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## Increasing body mass index steepens the learning curve for ultrasound-guided percutaneous nephrolithotomy

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### Abstract

**Objective**—To define how the learning curve for success in ultrasound-guided PCNL is impacted by body mass index (BMI). Previous research has shown ultrasound-guided percutaneous nephrolithotomy (PCNL) to be an effective method of nephrolithiasis treatment comparable to fluoroscopy guided PCNL. A common concern for the ultrasound-guided approach is potential imaging difficulty in the obese patient population.

**Methods**—A prospective cohort study of consecutive patients undergoing PCNL with ultrasound guidance for renal tract access was performed. Clinical data collected included success in gaining renal access with ultrasound guidance, patient BMI, and clinical outcomes over time. Nonparametric LOWESS regression modeling was performed in R using locally weighted scatterplot smoother (R version 3.3.3) for gradations of patients by BMI group (<30, 30–40, >40).

**Results**—A total of 150 cases were examined. Case number and BMI were evaluated as continuous variables. Multivariate logistic regression revealed that BMI (p = 0.010; OR 0.93) and case number (p<0.001; OR 1.03) were significantly correlated with ultrasound success. Sex, age,

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hydronephrosis, stone type, puncture location, and stone size did not influence success at obtaining ultrasound-only access in a statistically significant fashion. LOWESS regression modeling of the relationship between case number and renal access success depicts the curve representative of the BMI>40 group is downward and right-shifted relative to the other two groups.

**Conclusion**—The learning curve for successful ultrasound-guided PCNL is impacted by patient BMI as well as case number. Increasing BMI makes access more challenging when performing ultrasound-guided PCNL.

#### Keywords

Ultrasound-guided PCNL; BMI; Learning curve; Urolithiasis

#### Introduction:

The first percutaneous nephrostomy performed for renal stone extraction was described by Drs. Fernström and Johansson in 1976 [1]. Since then, percutaneous nephrolithotomy (PCNL) has become a procedure widely utilized in Urology.

Current national and international urological guidelines recommend the procedure as a standard for treatment of renal urolithiasis larger than 2 cm [2–3].

Imaging modalities applied to renal collecting system access for PCNL include both fluoroscopy- and ultrasound-guided approaches. Ultrasound-guided approaches offer the advantage of radiation exposure reduction [4–5] and have been shown to be both safe and effective in comparison to fluoroscopy-guided PCNL [6–7]. Competency in learning ultrasound techniques for PCNL access has been shown to be achievable after 20–60 cases [8–9].

Obesity is increasingly common in the United States and other developed nations [10–12]. Obesity is a well-established risk factor for kidney stone formation [13–15]. Some of the effectiveness of treatment modalities for kidney stone disease is diminished in obese patients. For example, Shock Wave Lithotripsy (SWL) has lower stone clearance rates in obese patients relative to non-obese patients [16–18]. PCNL procedures also present challenges in patients with higher BMIs relative to patients who are not obese, such as patient positioning concerns and increased skin to stone distance [18].

Prior studies examining the learning curve for gaining competence in ultrasound-guided PCNL have not considered the influence of patient body weight [8] or controlled for patient BMI [9]. Obesity is a factor commonly associated with difficulty accessing the renal collecting system under ultrasound guidance [19–20]. The objective of the current study was to investigate the impact of body habitus on success obtaining renal access using ultrasound-guidance only. We hypothesized that an obese habitus would be associated with lower likelihood of successful renal access under ultrasound-only guidance. Our secondary hypothesis was that the effect of obesity on likelihood of obtaining access using ultrasound-only guidance would decline with increasing surgeon experience.

### **Methods and Materials**

#### **Study Population**

This is a prospective cohort study of consecutive PCNL procedures performed at two academic medical centers between May 2014 and October 2016. All procedures were performed by a single fellowship-trained urologist specialized in endourology (TC). This study was approved by the Institutional Review Board (IRB) for prospective collection of human clinical information in patients with nephrolithiasis (CHR #14–4533). Consent was obtained for each patient in the preoperative unit prior to surgery. Data was entered prospectively into an excel database. Data on BMI was calculated using the formula weight in kilograms divided by height in meters squared.

