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Introduction:

Management of renals and ureterals stones changed a lot in the past few years. Technical improvements as well as endoscopes miniaturization and better deflection have led to an increased use of ureteroscopy (URS). According to the European Association of Urology (EAU), flexible ureteroscopy (fURS) is now recommended in first line treatment for renal stone inferior to 20 mm. It is also available for lower pole renal calculi with unfavorable factor for extracorporeal shockwave lithotripsy (ESWL). URS is also recommended as second line treatment for renal stone superior to 20 mm.[1]
Double J stenting (DJS) after URS is still debated between urologists.[2,3] In the last edition of the urolithiasis EAU recommendation, stenting after URS is not mandatory in uncomplicated URS with complete stone removal.
DJS after URS is used to prevent risk of obstruction resulting from a residual fragment or postoperative edema. It may also reduce postoperative ureteral stenosis. Risk of ureteral stenosis after ureteroscopy is estimated at 1%. It is higher in case of prolonged operative time, ureteroscope's diameter greater than 9.5F, ureteral perforation or impacted calculi[4] and may go unnoticed with repercussions on renal function.[5] However, those devices are not insignificant and patient's life quality can be affected with clinical symptoms like urgency, hematuria and social and sexual repercussions. In 2003, Joshi reported 80% of stent related pain with daily disruption of daily activities, 80% of urinary symptoms and 32% of sexual dysfunction. Other studies revealed, between 50 and 80% of morbidity.[6,7]

Further, stent migration, encrustation, pyelonephritis and forgotten stent can occur after stent placement.[8] Consequently, DJS after URS is still debated among the urologist.[2,3]
In our study we assessed if ureteral stenting with double J modify pain among patients after URS. We also search for risks of complications.

Methods:

We retrospectively included every URS between May 2014 and January 2017 for ureteral and/or renal stone. Patients were eighteen years old or older. Interventions were excluded if the follow up was made in another center or if drainage of the upper urinary tract was made with a ureteral catheter. Urine sterility was controlled before every intervention and antibiotics were given if necessary. Patients received general anesthesia and prophylactic antibiotics during anesthesia induction. fURS were performed with a 7,5 Fr Karl Storz endoscope and semi-rigid with a 7 Fr Karl Storz uretero-renoscope. A 0.035 inch stiff terumo security wire and an access sheath (Flexor Ureteral Access Sheath) were used at the surgeon discretion. Position was controlled using fluoroscopy. A holmium laser YAG (Dornier Medilas H20) was used for stone fragmentation (200 to 550 um fiber) and a basket for stone evacuation if necessary. Every procedure lasted 90 minutes or less to minimize complications. At the end, 24 cm and 7 Fr silicone DJS was used according to the operator. The stent was removed 1 to 4 weeks after the intervention, in consultation under local anesthesia, or during the next procedure. Each patient received non-steroidal anti-inflammatory drug (NSAID) after the intervention for 3 days. Thirteen surgeons performed URS and were categorized between two groups, junior or senior. Seniors were titular surgeons and junior, one or two years after graduation. Data protection commission and ethic comity approved the study. Prestenting was used in case of emergency or if renal access was not possible in a prior intervention.

Pain was evaluated using verbal rating scale (VRS). A telephone interview was conducted on day one for outpatient surgery; otherwise, the nurse used VRS during the hospitalization.

Our primary outcomes were post-operative pain and post-operative complications. Patient's data included age, gender, body mass index (BMI) and American Society of Anesthesiologists (ASA) score. Surgical data included presence of preoperative stent, use of ureteral access sheath, stone free status based on preoperative view or renal ultrasound or CT scan at 3 month, stone location, surgeon's experience, length of hospitalization and outpatient surgery status. Stone dimensions were measured with a CT scan; stone burden was evaluated with the biggest stone size and the cumulative size. Complications were recorded according to Clavien Dindo classification.[9] Both groups were compared on the basis of these parameters. We also made a multivariate regression analysis to highlight complications factors.

