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Ultrasound guidance can be used safely for renal tract dilation during percutaneous nephrolithotomy

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Abstract:

Objectives: To compare clinical outcomes between patients who underwent percutaneous nephrolithotomy with renal tract dilation performed under fluoroscopic versus ultrasound guidance.

Patients and Methods: A prospective observational cohort study enrolled successive patients undergoing PCNL between July 2015 and March 2018. Included in this retrospective analysis were cases where renal puncture was successfully obtained with ultrasound guidance. Cases were then grouped according to whether fluoroscopy was used to guide renal tract dilation or not. All statistical analyses were performed on Stata version 15.1 including univariate (Fisher's exact test, Welch's t-

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test) and multivariate analyses (binomial logistic regression, ordinal logistic regression, and linear regression).

Results: 176 patients underwent PCNL with successful ultrasound-guided renal puncture of which 38 and 138 underwent renal tract dilation with fluoroscopic versus ultrasound, respectively. There were no statistically significant differences in patient age, gender, body mass index, preoperative hydronephrosis, stone burden, procedure laterality, number of dilated tracts, and calyceal puncture location between the two groups. Among ultrasound tract dilations, a higher proportion of patients were positioned modified dorsal lithotomy as opposed to prone and a significantly lower operative time was seen. Only modified dorsal lithotomy remained statistically significant after multivariate regression. There were no statistically significant differences in postoperative stone clearance, complication rate, or intraoperative estimated blood loss. A 5-unit increase in a patient's body mass index was associated with 30% greater odds of increasingly severe Clavien-Dindo complications. A 5mm decrease in the preoperative stone burden was associated with 20% greater odds of stone-free status. No variables predicted estimated blood loss with statistical significance.

Conclusions: Renal tract dilation can be safely performed in the absence of fluoroscopic guidance. Compared to using fluoroscopy, our study demonstrated that ultrasound dilations can be safely performed without higher complication or bleeding rates. This can be done using a variety of surgical positions, and future studies centered on improving dilation techniques could be of impactful clinical value.

Introduction:

The cumulative incidence of experiencing an episode of symptomatic urolithiasis among the non-institutionalized United States population has been estimated to be 8.4% with variation when stratified by gender, race, and socioeconomic class [(1)]. In 2006, upper urinary tract stones incurred

$10 billion in charges mainly from inpatient and ambulatory surgery services [(2,3)]. Large or complex renal stones are generally treated with percutaneous nephrolithotomy (PCNL). The American Urological Association strongly recommends PCNL as a first-line treatment for large renal stones (>20mm) or large lower pole stones (>10mm) [(4)]. PCNLs account for 4.5% of kidney stone procedures in the United States and are more commonly performed by endourologists [(5)]

PCNL requires access to the pelvicalyceal collecting system comprised of two steps – renal puncture and tract dilation. In the United States, the majority of PCNLs are performed under fluoroscopic-guidance, commonly by an interventional radiologist [(6,7)]. However, concern for radiation exposure to patients and providers makes ultrasound an appealing alternative. Once access to the collecting system is established, surgeons face the additional decision of performing dilation with or without fluoroscopic imaging guidance. In previous studies, we have demonstrated ultrasound-guided renal puncture and its advantages over fluoroscopy. It both reduces cost [(8)] and radiation exposure for patients [(9)]. While we have previously published on the feasibility of using ultrasound to guide both renal tract access and dilation [(10)], to the best of our knowledge, a comparison between fluoroscopic and ultrasound guided dilation specifically has not been examined in the urology literature. If alternatives to fluoroscopy were demonstrated to be safe, this approach would facilitate the practicing urologist in achieving X-ray free PCNL. In this study, our objective was to compare clinical outcomes between renal tracts dilated with and without fluoroscopic guidance. We hypothesized that there would be no differences in estimated blood loss, complication rates, and stone clearance rates between fluoroscopic and ultrasound renal tract dilation approaches during PCNL.

