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ORIGINAL PAPER

Pre- and perioperative predictors of short-term clinical outcomes in patients undergoing percutaneous nephrolitholapaxy

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Abstract Percutaneous nephrolitholapaxy (PCNL) with modern stone disintegration technologies is the treatment of choice for patients with extensive stone burden or stones refractory to extracorporeal shock wave lithotripsy. However, little is known about factors predicting unfavourable outcome in terms of perioperative complications, residual stone burden or prolonged hospitalization. The aim of this study was to evaluate preoperative, patient- and stone-related parameters that might influence the perioperative course and short-term clinical outcomes. In a prospective study, age, sex, body mass index (BMI), bidimensional size, side, pre-existent urinary tract infection, pre-existent hydronephrosis and previous kidney surgery were used as independent variables in both univariate and multiple regression models in 109 PCNL patients in order to predict the partition of patients rendered stone free at hospital discharge, duration of surgery, length of inpatient hospital stay and the occurrence of major complications. Univariate and multiple regression analysis revealed that stone size was the only factor influencing duration of surgery ($P < 0.001$) and hospitalization ($P = 0.02$), but had no predictive potential for major complications. Univariate analysis showed a trend towards longer inpatient hospital stay and clinically relevant residuals in patients with lower BMI ($P = 0.05$ and 0.06); however, after controlling for the other confounding variables, this was only reproducible for residual stone burden. The other patient- and stone-related factors did not adversely affect the outcome measures. In our patient sample treated with PCNL by LithoClast® Master/Ultra we found evidence that large stone burden is a prognostic factor predicting longer surgery and prolonged hospitalization. In addition, patients with lower BMIs might be at higher risk of not being stone free at hospital discharge accompanied by prolonged inpatient treatment.

Keywords Nephrolithiasis · Percutaneous surgery · Prognosis · Short-term outcome

Introduction

Over the last three decades the therapeutic approach to urolithiasis has changed substantially. The advent of extracorporeal shock wave Lithotripsy (SWL) and the development of endourological devices to obtain endoscopic access to and direct visualization of the upper urinary tract by uretero—or nephroscopy forced open surgery into the second line of stone therapy [1–3]. Success rates of SWL are excellent in the kidney [4] as well as in the upper, middle and distal ureter [4, 5]. In the distal ureter interventional endoscopy appears to be even more effective than SWL [6]. Percutaneous nephrolithotomy (PCNL) was introduced in the 1970s and has opened another door to intracorporeal stone therapy [7]. Profound knowledge of the kidney's vascular anatomy, high-quality imaging [8] and refinement of access procedures have reduced access related complications, i.e. especially severe hemorrhage, to a minimum. Multiple punctures and supracostal access to the upper pole are feasible and safe alternatives for complex stones in experienced hands [9, 10]. In the 1980s and 1990s many

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disintegration technologies like electrohydraulic lithotripsy (EHL), ballistic lithotripsy, ultrasonic lithotripsy and laser lithotripsy have been developed and evaluated for the use in PCNL. Nowadays, the combined application of ballistic and ultrasonic lithotripsy (LithoClast Ultra®) seems to be a very efficient tool for the disintegration of large stone burden and has been used in several published series on PCNL in the last years [11, 12]. Laser technology for PCNL is very promising and has the advantage of being applicable in flexible devices. However, there is little evidence about which patient- and stone-related factors are related to the complication profile and clinical outcome of patients undergoing PCNL. Recent publications usually investigate only one outcome variable, e.g. fever [13], postoperative pain, blood loss [14] or occurrence of urosepsis [15] or a restricted set of independent variables like pretreatment of the affected kidney [16], bilaterality of the intervention, type of nephrostomy tube, patient age [17] or obesity [18]. To our knowledge, there is only one multiple regression analysis from Desai's group that showed preoperative haemoglobin, multiple access tracts and stone size to be independent predictors of perioperative transfusion requirement [14]. Thus, the purpose of the present study was to evaluate prospectively under standardized conditions in a multiple regression approach, if there are predictors of short-term therapeutic success in terms of stone free status, duration of surgery, length of hospital stay and peri- and postoperative complication profile.

