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ORIGINAL ARTICLE

Stone-free rate Post Extracorporeal Shock Wave Lithotripsy (ESWL) in the management of Adult Renal Stones

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Background: Extracorporeal Shock Wave Lithotripsy (ESWL) has been, and still is, one of the main kidney stone treatments available at Mater Dei Hospital in Malta and worldwide. This audit is aimed at identifying stone free rates (SFR) and stone factors that influence treatment outcomes.

Methods: Retrospective data collection was conducted by collating stone density, size and type, skin to stone distance and stone free rates for all ESWL treatment sessions performed over a 14-year period between 2008 and 2022. Statistical analysis was performed to identify stone free rates after treatment and stone factors which were shown to be significant in influencing outcome.

Results: The overall SFR was calculated as 30.1% from the 719 ESWL sessions included in this audit. Stone density in Hounsfield Unit (HU) was significantly associated with stone free status after treatment (p=0.0001). Stone size was also associated with SFR (p=0.001). Skin to stone distance, presenting and stone position were not significantly related to SFR.

Conclusion: The overall SFR was found to be lower than that quoted in most studies, even when accounting for the strict definition of complete clearance of the treated stone used. This audit should hopefully lead to development of treatment protocols in terms of multiple sessions and power ramping, as well as stricter follow-up and continuous re-audit to improve future outcomes.

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The incidence and prevalence of nephrolithiasis is increasing steadily, especially in affluent countries.[1] This is probably attributed to the 'Western way of living' and the rising rates of metabolic syndrome, diabetes and obesity. Kidney stone disease (KSD) poses a significant burden on healthcare system resources – in 2000, it is estimated to have cost around $2 billion in the US and is increasing by $1.24 billion per year till 2030.

Treatment of nephrolithiasis involves both the medical and the surgical aspects, though more importance is probably attributed to surgery rather than medical management.[2] To this time, surgery for KSD involves three main options – extracorporeal shockwave lithotripsy (ESWL), ureteroscopy (URS) and laser lithotripsy or percutaneous nephrolithotripsy (PCNL). ESWL is the earliest and least invasive mode of treatment[3] and is still recommended as first or second line treatment for diverse stones in international guidelines.[4]

The primary aim of this audit is to assess stone free rates (SFR) after ESWL treatment offered by the Urology Unit at Mater Dei Hospital in Malta. Stone free was defined as complete clearance of the treated stone as determined by either ultrasound (USS) or Computed Tomography (CT) scan performed a few weeks after the procedure.

Secondary outcomes measured were the SFRs related to stone density, position, size (in longest diameter only), skin to stone distance and in patients with stented ureters.

METHOD

Data was collected retrospectively in November 2023 after the relevant Data Protection clearances were obtained as per GDPR criteria.

All ESWL treatment sessions performed between September 2008 and February 2022 were identified and data pertaining to the stone and patient treated obtained from the hospital online systems – iSOFT Clinical Manager (ICM) and PACS. Data was anonymized throughout. ESWL treatment was performed using a Dornier lithotripter S II with ultrasound localization and a standard protocol throughout.

Stones treated were classified by size, position and density (where CT was available) according to imaging investigations done prior to the procedure. Stone size was measured in mm and grouped into 0-5mm, 6-10mm, 11-15mm, 16-20mm, 21-25mm and 26-30mm in the longest measured diameter. Stone density was measured in Hounsfield Units (HU) where CT scan was available and grouped as <500, 500-1000 and >1000. Stone position was classified into upper, middle or lower calyx, renal pelvis or pelvi-ureteric junction (PUJ). Skin to stone distance was measured in mm where CT was available. Those patients who had an indwelling stent during their ESWL procedure were also identified.

Stone free status was defined as complete clearance of the treated stone, as determined by USS or CT done within 3 months of the ESWL procedure. Patients who did not have follow-up investigations or an incomplete operation note, were excluded from this audit. Where available, stone composition was also recorded. SFRs in relation to the secondary outcomes were analysed using the Chi-squared test for categorical variables and the Mann-Whitney U test for continuous variables; a p-value of <0.05 was considered as statistically significant.

RESULTS

A total of 778 patients underwent ESWL at MDH during the audit period; 59 were excluded as per pre-defined criteria, leaving 719 patients in the final sample analyzed. Of those not eligible for inclusion in this audit, 48 were lost to follow up or had no follow-up imaging investigations, while the rest did not have a complete operation note. 70% of the treated cohort were male patients.

The most common diagnostic imaging modality used to book patients for ESWL treatment was a non-contrast CT KUB (55%), followed by USS (26.8%) (Figure 1).

