Published online 2016 January 27.

Research Article

# The Effect of a Double-I Stent in the Treatment of Kidney Stones Larger Than 10 mm in Children Under 13 Years, Using Extracorporeal Shock Wave Lithotripsy (ESWL)

## Heshmatollah Sofimajidpour,<sup>1,\*</sup> Mesbah Rasti,<sup>2</sup> and Fardin Gharibi<sup>2</sup>

<sup>1</sup>Department of Urology, Faculty of Medicine, Kurdistan University of Medical Sciences, Sanandaj, IR Iran <sup>2</sup>Tohid Hospital, Kurdistan University of Medical Sciences, Sanandaj, IR Iran

Received 2014 October 21; Revised 2015 June 23; Accepted 2015 December 7.

#### **Abstract**

Background: Kidney stones were previously rare among children, but now its prevalence and frequency among children has increased. Objectives: The aim of this study was to investigate the effect of a double-I stent on the treatment of kidney stones larger than 10 mm in children under 13 years, using extracorporeal shock wave lithotripsy.

Patients and Methods: This double blind clinical trial study was conducted on 68 children younger than 13 years with renal calculi at pelvic, referred to Tohid hospital in Sanandaj during 2010 - 2014. The patients were randomly divided into two groups: the double-I stent group (34 patients) and the control group (34 patients). 2000 shock waves were given during each period to all subjects. Data were analyzed using SPSS version 18, and descriptive statistics (frequency, ratio, mean, and standard deviation) were collected.

Results: The stone sizes of the intervention and control groups were  $13.76 \pm 2.62$  mm  $13.91 \pm 2.79$  mm, respectively (P = 0.69). In 58.8% of the children in the intervention group and 76.5% of those in the control group, the right kidney was involved (P = 0.12). In terms of postlithotripsy outcome frequency, including fever, hospitalization and steinstrasse, there were no statistically significant difference between the intervention and the control groups (P > 0.05). The frequency of urinary tract infection in the intervention group and the control group was 23.5% and 5.9%, respectively, meaning there was a statistically significant difference between the intervention and the control groups (P=0.04).

Conclusions: The kidney stone clearance rate in children with and without using the stent was almost equal. Considering the problems of kidney stents and additional charges, extracorporeal shock wave lithotripsy (ESWL) without stents is recommended for treatment of 8 to 15 mm kidney stones

Keywords: Stents, Children, Lithotripsy, Kidney Calculi

### 1. Background

The prevalence of kidney stones in children is increasing, though it was rare among children previously (1). There is a difference of opinion between urologists on to treat renal calculi in some patients. Complex and problematic stones traditionally were removed by surgery, but nowadays surgery has been replaced with minimally invasive methods such as extracorporeal shock wave lithotripsy (ESWL) (2). The treatment process for kidney stones in children and adults in terms of the type of device and method, except in children the devices are smaller in size (3). Extracorporeal shock wave lithotripsy (ESWL) has recently been introduced as a method with high effectiveness and a minimally invasive treatment for nephrolithiasis in the children (4, 5). In ESWL, shock waves are generated by a source (lithotripter) external to the patient's body, and are then propagated into the body and focused on a renal stone, with the goal of fracturing the stone and allowing passage of the stone fragments

via the urinary tract (6). There was a concern with this method, since the lumen of the ureter in young children is definitely smaller than the adult ureter and transports stone fragments less efficiently (7). Despite these considerations, the child ureter's dispensability permits stone fragments to pass more easily compared to the adult. In addition, we know that children are much more active than adults, which helps pass the crushed stones (8, 9). Before and after studies conducted on treated children with ESWL have shown few harmful effects on the growth of the kidney (2). The use of a ureteral double-I stent prior to extracorporeal shock wave lithotripsy is controversial, although most urologists prefer to use a stent in shock wave lithotripsy procedure for stones larger than 20 mm, to prevent the risk of developing steinstrasse (2). The reason for using a ureteral double-I stent prior to ESWL is the fear of blocking the ureter at the time of passing broken stones.

Copyright @ 2016, Iranian Red Crescent Medical Journal. This is an open-access article distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 International License (http://creativecommons.org/licenses/by-nc/4.0/) which permits copy and redistribute the material just in noncommercial usages, provided the original work is properly cited.