Patients and Methods:

A prospective cohort study was conducted with enrollment of successive patients undergoing PCNL between July 2015 and March 2018 at the University of California, San Francisco (UCSF) Helen Diller Medical Center, a tertiary referral center for stone disease. We obtained Institutional Review Board approval and patient written consent to prospectively collect patient demographic and clinical data (CHR #14-4533) as part of the Registry for Stones of the Kidney and Ureter (ReSKU) [(11)].

Included were patients undergoing PCNL for definitive stone treatment that underwent a successful ultrasound renal puncture and subsequently underwent renal tract dilation with a balloon dilation technique. We categorized patients within this cohort into two groups: successful ultrasound tract dilation and successful fluoroscopic tract dilation. We categorized patients by the initial imaging modality intended for the renal dilation attempt in accordance with an intention-to-treat analysis. In other words, dilation attempts that began with ultrasound-guidance were categorized as such, irrespective of any subsequent fluoroscopic guidance during the attempt. All surgical procedures were performed by two surgeons (TC and MLS).

Surgical Technique

We have previously published details regarding our surgical technique for ultrasound guidance during PCNL access and tract dilation [(7)]. In brief, first, an externalized ureteral stent was placed into the ipsilateral ureter via a flexible cystoscope for retrograde saline injection to induce calyceal dilation. Patients were positioned prone or in a modified supine lithotomy position as described in the literature [(12)]. We used a 3.5 MHz range curved array ultrasound transducer (Hitachi Aloka Medical America, Wallingford, CT) to visualize the renal parenchyma, pelvicalyceal system, stones, and surrounding organs. To perform the renal puncture, we directed an 18-gauge echogenic needle (Cook Medical) into the target calyx under ultrasound guidance. The needle stylet is removed and a J-tip coaxial guidewire is inserted into the renal pelvis and down the proximal ureter under ultrasound guidance. The wire tip can be located by gently moving the wire forward and back [(35)]. The needle is subsequently removed and a 1-cm skin incision is created surrounding the guidewire. Tract dilation proceeded with fluoroscopic guidance, ultrasound guidance, or direct retrograde visualization with a ureteroscope [(13)]. In cases where direct visualization of tract dilation was performed, ureterorenoscopy (URS) was performed retrograde while dilation was performed antegrade. For all tract dilation, we dilated the tract using first a 10F fascial dilator (Cook Medical) followed by a 24F high-pressure balloon dilator and sheath (BARD X-Force, Bard Medical). Kidney movement during tract dilation can be mitigated or prevented by applying a staccato motion to the access needle during its advancement. Once the wire is in place, utilizing a twisting motion while advancing the fascial dilator helps with smooth dilator advancement. An inherent advantage of ultrasound is that that it allows the operator to have continuous live imaging, so the mobility of the kidney can be monitored at all times. Ultrasound attempts at dilation were abandoned in favor of fluoroscopy if at any point ultrasound visualization of the kidney or access instrumentation was felt to be poor enough to be unsafe to proceed by the operating surgeon. An offset rigid nephroscope and lithotripter were used for stone fragmentation and removal. Nephroscope mobility in the supine position can be optimized with diligent consideration of patient positioning. By bumping the patient's flank 30-45 degrees from supine and moving the patient toward the lateral edge of the bed, we provide adequate space for the nephroscope to enter into all desired areas of the collecting system intraoperatively. After stone removal, we placed a 10F antegrade nephrostomy tube.

Data Acquisition

Demographic, perioperative, and primary outcomes were collected as part of ReSKU. Demographic characteristics included age, gender, and BMI. Perioperative data included preoperative stone size, presence of preoperative hydronephrosis, procedure laterality, surgical position, calyx puncture location, number of tracts dilated, and operative time. Primary outcomes of interest were complications, estimated blood loss, and stone-free status. Complications were defined using the

Clavien-Dindo (CD) classification system [(14)]. Stone free status was determined by a review of postoperative imaging, including plain radiographs, renal ultrasound, or CT scan of the abdomen, at the first-clinical visit within ninety days of the operation. Patients without postoperative imaging were excluded from the analysis. Patients scheduled for a future second-stage procedures were categorized as not stone-free.