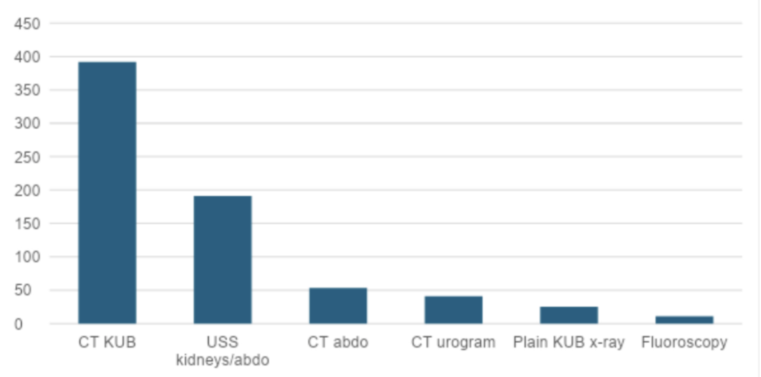

Figure 1 *Diagnostic Imaging Modalities used*

Diagnostic Imaging Modalities used

The overall SFR as defined for the scope of this audit was 30.1% on first follow-up. The majority of these patients were given only one treatment session per stone.

Subgroup analysis according to secondary objectives was performed. Information regarding indwelling stenting was only available for 497 patients (69.1%) from the audited cohort; of these, only 24 (4.82%) had an indwelling stent during their ESWL session. SFRs for pre-stented patients were worse at 20.8% but this was not found to be statistically significant (p=0.279).

The majority (37.9%) of treated stones were located in the lower calyces of the kidneys. SFRs for different locations of stones were not deemed to be statistically significant (p=0.259) (Figure 2).

The majority (57.7%) of stones treated were between 6 and 10mm in their longest diameter. On univariate analysis, stone size was found to be statistically significant, p=0.001. Stone density could be calculated in 70.2% of cases; 46.1% of these were very dense stones with HUs >1000 (Figure 3). Stone density was strongly significant with regards to SFR (p=0.0001), with harder stones having significantly less SFRs than those which were less dense. The average skin-to-stone distance (SSD) measured was 94.4mm. The variation in SSD was not found to be statistically significant for SFRs (p=0.245).

Stone analysis was performed where stone fragments were available. A total of 181 stones were sent for analysis, with the commonest stone type detected being calcium oxalate (60%) (Figure 4). SFRs with respect to stone type were not calculated in view of the small numbers available for most stones.

