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Quantitative factors of unenhanced CT for predicting fragmenting efficacy of extracorporeal shock wave lithotripsy on pancreatic duct stones

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AIM: To find potential predictors at unenhanced computed tomography (CT) to evaluate the stone clearance rate (SCR) of pancreatic duct stones (PDS) by extracorporeal shock wave lithotripsy (ESWL).

MATERIALS AND METHODS: A total of 106 consecutive patients with multiple stones of maximal transverse length (MTL) 0.3–3.6 cm in pancreatic head region were enrolled. Unenhanced CT was performed both before and after ESWL therapy. All patients underwent ESWL therapy using an electromagnetic lithotripter, and were divided into three groups with threshold values of >90%, 50–90% and <50% of SCR. Factors including sex, age, MTL, mean stone density (MSD), standard deviation of stone density (SDSD), variation coefficient of stone density (VCSD), attenuation density (AD), pancreatic duct diameter (PDD), skin-to-stone distance (SSD), and number of ESWL sessions were analysed, and their impact on SCR was evaluated by univariate and multivariate analyses. The diagnostic threshold of the independent predicting index was further calculated, and its relationship with SCR and ESWL was analysed by drawing a trend line.

RESULTS: The only significant predictor of SCR by ESWL was MSD ($p<0.05$). More courses of ESWL therapy are required in PDS patients with an MSD higher than the cut-off value of 375.4 HU (mean, 2.6 versus 1.8), but with a relatively lower SCR (mean, 43.96 versus 88.68%) .

CONCLUSION: MSD on pre-treatment unenhanced CT is an independent predictor for SCR of PDS patients treated with ESWL. Using a cut-off value of 375.4 HU, patients with low MSD are good candidates for ESWL therapy.

Introduction

Chronic pancreatitis is a progressive inflammatory condition with a multifactorial aetiology, and is characterised by constant impairment of pancreatic structure and function, and manifested as continuous or intermittent abdominal

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pain. Pancreatic ductal stones (PDS) are one of its main complications, and are correlated to increased calcium deposition in the pancreatic juice that results from pancreatic duct obstruction, or with insufficient pancreatic stone protein and redundant lactoferrin secretion.[1,2] The formation of PDS can exacerbate ductal hypertension and dysfunctional endocrine or exocrine secretion by occluding pancreatic ducts or damaging pancreatic tissue, thus worsening the patients' condition.

As the formation and development of PDS is both the cause and effect of chronic pancreatitis, PDS removal is critical for patients with chronic pancreatitis. Traditional surgical drainage cannot avoid damage to normal tissue and function, and is accompanied with a high complication rate of 30% and mortality rate of 2%[3] In the past decades, the European Society of Gastrointestinal Endoscopy (ESGE) has recommended extracorporeal shock wave lithotripsy (ESWL) combined with endoscopy as the first-line therapeutic regimen. For example, a long-term follow-up study by Hu *et al.*[4] indicated that ESWL and endoscopic retrograde cholangiopancreatography (ERCP) could effectively relieve PDS-related pain. Recently, more studies have shown that ESWL alone can work as an optimal treatment option for patient with chronic pancreatitis, offering advantages of high efficacy with stone-free rate ranging from 46% to 91%, safety with little complications, non-invasiveness, etc.[5,6]

Calcium carbonate is a common constituent of PDS, making the stones easily detectable in non-contrast computed tomography (CT). Several studies have used various CT quantitative parameters (location,[7] size,[8] density,[9] composition,[10] body fat,[11] severity of obstruction or infection,[12] etc.) to predict ESWL efficacy for urinary stones; however, similar reports on the utility of unenhanced CT for PDS are rare. This retrospective study analysed comprehensive stone parameters with unenhanced CT, with the aim of identifying potential predictors for ESWL necessity and success rate, thus facilitating the options for appropriate treatment strategy, referring the patient for ESWL, and minimising unnecessary patient pain and additional medical costs.

Materials and methods

Patient population

This study was approved by the institutional review board. A total of 106 patients with PDS who underwent ESWL therapy between Oct 2014 and Oct 2016 were enrolled. Each patient had multiple stones in the head region of pancreas, with stone size ranging from 3.1 to 36 mm. All patients suffered from the typical abdominal pain caused by pancreatitis, and received a pretreatment unenhanced CT examination. This retrospective study was approved by the institutional review board, and written informed consent was obtained from patients before ESWL therapy. Patients with stones <3 mm, a history of pancreatic surgery, or without ascertained treatment outcomes were excluded from this study.