Statistical Analysis

All statistical analysis was performed on Stata version 15.1. Univariate analyses (Fisher's exact test, Welch's t-test) were conducted to find differences in demographic characteristics, perioperative characteristics, and surgical outcomes between patients who underwent ultrasound and fluoroscopic renal tract dilation. We then performed multivariate binomial logistic regression, ordinal logistic regression, and linear regression to determine what patient variables, including the imaging modality utilized during renal tract dilation, predicted stone clearance, complication severity, or estimated blood loss. The variables included in our regression modeling were imaging modality used during tract dilation, age, gender, body mass index, preoperative stone size, surgical position, and operative time. Statistical significance was defined as $p < 0.05$.

Results:

176 patients underwent PCNL with successful ultrasound renal puncture including sixteen who underwent an ultrasound-guided puncture that was confirmed on direct visualization with URS and 151 patients with puncture and confirmation performed solely under ultrasound-guidance. This cohort of patients underwent renal tract dilation either with (n=38) or without fluoroscopic guidance (n = 138) (Figure 1). The demographic and perioperative characteristics for both groups are summarized in Table 1. There was a higher proportion of patients positioned in modified dorsal lithotomy for PCNLs in which renal tract dilation occurred without fluoroscopic guidance ($p < 0.01$). Additionally, ultrasound tract dilations had a significantly lower operative time than fluoroscopic

tract dilations ($p < 0.05$). There were no statistically significant differences between patient age, gender, body mass index, preoperative hydronephrosis, preoperative stone-burden, procedure laterality, number of dilated tracts, and calyx puncture location. Multivariate logistic regression to evaluate for correlation between demographic or perioperative characteristics with ultrasound renal tract dilation demonstrated that only modified dorsal lithotomy remained significantly associated ultrasound tract dilation ($p < 0.05$; OR 3.5). Age, gender, body mass index, presence of hydronephrosis, preoperative stone size, procedure laterality, number of tracts dilated, calyx puncture site, and operative time were not statistically significant associated with ultrasound tract dilation.

Univariate analysis of primary outcomes comparing both of these groups is summarized in Table 2. There were no statistically significant differences in postoperative stone clearance, complication rate, or intraoperative estimated blood loss between ultrasound and fluoroscopic nephrostomy tract dilations cases. In order to confirm our findings, we conducted an additional analysis that included all PCNLs performed during the study duration, irrespective of imaging used to guide the renal puncture, and still found no differences in EBL, stone-free status, and complications between fluoroscopic and ultrasound dilation. With multivariate regression, neither imaging modality used during tract dilation predicted stone clearance, complication severity, or estimated blood loss (Table 3). However, a 5-unit increase in the patient's body mass index was associated with higher odds of increasingly severe Clavien-Dindo complications ($p < 0.05$; OR 1.3). Similarly, a 5mm decrease in the preoperative stone burden was associated with higher odds of stone-free status after PCNL ($p < 0.05$; OR 0.8). Additionally, the modified dorsolithotomy position had 0.3 times the odds of stone-clearance relative to the prone position. However, this difference was not present when excluding the first half of cases performed. No variables included in the multivariate linear regression of estimated blood loss were statistically significant.

Discussion:

The two critical steps to initiate successful PCNL include renal collecting system puncture followed by tract dilation, with each step necessitating imaging guidance. The majority of renal punctures and tract dilations across the world, including both Europe and the United States, are performed with fluoroscopy [(6)], but a growing body of literature has supported ultrasound guidance. Ultrasound use for PCNL has many reported benefits over fluoroscopy. During pelvicalyceal access it allows the surgeon to distinguish between the kidney and surrounding structures [(15)]. Ultrasound identifies the posterior calyces more easily than fluoroscopy [(16)]. Doppler ultrasonography during renal puncture facilitates vessel visualization and results in less bleeding and transfusions [(17)]. Radiation exposure for patient and provider can be reduced by ultrasound substituting fluoroscopy for some or all steps in which imaging is used for PCNL. Limiting radiation exposure is especially beneficial in pediatric and pregnant patients, populations where radiation is best avoided.