Patients and methods

Between January 2003 and July 2005 all 109 consecutive patients undergoing PCNL at our department were prospectively evaluated; no in- or exclusion criteria were defined. Patients without preoperative urinary tract infection (UTI) received perioperative antibiotic prophylaxis (Cefuroxim 1.5 g i.v.). Patients with pre-existing UTI were pretreated for at least 2 days according to antibiogram of the urine culture; antibiotic therapy in these patients was continued until removal of nephrostomy and/or internal stent. After accessing the pelvicaliceal system by puncture and standardized tract dilation by coaxial rigid bougies, stone disintegration was performed by combined ultrasonic and pneumatic lithotripsy using the LithoClast® Master/Ultra system (EMS Medical, Nyon, Switzerland). Demographic, peri- and postoperative data were collected on a standardized data acquisition form. A summary of the sample is depicted in Table 1. The following parameters were chosen as independent variables: age, sex, body mass index (BMI in kg/m^2), affected side, stone size (largest diameter on KUB—film in mm), presence or absence of preoperative hydronephrosis, presence or absence of preoperative UTI and presence or absence of previous open or percutaneous kidney surgery. Four outcome measures were evaluated: stone-free status after one treatment session, length of inpatient hospital stay in days, duration of surgery and occurrence of major complications. Stone-free status after one treatment session was reported after review of the postoperative KUB—X-ray by an independent investigator. The definition of stone free was the complete absence of residual fragments on KUB or the endoscopic absence of residuals in case of radiolucent stones. Duration of surgery was defined as the time in minutes from starting puncture to radiographic control of nephrostomy tube position and documented by the scrub nurse. Major complications were defined as complications requiring active therapy or prolonging hospital stay (sepsis, urinoma, hemorrhage requiring transfusion and fistula).

Table 1 Patient characteristics ($n = 109$)

Variable	Mean (range) or per cent
Age [years]	53.4 (12–83)
Stone size [mm]	28 (6–70)
Body mass index	28.8 (17–45)
Sex (female/male)	50/50
Side (right/left)	40.6/59.4
Pre-existent hydronephrosis (yes/no)	43.8/56.6
Pre-existent urinary tract infection (yes/no)	9.1/90.9
Stone composition (proportion struvite)	19.2
Previous open or endoscopic kidney surgery on affected side (yes/no)	27.4/72.6

Statistical analysis

Each outcome was first analysed by univariate logistic regression analyses. Due to hints for violations of assumptions for quantitative analyses (data not shown) and in order to simplify the presentation, it was decided to dichotomize the quantitative outcomes by a median-split which of course implies a violation of the rare disease assumption. All outcome evaluations were also done in a multiple logistic regression framework jointly including all independent variables. Furthermore, all variable selection methods implemented in SAS (PROC LOGISITIC, Version 8.2) were used to explore the robustness of the results (data not shown). Due to the relatively small sample size, no interactions effects were investigated. Deviations from the additivity assumption of the logistic regression were explored by Hosmer and Lemeshow [19] procedure. No cross-validation of the derived prognostic model was possible. A nominal significance level α of 0.05 (two-sided) was used.

