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Original Research Article

Comparison of stent-related symptoms, passive ureter dilatation and stone clearance rate using 4.5 French versus 6 French double J stenting of unfavourable ureter: a prospective randomized controlled trial in a tertiary care centre

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ABSTRACT

Background: Retrograde intrarenal surgery (RIRS) is the standard of care for renal stones of less than 1.5 cm and less than 1000 Hounsfield units (HU). Most virgin ureters do not allow the flexible ureteroscope in the first setting. Placement of a D-J stent in the ureter dilates the ureter. Therefore, our study aimed to compare stone clearance rates and symptom complex of passive ureteral dilation following 4.5 French/Fr versus 6 French/Fr double J (DJ) stent placement.
Methods: After obtaining ethics approval and written informed consent, 100 patients satisfying the inclusion and exclusion criteria were included and data recorded. patients were randomized into group A (4.5 Fr) and group B (6 Fr). Stent was placed. After 4 weeks, symptoms were assessed by the ureteral stent symptom questionnaire (USSQ). Following retrograde intrarenal surgery (RIRS) successful passage of ureteric access sheath (UAS) and stone clearance rates were assessed.
Results: The surgical success rate, stone clearance rate was similar in the two groups (p value: more than 0.05). The USSQ score was significantly lower in group A (p value: 0.001).
Conclusions: Stent of smaller diameter (4.5 Fr) is associated with less patient discomfort with similar surgical completion rates and stone clearance.

Keywords: Renal stones, RIRS, Stent diameter, Stent related symptoms, USSQ score, Ureteral stent

INTRODUCTION

Retrograde intrarenal surgery (RIRS) is the most common minimally invasive procedure for renal stones less than 2 cm. Understandably, it is preferred in case of smaller stones due to less patient discomfort and shorter recovery periods.[1] As with any endourological surgery, stent placement is an integral part of the procedure, particularly in patients with narrow unfavourable ureters.[2] The first documented stent placement was in 1967.[3] The placement of stent serves multiple purposes. On one hand, it allows the passing of urine escaping the internal obstructions and preventing hydronephrosis and kidney damage while at the same time it also causes passive dilatation of the ureter by exerting pressure on the ureteral walls facilitating the passing of access sheath for RIRS at a later stage.[4]

However, stent being a foreign material, the stent placement itself causes discomfort which increases multifold upon size mismatch. It may cause localized inflammation and bladder irritation with pain and hematuria. Urinary reflux may increase kidney pressure and cause discomfort while urination. As stents have to be placed for long durations (4 to 8 weeks), any discomfort

can significantly compromise the quality of life of the patient and adversely affect the surgical outcome.

Over the years many studies have been conducted to assess the impact of different materials, coatings, design and placement. While the studies conducted before 2003 did not have a standard tool to assess the stent-related symptoms, it was changed with the development of the ureteral stent symptom questionnaire (USSQ) by Joshi et al.[5-8] With the development of questionnaire, symptomatology of the patients could be objectively measured. The questionnaire consists of 6 domains: urinary symptoms, restriction of performance in work, stent-related pain, general health, a sexual section and additional issues (if any).

There has been a paucity of literature to assess the effect of stent diameter on patient comfort and surgical success rates. Therefore, the present study was conducted to assess the effect of different diameter of the stent on patient's stent related symptoms (using USSQ score) and stone clearance in patients undergoing RIRS for intrarenal stones.

METHODS

A prospective randomized controlled trial was conducted at department of urology, Ramaiah Medical College, Bengaluru between January 2022 to December 2023. After taking approval of the institutional ethics committee and voluntary written informed consent from all the patients, those who satisfied the eligibility criteria were included in the study. We included all patients aged >18 years of either gender with a unilateral, intrarenal stone size of <1.5 cm and an unfavourable ureter in which 10/12 Fr access sheath cannot be negotiated. All patients <18 years of age, patients with bilateral stone disease, those with prior surgery for stones, acute renal failure, ureteral stricture, urothelial malignancies, active urinary tract infection pregnancy were excluded from the study.

