Initial experience of Extracorporeal shock wave lithotripsy with robotic navigation

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ABSTRACT

Aim: The main aim was to retrospectively assess the results of treatment of upper urinary tract stones with the Sonolith vision manufactured by EDAP.

Materials & Methods: In this study 200 patients who underwent extracorporeal shock wave lithotripsy (ESWL) alone as an initial treatment and could be followed up for at least 3 months were selected who underwent this therapy between January 2015-January 2016. Treatment effect was evaluated by kidney, ureter, and bladder X-ray or renal ultrasonography at 1 and 3 months after treatment. A stone-free status or status of stone fragmentation to 4 mm or smaller was considered to indicate effective treatment.

Results: At 3 months after treatment, the stone-free rate was 69% after single sitting while it was 85% after second sitting. Complications of this therapy included renal subcapsular hematoma and pyelonephritis in 2 and 1 case each respectively.

Conclusion: ESWL with the Sonolith vision manufactured by EDAP produced a treatment effect equivalent to those achieved with other models of ESWL equipment. ESWL seems to be an effective first-line treatment for patients who do not wish to undergo invasive procedure.

Keywords: Extracorporeal shock wave lithotripsy, robotic navigation, calculi

INTRODUCTION

Shock Wave lithotripsy (SWL) is a non invasive treatment of kidney stones using an acoustic pulse. It was first used by physicians from the university hospital Grobhadern (Munich, Germany) and technicians from Dornier System (Friedrichshafen, Germany) in 1980[1,2,3]. The device used is now displayed in the Deutsches Medizinhistorischen Museum in Ingolstadt.

The introduction of Shock Wave lithotripsy (SWL) has brought a paradigm shift in management of kidney stones. SWL as such is not the only instrument in treatment of kidney stones. Stone fragmentation rates depend upon many things such as ;type of lithotripsy system being used,stone density, stone location and bulk of the stone.The patient habitus , anatomy of the genitourinary tract and the most important aspect is the trained technician or urologist to focus the shock waves continuously on the stone[4,5].

The efficacy of ESWL lies in its ability to pulverize calculi in vivo into smaller fragments, which the body can then expulse spontaneously. Shockwaves are generated and then focused onto a point within the body. The shockwaves propagate through the body with negligible dissipation of energy (and therefore damage) owing to the minimal difference in density of the soft tissues. At the stone-fluid interface, the relatively large difference in density, coupled with the concentration of multiple shockwaves in a small area, produces a large dissipation of energy. Via various mechanisms, this energy is then able to overcome the tensile strength of the calculi, leading to fragmentation. Repetition of this process eventually leads to pulverization of the calculi into small fragments (ideally < 1 mm) that the body can pass spontaneously and painlessly[1,6,7,8].

When a shockwave is propagated through a medium (water), it loses very little energy until it crosses into a medium with a different density. If the medium is denser, compressive forces are produced on the new medium. Similarly, if the new medium is less dense, tensile stress is produced on the first medium. Upon hitting the anterior surface of a stone, the change in density creates compressive forces, causing fragmentation. As the wave proceeds through the stone to the posterior surface, the change from high to low density reflects part of the shockwave's energy, producing tensile forces, which again disrupt and fragment the stone[9].

In cavitation, shockwave energy applied at a focal point leads to failure of the liquid with generation of water-vapor bubbles. These gaseous bubbles collapse explosively, creating microjets, that fracture and erode the calculus. This process

can be monitored with real-time ultrasonography during the treatment and appears as swirling fragments and liquid in the focal zone.

Normally, 2000–4000 shock waves are used with a frequency of 60–120/min. Comparative studies found a higher efficacy of ESWL with a lower frequency of shock waves (60 vs. 120/min). This technology has made the Hippocratic oath of " I will never cut for a stone" a truth. This is an unparallel technology which is noninvasive with minimal need of anaesthetic agents and the procedure can be done on an outpatient basis. First therapy devices yielded excellent stone free rate upto 90% but subsequent second and third generation lithotriptors(The shock wave is generated by an electromagnetic coil, which moves a membrane An acoustic lens system reflects and focuses the shock wave)displayed inferior outcomes compared to the unmodified Dornier HM3(under water spark discharge reflcetd by an Ellipsoid-Electrohydroulic lithotripsy)[10,11,12].

