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Stone Disease

A Prospective Randomised Trial Comparing the Modified HM3 with the MODULITH® SLX-F2 Lithotripter

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Abstract

Background: The relative efficacy of first- versus last-generation lithotripters is unknown.
Objectives: To compare the clinical effectiveness and complications of the modified Dornier HM3 lithotripter (Dornier MedTech, Wessling, Germany) to the MODULITH® SLX-F2 lithotripter (Storz Medical AG, Tägerwilen, Switzerland) for extracorporeal shock wave lithotripsy (ESWL).
Design, setting and participants: We conducted a prospective, randomised, single-institution trial that included elective and emergency patients.
Interventions: Shock wave treatments were performed under anaesthesia.
Measurements: Stone disintegration, residual fragments, collecting system dilatation, colic pain, and possible kidney haematoma were evaluated 1 d and 3 mo after ESWL. Complications, ESWL retreatments, and adjuvant procedures were documented.
Results and limitations: Patients treated with the HM3 lithotripter ($n = 405$) required fewer shock waves and shorter fluoroscopy times than patients treated with the MODULITH® SLX-F2 lithotripter ($n = 415$). For solitary kidney stones, the HM3 lithotripter produced a slightly higher stone-free rate ($p = 0.06$) on day 1; stone-free rates were not significantly different at 3 mo (HM3: 74% vs MODULITH® SLX-F2: 67%; $p = 0.36$). For solitary ureteral stones, the stone-free rate was higher at 3 mo with the HM3 lithotripter (HM3: 90% vs MODULITH® SLX-F2: 81%; $p = 0.05$). For solitary lower calyx stones, stone-free rates were equal at 3 mo (63%). In patients with multiple stones, the HM3 lithotripter's stone-free rate was higher at 3 mo (HM3: 64% vs MODULITH® SLX-F2: 44%; $p = 0.003$). Overall, HM3 lithotripter led to fewer secondary treatments (HM3: 11% vs MODULITH® SLX-F2: 19%; $p = 0.001$) and fewer kidney haematomas (HM3: 1% vs. MODULITH® SLX-F2: 3%; p = 0.02).
Conclusions: The modified HM3 lithotripter required fewer shock waves and shorter fluoroscopy times, showed higher stone-free rates for solitary ureteral stones and multiple stones, and led to fewer kidney haematomas and fewer secondary treatments than the MODULITH® SLX-F2 lithotripter. In patients with a solitary kidney and solitary lower calyx stones, results were comparable for both lithotripters.

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1. Introduction

The introduction of the Dornier HM3 lithotripter (Dornier MedTech, Wessling, Germany) was soon followed by the development of new lithotripters to further minimise tissue trauma and pain. Although the new devices improved patient comfort, they were less effective at stone disintegration [1]. Few prospective randomised trials comparing the first-generation HM3 lithotripter and the new lithotripters exist [2–4]. Teichman et al showed that in vitro fragmentation was best with the MODULITH® SLX lithotripter (Storz Medical AG, Tägerwilen, Switzerland), followed by the LITHOSTAR® C (Siemens Healthcare, Erlangen, Germany) and HM3 lithotripters [5]. In comparative and randomised clinical trials, the HM3 lithotripter achieved better stone disintegration than the MODULITH® SLX and LITHOSTAR Plus lithotripters [3]. With its wide focus (F2), the MODULITH® SLX-F2 lithotripter can potentially achieve better results than its predecessor models [6,7], as underlined by the in vitro evaluation of Leistner et al, which showed that although the two foci have similar disintegration capacity, the wider focus requires fewer shock waves. However, the two foci caused comparable tissue injury in a porcine ex vivo model [8].

In this prospective randomised trial, we compared the relative clinical effectiveness and complications of the modified HM3 lithotripter and the MODULITH® SLX-F2 lithotripter.

