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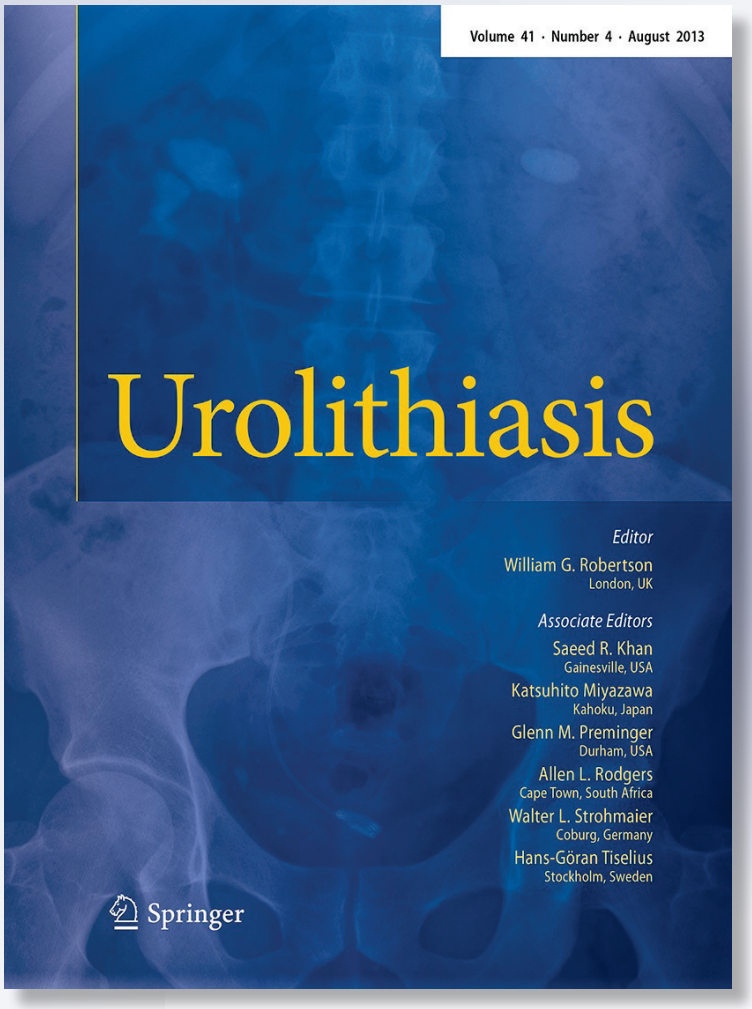

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ORIGINAL PAPER

Reproducibility of percutaneous nephrolithotomy in the Galdakao-modified supine Valdivia position

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Abstract To demonstrate that percutaneous nephrolithotomy (PCNL) in the Galdakao-modified supine Valdivia position can be safely and effectively reproduced by different surgeons. A multicentre retrospective cross-sectional case study on 317 patients was conducted. The centres enrolled were four hospitals from the Spanish National Health System and provided data for consecutive PCNL from January 2008 to December 2010. The patients were divided into two groups: the Galdakao group (134; operated on by the master PCNL surgeon) and the other surgeons group (183; operated on by the other surgeons). The results of the technique were analysed relative to success and complications. Finally, a multivariate analysis introducing the covariates age, gender, BMI, ASA and type of stone was performed (backward stepwise logistic regression). The univariate analysis did not reveal differences in age, gender and ASA scores ($p > 0.05$) between the Galdakao group and the other surgeons group. The success rate was 80.6 % in the Galdakao group and 72.7 % in the other surgeons group ($p = 0.01$), and the complication rate was 16.4 and 26.2 %, respectively ($p = 0.03$). Complications were categorised based on the Clavien classification, and no differences were discovered between the groups ($p = 0.19$). The logistic regression confirmed only the surgeon and the stone type as independent predictive variables. PCNL in the Galdakao-modified supine Valdivia position is feasible for the use by different urologic surgeons. The results depend on the surgeon's experience, but with specific training and, maybe, selecting the simplest cases at the beginning, it is possible to achieve competitive results.

