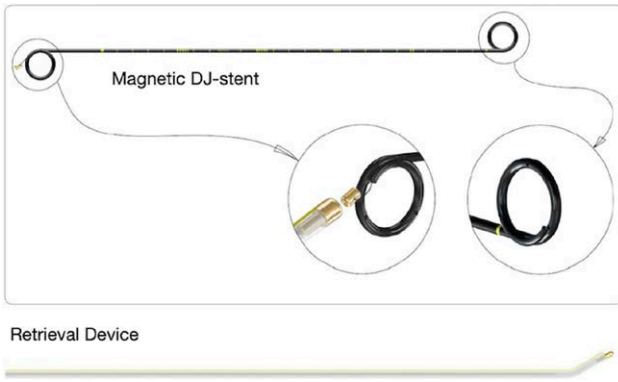

FIGURE 2. Magnetic Black Star ureteral stent and the corresponding retrieval device from Urotech, Achenmühle, Germany. DJ, double-J.

Nonmagnetic titanium forceps were used during insertion to prevent entanglement with the magnetic distal end. Insertion of the retrieval device mimicked the procedure for a urinary catheter, with the magnetic ends facilitating the seamless removal of the magnetic ureteral stent. Surgeons could discern the connection between the 2 magnets through tactile feedback and, at times, auditory cues.

Baseline characteristics of patients, such as sex, age, body mass index, and ABO compatibility, were collected after inclusion in the study. The primary endpoints include the QoL with the DJ stent in situ, measured using a USSQ validated for the German language,[11] encompassing domains such as pain, overall health status, sexual health, voiding symptoms, and other stent-related issues. Patients completed the questionnaire around the fifth day posttransplantation. The USSQ was selected to compare QoL between the mDJ and sDJ groups, aiming to demonstrate that the mDJ is not inferior to the sDJ in terms of QoL. Although the USSQ is validated for stent-related evaluations, it may not fully capture short-term differences, which was taken into account. To address this, additional secondary endpoints were included to complement the primary results. The secondary endpoints were measured immediately after DJ removal using a self-designed questionnaire for the physician and a questionnaire for the patient. Patients were to assess their peri-interventional experience using a Likert scale based on 6 questions. Additionally, they were asked to answer a dichotomous question regarding whether the procedure was painful and to indicate the intensity of pain using a visual analog scale. Finally, satisfaction with the procedure was to be determined using a grade. These aimed to determine whether mDJ removal caused less or at least the same level of pain as sDJ removal and to evaluate overall patient comfort. Physicians were instructed to note any potential issues during removal, the macroscopic condition of the ureteral stent, signs of bleeding, any special occurrences, and the duration of removal in their questionnaire. Finally, they were also asked to assign a grade for the practical feasibility of mDJ removal (**Tables S1 and S2, SDC,** http://links.lww.com/TXD/A744).

Cost analysis was conducted to compare the costs per DJ removal between the 2 groups. For the mDJ group, the cost calculation included the purchase price of the mDJ catheter with the retrieval catheter. The cost of removing a conventional DJ catheter consists of several components. In addition to the purchase price of a standard DJ stent, costs for sterile drapes for cystoscopic removal, fees for the treating urologist and the assisting nurse, cost of medical infrastructure and nonmedical infrastructure, the procedure itself, and sterilization of the instrument must be calculated.

Data analysis involved appropriate statistical methods, including chi-square tests, Fisher exact tests, and Mann-Whitney *U* test for categorical and continuous variables, with statistical significance set at a *P* value of <0.05. All statistical analyses were conducted using SPSS version 28 (IBM SPSS Statistics, Armonk, NY).

RESULTS

A total of 31 participants were enrolled in this RCT conducted at a single center. A participant passed away following readmission 1 wk after initial discharge due to severe influenza infection with consecutive lung failure, leading to her subsequent exclusion from the study. Participants were randomly assigned to receive either the sDJ stent (n = 15) or the mDJ stent (n = 15). Baseline demographics and clinical characteristics were well balanced between the 2 groups (Table 1). Stent removal was successful in all cases. There was no difference in the duration of DJ stent placement between the mDJ group (24.1 ± 19.1) and the sDJ group (28.9 ± 25.2; *P* = 0.35).