2. Patients and methods

From April 2006 to March 2008, all patients >18 yr of age requiring elective or emergency extracorporeal shock wave lithotripsy (ESWL) for previously untreated urinary stones ($n = 903$) were randomly assigned for treatment with either the HM3 ($n = 405$) or MODULITH® SLX-F2 ($n = 415$) lithotripter. Eighty-three patients were excluded because of prior unsuccessful ESWL for the same stone, staghorn calculi, stones

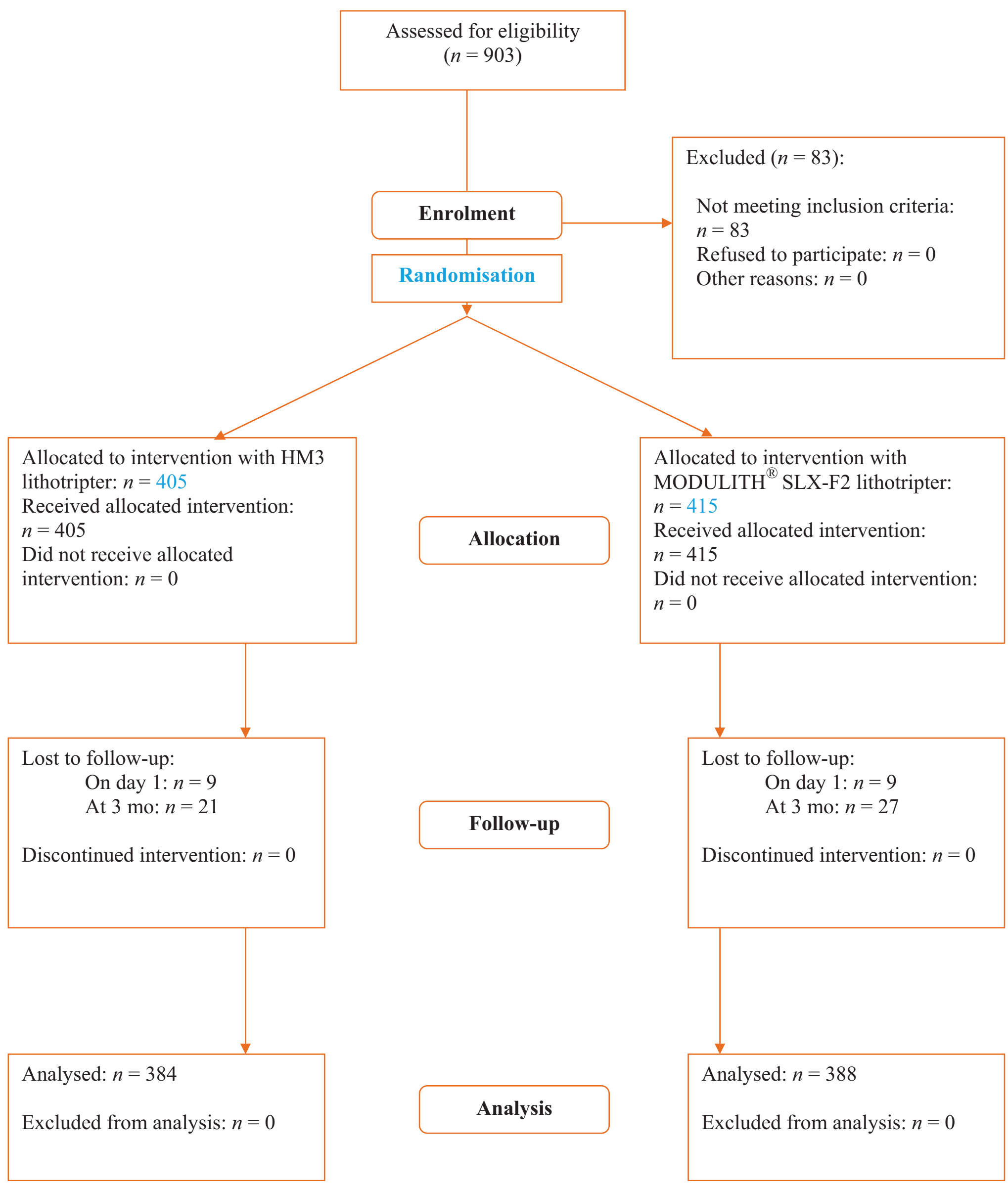

Fig. 1 – The CONSORT E-flowchart (HM3 lithotripter vs MODULITH® SLX-F2 lithotripter).

>30 mm, urinary tract infection, or technical problems/impossibility to localise the stone (eg, because of obesity) on the day of intervention. All patients provided informed written consent (Fig. 1).

