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Modular training for percutaneous nephrolithotripsy: The safe way to go

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ABBREVIATIONS

MTS, modular training scheme;
PCNL, percutaneous nephrolithotripsy;
GRS, global rating scale

Abstract Objectives should be describe a modular training scheme (MTS) which aims to provide training in percutaneous nephrolithotripsy (PCNL) and ensure the safety of the patients.

Subjects and methods: Two trainees with no experience in PCNL attended the MTS under the supervision of an experienced mentor. The MTS included five modules, comprising an initial animal laboratory course (using pigs), to acquire basic skills (Module 1), and Modules 2–5 included making the puncture, tract dilatation, single-stone and large-stone management in clinical cases, respectively. Each participant progressed from one module to the next under constant mentoring and evaluation by the mentor. When the trainees completed the MTS they proceeded to perform 60 PCNL procedures independently while the mentor performed 25 for comparison purposes. A global rating scale was used for the objective evaluation of the trainees. Peri-operative variables were recorded and statistically compared as appropriate. Statistical significance was defined as $P < 0.05$.

Results: One pig and 16 patients, and two pigs and 22 patients, were necessary to complete the MTS by each subject. There were no significant differences among the

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characteristics of the independently performed operations. The duration of surgery and fluoroscopy achieved a plateau similar to those of the mentor after ≈ 30 patients. The decrease in haemoglobin level, stone-free and complication rates in the patients were similar among the two trainees and the mentor. The complication rate of the trainees and the mentor never exceeded 13.3%.

Conclusion: The MTS successfully combined animal and stepwise clinical training based on a standardised technique and objective evaluation.

Introduction

Percutaneous nephrolithotripsy (PCNL) is a standard of treatment for renal stones and the technique is associated with a steep learning curve [1]. Reports of structured training programmes including both laboratory and clinical practice are currently lacking [2–4]. In the present study we assessed a training scheme for PCNL which is based on stepwise training.

Subjects and methods

The modular training scheme (MTS) was divided into five modules. The main concern of the MTS design was to guarantee the safety of the patients. The aim of the first module was to obtain the necessary technical skills in a pig model, with no involvement of patients. The remaining modules were based on the performance of the PCNL steps by the trainees under the supervision of the mentor, until the trainee reached a satisfactory level of competence. After successfully accomplishing the MTS, a series of independent clinical patients were operated on by the trainees to evaluate the efficacy of the MTS and to estimate the learning curve for PCNL.

For the purpose of the MTS a standardised PCNL technique was divided into specific steps that were followed by all participants for all procedures of this study. A ureteric catheter was placed with the patient in the lithotomy position. The patient was placed prone and the collecting system was punctured at 30° from the perpendicular of the long axis of the patient, under fluoroscopic guidance. The puncture depth was monitored through a 0° fluoroscopic view, the entrance to the collecting system was confirmed by urine aspiration, and appropriate guidewires were inserted. The tract was dilated to 30 F using Amplatz dilators. A Malecot catheter was inserted at the end of the procedure.

One resident and one fellow in endourology with no previous experience of PCNL attended the MTS (Table 1). The mentor had a long experience of > 1500 PCNLs.

For each step of the MTS the trainee was scored by the mentor. The scoring system was based on a previously described global rating scale (GRS) [5]. For the purpose of this study, we expanded the GRS, and it consisted of six domains using a 5-point Likert-type scale (Table 2, intermediate scores 2 and 4 not shown). Different variables of the PCNL procedure were assessed, e.g., knowledge of renal anatomy and planning the trajectory. If the trainee achieved an average overall performance of 4 in the procedures undertaken in both kidneys of a pig, the trainee was considered to be competent enough to proceed to operating on patients. Otherwise, the animal laboratory course was repeated.

The MTS

Module 1 included renal puncture, tract dilatation using the Amplatz dilators, and orientation with the nephroscope in a pig. The live pig model was chosen as it closely replicates the human kidney and simulates realistically the performance of PCNL under both fluoroscopy and ultrasonographic guidance [3]. The renal puncture is extremely close to the clinical setting in terms of the anatomy and 'tissue feel', and the only difference is that the pelvicalyceal system is relatively smaller and more fragile [3,6]. Three to four punctures per kidney could be made before contrast extravasation distorted the fluoroscopic vision. There were multiple punctures and insertion of guidewires, then each tract was dilated and nephroscopy followed. The tasks were repeated for the contralateral kidney of the pig. The mentor scored the trainee using the GRS after each access.