#### Surgeon and Surgical Technique

Prior to this study period, the operative surgeon had experience exclusively in fluoroscopyguided PCNL for renal tract access and had been in practice for two years performing strictly fluoroscopy-guided PCNL. He subsequently received one-on-one mentored training in ultrasound-guided PCNL for six cases and thereafter transitioned to applying ultrasound to the practice of renal tract access and dilation. The surgical technique for this study has been published previously [21]. Briefly, all of the surgical cases were performed under general anesthesia with the patient in a prone position. A ureteral catheter was placed for retrograde saline infusion in patients with minimal to no hydronephrosis with the patient in supine position prior to flipping prone. Puncture of the collecting system was performed using a real-time ultrasound-guided freehand technique without the use of a needle guide on the ultrasound probe [21]. A 1.8–5 MHz convex abdominal transducer was used (Hitachi Aloka Alpha 7; Hitachi Aloka Medical) to image renal anatomy and stone location. Dilation and sheath insertion were performed using a high-pressure 24 French balloon dilator set (BARD X-Force; Bard Medical). Retrograde saline infusion was performed with manual hand irrigation as needed to assist with collecting system visualization.

#### **Definition of Success**

A successful ultrasound-guided puncture was defined as achieving access into the renal calyx of choice using only ultrasound guidance. A target calyx was chosen based on stone anatomy and perceived ideal access to the target stone. Puncture attempts were performed with up to 6 needle passes under ultrasound guidance prior to conversion to fluoroscopy, and typically access to one or two calyces was attempted. When access could not be achieved solely with ultrasound, fluoroscopic guidance was utilized (GE OEC 9800 Plus Mobile C-arm; GE Healthcare). Regardless of success with ultrasound for initial access, subsequent dilation was performed under either ultrasound guidance only or a combination of ultrasound and fluoroscopy, where 8 to 10F facial dilation was performed with ultrasound and balloon dilation under ultrasound was performed if there was good visualization of the wire using the ultrasound probe, but if visualization was difficult, dilation was performed under fluoroscopy. Nephrostomy tubes were placed at the conclusion of surgery in all patients.

#### **Patient Categorization**

Case number was defined by the position in case sequence between 1–150 starting at 1 on May 2014 and ending at 150 on October 2016. Case number and BMI were evaluated as continuous variables. Hydronephrosis was categorized according to preoperative imaging [22] and were categorized as none, mild, moderate, or severe. We created a dummy variable for hydronephrosis with the cut off of greater than or equal to moderate hydronephrosis based on preoperative imaging. Stone location was categorized as calyceal, renal pelvis, staghorn, ureteral, or multiple locations. Puncture location was categorized as lower pole, mid pole, upper pole, or multiple locations. Stone clearance was recorded in a binary fashion based on post-operative imaging using antegrade nephrostogram or ultrasound in the immediate post-operative period (post-operative day 1). Complications occurring within 30 days of the procedure were categorized according to the Clavien-Dindo classification system [23].

#### **Statistical Methods**

Descriptive statistics were reported on the cohort. Analyses using univariate and multivariate regression were performed in R (R version 3.3.3). Nonparametric LOWESS regression modeling was performed in R using locally weighted scatterplot smoother (R version 3.3.3).

Our primary outcome was access into the renal calyx of choice using ultrasound-only guidance, reported as a binary variable (yes/no). Secondary outcomes were complications greater than or equal to Clavien-Dindo classification 2, presence or absence of residual stone, and operative time. Differences in continuous variables between patients in whom ultrasound access was successful and patients in which ultrasound access was unsuccessful were compared using Welch's T test. Univariate analysis was performed using Fishers Exact test for binary outcomes. Multivariate analysis was generated with multivariate logistic regression for binary outcomes and multivariate linear regression for continuous variables. Full models were generated from variables BMI, stone size based on preoperative imaging, case number, hydronephrosis, fluoroscopy time used during dilation, stone type (including calyceal, renal pelvic, staghorn, ureteral, and multiple stones each expressed as dummy variables), and puncture location (including lower pole, mid kidney, upper pole, and multiple punctures each expressed as dummy variables). Factor selection for our final model was narrowed using analysis of deviance for the best variables for model fit.