Patients with solitary stones (n = 588) were stratified according to localisation (kidney stones, ureteral stones, or lower calyx stones) and stone size (0–10 mm, 10–20 mm, >20 mm). The localisation of ureteral stones was not further specified. Irrespective of the localisation, anyone with more than one stone was assigned to the group with multiple stones (n = 232) and stratified according to the size of the largest stone. Intervention planning was based on kidney, ureter, and bladder (KUB) x-ray and noncontrast computed tomography (CT) scan or intravenous urography. Collecting system anatomy and stone density were not analysed. Patient characteristics of the HM3 and MODULITH® SLX-F2 cohorts were comparable (Table 1).

2.1. The modified HM3 lithotripter

Electrohydraulic shock waves are generated between two electrodes in a water bath. The original HM3 lithotripter was modified in the early 1990 s to enable anaesthesia-free treatment. The ellipsoid aperture was increased from 15.0 cm (176 cm^2) to 17.2 cm (232 cm^2) to distribute the shock wave energy over a larger skin surface, and the generator capacity of most modified HM3 lithotripters was reduced to 40 nF. The "hybrid" HM3 lithotripter used for the present trial combines the wider ellipsoid (Ø 17.2 cm) with the original generator capacity of 80 nF. Its focal point is 13.0 cm off the reflector, varying from 7.5 mm to 16 mm laterally and from 40 mm to 100 mm axially. Its peak positive pressure is estimated at 37 ± 3 MPa. Precise energy measurements have never been performed for this modified hybrid model, but it is estimated to deliver focal energy of at least 45 mJ.

2.2. The MODULITH® SLX-F2 lithotripter

Electromagnetic shock waves are generated using a mechanism similar to a loudspeaker. The parabolic reflector aperture is 30 cm (707 cm^2), its focal point 16.5 cm off the reflector. We exclusively used the extended focus (F2), varying from 9 mm laterally and 50 mm axially. With a median energy level of 9, total focal energy is 150 mJ—more than twice that of the HM3 lithotripter.

2.3. Extracorporeal shock wave lithotripsy treatment

All ESWL treatments were given under anaesthesia (Table 1) to eliminate pain as a limiting factor and to keep respiratory movements regular. All patients were – under supervision and guidance by a senior staff member and especially trained resident – treated by the same technician (R.S.); this technician has 22 yr of experience and was trained to use the MODULITH® SLX-F2 lithotripter by a Storz Medical AG representative in a run-in phase of 47 patients before beginning randomisation. Acoustic coupling in the water bath (HM3) was performed with degassed water. The coupling protocol for the MODULITH® SLX-F2 lithotripter involved application of oil (provided by Storz Medical AG) on the treatment head and degassed water between the patient and the foil. Special attention was given to avoid any entrapped air bubbles.

Shock wave delivery was heart beat triggered [9]. Before ESWL of ureteral stones, JJ stents were removed to eliminate stent-related energy absorption [10]. Treatments began with a series of 500 shocks of moderate energy (HM3: 19 kV; MODULITH® SLX-F2: level 7). If the fluoroscopic control showed no fragmentation, energy was continuously increased to 21–22 kV for the HM3 lithotripter and level 9 for the MODULITH® SLX-F2 lithotripter [11]. In case of partial stone disintegration, energy was progressively lowered to prevent unnecessary trauma [12]. Treatment was stopped before reaching the maximally allowed number of shock waves (kidney stones: 2500; ureteral stones off the kidney: 3000) if x-ray snapshots showed no residual fragments. With both lithotripters, continuous-mode fluoroscopy was used. Treatment time started with stone localisation and ended after the final radiologic evaluation. After ESWL, α-blocking agents were given to patients with ureteral stones.

2.4. Follow-up

The degree of stone disintegration, dilatation of the collecting system (absent/present), colic pain (absent/present), and the presence of kidney haematoma were evaluated by KUB x-ray and renal ultrasound 1 d and 3 mo after ESWL. CT scans were only used if deemed necessary to reduce the exposure to ionising radiation and to limit the costs. Treatment outcome was classified as stone free, fragments <2 mm, fragments 2–5 mm, and fragments >5 mm. To avoid interobserver differences, all radiographic studies were interpreted by a blinded urologist. Complications, ESWL retreatments, and adjuvant procedures were prospectively documented. Total secondary treatments included ESWL retreatments and adjuvant procedures. The efficacy quotient (EQ) was also calculated [13].

