Introducing the POPVESL Score for Intrarenal Vascular Complications of Percutaneous Nephrolithotomy: Experience from a Single high-volume Referral Center

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Purpose: Percutaneous-nephrolithotomy (PCNL), is the current modality of choice for large renal stones. Delayed post-op bleeding may herald pseudo aneurysm (PA) or arteriovenous fistula (AVF) necessitating costly and inconsistently available angioembolization, or prolonged hospitalization. The goal of this study is to identify criteria that may predict response to conservative therapy, for delayed bleeding from post PCNL intrarenal vascular lesions.

Materials and methods: We reviewed all data on patients re-admitted for post PCNL gross hematuria at our high volume center between 2011 and 2016. Perioperative findings, factors related to the stone and management details, were subjected to multifactorial analysis. Logistic regression for multivariable analysis and ROC curves to find thresholds predicting mandatory angioembolization.

Results: Of 4403 PCNLs, 83 (1.9%) with delayed bleeding were diagnosed with intrarenal vascular lesions: Arteriovenous fistulas in 54 (AVF, 65%) and pseudoaneurysm in 29 (PA, 35%). Overall 49 (59%) responded to conservative management but 34 (41%) eventually required angioembolization. On multivariable analysis, predictive factors for poor response to conservative treatment were requiring transfusion beyond initial stabilization, pseudoaneurysm, history of open renal surgery, longer interval-to-second-admission, and size of vascular lesion. The proposed POPVESL score (short for Post PNL Vascular Embolization selection) when below 11, correctly predicts success of conservative management with 81.6% sensitivity & 100% specificity.

Conclusion: Our findings including the proposed POPVESL score have the potential for clinical application and enhancing practical guidelines on the management of post-PCNL bleeding.

Keywords: arteriovenous fistula; angioembolization; conservative management; percutaneous nephrolithotomy; postoperative complications; pseudo aneurysm

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) was introduced in the 1970s and withstanding the test of time, it remains the less invasive modality of choice for renal stones above 20mm.[1] Streamlined by smaller nephroscope footprint, flexible devices to address residual fragments and more efficient intracorporeal lithotripters; PCNL now affords over 90% success.[2] However, despite these advances and being less invasive compared to open surgery, complications of the initial puncture exacerbated by dilation and maneuvering to clear the kidney, remain inherent to PCNL. Even in the most experienced hands, major complications occur in up to 7% of cases.[2] Bleeding is the most common complication, requiring transfusion in 1 to 10% of cases.[3] Delayed bleeding in the form of hematuria or retroperitoneal hematoma is encountered in less than 1 % of cases and heralds pseudoaneurysm (PA) or arteriovenous fistula (AVF) formation.[3,13] These intrarenal vascular lesions usually manifest within 3 weeks after PCNL and may require endovascular intervention. In patients with unstable hemodynamics, significant hemoglobin drop or prolonged bleeding, the modality of choice is angioembolization with over 95% success in various reports.[4,14,15] Although some authors recommend having a lower threshold for angioembolization to avoid blood transfusion,[3] the costs and complications of this modality should also be considered.

Studies on predictive factors for the success of conservative therapy are limited. Possibly because most surgeons rush to early angioembolization for managing all such lesions. In contrast, some centers in the world give conservative management a chance whenever possible. Sharing the lessons learned from such large-volume centers can be insightful.

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Figure 1. pseudo aneurysm and AVF during DSA. **A:** AVF before embolization (Black arrow), **B:** The same patient after embolization. **C:** PA before embolization (black arrow), **D:** The same patient after angioembolization.

The aim of this study is to look back at the data from our exceptionally high-volume single center experience, concentrating on demographics, stone related and procedure-specific prognostic factors to look for possible predictive factors of response to conservative therapy. By analyzing these factors, we have searched for sentinel criteria to assist with the decision to switch from watchful waiting and conservative management to vascular intervention.

MATERIALS AND METHODS

After institutional ethical committee approval for studying this historical cohort, we reviewed the records of all patients who were re-admitted for gross hematuria after being discharged following PCNL at our center, and diagnosed with intrarenal vascular lesions, between December 2011 and January 2016.