Relatively little is written about the specific step of tract dilation, and our study demonstrates that performing this important surgical step without fluoroscopy is safe and effective. Various studies have assessed ultrasound use during access, but there exists a relative paucity in the literature regarding ultrasound guidance during tract dilation. The feasibility of ultrasound-guided renal tract dilations has been demonstrated in descriptive studies utilizing various dilation techniques including metal Alken telescopic dilation [(18)], Amplatz fascial dilation [(19)], and balloon dilation [(19)] with stone-free rates of 94%, 86%, and 89%, respectively. However, this is the first analytic study comparing surgical outcomes between fluoroscopic and ultrasound tract dilation.

Some have noted concern for the feasibility of conducting ultrasound-guided tract dilation. We have identified kidney and guidewire visualization as crucial determinants in deciding whether to proceed with an ultrasound-guided dilation attempt. If this is achieved, it is then also possible to locate the fascial dilator and balloon dilator with the ultrasound probe making ultrasound guided dilation a viable option. One challenge in completing the ultrasound dilation is placing the sheath over the balloon as active visualization is often impractical. Therefore, tactile feedback as we maintain the balloon in place and gently rotate the sheath back and forth over the balloon is of utmost importance. This approach to ultrasound-guided dilation has been previously depicted in detail [35].

We found no differences in stone clearance, complication rates, and estimated blood loss between ultrasound and fluoroscopic tract dilations. Similarly, multivariate regression modeling found no association between the imaging modality used to guide the tract dilation and any of the study's outcomes. Only modified dorsal lithotomy was a statistically significant predictor of ultrasound tract dilation. While some have demonstrated that fluoroscopic access is feasible and safe in the supine position[(20,21)], our practice is to utilize ultrasound or simultaneous ureteroscopic visualization to guide tract access and dilation when in this position. This particular association is most likely a reflection of practice pattern and illustrates the utility of ultrasound and direct vision tract dilation when the patient is supine.

The relatively lower odds of stone-clearance in the modified dorsolithotomy versus prone position likely reflects an inclusion of cases early in our learning curve. We began incorporating modified dorsolithotomy position at the onset of our cohort. In total, we had 75 patients positioned in this way. To see how much of an effect the learning curve had on our results, we conducted a regression sensitivity analysis that excluded the first half of cases conducted in this position and found that position no longer predicted stone-free status after PCNL ($p = 0.3$). This suggests that differences in stone-free status between prone and dorsolithotomy cases can likely be attributed to the learning curve of our endourologists.

In our study, a 5-unit increase in the body mass index had 30% greater odds of increasingly severe complications. Multiple studies assessing the impact of body mass index on surgical complications after PCNL have found no relationship [(28–31)]. Pulmonary complications after PCNL in the obese are theoretically more likely as the prone position can reduce ventilation and oxygenation, especially since obese patients have higher prevalence of specific pulmonary pathologies and generally higher odds of intra- and post-operative pulmonary complications [(32)]. While positioning predicted neither complication occurrence nor severity in our study, confounding may at least in part have played a role as we did not assess for differences in comorbid characteristics between obese and non-obese patients.

Another possibility is that this relationship between body mass index and severe complication occurrence is true for patients undergoing an ultrasound-guided renal puncture. The regression modeling included the entire study cohort and all individuals in the cohort underwent a successful ultrasound renal puncture. Dauw et al and Torrecilla Ortiz et al assessed body mass index and complication occurrence after PCNL in patients undergoing fluoroscopic-guided renal punctures, a difference which may explain the lack of predictive value body mass index had in those studies [(28,29)]. The difficulties of ultrasound with obese patients have been characterized. Signal attenuation occurs when ultrasound signals travel through subcutaneous fat, with a substantial signal reduction [(33)]. This can result in poor visualization of the kidney and surrounding structures. We previously demonstrated that patients with a body mass index greater than 30 had more failed ultrasound access attempts compared to patients with lower body mass indices [(34)]. In light of this finding, when performing ultrasound-guided renal punctures in obese patients, fluoroscopy should be available as backup with a low threshold for switching to fluoroscopy especially in stone centers where PCNLs are infrequently performed.