<sup>\*</sup>Corresponding Author: Heshmatollah Sofimajidpour, Department of Urology, Faculty of Medicine, Kurdistan University of Medical Sciences, Sanandaj, IR Iran. Tel: +98-8733629775, Fax: +98-87336660089, E-mail: Hsmajidpour@gmail.com

## 2. Objectives

The aim of this study is to investigate the effect of double-J stents on the results treating kidney stones in children under 13 years, using extracorporeal shock wave lithotripsy.

#### 3. Patients and Methods

This double blind clinical trial study was conducted on 68 children younger than 13 years old with renal calculi at pelvic, referred to Tohid hospital in Sanandaj in during 2010 - 2014. Patients and urologist surgeon were unaware of patient grouping. A fellow nurse who working in Urology ward and had no role in the study divided patients into two groups namely stent and no stent groups randomly. Inclusion criteria included age less than 13 years and stone size larger than 8 mm. Exclusion criteria included bilateral stones, kidney dysfunction, and urinary infection. Assuming a success rate in the double-J stent group of 48% and a rate of 81% in the group without it (9), along with a 95% confidence level and power of 80%, the sample size in each group was determined as 34 patients (Figure 1).

Using ultrasound or KUB, the location and size of the stone was specified. If these methods did not determine the location and size of the stones, a complementary modality CT scan without contrast or IVP was used (10).

In order to rule out urinary tract infection, a urine culture was performed. To check renal function and also to reject kidney dysfunction, a BUN/Creatinine was performed. In the case of one-sided stone, no urinary tract infection, and no kidney dysfunction, the children underwent ESWL. Children were randomly divided into two groups, the double-I stent group (34 patients) and the control group (34 patients), by a fellow nurse on the urology ward who had no role in the study. Patients and the surgeon urologist were unaware of the grouping. A 2000-shock wave was administered during a single ESWL session to all subjects. For the extracorporeal shock wave lithotripsy (ESWL), a Swiss-made SLK Storz was used. The remaining stones, steinstrasse, number of ESWL sessions, and required hospitalization of patients in both groups were determined. After two months of treatment, an ultrasound, KUB, Creatinine, BUN, and if necessary CT scans were performed for the two groups to determine the effect of ESWL on renal function and the treatment results. Data were analyzed using SPSS version 18, and descriptive statistics (frequency, ratio, mean, and standard deviation) were calculated. A Kolmogorov-Smirnov test was used to evaluate the normality of the data. To compare the nominal variables, a chi-square test and Fisher's exact test were used. Also, to compare the quantitative variables in the two groups, an independent t-test and a Mann-Whitney U was used.

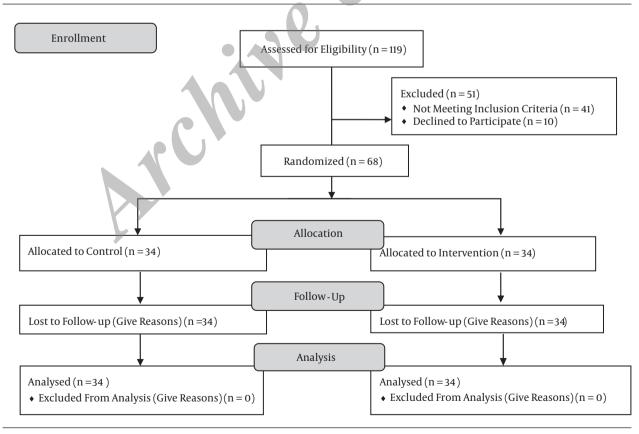


Figure 1. Randomized Clinical Trial Flowchart

#### 4. Results

The results showed that the mean age of the children in the intervention group and in the control group was  $4.55 \pm 2.27$  and  $4.13 \pm 3.05$  years, respectively (P = 0.53). The sizes of the stones in the intervention group and control group were 13.76  $\pm$  2.62 and 13.91  $\pm$  2.79 mm, respectively (P = 0.69). In 58.8% of the children in the intervention group and 76.5% of those in the control group, the right kidney was involved (P = 0.12) (Table 1).