Keywords Percutaneous nephrolithotomy · Supine position · Urolithiasis · Endourology

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Introduction

The first attempts to perform minimally invasive surgical procedures for treating urinary stones were in the 1970s [1–3] and they were always based on the first report of a percutaneous nephrostomy in the prone position [4]. Alken refined the percutaneous nephrolithotomy (PCNL) surgical technique in 1981 [5]. However, after the introduction of extracorporeal shockwave lithotripsy (SWL) in the 1980s, the use of the procedure declined. As clinical experience with SWL increased and the limitations of the technique became obvious, PCNL reemerged as an elective treatment for patients with large, multiple or staghorn stones. Over time, the therapeutic indications of each procedure have become fixed and a "co-existence" has been achieved.

For many decades, the prone position has been considered the only position by which to approach the kidney. In 1987, Valdivia described the supine approach for PCNL [6]. However, most urologists are reluctant to change from the prone position to the supine one. Two conditions may explain this reluctance. First, the prone position is the safest position due to the believed low risk of colonic and vascular injuries. Secondly, it is difficult to shift from a surgical technique that has a low rate of complications.

More recently, the Galdakao-modified supine Valdivia position has been described [7]. This technique is an additional step forward because it allows surgeons to perform a simultaneous anterograde and retrograde approach to the upper urinary tract for the treatment of complex ureteral and renal stones.

The aim of this study is to demonstrate that PCNL in the Galdakao-modified supine Valdivia position can be used by different surgeons and that it is a safe and effective surgical technique for patients.

Materials and methods

Study design

A retrospective transversal (cross-sectional) case study of 317 patients was conducted. To analyse the reproducibility of the technique, patients were divided into two groups: the Galdakao group (183 patients; operated on by the master or experienced PCNL surgeon and the other surgeons group (134 patients; operated on by the other surgeons). The results of the technique were analysed relative to success of stone removal and the rate of complications.

The main variables of interest were the stone-free rate and the rate of complications. The stone-free rate, as a predictor of procedural success, was defined as the absence of the stone or the presence of non-obstructive fragments of less than 5 mm. Thus, failure of the procedure was defined as the presence of obstructive residual stones or fragments larger than 5 mm.

The secondary variables were patient characteristics, stone type, complication type, fever rate and transfusion rate. Stone types were defined as *simple* (a pelvic and/or calyceal stone requiring only an easy single approach and the use of only a rigid nephroscope), *complex* (when more than one percutaneous approach and/or flexible endoscopes and/or combined access to the upper urinary tract with percutaneous and transurethral access were required) or *extremely complex* (a complete staghorn stone or anomalies in anatomy, such as multiple calyceal stones, a narrow infundibulum, an intrarenal pelvis or excluded calyces). The modified Clavien grading system [8] was used to standardise the classification of the overall perioperative morbidity and to enable comparisons between groups. The 9th International Classification of Diseases (ICD-9) [9] was used to label the complications in both groups.

The body mass index (BMI) was assessed based on the World Health Organization (WHO) classifications. Comorbidities were scored in four groups according to the ASA (American Society of Anesthesiologists).

The Chi-square test was used for statistical analyses of gender, ASA scores, stone-type data, access number, number of PCNLs per case, access type (subcostal, intercostal), calyx plane (anterior, posterior), dilation method (Alken, Amplatz, Amplatz one-shot, baloon) and urinary drainage (ureteral stent, nephrostomy, stent and nephrostomy, tubeless). The age, BMI and surgical time were compared using Student's t tests for independent groups. Finally, a multivariate analysis introducing the covariates age, gender, BMI, ASA and type of stone (variables with $p < 0.10$ were excluded) was performed (backward stepwise logistic regression). The criterion for statistical significance was set to $p < 0.05$ for all comparisons. Data were analysed using PASW Statistics version 18 (Statistical Package for the Social Sciences; SPSS Inc., Chicago, USA).

