Impact of ureteric stent on outcome of extracorporeal shockwave lithotripsy: A propensity score analysis

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Introduction
Extracorporeal shockwave lithotripsy (SWL) is one of the most frequently performed procedures in patients with urolithiasis. For ureter-localized stones, SWL is often preceded by a double J stent insertion. However, fear of serious complications, including sepsis associated with stents, is often expressed. The following study assessed the impact of stent insertions on the results of SWL in patients with ureteric stones.

Material and methods
The study group consisted of 411 ureteric stone patients who were treated with SWL from January 2010 to December 2014. In 60 cases, treatment was preceded by ureteric stent insertion. A propensity scoring system was used to pair non-stented patients with the stented group. Success rates were assessed and compared using the chi-squared test. Multivariate logistic regression analysis was used to evaluate the influence of particular variables on the stone-free rate.

Results
The overall success rate was 82.2%. After matching, the success rate of the stented group was not significantly different from the control group (85.0% vs. 83.3% respectively, p = 0.80). The mean number of sessions was higher in the stented group (1.88 per patient). Stones located in the lower part of the ureter have the greatest chance of being successfully treated.

Conclusions
The double J stent has no influence on the outcome of SWL treatment. In view of the greater likelihood of having additional sessions, this approach should be reserved for selected cases.

Key Words: extracorporeal shockwave lithotripsy ◆ ureter ◆ stent ◆ stone

INTRODUCTION
Extracorporeal shockwave lithotripsy (SWL) is a minimally invasive technique for treatment of renal and ureteric stones. The majority of SWL procedures can be performed on an outpatient basis. Since shock waves were first used to treat urolithiasis in humans in the 1980s, the procedure has developed considerably. The newest generation of lithotryptor uses electroconductive or electromagnetic mechanisms for better concentration of energy onto the stone. The effectiveness of lithotripters has been reported to be as high as 90% in some studies [1]. However, the newest apparatus cannot eliminate all factors that worsen the outcome of the treatment. Most of these factors are relative to the stone’s features.

For instance, some studies have reported a linear relationship between stone density and fragmentation rate [2]. Furthermore, patients’ characteristics also have a strong influence on success rates. Different treatment outcomes are observed depending on the body mass index (BMI). Failure of SWL procedures is frequently observed in patients with BMI above 25 kg/m² [3]. In patients suffering from pain with hydronephrosis, and with the high risk of sepsis, kidney decompression should be considered before SWL. Decompression can be achieved by inserting a ureteric stent or percutaneous nephrostomy and is generally performed on ureteric stone patients with totally obstructed urine flow. In contrast to nephrostomy, the entire ureteric stent is inside the body; this approach is usually tolerated better by patients. Other studies
have shown that double J stents can reduce the effectiveness of SWL and delay expulsion of the stones [4, 5]. Therefore, the following study assessed the results of SWL in stented and non-stented patients with ureteral calculi.

MATERIAL AND METHODS

This cohort retrospective study was conducted on patients treated in our department from January 2010 to December 2014 due to ureteric stone. All diagnoses were confirmed by computed tomography (CT) or intravenous urography. Only adults who were previously untreated with SWL, as a treatment of choice, were recruited to the study. A further inclusion criterion was the presence of a single, radiopaque stone, measuring below 20 mm. The study incorporated patients with stones localized in all parts of the ureter. Patients in whom a percutaneous nephrostomy had been inserted previously were excluded from the study. The final study population consisted of 411 cases. These patients were divided into two groups: (1) patients without a ureteric stent and (2) those in whom insertion of ureteric stents has been performed. The with- and without-stent groups consisted of 60 and 351 patients respectively. The clinical situation and patients’ symptoms were indications for stenting. Complicated renal colic (defined as hydronephrosis associated with intolerable pain, deteriorating renal function or pyelonephritis) was a semi-elective criterion for insertion of double J stents (the procedure is performed to preserve the patient’s health, but urgent implementation is not needed). SWL was the treatment of choice for patients with a solitary kidney without renal colic and hydronephrosis. In those patients stenting was an elective approach (procedure scheduled in advance). Renal colic and hydronephrosis were indications for ureteroscopic lithotripsy in patients with a solitary kidney.

