The clinical research office of the endourological society percutaneous nephrolithotomy global study: Outcomes in the morbidly obese patient – a case control analysis

Andrew Fuller, MBBS, FRACS;[*] Hassan Razvi, MD, FRCSC;[*] John D. Denstedt, MD, FRCSC, FACS;[*] Linda Nott, RN;[*] Ad Hendrikx, MD;[†] Michael Luke, MD;[§] S.K. Pal, MD;[¥] Jean de la Rosette, MD, PhD;[€] on behalf of the CROES PCNL study group

[*]Division of Urology, Department of Surgery, Western University, London, ON; [†]Department of Urology, Catharina Hospital, Eindhoven, The Netherlands; [§]Department of Urology, Herlev Hospital, Herlev, Denmark; [¥]Department of Urology, Lions Kidney Hospital and Urology Research Institute New Friends Colony, New Delhi, India; [€]Department of Urology, AMC University Hospital, Amsterdam, The Netherlands

Cite as: *Can Urol Assoc J* 2014;8(5-6):e393-7. http://dx.doi.org/10.5489/cuaj.2258
Published online June 19, 2014.

Abstract

Background: Efficacy and safety of percutaneous nephrolithotomy (PCNL) have been demonstrated in obese individuals. Yet, there is a paucity of data on the outcomes of PCNL in morbidly obese patients (body mass index [BMI] >40).

Methods: Perioperative and stone-related outcomes following PCNL in morbidly obese patients was assessed using a prospective database administered by the Clinical Research Office of the Endourological Society (CROES). A multidimensional match of 97 morbidly obese patients with those of normal weight was created using propensity score matching. Student's t-test and Chi-square tests were used to assess for differences between the groups.

Results: In total, 97 patients with a BMI >40 kg/m^2 were matched by stone characteristics with 97 patients of normal weight. The morbidly obese population demonstrated higher rates of diabetes mellitus (43% vs. 6%, $p < 0.001$) and cardiovascular disease (56% vs. 18%, ($p < 0.001$). Access was achieved more frequently by radiologists in the morbidly obese group (19% vs. 6%, $p = 0.016$). Mean operative duration was longer in the morbidly obese group (112 ± 56 min vs. 86 ± 43.5 min, $p < 0.001$). Stone-free rates were lower in the morbidly obese group (66% vs. 77%, $p = 0.071$). There was no significant difference in length of hospital stay or transfusion rate. Morbidly obese patients were significantly more likely to experience a postoperative complication (22% vs. 6%, $p = 0.004$).

Interpretation: PCNL in morbidly obese patients is associated with longer operative duration, higher rates of re-intervention and an increased risk of perioperative complications. With this knowledge, urologists should seek to develop strategies to optimize the perioperative management of such patients.

Introduction

As the worldwide prevalence of obesity continues to rise, surgeons will increasingly face the challenges associated with providing safe, high quality care to obese patients. In 2008, 1.5 billion adults worldwide were overweight.[1] By 2030, it has been projected that this number will increase to 2.16 billion.[2] Obesity is closely associated with comorbid conditions, such as diabetes mellitus, hypertension and the metabolic syndrome, which have been implicated in the increased prevalence of urolithiasis.[3-6]

The surgical outcomes related to PCNL in overweight and obese individuals have been investigated, with most studies suggesting that PCNL may be performed with acceptable stone-related outcomes with minimal or no increased risk of major perioperative complications.[7-11] The outcomes of PCNL in patients who are morbidly obese (WHO class III: body mass index [BMI] >40 kg/m^2) remain poorly defined. Using prospectively collected data from the multicentre Global PCNL database administered by Clinical Research Office of the Endourological Society (CROES), we review the safety and efficacy of PCNL.

Methods

Data collection

Eligibility criteria and the method of data collection have been previously described.[12] In summary, a steering committee of global experts in PCNL was invited by the CROES council to direct the study. The target was to enroll 100 centres worldwide, including low- (<25 cases/year) and

high-volume (>100 cases/year) centres. Electronic databases were made available to participating centres and data were sent encrypted to the headquarters of CROES. Institutional Research Ethics Board approval was obtained at participating centres according to local regulations. The lead investigator at each centre coordinated data collection and submitted regular updates to the central database. Each centre provided data for consecutive PCNL patients for a study period of 1 year starting from the date of inclusion of the first patient. The first patient was entered into the database in November 2007. The database was closed December 2009.