In terms of post lithotripsy outcome frequency, including fever, hospitalization, and steinstrasse, there were no statistically significant differences between the intervention and the control groups (P > 0.05). The frequency of urinary tract infections in the intervention group was 23.5% and in the control group it was 5.9%, a statistically significant difference (P = 0.04) (Table 2).

The frequency of free stones in the intervention group and the control group was 73.5% and 85.3%, respectively (P = 0.23). Regarding the need for additional actions, there was no statistically significant difference between the groups (P = 0.99) (Table 3).

Table 1. Comparison of Variables Between Study Groups<sup>a</sup>

1		J 1	
Variables	Intervention	Control	P Value
Age	$4.55 \pm 2.27$	4.13 ± 3.05	0.53
Stone Size	$13.76 \pm 2.62$	13.91 ± 2.79	0.69
Involved Kidney			0.12
Right	20 (58.8)	26 (76.5)	
Left	14 (41.2)	8 (23.5)	
Gender			0.99
Male	24 (70.6)	24 (70.6)	
Female	10 (29.4)	10 (29.4)	

 $<sup>^{\</sup>text{a}}\text{Values}$  are expressed as mean  $\pm\,\text{SD}$  unless otherwise indicated No. (%).

**Table 2.** Comparison of Treatment Outcomes in the Two Study Groups<sup>a</sup>

Variables	Intervention	Control	P Value
Fever			0.71
Yes	5 (14.7)	3 (8.8)	
No	29 (85.3)	31 (91.2)	
Urinary Tract Infection			0.04
Yes	8 (23.5)	2 (5.9)	
No	26 (76.5)	32 (94.1)	
Need For Hospitalization	n		0.49
Yes	6 (17.6)	4 (11.8)	
No	28 (82.8)	30 (88.2)	
Steinstrasse			0.99
Yes	5 (14.7)	4 (11.8)	
No	29 (85.3)	30 (88.2)	

<sup>&</sup>lt;sup>a</sup>Values are expressed as No. (%).

**Table 3.** Comparison of the Variables Related to Stone Clearance in the Two Study Groups<sup>a</sup>

Groups	Intervention	Control	P Value
Stone Clearance			0.23
Yes	25 (73.5)	29 (85.3)	
No	9 (26.5)	5 (14.7)	
<b>Complementary actions</b>			0.99
Yes	3 (8.8)	4 (11.8)	
No	31 (91.2)	30 (88.2)	

<sup>&</sup>lt;sup>a</sup>Values are expressed as No. (%).