Our study has important limitations to consider. Firstly, the decision to conduct dilations with fluoroscopic or ultrasound guidance is not necessarily stochastic. Our surgeons have gained expertise with ultrasound use during all aspects of PCNL and successfully complete access and dilation without switching over to fluoroscopy. However, fluoroscopy is always available as a backup if any part of the procedure proves impractical or difficult with ultrasound. For this analysis, we categorized any fluoroscopy dilations that began as an ultrasound dilation attempt as an ultrasound dilation attempt, in accordance with the principle of an intention-to-treat analysis. Only seven patients had a switch to fluoroscopy. This approach does not account for the surgeon's selection bias in choosing one dilation modality over another based on perceived difficulty of the dilation process for a given patient. Another limitation of our study is potential lack of statistical power given the small sample size for fluoroscopic dilations.

The clinical implications of using ultrasound guidance techniques to facilitate tract dilation warrant discussion. We recognize that switching to fluoroscopy at any point can be burdensome for the surgical, nursing, and anesthesia team. It leads to delays since the radiology technician must be called into the room and the proper safety attire must be worn. This burden continues to exist with switching during dilation if renal puncture required no fluoroscopy.

Nonetheless, there are several significant advantages that ultrasound guided PCNL offers the practicing urologist. First, we consider the reduction in radiation an important benefit. We have presented our data at national and international meetings (manuscript submitted) demonstrating radiation exposure during renal tract dilation is not insignificant and therefore relevant to our goal of radiation exposure reduction. While our ability to reduce radiation exposure in the patients we treat with PCNL during a single surgery may arguably be limited with this approach alone, some patients undergo multiple PCNLs in their lifetime, and most urologists perform multiple PCNLs during the course of their lifetimes. This exposure may be clinically significant over the course of a lifetime for both patients and practitioners. Second, we previously described the cost savings associated with the substitution of fluoroscopy for ultrasound during the renal puncture [8]. By further reducing the need for fluoroscopy by incorporating ultrasound during dilation, there is potential for even greater cost-savings. Lastly, we have shown ultrasound guided procedures may be faster. This time savings is of both a monetary and a physical value for surgeons and hospital systems. Endoscopic combined intrarenal surgery (ECIRS) is another terrific and valuable technique which limits radiation and one that we certainly keep in our armament of surgical approaches. Compared to ultrasound guided PCNL, however we discern two significant disadvantages. First there is likely a larger cost associated with having a separate ureteroscopic team utilizing a ureteroscope and its associated disposables compared to performing the entire procedure with US. Second, the logistics of performing ECIRS for most urologists entails having a surgeon at the table side performing the puncture and dilation and a second surgeon at the foot of the bed performing ureteroscopy.

While mastering any new surgical skill is challenging, we have developed a training system that consistently brings trainees to a skill level such that they can obtain their own access and dilation under ultrasound guidance by the time they reach their chief year of urology residency. With wider adoption of this training, we envision a future time where radiation-free PCNL is one of many tools in the surgical armament of endourology. We would also point out that currently we perform pure ultrasound guided PCNL by adapting fluoroscopic instruments to ultrasound imaging. These are not designed for these purposes. If we can encourage wider adoption, the field of endourology will benefit as companies design instruments specifically suited for ultrasound guided renal access. With the advent of better suited technology, the procedure should also become easier over time, and ultrasound guided PCNL will be possible for more practitioners.