Patients and procedures

We included patients who underwent PCNL for the primary or secondary treatment of kidney stones during the study period. The technique of PCNL has been described.[12] No attempt was made to standardize the technique for the purposes of the study. Patients with a history of previous PCNL, solitary kidney and known congenital abnormalities were excluded from the analysis.

Data analyses

A multidimensional match of 97 morbidly obese patients with 97 patients of normal weight was created using propensity score matching (PSM). PSM was used to minimize the bias introduced by the lack of randomization in this observational study by balancing a range of covariate stone related factors in the two groups. Matching variables included stone burden, stone location-multiplicity and the presence or absence of staghorn-type calculi. Demographic, operative and outcome characteristics of the two groups were then subjected to direct comparison using mean (standard deviation) for continuous variables and proportions/percentages for categorical variables. Student's t-test and Chi-square test were used to test for differences between the two groups. The data were analyzed with SPSS version 16.0.

Results

Patient characteristics

Data was collected from a total of 5803 patients who underwent PCNL at one of 96 centres in Europe, Asia, North America, South America and Australia. After exclusion criteria were applied, 3709 eligible patients were reviewed of whom 97 were identified as morbidly obese, with a BMI in excess of 40 kg/m^2. These patients were matched by stone characteristics with 97 patients of normal weight.

We tallied the demographic variables for each group (Table 1). The proportion of female patients was significantly higher in the obese cohort. Obesity has been closely linked with the development of the metabolic syndrome, which is characterized by a combination of central obesity, hypertension, dyslipidemia and impaired glucose tolerance. Accordingly, patients in the obese group were significantly more likely to have comorbid conditions, such as cardiovascular disease and diabetes.

Intra-operative outcomes

Table 2 contrasts the two groups with regard to intra-operative variables. Although the attending urologist achieved access in the majority of cases in both groups, the involvement of an interventional radiologist was significantly more common in the obese group. Supine positioning was used less commonly in the context of obesity. No statistical difference was demonstrated with regard to location of puncture, method of tract dilation, postoperative drainage or intraoperative complications. Although there was a significant difference between the two groups with regard to mean change in hemoglobin, the clinical relevance of this finding is questionable given the lack of a statistical difference in the requirement for blood transfusion.

Stone-related outcomes

The two groups were comparable with regard to stone size, location and multiplicity (Table 3).

Table 1. Patient demographics

Characteristics	Normal weight n = 97	Morbidly obese n = 97	*p* value
Mean age, years (SD)	48.9 (13.4)	55.3 (12.1)	<0.001*
Mean weight, kg (SD)	71.2 (9.9)	120 (21.4)	<0.001*
Gender, %			
Male	53.6	33.0	0.005*
Female	46.4	67.0	
Comorbidities, %			
DM	6.2	43.3	<0.001*
CVD	18.6	56.2	<0.001*
Medications, %			
Anticoagulants	5.2	22.7	<0.001*
Prednisone	0.9	5.2	0.023*
ASA classifications, %			
I	59.1	8.6	<0.001*
II	36.6	29.0	
III	3.2	58.1	
IV	1.1	4.3	

SD: standard deviation; DM: diabetes mellitus; CVD: cardiovascular disease; ASA: American Association of Anesthesiologists. *Indicates statistical significance at $p < 0.05$ level

