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ORIGINAL ARTICLE

Efficacy and safety of the EMS Swiss LithoClast® Trilogy for PCNL: results of the European multicentre prospective study on behalf of European Section of UroTechnology

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Abstract

Purpose PCNL requires a lithotrite to efficiently break stones, and some devices include active suction to remove the fragments. We set out to determine the efficacy and safety of the Swiss LithoClast® Trilogy, in a prospective European multicentre evaluation and compared it to published stone clearance rates for Trilogy based on surface area (68.9 mm^2/min) and using the 3D calculated stone volume (526.7 mm^3/min).

Methods Ten European centres participated in this prospective non-randomized study of Trilogy for PCNL. Objective measures of stone clearance rate, device malfunction, complications and stone-free rates were assessed. Each surgeon subjectively evaluated ergonomic and device effectiveness, on a 1–10 scale (10 = extremely ergonomic/effective) and compared to their usual lithotrite on a 1–10 scale (10 = extremely effective).

Results One hundred and fifty seven PCNLs using Trilogy were included (53% male, 47% female; mean age 55 years, range 13–84 years). Mean stone clearance rate was 65.55 mm^2/min or 945 mm^3/min based on calculated 3D volume. Stone-free rate on fluoroscopy screening at the end of the procedure was 83%. Feedback for suction effectiveness was 9.0 with 9.1 for combination and 9.0 for overall effectiveness compared to lithotrite used previously. Ergonomic score was 8.1, the least satisfactory element. Complications included 13 (8.2%) Clavien–Dindo Grade II and 2 (1.3%) Grade III. Probe breakage was seen in 9 (5.7%), none required using a different lithotrite.

Conclusions We have demonstrated that Trilogy is highly effective at stone removal. From a user perspective, the device was perceived by surgeons to be highly effective overall and compared to the most commonly used previous lithotrite, with an excellent safety profile.

Keywords Trilogy · LithoClast® · PCNL · Lithotrite · Technology · Urolithiasis

Introduction

Percutaneous nephrolithotomy (PCNL) remains the preferred and first-line option for renal stones more than 20 mm in size, as recommended by both AUA and EAU guidelines [1, 2]. The most substantial technological advancements have been in the field of intracorporeal lithotripsy, as the outcome of the procedure depends on the efficiency of the lithotrite to a large extent.

The Swiss LithoClast® Trilogy (EMS, Nyon, Switzerland) is the most recent innovation in intracorporeal lithotripsy, with a single probe delivering ultrasonic and electromagnetic energy to generate a combination of ultrasonic and ballistic discharge. Additionally, its suction capability creates a trifecta effect for faster stone clearance. A high efficiency of fragmentation has been reported based on both stone surface area and 3D stone volumes [3, 4]. We aim to evaluate the efficacy and safety of Trilogy for PCNL and report the results of our European multicentre prospective non-randomized study on behalf of The European Society of UroTechnology (ESUT).

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Patients and methods

Recruitment

In a prospective fashion, 10 European centres were invited to collect data for up to 20 cases each where the Trilogy was used for PCNL. Consecutive patients undergoing PCNL in each centre were included. The study was registered with the local clinical audit department. Informed consent was gained from all patients.

Data acquisition

A standardised proforma was used for data collection and completed for each patient by one of the local investigators in each respective institution.

Stone characteristics

Stone size was recorded in three dimensions, a = equatorial diameter, b = polar diameter, and c = third measurable diameter, in millimetres from the non-contrast CT images. Using these measurements, stone cross-sectional area was calculated by using the formula $\pi \times a/2 \times b/2$ (same as used by Nottingham et al. [3]) and three-dimensional volume was calculated using the formula $4/3 \times \{\pi \times (a/2) \times (b/2) \times (c/2)\}$. Stone density in Hounsfield Units (HU) was documented for the index stone in each patient, as was Guy's stone score [5]. Stone location and associated renal anomalies were also noted.

