

EFFICACY AND SAFETY OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL) IN PIELIC STONES AND INFECTED HYDRONEPHROSIS AFTER DOUBLE-J STENT INSERTION

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EFFICACY AND SAFETY OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL) IN PIELIC STONES AND INFECTED HYDRONEPHROSIS AFTER DOUBLE-J STENT INSERTION (Abstract): Extracorporeal shockwave lithotripsy (ESWL), along with flexible retrograde ureteroscopy (RIRS), is the treatment of first choice for pelvic stones up to 10 mm, and double-J catheters are not routinely inserted prior to the procedure. However, their insertion is mandatory in patients with infected secondary hydronephrosis. The **aim** of the study was to evaluate the efficacy and safety of ESWL in this particular group of patients compared to patients without double-J ureteral catheters. **Materials and methods:** We conducted a retrospective case-control study of patients with pelvic stones up to 10 mm in whom a double-J ureteral catheter was inserted due to infected hydronephrosis and subsequently underwent ESWL between January 1, 2018 and December 31, 2023. As a control group, we included the patients with pelvic stones without a double-J catheter who underwent ESWL during the same period. We analyzed the demographic data, the stone-free rate and the occurrence of complications in the two patient groups. **Results:** We identified a number of 46 patients with double-J catheters and a number of 118 patients without double-J catheters who underwent ESWL for pelvic stones up to 10 mm. Patients in both groups were over 46 years of age, were predominantly male and had a body mass index (BMI) between 25 and 29.9. There were no statistically significant differences between the 2 groups in terms of stone-free rate, both after the first (78.3% vs. 73.7%, $p=0.866$), second (89.58% vs. 89.8%) and third ESWL sessions (93.7% vs. 95.7%, $p=0.583$). The complication rate was reduced in both groups, with no statistically significant differences (14.6% vs. 6.77%, $p=0.324$). **Conclusions:** The presence of double-J ureteral catheters inserted due to infected hydronephrosis did not reduce the efficacy of ESWL in patients with pelvic stones up to 10 mm. In this patient group, ESWL can be recommended as a first-line treatment alongside RIRS. **Keywords:** PIELIC STONES, INFECTED HYDRONEPHROSIS, ESWL, DOUBLE-J STENT SYNDROME.

According to European practice guidelines (1), extracorporeal shock wave lithotripsy and flexible retrograde ureteroscopy are the treatment methods of first choice

for pelvic stones smaller than 10 mm, with an almost stone-free rate of over 90% (2). Some studies show that prior insertion of a double-J catheter before ESWL would reduce the risk of complications (3, 4) or increase the efficacy (5), others show an equal stone-free rate (6) and even a decrease in the efficacy of the procedure (7), both after the first (8) and after several sessions (9, 10), especially for ureteral stones.

In the case of pelvic stones, prior insertion of the double-J catheter is only indicated for large stones (over 2 cm) with post-procedural risk of renal colic, *stein-strasse*, and ureteroscopy (1). Ureteral stenting prior to ESWL is generally contraindicated in patients with pelvic stones smaller than 10 mm, as the stone-free rate in these patients is high (2). In practice, however, some patients with pelvic stones in the pyeloureteral junction or with obstructive ureteral stones present to the emergency room with infected hydronephrosis. Insertion of a double-J catheter is then a necessity to prevent progression of urosepsis and to cure the additional urinary tract infection associated with antibiotic therapy.

After the obstruction and infection are resolved, patients present with localized pelvic stones and a double-J catheter. In this particular case, it is not known whether ESWL can be an alternative to flexible ureteroscopy, as in the case of patients without a double-J catheter. Therefore, we conducted a retrospective comparative study in which we compared the efficacy of ESWL in patients with pelvic stones less than 10 mm without double-J catheters with patients in whom double-J catheters were inserted due to infected hydronephrosis. We mention that in our clinic double-J catheters are not routinely inserted before

ESWL to increase the efficiency of the procedure. As a secondary aim of our research, we analyzed the complications that occurred in patients with double-J catheters, especially since in some of them the catheters were inserted over a period of up to 3 months because 2 or even 3 sessions of ESWL were required to achieve stone-free status.