LOWESS regression was performed for gradations of patients by BMI group (<30, 30–40, >40). We plotted success rate versus case number for each group. We utilized the "lowess" function available in R to fit a curve to this plot.

### **Results:**

A total of 150 cases were examined. Data on age, sex, BMI, hydronephrosis, stone size, puncture location, stone type, complication rates, transfusion rates, fluoroscopy time, and operative time are depicted in Table 1. Failure to obtain ultrasound-only renal access was associated with higher BMI (p=0.012), presence of staghorn stones (p=0.026), and longer operative time (p<0.001) (Table 1).

LOWESS regression modeling of the relationship between case number and renal access success depicts substantial differences in the shape of the success curve when comparing the curves representative of groups composed of patients with BMI <30 and BMI between 30 and 40 relative to the curve representative of the group composed of patients with BMI >40. The curve representative of the BMI>40 group is downward and right-shifted relative to the other two groups (Figure 1).

Multivariate logistic regression revealed that BMI (p = 0.010; OR 0.93) and case number (p<0.001; OR 1.03) were significantly correlated with ultrasound success. Sex, age, hydronephrosis, stone type, puncture location, and stone size did not influence success at obtaining ultrasound-only access in a statistically significant fashion. Hydronephrosis was associated with increased ultrasound success but this did not meet the threshold for statistical significance (p=0.052) (Table 2). Univariate analysis showed that staghorn stones were significantly more common in ultrasound failure (p=0.026) (Table 1). Rates of staghorn stones were similar in each BMI group: 13/39 (33%) of BMI 30–40 patients had a staghorn stone, 7/18 (39%) patients with BMI >40 had a staghorn stone, and the overall staghorn stone rate for all 150 patients was 30%. When accounting for all other variables, multivariate analysis showed that staghorn stones did not significantly impact successful ultrasound access (p=0.144) (Table 2).

Multivariate analysis showed no statistically significant predictive variable for Clavien-Dino complications of class 2 or greater, including puncture location, stone type, sex, age, BMI, case number, hydronephrosis, or stone size. Clearance rate was impacted by stone size (p <0.001; OR 1.12), but not by any other variable. Increased operative time was only associated with a lower case number (p = 0.001), failed ultrasound-only puncture (p=0.009), and the presence of a ureteral stone (p = 0.023).

For those cases where ultrasound access was successful, there was no correlation between amount of fluoroscopy time used during dilation (range 0-379 seconds) and complication rate (p=0.554). Dilation was accomplished using ultrasound alone in 26/150 (17%) of cases; complications among this group were 2/26 (8%). No patients in this group required a transfusion.

#### Discussion:

Our results show a prolonged learning curve for ultrasound-guided PCNL in obese patients stratified by severity of obesity. Competency in gaining access using ultrasound-alone in patients independent of BMI can be obtained with increasing case volume. We did not note any statistically significant effect of age, sex, hydronephrosis, stone size, stone type, or puncture location on ultrasound success based on multivariate analysis. With increasing number of cases, there was an increase in the rate of successful access using ultrasound. Operative time decreased and stone clearance increased with increasing case numbers. In patients with lower BMI the likelihood of ultrasound-only access success increased. Overall, complication rates and transfusion rates were low in this cohort of patients as there were no variables that were significantly associated with complications or need for transfusion.