Clinical modular training (modules 2–5)

When the trainees successfully completed module 1, they proceeded to making the puncture in patients (module 2). The mentor then performed the remaining steps of the procedure with the trainee as an assistant. The schedule was repeated during subsequent procedures until the mentor decided that the trainee could continue to the next module. The trainee then proceeded to modules 3, 4 and 5 consecutively, performing all previous modules and the new module for each case. Eventually

Table 1 Endoscopic experience of the residents at the beginning of the MTS, and the number of cases required for each trainee in every module to achieve competence for the next module.

Experience	Trainee	
	1	2
Previous endoscopic	40 URS (surgeon) 30 PCNL (assistant)	5 URS (surgeon) 10 PCNL (assistant)
Operations on module		
1	5 accesses in 1 pig	9 accesses in 2 pigs
2	3	5
3	3	4
4	4	6
5	6	7

URS, ureteroscopy.

Table 2 The GRS for PCNL used in the evaluation of the trainees.

Task*	Score		
	1	3	5
Identify anatomy	No knowledge	Identified most landmarks	Identified all landmarks
Plan needle puncture**	Targeting incorrect calyx or wrong angle	Eventually targets correct calyx at appropriate angle	Correct calyx targeted Needle at appropriate angle.
	Multiple needle passes	A few needle passes	Minimum needle passes
Use of instruments	Difficulty coordinating access needle and guidewire	Able to use access needle and guidewire although awkward at times	Able to use access needle and guidewire smoothly
Efficacy in dilating the tract	Failure to dilate the tract Inappropriate use of dilation device and wires	Dilation was achieved but not with the optimal technical efficacy and control	Dilation under efficient control and technique
Ability to perform tasks	Frequently stopped or needed advice/ assistance from mentor	Performed procedure with little advice/ assistance from mentor	Performed procedure with no advice/ assistance from mentor
Overall performance	Poor	Average	Excellent

* Intermediate scores 2 and 4 are not shown.
** The number of needle passes was defined as: minimum, one puncture per access; few, 2–3 punctures/access; multiple, >3 punctures/access.

the trainee was able to perform all the steps independently. The GRS scale was used to objectively evaluate the trainees whilst they were proceeding from one module to the next. As the trainees were only making the puncture in the first clinical module, the GRS was reduced by one domain during the evaluation of module 2. Specifically, the domain referring to the dilatation was omitted. An objective overall performance score of 4 in at least three cases was necessary for the further progress of the candidate to the next module.

When the trainees had successfully accomplished the MTS, several consecutive patients were operated on by them independently.

The MTS and clinical operations took place between January 2011 and December 2013. The stone-free status was defined as complete stone clearance or the presence of clinically insignificant fragments of $\leqslant 3$ mm, evaluated with a plain abdominal film or CT before discharge or at the 4-week follow-up appointment. The data obtained from the first 60 patients of each trainee were divided in four segments of 15. These data were compared to 25 patients of the mentor, to estimate the learning curve. Complications were reported according to the Clavien-Dindo classification [7–9].

The data were analysed statistically, with significance defined as $P < 0.05$.

Results

The number of cases required for each trainee to proceed to the next module of training is shown in Table 1. Table 3 shows the results of the GRS scale evaluation. Three pigs were needed for the trainees to achieve the level of competence defined by the GRS. The number of clinical patients for progression to the next module varied among modules and trainees, from three to seven. The more experienced trainee (Trainee 1) seemed to progress more rapidly from one module to the other. Thus, he required one pig and 16 patients to complete the MTS, whilst the other required two pigs and 22 patients. The statistical comparison of the GRS data of the modules showed significance between the trainees only in Module 5 ($P = 0.001$; Table 3). The errors of each trainee during the MTS are presented in Table 4. There were more errors during the animal training than in modules 2–4. Module 5 (complex stone management) was associated with the most errors by both trainees.

Table 3 GRS scores and errors at each module for both trainees (T1 and T2).