2.5. Statistical analysis

For statistical analyses (Department of Mathematics and Statistics, University of Bern, Bern, Switzerland), StatXact v.8 statistical software

Table 1 – Patient and treatment characteristics

	HM3	MODULITH® SLX-F2	p value
Patients, no.	405	415	–
Male-to-female ratio	2.04:1	2.16:1	–
Age, yr, mean ± SD	47 ± 16	48 ± 15	0.42
BMI, kg/m^2, median (range)	26.8 (15.3–43.6)	26.2 (13.0–50.5)	0.44
Anaesthesia			
Peridural anaesthesia, No. (%)	309 (76)	325 (78)	–
Spinal single shot, No. (%)	78 (19)	58 (14)	–
Intubation, No. (%)	18 (5)	32 (8)	–
Treatment time, min, median (range)	39 (17–176)	40 (10–149)	0.01
Fluoroscopy time, s, median (range)	44 (9–620)	125 (29–941)	<0.0001
Shock waves, No., mean ± SD			
Kidney stones	2071 ± 1042.3	2309 ± 724.9	<0.0001
Ureteral stones	2320 ± 585.6	2552 ± 470.9	<0.0001
Shock wave energy applied, median (range)	19 kV (16–22 kV)	Level 9 (level 3–9)	–

SD = standard deviation; BMI = body mass index.

(Cytel, Cambridge, MA, USA) was used. Based on the assumption that the overall stone-free rate at 3 mo is 70% after treatment with the HM3 lithotripter and 60% after treatment with the MODULITH® SLX-F2 lithotripter and considering a two-sided test at the significance level of 5% ($\alpha = 0.05$), a sample size of 752 patients ($n = 376$ for each group) was needed to obtain a statistical power of 80% ($\beta = 0.2$). Patients were stratified and randomised according to a minimisation randomisation procedure within strata. Success rates were compared using Fisher exact test by analysing contingency tables. The different stone size groups were analysed together for each of the three single-stone localisations and for multiple stones. Subgroup success rates were compared descriptively. Nonparametric tests were applied to compare metric variables in independent groups; p values <0.05 were considered significant.

3. Results

A total of 1345 stones in 820 patients were treated. Median treatment time using the modified HM3 lithotripter was 39 min (range: 17–176) versus 40 min (range: 10–149) for the MODULITH® SLX-F2 lithotripter ($p = 0.01$). Median fluoroscopy time with the modified HM3 lithotripter (44 s; range: 9–620) was significantly shorter ($p < 0.0001$) than with the MODULITH® SLX-F2 lithotripter (125 s; range: 29–941). Treatment with the modified HM3 lithotripter required fewer shock waves for both solitary kidney ($p < 0.0001$) and solitary ureteral ($p < 0.0001$) stones. Median shock wave energy applied was 19 kV (range: 16–22 kV) for the modified HM3 lithotripter and level 9 (range level 3–9) for the MODULITH® SLX-F2 lithotripter (Table 1).

Treatment outcome was evaluable in 98% of patients on day 1 and in 94% at 3 mo. Ultrasound revealed fewer kidney haematomas in the modified HM3 group (1% vs 3%; $p = 0.02$; Table 2). Although most patients had subcapsular bleeding only, three patients showed extensive retroperitoneal haematomas requiring blood transfusions after ESWL with the MODULITH® SLX-F2 lithotripter.

Overall, significantly fewer patients required ESWL retreatment ($p = 0.02$) and secondary treatments ($p = 0.001$) after therapy with the modified HM3 lithotripter (Table 3). The overall EQs for the modified HM3 and MODULITH® SLX-F2 lithotripters were 67% and 58%, respectively.