Some of the initial barriers to successful ultrasound-guided access in individuals with higher BMIs may be a consequence of the poorer quality of ultrasound images often found in obese individuals that can impair needle guidance. Increased distance between the ultrasound probe at the skin surface and the target image (depth of insonation) as well as the obscuring of the ultrasound image by fat (absorption of ultrasound energy by adipose tissue) contribute to poor image quality [24]. Ultrasound adjustments have been described to increase image quality in obese patients. In some instances, use of lower frequency ultrasound probes can gain deeper imaging penetration. Adjustments to brightness, gain, and focal zone can also be utilized to assist in imaging an obese patient [25]. We utilize a 1.8 to 5Hz 60mm, 60-degree probe and tend to adjust gain to improve depth of imaging in obese patients. Although utilization of harmonic tissue imaging settings [26] has been described to improve imaging quality in obese and gravid patients, we have not regularly utilized tissue harmonic settings in our obese PCNL patients. Additionally, various patient positioning adjustments have been described to assist ultrasound imaging in obese patients such as the Sims position where ultrasound of the uterus is performed through the flank [27], but we find that for PCNL, the prone position with standard chest and abdominal bolsters to displace abdominal fat anteriorly ideal for imaging the kidney. It is our opinion that utilization of a freehand technique without the use of a needle guide on the ultrasound probe best allows one to optimize real-time adjustments needed to guide the needle across a long distance in multiple planes [21].

It is important to place the results of this study in context with how it might translate to most urology practitioners. Thirty-five percent of Americans have a BMI greater than 30 [11]. Therefore, given obesity is a known risk factor of stone formation [13–15], it is a reasonable extrapolation that even greater than one-third of nephrolithiasis patients that practitioners encounter will likely be obese. From our analysis, the learning curve for ultrasound-guided renal access is shifted the furthest to the right for the morbidly obese, in patients with BMI > 40-.

The morbidly obese are at higher risk for complications related to major surgical procedures compared to normal weight individuals [28] and may warrant care at specialized centers. The value of learning ultrasound-guided renal access in obese patients is especially high given that obese individuals are more susceptible to increased radiation exposure during fluoroscopy guided PCNL [29–30]. In obese patients, ultrasound-guided PCNL carries the advantage of a significant reduction in radiation exposure relative to fluoroscopy-guided PCNL compared to non-obese patients [31]. This suggests that gaining competence in ultrasound-guided renal tract access is particularly important in obese patients.

Previous studies have shown staghorn stones and hydronephrosis as significant factors influencing success rates for completely X-ray free PCNL [32], but did not take into account case number in the analysis. In this study, hydronephrosis was not found to be predictive of successful ultrasound access. However, while we did record whether a retrograde catheter was placed, we did not record its use. We place a retrograde ureteral catheter with ultrasound guided PCNL in 69% of our cases. This is dictated by surgeon preference and tends to be placed in cases without hydronephrosis. When the collecting system is difficult to image, or access is challenging, the catheter is injected to fill the collecting system. Therefore,

preoperative hydronephrosis may not correlate completely with intraoperative presence of hydronephrosis. While the data was not recorded, anecdotally, retrograde filling is not used very often, as the collecting system can be seen in most kidneys, even in the absence of hydronephrosis on preoperative imaging. The presence and use of the retrograde catheter could, however, explain why hydronephrosis approached significance but was not a significant predictor of ultrasound success in our multivariate analysis.

This study is limited by the fact that it is based on a single surgeon's experience. This surgeon received training in fluoroscopy-guided renal access for PCNL during Endourology fellowship. In addition, the surgeon received direct mentorship with a surgeon experienced in ultrasound-guided PCNL. This may contribute to a short learning curve and limit applicability to urologists with less formalized training. Furthermore, small sample size makes it difficult to find significant trends in complication associations and need for transfusion, and the fact that we did not keep data on the number of needle passes required to obtain access may contribute to unaccounted for variations in post-operative complication and transfusion rates. This study is also limited by the lack of data on utilization of retrograde ureteral catheters and retrograde saline infusion to facilitate obtaining access in the absence of hydronephrosis. Nevertheless, this study offers evidence that high success with ultrasound-guided renal access can be achieved in obese patients.

To our knowledge no prior study has reported the number of cases required to attain high success rates with ultrasound-only guided renal access in obese patients undergoing PCNL. This study demonstrates that percutaneous ultrasound-guided access can be obtained in obese patients with increasing experience although the number of cases required to achieve high success in the obese populations exceeds previously quoted figures in general PCNL populations [8–9]. When starting to perform ultrasound-guided access for PCNL, we recommend that surgeons gain facility with this approach in non-obese patients before utilizing it in obese patients.

