letters

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FOURTH GENERATION LITHOTRIPTER: DO WE HAVE A NEW BENCHMARK FOR COMPARISON?

Sir,

We read with great interest the report by Nomikos *et al.* [1] evaluating a fourth-generation lithotripter, the Sonolith Vision, for treating a selected population with single previously untreated renal calculi. They had an initial fragmentation rate of 94%, with an overall 3-month stone-free rate of 75% and an overall efficiency quotient (EQ) of 62%. They provocatively concluded that this new machine can be regarded as the new benchmark for the comparative assessment of new-generation lithotripters. The same group from the Scottish Lithotripter Centre had previously published a report on this same new machine in the treatment of ureteric calculi, again with encouraging results [2].

The Dornier HM3 has traditionally been considered the reference standard by which all other lithotripters should be judged [3]. Following the development of the first-generation lithotripters, manufacturers tried many modifications and improvements. There have been four areas of technical advances in lithotripter technology, i.e. the shock wave source, the focusing element, the coupling device and the calculus imaging unit [4]. ESWL is being pushed toward smaller, more portable, less-expensive machines, which do not require extensive installation.

We recently reported on the efficacy of the Modulith SLX-F2 lithotripter (Storz Medical) in the treatment of urolithiasis [5]. The main advantage of this machine is represented by the dual-focus system, which enables the operator to adapt shock wave parameters to specific anatomical conditions. Our results showed that the Modulith SLX-F2 is effective in fragmenting solitary stones throughout the urinary tract, with an overall stone-free rate of 76.3% and EQ of 0.64. When considering the outcome of patients with renal stones, in terms of clinical success, 3-month stone-free rate, re-treatment rate, auxiliary procedures and EQ, this is comparable to that reported by Nomikos *et al.* [1].

Overall, it should be recognized that comparing the results achieved with various lithotripsy units at various institutions is difficult, if not impossible, due to variability in patient selection, definition of success, follow-up methods, and the reported use and classification of auxiliary procedures. In this setting, claiming a new standard for the comparative assessment of new-generation lithotripters can be misleading, even if it is stimulating for the scientific debate on this intriguing issue.

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1 **Nomikos MS, Sowter SJ, Tolley DA.** Outcomes using a fourth generation lithotripter: a new benchmark for comparison? *BJU Int* 2007; **100**: 1356–60

2 **Pemberton RJ, Tolley DA.** Comparison of a new-generation electroconductive spark lithotripter and the Dornier Compact Delta for ureteral calculi in a quaternary referral center. *J Endourol* 2006; **20**: 732–36

3 **Drach GW, Dretler S, Fair W *et al.*** Report of the United States cooperative study of extracorporeal shock wave lithotripsy. *J Urol* 1986; **135**: 1127

4 **Rassweiler J, Tailly G, Chaussy C.** Progress in lithotriptor technology. *EAU Update Ser* 2005; **3**: 17–36

5 **De Sio, Autorino R, Quarto G *et al.*** A new transportable shock-wave lithotripsy machine for managing urinary stones: a single-centre experience with a dual-focus lithotripter. *BJU Int* 2007; **100**: 1137–41

WHAT'S NEW IN MINIMALLY INVASIVE SURGERY IN UROLOGY?

