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IS NEWER ALWAYS BETTER? A COMPARATIVE STUDY OF 3 LITHOTRIPTOR GENERATIONS

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ABSTRACT

Purpose: At a single center we compared the efficacy of 3 generations of lithotriptors using identical protocol inclusion and followup criteria but with different modes of anesthesia.

Materials and Methods: We compared stone disintegration and dilatation of the pyelocaliceal system achieved in a prospective, randomized trial comparing the original HM3 (Dornier Medtech, Kennesaw, Georgia) and Lithostar® Plus (LSP) lithotriptors, and a matched, consecutive series of 107 treatments with the Modulith® SLX. Stone disintegration and dilatation of the pyelocaliceal system were evaluated by abdominal plain x-ray and renal ultrasonography 1 day and 3 months after treatment.

Results: A total of 82 treatments with the HM3, 75 with the LSP and 107 with the SLX were analyzed, matched for stone burden and location within the pyelocaliceal system. On postoperative day 1, 91%, 65% and 48% patients treated with the HM3, LSP and SLX, respectively, were stone-free or had fragments that were 2 mm or less (HM3 vs LSP $p < 0.001$, HM3 vs SLX $p < 0.001$ and LSP vs SLX $p = 0.015$). Three to 5 mm fragments were found in 7%, 21% and 35% of patients ($p = 0.006$, < 0.001 and 0.06), and fragments 6 mm or greater were found in 1%, 14% and 15% ($p = 0.002$, < 0.001 and 0.1, respectively). The re-treatment rate was 4% in the HM3 group, 13% in the LSP group and 38% in the SLX group (HM3 vs LSP $p = 0.05$, HM3 vs SLX $p < 0.001$ and LSP vs SLX $p < 0.001$). Obstructive pyelonephritis occurred in 1% of the HM3 group, 8% of the LSP group and 5% of the SLX group (HM3 vs LSP $p = 0.02$, HM3 vs SLX $p = 0.12$ and LSP vs SLX $p = 0.4$). All re-treatments except those in 5 patients were performed with the HM3. Therefore, the 3-month stone-free rate was comparable in all 3 groups (HM3 87%, LSP 80% and SLX 81%).

Conclusions: This study indicates that the HM3 lithotriptor disintegrates caliceal and renal pelvic stones better than the LSP and SLX machines, resulting in fewer complications and re-treatments. Disintegration with the LSP machine was also superior to that of the SLX with a need for fewer re-treatments.

KEY WORDS: renal calculi, ESWL, HM3, Lithostar Plus, Modulith SLX

The introduction of the first lithotriptor for extracorporeal shock wave lithotripsy (ESWL), that is the original HM3 in the 1980s, revolutionized renal stone treatment. High success rates with up to 90% or more primary stone disintegration were achieved worldwide and open surgery was replaced by ESWL for almost any stone location in the upper urinary tract.[1–3]

In the following years new lithotriptors were developed to increase patient comfort using dry systems and intravenous sedoanalgesia instead of general or epidural anesthesia, although sedoanalgesia is also used with the HM3 lithotriptor at several institutions. This higher treatment comfort was paid for with less effective stone disintegration and a higher re-treatment rate.[4] At the same time broadening the shock wave aperture in the new Modulith® SLX lithotriptor resulted in a smaller focal zone and should have resulted in stone fragmentation equal to that of the HM3 but in a shorter time.[5] In our single center study we evaluated the efficacy and complications of ESWL of a fourth generation lithotriptor, the SLX, and matched these results to those of a previously published, prospective, randomized study comparing the HM3 and Lithostar® Plus (LSP).[4]

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PATIENTS AND METHODS

In an earlier, prospective, randomized trial at our institution we compared the efficacy of the unmodified HM3 and the LSP lithotriptors on caliceal stones and stones in the renal pelvis.[4] Of the total of 157 solitary, unilateral or bilateral kidney stones in 145 patients 82 were randomized to ESWL with the HM3 and 75 were randomized to ESWL with the LSP. The criteria for randomization, treatment and followup were defined according to a standardized study, as previously published.[4] To determine the efficacy and side effects of the fourth generation SLX lithotriptor we evaluated 89 patients with a total of 107 stones in the calices or renal pelvis that were treated with this new lithotriptor. Stone burden and location in the pyelocaliceal system in the SLX series were matched with stone burden and location in the former trial.