ESWL

ESWL therapy was performed by two gastroenterologists using a third-generation electromagnetic lithotripter (Compact Delta II; Dornier Med Tech, Wessling, Germany), and the bi-dimensional fluoroscopic capability was applied to localise and target PDS. Prior to ESWL, all patients received intravenous anaesthesia (flurbiprofen and remifentanil) to alleviate pain, and stayed in supine position with the hock head touching the abdomen. The intensity of the shock wave was 6 (16,000 kV) on a scale of 1–6 with a frequency of 100 shocks/min. The lasting time of each ESWL session ranged from 60 to 90 minutes with a maximum of 5,000 shocks per sitting. Repeated ESWL on successive days were not terminated either until the PDS were broken down into fragments <3 mm, or any concomitant symptoms occurred.

Stone characteristics on unenhanced CT

Unenhanced CT was performed using a 320-detector CT system (Brilliance 320; Toshiba, Japan) with regular precalibration by air and a water phantom for reliable measurements. Each patient received strict and normative breath-holding training before examination and was instructed to stay in a supine position during scanning. CT imaging parameters were as follows: 120 kV tube voltage, 500 mA tube current, 200×200 cm field of view (FOV), 128×0.625 mm collimation, 0.5 second gantry rotation time, 0.915 beam pitch. Both section thickness and reconstruction interval were set at 1 mm, and all images were reconstructed using a standard algorithm. The scanning range was from the superior border of the liver to the anterior superior iliac spine.

Raw DICOM images of 1 mm thickness were transferred to the workstation of Philips Intellispace portal v6.0.4 (Nederland), and analysed based on a bone window protocol. The software can automatically recognise all PDS accurately and efficiently, then calculate and output stone parameters including volume before (V_0) and after ESWL (V_1). Subsequently, the biggest stone was located and measured using electronic callipers on the workstation to obtain the maximum transverse length (MTL) value. Three regions of interest (ROIs) smaller than one-third of the slice area was drawn manually, and after obtaining the mean stone density (MSD) and standard deviation of stone density (SDSD) values of each ROI, the average value of three ROIs were calculated to represent the density level of the biggest stone (Fig 1). The pancreatic duct diameter (PDD) was measured at the dilated position of the obstructed pancreatic duct just distal to the head of pancreas. As described by Pareek *et al.*,[13] the skin-to-stone distance (SSD) was the average of mean vertical distance from the centre of the biggest stone to skin surface at 0°, 45°, and −45° (Fig 2). The final stone clearance rate (SCR) was calculated by the formula:

$$SCR=\{[(V_0)-(V_1)]/(V_0)\}\times 100\ (\%)$$

The variation coefficient of stone density (VCSD) was calculated by dividing the SDSD by the MSD. According to

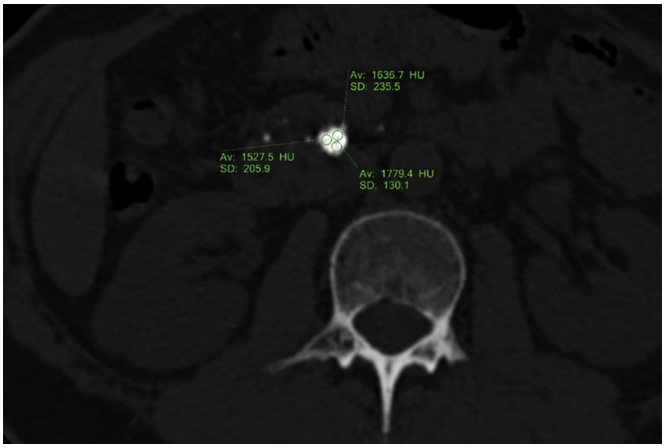

Figure 1 Software for measuring CT stone attenuation value. The biggest stone was selected on the section with maximal MTL. Three consistent (perimeter 8.01 mm), non-overlapping ROI were drawn, and the measured attenuation values were 1,714.6±234.9, 1,633.8±324, and 1,903.7±79.2. By calculating the average value, MSD (1,750.7 HU) and SDSD1 (212.7HU) values were obtained.

Motley *et al.*,[14] attenuation density (AD; density of Hounsfield units) was obtained by calculating the ratio of MSD and MTL.

