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RESEARCH

A proposed mathematical model to help preoperative planning between RIRS and MiniPerc for renal stones between 10 and 20 mm using holmium:Yag laser (Cyber Ho): the stone management according to size-hardness (SMASH) score

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Abstract

To evaluate the performance of a mathematical model to drive preoperative planning between RIRS and MiniPerc (MP) for the treatment of renal stones between 10 and 20 mm. Patients with a renal stone between 10 and 20 mm were enrolled. A mathematical model named Stone Management According to Size-Hardness (SMASH) score was calculated: hounsfield units (HU) χ stone maximum size (cm)/100. Patients were divided into 4 groups: RIRS with score < 15 (Group A), RIRS with score ≥ 15 (Group B), MP with score < 15 (Group C), MP with score ≥ 15 (Group D). Cyber Ho device was always used. Stone free rate (SFR) was assessed after 3 months. Complication rate and need for auxiliary procedures were evaluated. Between January 2019 and December 2021, 350 patients were enrolled (87, 88, 82 and 93 in Groups A, B, C and D). Mean stone size was 13.1 vs 13.3 mm in Group A vs B ($p = 0.18$) and 16.2 vs 18.1 mm in Group C vs D ($p = 0.12$). SFR was 82%, 61%, 75% and 85% for Groups A, B, C and D. SFR was comparable between Groups C and D ($p = 0.32$) and Groups A and C ($p = 0.22$). SFR was significantly higher in Group A over B ($p = 0.03$) and in Group D over B ($p = 0.02$). Complication rate was 2.2%, 3.4%, 12.1%, 12.9% for Groups A, B, C, D. RIRS and MP are both safe and effective. The mathematical model with the proposed cut-off allowed a proper allocation of patients between endoscopic and percutaneous approaches. *Registration number of the study* ISRCTN55546280.

Keywords Holmium · YAG laser · Hounsfield units · MiniPerc · RIRS · Score

Introduction

Advancement of technology has improved the management of kidney stones. New laser devices and flexible ureteroscopes with smaller calibre and better vision have made endoscopy a reliable treatment for stones even > 20 mm [1]. However, miniaturisation of instruments has reduced the invasiveness of percutaneous nephrolithotripsy (PCNL), making it a reasonable alternative for stones < 20 mm [2]. Maximum diameter and location within the intrarenal

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collecting system are the main factors considered when planning treatment of a renal stone. Hounsfield units (HUs) measurement, which is an expression of stone hardness, is often overlooked. Stone hardness is a negative predictor for stone-free rate (SFR) after shock-wave lithotripsy (SWL) [3]. Similarly, studies showed a higher SFR when dusting low-HUs stones [4, 5].

Scoring systems have been developed to predict SFR of Retrogreade IntraRenal Surgery (RIRS)/ureteroscopy and PCNL, including the STONE nephrolithometry score [6, 7], the CROES nephrolithometric nomogram [8], the SReSC score [9], the T.O.HO score [10], the RUUS score [11] and the R.I.R.S. scoring system [12]. Thomas et al. described the Guy's Stone Score to stratify the complexity of the renal stone [13]. These scoring systems have been validated for both endoscopic and percutaneous approaches and correlated with SFR and complications [7, 14, 15].

However, currently there is no agreement on the ideal predictive model and despite the number of available nomograms, they are still deeply underused. Comparisons didn't show a significant superiority of one score over the others [16]. Karsiyakali et al. stated that nomograms were not superior to stone burden alone in predicting surgical success [17]. Consequently, we performed a prospective comparison between RIRS and MiniPerc to evaluate the performance of a new, easily applicable mathematical model named Stone Management According to Size-Hardness (SMASH) score to drive preoperative planning in the treatment of renal stones between 10 and 20 mm with the use of the same laser device.

Material and methods

Between January 2019 and December 2021, patients with a renal stone between 10 and 20 mm were randomly assigned to RIRS versus MiniPerc. A computed tomography (CT) scan was performed to assess side, location, number, size and hardness of the stone (mean HUs value). Exclusion criteria were age < 18 or > 75, coagulation impairments, anticoagulant therapy, multiple or bilateral stones, ureteral stones or strictures, previous placement of ureteral stent or nephrostomy tube. Patients with emergency criteria for immediate urinary drainage were excluded. For each patient a mathematical model named Stone Management According to Size-Hardness (SMASH) score was so calculated: hounsfield units x stone maximum size (cm)/100. Subsequently, patients were divided into 4 groups: RIRS with score < 15 (Group A), RIRS with score ≥ 15 (Group B), MP with score < 15 (Group C), MP with score ≥ 15 (Group D).