Of 89 patients 83 were treated with sedoanalgesia using 0.04 $\mu g/kg$ remifentanil per minute. Six patients were given epidural anesthesia because of pain experienced during treatment under sedoanalgesia.

The lithotriptors were operated by the same technician at our institution with longtime experience under the supervision of a urologist. Treatment time, defined as time from the first to the final shock wave, as well as fluoroscopy time and the number of applied shock waves were documented in each patient.

Stone volume was calculated from abdominal plain x-rays using the computerized stone volumetry system PICA 88.[6]

Patients were followed according to the protocol of our previous study. Stone disintegration and dilatation of the pyelocaliceal system were evaluated by abdominal plain x-ray and renal ultrasonography 1 day and 3 months after treatment.

Stone disintegration was classified as stone-free status or fragments 2 mm or less, fragments 3 to 5 mm or fragments 6 mm or greater. Dilatation of the collecting system was classified as grade I—calices not or barely visible, grade II—prominent dilatation of calices with direct extension into the renal pelvis and grade III—an infundibulum of 5 mm or greater. Statistical analysis was performed using the unpaired t, chi-square and Fisher's exact tests.

RESULTS

A total of 82 stones in 76 patients in the HM3 group and 75 stones in 69 patients in the LSP group were compared with 107 stones in 89 patients treated with the SLX. In the HM3 group 75 of 76 treatments (99%) were done using epidural anesthesia and 1 of 76 (1%) used general anesthesia. In the LSP group 66 of 69 (96%) treatments were done using epidural anesthesia and 3 of 69 (4%) used general anesthesia. In the SLX group 83 of 107 treatments (94%) were done using sedoanalgesia and 6 of 107 (6%) used epidural anesthesia. Stone burden and stone distribution in the pyelocaliceal systems were comparable among the 3 groups (see table). Fluoroscopy time and treatment time in the HM3 and LSP groups were significantly shorter than in the SLX group (all $p \leq 0.05$, see table). Significantly fewer shock waves were applied in the HM3 and LSP groups than in the SLX group (each $p \leq 0.001$, see table). As a consequence, shock wave rates showed significant differences when comparing the HM3 and LSP groups with the SLX group (each $p \leq 0.001$, see table). On postoperative day 1, 91%, 65% and 48% patients treated with the HM3, LSP and SLX, respectively, were stone-free or had fragments 2 mm or less (HM3 vs LSP $p < 0.001$, HM3 vs SLX $p < 0.001$ and LSP vs SLX $p = 0.015$). Three to 5 mm fragments were found in 7%, 21% and 35% of patients ($p = 0.006$, < 0.001 and $= 0.06$), and 6 mm or greater fragments were found in 1%, 14% and 15% ($p = 0.002$, < 0.001 and 0.1, respectively, fig. 1). There were significantly more patients without collecting system dilatation 1 day after treatment in the HM3 group than in the LSP and SLX groups (85% vs 73% and 71%, respectively, HM3 vs LSP $p = 0.05$, HM3 vs SLX $p = 0.02$ and LSP vs SLX $p = 0.69$, fig. 2). The re-treatment rate was 4% in the HM3 group, 13% in the LSP group and 38% in the SLX group (HM3 vs LSP $p = 0.05$, and HM3 and LSP vs SLX $p < 0.001$, fig. 3). In the SLX group the 38% of re-treatments were performed with the HM3 except in 5 patients. Obstructive pyelonephritis occurred in 1% of cases in the HM3 group, in 8% in the LSP group and in 5% in the SLX group (HM3 vs LSP $p = 0.02$ HM3 vs SLX $p = 0.12$ and LSP vs SLX $p = 0.4$). The obstructed kidney was drained with a nephrostomy tube in all patients.

