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ARTICLE

Single centre versus multi-centre pooled morbidity data in PCNL and the implications for informed consent

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ABSTRACT

Background: National and international outcome data following PCNL have been available for many years, but multi-centre data may not reflect the outcome from an individual surgeon or hospital.

Methods: A combination of retrospective and prospective single centre data was collated from 2000–2016 and are compared to large single and multi-centre series.

Results: Data were available on 801 unique cases performed between 2000 and 2016, mean age = 55.2 (SD = 14.8) (range = 17–93). The mean change in haemoglobin after PCNL was 1.65 g/dL ± 0.05, $n = 630$. Twenty-seven patients required a blood transfusion (3.37%). In 470 cases, data on pre-operative urine culture was available. One hundred and nineteen (25%) demonstrated evidence of bacteriuria pre-operatively. The most common isolated species were E. Coli and Proteus Mirabilis. Pre-operative urine infection was associated with a greater drop in haemoglobin following surgery, but this difference was not found to be statistically significant. Changes in serum creatinine and eGFR rise following surgery were calculated. The mean rise was found to be 15.21 µmol/L (SE = 2.08, $n = 208$). The mean drop in eGFR was estimated to be 7.35 ml/min/1.73 m^2 (± 0.895, $n = 205$). Eight cases of 801 (1%) required admission to higher level care. There was one small bowel puncture and one pleural perforation recorded. Sub-selective embolization due to bleeding occurred in six cases (0 .75%) and there were no peri-operative deaths in this series. Published data comparing single centres with > 500 cases are presented.

Conclusion: To facilitate transparent consent, single-centre rather than pooled outcome data should be utilized.

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KEYWORDS
PCNL; consent; outcome data

Introduction

Percutaneous nephrolithotomy (PCNL) has been part of routine urological practice for over four decades and considerable variation exists within the published literature on objective surgical outcome and post-operative morbidity [1–4]. Data on post-operative morbidity that are utilised both during the process of obtaining informed consent and to guide and rationalise regional and national clinical practice often rely on centrally collected, pooled data [5].

A patient registry has been defined as 'an organized system that uses observational study methods to collect uniform data to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s)' [6]. Data entry into such registries is reliant on the engagement of the individual surgeon as well as the accuracy and completeness of the data entered [7]. This could act as a confounding factor when comparing complications following any surgical procedure.

The interpretation of this information by patients is also affected by their ability to appreciate the impact of outcomes in smaller series, where one complication can dramatically skew the data, and across the heterogeneous effects of PCNL in varying treatment subgroups. Furthermore, the complexity of cases may vary between institutions and individual surgeons. The implications of a surgeon or centre being an outlier in these series may therefore be poorly understood.

Discussions around consent for a procedure should be tailored to the individual patient. This includes the options for treatment, including non-operative care and no treatment, the clinicians involved in their treatment, the risks inherent in the procedure, however small the possibility of their occurrence, side-effects and complications and the likelihood of success. The relevance of data informing this process is compared between a very large UK single-centre series, performed over 16 years, with outcome data from other large national and international single-centre and pooled data series.

Methods

Combinations of retrospective and prospective data were collected in a large UK district general hospital with a tertiary referral population of over one million.

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All procedures were performed by one of three experienced endo-urological surgeons with the patient in the prone-flexed position. Two cases were performed supine.

Radiological access was achieved by the operating surgeon under fluoroscopic guidance, utilising either graduated, semi-rigid dilators or balloon tract dilatation (Nephromax™) [8] and a 30 F Amplatz sheath. Both mechanical stone destruction and ultrasound with suction (Swiss LithoClast™) were used in all cases throughout this series.

There were no mini or ultra-mini PCNL procedures in this series of adult cases.

Data were analysed using SPSS software with the appropriate statistical test depending on the distribution of data and results were compared to a published large case series with over 500 PCNLs.

Results

Eight hundred and one consecutive PCNL cases were performed between January 2000 and June 2016. The mean age of the cohort was 55.2 years (range = 17–93).