Data collection

The centres that were enrolled in this study were 4 hospitals of the Spanish National Health System: Galdakao Usansolo Hospital (Basque Country), Santiago de Compostela University Hospital (Galicia), Jerez Hospital (Andalusia) and Fuenlabrada University Hospital (Madrid). Ibarluzea's previous experience includes more than 1500 PCNLs, initially performed in the prone position and from 1993 performed only in the supine position. Surgeons A. J. and L. Ll. had previous experience of PCNL in the prone position and were instructed by Ibarluzea (as the PCNL master) in at least 2 PCNL procedures in the Galdakao-modified supine Valdivia position, after this they started operating on their own. D.F. previously performed a considerable amount of endourological procedures: flexible and rigid ureteroscopy and nephrostomy. He had 2 months training with the master surgeon and later began to operate alone.

Electronic databases were made available to the participating centres, and encrypted data were sent to the lead investigator. The lead investigator at each centre coordinated the data collection and submission to the central database. Each centre provided data for PCNL patients treated during the 2-year study period beginning in January 2008 and ending in December 2010.

Patients and procedures

Eligible patients for inclusion in this study were all those who underwent PCNL for the primary treatment of kidney stones that were larger than 2.5 cm or that were complex or

staghorn kidney stones. There were no specific exclusion criteria for age, body mass index (BMI), ASA classification or previous renal surgery. PCNL procedures were performed according to local clinical guidelines and practices and always used the Galdakao-modified supine Valdivia position [7].

The patients were placed in a supine position, with the leg of the operated side extended, while the contralateral one is well abducted. The patient lies supine with a 3-L saline bag under the flank, filled with air and clamped with forceps, allowing volume control by adding or subtracting air with a syringe, to find the best position. The ipsilateral arm crossed the chest. Care is taken to prevent pressure injuries using stirrups with padding for the upper and lower extremities.

This position allowed retrograde access to the urinary tract throughout the intervention. Two surgeons started to operate simultaneously, allowing them to share operative tasks during the entire intervention (Fig. 1).

To opacify the proposed target calix, retrograde pyelography was performed and a ureteral catheter was inserted. Ultrasonography and/or fluoroscopy during PCNL was used to locate the upper tract. The nephrostomy tract was achieved using an 18-gauge needle and dilation was performed using Amplatz serial dilation, high pressure baloon or metal telescopic dilation. After puncturing, the collecting system, a 0.038-in. nitinol guide-wire was inserted into the ureter. For balloon dilation, the dilator was inserted with the distal end in the collecting system and placed as close to the stone as possible. The balloon was then inflated using a pressure inflation device until fully inflated. The Amplatz sheath was inserted over the balloon and the balloon was then deflated and removed. For metallic telescopic dilators, each dilator was inserted over the previous dilator; thus, making the tract progressively larger; the Amplatz sheath was placed over and the dilators were then removed. Amplatz dilation involved the serial passage of plastic fascial dilators ranging from 10 to 24–30F. The Amplatz sheath was passed over the final dilator, and the dilator was again then removed. Amplatz one-shot dilation consisted of a direct pass of the final dilator after a minimal previous dilation, which was typically 10F or 12F. The sheath was passed over this final dilator as described above.

