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Can magnitip double-J stent serve as a substitute for a standard double-J stent?

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ABSTRACT

Objective: To evaluate the morbidity of the magnitip double-J stent (DJ), compare its morbidity to the standard stent, and evaluate the possibility of retrieving the magnetic tip of the DJ stent without cystoscopy.

Material and methods: A total of 50 patients having a lower ureteric stone, who underwent uretroscopic stone retrieval and required the use of a DJ, were randomly assigned to 2 groups, each containing 25 patients. Patients in group A were subjected to exploration with a uretroscope and a magnitip DJ while those in group B received a uretroscope and a standard DJ. The morbidity of both types of DJs was assessed by the Arabic version of the ureteral stent symptom questionnaire (USSQ).

Results: There was a high level of statistically significant differences between the two groups with regards to the total score of the USSQ, which were higher in group A as compared to group B (126.96±14.76 vs. 98.24±12.9) (p=0.001). Further, the cost of the total procedure was significantly higher in group B (9600±1456.59 vs. 8444±783.73) (p=0.001). No statistically significant difference was found between both groups regarding the application, retrieval accuracy, and discomfort caused by DJ removal.

Conclusion: The morbidity caused by the magnetic DJ was found to be higher. However, the removal of the magnetic DJ was less costly than the standard DJ.

Keywords: Magnitip DJ; non-cystoscopy DJ removal; standard DJ; simple DJ removal.

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Introduction

In 1978, Finney first described the double-J® (American Cystoscope Makers [ACMI], Southborough, MA) stent. Since then, ureteral stents have become an important part of contemporary urological practice.[1] The use of a ureteral stent for the drainage of the upper urinary tract is the most frequently used urological intervention in the present time.[2]

"Indwelling ureteral stents" have significant adverse effects such as discomfort, infection, migration, and encrustation, known as "stent syndrome," which can lead to significant morbidity.[3] Further, most children and some adults require general anesthesia or sedation for removal, which is expensive, time-consuming, and carries a risk of anesthesia for the patient.[4]

Then, Macaluso et al.[5] came up with the idea of removing a double-J stent (DJ) without cystoscopy or general anesthesia using two magnets in 1989. However, as stent insertion was difficult and there was a low success rate for the retrieval (in males the success rate was only 76%), the device never gained acceptance.

With the development of ureteral stent design and small magnets with enough power, the idea could be put into practice. The first endpoint is to evaluate the morbidity of the magnetic-tip DJ and compare it with the standard DJ. The second endpoint of this study is to determine the accuracy of stent removal without cystoscopy.

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Material and methods

Between December 2018 and March 2019, 172 patients presented at the urology department of Ain Shams University Hospital with a lower ureteric stone. They were scheduled for a uteroscopy and DJ application. Of these, 50 patients were included in the study based on the following inclusion criteria: patient age being more than 18 years old and the size of the lower ureteric stone being greater than 1 cm. We excluded patients with bilateral ureteral stones, age of less than 18 years, height of less than 160 cm in height, a planned MRI examination at the time of the study, presence of a cardiac pacemaker, those with uncorrectable bleeding disorders or urinary tract infections, and pregnant patients.

We divided them into two groups using the closed envelop method. Each group consisted of 25 patients. In Group A, patients were subjected to a uteroscopy with a magnetic-tip DJ, while in group B, patients were subjected to a uteroscopy with a standard DJ.

All patients were assessed preoperatively by recording their detailed medical history, physical examination, urinalysis and urine culture, renal ultrasonography (US), radiography of the kidneys, ureters and bladder (KUB), and a computerized tomography of the urinary tract, in addition to routine preoperative evaluation. The study design and work flow is summarized in the CONSORT flow chart (Figure 1).

Operative procedure

Under spinal anesthesia and in the lithotomy position, cystoscopy was performed with a cystoscopic sheath of 22 Fr and a 30-degree telescope. Following an initial "check" cystoscopy of the urinary bladder, the cystoscope was positioned near the ureteral orifice. A 6 Fr Teflon ureteral dilator was introduced into the ureteral orifice, after which a diluted contrast medium was injected under real-time fluoroscopy to generate images of the ureter and the collecting system.