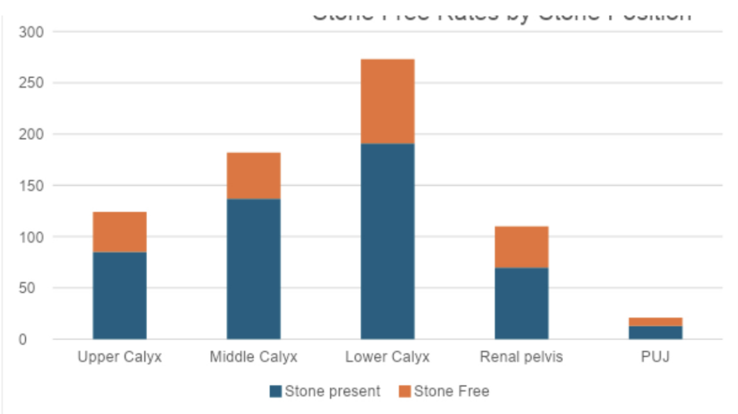

Figure 2 *SFRs according to treated stone position*

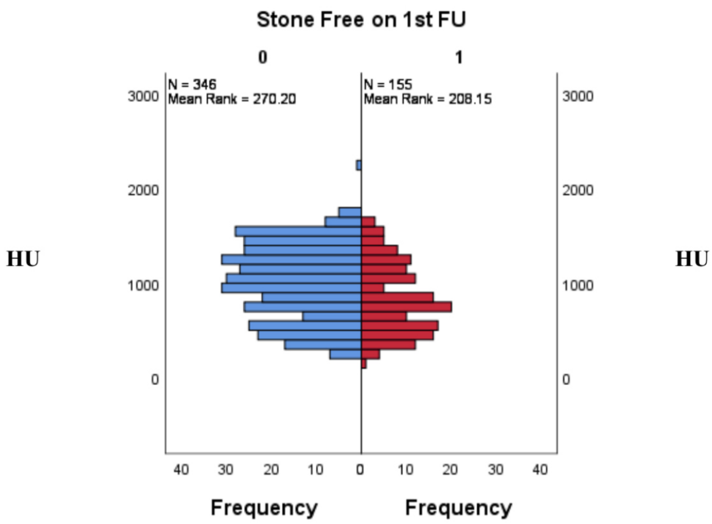

Figure 3 *Stone-Free Rate in relation to calculated Hounsfield Unit*

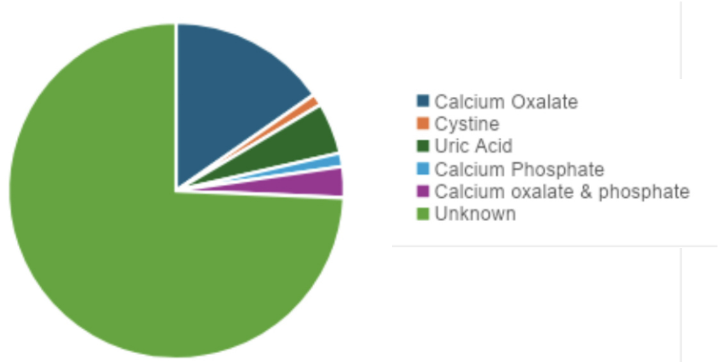

Figure 4 *Stone types identified following stone analysis. Stones that were not examined were labeled as "unknown"*

DISCUSSION

Since its introduction in the 1980s, ESWL remains in widespread use by Urology Departments worldwide.[5] Its use is recommended as first line treatment for certain kidney and ureteric stones by several international guidelines.[6] ESWL is often considered to be the safest stone treatment available, with complication rates being lower than those observed after ureteroscopic (URS/RIRS), percutaneous (PCNL), laparoscopic or open surgery.[7] The downside to ESWL is that SFRs are often lower when compared to those obtained after PCNL or RIRS.

SFRs quoted in the literature vary significantly, often depending on the criteria used by the specific centre when referring patients for ESWL treatment (stone and patient characteristics), operator experience and number of treatment sessions given per stone. Quoted

SFRs are as variable as 86.7% (with over 53% having repeat sessions)[8] to 46% after one session only.[9]

Several factors have been shown to have a significant effect on ESWL outcome in terms of SFRs. Lower pole stones are notorious for having significantly poorer outcomes compared to other positions in the kidney (47% vs 68-70.5% SFRs).[10] Stone size has also been shown to influence outcomes; smaller stones have a significantly higher chance of being cleared completely, even when they have a high density of >1000HUs.[11] High stone density and longer skin to stone distance have also been shown to decrease SFRs after ESWL though results were not consistent across all studies performed.[12,13]

Several nomograms have been developed to try and predict success of ESWL depending on stone characteristics. One of the most commonly used nomograms is the Triple-D score, which uses stone density (>600HU), skin to stone distance (>12cm) and stone volume (>150mm^3) to predict chances of complete stone clearance after one session of ESWL. This was recently updated to a Quadruple-D score with the addition of stone position (lower pole).[14]

Besides patient and stone characteristics, centre experience with ESWL and operator skill with targeting have been shown to significantly affect outcomes after treatment.[15] Centres who have dedicated personnel performing a high number of ESWL sessions are expected to have higher SFRs, mainly because of better targeting of shockwaves onto stones.

Another factor which affects quoted SFRs depends on the definition of "stone-free" status used by the respective studies. Studies quoting complete "stone-free" rates will likely show a poorer outcome compared to those quoting "clinically insignificant" stone fragments (smaller than 5mm).[16] Clinically insignificant stone fragments are usually considered as being residual stones smaller than 5mm in their longest diameter after treatment. Whether this is sufficient to consider the treatment as being successful is controversial – even small stone fragments have been shown to be a nidus for potential future stone formation, needing more treatment eventually. Nowadays, a stricter definition of stone free status is often used and defined as no stones seen on cross-sectional imaging.[17]

CONCLUSION

Our audit serves as an assessment of our ESWL outcomes compared to internationally quoted SFRs. In fact our SFR is lower than those quoted in many studies (30.1%), though this could be attributed in part to the fact that a very strict definition of SFR was taken.

Looking at our secondary objectives, only stone density and stone size were significantly associated with a stone free status after treatment. Unfortunately a significant proportion of patients did not have cross-sectional imaging with CT scan prior to their ESWL treatment as recommended by EAU guidelines.[18] This means that we could not measure stone size accurately in a reproducible manner or calculate stone volume. Stone density and skin to stone distance also could not be measured in those patients having no CT scan.

Another limitation of our audit is inconsistent follow-up with imaging being done at variable time frames and using different types (USS vs CT vs KUB).

We recommend that this audit leads to better patient investigation and selection prior to ESWL treatment. Due consideration should be given to having multiple treatment sessions to the same stone over a few weeks to maximise stone fragmentation. Stricter follow-up and regular re-audit could highlight areas where the ESWL service can be improved to obtain better SFRs.

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