Statistical analysis

SPSS statistics software (version 21.0, Chicago, IL, USA) was used for data analyses. Basic patient data were presented as mean (±SD) or frequency (percentage). Predictive factors for SCR by ESWL were determined by univariate analysis and multivariate analysis in a logistic regression algorithm. Regression coefficient (B), standard error (SE), odds ratios (OR), 95% confidence intervals (95% CI), and *p*-value were closely observed. Percentiles of the predictor at 25%, 50%, and 75% were calculated to compare the value of SCR and number of ESWL sessions among stones with different MSD. Finally, X-tile (version 3.6.1) software was utilised to determine the cut-off value of MSD for diagnosing the SCR of PDS patients, and a trend line was drawn to describing the varying trend of MSD with number of ESWL sessions.

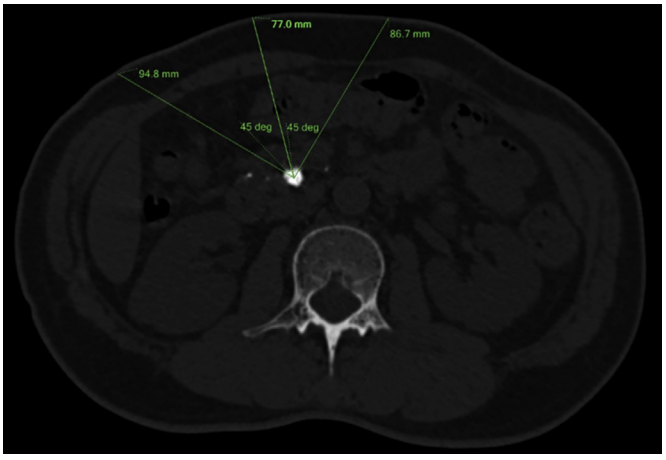

Figure 2 Axial unenhanced CT image (bone window) showed the SSD value at 0°, 45°, and −45° were 95.1, 74.5, and 105.3 mm, respectively. The average value of SSD was 91.6 mm.

Results

Patients and ESWL outcome

One hundred and six patients (71 men and 35 women; mean age 45.2±13.3 years; range 12–75 years) were enrolled in the study. The primary average V_0 was 5647.8 mm^3. All patients were given ESWL therapy for a total of 263 sessions, with an average of 2.5±1.3 sessions per patient (range 1–8). The postoperative V_1 value was 1,918.8±2,944 mm^3. The average final computed SCR value was 65±25.9%. Other baseline characteristics and imaging findings are summarised in Table 1.

Logistic regression for predicting factors

All patients received ESWL treatment several times until the stone was fragmented to ≤3 mm (Fig 3). To find the significant predictors for SCR by ESWL, all patients were divided into three groups based on their SCR values: >90% (n=31; mean 31.3%), 50–90% (n=51; mean 71.6%), and <50% (n=24; mean 94.5%). Univariate and multivariate analyses revealed that MSD was the only independent predictor of ESWL fragment efficacy. Other factors showed no significant association as shown in Table 2.

Relationship of MSD with SCR and number of ESWL sessions

The above result demonstrated that MSD is the independent predictor for SCR, and this trend was explored further to obtain a threshold for SCR and the number of ESWL sessions. As shown in Table 3, stones with a higher MSD value tended to need more courses of ESWL and

Table 1
Baseline patient characteristics and imaging findings (n=106).

Variable	Value (mean ± SD)
Patient Characteristics	
Sex, *n* (%)	
Male	54 (51)
Female	52 (49)
Age, years	45.2±13.3
Imaging findings	
Maximal transverse length, mm	10.1±5.2
Mean value of stone density, HU	611.2±200.7
Standard deviation of stone density, HU	431.5±139.4
Variation coefficient of stone density, %	0.7±0.1
Attenuation density, HU/mm	71.2±31.9
Pancreatic duct diameter, mm	9±4.1
Stone volume before surgery (V_0), mm^3	5,647.8±6,487
Stone volume after surgery (V_1), mm^3	1,918.8±2,944
Skin-to-stone distance, mm	92.6±17.4
No. of ESWL sessions	2.5±1.3

Data are mean ± standard deviation or frequency (percentage).
ESWL, extracorporeal shock wave lithotripsy.