The 150 W Cyber Ho holmium:YAG laser generator (Quanta System, Samarate, Italy) was used in all groups. Energy and frequency settings were set at 0.8 J and 12 Hz and modified according to stone features. In all cases the Virtual Basket technology was used to reduce retropulsion. MiniPerc was performed in prone position with ultrasound-guided puncture and the 18 Fr Ultraxx nephrostomy balloon from Cook Medical for pneumatic dilatation. In all cases a single access was performed. A 10 Ch nephrostomy tube and a ureteral catheter were left in place at the end of procedure. Endoscopic treatment was performed with a reusable fiber-optic flexible ureterorenoscope after placement of a 10–12 Fr ureteral sheath. A ureteral stent was placed and removed 20 days later. In all patients who underwent RIRS, the ureteral sheath was successfully inserted. Otherwise, a ureteral stent was left in place and the procedure was rescheduled 1 to 2 months afterwards. These last patients have not been included in the study.

We collected preoperative and intraoperative data and assessed SFR, complication rate and need for auxiliary procedures. Procedural time was considered as the time effectively needed to dust the stone. A CT scan was performed after 3 months and SFR was defined as a negative CT scan or the presence of stone fragments < 3 mm.

Block randomization was performed using the adaptative randomization software (University of Texas) in order to equally balance sample size between groups. Mean and standard deviation (SD) vs. numbers and proportions were used to describe continuous and categorical variables, respectively. Student's t-test was used to test continuous variables conforming to a normal distribution. Previous uni- and multivariate logistic regression was performed to identify variables with a statistically significant correlation to stone-free rate. A Wald chi-squared test was used to assess p value and a significant correlation was observed for stone maximum size and stone hardness. A discriminant function analysis was carried out to define the cut-off value. The chi-square test was used for the comparison of the study groups. Data were analyzed with R software version 3.4.1. All statistical tests were two-sided with a level of significance set at $p < 0.05$. The sample size was calculated with a confidence level of 95% and a confidence interval of 5%.

Results

Overall, 350 patients were enrolled. RIRS was performed in 175 patients (50.0%), among which 87 (24.9%) for stone with a SMASH score < 15 (Group A) and 88 (25.1%) with a score ≥ 15 (Group B). MP was performed in 175 patients (50.0%), of which 82 (23.4%) for stone with a SMASH score < 15 (Group C) and 93 (26.6%) with a score ≥ 15 (Group D). Table 1 summarizes descriptive characteristics. Mean stone size was 13.1 vs 13.3 mm in Group A vs B ($p = 0.18$) and 16.2 vs 18.1 mm in Group C vs D ($p = 0.12$). Mean HUs were 882 vs 1156 in Group A vs B ($p = 0.09$) and

Table 1 Descriptive characteristics of 350 patients treated for a single renal stone between 10 and 20 mm through RIRS with a SMASH score < 15 (Group A) vs. ≥ 15 (Group B) or MiniPerc with a SMASH score < 15 (Group C) vs. ≥ 15 (Group D)

		Group A (n = 87)	Group B (n = 88)	p	Group C (n = 82)	Group D (n = 93)	p
Age, years	Mean (SD)	61.1 (22.2)	59.3 (24.7)	0.22	59.8 (17.3)	62.4 (16.8)	0.14
Sex	M/F	46/41	45/43	0.54	41/41	45/48	0.39
BMI	Mean (SD)	26.6 (5.6)	25.9 (6.1)	0.11	25.2 (3.4)	24.9 (3.7)	0.23
Stone side	Right/Left	40/47	47/41	0.23	39/43	50/43	0.12
HU	Mean (SD)	882 (221)	1156 (289)	0.09	798 (401)	1201 (379)	0.07
Stone size, mm	Mean (SD)	13.1 (2.2)	13.3 (2.8)	0.18	16.2 (2.6)	18.1 (1.3)	0.12

SD Standard Deviation, *M* males, *F* females, *HU* hounsfield units

798 vs 1201 in Group C vs D (p = 0.07). No significant differences were observed according to preoperative features, including stone location.