Pre- and post-operative haemoglobin (Hb) results were available for 630 patients (Table 1; Figure 1). The mean drop in haemoglobin was 1.6 g/dl (range = −1.7 to 9.3). Pre- and day 1 post-operative eGFR results were available for a subset of 205 patients.

Information on pre-operative urine culture results was available in 407 cases. One hundred and nineteen cases demonstrated pre-operative bacteriuria: *E. Coli*, 3.6%, *Proteus*, 3%, *Enterococcus*, 1.1%.

Three hundred and sixty-eight patients had data available on both pre-operative urine culture and post-operative change in haemoglobin.

Patients with a positive pre-operative urine culture were managed pragmatically; an attempt was made to clear the urine of infection, but those cases who were considered chronically colonised were treated with antibiotics pre-, peri- or post-operatively based on individual comorbidity and risk. The mean reduction in haemoglobin in those with a positive pre-operative urine culture was 1.75 g/dl (SE = 0.117) compared with 1.5 g/dl (SE = 0.0726) in those patients with no pre-operative infection.

The mean reduction in haemoglobin had a non-normal distribution and a Mann-Whitney test revealed a *p*-value of 0.452.

Of the 801 patients, 666 had data on blood transfusion; 27 patients (4.05%) received a blood transfusion (Table 1).

The mean change in serum creatinine on day 1 post-PCNL was −15.21 μmol/L (SE = 2.082, range from 186 loss to 36 gain) (Table 2).

Two hundred and five cases performed from 2012–2016 had data on change in eGFR. The mean change in eGFR at day 1 was 7.35 mL/min (range from 51 loss to 18 gain) (Table 3; Figure 2) and the data had a non-normal distribution. Interestingly, the three patients who had the greatest drop in eGFR were not in the group admitted to a higher level of medical care.

Table 1. Haemoglobin and transfusion.

Haemoglobin and transfusion	
Mean Pre Op Hb (g/dL)	13.94
Mean Post Op Hb (g/dL)	12.23
Mean Hb Drop (g/dL)	1.65
No with Hb drop over 2g/dL	76.00
% with Hb drop over 2g/dL	32.76
No patients transfused	27
% of patients transfused	3.37

Table 2. Renal function.

Renal function	
Mean creatinine rise (μmol/L)	15.21
Mean eGFR drop (ml/min/1.73 m^2)	7.35
% with eGFR drop over 25%	18.3%

Table 3. Major complications.

Major complications	*n* (%)
Bowel Injury	1 (0.12)
Need for Embolisation	6 (0.75)
Pneumothorax	1 (0.12)
Nephrectomy	1 (0.12)
ITU Admission	8 (1)
Death	0 (0)

Table 4. PCNL series with > 500 cases.

Series	*n*	Transfusion rate %	Embolisation rate
Single series			
Keoghane et al. 2020	801	3.37	0.75
Revzi et al. 2017	3402	8.2	0.25
Saucy et al. 2009	1338	0.7/1.2	N/A
Jones et al. 1990	1000	29/55	0.6
Martins et al. 2000	808	N/A	1
Kessearis et al. 1995	2200	N/A	0.8
Multicentre series			
Armitage et al. 2013 (HES)	5750	N/A	0.3
De la Rosette et al. 2011 (CROES)	5803	3.8	N/A
BAUS PCNL data registry			
Finch et al. 2018	9536	2.2	N/A

Eight cases (1%) required admission to intensive care. There was one documented bowel injury and six cases required sub-selective arterial embolization for bleeding (0.75%).

One emergency nephrectomy was performed for massive bleeding refractory to embolization. One pleural injury was documented which was managed with a chest drain (Table 4).

There were no deaths in this series.