Patients satisfying the eligibility criteria were randomised into two groups for the different sizes of the double J (DJ) ureteral stent: group A (4.5 Fr) and group B (6 Fr). The consolidated standards of reporting trials (CONSORT) 2010 flow diagram is mentioned in Figure 1. Baseline demographic characteristics were noted for all patients. Detailed past and personal histories were recorded. All patients underwent preoperative non-contrast computed tomography (CT) scan and the findings were noted in terms of size and number of the stones, location of the stones and the Hounsfield units (HU).

All patients underwent stent placement as per the assigned group. Unfavorable ureter was confirmed when 6 Fr ureteroscope could not be negotiated and 10/12 Fr access sheath could not be passed. DJ stenting was then done as per the assigned group and following the standard surgical protocol.

Thereafter, the patients were followed up after 4 weeks. The stent-related symptom score was assessed using standardised USSQ. DJ stent was removed at or after 4 weeks and 10/12 Fr ureteral access sheath placement was attempted. In all cases where the access sheath could be placed were considered to have successful passive ureteral dilatation.

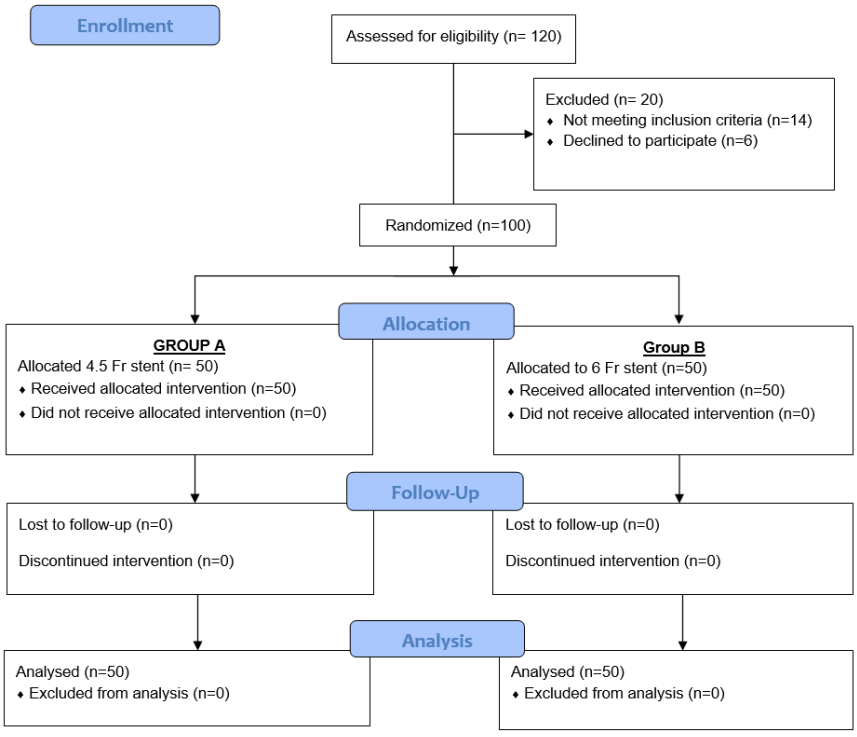

Figure 1: CONSORT 2010 flow diagram.

RIRS was performed using holmium laser at standard dusting settings and DJ stent was placed again as per the standard protocol. Postoperatively, non-contrast CT scan was done 4 weeks following stent removal to document clearance of stones. Stone clearance was considered when there was no significant residual fragment (size more than 2 mm).

Data was analysed using the statistical package for the social sciences (SPSS) software version 22.0. All the qualitative data was expressed as percentages. The p values were assessed by Chi square test (Fischer's exact test was used when more than 20% of the cells had value less than 5). All the quantitative data was expressed as mean±standard deviation. P values were assessed by the student t test. P value of less than 0.05 was considered as "statistically significant" and indicated by "*" in the tables.

