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European Association of Urology

Letter to the Editor

Re: Pascal Zehnder, Beat Roth, Frédéric Birkhäuser, et al. A Prospective Randomised Trial Comparing the Modified HM3 with the MODULITH® SLX-F2 Lithotripter. Eur Urol 2011;59:637–44

The authors have to be congratulated for this large randomised clinical trial comparing two lithotripters including >900 patients [1]. On first sight, the data of the study favour the old electrohydraulic Dornier HM3 with the modified (enlarged) ellipsoid requiring fewer shock waves and a shorter fluoroscopic time, inducing less perirenal haematoma, and providing better stone-free rates for multiple renal and ureteral calculi. However, some issues need a closer look.

Does the design of the study reflect the idea of the dual focus of the Modulith SLX-F2?

The basic idea of the dual focus was to adapt the focal zone to the size and localisation of the stone [2]. Based on this, renal stones should be treated with the enlarged focus to reduce the energy density (ED), whereas for ureteral stones the original focus comparable with the Modulith SL20 [3] should be applied. Based on my personal experience, particularly for ureteral stones, the smaller focus has proven to be very effective with minimal side effects [4]. Another application of the dual focus could include starting with the small focus and then switching to the larger one once disintegration begins.

Does the design of the study really reflect daily clinical practice?

In the discussion section, the authors comment that the study included multiple stones, commenting this is "daily clinical practice." However, in all cases epidural anaesthesia was used. This is *not* daily practice at most centres worldwide, and one of the main reasons for the introduction of the modified HM3 was to enable treatment under intravenous (IV) analgesia [5,6]. The Modulith SL 10/20 was especially designed for this purpose with a large aperture of 30 cm [7]. Based on our own experience with the device, this has never been a major problem. However, when using the 80nF generator with the enlarged ellipsoid, the use of IV analgesia is limited [5,6]. In other studies of the Modulith SLX-F2, the larger focal zone did not present any problems of pain management [8]. Thus the advantage of the newer generation lithotripter enabling treatment under IV analgesia is not considered in this study [9].

Are there any biases concerning the operator?

Interestingly, this study was carried out by a technician, supervised by urologists, with 22 yr of experience with the Dornier HM3. Compared with the 22 yr, he had "only" 47 cases to get trained on the Modulith SLX-F2. Positioning (stretcher vs acoustic cradle), coupling (water tank vs water cushion plus impedance-adapted foil), localisation (two oblique converters vs inline fluoroscopy), and application parameter (kV vs energy level; electrocardiogram triggering vs 1–2 Hz) is completely different when comparing both devices. In my personal experience with both lithotripters [3–7], 50 cases are not sufficient to guarantee equivalent performance. Because the success of extracorporeal shock wave lithotripsy (ESWL) is strictly operator dependent, particularly concerning the use of newer devices, there was still a learning curve during the study. This is clearly reflected by the longer fluoroscopy time for the Modulith SLX-F2, probably due to inline fluoroscopy. Interestingly, the treatment time was almost identical in both groups (39 vs 40 min).

Apart from this, I strongly believe a technician should not perform the treatment in such a study (and even not in daily practice) as was also the case in the trial by De Sio et al [8]. In contrast, such excellent studies may motivate young urologists (ie, supervised by the technician) like we were in the 1980 s and 1990 s [3–7].

What is the real message of this trial?

There is evidently a clear trend away from high shock wave pressure based on recent research results concerning mechanisms of stone fragmentation and shock wave induced renal trauma. A larger focal zone based on a smaller aperture of the shock wave source is associated with larger focal zone and a lower peak pressure [2]. Accordingly, ED representing the main parameter for induction of renal trauma is lower. Because the threshold for stone breakage amounts to 30 MPa, the peak pressure of such systems like the Dornier HM3 is still sufficient. A larger focal size also compensates much better for any respiratory movement, particularly in (multiple) renal calculi. The coupling with a complete water bath results in 15–20% fewer shock waves when comparing identical sources (HM3 vs HM4 [10]). Based on this, the lower number of impulses with the modified HM3 is obvious. However, it had no

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significant impact on the treatment time. From a scientific standpoint, at least the results concerning multiple renal stones as well as the lower incidence of renal haematoma are important. This means that even the larger focal zone of the Modulith SLX-F2 does not per se guarantee minor trauma, which is in accordance with the studies by Leistner et al [11].

However, we will not turn the wheel back to the use of a water tank and epidural anaesthesia. So we may have to accept a slightly higher rate of impulses and retreatment in the case of multiple stones. And the real chances of the dual focal system have not yet been explored [1,8].

What are future perspectives?

Because we face a decrease of ESWL patients due to the increased number of symptomatic ureteral calculi, almost all recently introduced lithotripters (Siemens Lithoskop, Dornier Gemini, Storz Modulith SLX-F2, Edap-TMS-Sonolith-I-sys) are designed as multifunctional urologic working stations equipped with digital fluoroscopy. In contrast, devices with larger focal zones are manufactured (AST Lithospace, LithoGold, Xinin-X-ES) that may provide better results and minimal side effects. The Xinin-X-ES represents the most interesting alternative, showing better stone in vitro fragmentation compared with Dornier HM3 and no renal lesions in the porcine model [2].

More important, we have to motivate the upcoming generation of urologists to perform experimental and clinical research on ESWL as well as to carry out the treatment personally based on profound physical and medical know-how.

Conflicts of interest: The author has nothing to declare.

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Jens Rassweiler
Department of Urology, University of Heidelberg, Heilbronn, Germany
E-mail address: jens.rassweiler@slk-kliniken.de

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