Case-control Study

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Shock-wave lithotripsy, ureterorenoscopy and percutaneous nephrolithotomy for 1–2 cm renal stones: A randomised pilot study

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Abstract

Objectives: This study aimed to assess which of extracorporeal shock-wave lithotripsy (SWL), ureterorenoscopy (URS) or percutaneous nephrolithotomy (PCNL) offers the best stone-free rate (SFR) for 1–2 cm renal stones.

Patients and methods: A total of 31 patients with renal stones between 1 and 2 cm were randomised to SWL, URS or PCNL. Repeat treatments or alternatives were performed until the patient was stone free or clinically in no further need of treatment. All patients were assessed with computed tomography scanning independently reviewed by a radiologist blinded to the treatment.

Results: Overall, 10 well-matched patients were randomised to SWL, 11 to URS and 10 to PCNL. SFRs were 60% for SWL, 55% for URS and 80% for PCNL (no significant difference). The mean number of procedures required were 2.6 (range 1–7) for SWL, 2.5 (range 1–4) for URS and 1.3 (range 1–3) for PCNL (p=0.072). There were no major complications, but 50% of SWL had minor complications compared with 9% for URS and 20% for PCNL.

Conclusion: The results for SWL were disappointing for SFR, number of procedures and complications. In common with other recent studies, the SFR following URS was also poor. PCNL had the best results for SFR with the fewest procedures. We calculate that an adequately powered study will require 42 patients per arm.

Level of evidence Level 2b

Keywords

Renal stones, ureterorenoscopy, extracorporeal shock-wave lithotripsy, percutaneous nephrolithotomy

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Introduction

There is no consensus on the best treatment for renal stones with a maximum measurement between 10 and 20 mm.[1–3] Extracorporeal shock-wave lithotripsy (SWL), ureterorenoscopy with laser fragmentation/dusting (URS) and percutaneous nephrolithotomy (PCNL) have all been used with varying degrees of success.[4,5] The latest recommendations from the European Association of Urology are that for stones >20 mm, PCNL should be used (though SWL or URS can be considered), and for stones 10–20 mm SWL or endourology can be used.[1] SWL is probably the most commonly used method around the world, but the stone-free rate (SFR) can be as low as 33%.[5]

A number of reviews[6,7] have lamented the lack of randomised trials for renal stones. At the start of this study in 2015, there had never been a randomised study comparing

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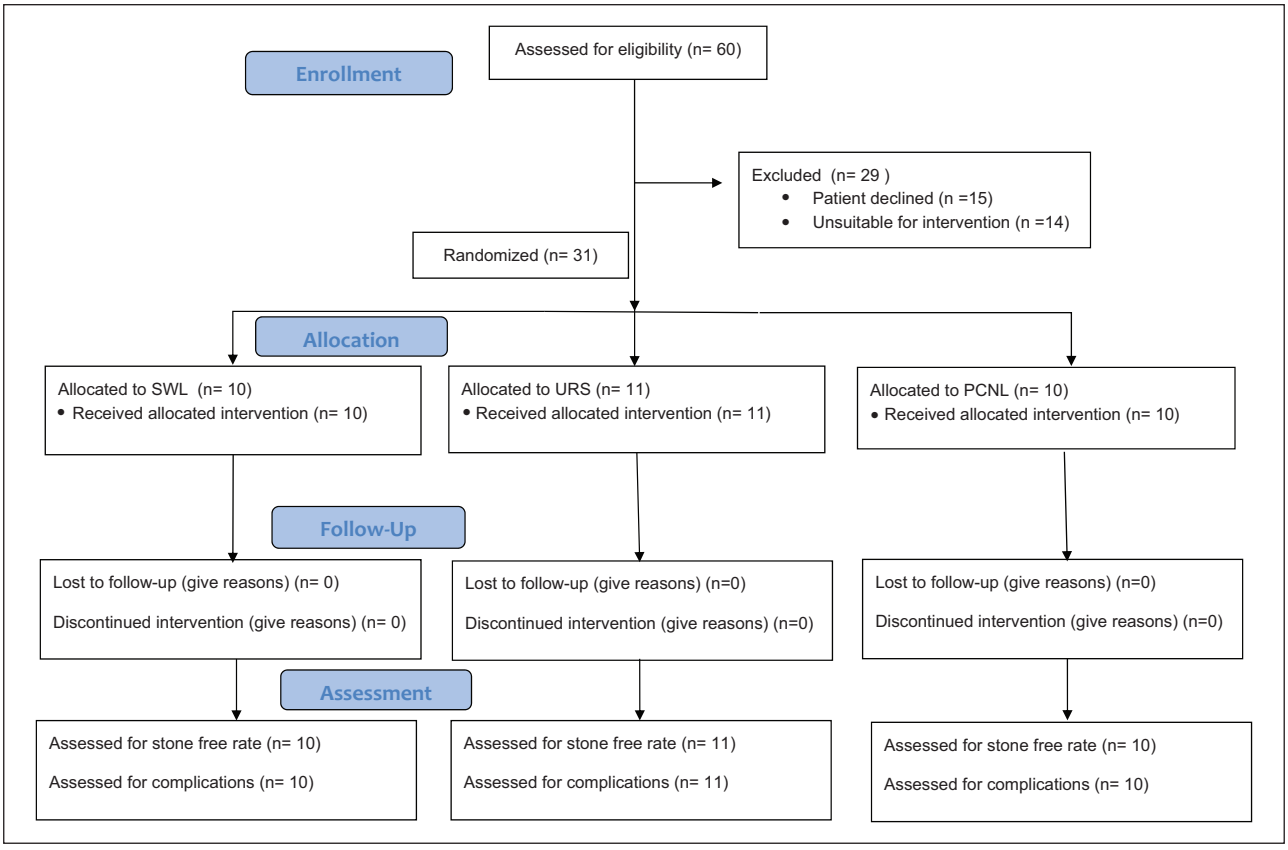