The electroconductivity EDAP TMS Sonolith I-move was used to treat both groups. The average number of impulses was 4010.78 and the peak was 2 Hz. An electrode with a maximum voltage of 22 kV was used. The priming technique was selected. The escalating protocol was initiated with 1000 shocks at 25% power and was increased by increments of 25% to the highest level tolerated by the patient. The procedures were conducted under intravenous analgesia (2.5 g metamizole). In case of procedure intolerance, patients received additional oral or intravenous analgesia. The treatment was carried out under x-ray control. Patients with stones placed in the lower ureter were treated in the prone position, whereas those with stones localized elsewhere were treated in the supine position. All treatments during the study were overseen by the same medical staff. The SWL procedure was performed by two persons (an urologist and a nurse). The time period between the insertion of the double J stent and the first session of SWL ranged from 2 weeks to 1 month in semi-elective approach patients, whereas in non-stented patients and in those undergoing an elective procedure the time from colic onset to treatment ranged from 2 to 7 days. If a patient suffered from uncontrolled urinary infection or severe pain, or in case of significant elevation of inflammatory and renal parameters, the SWL was not preformed. After the SWL, tamsulosine and drotawerine were administered for 2 weeks.

The effectiveness of the treatment was evaluated radiologically 2 weeks after the first and all subsequent procedures. The treatment was described as successful if the stone was completely eliminated from the urinary tract or if a residual asymptomatic stone measured <4 mm. The asymptomatic stone was defined as one not causing neither symptoms nor hydronephrosis. When the criteria of successful treatment had been achieved, the stents were removed within 6 weeks after SWL.

Data including gender, age, body mass index (BMI), stone localization by side, location within the ureter (upper, middle or lower) and exact size of the stones in two dimensions were recorded. A review of the electronic medical records was performed to collect all data. An independent t-test and a chi-squared test were used to compare the two groups. The groups were not homogeneous. The propensity score was calculated based on all measured variables. The nearest neighbor method without replacement was applied to match patients without stents to patients with intervention. Each patient from the intervention group was paired with one patient from the control group. Paired patients had the closest propensity score. After matching, a Pearson’s chi-squared test was used to compare treatment results between the two groups. Analyses were also performed in subgroups according to stone size. Furthermore, logistic regression was performed to estimate the influence of particular variables on patient’s outcome. Statistical analyses were done using Statistica 12 software.

RESULTS

The study population was 68.3% male and 31.7% female, with an overall average age of 49.7 years (range: 18 to 83 years old). Stones were mainly situated in the middle part of the ureter (67.5%) and a similar frequency was identified on each side: 49% on the left and 51% on the right side. The shortest
mean dimension was 5.1 ± 2.2 mm and the longest dimension was 8.2 ± 3.5 mm. Initial analysis indicated a difference in stone localization between the groups. The characteristics of the groups before matching are shown in Table 1. Stones were more frequently situated in the middle part of the ureter in the stented group than in the non-stented group (80.0 and 47.9% respectively). The overall success rate was 82.2% (n = 338/411). After matching there was no significant statistical difference between the groups (p = 0.80). The success rates in the stented and non-stented groups were 85.0 and 83.3% respectively, with an estimated odds ratio (OR) of 1.13 CI 95% (0.42–3.06). An additional analysis of the results after the first session also emphasized the lack of difference between the groups. In the non-stented group the success rate after the first session was 53.33% and in the stented group was 43.33% (p = 0.27). Again, the subgroup analysis illustrated no difference in the success rate between the groups (Table 2), although the mean number of sessions was higher among the stented patients (Table 3). Multivariable logistic regression indicated that stone location could affect the treatment outcome. Stones localized in the lower ureter are associated with an OR for the stone-free rate of 3.28 CI 95% (1.28–8.38) compared to stones localized in the upper ureter (Table 4).

**DISCUSSION**

Ureter-localized stones can cause intolerable pain, acute kidney dysfunction and other serious complications, including sepsis. There is an increased risk of complications associated with the application of double J stenting before SWL. Several authors have shown that this approach can relieve obstructions and increase the percentage of fragmentation.