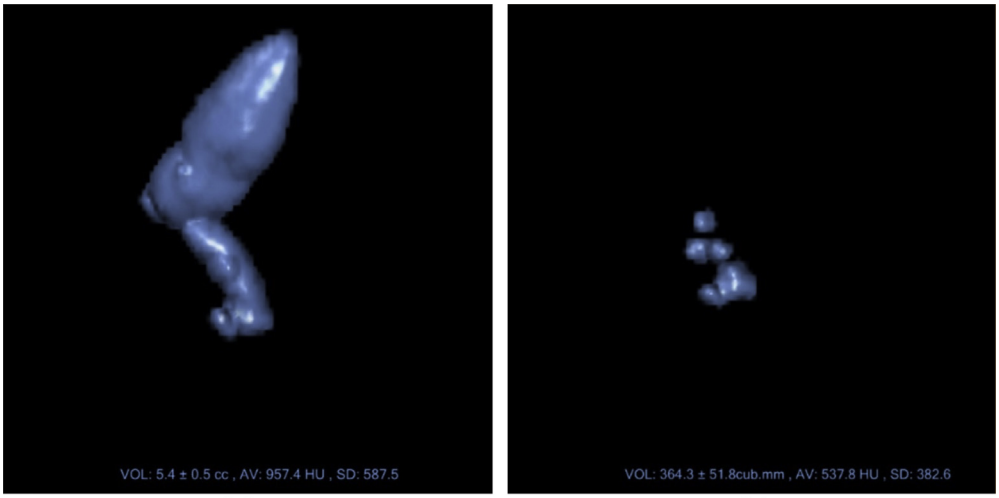

Figure 3 A 52-year-old woman with PDS (MTL: 15 mm) underwent three sessions of ESWL therapy. The 1 mm thickness unenhanced CT images were analysed using Philips Intellispace portal software before (a) and after (b) ESWL therapy. Preoperative stone parameters were: 112.4 mm SSD, 954.4 HU MSD, 588.5 HU SDSD, 0.62 VCSD, 63.6 HU/mm AD, and 13.1 mm PDD. After three sessions, the mean stone volume was reduced from 5,400 mm^3–334 mm^3, and the SCR increased to 94.15%. The patient's primary abdominal pain was greatly relieved, and her mental state and quality of life improved.

relatively lower SCR. In Fig 4, the calculated cut-off value of MSD was found to be 375.4 HU, and 12 (11.32%) of 106 patients with stone MSD >375.4 HU had an average SCR of 43.96% (range, 7.75–81.99%); and 88.68% patients with MSD <375.4 HU revealed an average SCR up to 67.71% (range, 0.32–100%). Fig. 5 illustrated the trend of stone MSD with number of ESWL sessions.

Discussion

Chronic pancreatitis is a progressive and irreversible fibro-inflammatory disease, with nearly 50% cases presenting PDS,[15] which can lead to upstream hypertension, increased parenchymal pressure and even ischaemia. Currently, treatments for PDS include surgery, endoscopic therapy, and ESWL, of which ESWL has gained more attention by clinicians for its higher efficiency, safety, and non-invasiveness; however, failed ESWL therapy can also cause unnecessary exposure of the pancreatic parenchyma to shock waves, thereby increasing pain and medical costs. Therefore, it is vital to judge the necessity and efficacy of ESWL before performing the procedure. In the past decades, many studies have tried to find a relationship between the radiographic characteristics of the stones and ESWL outcome, and unenhanced CT has proven to be the most sensitive and accurate imaging technique in diagnosing urinary stones.[16] To the authors' knowledge, however, relevant studies on PDS are rare and incomplete. The aim of this study, therefore, was to carry out a comprehensive analysis of the unenhanced CT features of PDS to find potential predictors of ESWL efficacy.

Previous studies[17,18] had extensively adopted the mean value of CT attenuation (or MSD), which can reflect average stone hardness, as the most representative and valuable factor for predicting ESWL efficiency. For example, Wang

Table 2
Univariate and multivariate analyses of the association of patient characteristics and imaging features parameters with SCR.

	Univariate analysis					Multivariate analysis				
	B	SE	OR	95% CI	*p*- Value[a]	B	SE	OR	95% CI	*p*- Value[a]
Age (years)	−0.028	0.017	0.972	0.940–1.005	0.098					
Male	0.966	0.513	2.627	0.962–7.176	0.060					
No. of ESWL sessions	0.192	0.175	1.212	0.860–1.707	0.272					
MTL (mm)	0.097	0.051	1.101	0.996–1.218	0.059					
SSD (mm)	0.000	0.011	1.000	0.979–1.022	0.972					
MSD (HU)	0.002	0.001	1.002	1.000–1.005	0.045	0.016	0.008	3.985	0–0.032	0.046
SDSD (HU)	0.002	0.002	1.002	0.999–1.005	0.273					
VCSD (%)	−4.543	2.429	0.011	0.000–1.244	0.061					
AD (HU/mm)	−0.007	0.007	0.993	0.980–1.006	0.283					
PDD (mm)	0.087	0.055	1.091	0.980–1.215	0.112					

B, regression coefficient; SE, standard error; OR, odds ratio; CI, confidence interval; ESWL, extracorporeal shock wave lithotripsy.
MSD, mean stone density; SDSD, standard deviation of stone density, VCSD, variation coefficient of stone density; AD, attenuation density, PDD, pancreatic duct diameter; SSD, skin-to-stone distance.
[a] Logistic regression analysis. P<0.05 was considered to be significant.