MATERIALS AND METHODS

We conducted a comparative, retrospective study over a 5-year period in patients admitted to Elytis Hospital between January 1st, 2018 and December 31st, 2023 with pelvic stones up to and including 10 mm, with or without double-J catheters, in whom we performed extracorporeal shock wave lithotripsy. The study was approved by the hospital ethics committee. We invite all patients to sign a general consent allowing us to register healthcare data for retrospective studies (laboratory, demographics, therapy and comorbidities). The patients' data were obtained from the observation forms, surgical records and the hospital's electronic registry. Patients were followed until they reached stone-free status or up to one month after the last ESWL session.

The study group consisted of all patients with radiopaque pelvic stones between 5 and 10 mm inclusive who had double-J catheters inserted at least 3 weeks ago, namely 56 patients. All double-J catheters inserted were 7CH, with a length between 24 and 28 cm. We mention that there were 10 patients who originally had ureteral stones and in whom these were pushed back into the renal pelvis by the insertion of the double-J catheter. All patients had negative urine cultures prior to the ESWL procedure.

This explains why the procedure was

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performed 3 weeks after insertion of the double-J catheter to allow resolution of the pyelonephritic process. Patients with radiolucent stones, patients with multiple pelvic or pyelocaliceal lithiasis and patients in whom the double-J catheter was inserted because of hyperalgetic renal colic or non-functioning kidneys detected by urography or contrast CT were excluded from the study.

Patients with double-J stent syndrome were treated with tolterodine 2 mg twice daily until the catheter was removed. We defined double-J stent syndrome as the presence of lower urinary tract symptoms (LUTS) and/or the presence of macroscopic hematuria. In the absence of improvement of symptoms, flexible retrograde ureteroscopy was proposed to patients and performed, considering the failure of the ESWL procedure, even if the 3 sessions of ESWL were not performed. All patients in this group received prophylactic antibiotic treatment with one tablet of cefuroxime 0.5 g before the procedure.

To form the control group, all patients with pelvic stones between 5 and 10 mm who were treated during the same period were included in the study. This resulted in a total of 126 patients. Patients with secondary 2nd, 3rd and 4th degree hydronephrosis according to the Onen classification (11) and patients with radiolucent pelvic stones were excluded from the study. We excluded patients with significant secondary hydronephrosis because we assumed that obstruction of the pyeloureteral junction may affect the efficacy of the ESWL procedure and because patients in the double-J catheter group did not have this degree of hydronephrosis. We included patients in the study who had secondary 1st grade hydronephrosis because some pa-

tients in the study group also had this grade of hydronephrosis.

The ESWL procedure was performed with a Siemens Sonolith device by 3 urologists using the same technique of shock wave application by the ramping method and the same protocol for patient follow-up. Each patient had a maximum of 3 ESWL sessions 4 weeks apart. This interval was chosen to allow for spontaneous elimination of the fragments (12) and recovery of the renal parenchyma after exposure to the shock waves. After each session, the stone-free status was assessed after 4 weeks. In the presence of stones or remaining fragments larger than 4 mm, ESWL procedure was continued.

For fragments less than 4 mm, the double-J catheter was suppressed in the patients in the study group, and the elimination of all fragments was monitored in all patients studied up to an interval of one month. If they had no remaining fragments one month after the last ESWL session, the procedure was considered successful. In the absence of fragmentation or the presence of fragments of any size still present, the procedure was considered a failure and patients underwent an active follow-up program every 6 months.

For all patients in the 2 groups, we collected demographic data and information related to the diagnosis, including age, gender, BMI, location and size of the stones. Their analysis was necessary because we knew that they could influence the stone-free rate of stones, so if there were bias factors in the comparison analyzed. We compared the ESWL parameters, i.e. the number of sessions, the total number of shock waves applied per patient, the average and maximum energy of the shock waves applied and the total energy applied

to each patient regardless of the number of sessions. We analyzed the stone-free rate in the 2 groups, the type of complications and the total number of complications in the 2 groups.