PCNL technique and equipment

The procedure was performed by surgeons using their own standardised technique. Probe active time was automatically detected by the Trilogy control box in minutes, whereas nephroscopy time and total procedure time were recorded using a clock or stopwatch.

Outcomes

The primary outcome measures were stone-free rate, stone clearance efficiency and surgeon feedback. Visual clearance, defined as no visible stone fragments seen in the collecting system at the end of the procedure endoscopically, and clearance on fluoroscopy were noted by the surgeon at the end of the procedure. Stone-free rates were assessed on imaging either in the immediate post-operative period or at follow-up, for a duration of up to 6 months. Follow-up imaging modalities included X-ray, US and CT scan. Stone clearance efficiency was calculated using stone cross-sectional area divided by probe active time (in mm^2/min) and calculated three-dimensional stone volume divided by probe active time (in mm^3/min).

Subjective feedback from surgeons was documented for each case to include a score of 1–10 (on an ascending scale; 10 = highest score) for ergonomics, ultrasound effectiveness, ballistic effectiveness, combination effectiveness, suction effectiveness and overall effectiveness compared to the most commonly used previous lithotrite.

Device malfunction and intra-operative complications were recorded. Change in haemoglobin and post-operative complications (using the Clavien-Dindo classification) were assessed. Analyses were performed using the IBM SPSS statistical software (version 26).

Results

A total of 157 patients between June 2019 and March 2020 were included in the study, with each centre starting once local approvals had been obtained and equipment delivered. Due to the COVID-19 pandemic and the interruption of elective PCNL lists, enrolment was discontinued in some units before they reached their set target of 20 patients.

The median age of patients was 57 years; mean 55 (± 16.6); range 13–84 years. Gender distribution was 53% male and 47% female. Mean stone diameter was 24.5 mm (range 8–70 mm), mean cross-sectional area was 393.89 ± 326 mm^2 and calculated mean 3D stone volume was 7117.63 (± 9581.5) mm^3. Mean stone density was 858.22 HU and Guy's stone score (median) for stone complexity was III. Percentage of patients with Guy's stone score I, II, III and IV were 14%, 27%, 30% and 29%, respectively. Stone location was lower pole in 20%, staghorn or partial staghorn in 32% and renal pelvis in 43%. The demographics and stone characteristics are summarised in Table 1. Supine PCNL using the Galdakao-modified supine valdivia (GMSV) position was performed in 59.2% and prone PCNL was performed in 40.8% cases. Image guidance for puncture and tract formation included combined fluoroscopy and ultrasound in 71.3%, fluoroscopy only in 26.8% and ultrasound only in 1.9%. A total of 133 cases were performed using a standard tract size (≧ 22 Fr) and 24 were undertaken using tract size less than 20 Fr. Median nephroscopy time was 37 min (mean = 44 min) and median probe active time was 7 min (mean = 11 min).

Stone clearance rate assessed at the end of the procedure using fluoroscopy was 83%, with 90% visual clearance and a 92% concordance between the two. Post-operative stone-free rates for Guy's stone score I, II, III and IV were 89%, 97%, 84% and 65%, respectively, for fluoroscopy clearance and 94%, 100%, 89% and 73% for visual clearance. Post-operative and follow-up imaging data were available for 97

Table 1 Demographics and stone characteristics of patients undergoing PCNL using the Swiss LithoClast® Trilogy