Table 3
SCR and number of sessions of extracorporeal shock wave lithotripsy (ESWL) for stones with different CT attenuation.

MSD (HU)	SCR (%)	No. of ESWL
~437.1 (27)	7.8–98.1 (51.8)	1–5 (1.7)
437.1–588	16.7–98 (72.1)	1–5 (2.3)
588.1–778	18.7–100 (68.4)	1–8 (2.6)
778~	0.3–99.4 (66.3)	1–6 (3.3)

MSD, mean stone density; SCR, stone clearance rate.

et al.[19] found that stones with densities >900 HU had a greater possibility of ESWL failure. Subsequent studies speculated that stone heterogeneity may also be a predictor for ESWL success. In a retrospective study by Lee *et al.*,[20] SDSD, considered to represent stone fragility, was shown to be an independent predictor of ESWL outcome in patients with ureteral calculi. A recent study[21] proposed VCSD, a novel parameter speculated to indicate heterogeneity and dispersion of stone densities, with a stronger predictive power on ESWL outcome compared to the other indices. In present study, MSD was found to be an independent indicator for predicting ESWL outcome, and patients with an MSD value <375.4 HU tended to have better SCR, which provide accurate guidance in the preoperative assessment of PDS patients. It was speculated that the mechanism is related to stone composition, i.e., stones with a higher MSD value may contain a higher proportion of more high-density compounds such as $CaCO_3$, which can increase stone hardness and decrease ESWL efficacy. Future studies will be undertaken to correlate stone composition with MSD to further determine the effect of chemical composition on MSD values; however, in contrast to studies on kidney stones, no predictive values of SSD, SDSD, and VCSD on ESWL outcome were found. This may be partly due to the limited number of patients, or the methods used for measuring multiple PDS. To measure stone CT attenuation, the biggest stone was selected manually and measured, which may be the main cause of the clinical symptoms, or

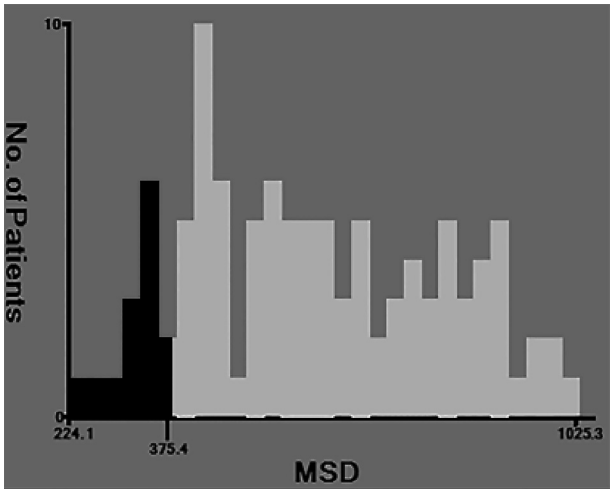

Figure 4 Cut-off value of stone MSD for diagnosing SCR of PDS patients.

may influence ESWL efficacy and outcome. Although this may be a sub-optimal method for patients with more than one large stone, measurement error caused by personal subjectivity or stone shape was minimised as much as possible by taking the average of multiple ROIs in a maximal transverse section.

In previous studies on kidney stones, stone composition was shown to be an important predictor of its susceptibility to ESWL,[10] and Youssefzadeh & Lumerman[22] found that urinary stone composition was correlated with its attenuation value at unenhanced CT. Motley *et al.*[14] first defined Hounsfield unit density (AD) as the quotient of HU/MTL to delete the confounding bias caused by stone size and attenuation (in Hounsfield units), and proved that it could better characterise the differences in radiodensities in urinary stones, and distinguish calcium from uric acid stones. Furthermore, Shahnani *et al.*[23] demonstrated the relationship between kidney stone composition and AD ($p<0.0001$), which was more significant than with attenuation ($p=0.001$) or size ($p=0.001$); however, a predictive role of AD was not found in PDS fragmenting efficacy, which may be related with the histopathology of the pancreas itself or may be influenced by the measurement techniques or sample size. The stone size is another common indicator in primary studies, and expressed by MTL. Stones with an MTL of >5 mm were not amenable to routine endoscopic retrograde cholangiopancreatography ERCP therapy, and stones of 1 cm in size were indicated for ESWL. According to a previous study,[24] the efficacy of ESWL varied according to stone size. In the present study, the MTL of the biggest stone was measured, but the second largest stone may decrease the average disintegrating efficacy and may have contributed to the negative statistical result.