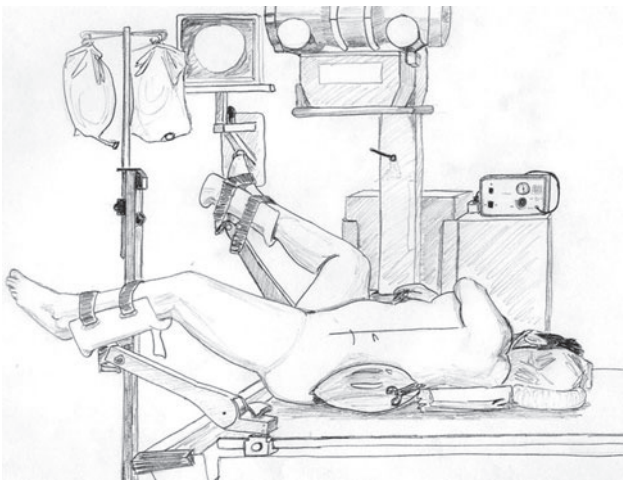

Fig. 1 Galdakao-modified supine Valdivia position. (*lateral view*). Drawing of Dr. M. Gamarra

The stone fragmentation devices used were pneumatic, a laser Holmiun-YAG or an ultrasonic lithotrypter. On many occasions, different lithotripters were used in the same operation.

The patients were followed-up at an outpatient clinic using plain abdominal radiography, ultrasonography or CT scans (depending on the local clinical practices) until their clinical status was clear (stone free, with clinically insignificant residual fragments, or failure of the procedure). Only the Santiago de Compostela group, encompassed within the Other surgeons group, evaluated the results using CT scans. The Galdakao group and the remaining other surgeons evaluated their results through simple radiology and ultrasonography.

The severity of bleeding, fever, other complications and the requirement for blood transfusions were assessed, and the patients were treated according to local practice guidelines. Patient characteristics, perioperative complications, and treatment outcomes were assessed by the treating physician. Institutional Review Board approval was not required at participating centres, and the lead investigator was responsible to ensure the quality of clinical data collected.

The univariate analysis did not show differences between the Galdakao group (surgeon Ibarlucea) and the other surgeons group relative to age, gender, BMI and ASA score ($p > 0.05$). However, the Galdakao group included more extremely complex stones than the other surgeons group ($p = 0.002$; Table 1).

Results

The first patient was entered into the database in January 2008 and the database closed in December 2010. The study database included 317 patients. The patients were distributed as follows: 134 (42.4 %) in the Galdakao (G.I.) group, 65 (20.57 %) in the Fuenlabrada (L.Ll.) group, 42 (13.30 %) in the Jerez (A.J.) group and 76 (24.05 %) in the Santiago (D.P.) group. Finally, patients were grouped based on surgical proficiency. Thus, two groups were generated: the Galdakao group, in which patients were operated on by the PNCL master surgeon, and the other surgeons group.

Table 1 Demographics of the patients

Characteristics	Galdakao group ($n = 134$)	Other surgeons ($n = 183$)	p value
Gender (%)			
Female	86 (64.2)	112 (61.2)	0.59
Male	48 (35.8)	71 (38.8)	
Mean age (95 % CI)	52.02 (49.54–54.51)	53.53 (51.51–55.54)	0.35
Mean BMI (95 % CI)	28.11 (26.98–29.23)	29.20 (27.82–30.58)	0.22
ASA score (%)			
1	36 (26.9)	45 (24.6)	0.50
2	67 (50)	105 (57.4)	
3	29 (21.6)	32 (17.5)	
4	2 (1.5)	1 (0.5)	
Stone type			
Simple (%)	16 (11.9)	51 (27.9)	0.02
Complex (%)	74 (55.2)	74 (40.4)	
Extremely complex (%)	44 (32.8)	58 (31.7)	

ASA American society of anesthesiologists, *BMI* body mass index (kg/m^2), *CI* confidence interval

The success and complication rates were, respectively, larger and lower in the Galdakao group when compared with the other surgeons group. The success rate was 80.6 % in Galdakao group and 72.7 % in the other surgeons group ($p = 0.01$) and the complication rate was 16.4 and 26.2 %, respectively ($p = 0.03$). No differences in the severity of complications, based on the modified Clavien grading system, were found between groups. However, the severe Clavien 3a to 5 complications were 100 % more frequent in the other surgeons group (15/48) than in the Galdakao group (7/22) (Tables 2, 3).