Age	(Years)	Stone cross-sectional area	(mm^2)	Stone density	(HU)	Stone location	
Mean	55 ± 16.6	Mean	393.89 ± 326	Min	617.2	Renal Pelvis	68 (43%)
Median	57	Median	293.6	Max	1033	Upper pole	4 (3%)
Range	13–84	Range	13.13–2198	Mean	858.2	Interpolar	2 (1%)
				Guy's stone score		Lower pole	32 (20%)
Gender		**Calculated 3D volume**	**(mm^3)**	1	14%	Partial Staghorn UP	2 (1%)
Male	83 (53%)	Mean	7117.63 ± 9581.5	2	27%	Partial Staghorn IP	5 (3%)
Female	74 (47%)	Median	3532.5	3	30%	Partial Staghorn LP	16 (10%)
Ratio	1.1: 1	Range	49.88–54,158.72	4	29%	Staghorn	28 (18%)

patients, with overall stone-free rate of 81.4%. Follow-up imaging was not available for the remaining 60 patients (38%) either due to delayed follow-up with imaging due the COVID-19 pandemic, or due to follow-up in the community. 86% patients were stone free on X-ray and/or USS, whereas 75% were stone free on CT scan. Stone clearance efficiency was 65.55 (± 77.7) mm^2/min and 945.23 (± 1248.9) mm^3/min.

Surgeon feedback was highest for combination effectiveness (mean 9.1; median 9.5) and lowest for ergonomic score (mean 8.1 and median 8.0). The score for overall effectiveness compared to previously used lithotrite was high at 9.0 and LithoClast Master (82%) was the most commonly used previous lithotrite. One user commented on excessive noise during handpiece activation. The outcomes for stone clearance, operating times, stone clearance efficiency and surgeon feedback are presented in Table 2.

Probe breakage occurred in 9 (5.7%) cases, however, the procedure was continued with a new probe and there was no need to switch to another lithotrite. Intra-operative adverse events included one case of renal pelvis perforation. Post-operative haemoglobin drop was 1.5 g/dl (mean) and overall complication rate was 9.5% ($n = 15$). Post-operative complications were as follows: Clavien I–II complications included fever ($n = 2$), urosepsis ($n = 3$), blood transfusion ($n = 3$), AV fistula ($n = 1$), abdominal wall and perirenal haematoma ($n = 2$) and extracorporeal lithotripsy for ureteric fragments ($n = 2$). Ureteric JJ stent insertion was performed for two patients for obstruction due to ureteric fragments (Clavien grade III) and there were no major (grade IV or V) complications.

Discussion

The first prospective clinical evaluation of the Swiss Lithoclast® Trilogy in PCNL was published by Sabnis et al. [4] with 31 patients (20 standard and 11 miniaturised) from a single centre. Nottingham et al. [3] have published their initial clinical experience from a multicentre prospective cohort of 43 patients (and 50 kidney units). The results of a comparative study by Chong et al. [6] showed superior treatment efficiency of Trilogy to a matched cohort of LC Select. Our multicentre prospective study represents the largest clinical study to date assessing the efficacy and safety of Trilogy. By including data from ten different European centres, we have included a range of operative techniques and would, therefore, suggest that the results can be generalised across a range of stone types, kidney types and operative techniques.

The Olympus ShockPulse-SE is also a dual-energy single-probe device. In vitro studies comparing ShockPulse-SE with LithoClast® Master and the ultrasonic dual-probe Cyberwand showed that ShockPulse-SE has a significantly faster stone clearance [7]. Although Trilogy has not been clinically directly compared to ShockPulse-SE or other lithotrites, several benchtop studies support its higher efficacy for stone fragmentation. The first in vitro assessment using begostones established the superiority of Trilogy in comparison with ShockPulse-SE and LC Select [8]. Similarly, the most recent experimental evaluation by Bader et al. [9] (2020) showed that Trilogy was significantly more efficient.