According to the urologic emergency management policy guidelines at our center, all patients with delayed post PCNL bleeding (i.e., presenting with gross bleeding after being discharged from hospital) are seen at the emergency department. After resuscitation and stabilization, search for an underlying cause for the bleeding begins by combined color Doppler and greyscale ultrasonography of the kidneys, performed by experienced in-house vascular interventionists.

We perform a non-contrast CT scan in all such readmissions to screen for residual fragments and quantify the extent of any retroperitoneal hematoma. Cases of isolated hematoma without hematuria were rarely encountered and are self-limited and minimally symptomatic. Color Doppler ultrasound combined with non-contrast CT usually provides adequate diagnostic information in post PCNL bleeding. Those with equivocal findings and all those requiring intervention were then scheduled for digital subtraction angiography as the modality of choice at our center (compared to CT angiography) for its higher accuracy and needing less contrast, while allowing for immediate intervention if required.[12]

Any persistently unstable hemodynamics would entail emergent angioembolization. Otherwise, all stable patients diagnosed with intra-renal vascular lesions on color Doppler, undergo a period of watchful management, monitoring vital signs and hemoglobin levels aside bladder irrigation via a three-way Foley. The severity of bleeding is assessed by two factors: First, the magnitude of pre-hospital bleeding (judged by comparing the hemoglobin level before PCNL with that upon the second admission). Second, is the number of packed cell units required beyond correcting the initial deficit and primary stabilization (i.e., achieving 10 g/dl). These reflect the severity of bleeding before and after initial management, and were regarded separately

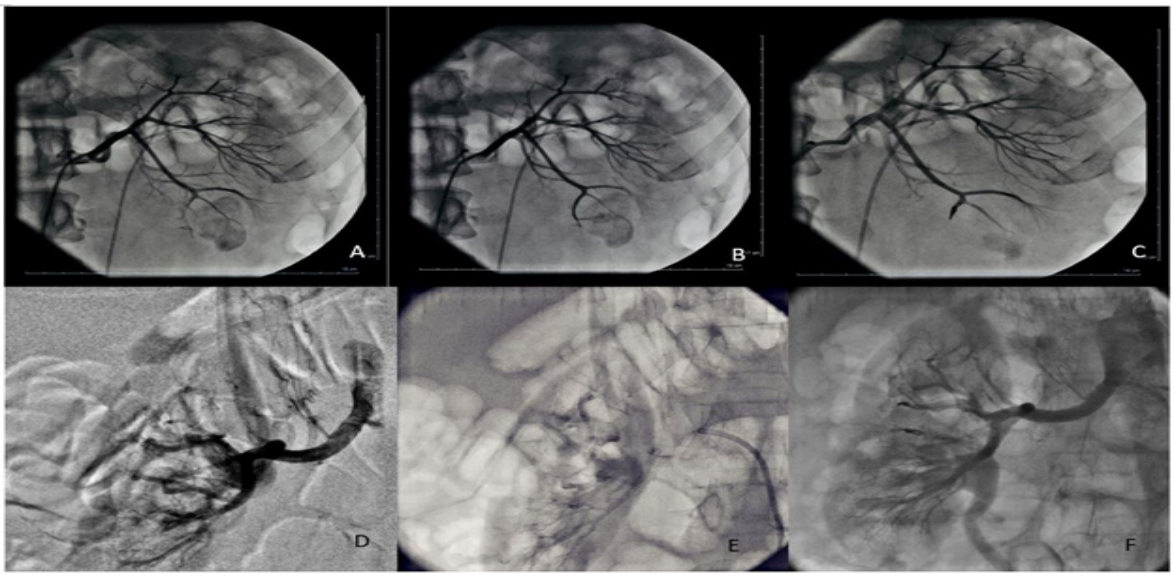

Figure 2. Sonographic view of an iatrogenic pseudoaneurysm.