As a result of our findings, we have changed our practice over time to now attempt an ultrasound renal puncture for all cases. This can be successfully performed with ultrasound alone in 70% of our PCNL cases. Among those cases with a successful ultrasound renal puncture, when ultrasound visualization of the wire is adequate, we make an attempt to perform ultrasound guided tract dilation for all patients. This is successfully completed with ultrasound alone in 73% of those cases. We will transition to fluoroscopy if there is poor renal or guidewire visualization after obtaining ultrasound renal access. Additionally, we also find that if a patient has known anatomical abnormalities that will make ultrasound access challenging/risky (e.g. renal malrotation or a history of prior difficulty with obtaining access using ultrasound), we will typically commence with fluoroscopic guidance for renal puncture and tract dilation.

Conclusions:

Renal tract dilation can be safely performed in the absence of fluoroscopic guidance safely and without higher complication or bleeding rates. Training urologists in ultrasound imaging guidance techniques for renal tract dilation may help reduce radiation exposure for intraoperative personnel and also facilitate variable procedural positioning. Future studies centered on improving dilation techniques could be of impactful clinical value.

Acknowledgments:

Conflict of Interests:

The authors declare that there is no conflict of interests regarding the publication of this paper.

Authors' Contribution**:**

Manuel Armas-Phan, David T. Tzou, David B. Bayne, and Scott V. Wiener made substantial contributions to the acquisition, analysis, and interpretation of data. David T. Tzou, Marshall L. Stoller, and Thomas Chi made substantial contributions to the research design. All authors made

substantial contributions to the manuscript draft and critical revised it. All authors approved the submitted and final versions.

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Table 1: Patient Demographic and Perioperative Characteristics

	Ultrasound Dilation (n = 138)	Fluoroscopic Dilation (n = 38)	*P* Value
Age, mean (SD), years	54.6 (17.2)	51.0 (15.6)	NS
Male, No. (%)	63 (46)	18 (47)	NS
BMI, median (IQR)	28.8 (23.8-33.0)	30.1 (24.8-33.1)	NS
Hydronephrosis			
Y, No. (%)	65 (61)	15 (56)	NS
N, No. (%)	41 (39)	12 (44)	
Stone Burden, median (IQR), mm	30 (17-50)	32 (18-56)	NS
Surgical Position			
Prone, No. (%)	71 (52)	29 (76)	** / ***
Modified Lithotomy, No. (%)	66 (48)	9 (24)	
PCNL Laterality			
R, No. (%)	60 (44)	18 (47)	
L, No. (%)	71 (51)	20 (53)	NS
Other	7 (5)	0 (0)	
No. of Tracts Dilated			
Single, No. (%)	125 (91)	36 (95)	NS
Multiple, No. (%)	13 (9)	2 (5)	
Calyx Puncture Location			
Upper Pole, No. (%)	41 (29)	15 (30)	
Middle Pole, No. (%)	44 (31)	16 (32)	NS
Lower Pole, No. (%)	57 (40)	17 (34)	
Prior Nephrostomy Tract (%)	0 (0)	2 (4)	
Total (191)	142	50	
Operative Time, mean (SD), min	117 (42)	138 (69)	*

NS: Indicates comparison did not achieve statistical significance $p < 0.05$

*: Indicates comparison achieved statistical significance $p < 0.05$

**: Indicates comparison achieved statistical significance $p < 0.01$

***: Indicates multivariate logistic regression modeling achieved statistical significance $p < 0.05$

Table 2: Surgical outcomes comparing cases where fluoroscopic versus ultrasound guidance was used for renal tract dilation

	Ultrasound Dilation (n = 138)	Fluoroscopic Dilation (n = 38)	*P* Value
Stone Clearance[1]			
Yes, No. (%)	72 (57)	19 (56)	NS
No, No. (%)	55 (43)	15 (44)	
Complications[2]			
CD 0, No. (%)	113 (82)	33 (87)	NS
CD 1, No. (%)	3 (2)	1 (3)	
CD 2, No. (%)	17 (12)	2 (5)	
CD 3, No. (%)	3 (2)	0	
CD 4, No. (%)	2 (1)	2 (5)	
CD 5, No. (%)	0	0	
Estimated Blood Loss, mean (SE), mL	90 (12)	70 (10)	NS