With the use of Trilogy, our stone-free rates on fluoroscopy at the end of the procedure for Guy's stone score I, II, III and IV were 89%, 97%, 84% and 65%, respectively. This is despite the fact that this is a new device, and these cases were at the start of the learning curve for the use of the device. The UK national PCNL audit data [10] (2017–2019) published by BAUS, reported stone-free rates of 85%, 78%, 65% and 46% on post-operative radiological imaging for Guy's stone score I, II, III and IV, respectively. The global 30-day stone-free rates for PCNL in general have been quoted as 75.7% by the Clinical Research Office of the Endourological Society (CROES) study [11]. The Trilogy series by Sabnis et al. [4] reported a significantly high stone-free rate of 93% immediately post-operatively and 96% at 1-month on imaging. In the Trilogy series by Nottingham et al. [3], stone-free rates were lower (67%). In comparison, clinical evaluation of ShockPulse-SE has shown high stone-free rates of 78–83% [7, 12] and are higher than those for LC Master [13]. A randomised controlled trial by York

Table 2 Summary of clearance rate and efficiency, operating times and surgeon feedback for PCNL using the Swiss LithoClast® Trilogy

Clearance		Surgeon feedback	
Fluoroscopy clearance	83%	Ergonomic score	10 = extremely ergonomic
Guy's stone score		Mean	8.1
I	89%		
II	97%	Median	8
III	84%	Range	5–10
IV	65%	Ultrasound effectiveness	10 = extremely effective
Visual clearance	90%	Mean	8.6
Guy's stone score		Median	9
I	94%		
II	100%	Range	4–10
III	89%	Ballistic effectiveness	10 = extremely effective
IV	73%	Mean	8.5
Concordance visual vs fluoro 92%		Median	9
Stone-free post-op/on follow-up 79 (81.4%)*		Range	1–10
		Combination effectiveness	10 = extremely effective
Total operating time	mins	Mean	9.1
		Median	9.5
Mean	82	Range	1–10
Median	72	Suction effectiveness	10 = extremely effective
Nephroscopy time	mins	Mean	9.0
Mean	44	Median	9
Median	37	Range	2–10
Probe active time	mins	Overall effectiveness	10 = extremely effective
Mean	11	Mean	9
Median	7	Median	9
Efficiency: area per min	mm^2/min	Range	1–10
Mean	65.55 ± 77.7	**Commonly used previous lithotrite**	
Median	44.07	LC Master	129 (82%)
Efficiency: vol. per min	mm^3/min	ShockPulse-SE	21 (13%)
Mean	945.23 ± 1248.9	Laser	2 (1%)
Median	501.85	Calcuson	5 (3%)

*Data not available $n = 60$ (38%)

et al. [14], which evaluated Cyberwand, LC Select and StoneBreaker showed stone-free rates of 56.5%, 65.2% and 51.6%, respectively. It is important, however, to note variability of reporting stone rates which are used in the literature, with regard to timing of follow-up, imaging modality used, and definition of stone free. This could explain the lower stone-free rates for Trilogy reported by Nottingham et al. compared to other evaluations of Trilogy.

The fluoroscopically assessed stone-free rate of 83% was found to be lower than that assessed endoscopically (90%). This may be due to the fact that calcifications seen on fluoroscopy at the end of the procedure were not present within the collecting system, and either lay outside of the kidney, or were parenchymal or submucosal. Another reason may be that endoscopic evaluation was incomplete, and not all the calyces could be inspected.

In our study, stone fragmentation is more efficient to that reported by Sabnis et al. [4], with volumetric clearance efficiency of 945.2 mm^3/min compared to 526.7 mm^3/min [4]. Again, this is despite the fact that the learning curve is likely to affect efficiency of device use for this new device. Nottingham et al. [3] quoted the clearance efficiency in area per minute (68.9 mm^2/min), which is similar to our study (65.55 mm^2/min). The stone burden (mean area = 345 ± 387 mm^2) is also comparable to ours (mean area = 393.89 ± 326 mm^2). Stone clearance efficiency for ShockPulse-SE has not been reported in any of the clinical studies, hence at present, it is difficult to compare the devices for fragmentation efficiency. York et al. [14] showed lower clearance efficiency for Cyberwand, LC Select and StoneBreaker (32.3 ± 23.4 mm^2/min, 28.9 ± 16.2 mm^2/min and 24.0 ± 13.9 mm^2/min, respectively), with no significant difference between the three (p value 0.036).