A straight floppy-tipped guidewire was advanced through the dilator into the renal pelvis under fluoroscopic guidance. If difficulty was encountered in passing the straight guidewire, a 6 Fr Teflon ureteral dilator was used to facilitate the passage of "sensor guidewire." The guidewire was kept inside the ureter throughout the procedure.

The ureteral orifice and the intramural part of the ureter was dilated with graduated Teflon ureteral dilators that were passed to the ureter over the guidewire under fluoroscopic guidance up to 14 Fr. A rigid ureteroscope was used, which was introduced along the guidewire into the ureteral lumen until the stone was disintegrated under direct vision with ballistic lithotripsy. The fragments were then removed by forceps.

After retrograde pyelography in group A with a 7 Fr, 26 cm magnetic BLACK-STAR DJ ureteral stent with a magnet at its distal end was inserted directly over the guidewire through the cystoscope (Figure 2). A stent pusher was used to deploy the stent until its proximal end coiled in the renal pelvis. The guidewire was then withdrawn, and the distal end of the stent was made to coil in the urinary bladder while making sure that the magnet inside the bladder was still fixed to that end (Figure 3). In group B, a 7Fr, 26 cm slandered DJ "Percuflex™ Plus Ureteral Stent–Boston Scientific" was inserted directly over the guidewire.

Lastly, in both groups, a 16 Fr Foley urethral catheter was fixed and left for one day. A KUB was done on the first post-operative day to confirm and document the exact location of the stent. The stent was removed after 2 weeks. Before the stent removal, KUB was performed again to determine the exact location of the stent and check for any encrustations.

In group A, the stent was removed under complete aseptic conditions with the patient in the prone position, and lidocaine gel was injected into the urethra. Afterwards, the stent retrieval device was introduced into the bladder. The Tiemann tip of the retrieval device was rotated (in front of the corresponding osteum) until the magnets on the ureteral stent and the retrieval device clicked together, upon which the retrieval device was carefully pulled out with the stent (Figure 4). In group B, the stent removal was performed under local anesthesia using flexible cystoscopy.

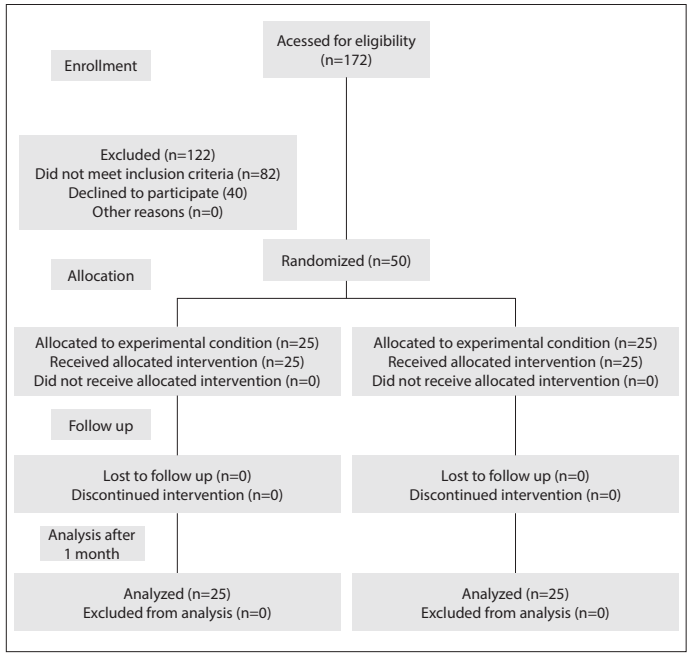

Figure 1. CONSORT flow chart

The following data were recorded: patient age, gender, site, application accuracy, retrieval accuracy, discomfort caused by the DJ removal (which was assessed via a visual analogue scale (VAS) in the same day of the DJ removal), the morbidity of the stent (which was assessed via the Arabic version of ureteral stent symptom questionnaire (USSQ)[6] on the same day of the DJ removal), the cost of the first and second procedure, and the total cost (hospital pills).