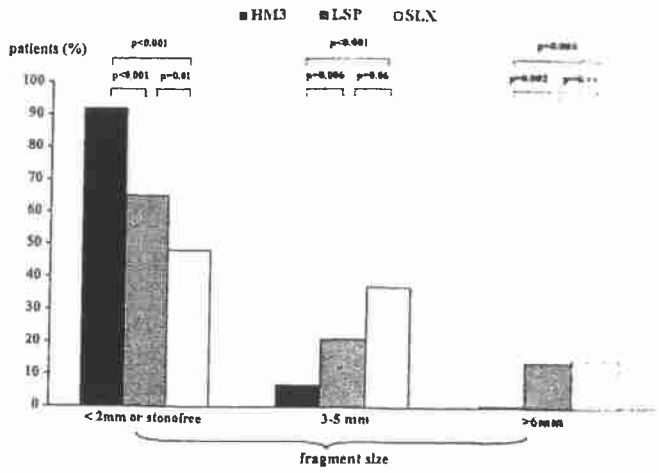

FIG. 1. Stone disintegration rate assessed by abdominal plain x-ray 1 day after ESWL with HM3, LSP and SLX.

Three months after treatment 66 of 76 patients (87%) in the HM3 group, 57 of 69 (82%) in the LSP group and 82 of 89 (92%) in the SLX group were available for evaluation. Of the 66 patients in the HM3 group 58 (89%) were radiologically stone-free, as were 47 of 57 (83%) in the LSP group and 66 of 82 (81%) in the SLX group (no significant differences). Residual fragments 2 mm or less were found in 10%, 10% and 9% of patients in the HM3, LSP and SLX groups, respectively (no significant differences). Three to 5 mm fragments were found in 1%, 5% and 9% of the groups (HM3 vs LSP $p = 0.52$, HM3 vs SLX $p = 0.005$ and LSP vs SLX $p = 0.02$) and 6 mm or greater fragments were found in 0%, 2% and 1%, respectively (no significant differences). No sonographic dilatation of the upper urinary tract was seen in any patient after 3 months.

DISCUSSION

Since the first clinical study of the SLX system in the early 1990s, which showed sufficient disintegration at hospital discharge in 93% or patients[7] and a success rate (stone fragments less than 3 mm) of 92.3%,[8] sparse data have been published about the treatment efficacy of this new, fourth generation lithotriptor. With its broader shock wave aper-

Baseline characteristics and treatment parameters in 234 patients (264 caliceal or renal pelvis stones) treated with HM3, LSP or SLX

	HM3	p Value	LSP	p Value	SLX	p Value HM3 vs SLX
No. stones	82		75		107	
No. pts (% men/women)	76 (66/10)		69 (46/23)		89 (58/31)	
Mean age ± SD	47 ± 16	0.3	45 ± 15	0.06	49 ± 16	0.43
Mean stone vol ± SD:						
Renal pelvis	0.64 ± 0.36	0.55	0.7 ± 0.42	0.07	0.5 ± 0.36	0.15
Upper calix	0.36 ± 0.33	0.4	0.25 ± 0.26	0.79	0.27 ± 0.23	0.38
Mid calix	0.18 ± 0.13	0.95	0.19 ± 0.13	0.84	0.19 ± 0.13	0.86
Lower calix	0.34 ± 0.28	0.97	0.35 ± 0.28	0.79	0.37 ± 0.35	0.75
No. anesthesia (%):						
Sedoanalgesia	0		0		83 (93)	
Epidural	71 (94)		61 (88)		6 (7)	
Spinal	4 (5)		5 (8)		0	
General	1 (1)		3 (4)		0	
Mean fluoroscopy time (secs)	53 ± 48	0.46	61 ± 72	<0.001	106 ± 50	<0.001
Mean No. applied shock waves	1,702 ± 628	<0.001	2,297 ± 430	<0.001	3,349 ± 401	<0.001
Mean treatment time (mins)	27 ± 11	<0.001	35 ± 11	0.009	39.6 ± 11	<0.001
Shock wave rate (No./min)	67 ± 19	0.52	69 ± 19	<0.001	84 ± 26	<0.001