#### 5. Discussion

In our study, the frequency of fever in the double-I stent group was 14.7% and in the control group it was 8.8%. Although the frequency was higher in the stent group, the difference was not statistically significant. In the Mohayuddin et al. study 2.5% of the control group patients and 7.5% of the stent group patients had a fever (11). In the Musa study (4) fever incidence was a bit higher (4). In the Turki et al. study (12) 75% of patients with stents had a slight fever, but none of the patients without stent had a fever. In terms of fever, Pengfei et al. in his review study also reported that there were no significant differences between the two groups (13). The probable cause of the fever in patients with the stent is that these patients underwent two procedures and a foreign object was placed in a sterile environment, which caused the body's reaction and resulting fever. In terms of steinstrasse frequency, in the double-I stent group it was 14.7% and in the control group it was 11.8%, which does not show a statistically significant difference. In the Mohayuddin et al. study steinstrasse was observed in 10% of patients without stents and in 5.7% of patients with stents (11). In the Sulaiman et al. study the prevalence of steinstrasse was 6.3% (14). In the Ammar study, 10.9% of patients without double-J stents developed steinstrasse (15). In the Turki et al. study, in the group without stents only one patient had steinstrasse and none of the patients in the stent group had steinstrasse, but the difference was not statistically significant (12). Although the frequency of steinstrasse in these studies is not very different from the frequency in our study, in all of them the frequency of steinstrasse was less than in our study. Alwadi et al. reported that the incidence of steinstrasse increases with the size of the calculi, whether or not a J-stent is present; J-stenting has no apparent effect on the mode of presentation or the subsequent management of steinstrasse (16). Kumar et al. also concluded that ureteral obstruction would happen despite a double-I stent; they suggested avoiding preventive stenting before ESWL (17). Stent placement before ESWL does not prevent steinstrasse, but reduces the complications (15). Bierkens et al. also found no relationship between steinstrasse in patients with or without stents (18). If ignored, steinstrasse may cause many further complications. Selecting a method that reduces the remaining pieces of the stone and steinstrasse after ESWL is up to the urologist (19, 20). In recent years, several centers have studied the effect of stenting before ESWL in terms of preventing steinstrasse and other complications. According to Pengfei et al., stenting did not benefit the stone-free rate and auxiliary treatment after extracorporeal shock wave lithotripsy, and it induced more lower urinary tract symptoms (13). Most urologists prefer to use a stent in shock wave lithotripsy procedures for stones larger than 20 mm, to prevent the risk of developing steinstrasse. When the stone is less than 10 mm, stents are only used occasionally. For stones between 10 mm and 20 mm there appears to be no general consensus about the usefulness of stenting (21). Younesi et al. used double-I stents for 11 patients with stone sizes between 13 and 22 mm, and concluded that the stent helps to prevent steinstrasse (2). In our study, the frequencies of stone clearance in the intervention group and the control group were 73.5% and 85.3%, respectively, and there was no statistically significant difference. In the Mohayuddin et al. study stone clearance occurred in 82.5% of patients with the stent and 77.5% in patients without stents (11). In the Bierkens et al. (18) and Kirkali et al. (22) studies, the stone clearance rates in groups with and without stents were also not significantly different, which is consistent with our findings. But in Turki et al.'s study, the stone clearance rate in the stent group was 35% and among the non-stent patients it was 55%, a significant difference (12). In Turki et al.'s study the size of kidney stones was 20 to 25 mm, whereas in our study the mean stone size was about 13 mm in both groups. This probably means that in patients with large stones a double-I stent helps in passing pieces of stone, so the success of stone clearance in Turki et al.'s study decreased. The stone clearance rate was 93.1% in El Nashar et al.'s study; it became 100% in the second session of lithotripsy after three months follow-up (23). In similar studies the stone clearance rate was 88% to 100% after three months (24-26). Lottmann et al. (24) reported that the stone clearance rate in 19 children age 5 to 24 months was 100% after the second session with shock-wave lithotripsy. Ramakrishnan et al. (26), who evaluated 74 children under 2 years, reported a stone clearance rate of 88% after a session of s-wave lithotripsy. So we can say that increasing ESWL sessions will increase the success rate of the stone clearance rate. For all the children in our study, only one ESWL session was performed. Although multiple sessions of ESWL confer increased stone clearance, they require repeated anesthesia, which is considered a stress on the patients' families (27). In El Nashar et al.'s study, if after three months follow-up there were no stone fragments then the ESWL was defined as successful (23), but in some studies non-obstructive fragments smaller than 4 mm were considered to indicate a successful ESWL (27). More guidelines have introduced ESWL as the first treatment option for kidney stones smaller than 20 mm, and successful stone clearance has been reported by several

authors (28, 29). This success in stone clearance is directly related to the remaining fragments after ESWL (13). Despite children having small ureteral diameters, they have a higher clearance rate of stone fragments than adults, due to their shorter and more distensible ureters (30-32). Double-J stents impair upper urinary tract motility and experimental calculus transit time, and may delay the passage of ureteric calculi or calculus fragments following extracorporeal shock wave lithotripsy (34). Although this study found no statistically significant differences between the stent and non-stent groups, clinically the differences are important. The kidney stone clearance rate in children with and without stents is almost equal. Considering the problems of kidney stents and additional charges, Extracorporeal Shock Wave Lithotripsy (ESWL) without stents is recommended is recommended for patients with 8 to 15 mm kidney stones.

## Acknowledgments

The authors are thankful to those who helped us do this study, particularly the staff of the lithotripsy ward of Tohid hospital. Also we thank the vice chancellor for research at Kurdistan university of Medical Sciences for the university's financial support of this study.

### **Footnote**

Authors' Contribution: Heshmatollah Sofimajidpour: writing the manuscript and examining patients; Mesbah Rasti: designing the study and examining patients; Fardin Gharibi: analyzing the data and and writing the manuscript.