Figure 1. CONSORT flow chart detailing patient recruitment.

SWL, PCNL and URS for the treatment of 10–20 mm renal stones. We therefore established a pilot study to assess the feasibility of a major randomised trial and to provide statistical data to determine the required numbers for an adequately powered major study.

Patients and methods

This pilot study consisted of 31 patients allocated to each of the three treatment arms – SWL, PCNL and URS – with recruitment as detailed in the CONSORT flow chart (Figure 1). All adult patients with a maximum stone measurement of between 10 and 20 mm on a computed tomography (CT) scan referred to our centre were offered the opportunity to join the trial. Patients were randomised to one of the three treatment arms. A computer-generated list of random treatment allocations was used to assign patients to treatment in a 1:1:1 ratio. Block randomisation was employed to ensure approximate balance of treatment allocation within each stratum.

Treatments were carried out using our standard protocols, as described in the following. Repeat treatments or alternative treatments were performed as clinically appropriate until the patient was either deemed stone free or adequately treated. At this point, all patients then underwent a post-treatment CT scan to assess SFR (defined as no residual fragments) and any renal trauma. These images were all reviewed by a radiologist (I.B.) who was blinded to the treatment.

All SWL was performed without general anaesthesia on a Modulith SLK in-line lithotripter (Storz Medical, Tägerwilen Switzerland) in a dedicated lithotripsy room within diagnostic imaging. Treatment was performed according to the manufacturer's instructions, with a maximum of 3000 shocks per treatment. URS was performed using a flexible ureterorenoscope (Olympus, Tokyo, Japan) through ureteric access sheaths (Boston Scientific, Marlborough, MA). Routine prestenting was not performed. Laser fragmentation/dusting was performed using a 100W Hol:YAG laser (Lumenis, Yokneam, Israel), and the decision about post-treatment stenting was left up to the treating surgeon. All PCNL were performed in the modified supine position previously described.[8] Tracts were created by the operating urologist using image intensification after initial retrograde placement of a ureteric catheter. The tract was dilated to allow a 24F Amplatz sheath using a Nephromax balloon dilator (Boston Scientific), and a 22F Olympus nephroscope was used to visualise the stones. Fragmentation was dependent on the surgeon's choice using a Swiss Lithoclast Master (EMS, Herrliberg, Switzerland) or a Hol:YAG laser. A postoperative nephrostomy tube was not routinely left, but when required, a 20F silicone catheter was used.

Table 1. Patient demographics.

	SWL	URS	PCNL	*p*
Number	10	11	10	
Age, median (range)	60 (32–80)	59 (30–68)	57 (34–75)	0.85
Sex (male:female)	7:3	8:2	7:3	0.55
Stone size (mm)	13.5 (10–17)	14.5 (10–19)	14 (10–19)	0.99
Stone position:				
Pelvis	6	4	5	
Lower pole	2	5	3	
Middle/upper pole	2	2	2	
Stone HU, median (range)	753 (421–1406)	1342 (236–1522)	1078 (331–1683)	0.71
Side (left:right)	4:6	6:5	6:4	0.74

SWL: shockwave lithotripsy; URS: ureterorenoscopy; PCNL: percutaneous nephrolithotomy; HU: Hounsfield units.