Statistical analysis. Quantitative variables were described by mean and standard deviation and compared using the t-Student test after analyzing the homogeneity of the batches using the Kolmogorov-Smirnov test. Qualitative variables were described by percentages and compared using the chi-square test or the Fischer test if the values of the variables were less than 5. Stone-free rates were compared after each session by calculating the odds ratio and confidence interval.

RESULTS

During the study period, a total of 182 patients with pelvic stones between 5 and

10 mm underwent ESWL. Of these, 56 patients had a double-J catheter and 126 were without a double-J catheter. From the group of patients with double-J catheters, 4 patients with radiolucent stones, 3 patients in whom the double-J catheter was inserted due to hyperalgiac renal colic and 3 patients with multiple pyelocaliceal lithiasis were excluded. The result was a number of 46 patients with double-J catheters who formed the study group. Of the 126 patients without double-J catheters, we excluded 3 patients who had concomitant secondary hydronephrosis of the second, third or fourth degree and 5 patients with radiolucent stones. The result was a number of 118 patients without double-J catheters, which constituted the control group.

The demographic characteristics and information on the size and location of the stones are shown in the first table.

TABLE I.
The characteristics of the two groups

		Double-J catheter group (n=46)	Non-Double-J catheter group (n=118)	Statistical test	p value
Age, mean \pm SD (median/limits)		49.33 \pm 15.0 (49/19-79)	46.24 \pm 12.59 (45/19-84)	t-Student	0.183
Gender	Male (No., %)	21 (45.7)	67 (56.8)	Chi2	0.201
	Female (No., %)	25 (21.3)	51 (43.2)	Chi2	0.201
BMI	< 24.9	14 (30.4)	14 (11.9)	Chi2	0.005
	25-29.9	29 (63.0)	102 (86.4)	Chi2	0.001
	> 30	3 (6.5)	2 (1.7)	Chi2	0.107
Size of the calculi (mm), mean \pm SD (median/limits)		9.22 \pm 1.09 (10/6-10)	9.14 \pm 1.23 (10/6-10)	t-Student	0.694
	Right side (No., %)	20 (43.5)	59 (50.0)	Chi2	0.452
	Left side (No., %)	26 (56.5)	59 (50.0)	Chi2	0.452

There were no differences between the two groups in terms of average age at the time of ESWL, gender, size and location of the calculi. Regarding BMI, overweight patients were more numerous in the group

without double-J catheter ($p=0.001$). In both groups, the average age was over 46 years, with men predominating and the majority of patients being overweight (63% and 86.4% respectively). The stones were

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on average between 9 and 10 mm in size and were predominantly located on the right side in the study group, while they were the same size in the control group,

with no significant differences between the two groups ($p=0.452$)

The parameters of ESWL in the 2 groups are presented in table II.

**TABLE II.
The parameters of ESWL in the 2 groups**

		Double-J catheter group (n=46)	Non-Double-J catheter group (n=118)	p value for t-Student
Mean no. of sessions \pm SD (median/limits)		1.26 \pm 0.54 (1/1-3)	1.32 \pm 0.58 (1/1-3)	0.538
Total no. of shockwaves, Mean \pm SD (median/limits)		2218 \pm 306 (2300/1180-2626)	2193 \pm 409 (2300/765-3203)	0.707
Energy level	Mean, mean \pm SD (median/limits)	0.73 \pm 0.19 (0.75/0.20-1.10)	0.72 \pm 0.21 (0.75/0.25-1.25)	0.699
	Maximum, mean \pm SD (median/limits)	1.22 \pm 1.29 (1.0/0.50-1.50)	1.02 \pm 0.33 (1.0/0.10-2.00)	0.119
Total delivered energy, Mean \pm SD (median/limits)		27.36 \pm 6.82 (27.82/8.90-47.39)	26.30 \pm 8.40 (26.34/3.04-68.00)	0.447

There were no statistically significant differences between the two groups in terms of the average number of sessions required to achieve stone-free status ($p=0.538$), the total number of shock waves applied ($p=0.707$), the average and maximum energy levels and the total energy dose ($p=0.447$). In both groups, between 1 and 2 ESWL sessions were required, over 2000 shock waves, with an average intensity between 0.7 and 0.8 and with a total dose of energy below 30 joules. However, the total dose of applied energy varied in both groups fluctuated in wide intervals, with large differences between minimum and maximum.