#### Conclusion:

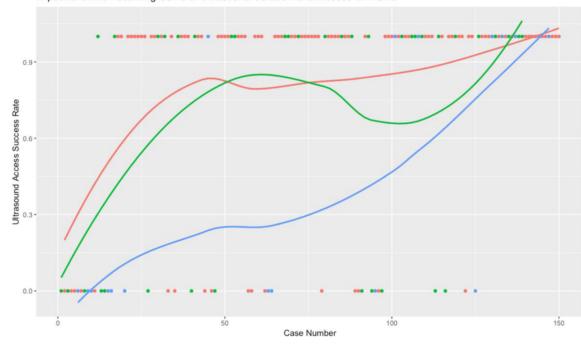
The learning curve for successful ultrasound-guided PCNL is impacted by patient BMI as well as case number. Increasing BMI steepens the learning curve, making successful ultrasound-guided access more challenging when performing ultrasound-guided PCNL.

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#### Impact of BMI on Learning Curve of Ultrasound-Guided Renal Access for PCNL

#### Figure 1.

Non parametric lowess plot BMI learning curves. Points of ultrasound access failure are plotted at 0 and successes are plotted at 1. Patient cohort curves are color coded according to BMI with red being BMI less than 30, green being BMI between 30–40, and blue being BMI greater than 40.

#### Table 1:

#### Patient Characteristics

	US Success (total = 110)	US Failure (total = 40)	р
Age (mean in years, range)	53, (27–69)	51, (17–87)	p=0.463
Sex (% Female)	58%	50%	p=0.457
BMI mean (range)	28.4, (15.7–60.8)	33.7, (17.7–78.8)	p=0.012
Hydronephrosis (n, %)	24, 21.8%	5, 12.5%	p=0.248
Stone size mean in mm (range)	32.9 (8–119)	37.1 (7–104)	p=0.266
Clavien-Dino Complications Class >1 (n, %)	13, 11.8%	3, 7.7%	p=0.563
Transfusion rates (n, %)	3, 2.7%	0, 0%	p=0.565
Lower pole puncture (n, %)	35, 31.8%	20, 50%	p=0.055
Mid pole puncture (n, %)	26, 23.6%	6, 15%	p=0.367
Upper pole puncture (n, %)	38, 34.5%	9, 22.5%	p=0.171
Multiple pole puncture (n, %)	11, 10%	5, 12.5%	p=0.765
Caliceal Stone (n, %)	28, 25.4%	8, 20%	p=0.665
Renal pelvis Stone (n, %)	28, 25.4%	7, 17.5%	p=0.386
Staghorn Stone (n, %)	27, 24.5%	18, 45%	p= 0.026
Ureteral Stone (n, %)	6, 5.5%	2, 5%	p=1
Multiple stones (n, %)	21, 19%	5, 12.5%	p=0.466
<b>Operative time</b> in minutes (range)	128.5 min, (43–295)	176.1min (83–412)	p < 0.001
Residual Stone (n, %)	17, 15.5%	11, 27.5%	p=0.103

#### Table 2:

Multivariate analysis for predictors of successful ultrasound access

#### OR 95% CI р Age 1.00 (0.97-1.04) 0.928 0.67 0.427 Sex (0.24 - 1.81)BMI 0.93 (0.88-0.98) 0.010 Case number 1.03 (1.02–1.05) < 0.001 Hydronephrosis 4.78 (1.09-26.7) 0.052 Lower pole puncture 0.25 (0.04–1.42) 0.132 Mid pole puncture 0.65 (0.09 - 4.48)0.662 Upper pole puncture 0.49 (0.07-3.00) 0.452 Caliceal stone 2.24 (0.44–12.0) 0.332 Renal pelvis stone 1.17 (0.23-5.81) 0.852 0.30 (0.05-1.45) 0.144 Staghorn stone Ureteral stone 0.72 (0.07-8.94) 0.783 Stone size 1.01 (0.98 - 1.04)0.622