RESULTS

A total of 100 patients were included in the study. A male preponderance was noted across both the groups. Both the Groups were identical in terms of baseline demographic findings and preoperative CT scan findings (Tables 1 and 2). Majority of the cases had stones located in the middle calyx (Table 2).

Table 1: Distribution of the demographic characteristics in the two groups (n=100).

Parameters	Group A (n=50)	Group B (n=50)	P value
Age (in years)	42.34±2.4	40.44±3.7	0.657
Males (%)	65	61	0.558

Table 2: Distribution of baseline CT scan findings in the two groups (n=100).

Parameters	Group A (n=50)	Group B (n=50)	P value
Stone size (in mm)	10.65±1.71	10.24±1.93	0.776
Mean number of stones	2.21±1.89	2.34±1.72	0.988
Hounsfield unit	988±312	976±367	0.988
Stone in middle calyx (%)	60	52	0.254
Stone in lower calyx (%)	40	48	

Passive ureteral dilatation was achieved in all cases in both the groups. Postoperatively, it was observed that there was good rate of stone clearance with both the stents. However, the symptomatic score was significantly lower in group A as compared to group B; p value: less than 0.001 (Table 3). One patient in group A and 2 patients in group B had infection in the postoperative period. Stone rates were similar across both the groups (Table 3).

Table 3: Distribution of postoperative findings in the two groups (n=100).

Parameters	Group A (n=50)	Group B (n=50)	P value
Successful RIRS rate (%)	94	90	0.297
Stone clearance rate (%)	96	94	0.516
Infection (%)	2	4	0.407
USSQ score	54.34±5.21	72.38±2.41	0.001*

*Statistically significant.

DISCUSSION

In the present study, we observed that the rates of successful RIRS and stone clearance were similar with both the DJ stents (4.5 Fr and the 6 Fr). All the cases in both the groups achieved successful passive ureteral dilatation in both the Groups. However, there was a significant difference in the USSQ score with lower scores reported by the patients with smaller stents.

In the study by Cubuk et al, a total of 126 patients underwent stent placement (63 each for 4.8 Fr and 6 Fr) and 62 patients in the control group without stent.[9] The demographic characteristics of our study was similar and so was the stone free rate in the two groups with stent (92.1% versus 88.9%; p value: 0.548). They also observed a significantly lower postoperative USSQ scores in cases with 4.8 Fr stent as compared to 6 Fr stent; p value: 0.01. Similarly, the studies by Kim et al and Nestler et al also found lower USSQ scores with smaller stents with similar stone free rates.[10,11]

A systematic review and meta-analysis by Diatmika et al, including 6 studies recommended the use of smaller ureteral stents for reducing stent-related patient symptoms and discomfort without any significant differences in the incidence of stent migration, analgesic use and stone free rate.[12]

It may be hypothesized that the USSQ score can be influenced by different parameters like the stent material, placement technique, patient characteristics, and use of analgesics, in addition to the stent size.[13-16] However, stent size seems to be the most effective way for improving patient comfort with smaller stent sizes leading to lesser discomfort. Several theories have been hypothesized. The stent with smaller diameter may create less pressure on the walls of the ureter and consequently lead to lesser incidence of back and flank pain. Additionally, a stent with smaller distal curl may have less contact with the bladder mucosa and consequently cause lesser bladder irritation. Smaller stent size is more flexible, semirigid and could also reduce the degree of urinary reflux through the stent lumen. All these may lead to lower incidence of pain and urinary symptoms.[10] Overall lower incidence of pain may lead to a general improvement of the overall health status, work performance and sexual activity lowering the USSQ

scores in these domains as well. Thus, smaller stents have lower USSQ scores indicating improved patient comfort in all the domains.

Limitations

A larger cohort with comparison of multiple stent sizes is required for further validation.

CONCLUSION

Ureteral stents are associated with adverse effects on patients comfort and high USSQ scores. Using 4.5 Fr DJ stents improves stent-related symptoms and decreases the USSQ score as compared 6 Fr DJ stents with comparable passive dilatation of the ureter and surgical success rates. Therefore, we recommend using 4.5 Fr stent over 6 Fr Dj stent.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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