### References

- Minevich E. Management of ureteric stone in pediatric patients. Indian J Psychiatry. 2010;26(4):564. doi: 10.4103/0970-1591.74462.
- Younesi Rostami M, Taghipour-Gorgikolai M, Sharifian R. Treatment of kidney stones using extracorporeal shock wave lithotripsy (eswl) and double-j stent in infants. Adv Neurol. 2012;2012:1-4. doi:10.1155/2012/589038.
- 3. De Dominicis M, Matarazzo E, Capozza N, Collura G, Caione P. Retrograde ureteroscopy for distal ureteric stone removal in children. *BJU Int.* 2005;**95**(7):1049–52. doi: 10.1111/j.1464-410X.2005.05464.x. [PubMed:15839930]
- Musa AA. Use of double-J stents prior to extracorporeal shock wave lithotripsy is not beneficial: Results of a prospective randomized study. *Int Urol Nephrol*. 2008;40(1):19–22. doi: 10.1007/ s11255-006-9030-8. [PubMed: 17394095]
- Shukla AR, Hoover DL, Homsy YL, Perlman S, Schurman S, Reisman EM. Urolithiasis in the Low Birth Weight Infant: The Role and Efficacy of Extracorporeal Shock Wave Lithotripsy. Adv Neurol. 2001;165(6):2320–3. doi:10.1016/s0022-5347(05)66194-0.
- McAdams S, Shukla AR. Pediatric extracorporeal shock wave lithotripsy: Predicting successful outcomes. *Indian J Urol.* 2010;26(4):544–8. doi: 10.4103/0970-1591.74457. [PubMed: 21369388]
- Gofrit ON, pode D, meretyk S, katz G, shapiro A, golijanin D, et al. Is the pediatric ureter as efficient as the adult ureter in transporting fragments following extracorporeal shock wave lithotripsy for renal calculi larger than 10 mm.? *Adv Neurol*. 2001;166(5):1862-4.
- 8. Muslumanoglu AY, Tefekli AH, Altunrende F, Karadag MA, Baykal M, Akcay M. Efficacy of extracorporeal shock wave lithotripsy for

- ureteric stones in children. *Int Urol Nephrol*. 2006;**38**(2):225–9. doi: 10.1007/s11255-005-4792-y. [PubMed: 16868687]
- Pettenati C, El Fegoun AB, Hupertan V, Dominique S, Ravery V. Double J stent reduces the efficacy of extracorporeal shock wave lithotripsy in the treatment of lumbar ureteral stones. *Cent European J Urol.* 2013;66(3):309–13. doi: 10.5173/ceju.2013.03.art14. [PubMed: 24707370]
- Stamatiou KN, Heretis I, Takos D, Papadimitriou V, Sofras F. Extracorporeal shock wave lithotripsy in the treatment of pediatric urolithiasis: a single institution experience. *Int Braz J Urol.* 2010;36(6):724-30. [PubMed: 21176279]
- Mohayuddin N, Malik HA, Hussain M, Tipu SA, Shehzad A, Hashmi A, et al. The outcome of extracorporeal shockwave lithotripsy for renal pelvic stone with and without JJ stent-a comparative study. J Pak Med Assoc. 2009;59(3):143-6. [PubMed: 19288938]
- Turki A, Rafid O, Hussen F. Role of double j stent in patients with renal stones undergo extracorporeal shock wave lithotripsy. MJB. 2012;9(3):629-42.
- Pengfei S, Min J, Jie Y, Xiong L, Yutao L, Wuran W, et al. Use of Ureteral Stent in Extracorporeal Shock Wave Lithotripsy for Upper Urinary Calculi: A Systematic Review and Meta-Analysis. Adv Neurol. 2011;186(4):1328–35. doi: 10.1016/j.juro.2011.05.073.
- Sulaiman MN, Buchholz NP, Clark PB. The role of ureteral stent placement in the prevention of Steinstrasse. *J Endourol*. 1999;13(3):151-5. [PubMed:10360492]
- Ammar FA. Shock Wave Lithotripsy for Medium to Large Renal Pelvic Stone without Ureteral Stent. Postgrad Med J. 2009;8(2).
- Alwadi A, Abdul H, Kehinde Al T. Steinstrasse: a comparison of incidence with and without J stenting and the effect of J stenting on subsequent management. BJU International. 2001;84(6):618– 21. doi:10.1046/j.1464-410x.1999.00280.x.
- Kumar S, Sakthivel A, Chacko KN, Kekre NS, Ganesh G. Shock wave lithotripsy in solitary functioning kidneys: is prophylactic stenting necessary? *Urol Int.* 2006;77(2):179–81. doi:10.1159/000093916. [PubMed: 16888427]
- Bierkens AF, Hendrikx AJ, Lemmens WA, Debruyne FM. Extracorporeal shock wave lithotripsy for large renal calculi: the role of ureteral stents. A randomized trial. J Urol. 1991;145(4):699-702. [PubMed: 2005681]
- Anagnostou T, Tolley D. Management of ureteric stones, Eur Urol. 2004;45(6):714–21. doi: 10.1016/j.eururo.2003.10.018. [PubMed: 15149742]
- Puppo P. Steinstrasse 20 years later: Still a problem after ESWL?
  Eur Urol. 2006;50(4):643-7. doi: 10.1016/j.eururo.2006.07.002.
  [PubMed: 16893602]