MATERIALS & METHODS

In this study 200 patients who underwent ESWL alone as an initial treatment and could be followed up for at least 3 months were selected who underwent this therapy between January 2015-January 2016. The subjects included 136 male ,52 female aged from 17 to 86 years (mean: 50.5 years) and 12 children aged from 5 to 15 years . The stones were on the left side in 112 subjects and on the right side in 88. Treatment was performed during a hospital stay of three days and two nights, and the subjects were only fasted before operation. Preoperative medication included antibiotics ,antacid and analgesic. When subjects complained of severe pain during operation, Fentanyl (i.v.) was additionally administered. Renal stones were treated at a maximum energy level of 80%, while ureteral stones were treated at a level of 100%.

Both renal and ureteral stones were treated with up to 3000 shock waves. Treatment effect was evaluated by kidney, ureter, and bladder (KUB) X-ray or intravenous pyelography at 1 and 3 months after operation, and was classified as stone-free status (absence of residual stones), effective (presence of residual stones 4 mm or smaller), and inadequate (status other than the above). If stone fragmentation was found to be inadequate, a second ESWL session was performed after about 1 to 4 weeks. Subjects with an inadequate or no response (ineffective) to ESWL underwent Retrograde intrarenal surgery with flexible scope or percutaneous nephrolithotripsy (PNL). Subjects with urinary tract infection or with stones 10 mm or larger underwent placement of a double-J stent. During the procedure, subjects were placed in the ipsilateral supine position. Subjects with X-ray-negative stones underwent intravenous pyelography (IVP) and ureteral catheter insertion in combination with ESWL.

The patient lies on a water-filled cushion, and the surgeon uses X-rays or ultrasound tests to precisely locate the stone. The process approximately takes about an hour and patient may be administered sedatives. The urot holds the ureter open, this helps the small stone pieces to pass without blocking the ureter.

The short comings and contraindications of SWL are: it cannot be used on patients on anticoagulants or taking antiplatelet agents.It is strictly contraindicated in pregnant patients. It also should be avoided if the patient is harbouring active infection. It is also difficult to use in morbidily obese patient where focussing becomes difficult.Stones in mid or lower ureter also are not suitable for SWL.

We have acquired for the first time in India a very advanced SWL based on electroconductive technology with Robotic navigation system.It's a new Diatron V shockwave generator with exclusive and patented electrode encapsulated in a highly conductive solution (Electrolyte), the shockwave is generated at the same geometric point and at the same intensity from one firing to the next.

RESULTS

Of the 200 cases done at Yashoda Hospital Hyderabad, 62 cases underwent placement of a double J stent and 14 cases underwent IVP. When the stones were classified by location, pelvic renal stones were the most frequent (82 cases) among subjects with renal stones, while upper ureteral stones (35 cases) were the most frequent among subjects with ureteral stones. When the stones were classified by size, those 10 - 15.0 mm were the most frequent of renal stones, while those 4.1 - 10.0 mm were the most frequent of ureteral stones.

In our study patients were given maximum of two sessions that too with a gap period of one month between each session . Three months after operation, the stone-free rate was 69% after one session and 85 % after second session.The stone free rate in children after first session was 83.33%. When the treatment effect was analyzed by the location of stones, a stone-free rate of 84% were achieved in subjects with ureteral stones with one or two ESWL treatment sessions at three months after operation . Fourteen subjects with X-ray-negative stones underwent intravenous pyelography (IVP) and ureteral catheter insertion in combination with ESWL. These patients had a stone-free status with only ESWL therapy.