Table 2 shows intra and postoperative parameters. Mean total operative time was 52.3 vs 63.7 min with RIRS and 89.1 vs 93.4 min with MP for stones with a SMASH score < 15 vs ≥ 15, respectively. Mean procedural time was 23.4 vs 38.1 min with RIRS and 22.4 vs 24.8 min with MP for stones with a SMASH score < 15 vs ≥ 15, respectively. Operative and procedural time were significantly lower when treating endoscopically stones with a score < 15 compared to stones with a score ≥ 15 (p = 0.04 and p = 0.03, respectively). On the contrary, no significant differences were observed with the percutaneous approach (p = 0.28 and p = 0.18) (Table 2). When specifically considering stones with a score < 15, RIRS showed a significantly lower total operative time compared to MP (p = 0.02) but no difference in procedural time only (p = 0.21). Instead, stones with a score ≥ 15 were managed more rapidly through RIRS, but the procedural time only significantly favoured MP (p = 0.03) (Table 2).

An auxiliary procedure was performed in 1 case (1.1%) in Group A, 9 (10.2%) in Group B, 2 (2.4%) in Group C and 2 (2.1%) in Group D. In Groups A and B a MP was performed, whereas in Groups C and D a RIRS was needed (Table 2). A significant difference was observed when comparing Group A vs B (p = 0.04) and Group B vs D (p = 0.04) (Table 2).

Overall, we observed 2 (2.2%) and 3 (3.4%) complications in Group A and B, 10 (12.1%) and 12 (12.9%) complications in Group C and D (Table 2). A significant difference was observed when comparing RIRS and MP for the treatment of both renal stones with a score < 15 (p = 0.02) or ≥ 15 (p = 0.02) (Table 2). The majority of complications were low grade and managed through antibiotics (2 urinary tract infections in Group B and 2 in Group D), non-steroidal anti-inflammatory drugs to control pain or conservative treatment

Table 2 Outcomes of 350 patients treated for a single renal stone between 10 and 20 mm through RIRS with a SMASH score < 15 (Group A) vs. ≥ 15 (Group B) or MiniPerc with a SMASH score < 15 (Group C) vs. ≥ 15 (Group D)

		Group A (n = 87)	Group B (n = 88)	Group C (n = 82)	Group D (n = 93)
Operative time, min	Mean (SD)	52.3 (4.3)	63.7 (7.7)	89.1 (12.3)	93.4 (7.2)
Procedural time, min	Mean (SD)	23.4 (8.9)	38.1 (12.7)	22.4 (12.5)	24.8 (8.7)
Energy delivered, KJ	Mean (SD)	10.5 (3.1)	16.4 (5.9)	12.8 (3.3)	17.1 (4.1)
Need for auxiliary procedures	n (%)	1 (1.1)	9 (10.2)	2 (2.4)	2 (2.1)
Type of procedure	Type (n)	MP (1)	MP (9)	RIRS (2)	RIRS (2)
SFR at 3 month	n (%)	82 (94.2)	61 (69.3)	75 (91.4)	85 (91.3)
Complications	n (%)	2 (2.2)	3 (3.4)	10 (12.1)	12 (12.9)
		P Group A vs B	**P Group C vs D**	**P Group A vs C**	**P Group B vs D**
Operative time, min		**0.04**	0.28	**0.02**	**0.05**
Procedural time, min		**0.03**	0.18	0.21	**0.03**
Energy delivered, KJ		**0.05**	**0.02**	0.18	0.34
Need for auxiliary procedures		**0.04**	0.23	0.19	**0.04**
SFR at 3 months		**0.03**	0.32	0.22	**0.02**
Complications		0.34	0.29	**0.02**	**0.02**

Bold values are those statistically significant

SD Standard Deviation, *MP* MiniPerc, *RIRS* Retrograde IntraRenal Surgery, *SFR* stone-free rate in case of haematuria due to ureteral lesion (1 case in Group A) or calyx perforation (5 cases in Group C and 4 in Group D). Only 1 patient from Group B experienced a steinstrasse which required ureteroscopy, whereas blood transfusions were needed in 5 patients after MP (2 from Group C and 3 from Group D) (Table 3).