Task	Module									
	1		2		3		4		5	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Identify anatomy	4	3.89	5	4.6	4.67	4.5	4.75	4.83	5	5
Needle puncture	4.2	3.67	4.67	4	4.67	4.5	4.75	4.67	4	4.14
Instrument use	4	3.78	4.33	4.3	4.33	4	4	4	4.17	3.57
Dilatation	4.2	3.78	–	–	3.67	3.5	4.25	4	3.5	3.57
Ability for tasks	4	3.56	4	3.8	5	4.75	4.75	4.83	4.67	4.28
Overall performance	3.6	3.45	4.33	4	4.67	4.5	4.75	4.67	4.33	4.57
P		0.69		0.21		0.12		0.21		0.001
Number/cases										
Needle punctures	8/5*	15/9*	3/3	6/5	4/3	4/4	5/4	8/6	16/6**	20/7**
Rib collisions	4	6	1	1	1	0	1	1	5	6
Blood vessel injuries	1	1	0	0	1	1	0	0	2	1
Collecting system injury	1	1	0	0	1	1	1	0	2	2
Infundibular punctures	4	6	0	1	1	0	1	1	3	6

The Kruskal–Wallis test was used for the statistical analysis.
* The total number of punctures per number of accesses in the given pigs.
** More than one puncture in each case, as multiple punctures were made in these cases.

The independent clinical cases represent consecutive patients undergoing PCNL in our institution and no specific selection criteria were applied. There was no significant difference among the patients operated by the trainees and the mentor in patient age and stone size ($P = 0.65$ and 0.19, respectively). The patients included those previously treated for lithiasis in renal units, and those with concomitant renal conditions (Table 4).

The peri-operative data (Table 4) showed that the trainees improved rapidly in terms of the duration of surgery and fluoroscopy. Both trainees improved these times between the first 15 and the second 15 cases. The last 30 cases of each trainee were accomplished in similar operative and fluoroscopy times to those of the mentor. The mean decline in haemoglobin level was similar for all participants throughout the investigation. The stone-free rates were high, at 73.3–86.6% among the trainees, and the mentor had a slightly higher stone-free rate of 88%. The hospitalisation time was similar among the trainees and the mentor (3–8 days).

In all, four transfusions were required in 185 patients (2.1%). The need for transfusion was rare and thus cannot be correlated with the learning curve of the trainees. Major complications were one case of pseudoaneurysm (Clavien Grade IIIa) requiring embolisation, and one case of a retroperitoneal haematoma requiring transfusion (Grade II). There was one case of pneumo-hydrothorax and the procedure was aborted after placing thoracic drainage. Minor complications such as infundibular tear and postoperative fever were more common and were managed conservatively. Two cases of prolonged bleeding through the Malecot tube resulted in transfusions. The complication rate of the trainees was similar to that of the mentor and never exceeded 13.3% (Table 4).

Discussion

Various different studies using virtual reality training, dry and wet laboratory models, and patient training for PCNL have been proposed [2–4]. Currently, there are few reports of structured training schemes [3]. A structured training programme, including acquiring technical and cognitive skills combined with clinical training under continuous mentoring and controlled conditions which ensure the safety of the patients, has not been proposed [2,3,5,6,10–13]. Structured training schemes such as the MTS have been described for laparoscopy [14–16]. Modular training is based on the division of the procedure into steps according to their difficulty (modules). Each module is undertaken by the trainee under continuous mentoring until the trainee masters the module and progresses to the next step. This stepwise training allows the efficient performance of the procedure while ensuring the safety of the patients [15]. Based on the above concept we propose a MTS in PCNL.

Two main axes were established to achieve these purposes, the first being the stepwise training of a standardised technique under constant mentoring. This allowed the acquisition of cognitive skills, which is important for efficient and safe training [5]. The second included an objective evaluation of the candidates for the acquisition of skills by the use of a GRS during their progression. The latter was necessary because lack of objective feedback might result in difficulties in correcting any deficiencies in training and performance [3].

The results showed that the pig model was effective in preparing the trainees for the clinical segment of the MTS. The basic skills were acquired rapidly by the can-

Table 4 Pre-operative data of the patients operated independently by the trainees and the mentor, and the complications encountered.