Results

Patient characteristics are summarized in detail in Table 1. The BMI in our study population was below 25 in 26%, 25–29.9 in 32% and 30 or higher in 42% of patients. Maximal stone diameter (25, 35 and 29 mm, respectively) did not differ significantly between the three groups. In 30.2% only the lower calyx was affected, 34% had isolated renal pelvic stones and 35.8% had partial staghorn calculi. In our patient sample, there was no staghorn—or isolated upper calyx calculus. Multiple tract procedures were necessary in only three patients. About 8.4% of the patients had a second look PCNL, 17% underwent an additional SWL during the same hospital stay. Stone size (33 mm vs. 25 mm, $P = 0.08$) and duration of surgery (66 min vs. 54 min, $P = 0.17$) were not significantly different in patients with and without auxiliary interventions. Overall, stone-free rate after the first PCNL was 72% and increased to 81% until discharge from hospital; the duration of surgery was 56 (range 10–175) min. Major complications occurred in 9% of the patients treated with PCNL (fistula, managed by internal stenting: two pts.; acute hemorrhage: five pts.; sepsis: four pts.) such that the non-significant correlations with the predictors may also be due to a reduced variablity within our sample. A percutaneous nephrostomy tube and internal stent were placed intraoperatively in 98 and 100% of patients. The devices were removed after 4 (range 0–16) and 15 (range 1–29) days in average. Median length of hospital stay was 7 days (range 3–26).

In the univariate analyses (see Table 2) BMI showed a trend towards being a positive predictor of absence of stones after surgery, i.e. larger BMIs were associated with a higher probability of absence of stones. Furthermore, stone size was the only significant predictor of duration of surgery. However, there was some evidence that previous kidney surgery may also be related with longer duration of surgery. Lower BMI and again stone size were the only variables that could be associated with longer patient hospitalization. Finally, the occurrence of major complications was not significantly related to any of the investigated variables.

After multiple regression analyses including all other predictor variables, there remained some evidence that a higher BMI is associated with a higher probability for the patient to be rendered stone free at hospital discharge. For duration of surgery, the multiple regression model indicated the side of the stone (right) and to some extent the size of the stone as independent predictors. Here it has to be noted that the side of the stone was no significant predictor in the univariate analyses and that a closer look at that data revealed that right sided stones were slightly larger than left sided stones (35 mm vs. 30 mm, $P = 0.09$). Thus, in either case "stone size" might have been the relevant variable. On the other hand, there was evidence that both lower BMI and to some extent the stone size remained independent predictors for the length of inpatient hospital stay after controlling for the other independent variables. The lack of association of any of the chosen independent variables with the occurrence of major complications was also found in the multiple regression analyses.

Discussion

Today, PCNL is considered to be the standard procedure for the treatment of nephrolithiasis in patients with large stones (larger than 2 cm in diameter), especially staghorn calculi or smaller symptomatic stones refractory to SWL therapy. Depending on stone size and formation, 80% of patients or more are rendered stone free after one therapy session and complication rates are supposed to be low with major complications occurring in 10% or less of cases [20, 21]. Although open surgery might still have its role in selected patients, the advantages of PCNL in terms of perioperative morbidity appear to be evident [22]. Over the last two decades, four outcome measures have evolved, probably giving endourologic surgeons a reasonable tool to appraise the quality of PCNL in terms of therapeutic success, safety and economic efficiency: stone-free rates at hospital discharge, duration of surgery, length of hospital stay and the rate of major complications. The present study was intended to evaluate the most important patient- and stone-related variables in order to predict these outcome measures. This was done by univariate and multiple logistic regression models. The LithoClast® Master was chosen as disintegration device, because of its high-disintegration efficiency, not depending on stone composition or hardness [11].

The portion of patients rendered stone free at discharge from our institution was in accordance with the literature [20, 21]. By second look PCNL or SWL after the first therapeutic session it could be increase to 81% until discharge; stone size did not seem to influence the need for auxiliary interventions. However, analysing therapeutic success in comparison with the literature using the surrogate parameter of "stone free" status harbours some pitfalls. In the literature, there is no general agreement about the correct and clinically relevant definition of "stone free" [23, 24]. Is it necessary to remove every fragment and render the patient radiologically and endoscopically free of residuals, as advocated by some [25–27]? Or is it acceptable to leave small fragments (4 mm or smaller) in situ that are likely to be clinically irrelevant and pass spontaneously [28]? Both definitions are used in the recent literature, but there is only longer-term follow-up data for SWL and there are no conclusive data about reintervention and hospital readmission

Table 2 Univariate and multiple logistic regression analysis; odds ratio (95% confidence interval); nominal two-sided *P*-value with $P \leq 0.05$ in the univariate or in both analyses in bold