Table 2. Results summary.

	SWL	URS	PCNL	*p*
Stone free (%)	60	55	80	0.52
Procedures, median (range)	2.6 (1–7)	2.5 (1–4)	1.3 (1–3)	0.072
Hospital stay, median (range)	1.2 (1–2)	1.2 (1–2)	1.3 (1–3)	0.203
Complications (%)	50	9	20	0.24

SWL: shockwave lithotripsy; URS: ureterorenoscopy; PCNL: percutaneous nephrolithotomy.

Data collected during the study included: pretreatment stone size, Hounsfield units (HU), pre-and post-treatment patient global health scores (standardised score sheet), number and duration of treatments, operative time (defined as start of patient preparation to final suture or scope withdrawal), complications of treatment and post-treatment SFR. These data were statistically analysed to see if there was any significant difference in SFR.

The study was approved by the local human ethics review board (reference: 15043A), and all patients provided written consent, having been given approved written information.

Sample size

Due to the exploratory nature of this study, effect sizes are reported in terms of standard deviations of the outcome variable. The study aimed to recruit 16 subjects per group, giving an 80% power to detect a difference in continuous variables equivalent to one standard deviation between any two groups with a two-sided *p*-value of 0.05. Based on the assumption of normality, a reduction of one standard deviation would be equivalent to a difference of approximately 24%. A difference of this magnitude is perceived to be of clinical importance.

Statistical analysis

All data were analysed using SAS v9.4 (SAS Institute, Cary, NC). Comparison between treatment groups was performed using analysis of variance for normally distributed continuous variables, Kruskal–Wallis test for continuous variables with skewed distributions and chi-square test for categorical variables. A two-sided *p*-value of 0.05 was considered to be statistically significant.

Results

The three groups of patients were well matched for patient demographics and stone size and density (Table 1). The SFRs, total number of procedures performed in each group, overall time spent in hospital and complication rates are shown in Table 2. The details of what procedures were performed in each group are shown in Table 3. All

Table 3. Types of procedures for each group.

	SWL	URS	PCNL	Stent insertion	Stent removal
SWL group	14	6	0	3	3
URS group	0	14	0	4	9
PCNL group	0	1	10	0	2

SWL: shockwave lithotripsy; URS: ureterorenoscopy; PCNL: percutaneous nephrolithotomy.

Table 4. Details of complications.

Clavien–Dindo classification	SWL	URS	PCNL
I	2	1	2
II	0	0	0
III	3	0	0
IV	0	0	0
V	0	0	0

SWL: shockwave lithotripsy; URS: ureterorenoscopy; PCNL: percutaneous nephrolithotomy.

operating-theatre procedures were on teaching lists with major input from third or fourth year urology registrars supervised by consultants with endourology expertise. All lithotripsy treatments were supervised by consultant urologists. A total of 70% of the SWL required additional procedures, either further SWL or URS with stent insertion. Only one of the URS group was considered to be successfully treated in a single treatment, with four requiring an initial stent. A total of 80% of the PCNL group had a single procedure, with one patient being stented at the time of the PCNL and another having a URS for a small amount of residual stone. Four (40%) of the PCNL operations were performed totally tubeless. The stented patient did not have a nephrostomy, and the remaining five (50%) patients had a nephrostomy post procedure which were all removed on postoperative day 1. Imaging was performed 6–45 weeks (median 12 weeks) following initial treatment, with the delayed imaging related to those patients requiring multiple treatments.

Whilst the small numbers involved prevented any statistical difference, SWL and URS had overall disappointing SFRs, and SWL had the most complications. Details of the complications are shown in Table 4. PCNL required the fewest procedures for the best results. All the Clavien–Dindo group III complications in the SWL group were due to steinstrasse requiring stent insertion.

Median operation times for the various groups were: PCNL 78 minutes (range 32–159 minutes), URS 79 minutes (range 34–138 minutes) and SWL 50 minutes (range 49–107 minutes), with the latter only for those cases requiring additional surgical procedures, as all SWL treatment was performed outside theatre.

Because of the small differences in overall SFR, the numbers needed for an adequately powered study to show a 20% difference between the groups would be 130 patients per arm. Assuming a goal of 100% SFR, to show a 30% difference in number of procedures would require 42 patients per arm.

