Novel Electromagnetic Lithotriptor for Upper Tract Stones With and Without a Ureteral Stent

Christian Seitz,*,† Hans-Martin Fritsche,† Thomas Siebert, Thomas Martini, Wolf Ferdinand Wieland, Armin Pycha and Maximilian Burger

From the Departments of Urology, General Hospital Bolzano, Bolzano, Italy, and Caritas-St. Josef Medical Center, University of Regensburg (HMF, TS, WFW, MB), Regensburg, Germany

Abbreviations and Acronyms

DAP = dose area product

FT = fluoroscopy time

KUB = plain x-ray of kidneys, ureters and bladder

PNL = percutaneous nephrolithotomy

SA = stone surface area

SFR = stone-free rate

SWL = shock wave lithotripsy

URS = ureterorenoscopy

Submitted for publication February 18, 2009.

† Equal study contribution.

* Correspondence and requests for reprints: General Hospital Bolzano, Via Lorenz Böhler 5, 39100 Bolzano, Italy (telephone: +39 0471 908686; FAX: +39 0471 909738; e-mail: christian.seitz@asbz.it).

Purpose: We compared the treatment efficacy and safety of the novel Lithoskop® electromagnetic extracorporeal shock wave lithotriptor for upper urinary tract stones with and without prior ureteral stent placement.

Materials and Methods: A total of 665 consecutive patients harboring single renal or ureteral stones underwent shock wave lithotripsy between August 2006 and July 2008. In 75 and 46 patients with renal and ureteral stones, respectively, stents were placed before the first shock wave lithotripsy session. Treatment outcome was assessed in relation to stent placement. All data were derived from a prospectively maintained database.

Results: The mean size of nonstented vs stented renal and ureteral stones was 8.6 vs 12.5 mm ($p < 0.0001$) and 7.1 vs 7.3 mm ($p = 0.6$), respectively. The stone-free rate in nonstented vs stented renal and ureteral stone cases was 76.3% vs 77.3% and 91.4% vs 93.5%, respectively (each $p > 0.99$). The total energy applied per stone was 110 ± 83 vs 150 ± 89 J ($p < 0.0001$) and 183 ± 131 vs 209 ± 125 J ($p = 0.1$), respectively. Auxiliary measures were required after shock wave lithotripsy for renal and ureteral stones in 5.4% and 10.8% of nonstented, and in 1.3% and 4.3% of stented cases, respectively. No complications were detected in stented renal and ureteral stone cases compared to 2.9% and 6.9% in nonstented cases, respectively.

Conclusions: A high success rate and a low complication rate were achieved in renal and ureteral stone cases with and without prior ureteral stent placement. Total energy needed to achieve a stone-free state did not differ between stented and nonstented ureteral cases, suggesting the absence of a significant influence of the stent. Overall stents decreased complications necessitating hospitalization and auxiliary invasive measures.

Key Words: ureter, kidney, urolithiasis, lithotripsy, stents

The original Dornier® HM3 achieved good results but with some limitations and complications. Consequently new electromagnetic lithotriptors were developed that use different focusing components and coupling media. These new generation lithotriptors have improved functionality but an inferior SFR, partly due to a smaller focal zone compared to that of the HM3.[1] Recent retrospective studies of new generation lithotriptors showed a favorable disintegration rate with further improvement in treatment safety.[2,3]

Treatment success correlates with stone size. Thus, placing ureteral stents before SWL has been advocated.[4] However, whether stents contribute to successful stone passage is an issue of long-standing debate with conflicting

0022-5347/09/1824-1424/0
THE JOURNAL OF UROLOGY®

Vol. 182, 1424-1429, October 2009
Printed in U.S.A.
DOI:10.1016/j.juro.2009.06.045

data.[5–9] We performed a study at 2 academic centers to evaluate the newest electromagnetic lithotriptor, the Lithoskop®, for upper urinary tract stones. We evaluated its success and complication rates for upper urinary tract stones with and without prior stent placement.

PATIENTS AND METHODS

Between August 2006 and July 2008, 665 consecutive patients with radiopaque renal or ureteral stones underwent SWL. Data were extracted from a prospectively maintained database. Study exclusion criteria were stone manipulation before SWL, diverticular stones, pelvic urinary junction obstruction, ureteral stricture, clotting disorders, untreated urinary tract infection and suspected pregnancy.

Mean ± SD patient age was 51 ± 15 years with a 2:1 male-to-female ratio. Routinely each patient underwent renal function test, blood count, coagulation profile and urinalysis. Intravenous analgesia was administered directly before the procedure with further administration on demand with 50 mg petidine or 7.5 mg piritramid plus 2.5 mg midazolam.