Assuming that there is no interaction, i.e. that the type of complication has the same effect among any of the named surgeons and it was dealt with in the same manner, two-way ANOVA comparison demonstrated that there was no statistically significant difference in post-operative complications (blood transfusion, admission to higher level care) between fully trained urological surgeons at different stages of their careers ($p = 0.316$; $F = 2.17$ (2,2)) (Figure 3).

Discussion

What is the ideal marker for clinical excellence in stone surgery and does a surgically defined, clinical outcome measure meet the needs of patients and their carers [9,10]?

Transfusion rate can be utilised as a surrogate marker for expertise in complex stone disease. However, the relatively low rate of blood transfusion in most modern case series can be skewed by even low numbers of non-operative patient factors such as pre-operative chronic anaemia. Some variation certainly exists between the transfusion rates within large single-centre series, but there is a trend for rates to decrease in high throughput centres and with surgical experience [11].

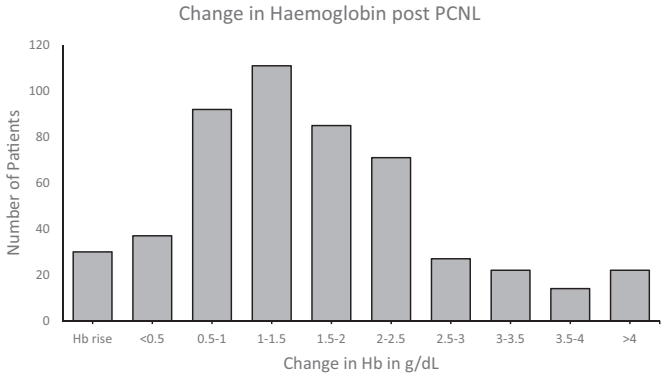

Figure 1. Change in Haemoglobin post PCNL.

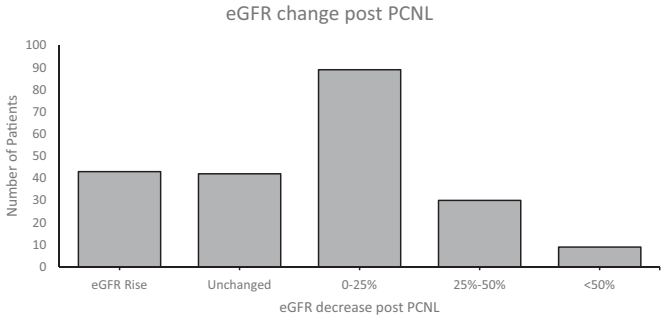

Figure 2. eGFR change post PCNL.

The post-operative transfusion rate in this study sits between the figure of 2.2% from the BAUS PCNL registry data (2011–2017) [5] and the rate of 5.7% from the international multi-centre CROES database [1]. No statistically significant difference was identified ($p = 0.2356$ and $p = 0.0856$, respectively). Furthermore, ongoing bleeding requiring subselective embolisation remains consistently below 1% across both this study (0.75%) and the BAUS registry (0.4%).

30-Day mortality from PCNL is rare; no cases at all in this series and rates of 0.2% in the BAUS database and just 0.03% in CROES.

The eGFR drop at day 1 was lower than recorded by Tabibi et al. [12] in a large single centre series ($n = 486$, mean day 1 eGFR drop = 10.1) and the rate of major complications compares favourably to other large case series in the published literature (Table 4).

How do these outcome data influence the process of informed consent? Following the landmark legal judgement in the UK in the case of Montgomery v Lanarkshire Health Board in 2015, a significant shift towards a more patient-centric informed consent procedure has been observed. Informed consent must now be shown to include all risks which a 'reasonable person in the patient's position' would view as significant [13]. Relevant to an individual's personalised risk are the outcomes specific to the centre in which they are considering treatment. Recent evidence has emphasised that being provided with information regarding potential major complications is viewed as an essential part of the consent procedure by patients themselves [13,14].