3.1. Solitary kidney stones (221 patients)

On day 1, there was a trend toward a higher stone-free rate (HM3: 31% vs MODULITH® SLX-F2: 20%; $p = 0.06$) with the modified HM3 lithotripter (Fig. 2a). Collecting system dilatation (HM3: 10 patients [9%] vs MODULITH® SLX-F2: 6 patients [6%]; $p = 0.31$) and colic pain rates (HM3: 9 patients [9%] vs MODULITH® SLX-F2: 18 patients [16%]; $p = 0.10$) were similar. Four patients (4%) treated with the modified HM3 lithotripter and six patients (6%) treated with the MODULITH® SLX-F2 lithotripter required ESWL retreatment ($p = 0.75$). Six patients (6%) required adjuvant procedures after therapy with the modified HM3 lithotrip-

Table 2 – Subcapsular and perirenal haematomas 1 d after ESWL treatment as diagnosed by ultrasound and according to initial stone localisation or presence of multiple stones

	No. of haematomas/total number of patients (%)		
	HM3	MODULITH® SLX-F2	*p* value
All stones	3/405 (1)	12/415 (3)	0.02
Solitary kidney stones	2/109 (2)	3/112 (3)	–
Solitary ureteral stones	0/130 (0)	0/139 (0)	–
Solitary lower calyx stones	0/63 (0)	3/35 (9)	–
Multiple stones	1/103 (1)	6/129 (5)	–

Table 3 – Synopsis of ESWL retreatments, type of adjuvant procedures, and total secondary treatments after ESWL treatment according to stone localisation or presence of multiple stones

	HM3	MODULITH® SLX-F2	*p* value
Solitary kidney stones, No. of patients treated (%)	109	112	–
ESWL retreatments	4 (4)	6 (6)	0.75
Single	4	5	–
Multiple	0	1	–
Adjuvant procedures	6 (6)	2 (2)	0.17
JJ stent	0	0	–
Nephrostomy	0	0	–
URS	4	1	–
PCNL	2	1	–
Total secondary treatments	10 (10)	8 (8)	0.63
Solitary ureteral stones, No. of patients treated (%)	130	139	–
ESWL retreatments	5 (4)	11 (9)	0.20
Single	5	9	–
Multiple	0	2	–
Adjuvant procedures	10 (8)	18 (14)	0.16
JJ stent	3	9	–
Nephrostomy	1	2	–
URS	6	7	–
PCNL	0	0	–
Total secondary treatments	15 (12)	29 (23)	0.03
Solitary lower calyx stones, No. of patients treated (%)	63	35	–
ESWL retreatments	4 (7)	3 (9)	1.0
Single	4	3	–
Multiple	0	0	–
Adjuvant procedures	3 (5)	2 (6)	1.0
JJ stent	1	0	–
Nephrostomy	0	0	–
URS	2	1	–
PCNL	0	1	–
Total secondary treatments	7 (12)	5 (15)	1.0
Multiple stones, No. of patients treated (%)	103	129	–
ESWL retreatments	12 (12)	24 (20)	0.14
Single	10	21	–
Multiple	2	3	–
Adjuvant procedures	2 (2)	13 (11)	0.01
JJ stent	0	3	–
Nephrostomy	0	0	–
URS	2	9	–
PCNL	0	1	–
Total secondary treatments	14 (14)	37 (31)	0.004
Overall ESWL retreatments	25 (6)	44 (11)	0.02
Overall adjuvant procedures	21 (5)	35 (8)	0.07
Overall secondary treatments	46 (11)	79 (19)	0.001

ESWL = extracorporeal shock wave lithotripsy; URS = ureteroscopy; PCNL = percutaneous nephrolithotomy.