The overall SFR was 94.2%, 69.3%, 91.4% and 91.3% for Groups A, B, C and D respectively (Table 2). We observed a significantly higher SFR with RIRS for the treatment of stones with a SMASH score < 15 compared to stones with a score ≥ 15 (p = 0.03). Similarly, MP significantly outperformed RIRS in the treatment of stones with a score ≥ 15 (p = 0.02) (Table 2).

Discussion

Stone hardness is often underestimated. Indeed, a small hard urolith could be more challenging than a soft urolith of bigger size. Therefore, a percutaneous approach could be preferable when coping with harder stones thanks to the use of laser fiber of larger diameter (800 µm in our study) compared to the ones inserted in the flexible ureteroscope (272 µm in our study). In order to link together stone size and hardness we assessed the clinical applicability of a new mathematical model named Stone Management According to Size-Hardness (SMASH) score in deciding when to perform RIRS or MP for the management of renal stones between 10 and 20 mm with the same laser device. Our study results in several noteworthy findings.

Firstly, mean operative and procedural time differed according to type of treatment and SMASH score. We observed a higher operative and procedural time to dust stones with score ≥ 15 compared to stones with score < 15. However, the difference was statistically significant for the endoscopic (Group A vs B) but not for the percutaneous approach (Group C vs D) (Table 2). In case of stones with score < 15, operative time with RIRS was significantly lower than MP (p = 0.02). Since procedural time was comparable (p = 0.21), RIRS seems to be more convenient in these cases. Interestingly, in patients with score ≥ 15, operative time was significantly lower with RIRS (p = 0.05),

Table 3 Complications of 350 patients treated for a single renal stone between 10 and 20 mm through RIRS with a SMASH score < 15 (Group A) vs. ≥ 15 (Group B) or MiniPerc with a SMASH score < 15 (Group C) vs. ≥ 15 (Group D)

	Group A (n = 87)	Clavien Dindo	Management
UTI, n (%)	0 (0)		
Gross haematuria, n (%)	1 (1.1)		
Reason (n)	Ureteral lesion (1)	I	Conservative treatment
Severe pain, n (%)	1 (1.1)		
Reason (n)	Ureteral stent (1)	I	NSAIDs
Total, n (%)	2 (2.2)		
	Group B (n = 88)	**Clavien Dindo**	**Management**
UTI, n (%)	2 (2.3)	II	Antibiotic therapy
Gross haematuria, n (%)	0 (0)		
Severe pain, n (%)	1 (1.1)		
Reason (n)	Steinstrasse (1)	IIIa	URS
Total, n (%)	3 (3.4)		
	Group C (n = 82)	**Clavien Dindo**	**Management**
UTI, n (%)	0 (0)		
Gross haematuria, n (%)	7 (8.5)		
Reason (n)	Calyx perforation (5)	I	Conservative treatment
	Calyx perforation (2)	II	Blood transfusion
Severe Pain, n (%)	3 (3.6)	I	NSAIDs
Total, n (%)	10 (12.1)		
	Group D (n = 93)	**Clavien Dindo**	**Management**
UTI, n (%)	2 (2.1)	II	Antibiotic therapy
Gross haematuria, n (%)	7 (7.5)		
Reason (n)	Calyx perforation (4)	I	Conservative treatment
	Calyx perforation (3)	II	Blood transfusion
Severe Pain, n (%)	3 (3.2)	I	NSAIDs
Total, n (%)	12 (12.9)		

Bold values are those statistically significant

UTI Urinary tract infection, *NSAIDs* Non-steroidal anti-inflammatory drugs, *URS* Ureteroscopy whereas procedural time was significantly lower with MP ($p = 0.03$). This is probably explained by the fact that the time needed to place the ureteral catheter, prone the patient and perform the puncture during MP is superior than the time needed to place ureteral sheet during RIRS. Consequently, MP allows a quicker dusting of stones with score ≥ 15.