The aim of minimally invasive surgery is to reduce access-related trauma whilst maintaining optimal operating conditions. There has been resurgent interest in Natural Orifice Transluminal Endoscopic Surgery (NOTES). NOTES is a growing experimental surgical technique that allows a variety of abdominal procedures to be performed in the absence of any anterior abdominal wall incisions. Recently, two transvaginal cholecystectomies were described, although not published. The first was in New York, in a 66-year-old patient [1] and the second in Strasbourg, France, in a 30-year-old patient [2]. Again, both groups of surgeons used at least one transabdominal port with instrumentation, which is not consonant with the traditional definition of NOTES. The first urological application of NOTES was by Gettman *et al.* [3], who performed six transvaginal NOTES nephrectomies in four pigs (five nephrectomies still required the use of one laparoscopic port), using standard laparoscopic and endourological instrumentation. Although the procedures were successful, the authors described the approach as somewhat cumbersome. A key requirement of NOTES surgery, as identified by the Natural Orifice Surgery Consortium for Advancement and Research, is a stable surgical platform to support and guide the flexible endoscope and instruments. Existing flexible endoscopes and instruments are limited in providing a platform for advanced surgery, and therefore the technique appears to have languished, until Clayman *et al.* [4] recently reported their experience with NOTES to perform a nephrectomy in the porcine model using a novel device. However, a 12-mm port still had to be placed in the midline to deploy a clip applier/stapler across the renal pedicle. However, it is only a matter of time before the necessary instrumentation is developed to allow for a formal NOTES nephrectomy to be carried out successfully.

Laparoscopic access offers a far better cosmetic outcome than open surgery. However, surgeons have been trying to improve on the issue by using fewer and smaller ports [5]. A single-trocar laparoscopic nephrectomy using a novel prototype magnetic anchoring and guidance system was recently reported in the porcine model [5]. The authors concluded that intracorporeal instrument manipulation might overcome the limitations of current laparoscopic and robotic surgery, by allowing unhindered intra-abdominal movement. Novel ports and wristed articulating hand-held instruments have been developed since then. It was exciting to gather that three groups working independently of each other have, this year, performed single-port nephrectomies, a pyeloplasty and indeed a single-port partial nephrectomy (personal communication), as well as several other laparoscopic urological procedures. Some of these were performed with intra-umbilical incisions, thereby offering a 'scarless' outcome.

The reduction in access-related and manipulative trauma as a result of advances in technology can only benefit patients; the techniques described above are only the end of the beginning of a new chapter in minimally invasive urology.

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1 **Grady D.** *Doctors Try New Surgery for Gallbladder Removal*. New York Times, April 20, 2007
2 **Marescaux J (Editorial).** Operation Anubis: A New Step in NOTES History! Available at http://www.websurg.com/notes/ Accessed 19 July 2007
3 **Gettman MT, Lotan Y, Napper CA, Cadeddu JA.** Transvaginal laparoscopic nephrectomy: Development and feasibility in the porcine model. *Urology* 2002; **59**: 446
4 **Clayman RV, Box GN, Abraham JB *et al*.** Transvaginal single-port NOTES nephrectomy: initial laboratory experience. Rapid communication. *J Endourol* 2007; **21**: 640–4
5 **Razdan S, Bagley D, McGinnis D.** Minimizing minimally invasive surgery: the 5-mm trocar laparoscopic pyeloplasty. *J Endourol* 2005; **19**: 533–6
6 **Zeltser IS, Bergs R, Fernandez R, Baker L, Eberhart R, Cadeddu JA.** Single trocar laparoscopic nephrectomy using magnetic anchoring and guidance system in the porcine model. *J Urol* 2007; **178**: 288–91

A NOVEL MIDSTREAM URINE-COLLECTION DEVICE REDUCES CONTAMINATION RATES IN URINE CULTURES AMONGST WOMEN

Sir,

With reference to this article by Jackson *et al.* [1], the authors found a contamination rate of 16% in antenatal women for their current system (as opposed to 11% for the Whiz CleanCatch). The results at one of the trial sites, the Oxford Radcliffe Hospitals (ORH) was stated as follows: 'At the John Radcliffe Women's centre all patients in group 1 were given a sterile pack containing a gauze and cotton wool to facilitate cleaning of the peri-meatal area and were instructed by staff on how to collect a MSU, which included separating the labia and to urinate into the toilet, then to stop, then to collect a sample and finish voiding into the toilet.' (p.362)

In clinical trial the methods are fixed, and once the trial is over these strict methods might not necessarily be continued, especially with the time-consuming explanation of a midstream urine (MSU) procedure as outlined above. To test this proposition I filed a Freedom of Information (FOI) Act request to the ORH for the contamination rates after the trial in the antenatal clinic for the period of the financial year April 2006 to March 2007 (FOI no 293 of 2007). The reply from the ORH FOI officer was received on 7 December 2007 and contained the following responses (in parentheses) to my questions:

'Can you let me know please for the financial year 2006 to 2007': 1) How many urine samples were cultured (114 608); 2) 'How many were antenatal (2531); 3) How many of the non-antenatal samples were from men (30 838); 4) How many of the non-antenatal samples from women: a) grew bacteria (26 771); b) had mixed growth (17 673); c) had no growth/no significant growth (39 326); 5) How many of the antenatal samples; a) grew bacteria (153); b) had mixed growth (545); c) had no growth/no significant growth (1833). These results show that for period assessed in the antenatal clinic at one of the main trial sites of Jackson *et al.*, of the 2531 patients who gave a sample, there was a 21.5% contamination rate of mixed growth in antenatal samples (545 of 2531). This is an increase from the 16% contamination rate reported by Jackson *et al.* of this trial site to 22% for the equivalent number of people at the same trial site in the year after the trial was completed. There are two possible explanations for this: the conventional methods followed by Jackson *et al.* at the ORH for explaining how to collect an MSU are not necessarily followed in practice outside the clinical trial, either by the patients who participate in a trial or by the staff who give the instructions to patients about to how to collect a MSU, or perhaps a combination of both.

This is a 22% increase in contamination, i.e. from 16% reported by Jackson *et al.*, to 22% in the financial year 2006–7, in contamination at the same site and with very similar number of patients. This corresponds closely to the 20.6%, i.e. a 21% increase in contamination of the clinical trial of Cabedo García *et al.* [2], which found that the general contamination rate of 56% in the GP environment could be improved to a rate of 41% contamination after following a careful and full explanation of how to collect an MSU (i.e. a 20.6% increase, 41% to 56%). The findings of Cabedo García *et al.* place the emphasis on an explanation to the staff, and indeed without such a full explanation there is no hope of the 21–22% reduction in contamination. However, Jackson *et al.* state: 'It was reported by staff at the John Radcliffe centre that several of these peri-meatal cleaning packs were thrown away unused, nor could staff verify that the instructions for given an MSU, i.e. separation of labia, were carried out in the privacy of the sample areas' (p 362). This suggests that user compliance could be as much a factor as an explanation to the staff.

The results obtained from the FOI of the ORH, when read in conjunction with Jackson *et al.* and Cabedo García *et al.*, might suggest first that clinical trials which involve patient and staff interventions that take some time (5 min explanation for the MSU) might yield results that are 21–22% more optimistic than in an outside a clinical trial. The reasons for this are that a careful and full explanation (procedure set out in BSOP41 Iv) that involves staff time (especially in a busy environment of urine sample collection) might not be given outside a clinical trial environment, or if it is given it is not followed by patients outside a clinical trial, or both. Furthermore, contamination rates in antenatal environments are generally

higher than in clinical trials, where the process of sample collection involves a detailed explanation by staff and active patient intervention to follow it. Patients simply might not use the equipment as instructed or not collect the sample from the midstream as instructed without interrupting the flow, but might simply collect the first stream.

In accordance with your publications code of conduct, I wish to declare an interest in the subject, in that I am the inventor of the Whiz CleanCatch used in the trials by Jackson *et al.* Other than this fact, no influence was or could have been brought to bear on the FOI or other information above.

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1 **Jackson SR, Dryden M, Gillett P, Kearney P, Weatherall R.** A novel midstream urine-collection device reduces contamination rates in urine cultures amongst women. *BJU Int* 2005; **96**: 360–64

2 **Cabedo García VR, Novoa Gómez C, Tirado Balaguer MD, Rodríguez Morquecho N, Rodríguez Bailo MT, Solá Sandtner A.** Is the technique used to collect urine important in avoiding contamination of samples? (Spanish). *Aten Primaria* 2004; **33**: 140–4