### Table 1. Clinical characteristics of patients in two groups (n = 411)

| Characteristic          | Group 1 (unstented) | Group 2 (stented) | p   |
|-------------------------|---------------------|-------------------|-----|
| Age, years              | 49.53               | 47.82             | 0.69|
| SD                      | 18.57               | 15.42             |     |
| Sex                     | 116                 | 16                | 0.32|
| Female                  | 235                 | 44                |     |
| BMI                     | 27.79               | 27.06             | 0.57|
| Mean                   | 16.02               | 3.94              |     |
| Side                    | 198                 | 29                | 0.24|
| Left                    | 153                 | 31                |     |
| Right                   |                     |                   |     |
| Part of ureter          |                     |                   |     |
| Upper                   | 35                  | 6                 | <0.01|
| Middle                  | 168                 | 48                |     |
| Lower                   | 148                 | 6                 |     |
| Longest dimension       | 8.01                | 7.95              | 0.90|
| Mean                   | 3.62                | 3.04              |     |
| Shortest dimension      | 5.11                | 4.98              | 0.68|
| Mean                   | 2.18                | 1.87              |     |
| SD – standard deviation, BMI – body mass index |

### Table 2. Success rate in matched groups

|               | Group 1 (unstented) | Group 2 (stented) | p   |
|---------------|---------------------|-------------------|-----|
| Overall       | 83.3%               | 85.0%             | 0.80|
| Subgroup <10 mm | 83.3%             | 86.4%             | 0.69|
| Subgroup ≥10 mm | 83.3%              | 81.3%             | 0.87|

### Table 3. Location of the stone and number of treatment sessions in matched groups

| Number of treatment session | Mean (session) |
|-----------------------------|----------------|
| 1                           | 2              |
| 2                           | 3              |
| 3                           | 4              |
| 4                           | 5              |
| 5                           | 6              |
| Group 1                     |                |
| Upper ureter                | 2              |
| Middle ureter               | 11             |
| Lower ureter                | 11             |
| All locations               | 1              |
| Group 2                     |                |
| Upper ureter                | 4              |
| Middle ureter               | 17             |
| Lower ureter                | 5              |
| All locations               | 1              |
| Total(n)                    | 68             |
| 35                           |
| 8                            |
| 5                            |
| 2                            |
| 2                            |
| 1.70                         |

### Table 4. Multivariable logistic regression analyses of outcome predictors

| Characteristic          | OR      | 95% CI |
|-------------------------|---------|--------|
| Age, years              | 1.01    | 0.99–1.02|
| Gender: female vs. male | 0.99    | 0.56–1.74|
| BMI: ≥25 kg/m² vs. <25 kg/m² | 0.69 | 0.38–1.24|
| Side: left vs. right    | 0.89    | 0.53–1.46|
| Location of stone:      |         |        |
| Middle vs. upper ureter | 1.48    | 0.62–3.54|
| Lower vs. upper ureter  | 3.28    | 1.28–8.38|
| Unstented vs. stented patients | 1.06 | 0.48–2.36|
| Stone size: ≥10 mm vs. <10 mm | 1.00 | 0.54–1.87|

CI – confidence interval; OR – odds ratio
by improving the stone-fluid interface [6]. However, the stent can cause spasm and constriction of the ureter, resulting in reduced stone clearance [7, 8]. In addition, stents can also interfere with shock wave propagation [9]. The newest guidelines of the European Urology Association do not recommend stenting as a part of SWL, as it might cause additional symptoms in patients with a ureteric stent. Stented patients usually complain of urinary frequency, urgency and dysuria [10]. However, the European Urology Association guidelines provide no information regarding the influence of double J stents on the results of SWL. This problem is especially important in cases of impacted calculi. Kumar et al. [11] performed a comparison between stented and non-stented patients with impacted upper ureteral stones, evaluating the effectiveness of the treatment 3 months after the procedure. The stone-free rates in the stented and non-stented groups were 90 and 86.7% respectively. No statistically significant difference between the groups was found. Retreatment rates were comparable in both groups. Similar results were reported by El-Assmy et al. [12] in a prospective trial. Additionally, both studies highlighted the side effects associated with stenting. These findings were different from those of Abdel-Khalek et al. [13], who found that stented patients had a lower stone-free rate (81.3%) compared to non-stented patients (89.8%).

Pettenati et al. found a higher failure rate with lumbar ureteral stones measuring >8 mm in diameter (OR = 2.82 CI 95% [1.088–7.307]) [4]. Likewise, Kageyama et al. suggested that, in patients with coexisting factors (e.g. stones measuring >8 mm in diameter, moderate or severe hydronephrosis, middle and lower ureteral calculus and failure of the first SWL session), the treatment modality should be changed to transurethral ureterolithotripsy [5]. Ozkan et al. emphasized that non-stented patients with renal pelvic stones measuring >1 cm² achieved significantly higher stone-free rates [14]. Sfoungaristas et al. found that stents reduce stone-free rates in patients with stones between 4 and 10 mm [15]. Again, in the study by Bierkens et al., the authors discovered no difference in stone-free rates between stented and non-stented patients with large kidney stones [16].