Independent variable (reference or units category for odds ratio calculation)	Duration of surgery (cut-off >40 min) OR (95% CI) *P*		Length of hospital stay (cut-off >6 days) OR (95% CI) *P*		Major complications OR (95% CI) *P*		Stone free at discharge OR (95% CI) *P*	
	Univariate regression analysis	Multivariate regression analysis	Univariate regression analysis	Multivariate regression analysis	Univariate regression analysis	Multivariate regression analysis	Univariate regression analysis	Multivariate regression analysis
Sex (female)	0.80	1.08	0.67	0.62	1.26	1.21	1.98	1.40
	(0.34–4.76)	(0.38–3.04)	(0.30–1.57)	(0.22–1.74)	(0.49–3.28)	(0.36–4.12)	(0.62–7.10)	(0.39–5.65)
	0.70	0.89	0.44	0.36	0.75	0.76	0.32	0.27
Age (10 years)	0.84	0.94	1.05	1.17	1.18	1.07	1.05	1.17
	(0.66–1.07)	(0.69–1.28)	(0.83–1.33)	(0.86–1.58)	(0.91–1.53)	(0.77–1.49)	(0.813–1.54)	(0.77–1.68)
	0.16	0.70	0.69	0.32	0.22	0.68	0.54	0.59
BMI (five BMI-points)	1.16	1.34	0.68	0.652	1.08	0.92	1.72	2.04
	(0.80–1.68)	(0.83–2.15)	(0.45–0.99)	(0.42–1.03)	(0.71–1.66)	(0.57–1.51)	(0.98–2.97)	(1.10–3.76)
	0.44	0.23	**0.05**	0.07	0.74	0.75	0.06	**0.02**
Side (right)	1.96	3.87	0.99	0.83	1.42	2.15	0.48	0.55
	(0.83–4.76)	(1.35–11.09)	(0.42–2.30)	(0.31–2.23)	(0.54–3.90)	(0.66–7.00)	(0.18–1.39)	(0.16–2.20)
	0.14	0.01	1.00	0.71	0.58	0.20	0.20	0.49
Size (5 mm)	1.27	1.20	1.16	2.16	0.95	0.93	0.97	0.99
	(1.10–1.51)	(1.00–1.45)	(1.02–1.34)	(1.09–4.30)	(0.83–1.10)	(0.78–1.11)	(0.80–1.19)	(0.77–1.22)
	<0.001	**0.05**	**0.02**	**0.03**	0.48	0.45	0.72	0.66
Previous surgery (no previous surgery)	2.654	2.75	1.40	0.63	0.63	0.40	0.89	1.59
	(1.00–7.54)	(0.77–9.79)	(0.55–3.63)	(0.19–2.03)	(0.23–1.78)	(0.12–1.42)	(0.24–3.52)	(0.39–7.05)
	0.05	0.12	0.58	0.43	0.44	0.16	1.00	0.48
Pre-existent UTI (no pre-existent UTI)	0.45	0.29	1.23	1.78	1.26	1.16	0.39	0.30
	(0.12–1.46)	(0.07–1.23)	(0.38–4.05)	(0.48–6.64)	(0.34–5.81)	(0.26–5.26)	(0.16–1.68)	(0.10–1.38)
	0.21	0.09	0.89	0.39	0.97	0.85	0.27	0.15
Pre-existent hydronephrosis (no pre-existent hydronephrosis)	1.19	1.66	0.79	0.83	0.76	2.321	1.11	0.84
	(0.51–2.78)	(0.59–4.63)	(0.34–1.82)	(0.30–2.29)	(0.30–1.97)	(0.70–7.74)	(0.35–3.78)	(0.29–3.30)
	0.81	0.34	0.68	0.71	0.69	0.17	1.00	0.76

BMI body mass index, *UTI* urinary tract infection rates (e.g. due to colic or hydronephrosis) after PCNL leaving those "irrelevant" residuals in the pelvicaliceal system. At least for SWL, there seems to be some evidence in favour of those patients rendered completely stone free. In our cohort, no patient was readmitted or needed reintervention due to stone-related obstruction, however, in line with the recent literature and the post-ESWL-data, we decided to accept only patients completely free of residuals (reviewed by an independent radiologist) for allocation into the stone free group. The issue of the relevance of small residuals is addressed in an ongoing evaluation with long-term follow up at the corresponding author's institution.