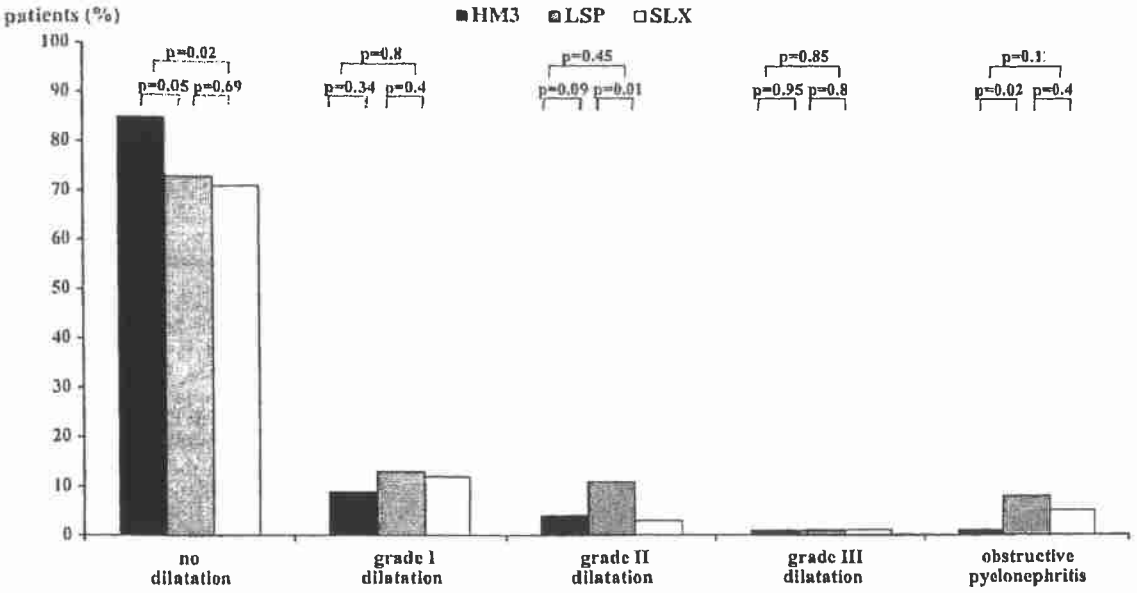

FIG. 2. Sonographic dilatation of renal collecting system 1 day after ESWL with HM3, LSP and SLX, and incidence of posttreatment obstructive pyelonephritis in each group.

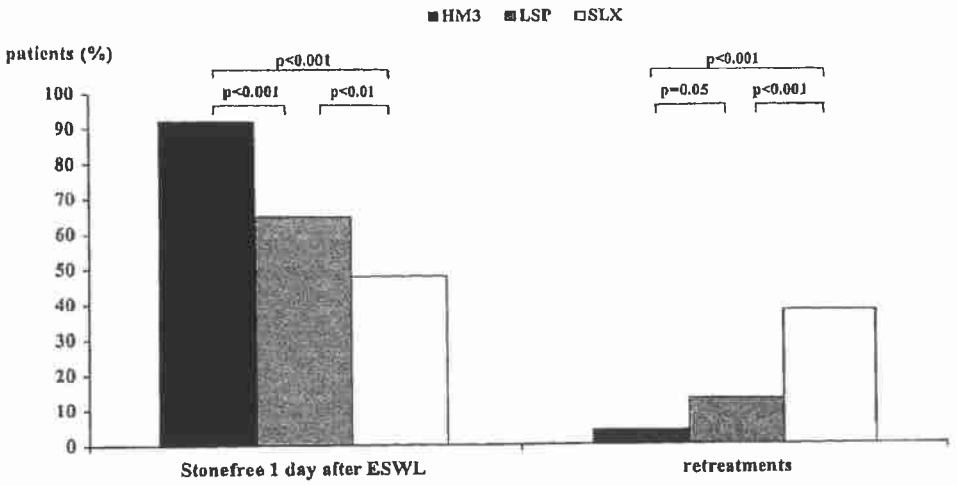

FIG. 3. Stone-free patients 1 day after ESWL with HM3, LSP and SLX, and re-treatment rate in each group

ture, resulting in a smaller focal zone[6] and less shock wave induced petechiae, the SLX achieves peak positive pressure at a maximum energy of 105 mPa, which is 2.5-fold higher than the 40 mPa that can be achieved with the HM3.[5]