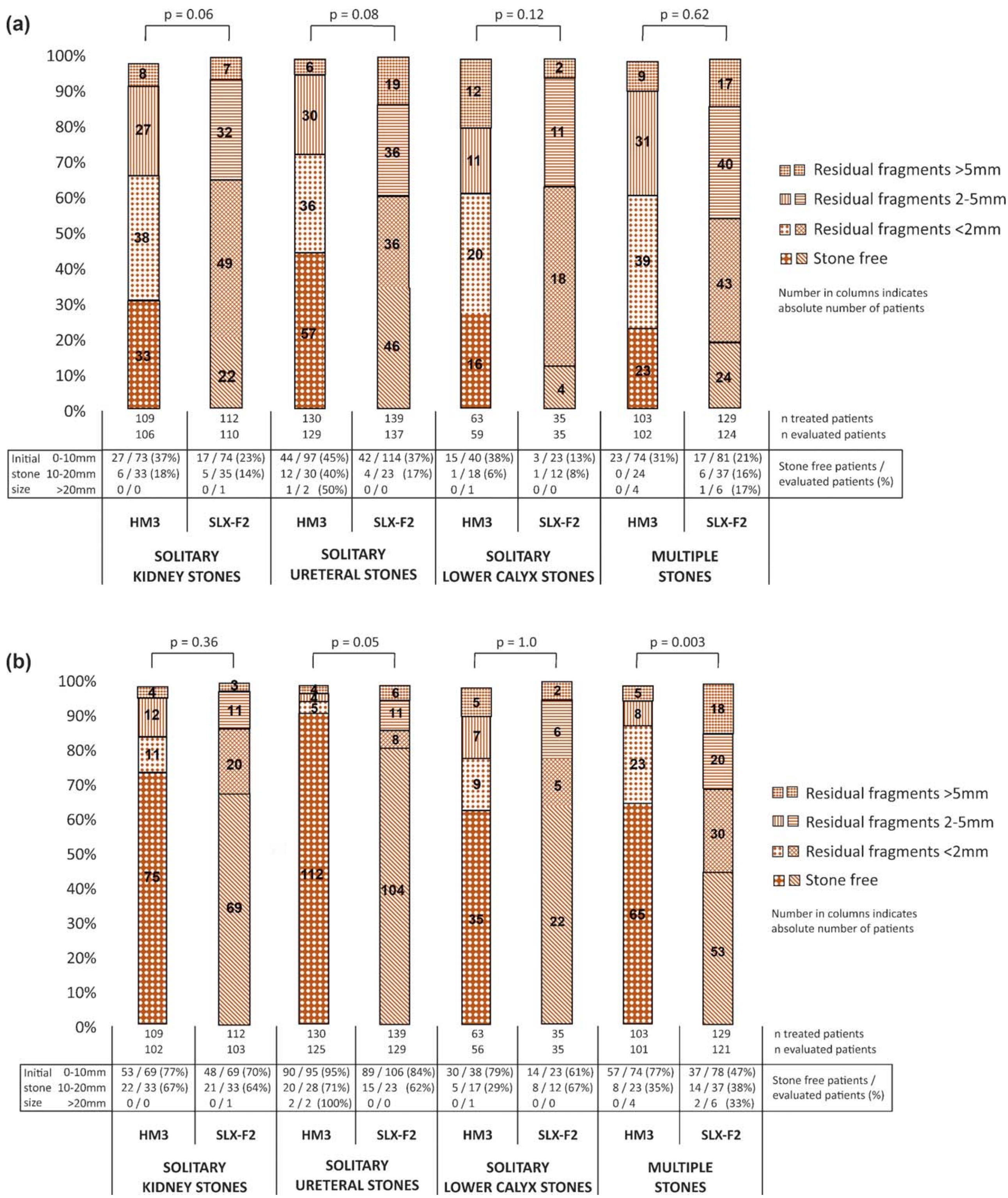

Fig. 2 – (a) Overall stone-free rate, stone-free rate related to initial stone size, and size of residual fragments on day 1 after ESWL treatment according to stone localisation or presence of multiple stones. (b) Overall stone-free rate, stone-free rate related to initial stone size, and size of residual fragments 3 months after ESWL treatment according to stone localization or presence of multiple stones. Included are patients with ESWL retreatments and/or adjuvant procedures for solitary kidney stones, solitary lower calyx stones and multiple stones.

ter versus two patients (2%) with the MODULITH® SLX-F2 ($p = 0.17$; Table 3).

At 3 mo, 74% of patients treated with the modified HM3 lithotripter were stone free versus 67% treated with the MODULITH® SLX-F2 lithotripter ($p = 0.36$, including patients undergoing secondary treatments; Fig. 2b). EQs for the HM3 and MODULITH® SLX-F2 lithotripters were 68% and 63%, respectively.

3.2. Solitary ureteral stones (269 patients)

On day 1, stone-free rates were 44% for the modified HM3 lithotripter versus 34% for the MODULITH® SLX-F2 lithotripter ($p = 0.08$; Fig. 2a). Collecting system dilatation (HM3: 41 patients [32%] vs MODULITH® SLX-F2: 53 patients [39%]; $p = 0.25$) and colic pain rates (HM3: 32 patients [25%] vs MODULITH® SLX-F2: 40 patients [29%]; $p = 0.49$) were similar. Five patients (4%) treated with the modified HM3 lithotripter and 11 patients (9%) treated with the MODULITH® SLX-F2 lithotripter required ESWL retreatment ($p = 0.20$). Ten patients (8%) required adjuvant procedures after therapy with the modified HM3 lithotripter versus 18 patients (14%) with the MODULITH® SLX-F2 lithotripter ($p = 0.16$; Table 3).