The stone-free rate after each ESWL session and the complication rate are presented in table III.

There were no statistically significant differences between the 2 groups in terms of stone-free rate after each of the 3 ESWL sessions. In both groups, the stone-free rate

was 70% after the first session, 80% after the second session and 90% after the third session. In the group with double-J catheters, 2 cases developed reflux nephropathy after the second session, necessitating the abandonment of the procedure. In addition, there were 5 cases with double-J stent syndrome, of which 1 case required abandoning the procedure after the first ESWL session. In the group without double-J catheters, there were 6 patients (5.1%) who presented with post-procedural renal colic that responded to analgesic and anti-inflammatory medications and did not require insertion of a double-J stent. In addition, two patients (1.69%) developed infected hydronephrosis after the first session, which necessitated the abandonment of the procedure and insertion of a double-J catheter.

There were no differences in the overall rate of complications between the two groups.

TABLE III.
Stone free rate and the complications incidence in the 2 groups

		Double-J catheter group (n=46)	Non-Double-J catheter group (n=118)	OR C.I.95%	p (chi square)
Stone free (No., %)	After 1 st session	34 (73.9%)	87 (73.7%)		0.862
	After 2 nd session	34+4=38 (82.60%)	87+19=106(89.8%)	0.97 0.32-2.93	0.315
	After 3 rd session	38+4 = 42 (91.30%)	106+7=113 (95.7%)	0.66 0.15-2.89	0.269*
Complications (No., %)	Reflux nephropathy	2 (4.3%)	0 (0.0%)	13.31 0.62-282.80	0.023*
	Double-J stent syndrome	5 (10.9%)	0 (0.0%)		0.001*
	Renal colic	0 (0.0%)	6 (5.1%)		0.044*
	Infected hydro-nephrosis	0 (0.0%)	2(1.69%)		1*
Total number of complications		7 (14.6%)	8(6,77%)		0.324

*Fischer Exact Test Calculator for 2X2 contingency table

DISCUSSION

The results of the study show that ESWL has a similar stone-free rate and the same complication rate for pelvic stones between 5 and 10 mm in patients with double-J catheters inserted for infected hydro-nephrosis. The main limitations of our study were the retrospective nature and the relatively small number of the study group. The number was limited by the inclusion criteria of patients with infected hydro-nephrosis due to stones up to 10 mm. A further limitation of the study was the lack of measurement of the density and all 3 dimensions of the stones on native CT, as this is known to influence the rate of fragmentation and elimination of the stones. However, for stones up to 10 mm this has only a minor influence compared to stones over 10 mm.

While in ureteral lithiasis the insertion of a double-J catheter could create an expansion chamber for the fragments that occurred after ESWL (13), in pelvic stones the pyelocaliceal system takes over this

role, so that the insertion of the double-J catheter would be useless, there is even the disadvantage of creating an obstacle in the path of the shock waves (13), thus reducing the efficiency of ESWL.

The two study groups had the same values for stone location and size, which allowed comparison of stone-free rates according to the presence or absence of double-J catheters with minimal error factors. In both groups, the age was under 50 years, younger than in other local studies (14), where the average age was over 50 years. This can be explained by the fact that in recent years more and more patients are having routine ultrasound examinations performed, or when symptoms are minimal, which allows diagnosis in the case of some still relatively small stones. As in previous studies, the majority of patients were overweight, with a predominance of males (14).

In both groups, the size of the stones was between 9 and 10 mm, a size at which spontaneous elimination is unlikely. It is likely that many patients with smaller

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stones had eliminated the stones spontaneously without the need for ESWL.