Mean (range), mean (SD) or *n* (%) variable	Trainee								Mentor
	1	1	1	1	2	2	2	2	
Case number	1–15	16–30	31–45	46–60	1–15	16–30	31–45	46–60	25
Age (years)	48.3	55.3	57.9	48.6	57.8	55.3	54.6	61.5	51.2
$P = 0.65$	(34–69)	(37–75)	(39–78)	(33–70)	(36–75)	(37–74)	(36–69)	(37–73)	(33–77)
Stone size (cm)	3.19	2.76	3.13	2.93	2.86	3.27	3.25	3.21	3.21
$P = 0.19$	(2.2–3.9)	(2–3.8)	(2.0–4.0)	(2.1–3.9)	(2.2–3.8)	(2.0–4.0)	(2.4–4.0)	(2.3–3.9)	(2–3.9)
Stone location									
Pelvis	3	6	5	4	5	4	5	6	7
Lower pole	5	4	5	7	6	7	5	6	8
Middle pole	2	2	1	2	1	0	2	0	3
Upper pole	2	1	1	1	1	2	2	1	3
Staghorn	3	2	3	1	2	2	1	2	4
Previous renal surgery	2 SWL 2 URS	1 PCNL	1 × OP 1 SWL	1 URS	2 PCNL 1 SWL	1 URS 1 SWL	2 SWL 3 URS	1 × EP	2 SWL
Concomitant urinary tract conditions	–	1 PUJO	–	–	1 × US	1 × PUJO	–	1 PUJO Urothelial tumour*	1
Duration (min)									
Operative	66.5 (13.7)	56.6 (12.1)	49.8 (13.1)	46.6 (14.4)	70.2 (11.2)	55.3 (12.2)	43.1 (12.8)	46.3 (13.4)	43.1 (13.2)
Fluoroscopy	2.5 (0.3)	1.9 (0.3)	1.8 (0.4)	1.7 (0.3)	2.4 (0.3)	2.1 (0.3)	1.7 (0.3)	1.8 (0.2)	1.7 (0.3)
Additional procedures	–	1 EP	–	–	–	1 EP	–	1 EP	–
Haemoglobin decrease, g/dL	1.86 (0.67)	1.68 (0.66)	1.78 (0.48)	1.88 (0.54)	1.77 (0.58)	1.68 (0.59)	1.99 (0.98)	1.66 (0.47)	1.71 (0.8)
Stone-free, *n*	11	13	13	13	12	13	13	13	22
Transfusion, *n*	1	0	0	1	0	0	1	0	1
Hospital stay (days)	3.3 (3–7)	3.1 (3–5)	3.1 (3–5)	3.2 (3–6)	3.1 (3–5)	3.3 (3–8)	3.3 (3–5)	3.3 (3–7)	3.3 (3–7)
Complications									
Intra-operative	1 IT/cons	1 PWT/cons	–	1 IT-B/cons 1 IT/cons	1 PWT/cons, thoracic drainage placement	1 P-H/abort/ removal of needle, pressure, select other site	1 puncture B** at Malecot placement/clamping	1 SB at 1 IP/cons	1 IP B
Postoperative (Clavien grade)	1 PA Emb + Tr/ AAC (IIIa)	1 Re-ad high fever/AAC (II) (II)	1 F/AAC	1 PB thru Malecot/ Tr (II)	–	1 F/AAC (II) Tr (II)	1 sig RPH + symptoms (pain)/cons	–	1 PB thru Malecot/Tr (II) 1 F/AAC (II)

The Kruskal–Wallis test was used for the statistical analysis.
SWL, shock-wave lithotripsy; URS, ureteroscopy; OP, open pyeloplasty; EP, endopyelotomy; PUJO, pelvi-ureteric junction obstruction; US, urethral stricture; IT, infundibular tear; B, bleeding; PWT, pelvic wall tear; P-H, pneumothorax/hydrothorax; SB, significant bleeding; IP, infundibular puncture; /cons, conservative; PA, pseudoaneurysm; Re-ad, re-admission of patient; AAC, antibiotics according to culture; Emb, embolisation; Tr, transfusion; RPH, retroperitoneal haematoma; F, postop. fever.

* Resection and follow-up.

** Of large parenchymal vessel.

didates and very few pigs were necessary. Furthermore, the performance of the candidates during the cases of Module 2 showed that the puncture was already mastered and the total number of mistakes was lower than in Module 1 (Table 3). The mastering of the puncture is a crucial step for the trainees, and the success of the procedure depends on it [3]. The puncture is more difficult in the pig than in the human collecting system, due to the smaller structures and space involved. The pig model set a high level of difficulty, which prepared the trainees for the efficient performance of Module 2 (puncture in humans). The statistical differences among the trainees in Module 5 could be attributed to the different endoscopic experience of the trainees and was probably associated with the increased difficulty of multi-access PCNL.