Statistical Analysis

Patients characteristics were summarized as counts (frequencies) for qualitative variables and with a mean ± standard deviation or median - [Inter-Quartile Range (IQR)], as appropriate, for continuous variables.

Patients characteristics were compared using the Fisher or chi square test for categorical variables and with Mann-Whitney for continuous variables, as appropriate.

A logistic regression was performed to find complications factors and validated, with manual backward variable selection process. This analysis is conducted to identify potential risk factors.

All tests were bilateral, with a type I error rate of 5%.

The statistical analysis was performed using Graphpad Prism 6.0 and R software version 3.4.1.

Results:

Population

We included 366 interventions, 259 with a DJS and 107 without. Age, BMI, ASA score and gender were similar in both groups (Table 1). Maximum stone size was significantly higher in stented group (12,7 ± 12,9mm versus 7,2 ± 2,5 mm; p<0,001). Cumulative stone size was also significantly slightly higher in stented group (18,3 ± 14,9mm versus 9,4 ± 5,2mm; p<0,001). Patients treated for renals stones used to have significantly more DJS (68,78% versus 44%; p<0,001). Also, tubeless patients benefited form ureteral preparation significantly more often before intervention (78,50% versus 62,55%; p = 0,004).

Table 2 shows per-operative data. fURS was significantly higher in stented group (58,69% interventions versus 36,45%; p<0,001) and significantly more access sheaths were employed (73,6% versus 42,4% p< 0,001). Surgeon's experience did not change postoperative drainage (43,63% versus 48,60%; p=0,4512). Significantly more outpatient procedures were realized in non-stented group (75,7% versus 52,51%; p<0,001) and patients had significantly less residuals fragments (89% versus 62,5%; p < 0,001). Length of stay was slightly longer in stented group (1,23 days versus 1; p=0,222).

Post-operative pain

No differences were found regarding post-operative pain, 22% patients in the stented group suffered pain versus 17,75 % (p=0,338) in tubeless group. Also the VRS was not significantly different among painful patients.

In fURS subgroup, (Table 3), those results were similar with no differences on pain and complications. Also, patients without DJS had fewer residuals fragments and were more ambulatory.

<u>Post-operative complication</u>

We did not highlight differences in complications (29% versus 20,5%, p=0,1181) (Table 4). More patients had postoperative fever (18.6% versus 9%) in DJS group and had grade 2 complications (7.7% versus 1.9%). One patient in tube-less group needed an early reintervention for double J stenting because of an obstructive pyelonephritis. Another in stented group needed an early fibroscopy 48 hours after ureteroscopy for double J ablation due to intense pain and one needed a nephrostomy under local anesthesia for a ureteral wound with an urinoma. One patient in each group had hematuria witch needed urethral stenting. One patient suffered from a sub capsular renal hematoma. Patients without DJS did not have more unplanned admissions.

In another analysis, presented ureters were less painful (Table 5) and access sheath would cause more pain.

Those results were confirmed in a multivariate analysis, (Table 6) unprepared ureter and experienced surgeons were more likely to have complications (p=0.0042 and p=0.0381), so is access sheath (p=0.0334). Otherwise, DJS, ambulatory status, age, stone diameter and stone localization were not associated with higher risks.

Discussion:

Our study reveals that ureteral stent after URS is not always necessary. Both groups were not similar; DJS group had bigger stone burden and less prestent ureter. We cannot certify that not stenting in this population will not increase pain or complications.

Preparing ureter with a DJS before URS may increases postoperative sepsis[10]. As shown in Assimos and al study's, it may be interesting to systematically implement a DJS preoperatively. They highlight that DJS before URS increases stone free rates and decreases complications for renal stones.[11] Nevertheless this would require a first intervention with anesthesia and cannot be feasible in routine.