Table 2. Intra-operative variables

Characteristics	Normal weight n = 97	Morbidly obese n = 97	*p* value
Access achieved by:			
Urologist, %	93.8	81.4	<0.016*
Radiologist, %	6.2	18.6	
Patient position, %			
Supine	34.0	18.6	0.022*
Prone	66.0	81.4	
Puncture site, %			
Upper	8.2	8.2	
Middle	21.6	21.6	0.991
Lower	64.9	63.9	
Multiple	5.2	6.2	
Location of access, %			
Above 11th rib	0.0	0.0	
Above 12th rib	16.1	12.6	<0.016*
Below 12th rib	83.9	87.4	
Dilation method, %			
Balloon	63.5	67.0	0.753
Telescopic	36.5	33.0	
% Postoperative stenting, %	41.7	33.0	0.272
% Postoperative nephrostomy, %	92.6	91.8	0.966
Mean operating time, minutes (SD)	86.0 (42.5)	112.2 (56.4)	<0.001*
Complications, %			
Failed access	1.0	3.1	0.613
Perforation	1.0	1.1	0.988
Hydrothorax	1.0	0.0	0.995
Blood loss parameters			
Reported bleeding, %	3.1	7.3	0.188
Blood transfusion, %	6.2	5.2	0.756
Mean change in hemoglobin as mg/dL (SD)	4.2 (3.6)	4.9 (4.0)	0.036*

SD: standard deviation; *Indicates statistical significance at $p < 0.05$ level

Table 3. Stone factors†

Characteristics	Normal weight n = 97	Morbidly obese n = 97	*p* value
% Staghorn stone	41.2	40.2	0.883
% Stone site			
Right	52.6	47.4	0.565
Left	47.4	52.6	
Mean stone burden in mm^2 (SD)	348.2 (350.3)	345.0 (340.9)	0.947
Single, %	38.1	38.1	0.961
Multiple, %	61.9	61.9	
Stone locations			
Upper calyx only, %	0.0	1.0	
Middle calyx only, %	0.0	0.0	
Lower calyx only, %	8.2	8.2	0.961
Pelvis only, %	33.0	33.0	
Multiple renal sites, %	58.8	57.7	

SD: standard deviation; †Factors used for matching the two groups except stone site; *Indicates statistical significance at $p < 0.05$ level.

Postoperative outcomes

Postoperative outcomes are summarized in Table 4. Stone-free status was achieved in 77.3% of normal weight individuals compared with 65.6% of obese patients ($p = 0.07$). Although statistical significance was not demonstrated, this finding corresponded with a significantly higher risk of re-intervention in the obese cohort.

Obesity did not influence the duration of hospital stay. The overall rate of complications was significantly higher in the obese group. This relationship persisted when the complications were subcategorized by Clavien criteria as minor (Clavien I-II) and major (Clavien III-V).[13] There were no deaths in either group, with most major complications being pulmonary in nature and requiring intervention without the need for general anesthesia (Clavien IIIa).

Discussion

With an increased prevalence of obesity in developed and developing countries worldwide, the ability to define and minimize the risks of surgical procedures in a bariatric context has taken on increased importance. It has been estimated that by 2030, 57.8% of the world's adult population will be overweight or obese.[2] Current surgical practices will need to be adapted to provide for the unique needs of the bariatric patient.

Obesity complicates the surgical management of urinary stone disease on a number of levels. In addition to limiting the therapeutic options available and increasing the complexity and complications associated with surgery, comorbid health conditions, such as diabetes mellitus and the metabolic syndrome, have been implicated in the pathogenesis of stone formation.[3-6] Obesity has been associated with alterations in urinary parameters, including increased excretion of calcium, oxalate, sodium and uric acid.[14,15] The magnitude of this effect is more marked in female patients who figured more prominently in the morbidly obese group in this study.

PCNL has been studied for the treatment of stones in both overweight and obese individuals, with acceptable stone-related outcomes and low complication rates.[7-11] This study was conceptualized on the basis that obese patients with a BMI in excess of 40 pose unique challenges in terms of intra-operative and postoperative care. To effectively manage such patients, urologists must be able to pre-empt the likely challenges and implement strategies to minimize risk. Obese patients should be provided with accurate and indi-

Table 4. Postoperative outcomes

Characteristics	Normal weight n = 97	Morbidly obese n = 97	*p* value
Stone-free rate, %	77.3	65.6	0.071
Retreatment rate, %	12.4	28.1	<0.0.21*
Retreatment modality, %			
URS	2.1	5.2	
PCNL	2.1	15.6	<0.010*
SWL	6.2	6.2	
Other	2.1	1.0	
Mean length of hospital stay in days (SD)	4.0 (3.1)	4.5 (4.3)	0.061
Complications within 30 days, %			
Minor (Clavien I and II)	5.4	11.6	0.004*
Major (Clavien III-V)	1.1	10.5	
Total	6.5	22.1	0.037*