The USSQ was used on the 7–10 postoperative days after KTx to assess the influence of the indwelling DJ stent on QoL. The categories "work performance" and "sexual matters" could not be evaluated because of the ongoing inpatient stay. The "general health" category could also only be assessed to a limited extent, as it was not yet possible to engage in strenuous sports or lift heavy objects. Fifteen USSQs from the sDJ group and 14 USSQs from the mDJ group were analyzed. In the "urinary symptoms" category, there was no significant difference in any of the aspects surveyed, such as micturition frequency (sDJ 3.5 ± 1.2 versus mDJ 3.3 ± 1, *P* = 0.43), nocturia (3.9 ± 1.2 versus 3.9 ± 1.2, *P* = 0.98), or hematuria (2.4 ± 1.4 versus 2.1 ± 1.3, *P* = 0.4). A similar picture emerges with regard to the incidence of pain (40% versus 42.9%, *P* = 0.59). In both groups, the localization of pain was predominantly localized in the bladder region (66.7% versus 50%). Other regions mentioned in the sDJ group were the penis (66.7%) and the inguinal region (16.7%), whereas patients in the mDJ group also reported the localization of pain in the inguinal region (33.3%) but also over the kidney (33.3%). The sum of all visual analog scale values of the regions labeled as painful did not differ between the 2 groups (8.4 ± 3.6 versus 7.4 ± 6.4, *P* = 0.49). There were also no differences with regard to pain during voiding in general (4 ± 1.3 versus 2.3 ± 0.5, *P* = 0.41)

TABLE 1.

Baseline characteristics

Characteristics	sDJ (N = 15)	mDJ (N = 15)	*P*
Sex (male/female)	9/6	8/7	0.78
Age, y	42.7 ± 15.1	51.5 ± 16.4	0.09
BMI	25.3 ± 4.6	24.6 ± 3.9	0.84
DJ placement, d	28.9 ± 25.2	24.1 ± 19.1	0.35
ABO compatibility (yes/no)	13/2	11/4	0.54
USSQ	15 (100%)	14 (93.3%)	
Patient Questionnaire	8 (53.3%)	15 (100%)	
Physician Questionnaire	7 (46.7%)	15 (100%)	

BMI, body mass index; DJ, double-J; mDJ, magnetic DJ; sDJ, standard DJ; USSQ, Ureteral Stent Symptom Questionnaire.

or around the kidney region (0% versus 7.2%, $P = 0.48$), nocturnal complaints (2.3 ± 2.1 versus 2.3 ± 1.5, $P = 0.41$), or pain after physical activities (3.3 ± 2 versus 3 ± 1.4, $P = 0.7$). Consequently, the use of analgesic medication (3 ± 1.8 versus 2.3 ± 1.5, $P = 0.59$), impact on QoL (3.7 ± 1.4 versus 2.2 ± 0.45, $P = 0.13$), and the pain category in general were similar in both groups (25.8 ± 9.6 versus 20.9 ± 9.1, $P = 0.49$).

Although general health is affected by both types of stents, there is no difference between both groups. Aspects investigated are difficulties with light physical exertion (1.9 ± 1.4 versus 1.6 ± 0.9, $P = 0.91$), tiredness and fatigue (2.7 ± 1.3 versus 2.4 ± 1, $P = 0.59$), well-being (2.6 ± 1.4 versus 2.1 ± 0.9, $P = 0.45$), and global QoL with stent in situ (3.9 ± 1.6 versus 3.1 ± 0.9, $P = 0.27$). Additional problems such as the feeling of a urinary tract infection also did not differ (2.5 ± 1.5 versus 1.8 ± 1.4, $P = 0.31$).

After the removal of DJ stents, different questionnaires were assessed by both physicians and patients. In the mDJ group, analysis was conducted on 15 questionnaires from physicians and patients alike. Conversely, within the sDJ group, 7 questionnaires from physicians and 8 questionnaires from patients were examined. From the physicians' perspective, there were no issues with removal in either group. Similarly, the duration of removal did not differ significantly (4.1 ± 2.2 versus 3 ± 1.5 min, $P = 0.24$; Figure 3A). Following removal, slight encrustation was observed in 1 mDJ stent, although the difference compared with the sDJ group was not significant (0% versus 6.6%, $P = 0.84$). Additionally, in the mDJ group, 1 case exhibited clotted blood postremoval and 2 cases with small amounts of blood after cystoscopic removal; however, again, the difference was not significant (28.5% versus 6.6%, $P = 0.41$). Ultimately, the handling and practical feasibility of mDJ removal were rated by physicians with a grade of 1.1 ± 0.4. In 1 instance, it was noted that the mDJ could only be removed after complete bladder emptying, whereas in another case, premature removal was necessary due to stent dislocation into the urethra.