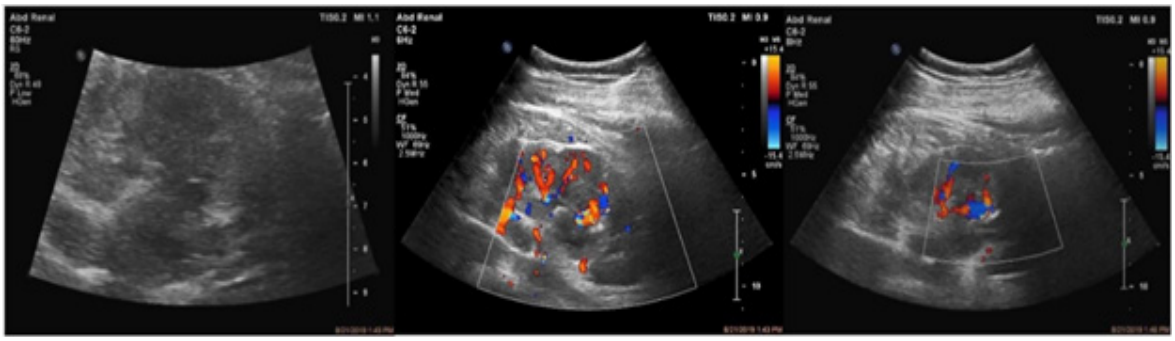

Figure 3. Sonographic view of an iatrogenic AVF.

in this analysis.

Patients requiring more than 3-4 units of blood following the initial correction of hemoglobin levels, also those with persistent hematuria into the tenth day of admission are generally scheduled for elective angioembolization. Some exceptions to this approach may be expected based on the clinical progress of individual cases as judged by their responsible urologist. Those who respond to conservative management are followed up by color Doppler ultrasonography to assess the fate of the vascular lesion. Patients are discharged if they no longer have hematuria and there is evidence of a shrinking vascular lesion.

Demographic and operative data were extracted from the records. In addition, further hemoglobin drop, the interval between PCNL and onset of delayed hematuria, number of packed cells required, type and size of vascular lesions, duration of the second admission, etc. were accounted.

Statistical analysis on IBM SPSS software version 19, using the Fisher exact test for categorical variables, Student's T-test and Mann-Whitney tests for continuous parametric and non-parametric variables. The *P*-value cut off for statistical significance was < 0.05 for this report. Logistic regression for multivariable analysis and receiver-operating characteristic (ROC) curves were utilized to suggest the threshold value for predicting the need for angioembolization.

RESULTS

After obtaining approval from the institutional review board, a search within data pertaining to all 4403 patients who had undergone PCNL at our single referral center between Dec 2011 and Jan 2016 (50 months) revealed 83(1.9%) individuals who had presented with delayed hematuria necessitating readmission after initial discharge from the hospital, and further diagnosed to have an intrarenal vascular cause, namely AVF or PA.

Data regarding this entire group was subsequently analyzed in depth with no exclusions. Mean age was 50.3 +/- 12.2, and 61 of the 83 were male (73.5%). All patients had achieved negative urine culture leading to PCNL, none had taken aspirin within the 5 days leading to this surgery. Also, coagulation panels were normalized perioperatively and therefore not included in further analysis. Chronic kidney disease (defined as glomerular filtration rate below 90ml/min/1.73m^2 estimated by the Cockcroft-Gault equation) was noted in 21.7%, diabetes in 12% and hypertension 14.5%. History of ipsilateral open renal surgery (pyelolithotomy in our cases) and SWL were 14.5% and 8.4% respectively, and 2.4% had abnormal ipsilateral renal anatomy.

Mean stone burden as defined by sum of the maximum length of all stones for each renal unit was 67 mm (range 20-140). Twenty-one patients had staghorn calculi (25.3%), 49.4% had renal pelvic stones and the remainder were in the calyces.

All surgeries were performed by endourology fellows under direct supervision of the attending. All initial punctures were performed under fluoroscopic guidance using an 18-gauge needle initial coaxial dilation to 12F followed by one-shot dilatation to place the Amplatz sheath. The initial punctures were not hematuric, but 22 of the 83 patients (26.5%) had required 2 or 3 attempts to achieve access of whom14 (25.9%) and 8 (27.5%) had AVF and PA respectively.