URS: ureteroscopy; PCNL: percutaneous nephrolithotomy; SD: standard deviation; SWL: shock wave lithotripsy. *Indicates statistical significance at $p < 0.05$ level.

vidualized information regarding the risks and likely outcomes of PCNL. This article adds to our previous report[11] considering outcomes of PCNL stratified by BMI. In particular, the matched comparison of morbidly obese patients with those of healthy weight provides useful insight, particularly regarding the significantly increased risk of postoperative complications, in the morbidly obese group.

The increased risks of surgery in morbidly obese patients have been best studied in the context of bariatric surgery. A large multicentre, observational study of 4776 patients with a median BMI of 46.5 kg/m^2 undergoing a bariatric surgical procedure reinforced the feasibility of surgery in obese individuals and demonstrated low rates of morbidity and mortality within 30 days of surgery.[16] This study highlighted the importance of risk stratification and particularly recognized the increased risk conferred by a history of deep venous thrombosis, pulmonary embolus, obstructive sleep apnea and impaired overall functional status.

Morbidly obese patients pose a number of anesthetic challenges. Preoperative high-risk anesthetic assessment is mandatory prior to any contemplated intervention. One should be aware of the considerable risk of peripheral nerve compression injuries in these patients. Pressure points should be well-padded. In a review of anesthetic considerations in the context of morbid obesity, Neligan outlined a triad of perioperative problems, including obstructive sleep apnea, airway intubation and prevention of atelectasis.[17] Abdominal compression in the prone position may reduce both total lung capacity and functional residual capacity. Compression of the inferior vena cava may impair preload and impair oxygenation. A number of investigators have proposed strategies to reduce risk including supine and lateral decubitus positioning, the use of conscious sedation, awake endotracheal intubation and prone patient self positioning.[18-24] Despite the findings of Manohar and colleagues,[25] who suggested supine PCNL is safe and effective for morbidly obese patients, the results of the current study suggest that supine positioning was utilized significantly less often in the obese cohort (18.6 vs. 34.0%).

The proportion of stones managed with ureteroscopy continues to increase with the advent and dissemination of improved optical systems, intracorporeal lithotripters and ancillary devices. The feasibility, success and safety of ureteroscopic management of both ureteric and renal calculi in obese patients has been described.[26] Particularly in the context of stones less than 2 cm in size, ureteroscopy offers several benefits, including less risk of hemorrhagic complications and the ability to perform the procedure in the dorsal lithotomy position under neurolept anesthesia on an outpatient basis. The utility of this approach for larger stones remains less well-defined, although in small series has been associated with stone-free rates after a single treatment session of up to 60%.[27]

When PCNL is chosen as the most appropriate form of management, preoperative planning is essential. Due to the long distance between skin and stone in obese patients, it may be necessary to use a longer access needle, working sheath and/or rigid nephroscope. A larger skin incision is also occasionally required to facilitate access to the working sheath. Commercially available balloon dilation devices range in length from 12 to 15 cm. When this is insufficient, the use of serial Amplatz dilators is a useful means of gaining additional length.

The results of this study conflict with many of the published series to date considering outcomes of PCNL in the context of obesity.[7-10] El-Assmy and colleagues[7] analyzed the outcomes of PCNL in a series of 92 patients at a single high-volume centre with a BMI >40 and found no significant effect on complication rates or stone-related outcomes. There are likely to be multiple factors contributing to the inferior stone-free rate and higher re-treatment rates demonstrated by this study. In particular, this study incorporates data from 96 centres worldwide and may more closely reflect "real world" outcomes. We propose that the inferior stone-related outcomes may be due to a combination of suboptimal access, reluctance to place a second tract (particularly where the first has been placed by an interventional radiologist), poor fluoroscopic image quality and attempts to expedite the procedure due to the risks associated with prolonged general anesthesia. Additionally, blood loss was higher in the obese group that may result in poor intraoperative visualization of the collecting system, increasing the possibility of retained stone fragments.