A questionnaire was used to assess patients' postremoval experiences after the DJ stent procedure. Specific inquiries were directed toward preintervention concerns, the procedural ease of removal, perceived duration, subjective burden, overall success, and willingness to undergo the intervention again. Analysis revealed no notable distinctions between the 2 cohorts concerning individual facets and aggregate scores (15.4 ± 4.8 versus 11.9 ± 4.5, $P = 0.065$). In the sDJ cohort, 62.5% of participants reported experiencing pain, compared with 60% in the mDJ cohort ($P = 0.63$). Although a trend favoring the mDJ cohort was observed regarding pain severity during ureteral stent removal, the result was not statistically significant (2.5 ± 2.2 versus 1.9 ± 1.9, $P = 0.55$; Figure 3B). Overall, patients from the mDJ cohort exhibited higher levels of satisfaction with the stent removal procedure, although this difference did not reach statistical significance (1.8 ± 0.9 versus 1.3 ± 0.5, $P = 0.27$).

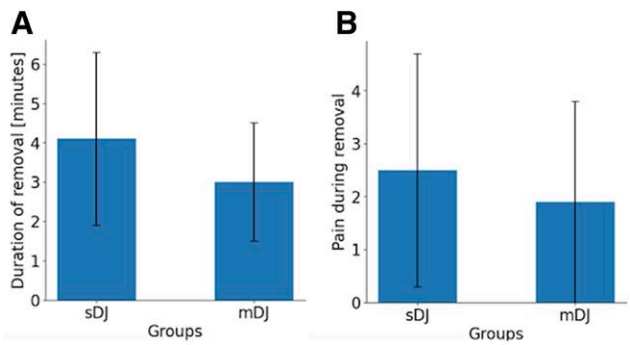

FIGURE 3. Pain and duration of removal. Duration of removal in minutes plotted for cystoscopic removal of a sDJ stent vs removal of a mDJ stent with a retrieval device (A). Removal of the magnetic stent was faster without any significant difference. Pain during the procedure was rated lower by patients for the removal of the mDJ stent, but no statistical significance was observed either (B). DJ, double-J; mDJ, magnetic DJ; sDJ, standard DJ.

In our local setting, the cost calculation for cystoscopic DJ stent removal includes several key components. The sDJ catheter costs €20. Material costs, such as sterile drapes, average €25 in our department. The cost for sterilization is approximately €100. According to the National Association of Statutory Health Insurance Physicians, the diagnosis-related group fees for a cystoscopy are €89.15 for men and €33.53 for women, with an additional €5.25 for the DJ stent removal.[12] Further costs per minute, as per internal accounting discussions, include €1.93 for the urologist, €0.59 for the assisting nurse, €0.73 for medical infrastructure, and €1.40 for nonmedical infrastructure, totaling €4.65/min. Given an average procedure duration of nearly 4 min, this results in an additional cost of approximately €19. Combining these components, the total cost for a cystoscopic DJ stent removal in our setting for a male patient sums to a total cost of €258.40. The cost analysis for the mDJ group included the acquisition costs for the DJ stent and the retrieval catheter at €80. In addition, there are personnel costs for the involved transplant surgeon, also at €1.93/min. With an average duration of 3 min per removal, this results in additional personnel costs of €5.79, bringing the total cost for the mDJ group to €85.79, which represents a cost reduction of €172.61 compared with cystoscopic removal.

DISCUSSION

The introduction of mDJ stents aims to render cystoscopic removal of conventional DJ stents, with all the potential complications and discomfort for the patient, unnecessary. After the successive refinement of mDJs to optimize patient comfort, our present study tests various aspects of QoL and removal of mDJs compared with standard DJs in a monocentric, RCT. In principle, mDJs showed no disadvantage regarding DJ-associated complications or QoL. Additionally, patients reported comparable pain and pain intensity during removal compared with the cystoscopic removal of conventional DJs. No difference in the duration of the removal procedure could be found either.

The majority of studies on mDJ stents focus on DJ use in urolithiasis. However, even in this context, our results can be further replicated. Rassweiler et al demonstrated in an RCT that the QoL before stone removal with an mDJ stent is comparable to that with a conventional DJ, with the only divergence being the location of pain. In the mentioned study, cystoscopic removal of the DJ stent was found to be more painful and even associated with a longer procedure duration, which was not reflected in our data.[13] Regarding QoL, Li et al[14] reported slight advantages in favor of conventional DJ stent, whereas Diranzo et al found no differences. [15] Another RCT supports the simpler, faster, and cost-effective removal

of the mDJ but emphasizes limitations in the QoL compared with sDJ stents.[16]