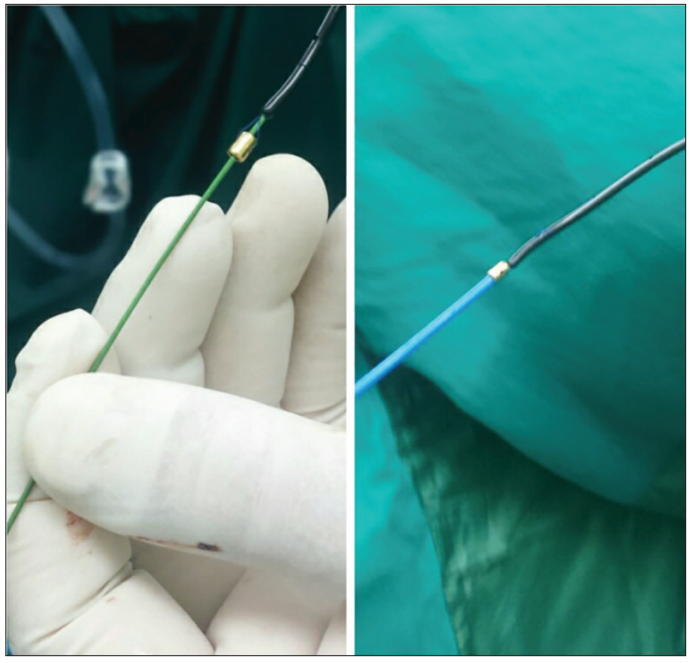

Figure 2. DJ stent with the magnet over the guidewire

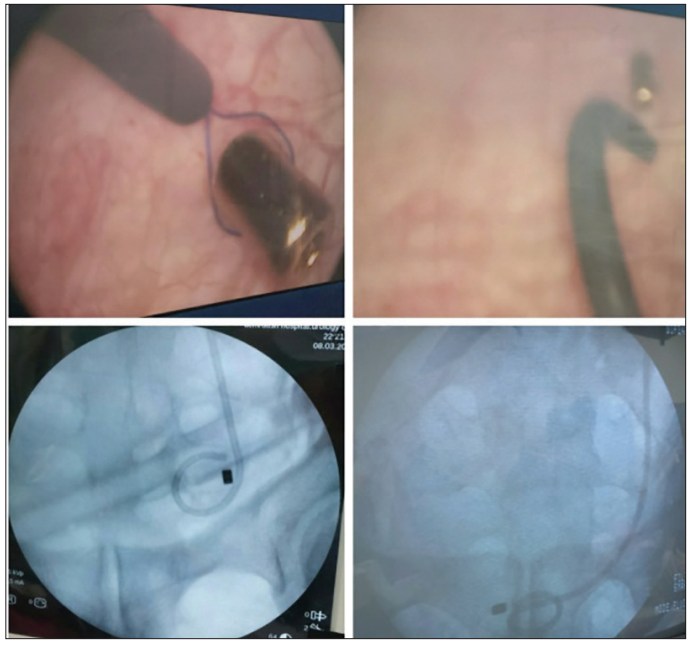

Figure 3. Distal end of the DJ with the magnet inside the bladder

Statistical analysis

Sample size was calculated using the stata program "StataCorp. 2001. Statistical Software: Release 7.0. College Station, TX: Stata Corporation." The type-1 error (α) was set at at 0.05 and the power (1-β) was set at at 0.8. Results from a previous study show that irritative LUTS occurred in 70% of the cases, assuming that irritative LUTS for experimental subjects would occur in 100% of the cases. Calculation according to these values produced a minimal sample size of 22 cases in each group.