DISCUSSION

EDAP-TMS a NASDAQ -listed company headquartered in Lyon,France has been delivering technological breakthroughs since 1979 in the field of SWL.Since 1994 the company has focussed its efforts on perfecting the elcetroconductive technology , the latest and the most advanced shock wave

generator. It has patented its electroconductive technology and the exclusive automatic pressure regulator. The electroconductive technology is filled with a highly conductive solution that allows an extremely accurate spark position thanks to a better conduction of electricity and a shorter inter -electrode distance.This technology has been recognised as the system which brings highest levels of pressure.To prevent decline of pressure with age of the machine the company has integrated hydrophone into the shock wave source (pateneted automatic pressure regulator).

This exclusive system also monitors the total energy delivered to the patient.This exclusive system guarantees a consistent and perfectly controlled efficacy,shock after the shock ,patient after the patient ,month after the month and year after the year[13,14].

The key element of the EDAP TMS SONOLITH is the user interface.It can be operated through a single touch screen interface that combines thepatient database, treatment parameters and ultrasound display and the control [Figure 1].By simply locating the stone on the Xray and the ultrasound image with the tip of the finger , the whole system calculates the position of the stone and brings it automatically to the focus of the shock wave , ready for the treatment.

Figure 1

The Exclusive Automatic Pressure Regulatormeasures and adjusts in real time the pressure at the focal point. This system ensures consistency shock after shock so every patient benefits from the same treatment quality, month after month.

The physical features of the Electroconductive technology offer a great flexibility in the choice of therapeutic protocol are extensive settings range,variable energy density and variable focal volume.

The unique Electroconductive technology (ECL) is endowed with just the right combination of high pressure and focal size adaptability to pulverize stones into fragments small enough to be eliminated naturally [Figure 2]. The comparison of residual fragments after the in-vitro fragmentation of a phantom stone (left) using an electromagnetic shockwave generator (middle) and the ECL source provides clear evidence of finer fragmentation... achieved with fewer shocks.

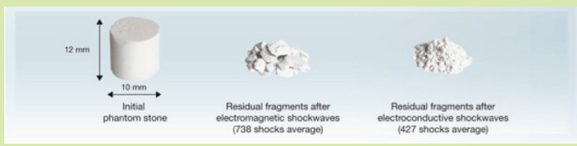

Figure 2

Figure 3

The focusing system is used to direct the generator-produced shockwaves at a focal volume in a synchronous fashion. The basic geometric principle used in most lithotriptors is that of an ellipse. Shockwaves are created at one focal point (F1) and converge at the second focal point (F2). The target zone, or blast path, is the 3-dimensional area at F2, where the shockwaves are concentrated and fragmentation occurs.The EDAP sonolith uses ellipsoidal reflector , specifically designed to harness benefits afforded by the Electroconductive technology benefits. The full power of the shock wave is transferred directly to the focal point F2 to guarantee superior fragmentation power and quality[15,16,17].

In this machine a small water-filled drum with a silicone membrane is used to provide air-free contact with the patient's skin [Figure 3]

It has a penetration depth of 180mm which adapts to patients' morphology and a wide diameter generator providing more comfort and easier pain management.This enhanced depth gives a lot of freedom to the treating urologist for treatment of stones in obese patients.

It has both fluoroscopy and ultrasonography techniques which are integrated and hence gives better localization and live visualization of stone fragmentation[17].

CONCLUSION

The EDAP TMS sonolith imove lithotriptor has given far superior results than the conventional lithotriptors being used in India now a days.This gives the treating urologists and patients a lot of respite by avoiding morbid interventional surgeries .The patient has a liberty to get treated on day care surgery and resume his work the very next day.In our practice SWL with EDAP TMS sonolith has unquestionably become the

first choice for renal calculi upto 2 cm of size with a normal anatomy of the urinary tract system.It has proved to be a revolutionary spark in the field of urolithiasis management.