We have also demonstrated the potential use of mDJ regarding post-KTx in a feasibility study. In this context, there were no issues with stent removal, while patients reported minimal pain.[17] After this, Capocasale et al[18] demonstrated in a retrospective study involving 100 deceased donor KTs a successful removal using a retrieval catheter in 98% of cases. Only 7% of patients reported distress regarding pain during removal. In our prospective survey with significantly fewer patients in the mDJ group, there was no need for cystoscopic DJ removal. Concerning pain, 60% of patients in our mDJ group reported minimal pain consistently, which did not cause distress. An RCT comparing the use of mDJ after deceased donor KTs with sDJ also concluded that the QoL is not more or less affected by mDJ compared with sDJs.[19] The size of the stent used in this study, 4.8 French with a 7 French magnet, appears to have no impact on QoL compared with larger sizes, such as the 6 French stent with a 9 French magnet used in our study. Contrary to our results, the mDJ was removed faster. One possible explanation for the lack of a time difference in DJ stent removal in our study could be the age structure of the patients. It is notable that cystoscopic removal of DJ stents in our study took, on average, 2 min less time compared with the study mentioned earlier. However, our mDJ cohort was also approximately 20 y younger on average, suggesting that with likely smaller prostate volumes, removal was easier, thereby nullifying the inherent difference in mDJ removal times. Furthermore, cystoscopy is a routine procedure, whereas the removal of mDJ stents represented a novelty, and with increasing experience, the time required for mDJ removal could potentially decrease.

In both groups, no major complications occurred, and in the mDJ group, cystoscopic removal was not necessary. In previous studies, an enlarged prostate occasionally posed an obstacle.[9,13,15] In our patient cohort, there was at least no discontinuation of mDJ removal. However, 3 cases reported minor issues with urethral passage, which could possibly indicate an enlarged prostate volume, thereby prolonging the duration of the procedure. Sevcenco et al[20] reported a case of magnet encrustation, making stent removal via the retrieval catheter impossible after 4 wk. In our case, we removed the mDJ slightly earlier and observed no encrustations. However, there is 1 case to report where the mDJ dislocated into the urethra prematurely, necessitating early removal via a retrieval catheter. Another potential issue to consider is the possibility of lost or migrated magnetic fragments during the removal of mDJs, which could pose additional challenges in clinical practice. Generally, the safety profile appears comparable with that of conventional DJs, even with durations >2 mo.

Our calculation indicates a cost reduction of approximately €172 per case when using mDJs. This magnitude of cost reduction aligns with findings from previous studies. For instance, cost analysis by O'Kelly et al[10] demonstrated a total cost saving of €10 150, averaging €203 per patient, by using a magnetic stent with a magnetic retrieval device. Similarly, Rassweiler's cost analysis at their institution calculated a reduction of €101.41 per case.[13] O'Connell's study reported mean cost savings per procedure ranging from €200 to €810, resulting in total savings of €47 790 during 9 mo.[21] Analysis by Kapoor et al[19] found savings of 304 CAD (approximately €206) per case. These studies collectively support the cost-effectiveness of using mDJs, reinforcing our findings and highlighting the potential for significant financial savings in medical practice.

In addition to cost calculation, the effort involved in removing the DJ stent is crucial. For cystoscopic removal, scheduling an appointment in a urological department and a medical intervention are necessary, which may prevent other patients from receiving therapy during that period. Furthermore, the transplanted patient must undertake travel, which can be time-consuming in some cases. In contrast, the removal of the mDJ using a retrieval catheter does not require a doctor or a urological department. O'Connell et al[21] demonstrated during 9 mo the satisfaction of patients following mDJ removal by nursing staff, suggesting that the absence of indirect costs for patients and the healthcare system likely leads to even greater cost savings. Given all these aspects, these results have led to the routine use of mDJ stents in KTx in our local setting.

Our study is limited by the small sample size and the monocentric design, which primarily reflects local conditions. Additionally, the USSQ could not be fully evaluated as patients were unable to assess categories such as sexual life during their hospital stay. Furthermore, we did not collect any data that could compare urinary tract infections between the 2 groups.

CONCLUSIONS

mDJ stents represent a safe alternative for patients following KTx. Our study demonstrated that a comparable level of pain is experienced during the removal of mDJ ureteral stents, with no difference in procedure duration compared with conventional cystoscopic removal. Additionally, the use of magnetic stents is associated with significant cost reduction and markedly less logistical burden for both patients and the hospital. Based on these findings, in our setting, KT recipients exclusively receive mDJ stents.

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