ICD-9 was used to label and compare complications in both groups, and no differences were found (Table 4).

The backward stepwise logistic regression confirmed that only the surgeon and the stone type were independent predictive variables. A multivariate analysis of the stone-free rate showed that the Galdakao group resolved 2.6-fold more than the other surgeons group (CI 95 % 1.38–4.9, $p = 0.003$). Similarly, the variable stone type was confirmed as a statistically independent variable ($p < 0.05$). The complex stones resolved 4.7-fold less and the extremely complex resolved 22 times less (CI 95 % 6.5–77.5, $p < 0.05$) than the simple stones. The other surgeons group presented with 1.86-fold more complications (CI 95 % 1.03–3.34, $p = 0.037$). The complexity of the stone was again a statistically independent variable ($p = 0.003$). Complications in cases with complex stones occurred 1.4-fold more than complications in cases with simple stones, whereas complications in cases with extremely complex stones occurred 3.2-fold more than in cases with simple stones (Table 5).

Discussion

The Galdakao-modified supine Valdivia position enables simultaneous retrograde and anterograde access to renal cavities for the treatment of kidney and ureteral stones in a single surgery. The technique also enables an absolute technical refinement of the means of access by allowing the puncture of the chosen calyx with endoscopic control via a flexible ureteroscope (endovision puncture). A prospective study showed that endoscopic-combined intrarenal surgery (ECIR) in the Galdakao-modified supine position is safe, effective and versatile, with a high stone-free rate following a single surgery and anaesthetic benefits without additional procedure-related complications [10].

There is a widely held view that the supine position during PCNL is as effective and safe as the prone position, and that it is also equivalent with regard to the stone-free rate, and rates of complications and transfusion fever. However, more importantly, this position offers some advantages over the prone position: lower rates of cardiovascular alterations, reduced requirement for repositioning the patient during surgery thus lowering overall operating time, less risk of injury to the central and peripheral nervous system, reduced exposure of the surgeon to X-rays because their hands are outside the irradiation field, and a lower risk of colonic injury [11–20].

Recently, two meta-analyses have been published [21, 22] that evaluated the efficacy and safety of PCNL in the supine and prone positions. It is noteworthy that the selection criteria of the meta-analyses were highly rigorous. The quality criteria (sensitivity analysis) allowed selection of only four articles: two controlled clinical trials and two case–control studies. Both meta-analyses showed that the length of time for NLP in the supine position is shorter than when in the prone position, although both are equivalent in the stone-free and complication rates. Finally, both studies concluded that the supine NLP is as effective and safe as the prone position, and therefore the supine position is an alternative option for treating kidney stones.

Table 2 Characteristics of the surgical procedures

Characteristics	Galdakao group ($n = 134$)	Other surgeons ($n = 183$)	p value
Mean surgical time (CI 95 %)	131.07 (120.49–141.64)	97.43 (91.23–103.58)	0.001
Access number (%)			
1	122 (91.04)	172 (93.98)	0.44
2	11 (8.20)	11 (6.01)	
3	1 (0.75)	0 (0)	
Number of PCNLs per case (%)			
1	114 (85.07)	165 (90.16)	0.25
2	16 (11.94)	16 (8.74)	
3	3 (2.24)	1 (0.54)	
Access type (%)			
Subcostal	133 (99.25)	182 (99.45)	0.82
Intercostal	1 (0.75)	1 (0.54)	
Calyx plane (%)			
Anterior	30 (22.38)	11 (6.01)	0.000
Posterior	103 (76.86)	144 (78.68)	
Anterior and posterior	1 (0.75)	0 (0)	
Dilation method (%)			0.000
Alken	0 (0)	1 (0.54)	
Amplatz	122 (91.04)	55 (30.05)	
Amplatz one-shot	0 (0)	1 (0.54)	
Ballon	12 (8.95)	126 (68.85)	
Urinary drainage (%)			
Ureteral stent	103 (76.86)	174 (95.08)	0.000
Nephrostomy	133 (99.25)	172 (93.98)	0.000
Both	97 (72.38)	162 (88.52)	0.001
Tubeless	0 (0)	10 (5.46)	0.02