Although stone fragmentation efficiency for Trilogy appears to be higher than those of other commonly used lithotrites, the variations in stone clearance could be due to the use of different formulas for calculation of stone surface area and 3D volume. We used the formulas $\pi \times a/2 \times b/2$ and $4/3 \times \{\pi \times (a/2) \times (b/2) \times (c/2)\}$, for stone cross-sectional area and three-dimensional volume, respectively, where a, b and c represent the three longest measurements in three dimensions of the stone, taken from the CT scan. Nottingham et al. [3] calculated the stone surface area using the same formula as ours for surface area of an ellipse ($\pi \times r1 \times r2$). Sabnis et al. [4] calculated the 3D volume using CT scan volumetric assessment software (3D-DOCTOR™). It is known that traditional formulae may over- or under-estimate three-dimensional stone volume in comparison to CT-computed measurements [15]. The lower stone volumes in Sabnis et al. [4] study possibly reflect this. As these discrepancies make comparative evaluations of outcomes difficult, a uniform system for measurement of stone burden and removal efficiency is recommended.

Assessment of surgeon feedback for Trilogy received higher scores in our study compared to Nottingham et al. [3], but they were high in both studies. Compared to previously used lithotrite, which was mostly LC Master for 82% of users, Trilogy was perceived by users as being highly effective (Score 9/10). Feedback for ergonomics was the lowest in both our study (8.0 out of 10) and that by Nottingham et al. [3] (6.7 out of 10). This can likely be attributed to the greater weight of the Trilogy handpiece with associated tubing, which has a cord with a hydrocooling system and pumps through the generator. This allows for the electromagnetic and ultrasonic energies but adds weight to the handpiece. In the future, modification of these components and inclusion of noise reduction or dampening system, which was an issue also mentioned regarding device feedback, might be able to resolve these issues.

Evidence with regards to tissue safety of Trilogy has been demonstrated by Khoder et al. [16]. In our study, there were no major (Clavien IV–V) complications and overall complication rate was 9.5%, with a blood transfusion rate of 2%. The probe breakage rate was 5.7%, and this could be due to the surgeon learning curve or related to specific compatibility issues between the Trilogy device and the nephroscope which it is used with. In our opinion, this should be investigated further.

The main limitation of our study is that this is not a randomised controlled trial comparing Trilogy to other dual-energy lithotrites. A randomised prospective study comparing the efficiency, stone-free rates and safety of ShockPulse-SE versus Trilogy would provide high-quality clinical comparative data. For further studies of Trilogy, where randomisation cannot be undertaken, accurate interpretation of results will be possible if study parameters are standardised. Heterogeneity of data and methods of calculations of stone burden should be addressed, with efficiency reported as a volume efficiency of stone removed, ideally calculated using CT 3D software. Other areas of future research include cost-effectiveness and impact of Trilogy use on theatre times and efficiency.

Conclusions

Our multicentre prospective study strongly supports the evidence for the safety and efficiency of the Swiss LithoClast® Trilogy. Stone clearance rates and post-operative stone-free rates are high. Surgeon user feedback is excellent, and it appears to be highly effective when compared to the previously used lithotrites. It is imperative that the results be cautiously interpreted in view of inconsistency in reporting of stone burden in previous studies. We recommend standardisation of parameters for calculating stone burden and stone-free rates for future evaluation of lithotrites for PCNL.

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Declarations

Conflict of interest Saeb-Parsy K consultant: Boston Scientific. Nuffield Health. Pérez Fentes D. faculty in courses organized by EMS and received honoraria. Turney B. consultant Research and Education, Boston Scientific, research grant EMS. Wiseman O. director StoneScreen, consultant: Boston Scientific, Porges Coloplast, EMS, education: Boston Scientific, Porges Coloplast, EMS, research: Porges Coloplast, EMS.

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Consent to participate Informed consent obtained from all patients.

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