At 3 mo, excluding patients requiring secondary treatments, 90% of patients in the modified HM3 group versus 81% in the MODULITH® SLX-F2 group were stone free ($p = 0.05$; Fig. 2b). Including secondary treatments, every ureter was stone free after 3 mo. The EQs for the HM3 and MODULITH® SLX-F2 lithotripters were 90% and 83%, respectively.

3.3. Solitary lower calyx stones (98 patients)

On day 1, the stone-free rate after ESWL with the modified HM3 lithotripter was twice as high as with the MODULITH® SLX-F2 lithotripter (HM3: 27% vs MODULITH® SLX-F2: 12%; $p = 0.12$; Fig. 2a). The rates for collecting system dilatation (HM3: 7 patients [12%] vs MODULITH® SLX-F2: 3 patients [9%]; $p = 0.74$) and colic pain (HM3: 10 patients [17%] vs MODULITH® SLX-F2: 5 patients [14%]; $p = 0.1$) were similar, as were the ESWL retreatment (HM3: 7% vs MODULITH® SLX-F2: 9%; $p = 1.0$) and adjuvant procedure rates (HM3: 5% vs MODULITH® SLX-F2: 6%; $p = 1.0$; Table 3).

At 3 mo, 63% of patients were stone free in both groups ($p = 1.0$, including patients undergoing secondary treatments; Fig. 2b). Both lithotripters exhibited an EQ of 55%.

3.4. Multiple stones (232 patients)

On day 1, stone disintegration (Fig. 2a), collecting system dilatation (HM3: 10 patients [10%] vs MODULITH® SLX-F2: 17 patients [14%]; $p = 0.42$) and colic pain rates (HM3: 9 patients [9%] vs MODULITH® SLX-F2: 22 patients [18%]; $p = 0.08$) for the two groups were comparable. In the modified HM3 group, 12 patients (12%) required ESWL retreatment and 2 patients (2%) required adjuvant procedures versus 24 patients (20%; $p = 0.14$) and 13 patients (11%; $p = 0.01$), respectively, in the MODULITH® SLX-F2 group (Table 3).

At 3 mo, stone-free rates differed significantly in favour of the modified HM3 group (HM3: 64% vs MODULITH® SLX-F2: 44%; $p = 0.003$, including patients undergoing secondary treatments; Fig. 2b). EQs for the HM3 and MODULITH® SLX-F2 lithotripters were 56% and 34%, respectively.

4. Discussion

The present clinical trial is to our knowledge the largest prospective, randomised, single-institution trial analysing two different lithotripters. Stone-free rates for solitary kidney stones observed at 3 mo with the modified HM3 lithotripter (74%) and the MODULITH® SLX-F2 lithotripter (67%) were similar and in line with published data [14,15]. ESWL retreatment and adjuvant procedure rates were also comparable to [1] or even lower than those in other series [16]. However, there was a difference in the results for solitary ureteral stones. Besides a significantly better stone-free rate, we documented fewer secondary treatments in the HM3 group. We do not attribute this result to poor handling of the MODULITH® SLX-F2 lithotripter, because our ESWL retreatment rate was still much lower than the rates Tiselius et al. [10] achieved using the MODULITH® SLX-F2 lithotripter. In addition, more patients required adjuvant procedures in Tiselius' cohort compared to our cohort treated with the MODULITH® SLX-F2 lithotripter for a solitary ureteral stone. This outcome may be attributable to our optimal treatment conditions under anaesthesia. For solitary lower calyx stones, the two lithotripters we used achieved equal stone-free rates (63%) at 3 mo and had comparable secondary treatment rates. This result accords with our earlier findings that lower infundibulum anatomy is not a limiting factor [17]. Similar success rates have been reported with the Sonolith® Vision lithotripter (TMS, Lyon, France) in a prospective observational study [18].