The stenosis and obstruction of pancreatic duct is one of the contributing factors of PDS formation. PDD, a parameter reflecting stenosis degree of pancreatic duct, can indirectly reflect the extent of stone fragmentation and therefore ESWL efficacy; however, the present study failed to support this hypothesis, and this may be due to the examination technology or measuring method to some extent. The impact of SSD on SWL outcome was also disputable,[25,26] and can be affected by fat percentage or distribution of the patient,[21] and no correlation was found between SSD and the outcome indexes in this study. Furthermore, the number of ESWL sessions were not correlated with SCR, negating the granted notion that more ESWL sessions could generate better outcomes and emphasising the importance of a rational therapeutic programme to avoid unnecessary or excessive treatment.

There are limitations of the present study. Although unenhanced CT is the most routine pre-treatment examination method for PDS patients, the accuracy for differentiating PDS based on pancreatic duct dilatation still remains disputable, especially for those accompanied by calcification in pancreatic parenchyma. Moreover, the accuracy of PDD measurement was also declined for the limited resolution. Alternatively, magnetic resonance cholangiopancreatography (MRCP), which is more sensitive than CT and less invasive than ERCP, should be a further consideration in

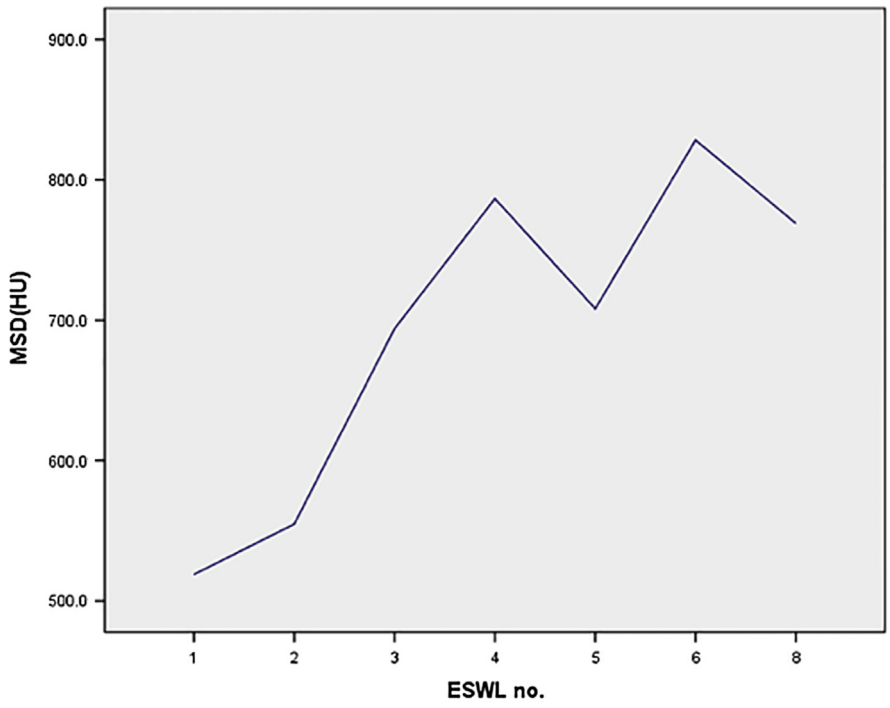

Figure 5 Line graphs for stone MSD and number of ESWL sessions.

future research. Most of the indexes analysed were based on stone density, and a few previous reports[27,28] had found that determining the composition of the calculi using dual-energy CT may be more sensitive in the preoperative estimation of optimal treatment. This will be investigated in future studies.

Based on this prospective study, MSD determination using pre-treatment unenhanced CT is a significant predictor for accessing the clearance rate of PDS by ESWL. Patients with MSD <375.4 HU should be considered for preoperative ESWL before receiving ERCP for better prognosis outcome, whereas patients with an MSD >375.4 HU should undergo alternative therapies to avoid unessential medical treatment and patient suffering .

Conflict of interest

The authors declare no conflict of interest.

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