The collected data was tabulated and introduced to a PC using the IBM Statistical Package for Social Science software version 20.0 (IBM SPSS Corp.; Armonk, NY, USA). Quantitative variables are expressed as mean and standard deviation (SD) in cases of non-parametric variables. Qualitative variables are expressed as frequencies and percentages. The Student's *t*-test or the Mann-Whitney U test was used to compare continuous variables between the two study groups. The Chi-square test was used to examine the relationship between categorical variables. A p-value of <0.05 was considered statistically significant.

Results

There were no statistically significant differences between the two groups with regards to the patients' demographic characteristics, except for the pre creatinine level, which was higher in group A (0.96±0.35 vs. 0.72±0.29), as shown in Table 1.

For the morbidity caused by DJ, there was a high level of statistically significant differences between the two groups with regards to urinary symptoms, pain, work performance, and to-

Figure 4. Removal of the BlackStar with the magnetriever

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Table 1. Comparison between the 2 groups regards to patients' demography, operative data, and the postoperative morbidity of the DJ assessed by (USSQ)

		Group A	Group B		
		Mean±SD (range)	Mean±SD (range)	p	Sig
Age in year		31.08±8.8 (19–50)	29.2±11.12 (19–70)	0.511	NS
Pre creatinine mg/dL		0.96±0.35 (0.5–1.4)	0.72±0.29 (0.4–1.4)	0.012	S
Gender	Male (n, %)	19 (76%)	16 (64%)	0.355	NS
	Female (n, %)	6 (24%)	9 (36%)		
Side	Right (n, %)	11 (44%)	7 (28%)	0.239	NS
	Left (n, %)	14 (56%)	18 (72%)		

	Group A		Group B			
Operative data	**Mean±SD**	**Median (IQR)**	**Mean±SD**	**Median (IQR)**	**p**	**Sig**
Discomfort caused by DJ-removal		5 (3–6)		4 (3–5)	0.4	NS
Cost of 1st procedure in L.E	8344±783.73		6844±1476.22		0.001	HS
Cost of 2nd procedure in L.E	100±0		2756±187.26		0.001	HS
Total cost in L.E.	8444±783.73		9600±1456.59		0.001	HS
Application accuracy	Yes	25 (100%)	Yes	25 (100%)		NS
Retrieval accuracy	Yes	25 (100%)	Yes	25 (100%)		NS

Post-operative morbidity of DJ assessed by (USSQ)

	Group A	Group B		
	Median (IQR)	Median (IQR)	p	Sig
Urinary symptoms	37 (30–44)	33 (30–35)	0.008	HS
Pain	25 (18–27)	15 (12–19)	0.001	HS
General health	17 (15–19)	17 (14–19)	0.27	NS
Work performance	30 (23–33)	17 (14–20)	0.001	HS
Sexual matter	5 (4–7)	5 (2–8)	0.9	NS
Additional problem	14 (11–16)	12 (9–16)	0.4	NS
Total score	126 (119–138)	95 (91–106)	0.001	HS

USSQ: ureteral stent symptom questionnaire; IQR: Interquartile Range; L.E.: Egyptian pound, DJ=double J

tal score of the USSQ, which all were higher in group A. On the other hand, no statistically significant difference was found between both groups regarding their general health, sexual matters, and additional problems of the USSQ as shown in Table 1. No statistically significant difference was found between both groups regarding the application, accuracy of retrieval, and discomfort caused by DJ removal as shown in Table 1.

A significant difference between both groups was found in relation to the cost of the second procedure and the total cost of both procedures, both of which were higher in group B (2756±187.26 and 9600±1456.59 vs. 100±0 and 8444±783.73). On the other hand, the cost of the first procedure was significantly higher in group A (8344±783.73 vs. 6844±1476.22) due to the cost of the metallic DJ as shown in Table 1.

There were no statistically significant differences with regards to the morbidity caused by DJ between males and females in both groups as shown in Table 2. However, the only statistically difference between males and females in both groups was the discomfort caused by DJ removal, which was higher in the male group as shown in Table 2.