It should be noted that PCNL was associated with a low rate of Clavien IV complications (1.1%), no deaths and no

increase in hemorrhagic complications. Where appropriate bariatric equipment, as well as surgical and anesthetic expertise, is available, PCNL is a safe and effective means of managing large renal calculi.

The Global PCNL study represents the largest prospectively collected database of patients treated with PCNL available to date. As the burden of obesity continues to affect surgical practice, the findings of the case control study serve as an important resource in counselling obese patients regarding the specific risks and likely outcomes associated with percutaneous stone surgery.

Conclusion

PCNL in morbidly obese patients is associated with longer operative duration, higher rates of re-intervention and an increased risk of perioperative complications. Faced with an ongoing increase in the proportion of patients with a BMI in excess of 40 kg/m^2, Urologists should continue to develop strategies to optimize the perioperative management of these challenging patients.

Competing interests: The PCNL Global Study was supported by an unrestricted educational grant from Olympus. Dr. Razvi has received royalties from Cook Urologic; Dr. Denstedt is a consultant for Boston Scientific, AMS, Interface Biologics, Cook Urologic; Dr. de la Rosette is a consultant for Boston Scientific.

This paper has been peer-reviewed.

References

1. World Health Organization. Fact sheet No.311: Obesity and overweight, March 2011. http://www.who.int/mediacentre/factsheets/fs311/en/index.html (Accessed September 13, 2012).
2. Kelly T, Yang W, Chen CS, et al. Global burden of obesity in 2005 and projections to 2030. *Int J Obes* 2008;32:1431-7. http://dx.doi.org/10.1038/ijo.2008.102
3. Taylor EN, Stampfer MJ, Curhan GC. Dietary factors and the risk of incident kidney stones in men: New insights after 14 years of follow-up. *J Am Soc Nephrol* 2004;15:3225-32. http://dx.doi.org/10.1097/01.ASN.0000146012.44570.20
4. Taylor EN, Stampfer MJ, Curhan GC. Diabetes mellitus and the risk of nephrolithiasis. *Kidney Int* 2005;68:1230-5. http://dx.doi.org/10.1111/j.1523-1755.2005.00516.x
5. Taylor EN, Stampfer MJ, Curhan GC. Obesity, weight gain, and the risk of kidney stones. *JAMA* 2005;293:455-62. http://dx.doi.org/10.1001/jama.293.4.455
6. Cappuccio FP, Strazzullo P, Mancini M. Kidney stones and hypertension: Population based study of an independent clinical association. *BMJ* 1990;12:1234-6. http://dx.doi.org/10.1136/bmj.300.6734.1234
7. El-Assmy AM, Shokeir AA, El-Nahas AR, et al. Outcome of percutaneous nephrolithotomy: effect of body mass index. *Eur Urol* 2007;52:199-205. http://dx.doi.org/10.1016/j.eururo.2006.11.049
8. Sergeyev I, Koi PT, Jacobs SL, et al. Outcome of percutaneous surgery stratified according to body mass index and kidney stone size. *Surg Laparosc Endosc Percutan Tech* 2007;17:179-83. http://dx.doi.org/10.1097/SLE.0b013e318051543d
9. Koo BC, Burtt G, Burgess NA. Percutaneous stone surgery in the obese: outcome stratified according to body mass index. *BJU Int* 2004;93:1296-9. http://dx.doi.org/10.1111/j.1464-410X.2004.04862.x
10. Pearle MS, Nakada SY, Womack JS, et al. Outcomes of contemporary percutaneous nephrostolithotomy in morbidly obese patients. *J Urol* 1998;160:669-73. http://dx.doi.org/10.1016/S0022-5347(01)62750-2
11. Fuller A, Razvi H, Denstedt JD, et al. The Clinical Research Office of the Endourological Society Percutaneous Nephrolithotomy Global Study: The Influence of Body Mass Index on Outcomes. *J Urol* 2012 May 15. Epub ahead of print. http://dx.doi.org/10.1016/j.juro.2012.03.013