Most studies evaluating postoperative drainage were performed with patients treated for ureteral stones. Song *and al.* in 2011 conducted a meta-analysis including 15 studies with 1496 patients. Their conclusions were that ureteral drainage should not be used systematically after semi rigid URS. Regarding postoperative pain, patients without DJS were less painful. Results are similar for lower urinary tract symptoms (LUTS) with increased risk of dysuria or urgency in DJS group. There was no differences in persistent fragments, stenosis risk, fever and emergency consultations rates.[12]

There are few studies on postoperative stent after fURS. Torricelli *and al.* in 2014 conducted a retrospective study comparing DJS drainage in patients treated with fURS using an access sheath. Their main outcomes were pain evaluated with a visual analogue pain scale and postoperative complications. Patients without DJS were statistically more painful and were more likely to need emergency room care. There were no differences regarding complications. In a subgroup analysis, they also showed that patients without DJS and without prepared ureter were more painful than patients with prepared ureter. They concluded that post-operative stent with DJS reduces pain but may be optional in case of preoperative ureteral preparation by DJS.[13]

Recently, a prospective multicenter study, accomplished by the Clinical Research Office of Endourological Society included 10437 patients who profit from a fURS or a semi rigid URS for renal or ureteral stones. The aim was to evaluate risks and benefits of ureteral drainage. For ureteral calculi, postoperative stents decreased both duration of hospital stay and complications. In the other hand there was more rehospitalizations. For renal calculi, patients with DJS had also fewer complications. In this study, the DJS postoperative rate was 60% after semi rigid URS and 80% after fURS. Complications rates were 1,4% for ureterals stones with DJS and 1,3% without. They were 4,1% and 10,2% for renals stones. Those rates are similar to ours. In this study, post operative drainage by DJS reduced number of complications after URS[14].

In our study, to minimize ureteral edema, patients received NSAIDs for a few days after the intervention. This may explain the dissonance with the previous study. Despite NSAIDs, we do not find more septics complications.

In addition, outpatient surgery is now properly codified and supervised. It seems feasible without adding risks for the patient. This is consistent with Oitchayomi *and al.* study in 2016. They found 6% of complications with an ambulatory load failure rate of 2,2% with 100 patients included.[15]

In addition, URS development with fewer complications than percutaneous nephrolithotomy leads us to treat more and more voluminous calculi.

We did not investigate DJS impact on LUTS. It must be considered before stenting as they can alter quality of life and sexual activity.[6,7] Bisio *and al.* evaluated stent-related symptoms after semi rigid URS and fURS. They used the Ureteric Stent Symptoms Questionnaire (USSQ). Two hundred and thirty-two patients completed the USSQ. They had 86.6% of urgency and 82.3% of burning mictions. Urinary tract symptoms were a problem for 88.4% of patients and pain disturb life patients in 92.2%. More than

50% were unhappy with the stent. Before using ureteral stent after URS, urologist should wisely think of consequences and inform patients of secondary effects.[16] It is also necessary to keep in mind necessity of stent removal under local anesthesia by fibroscopy. It increase costs and maybe responsible of infections or pain. To overcome this, using DJS with extractor wire can be an alternative. Patients can then remove stents at home alone or with a nurse or during a simple consultation. A recent meta-analysis compares regular DJS and wired DJS. Patient's majority were able to withdraw their stent at home (97%) and was satisfied (75%). They were also less painful than during cystoscopic ablation. Main risk of wired DJS was premature removal (10%), but it did not increased complications.[17] This technique can be intended in chosen patients, after clear informations.

Our study is limited because it is a retrospective mono centric study. We analyzed semi rigid URS and fURS to maintain important populations. This is responsible of disparate groups but we consider that it does not impact post-operative pain or our results. Furthermore, despite the large number of surgeons, procedures are standardized, decreasing inter operator variability.

Conclusion:

Not stenting after ureteroscopy seems to be safe for patients with centimeter stones and prepared ureter. Using an access sheath and lack of preoperative stenting may impact postoperative pain and complications. Outpatient surgery should be considered as soon as possible.