The data emerging from the UK PCNL patient registry and the BAUS website are valuable in creating a reference point which can be utilised by an individual to evaluate their own practice, but quoting pooled data and complication rates may now be insufficient for the purpose of informed consent. Furthermore, the interpretation of limited and somewhat crude outcome data by a patient or indeed the funders

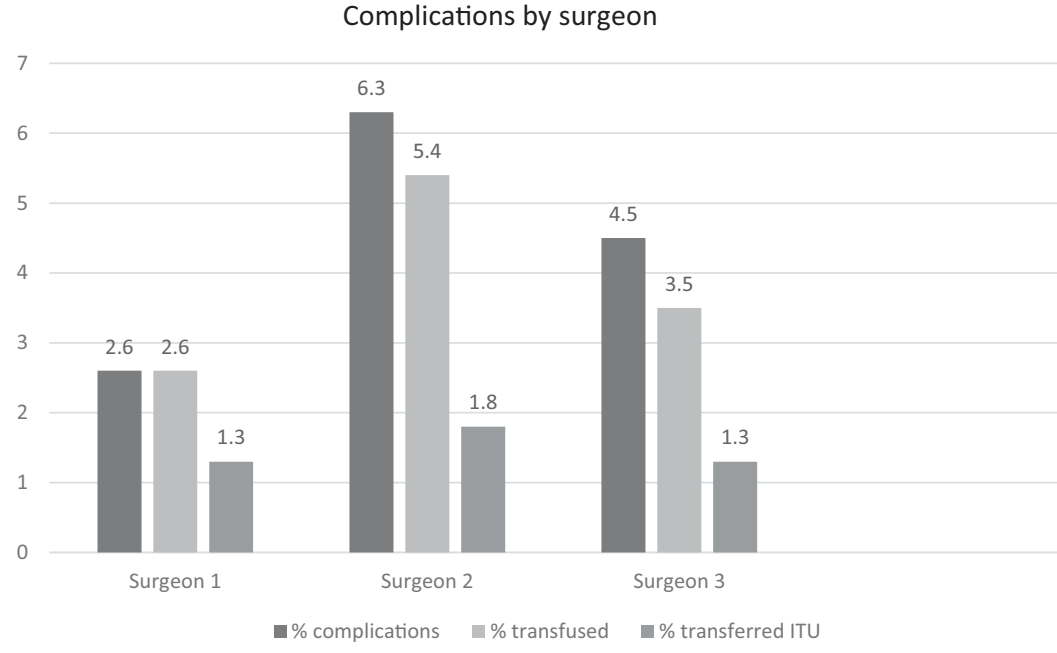

Figure 3. Complications by surgeon.

of healthcare does raise certain challenges as data may not necessarily reflect the complexity of a centre's caseload [6].

Parameters such as length of hospital stay are also now available in the public domain and could be interpreted with bias as both social and geographical factors influence this rather soft and unreliable outcome measure. Length of hospital stay may also be affected by baseline patient performance status and certain patient characteristics; for example smoking and alcohol consumption, which are notoriously difficult to accurately capture and could impact on outcome.

Openness and transparency, as well as accurate surgical outcome data, are essential to any pre-operative consultation and should form an inherent part of the consent process.

Patients deserve and expect to be informed of their own clinician's outcome data and the majority of malpractice claims are still due to poor communication rather than poor technical skill.

A percutaneous stone surgeon should, in the current medico-legal climate, consider the source of the information that patients are being given; has the patient been properly advised and would he or she have acted differently if given local rather than national outcome data? Is the patient aware of an individual urologist's own experience with a particular technique or has the patient been inadvertently quoted the generic surgical outcome data.

Evidence suggests patients value consent that has been tailored to their individual situation and a difference in the quoted complication risk can influence whether a patient would ultimately proceed with any procedure [15]. Surgeons should now consider allocating a greater proportion of an out-patient consultation to pre-operative counselling using high quality pooled and surgeon specific outcome data.

Complication rates extrapolated from another unit or from the use of multi-centre data are less relevant to an individual patient than the re-assurance from a clinician knowing and quoting his or her own figures, which should now become the standard of care.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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