- Hollowell CM, Patel RV, Bales GT, Gerber GS. Internet and postal survey of endourologic practice patterns among American urologists. J Urol. 2000;163(6):1779-82. [PubMed: 10799181]
- Kirkali Z, Esen AA, Akan G. Place of double-J stents in extracorporeal shock wave lithotripsy. Eur Urol. 1993;23(4):460-2. [PubMed: 8335050]
- 23. El Nashar AM, Metwally AH, Abd El Kader O, Ali EE, Abdelbaseer M. Efficacy of shock wave lithotripsy in management of kidney stones in infants. *African Journal of Urology.* 2014;**20**(1):14–7. doi: 10.1016/j.afju.2013.11.002.
- 24. Lottmann HB, Archambaud F, Traxer O, Mercier-Pageyral B, Helal B. The efficacy and parenchymal consequences of extracorporeal shock wave lithotripsy in infants. *BJU Int.* 2000;**85**(3):311–5. [PubMed: 10671889]
- Orsola A, Diaz I, Caffaratti J, Izquierdo F, Alberola J, Garat JM. Staghorn calculi in children: treatment with monotherapy extracorporeal shock wave lithotripsy. J Urol. 1999;162(3 Pt 2):1229–33. [PubMed: 10458473]
- Ramakrishnan PA, Medhat M, Al-Bulushi YH, Nair P, Al-Kindy A. Extracorporeal shockwave lithotripsy in infants. Can J Urol. 2007;14(5):3684-91. [PubMed: 17949522]
- 27. Hammad FT, Kaya M, Kazim E. Pediatric extracorporeal shock-wave lithotripsy: its efficiency at various locations in the upper tract. *J Endourol.* 2009;23(2):229–35. doi: 10.1089/end.2008.0133. [PubMed: 19187013]
- Pardalidis NP, Kosmaoglou EV, Kapotis CG. Endoscopy vs. extracorporeal shockwave lithotripsy in the treatment of distal ureteral stones: ten years experience. J Endourol. 1999;13(3):161-4. [PubMed:10360494]
- Seitz C, Fajkovic H, Waldert M, Tanovic E, Remzi M, Kramer G, et al. Extracorporeal shock wave lithotripsy in the treatment of proximal ureteral stones: Does the presence and degree of hydrone-phrosis affect success? Eur Urol. 2006;49(2):378–83. doi: 10.1016/j.eururo.2005.09.022. [PubMed: 16406241]
- Longo JA, Netto NR. Extracorporeal shock-wave lithotripsy in children. *Urology*. 1995;46(4):550-2. doi:10.1016/s0090-4295(99)80271-4. [PubMed:7571227]
- Marberger M, Turk C, Steinkogler I. Piezoelectric extracorporeal shock wave lithotripsy in children. J Urol. 1989;142(2 Pt 1):349–52. [PubMed: 2746751]
- 32. Andreessen R, Fedel M, Sudhoff F, Friedrichs R, Loening SA. Quality of semen after extracorporeal shock wave lithotripsy for lower ureteral stones. *The Journal of Urology.* 1996;**155**(4):1281–3. doi: 10.1016/s0022-5347(01)66243-8. [PubMed: 8632553]