Conflicts of interest:

None

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Table I : Demographic data and stones parameters (n=366)

	Double J stent (n=259)	No Double J stent (n=107)	pvalue
Age (years) †	56,12 ± 17,2 (18-93)	54,7 ± 16,3 (20-91)	0,469
Gender male/females (ratio)	1,76	1,56	0,679
ASA (n, %)			0,044
1	90 (36,14)	46 (51,11)	
2	113 (45,38)	36 (40)	
3	43 (17,27)	8 (8,89)	
4	3 (1,2)	0 (0)	
BMI (Kg/m2) †	27,2 ± 6,36 (16-52,5)	26,54 ± 4,98 (17,6-42,9)	0,637
Maximum stone size (mm) †	12,7 ± 12,9 (2-90)	7,2 ± 2,5 (3-16)	**<0,001**
Cumulative stone size (mm) †	18,3 ± 14,9 (2-90)	9,4 ± 5,2 (3-30)	**<0,001**
Stone location (n, %)			**<0,001**
Kidney	271 (68,8)	56 (44)	
Upper calix	48 (17,7)	5 (8,9)	
Middle calix	69 (25,5)	19 (33,9)	
Lower calix	91 (33,6)	22 (39,3)	
Pyelic	63 (23,2)	10 (17,9)	
Ureter	123 (31,2)	74 (56)	
Proximal	89 (72,35)	54 (73)	
Distal	34 (27,65)	20 (27)	
Pre-stent ureter (n, %)	162 (62,5)	84 (78,5)	**0,004**

pvalue significant (ie, <.05) indicated in bold.

† Mean ± Standard deviation (Range)

Table II: Operative data characteristics (n=366)

		Double J stent (n=259)	No stent (n=107)	pvalue
Access sheath (n, %)		190 (73,4)	45 (42,1)	**< 0,0001**
Intervention (n, %)				**< 0,0001**
	Flexible	152 (58,7)	39 (36,4)	
	Semi rigid	61 (23,5)	54 (50,5)	
	Both	46 (17,8)	14 (13,1)	
Surgeon (n, %)				0,4512
	Junior	113 (43,6)	52 (48,6)	
	Senior	146 (56,4)	55 (51,4)	
Stone free (n, %)		160 (62,5)	89 (89)	**< 0,0001**
Ambulatory (n, %)		136 (52,5)	81 (75,7)	**< 0,0001**
Hospitalization length (days) †		1,29 ± 1,2 (1-11)	1 ± 0,27 (1-2)	0,222

pvalue significant (ie, <.05) indicated in bold.

† Mean ± Standard deviation (Range)

Table III : fURS subgroup analysis (n=191)

	Double J stent (n=152)	No Double J stent (n=39)	pvalue
Maximum stone size (mm) †	10 ± 14.61 (2-90)	7 ± 3.08 (3-16)	**<0,001**
Cumulative stone size (mm)†	18 ± 16.12 (2-90)	10 ± 6.28 (5-30)	**<0,001**
Pre-stent ureter (n, %)	93 (61,18)	25 (64,10)	0.88
Access sheath (n, %)	148 (97,37)	35 (89,74)	0.056
Stone free (n, %)	77 (50,66)	30 (76,92)	**0,005**
Ambulatory (n, %)	72 (47,37)	30 (76,92)	**0,001**
Pain (n, %)	37 (24,34)	12 (30,77)	0,538
VRS †	4 ± 2.16	5 ± 2.4	0.611
Complications (n, %)	46 (30,26)	14 (35,90)	0.552
Clavien 1	32 (69,57)	12 (85,71)	
Clavien 2	12(26,09)	2 (14,29)	
Clavien 3a	1 (2,17)	0	
Clavien 3b	1 (2,17)	0	

pvalue significant (ie, <.05) indicated in bold.