Discussion

Forty years ago, Finney, Hepperlen, and their colleagues first introduced and described the DJ ureteral stent and the single-pigtail stent.[1,7] In the last twenty years, ureteral stent use has increased significantly with the advent of extracorporeal shock wave lithotripsy, ureterorenoscopy, and improved stent technology and has grown to become an essential part of the urological armamentari-

Table 2. Comparison between males and females in group A and B regarding the operative data and the postoperative morbidity of DJ assessed by (USSQ)

	Male		Female			
Group A	**Mean±SD**	**Median (IQR)**	**Mean±SD**	**Median (IQR)**	**p**	**Sig**
Discomfort caused by DJ-removal		5 (3–6)		2 (1–2)	0.001	HS
Cost of 1st procedure in L.E	8326.32±778.78		8400±871.78		0.846	NS
Cost of 2nd procedure in L.E	100±0		100±0			
Total cost in L.E	8426.32±778.78		8500±871.78		0.846	NS
	Male		**Female**			
Group B	**Mean±SD**	**Median (IQR)**	**Mean±SD**	**Median (IQR)**	**p**	**Sig**
Discomfort caused by DJ-removal		4 (3.5–5)		3 (3–4)	0.04	S
Cost of 1st procedure in L.E.	7106.25±737.99		6377.78±2265.93		0.24	NS
Cost of 2nd procedure in L.E.	2750±186.19		2766.67±200		0.84	NS
Total cost in L.E.	9856.25±765.04		9144.44±2214.22		0.25	NS
Post-operative morbidity of DJ assessed by (USSQ)						
	Male	**Female**				
Group A	**Median (IQR)**	**Median (IQR)**	**p**	**Sig**		
Urinary symptoms	37 (30-47)	35 (27–40)	0.49	NS		
Pain	25 (18–30)	23.5 (20–27)	0.60	NS		
General health	16 (15–19)	18 (14–22)	0.47	NS		
Work performance	30 (23–33)	32 (22–38)	0.69	NS		
Sexual matter	5 (4–7)	7.5 (2–8)	0.37	NS		
Additional problem	15 (11–16)	11 (9–12)	0.14	NS		
Total score	126 (120–139)	124 (118–138)	0.67	NS		
	Male	**Female**				
Group B	**Median (IQR)**	**Median (IQR)**	**P**	**Sig**		
Urinary symptoms	32.5 (30–34)	35 (27–37)	0.81	NS		
Pain	15 (11–18)	14 (13–19)	0.88	NS		
General health	14.5 (12.5–18)	18 (15–19)	0.15	NS		
Work performance	16.5 (14–19.5)	17 (14–20)	0.65	NS		
Sexual matter	5 (2–7)	8 (4–12)	0.11	NS		
Additional problem	12.5 (8.5–16.5)	10 (9–16)	0.78	NS		
Total score	94.5 (90.5–106)	105 (92–110)	0.28	NS		

USSQ: ureteral stent symptom questionnaire; IQR: Interquartile Range; L.E.: Egyptian pound; DJ: double J

um.[4] The disadvantages of stents are the intolerance of a foreign body, encrustation, urinary tract infection, and the need for an additional cystoscopic procedure to remove the stent.[8]

The common method of ureteral stent removal is by cystoscopy or by using endoscopic grasping forceps. Some non-endoscopic techniques for stent removal include using a nylon tether attached on the distal part of the stent, which dangles from the urethra. By pulling the string, the DJ can be removed without cystoscopy. This method is a convenient way for DJ removal when the DJ persists for short time, but if the DJ needs to be retained for a longer period, unintentional dislodgment of the stent can occur, leading to a rise in the risk of a urinary infection and subsequent patient complaints of incontinence.[9]

The idea to eliminate the need for anesthesia or cystoscopy for DJ removal using magnetic material-tipped ureteral stents was proposed by Macaluso et al.[5] in 1989, when they described the use of magnetic material-tipped ureteral stents in 50 patients.