SA was calculated by the approximation formula, SA = length × width × π × 0.25.[8] SWL is routinely performed in patients with renal stones 20 mm or less, or ureteral stones 10 mm or less. Patients with renal stones greater than 20 mm in greatest dimension and SA greater than 300 mm^2 are offered percutaneous nephrolithotomy. Patients refusing the recommended invasive treatment in favor for SWL were not excluded from analysis. Patients were offered stent placement before SWL for stones greater than 20 mm or with a SA of greater than 300 mm^2. Further indications for stent placement before SWL were obstructed and infected upper urinary tracts, therapy resistant colic pain and prevention of renal function deterioration, in accordance with European Association of Urology guidelines.[7] Patients were treated on an outpatient basis with a Lithoskop with the Pulso™ shock wave system. This novel electromagnetic lithotriptor contains a dual system for stone detection with ultrasound or fluoroscopic guidance. The digital fluoroscopic system is mounted on a C arm that can be rotated and the ultrasound tube of the Acuson X150™ ultrasound system can be placed into the shock wave head, which can rotate. A compression belt was routinely used to decrease stone excursion by respiration and immobilize the patient. The Lithoskop has a 135 mm focal length. Its focal width is between 12 mm (low power setting) and 8 mm (high power setting), and peak pressure is 8 to 75 MPa. The Appendix lists technical specifications.

For kidney stones shock wave intensity was gradually increased with approximately 300 impulses per level up to level 3.5 for a total of up to 3,500 impulses and a corresponding frequency of 1.5 Hz.[2] For ureteral stones distal to the lower renal pole projection intensity was directly increased up to a maximum of 8.0 for up to 4,000 impulses. The fragmentation rate, number of shock waves applied, DAP, FT and energy applied were recorded for each treatment. Ultrasound of the kidneys to exclude renal hematoma and KUB to assess stone fragmentation were done within 24 hours after each SWL session. Complications such as subcapsular renal hematoma, fever greater than 38C, urinary tract infection, renal impairment and colic pain necessitating hospital admission were recorded.

Treatment failure in kidney and ureteral stone cases was defined as residual stones greater than 4 mm after 3 months and any residual fragment 4 mm or less, respectively. When results were questionable, the patient was always assigned to the more unfavorable group. Stone-free status was established by ultrasound and high definition urinary tract plain x-ray. Since the computerized tomography related radiation dose and costs were prohibitive, nonenhanced computerized tomography was not routinely done to distinguish a stone-free state and the questionable presence of residual fragments on KUB or ultrasound. Patients underwent up to 3 SWL sessions. Exceptions were when 20 patients refused recommended endourological measures in favor of a further SWL session. Auxiliary procedures were defined as active stone removal or stent placement to alleviate therapy resistant colic pain after SWL. The efficiency quotient as a means of comparing lithotriptors was calculated using the formula, SFR/(100% + re-treatment rate in percent + auxiliary measure rate in percent) (see table).

JMP®, version 3.2.2 was used for statistical analysis. The Wilcoxon rank sum test, Kruskal-Willis test with more than 2 groups and Fisher exact test were applied to discriminate patient variables with $p < 0.05$ considered statistically significant.

RESULTS

The table lists overall treatment characteristics and the treatment outcome in stented and nonstented upper tract stone cases.

Renal Stones

Of 387 patients 312 (80.6%) underwent SWL without prior stenting. Nonstented vs stented cases had a mean ± SD stone size of 8.6 ± 4.5 (range 5 to 30) vs 12.5 ± 6.2 mm (range 5 to 35). Mean SA was 48.8 ± 58.1 (range 8 to 570) vs 78.8 ± 70 mm^2 (range 8 to 412). The cumulative applied energy per stone was 110 ± 83 vs 150 ± 89 J with a corresponding FT of 6.5 ± 4.3 vs 8 ± 4.9 minutes and a DAP of 1,000 ± 743 vs 1,171 ± 1,124 $\mu Gy/m^2$.

Therapy success was achieved in 89.4% nonstented vs 93.3% stented cases after a mean of 1.5 ± 0.9 vs 1.8 ± 0.9 sessions. Of these patients 76.3% vs 77.3% were completely stone free and 13.1% vs 16% harbored residual fragments 4 mm or less. Residual stones greater than 4 mm after treatment, defined as treatment failure, were found in 10.6% vs 6.7% of patients. In nonstented vs stented patients with stones 10 mm or less the SFR was 83.3% vs 74.3% ($p = 0.2$) and the success rate was 93.6% vs 97.1% ($p = 0.7$).

Only 1 session was required in 66.3% vs 41% of nonstented vs stented cases, after which 85% vs