† Mean ± Standard deviation (Range)

Table IV: Pain and Complications characteristics (n=366)

	Double J stent	No stent	pvalue
Pain (n, %)	57 (22)	19 (17,7)	0,338
VRS †	4,48 ± 2,32	4,8 ± 2,14	0,4450
Complications (n, %)	75 (29)	22 (20,5)	0,1181
Clavien 1	53 (20,5)	19 (17,7)	0.17
Clavien 2	20 (7,7)	2 (1,9)	0.145
Clavien 3a	1 (0,4)	0	0.5
Clavien 3b	1 (0,4)	1 (0,9)	0.5
Pain (n, %)	57 (76)	19 (86,4)	0,3979
Fever (n, %)	14 (18,6)	2 (9)	0,1664
Hematuria (n, %)	1 (1,3)	1 (4,5)	0,4998
Urinoma (n, %)	2 (2,6)	0	1
Hematoma (n, %)	1 (1,3)	0	1
Rehospitalization (n, %)	9 (3,5)	3 (2,8)	1

pvalue significant (ie, <.05) indicated in bold.

† Mean ± Standard deviation

Table V : Postoperative pain risks factors (n=366)

	Pain (n=85)	Painless (n=281)	p-value
Age (years) †	55,64 ±13,34 (20-89)	57,72 ±17,16 (21-94)	0,312
Ambulatory (n, %)	55 (64,70)	162 (57,65)	0,301
Double J stent (n, %)	64 (75,29)	195 (69,39)	0,361
Prestent ureter (n, %)	44 (51,76)	202 (71,88)	**0,0008**
Maximum stone size (mm) †	9,79 ±4,27 (3-20)	11,29 ±11,52 (2-90)	0.067
Cumulative stone size (mm) †	15,22 ±10,02 (3-60)	15,75 ±13,57 (2-90)	0.695
Access sheath (n, %)	64 (75,29)	173 (61,56)	**0.028**

† Mean ± Standard deviation (Range)

Table VI : Univariate (A) and multivariate (B) logistic regression models examining the postoperative complications (n=366)

A.	Complications (n=97)	No complication (n=269)	p-value
Age (years) †	54,45 ± 16,72 (19-88)	56,66 ± 16,99 (18-93)	0.2992
Ambulatory (n, %)	62 (63,92)	155 (57,62)	0.3349
Double J stent (n, %)	75 (77,31)	184 (68,40)	0.1181
ASA (n, %)			0.4237
1	38 (39,17)	98 (36,43)	
2	42 (43,3)	117 (43,49)	
3	12 (12,37)	39 (14,49)	
4	2 (2,06)	1 (0,37)	
Lower calix localization (n, %)	35 (36,08)	78 (29,00)	0.2021
Prestent ureter (n, %)	53 (54,64)	193 (71,75)	**0,0025**
Maximum stone size (mm) †	9,686 ± 4,337 (2-20)	11,57 ± 12,76 (3-90)	0.8517
Cumulative stone size (mm) †	15,40 ± 10,17 (2-60)	15,86 ±14,51 (3-90)	0.3579
Access sheath (n, %)	73 (75,26)	162 (60,22)	**0.0093**
Surgeon (n, %)			**0,0172**
Junior	43 (44,33)	158 (58,74)	
Senior	54 (55,67)	111 (41,26)	

B.

	OR	IC 95%	p-value
Double J stent	0,7214	[0,3924-1,2964]	0,28
Ambulatory	0,6532	[0,3890-1,0823]	0,102
Unprestent ureter	2,07	[1,2569-3,4113]	**0,0042**
No access sheath	0,5427	[0,3048-0,9436]	**0,0334**
Senior	1,6781	[1,03-2,7459]	**0,0381**

OR, odds ratio ; CI, confidence interval. pvalue significant (ie, <.05) indicated in bold.
Multivariate analysis

† Mean ± Standard deviation (Range)