REFERENCES

1. C. Chaussy, W. Brendel, E. Schmiedt. Extracorporeally induced destruction of kidney stones by shock waves. Lancet. 1980;2:1265-1268 .
2. G. Fuchs, K. Miller, J. Rassweiler, F. Eisenberger. Extracorporeal shock-wave lithotripsy: one-year experience with the Dornier lithotripter. Eur Urol. 1985;11:145-149.
3. J.J. Rassweiler, C. Renner, C. Chaussy, S. Thüroff. Treatment of renal stones by extracorporeal shock wave lithotripsy An update. Eur Urol. 2001;39:187-199.
4. J.J. Rassweiler, T. Bergsdorf, C. Bohris, et al. Consensus: shock wave technology and applica-tion—state of the art in 2010. C. Chaussy, G. Haupt, D. Jocham, K.U. Köhrmann (Eds.) Therapeutic energy applications in urology II: standards and recent developments (Thieme, Stuttgart, Germany, 2010) 37-52.
5. J.J. Rassweiler, G.G. Tailly, C. Chaussy. Progress in lithotriptor technology. EAU Update Series. 2005;3(1):17-36.
6. M. Lokhandwalla, B. Sturtevant. Fracture mechanics model of stone comminution in ESWL and implications for tissue damage. Phys Med Biol. 2000;45:1923-1940.
7. P. Zhong, X.F. Xi, S.L. Zhu, F.H. Cocks, G.M. Preminger. Recent developments in SWL physics research. J Endourol. 1999;13:611-617.
8. L.A. Crum. Cavitation microjets as a contributory mechanism for renal calculi disintegration in ESWL. J Urol. 1988;140:1587-1590.
9. O.A. Sapozhnikov, A.D. Maxwell, MacConaghy, M.R. Bailey. A mechanistic analysis of stone fracture in lithotripsy. J Acoust Soc. 2007;121:1190-1202.
10. W. Eisenmenger, X.X. Du, C. Tang, et al. The first clinical results of "wide focus and low-pressure" ESWL. Ultrasound Med Biol. 2002;28:769-774.
11. M. Lanski, N. Ulucan, L. Burnes, Lithoskop:. discover the future of urology today. C. Chaussy, G. Haupt, D. Jocham, K.U. Köhrmann (Eds.) Therapeutic energy applications in urology II: standards and recent developments (Thieme, Stuttgart, Germany, 2010) 71-77.
12. S. Hofsäß, M. Rheinwald, Dornier MedTech:. update on products for urology. C. Chaussy, G. Haupt, D. Jocham, K.U. Köhrmann (Eds.) Therapeutic energy applications in urology II: stand-ards and recent developments. (Thieme, Stuttgart, Germany, 2010) 57-69.
13. P. Partheymüller. Sonolith i-sys: the new standard in lithotripsy. C. Chaussy, G. Haupt, D. Jocham, K.U. Köhrmann (Eds.) Therapeutic energy applications in urology II: standards and re-cent developments (Thieme, Stuttgart, Germany, 2010) 65-70.
14. O. Wess. Storz Medical—shock wave technology for medival applications. C. Chaussy, G. Haupt, D. Jocham, K.U. Köhrmann (Eds.) Therapeutic energy applications in urology II: stand-ards and recent developments (Thieme, Stuttgart, Germany, 2010) 78-81.
15. M. De Sio, R. Autorino, G. Quarto, et al. A new transportable shock-wave lithotripsy machine for managing urinary stones: a single centre experience with a dual-focus lithotriptor. BJU Int. 2007;100:1137-1141.
16. S. Ginter, M. Burkhardt, P. Vallon. Richard Wolf: the piezoelectric ESWL—more than 20years of clinical success worldwide. C. Chaussy, G. Haupt, D. Jocham, K.U. Köhrmann (Eds.) Therapeutic energy applications in urology II: standards and recent developments (Thieme, Stuttgart, Germany, 2010) 87-92.
17. A. Hartung, W. Schwarze. LithoSpace by AST GmbH. C. Chaussy, G. Haupt, D. Jocham, K.U. Köhrmann (Eds.)Therapeutic energy applications in urology II: standards and recent develop-ments (Thieme, Stuttgart, Germany, 2010) 53-56.

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