Our study may be criticised for its inclusion of 232 patients with multiple stones among our cohort of 820 patients. This ratio, however, reflects clinical reality. Delivering the same maximal number of shock waves per patient but partitioned among multiple stones, the HM3 lithotripter achieved a higher stone-free rate with fewer secondary treatments and fewer large residual fragments at 3 mo.

To create a comparable treatment strategy and deliver energy with the MODULITH® SLX-F2 lithotripter similar to that delivered by the modified HM3 lithotripter so as to obtain optimal stone disintegration, Storz Medical AG advised us to place our patients under anaesthesia, to employ the wider F2 focus, and to use a high energy level whenever clinically justified. But even applying the higher focal energy and working at maximal power after ramping up, the overall ESWL retreatment rate was significantly higher with the MODULITH® SLX-F2 lithotripter. Hence, applying maximal energy over a wider target area alone does not guarantee disintegration. Applying excessive shock wave energy may result in early fragmentation of stones into larger fragments at separate locations, requiring individual sequential treatments [19] and thus prolonging fluoroscopy time, as we had previously observed with the predecessor model (MODULITH® SLX) [1].

When optimising ESWL, it is necessary to eliminate unnecessary shock wave exposure. Hence, energy was progressively decreased whenever clinically justifiable during ESWL treatment depending on fragmentation. We previously reported that the HM3 lithotripter delivered more energy per shock wave to the kidney than the Siemens LITHOSTAR® Plus, with generally minor kidney trauma that resolved within 2 d [3]. In the present series, the number of shock waves applied per patient was higher for the MODULITH® SLX-F2 group. This, together with the higher energy in the smaller focal zone, may explain the higher rate of haematomas observed with the MODULITH® SLX-F2 lithotripter. Still, the overall incidence of haematomas (2%) was low compared to rates as high as 13% reported elsewhere [20]. Although clinically irrelevant haematomas may have been missed, we attribute this low incidence to our exclusion of patients under antiaggregation/anticoagulation therapy.

One can only speculate about the technical reasons for the superior stone disintegration of the modified version of the first lithotripter ever built versus all of its successors. While shock wave energy from the HM3 lithotripter was measured with needle hydrophones (earlier standard), laser hydrophones were used to measure the energy delivered by the MODULITH® SLX-F2 lithotripter, making a direct comparison of energies impossible. The HM3 lithotripter's wider focus may be a reason for its more successful treatment of solitary ureteral stones. But the most important factor is probably the mode of energy coupling. Shock waves generated in water (HM3) enter the body with minimal energy reflection and absorption at the water/skin interface, whereas the dry setting of the MODULITH® SLX-F2 lithotripter may impair its efficacy. Even small air bubbles in the coupling medium significantly decrease the delivery of shock wave energy [21,22].

Successful ESWL treatment, therefore, does not depend on the lithotripter's performance alone but also on treatment planning, anaesthesia, shock wave frequency/intensity, energy transmission, stone monitoring, and adjuvant procedures. Although this study demonstrates the superiority in several aspects of the modified first-generation HM3 lithotripter versus the MODULITH® SLX-F2 lithotripter, effective ESWL can also be achieved with the latest-generation lithotripters.

5. Conclusions

Compared to the MODULITH® SLX-F2 lithotripter, the modified Dornier HM3 lithotripter achieves higher stone-free rates for solitary ureteral and multiple stones at 3 mo with fewer shock waves and shorter fluoroscopy times. It also produces fewer haematomas and has significantly lower overall secondary treatment rates. Only in patients with solitary kidney and solitary lower calyx stones does the MODULITH® SLX-F2 lithotripter obtain comparable results.

Author contributions: Urs E. Studer had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Studer.
Acquisition of data: Zehnder, Roth, Birkhäuser, Schneider, Schmutz, Thalmann, Studer.
Analysis and interpretation of data: Zehnder, Birkhäuser, Thalmann, Studer.
Drafting of the manuscript: Zehnder, Roth, Birkhäuser, Studer.
Critical revision of the manuscript for important intellectual content: Zehnder, Roth, Birkhäuser, Studer.
Statistical analysis: Zehnder, Studer.
Obtaining funding: Studer.
Administrative, technical, or material support: Zehnder, Schmutz, Thalmann, Studer.
Supervision: Thalmann, Studer.
Other (specify): None.

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