CI confidence interval

Some disadvantages or limitations of the supine position have been alleged. Firsty, nephroscopy is more complicated because the renal cavities are continually collapsed when working at low irrigation pressure, leading also to a limited space for a third nephrostomy tract. Secondly, the dilation is more difficult because of the anteromedial movement of the kidney during the manoeuvers. Moreover, both the anterior accesses and the superior calyx punctures are made difficult. The former due to the acute angle between the operating table and the anterior calyx, and the latter because the upper pole is more medial and posterior, sinking into the thoracic cage. Finally, critics have argued that this supine position is operator-dependient, hampering the reproducibility of the technique.

Solutions to some of these drawbacks have already been developed. For kidney-cavity collapse during nephroscopy, an infusion pump is recommended, which increases temporarily the flow of irrigation to the correct pyelocalyceal tree filling. The use of the Amplatz sheath in the supine position, decreases pelvicaliceal system pressure, because drainage through the sheath is enhanced by gravity. However, it is important to maintain pressure below 100 mm Hg to prevent pyelo-lymphatic and pyelovenous backflow, which can lead to bacteriemia.

To minimise anteromedial kidney movement during tract dilatation, manual extra-abdominal compression at the ipsilateral upper quadrant and flank could be performed [23]. The limited space for a third tract of access is a minor disadvantage because this position enables transurethral and percutaneous access in different combinations to reach all calyces [7, 11]. Only in cases of two lower calyceal groups with a very sharp infundibular-pelvic angle may a second access path be required.

In this report, we show that this surgical technique is feasible for use by different surgeons. Minimal experience in endourological intervention is sufficient at the beginning. However, to gain tips and tricks, to habituate to the creation of the nephrostomy tract and to anatomically orient oneself in an unusual position, the first operations must be supervised by an expert surgeon. The increasing experience of the surgeon enables them to undertake more technically complex surgeries over time, and this position

Table 3 Analysis of the success and complication rates based on surgical proficiency

	Galdakao group ($n = 134$)	Rest of surgeons ($n = 183$)	OR (CI 95 %)	p Value
Results (%)				
Success	108 (80.6)	133 (72.7)	2.59 (1.38–4.9)	0.01
Failure	26 (19.4)	50 (27.3)		
Complications (%)				
Yes	22 (16.4)	48 (26.2)	1.81 (1.03–3.18)	0.039
No	112 (83.6)	135 (73.8)		
Clavien (%)				
0[a]	112 (83.8)	135 (73.8)		0.19
1	7 (5.2)	19 (10.4)	2.25 (0.91–5.50)	
2	8 (6.0)	14 (7.7)	1.45 (0.58–3.58)	
3a	0 (0)	1 (0.5)	N.C.	
3b	6 (4.5)	6 (3.3)	0.83 (0.26–2.64)	
4a	0 (0)	2 (1.1)	N.C.	
4b	0 (0)	5 (2.7)	N.C.	
5	1 (0.7)	1 (0.5)	0.83 (0.05–13.41)	
Transfusion (%)				
Yes	10 (7.5)	14 (7.7)		0.3
No	124 (92.5)	169 (92.3)		
Fever (%)				
Yes	10 (7.5)	20 (10.9)		0.95
No	124 (92.5)	163 (89.1)		

The odds ratios were calculated based on the reference category (Galdakao group). The modified Clavien grading system was used to standardise the classification of the overall perioperative morbidity and to enable comparisons between groups

OR odds ratio, *NC* not calculated

[a] Reference category

Table 4 Complications categorised by the International Classification of Diseases (ICD-9)