Secondly, in Groups A and B percutaneous access as auxiliary procedure was performed in patients with stones located into the lower calyx, where endoscopic access may be uncomfortable and lead to damage of the flexible instrument. In Groups C and D, RIRS was due to migration of fragments into other calyxes or into the ureter (Table 2). Interestingly, the difference in the auxiliary procedure rate was significantly higher for patients treated with RIRS for stones with a score ≥ 15 compared to patients with a score < 15 ($p = 0.04$). Similarly, RIRS required a significantly higher rate of auxiliary procedures compared to MP for stones with SMASH ≥ 15 ($p = 0.04$). On the contrary, no significant difference was observed between RIRS and MP for stones with SMASH < 15 (Table 2). Therefore, our results suggest the endoscopic approach for stones with a score < 15 and MP for stones with a score ≥ 15 due to a lower risk to need an auxiliary procedure.

Thirdly, SFR after RIRS was significantly higher when the SMASH score was < 15 vs. ≥ 15 ($p = 0.03$), whereas the SFR after MP was comparable. When comparing the two treatments, MP provided a significantly higher SFR when the SMASH score was ≥ 15 ($p = 0.02$), while the SFR was similar with a lower score (Table 2). Again, our results suggest to prefer RIRS for stones with score < 15 and MP for stones with score ≥ 15.

Fourthly, we observed a significantly higher rate of complications with the percutaneous approach (Table 2). Surprisingly, the difference in mean delivered energy is opposite to that of complication rate, with a significant difference when comparing the two endoscopic groups ($p = 0.05$) and the two percutaneous groups ($p = 0.02$) (Table 2). These data suggest there is no strict correlation between delivered energy with laser settings used in our surgical practice and the occurrence of complications.

Our results show that the SMASH score represents a valuable tool to help surgeons in deciding how to treat patients with a renal stone between 10 and 20 mm. Indeed, this score allowed a proper allocation of patients between endoscopic and percutaneous approach. Patients with score ≥ 15 were effectively treated with MP, whereas RIRS resulted in a safe and effective approach for patients with score < 15. A key point of this model is the ease of its use. Complex nomograms are often underused. Our model is based on two data easily derived from CT imaging. Interestingly, results confirm the possibility to properly treat stones < 20 mm with a percutaneous approach by considering difficulties related to stone hardness. On the contrary, stones of nearly 20 mm can be easily dusted endoscopically if sufficiently soft.

The proposed model doesn't consider stone location. We previously showed that RIRS and MP perform better with upper and lower calyceal stones respectively [18]. However, each group comprised patients with stones in all renal calyxes or in the renal pelvis and there was no significant difference between the groups according to stone location. Therefore the proposed model can be reliably applied whatever the position of the stone. When dealing with upper calyceal stones with SMASH score ≥ 15 or lower calyceal stones with score < 15, surgeon may choose the approach based on his preference, but we highly recommend not to underestimate the stone hardness.

Despite its strengths, limitations of our study need to be considered. Firstly, the relatively low number of patients and the short-term follow-up. Secondly, the holmium:YAG laser was always used. Further studies using the thulium fiber laser (TFL) will eventually confirm the efficacy of the nomogram independently from the type of laser. Thirdly, all cases were performed by well-trained surgeons with a high expertise in endoscopic and percutaneous surgery. Fourthly, the study groups didn't differ according to stone location. A comparison between patients with different stone location might bring to different results and eventually lead to the construction of a model comprising also stone location. Lastly, due to the lack of coronal and sagittal scans at preoperative imaging, it was not possible to calculate stone volume for each patient. Further analyses replacing maximum size with stone volume might confirm the efficacy of this mathematical model. External validation is needed to assess the efficacy of this model.

Conclusions

RIRS and MP using the Cyber Ho are both safe and effective to reach stone clearance in patients with a renal stone between 10 and 20 mm. The mathematical model named SMASH score with the proposed cut-off allowed a simple, proper allocation of the patients between endoscopic and percutaneous approach thus aiding preoperative planning.

Author contribution PD: Protocol/project development, Data collection or management, Data analysis, Manuscript writing/editing MF: Data collection or management BU: Supervision PA: Protocol/project development, Data collection or management, Data analysis, Manuscript writing/editing ME: Data collection or management CM: Data collection or management PAL: Protocol/project development ROJ:Protocol/project development BF: Protocol/project development SMC: Supervision RB: Supervision MS: Supervision GAS: Protocol/project development LE: Protocol/project development Roche JB: Protocol/project development BG: Protocol/project development, Data collection or management, Data analysis, Manuscript writing/editing, Supervision.

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Declarations

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

Ethical approval All procedures were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Inform consent All patients included in the study signed an informed consent.

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