In an in vitro study Teichman et al noted that the best fragmentation was achieved with the SLX, followed by the Lithostar® C and HM3 lithotriptors.[9] Moran et al reported a 72% overall stone-free rate with the SLX at a mean followup of 10 months.[10]

This was comparable to the results of the SLX predecessor, the Modulith® SL20, with a stone-free rate of 65% to 92%.[11,12] Matin et al reported a study of consecutive patients, for the first time comparing the MFL-5000 electrohydraulic lithotriptor (Dornier Medtech) with the SLX.[13] This study showed an overall stone-free rate of 77% for the MFL-5000 vs 67% for the SLX ($p = 0.015$) 4 weeks after treatment despite a larger overall stone burden in the MFL-5000 group ($p = 0.015$) and with significantly fewer shock waves delivered ($p < 0.001$). The SLX results in that study are in accordance with our results showing a significantly lower stone-free rate 1 day after treatment with the SLX even with significantly more shock waves applied. As a consequence, the re-treatment rate for the SLX in our series was significantly higher than that with the HM3 or LSP (38% vs 4% and 13%, respectively).

Due to the smaller focal zone of the SLX precise stone focusing during treatment seems to be mandatory. The need for repeat refocusing during treatment leads to longer fluoroscopy time and overall treatment time for the SLX (see table).

Comparing posttreatment dilatation of the upper urinary tract 1 day after ESWL showed significantly less dilatation in the HM3 group than in the other groups, probably resulting from the high stone fragmentation rate with the HM3. Because early re-treatment in the SLX group was done with the HM3, results in the groups regarding posttreatment complications such as obstructive, febrile pyelonephritis as well as stone disintegration after 3 months were comparable, as expected.

What may be the reasons for the less favorable results with the newer lithotriptors? Direct positive pressure resulting in

direct action on the stone does not seem to be the only mechanism of stone fragmentation. It has been shown that the portion of the pressure wave traveling outside of the stone surface exerts circular pressure, resulting in a squeezing mechanism with cleavage perpendicular to the wave vector and a compression zone inside the stone.[14] Furthermore, it has been observed that cavitation is also important for opening the cleavage planes that propagate cracks and microcracks throughout the stone.[15] This effect may be enforced by slowing shock wave frequency and better subsequent fragmentation, as noted by Pace et al.[16] The significantly higher shock wave rate in our SLX group compared with that in the HM3 and LSP groups could be a reason for the poorer fragmentation results and it is currently being investigated in a prospective, randomized trail.

Furthermore, the focal positive pressure peak can be decreased to the lower range of 10 to 30 mPa (40 mPa for the HM3) because this seems to be sufficient to overcome the breaking threshold of calcium containing concrements and artificial stones.[17] According to this, kidney stones might be better treated with a larger focal area, a larger pulse width and decreased positive pressure. An increased focal area allows greater positional flexibility to account for kidney movements during respiration with the consequence of more overall shock wave energy being applied to the stones.

The mode of coupling may be another important source of energy transmission loss.[18] Careful coupling is mandatory to prevent bubbles from forming in the coupling jelly, which result in cavitation with subsequent energy loss and skin lesions. In addition, the surrounding medium also seems to have an additional important role in the contribution of stress waves and cavitation for stone comminution.[19]

Anesthesia should also be considered, in that general or epidural anesthesia keeps the patient quiet without being influenced by discomfort or pain and it maintains a regular respiration rhythm. These are important factors that also influence stone fragmentation results.[20]

CONCLUSIONS

Briefly, we noted that the best stone disintegration can be achieved with the oldest lithotriptor, namely the original HM3, followed by the LSP and SLX. The newest lithotriptor generation, that is the SLX, also caused the largest residual fragments after 1 day with the highest re-treatment rates, and the longest fluoroscopy and treatment times. Therefore, we conclude that newer is not always better.

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