Several groups addressed the question of PCNL in obese and morbidly obese patients. Koo et al. [29] found no influence of BMI on PCNL outcome as defined by stone-free rates, blood loss, analgesic use and hospital stay, complications, duration of surgery and hospital stay. Their results confirm the findings of other groups [18]; however, some authors described higher complication rates and prolonged hospital stay in very obese patients [30]. In our univariate analysis, we found some evidence for a negative correlation between BMI and hospital stay, i.e. a smaller BMI was predictive for a prolonged hospital stay. However, after controlling for the other confounding variables, this effect was no longer significant. Noteworthy, in our cohort, obesity was independently, but inversely correlated with the probability not to be stone free at discharge. It remains unclear how to interpret this unexpected result; however, it underscores that obesity is apparently no adverse factor for this outcome measure. To answer the question if extreme obesity might be of clinical relevance a study with a greater proportion of morbidly obese people needs to be conducted. Major complications were not predictable by BMI.

Retrospective case series comparing patients older than 60 or 65 years found PCNL to be a safe procedure, not associated with more frequent or more serious complications [17, 31]. The present work, focussing on the prediction of short-term outcomes, showed that there was no evidence for assuming that age is a strong predictor for any of the four investigated outcome variables. The same was true for the variable gender which is in accordance with all larger series of the last decade including sex into their analyses.

Furthermore, our analyses revealed no evidence for a relationship of potentially complicating patient-related factors like UTI or pre-existent hydronephrosis with the outcome measures in our study, neither in univariate nor after multiple regression analysis. In particular, for major postoperative complication rates there was no significant relationship to the presence of preoperative UTI. In general, postoperative fever seems to be a frequent phenomenon in the postoperative course of PCNL but the progression to sepsis is uncommon [13] in the era of perioperative antibiotic prophylaxis and it appears to be quite difficult to predict who is likely to develop an infectious complication and who is not [15]. In a multivariate approach, Kukreja et al. could not show properative UTI to be an independent predictor of intraoperative blood loss [14]. In our data, previous open or percutaneous kidney surgery seems to have some influence on duration of surgery in univariate analysis. However, when jointly investigated with the other predictors the effect vanished. This is in accordance with other, retrospective series examining PCNL in pretreated kidneys [16, 32].

Finally, the only parameter with a major prognostic value on operative time and inpatient hospital stay, but not on the complication rate nor on the stone-free status at hospital discharge, for our patient sample was stone size. Surprisingly, the body of literature analysing stone size as prognostic factor for clinical and economic outcome measures is small. Kukreja et al. found stone size to be an independent predictor of transfusion requirement; however average stone size in their cohort was larger than 500 mm^2 [14]. Other contemporary series showed PCNL to be a safe and efficient procedure in large and complex stones, even in children or in the elderly [17, 33].

In conclusion, in our series PCNL appears to be a highly standardized and safe procedure with a favourable clinical outcome profile that is comparable to the series of other groups. In this study short-term outcomes were not affected by the majority of patient- and stone-related variables. There was limited evidence that patients with lower BMIs showed prolonged hospitalization and had a higher probability of not being "stone free" at hospital discharge. This finding is difficult to interpret; however it underscores the fact that obese patients are not at higher risk for adverse outcome in PCNL. More clearly, stone size was found to be a predictor of both longer operating time and longer hospitalization. These results might be useful in counselling patients preoperatively, especially those with putative risk factors like a pretreated kidney. Again, overweight does not seem to be of disadvantage in terms of short-term clinical outcome.

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