The combination of the first module with the four clinical modules allowed a smooth transition from an animal training model to the independent clinical cases. The clinical modules provided valuable hands-on training under continuous supervision and mentoring. The repetition of each step until it was mastered gave significant experience and the trainees felt more confident. After the MTS process, the candidates operated independently, with complication and stone-free rates comparable to those of the mentor (Table 4). The only differences were the longer operative and fluoroscopy times. The trainees reached the efficiency of the mentor within 30 patients, which represented their learning curve. The latter result confirmed the previous estimation of the learning curve to be 24 cases [17]. Other investigators estimated the learning curve to be 60 cases when the operative duration was the criterion to define competence [10,13]. If the stone-free rate was regarded as the endpoint, the learning curve was a horizontal line and was overcome at the very first cases [13]. The fewer cases required to achieve a plateau in the operative duration after the MTS could probably be attributed to its efficiency. Hence, surrogate markers defining the learning curve need to be defined. The number of procedures necessary to achieve surgical competence contains no information on the complexity of the procedure. Stone clearance combined with complication rates are the most relevant clinical endpoints.

The complication rates were low for all the participants and directly comparable to those reported previously [7,9,18]. Most complications were minor and conservative treatment was adequate for their management. Major complications were scarce and reflected random events rather than lack of technical efficacy. The transfusion rates were comparable to those reported earlier [7,9,18]. The mean decrease in haemoglobin level reflected the blood loss, and was uniform among the participants. The latter variable, along with the stone-free and the complication rates, remained similar among cases performed by the trainees and mentor. Thus, these variables could probably be interpreted as indicators of the technical efficiency of the trainees on completing the MTS and practically demonstrated its efficiency.

The MTS was based on stepwise training in modules representing different steps of the PCNL technique. The previously described modular training programmes in laparoscopy include modules based on the difficulty of the steps of the techniques [15,16,19]. The first modules always represent the easier steps of the procedure and the candidate progresses to the more difficult steps in the more advanced modules. One could advocate that Module 3 is probably easier than Module 2 and probably should be undertaken earlier in the MTS. This concerned the authors during the design of the MTS. The authors' institution organises a monthly training course in PCNL which is attended by guests from European countries. The training course includes hands-on training in a pig model and attendance at several PCNL operations. The experience gained was applied in the design of the MTS. The training in the pigs represents a difficult model for learning the initial puncture, as the anatomical structures of the porcine kidney and pelvicalyceal system are smaller. All guests in our courses were satisfied by the training on the pig model. They mentioned that the difficulty of the puncture was a major issue for performing the procedure in their clinical practice (unpublished data). The importance of the latter step as proposed by the guests led the authors to decide on a more intensive training programme in puncturing the pelvicalyceal system, by assigning this step as Module 2. The candidates were making punctures throughout the MTS and achieved a high level of efficacy under expert guidance. The further division of the MTS into minor technical steps of the PCNL procedure, such as guidewire insertion or stone fragmentation, would probably render the MTS more complicated for the everyday clinical practice of the endourological team. The inclusion of these steps in two major modules, the evaluation based on the GRS scale and the recording of errors during the different modules, provided an easy-to-perform training programme.

A limitation of the current study was that it included only two trainees, and more trainees could further document the efficacy of MTS. This limitation should be considered in conjunction with the previously reported MTSs, which did not include more trainees [15,16,19]. It is also difficult to include many trainees in extensive training schemes that aim to provide highly skilled surgeons. Moreover, the use of a pig model represented some cost, and is probably not available for training in all countries. The selection of the model was based on the similarities of the porcine and human anatomy, which render it as an effective model for endourological training [20–22]. The use of simulators was another possible solution for safe training before the initiation of training in clinical cases. Nevertheless, these simulators are hampered by the lack of adequate haptic feedback [2,23]. The inclusion of the pig model in the MTS showed its efficiency in PCNL training and the preparation of the trainees in the clinical modules. Furthermore, only a few punctures and tract dilatations can be made in each renal unit, due to the associated extravasation which hindered the visualisation of the collecting system. Three or four renal punctures and one or two dilatations can usually be made in each side.

The GRS was selected as a practical tool for evaluating the candidates, despite the higher objectivity of other more extensive tools [24].

In conclusion, the MTS successfully combined animal-based and stepwise clinical training based on a standardised technique and the objective evaluation by the mentor. The trainees progressed rapidly from the training modules to the independent performance of PCNL with efficiency and minimal complications. The learning curve was estimated to be $\approx$ 30 cases.

Conflict of interest

None.

Source of funding

None.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.aju.2015.07.005.

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