NS: Indicates comparison did not achieve statistical significance $p < 0.05$

[1]Stone-free status was determined by a review of postoperative imaging within ninety days at the first clinical follow-up

[2]CD = Clavien-Dindo Classification

Table 3: Multivariate Regression of Clinical Outcomes

	Odds Ratio	*P* Value
Stone Clearance[1]		
Ultrasound Dilation (Y/N)	1.0	NS
Female (Y/N)	1.5	NS
BMI (5-unit increase)	1.0	NS
Preoperative Stone Burden (5-mm increase)	0.8	***
Modified Dorsal Lithotomy (Y/N)	0.3	***
Operative Time (1-min increase)	1.0	NS
Complications[2]		
Ultrasound Dilation (Y/N)	1.5	NS
Female (Y/N)	0.9	NS
BMI (5-unit increase)	1.3	***
Preoperative Stone Burden (5-mm increase)	1.0	NS
Modified Dorsal Lithotomy (Y/N)	1.9	NS
Operative Time (1-min increase)	1.0	NS
Estimated Blood Loss[3]	**Coefficient**	
Ultrasound Dilation (Y/N)	15	NS
Female (Y/N)	-2.7	NS
BMI (5-unit increase)	-0.2	NS
Preoperative Stone Burden (5-mm increase)	0.5	NS
Modified Dorsal Lithotomy (Y/N)	5.3	NS
Operative Time (1-min increase)	0.3	NS

NS: Indicates comparison did not achieve statistical significance $p < 0.05$

***: Indicates multivariate logistic or linear regression modeling achieved statistical significance $p < 0.05$

[1]Binomial Logistic Regression

[2]Ordinal Logistic Regression

[3]Linear Regression

[4]Regressions are age-adjusted

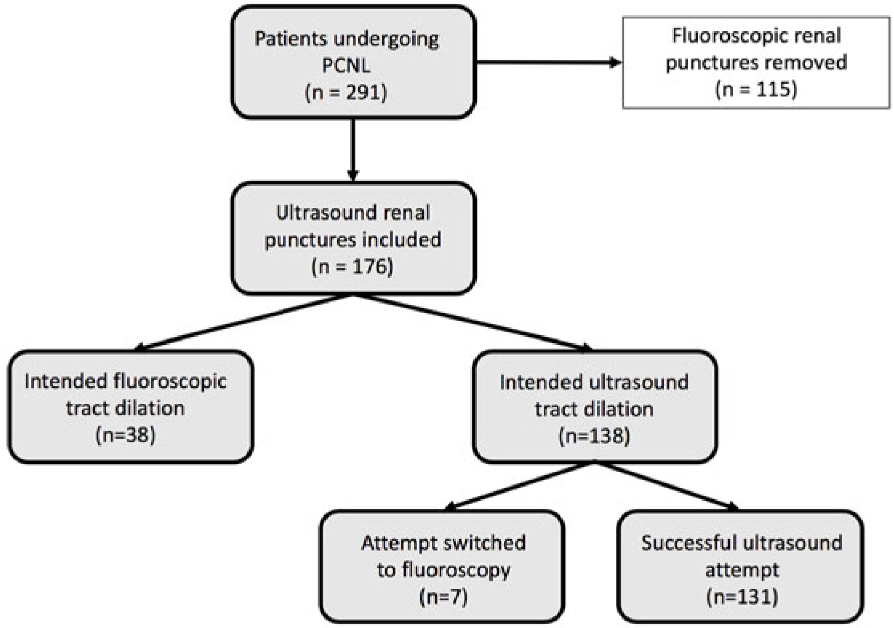

Figure 1: Patient flow diagram with inclusion criteria and intention-to-treat methodology