If we analyze the stone-free rate in the two groups, we see a good result, the same in both groups as in other studies (15), over 70% even after the first ESWL session, much higher than the rate below 50% in the case of ureteral stones performed with the same technique and device (14). In both groups, the application of the second and third sessions proved useful, increasing the efficiency of the procedure to over 80% and 90%, respectively. Even if we did not obtain results of 98-100% as in flexible retrograde ureteroscopy (RIRS) (2), we consider that the difference of a few percent is not clinically relevant to contraindicate the ESWL procedure, even in patients who wear double-J catheters. In addition, there are patients who do not want surgery and local or general anesthesia, which is necessary to perform RIRS, and who request the non-invasive ESWL procedure, even if stone-free status is achieved faster after RIRS (16). We also see that the presence of the double-J catheters did not lead to an increase but also not to a decrease in stone-free status. We used a combined radiologic and ultrasound guide to focus the calculi, and we changed the position of the patient on the treatment table so that the double-J catheter did not interfere with the stone and shock waves, so that higher energy doses were not required to fragment the calculi in the presence of double-J catheters.

Comparing ESWL parameters, we note that the number of sessions required for ESWL success was low, using lower energy doses than for ureteral stones (14), reducing the risk of renal hematoma, a reducible complication that otherwise did not occur in any treated case.

In terms of complications, although wearing the double-J catheters eliminated

the risk of renal colic, it did not reduce the risk of infection. Instead, complications related to the presence of the catheters occurred, such as double-J stent syndrome, which has been reported in high percentages in some studies (17, 18), but only in a low percentage in our study, similar to other local studies (19). However, the presence of double-J stent syndrome could be treated with medication. Only in one case ESWL treatment had to be abandoned, which proves that the presence of double-J stent syndrome does not significantly affect the efficacy of ESWL treatment. It is possible that double-J stent syndrome occurred immediately after catheter insertion, so some of them could not undergo ESWL and opted for RIRS, so the actual number of patients with double-J stent syndrome is higher than reported in our study.

The presence of double-J catheter did not increase the risk of post-procedural infection (20), as reported in some studies (21, 22). There were 2 patients in each group who had high UTIs. Double-J catheter carriers experienced reflux pyelonephritis, which has also been reported in other studies (22, 23), with possible progression to sepsis (22), even in the absence of an obvious inflammatory syndrome (24). This risk was probably reduced in the patients with double-J catheters by the fact that all of them received antibiotic prophylaxis with cefuroxime, one tablet 30-60 minutes before the procedure, and especially because all patients with double-J catheters underwent ESWL 3 weeks after stent insertion for infected hydronephrosis, which allowed the pyelonephritic process to resolve, and also only after a negative urine culture.

The advantage of having double-J catheters in our study, in contrast to other studies (25), was the elimination of the risk of

renal colic and the need to visit an emergency service (26), which can be a problem in patients in remote areas.

The fact that the fragmentation rate was already high after the first procedure made it possible in most cases to remove the double-J stents earlier than 2 months and thus minimize the risk of calcification of the catheters. Although some studies showed a higher recurrence rate in the first 5-10 years after ESWL compared to RIRS (27, 28), we did not find a high rate of residual fragments that would suggest this. In our study group, we found no patients with significant calcifications that required additional maneuvers to remove them, such as endoscopic lithotripsy or retrograde ureteroscopy. Further prospective studies in larger patient groups are needed to validate our results.

CONCLUSIONS

Our study demonstrated that ESWL for

pelvic stones up to 10 mm, in patients with double-J catheters inserted for infected hydronephrosis, is a safe and effective method, with minimal side effects, just like ESWL in patients without double-J catheters. In these patients, ESWL can be recommended as a first-line treatment along with RIRS.

CONFLICT OF INTEREST AND FUNDING

Patient consent was obtained for presenting this case in a medical publication to contribute to the expansion of the database on this pathology.

The ethics committee of the medical unit has approved the presentation of the case in a medical article in a medical publication while respecting personal data.

Regarding conflicts of interest, all authors have declared that they have not received any financial support from any organizations related to the published work.

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