12. de la Rosette JJ, Assimos D, Desai M, et al. The clinical research office of the endourological society percutaneous nephrolithotomy global study: indications, complications and outcomes in 5803 patients. *J Endourol* 2011;25:11-7. http://dx.doi.org/10.1089/end.2010.0424
13. Clavien A, Sanabria JR, Strasberg SM. Proposed classification of the complications of surgery with examples of utility in cholecystectomy. *Surgery* 1992;111:518-26.
14. Taylor EN, Curhan GC. Body size and 24-hour urine composition. *Am J Kidney Dis* 2006;48:905-15. http://dx.doi.org/10.1053/j.ajkd.2006.09.004
15. Ekeruo WO, Tan YH, Young MD, et al. Metabolic risk factors and the impact of medical therapy on the management of nephrolithiasis in obese patients. *J Urol* 2004;172:159-63. http://dx.doi.org/10.1097/01.ju.0000128574.50588.97
16. The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium. Perioperative safety in the longitudinal assessment of bariatric surgery. *N Engl J Med* 2009;361:445-54. http://dx.doi.org/10.1056/NEJMoa0901836
17. Neligan PJ. Metabolic syndrome: anesthesia for morbid obesity. *Curr Opin Anaesthesiol* 2010;23:375-83. http://dx.doi.org/10.1097/ACO.0b013e328338caa0
18. Shoma A, Eraky I, Kenawy M, et al. Percutaneous nephrolithotomy in the supine position: technical aspects and functional outcome compared with the prone technique. *Urology* 2002;60:388-92. http://dx.doi.org/10.1016/S0090-4295(02)01738-7
19. Gofrit ON, Shapiro A, Donchin Y et al. Lateral decubitus position for percutaneous nephrolithotripsy in the morbidly obese or kyphotic patient. *J Endourol* 2002;16:383-6. http://dx.doi.org/10.1089/089277902760261437
20. Valdivia Uria JG, Valle Gerhold J, Lopez Lopez JA, et al. Technique and complications of percutaneous nephroscopy: experience with 557 patients in the supine position. *J Urol* 1999;160:1975-8. http://dx.doi.org/10.1016/S0022-5347(01)62217-1
21. Kerbl K, Clayman RV, Chandoke PS, et al. Percutaneous stone removal with the patient in a flank position. *J Urol* 1994;151:686-8.
22. Kanaroglou A, Razvi H. Percutaneous nephrolithotomy under conscious sedation in morbidly obese patients. *Can J Urol* 2006;13:3153-5.
23. Wu SD, Yilmaz M, Tamul PC, et al. Awake endotracheal intubation and prone patient self-positioning: anesthetic and positioning considerations during percutaneous nephrolithotomy in obese patients. *J Endourol* 2009;23:1599-602. http://dx.doi.org/10.1089/end.2009.1524
24. El-Husseiny T, Moraitis K, Maan Z, et al. Percutaneous endourologic procedures in high risk patients in the lateral decubitus position under regional anesthesia. *J Endourol* 2009;23:1603-6. http://dx.doi.org/10.1089/end.2009.1525
25. Manohar T, Jain P, Desai M. Supine percutaneous nephrolithotomy: effective approach to high risk and morbidly obese patients. *J Endourol* 2007;21:44-9. http://dx.doi.org/10.1089/end.2006.0212
26. Andreoni C, Afane J, Olweny E, et al. Flexible ureteroscopic lithotripsy: first line therapy for proximal ureteral and renal calculi in the morbidly obese and superobese patient. *J Endourol* 2001;15:493-8. http://dx.doi.org/10.1089/089277901750299285
27. Grasso M, Conlin M, Bagley D. Retrograde ureteropyeloscopic treatment of 2cm or greater upper urinary tract and minor staghorn calculi. *J Urol* 1998;160:346-51. http://dx.doi.org/10.1016/S0022-5347(01)62892-1

Correspondence: Jean J.M.C.H. de la Rosette, Department of Urology, AMC University Hospital, Meibergdreef 9, 1105 AZ Amsterdam Z-O, The Netherlands; j.j.delarosette@amc.uva.nl