ICD 9-defined complications (%)	Galdakao group ($n = 22$)	Rest of surgeons ($n = 48$)	p Value
590.2 Renal and perinephric abscess	0 (0)	1 (0.5)	0.25
293.0 Delirium due to conditions classified elsewhere	1 (0.7)	0 (0)	
110.3 Dermatophytosis of groin and perianal area	1 (0.7)	0 (0)	
789.0 Abdominal pain	0 (0)	1 (0.5)	
788.0 Renal colic	0 (0)	2 (1.1)	
782.3 Oedema	1 (0.7)	0 (0)	
780.6 Fever and other physiologic disturbances of temperature regulation	7 (5.2)	16 (8.7)	
593.82 Ureteral fistula	0 (0)	4 (2.2)	
599.7 Haematuria	1 (0.7)	3 (1.6)	
998.1 Haemorrhage or hematoma or seroma complicating a procedure	4 (3.0)	6 (3.3)	
591 Hydronephrosis	5 (3.7)	3 (1.6)	
599.0 Urinary tract infection, site not specified	1 (0.7)	0 (0)	
956.3 Injury to perineal nerve	0 (0)	1 (0.5)	
787.01 Nausea with vomiting	0 (0)	1 (0.5)	
507.0 Aspiration pneumonia due to inhalation of food or vomitus	0 (0)	1 (0.5)	
682 Other cellulitis and abscess	0 (0)	1 (0.5)	
998.0 Postoperative shock during or resulting from a surgical procedure	1 (0.7)	6 (3.3)	

will ensure the greatest possible success rate. This report demonstrates that a group of 3 surgeons, with no previous experience in supine PCNL, almost reproduced the results of a PCNL master surgeon (80.6 % success rate in the Galdakao group versus 72.7 % in the other surgeons group; the complication rate was 16.4 and 26.2 %, respectively). Furthermore, the rate of complex and highly complex lithiasis operated on (72.1 % in the Galdakao group and

Table 5 Multivariate analyses (backward stepwise logistic regression) of the factors associated with postoperative complications and success of the procedure (variables with $p < 0.10$ were excluded)

Covariates	Postoperative complications				Procedural success			
	p value	OR	CI 95 %		*p* value	OR	CI 95 %	
			Inferior	Superior			Inferior	Superior
Stone type								
Simple[a]	0.003				<0.05			
Complex	0.45	1.37	0.61	3.08	0.016	4.71	1.34	16.53
Extremely complex	0.004	3.24	1.45	7.22	<0.05	22.41	6.47	77.56
Surgeon (Galdakao/Others)	0.04	0.54	0.30	0.96	0.003	2.60	1.38	4.9

[a] Reference category

88 % in other surgeons Group) was higher than in the series of supine and prone positions presented to date [21, 24, 25].

Our results may have been affected by the differences in previous experience between surgeons and the variability in th selection of cases between groups. All the groups had the same availiability of resources (lithofragmentation methods, flexible endoscopes and extraction devices) so the surgeon's experience and the stone complexity could account for differences in results more than the provision of material.

Differences in procedure characteristics reflect each surgeon personal choices: dilation method, type of urinary drainage and calyx puncture plane. No differences were found in the access number, number of PCNLs per case or access type (subcostal, intercostal). However, the mean operating time was significantly higher in the Galdakao group, which can be explained by the greater number of extremely complex stones.

Finally, we emphasise the creation of a system to classify renal stones that is easy to understand and very practical in a surgical environment. This classification would enable accurate discussion of the stone characteristics treated by PCNL.

Conclusions

One of the alleged limitations of the supine position during PCNL is the believed dependence of the results on the surgeon (operator-dependent surgery). With regard to this point, our paper demonstrates that PCNL in the Galdakao-modified supine Valdivia position is feasible for use by different urologic surgeons (not only by its creator), and that the results depend upon the surgeon's experience, as with any surgical technique, but that with specific training and, maybe, selecting the simplest cases at the beginning, it is possible to achieve competitive results with regard to rates of procedural success and complications.

Conflict of interest The authors declare that they have no conflict of interest.

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