Discussion

At its establishment in 2015, this was the first randomised trial comparing PCNL, URS and SWL as treatment for 1–2 cm renal stones. We were unable to achieve the targeted number of patients for this pilot study which will have an impact on the statistical analysis. As a tertiary referral centre, a number of patients were referred by their specialists for specific procedures and were not open to other options, preventing their inclusion in the study. Additional appropriate patients (Figure 1) were either not suitable for all procedures or had additional morbidity that prevented treatment at the primary site. Any further studies will need to be performed in collaboration with other centres.

The SWL results were disappointing in terms of SFR, the number of procedures required and the frequency of complications. The most common issue was with steinstrasse which at 30% was reported more frequently than previous studies.[9] The main advantage of SWL was that initial treatment was well tolerated and easily repeated, as there was no need for anaesthesia.

URS has been increasingly used even for large renal stones. In this study, nearly half of the patients still had stones present on the 2- to 3-month CT scan, despite the operating urologist feeling that they had completely dusted the stones with the high-powered Hol:YAG laser. This poor result is in keeping with recent reports[10] where SFR of between 50% and 60% have been recorded. The issue, as with SWL, is that stone fragments, even very small ones, must drain from the collecting system, and there is a possibility that fragments will accumulate in the lower pole calyces. These fragments may act as a nidus for further stone formation. Some reports suggest that surgeons may be ignoring these poor results by not arranging any postoperative imaging.[11] This oversight may actually be

worse than the manipulated data during the development of SWL.[12]

PCNL had the best stone clearance with the fewest procedures and an overall hospital stay equivalent to the other two treatment arms. The complication rate was higher than for URS but less than SWL, and there were no major complications throughout the study. The frequency of PCNL for all stones has remained static,[13] with many urologists seemingly more comfortable performing URS. This is despite advances in tract technology, instrument miniaturisation and better intra-corporeal lithotripters. There is also a tendency to have an extended hospital stay. As a centre that performs large numbers of PCNL, we routinely discharge patients early and have found that the modified supine position and an increasingly aggressive policy against routine nephrostomy have helped. The majority of patients in this study were discharged on postoperative day 1.

There have been two recently published studies[14,15] comparing PCNL, and smaller variations, with the other modalities which focused on the particular problems of lower pole stones. These studies had quite high SFRs and had much longer hospital stays than the current study. A metanalysis[16] of eight cohort studies covering 958 patients treated for 10–20 mm renal stones suggested that SFR for PCNL (91%) were considerably better than both URS (75.3%) and SWL (64.7%). There have been a number of studies looking at two of the three techniques,[17–20] but these have concentrated on either lower pole or non-lower pole stones. PCNL generally has the higher stone clearance rates but at the risk of more complications. Many of the reported PCNL cases have been performed with 30F tracts, which we feel is more damaging, and we have been using smaller tracts for the last decade.

The small numbers in this pilot study prevent any major revision of the guidelines for management of 10–20 mm renal stones at present, and large numbers from a multi-centre trial will be required to promote major change. We can encourage urologists and patients to use our results in pretreatment discussions. PCNL in experienced hands will safely allow the best stone clearance with the fewest procedures and a short hospital stay. SWL can rarely be used as monotherapy, and there are significant risks of steinstrasse and subsequent stent insertion. The results with URS need greater scrutiny, particularly as the number of procedures increases, with many presumably performed by urologists who may not have had the benefits of a stone fellowship or dedicated training and the ability to offer all potential modalities.

In summary, the small numbers in this pilot study have prevented any definitive recommendations, but the results for SWL were disappointing for SFR, number of procedures and complications. In common with other recent studies, the SFR following URS was also poor. PCNL had the best results for SFR with the fewest procedures. We calculate that an adequately powered study will require 42 patients per arm.

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Conflicting interests

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Ethical approval

The study was approved by the Monash Health Human Ethics Review board (reference: 15043A).

Informed consent

Written informed consent was obtained from the patients for their anonymised information to be published in this article.

Guarantor

P.M.

Author Contributions

P.M. conceived the study, attained ethics approval, developed protocol, recruited patients, maintained database and wrote first draft. M.H. was involved in patient recruitment, data analysis and script development. E.P. helped design study, wrote the statistical background for ethics and analysed the data. I.B. was involved in protocol development and reviewed all images. S.S. helped develop protocol and recruited patients. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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