Because of the risk of a steinstrasse, stents are sometimes placed in patients with minor symptoms to avoid additional procedures. Although steinstrasse is usually observed after fragmentation of a large calculus, Sulaiman et al. estimated that steinstrasse occurs in 6.3% of patients after the SWL procedure. In patients with large stones (>20 mm), the steinstrasse was rarely observed when the stent was inserted. The authors also stressed that, in patients with an episode of steinstrasse, acute clinical symptoms were reduced when stents were present [17]. This result was not reproduced in a meta-analysis by Shen et al., which found no significant difference in the total incidence of steinstrasse between stentless and stented groups [18].

Before deciding on the approach, one should consider the risk associated with the placement of a double J stent. The procedure is usually performed under regional or general anesthesia. For elderly patients with multiple co-morbidities, this procedure has a higher risk of morbidity. Moreover, stent insertion can be technically difficult in patients with a urinary tract abnormality or totally obstructed urine flow. Double J stent placement is associated with an increased risk of complications, such as procedure failure and perforation of a ureter. After failure, stenting must be converted to percutaneous nephrostomy in 20% of cases [19]. Stent migration is a further issue. Hastaoglu et al. described an astounding displacement of a double J catheter in a 59-year-old female patient. In this case, the top of the stent perforated the inferior vena cava and reached the right ventricle. Removal of the catheter required an endovascular operation [20]. Likewise, when stents are placed without a thread, removal requires an additional procedure, which is associated with a higher risk of complications.

Infections are also associated with stent placement. Joshi and colleagues assessed 46 stented patients and found a strong correlation between positive urine culture and positive double J tip cultures. E. coli was the most often commonly observed pathogen. Positive urine culture was confirmed in one third of patients after stent removal [21]. Ozgür et al. found that infection associated with double J stent insertion depends on the residing time of the stent. The authors discovered that stents can be safely used within 6 weeks (infection rate is low within this period) [22].

Stent fragmentation is another rare but serious complication. Fajih et al. [23] observed that fragmentation occurred in 0.3% of patients when the stents were residing for more than 12 weeks. Removal of the bladder portion of a DJ stent is usually not challenging and can be performed per urethra. More demanding procedures require removal of the pelvic part of a stent. Furthermore, spontaneous migration of the pelvic part of a fragmented stent to the urinary bladder has been described [24].

In our study, treatment groups varied according to stone location. The percentage of patients with stones placed in the middle part of the ureter in the stented group was almost twice as high as in the non-stented group. A significant difference was also
observed in stones located in the lower part of the ureter (10.0 and 41.2% in the stented and non-stented groups respectively). The stenting approach was often chosen when stones were high in the ureter. Logistic regression analysis found that stone location is a crucial factor influencing the stone-free rate. In daily practice in our department, most of the patients with diagnosed ureter stones are treated without the use of stents, which accounts for the prominent contrast (~1:6) in the number of patients in each group before matching. Therefore, propensity score analysis was performed in order to create comparable groups. This method was developed to minimize the differences in patients’ variables in a retrospective cohort study and is especially important when variables are potentially affecting study results. An ability to control covariates without the loss of observations is one of the most important advantages of this method. However, the propensity matched analysis also has its disadvantages. For a better pairing, this method required a large disproportion between the control and treatment group, as observed in our data. A selection bias is also a significant problem when using this approach. The patients included in our study may not be characteristic of a general population. In Northwestern Poland, our department is a referral centre for Szczecin and the surrounding area. Thus, the wide range of patients treated in the department reduces this effect.

CONCLUSIONS

Despite some constraints, our data confirm the absence of a relationship between stenting approach and effectiveness of the SWL. However, we found that stented patients require more sessions to obtain an equivalent effect. Potential complications associated with double J stent placement suggest that this procedure should be limited to selected cases. A multiple logistic regression analysis found that stents show no benefit in lower ureter stones. In this location, the probability of achieving a stone expulsion is more than three times higher than when the stone is in upper part of the ureter.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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