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The Magnetip® DJ stent was used in 83% of the cases, and retrieval was accomplished in 86% of cases using the Magnetriever®. In 1994, Mykulak et al.[10] reported the use of magnetic ureteral stents in 7 children after pyeloplasty, where the stents were removed with a magnetic-tip retriever without the need for cystoscopy and only 1 patient had required anesthesia.

As stent insertion was difficult and retrieval in males was only 75% successful, the device never gained acceptance.[5] In 2002, Taylor and McDougall[4] addressed the deficiencies of the above magnetic stents. They developed an approach that used a more powerful rare-earth magnet on the retrieval catheter and a stainless-steel bead attached to the end of the stent. In their study, the magnetic stent was removed without difficulty in 29 of 30 patients (97%) and there were no complications related to the placement or removal of the stent.

To our knowledge, the only published prospective randomized trial using magnetic-tip DJs was described by Rassweiler et al.[11] in 2017. With regard to the morbidity of the DJ, there was a significant difference between the groups, and these differences were more prominent in group A. this may be due to the properties of the magnet itself. On the other hand, Rassweiler et al.[11] reported that the magnetic DJ is comparable to the standard DJ. Taylor and McDougall[4] reported that they did not complete a validated questionnaire assessing the patients' stent intolerance due to the small size of their study.

With regards to the accuracy of stent removal without cystoscopy, there was no significant difference between the 2 groups and the removal was 100% successful in both groups. This is comparable to other studies whereby the retrieval accuracy was 97% and 95%, and reasons for failure were connected to an enlarged median lobe of the prostate.[4,11] On the other hand, Macaluso et al.[5] reported a low retrieval accuracy rate of 86%. This retrieval failure is due to the fact that the fixed magnet at the end of the stent lacked the mobility to align with the retrieval magnet.

There was no significant difference regarding the discomfort caused by DJ removal between the two groups. However, this discomfort was significantly higher in males than in females in both groups. This may be due to the natural anatomy of the male urethra. However, Rassweiler et al.[11] reported that there was a significant difference (p=0.019) regarding the pain caused by the DJ removal, which was lower with magnetic-tip DJ removal. However, no significant difference between males and females was found in this regard (p=0.695).

Flexible cystoscopy is a short-life device that adds financial burden on the healthcare system of our country. For the total cost of the procedure, there was a significant difference between the two groups, and these differences were higher in group B. This is comparable with Rassweiler et al.[11], who reported a reduction of € 101.41 when using the magnetic-tip DJ.

Auge et al.[12] found that biodegradable ureteral stents in a swine model degraded within 2-7 days. In an in-vitro study, Barros et al.[13] described that a stent made out of polysaccharides degraded within 2 weeks in artificial urine, rendering a DJ removal unecessary. Lingeman et al.[14] demonstrated the safety and efficacy of this stent on humans. Overall, 90% of the stents dissolved within 8 days and 89% of the patients were satisfied with this stent. To this end, this minimally invasive technique has the potential to be a substitute the current methods of cystoscopic stent retrieval. Future efforts will focus on refining the magnetic materials and capture devices placed on the stents.

Some limitations of our study were the less number of patients, the young age of all the patients (they lacked an enlarged prostate, which could cause retrieval failure), and our inability because of the above-mentioned reason to assess the factors that may have affected stent-related symptoms.

In conclusion, the magnetic DJ can be removed easily and with a high accuracy rate. It is a faster and less costly procedure compared to the standard cystoscopic removal of the DJ. Conversely, it shows a higher rate of morbidity as compared to the standard DJ. This magnet retrieval system is a feasible and simpler alternative to the cystoscopic retrieval of ureteral stents. It is especially suitable for use on an outpatient basis.

Ethics Committee Approval: Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – A.A.A., A.F.; Design – A.F., M.H.; Supervision – A.F.; Materials – M.H., A.A.A.; Data Collection and/or Processing – M.H., A.A.A.; Analysis and/or Interpretation – A.T., W.A.M.; Literature Search – A.T.; Writing Manuscript – A.T., W.A.M.; Critical Review – W.A.M., A.T.

Conflict of Interest: The authors have no conflicts of interest to declare.

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