Looking back at the original PCNL records, and as is standard practice for all PCNLs at our center, all but three patients had originally been furnished with an ex-

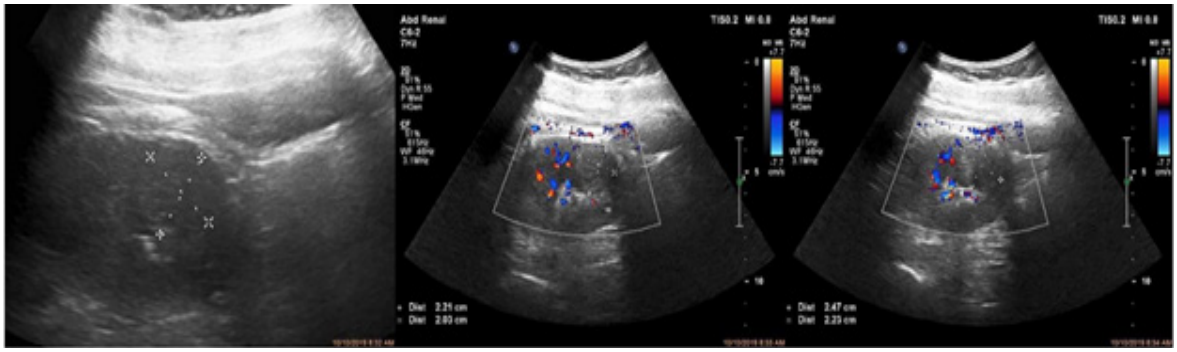

Figure 4. Follow up Sonographic view of the case of pseudoaneurysm which was managed conservatively.

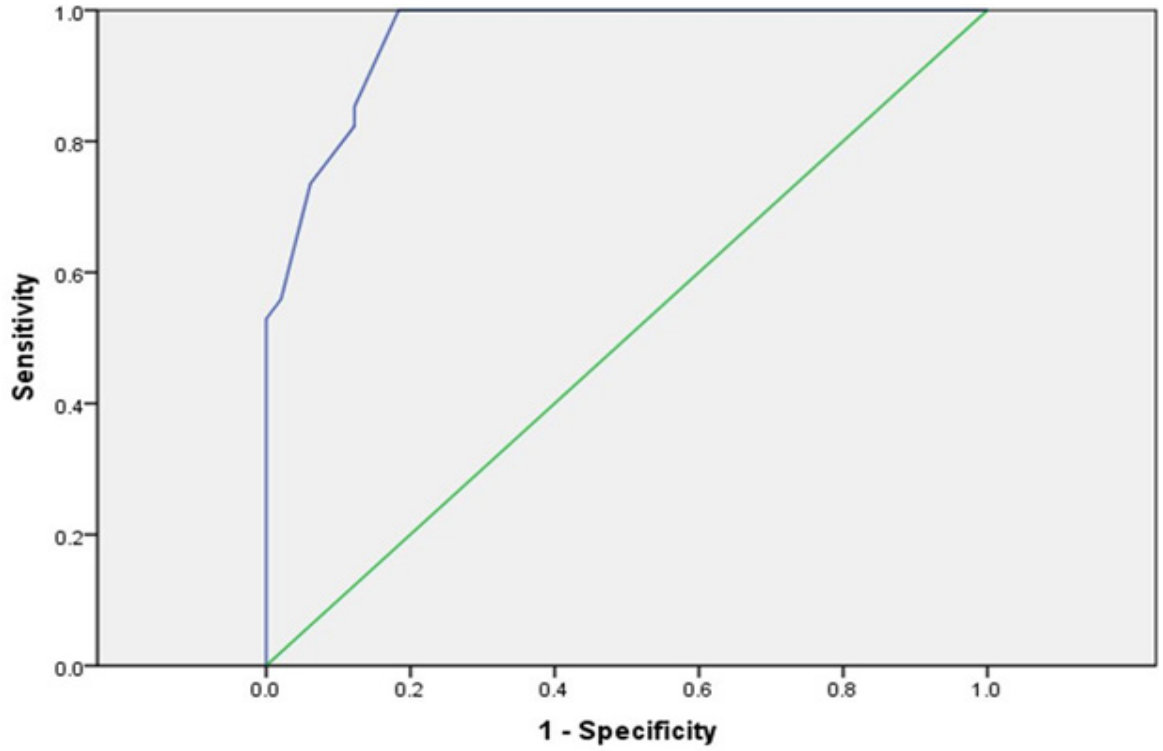

Figure 5. ROC analysis for POPVESL Score. The area under the curve is 0.958. Cut off point for best sensitivity and acceptable specificity is 10 yielding 100% sensitivity and 81.6% specificity.

teriorized ureteral catheter or indwelling stent, plus a urethral Foley. In the remaining three a nephrostomy tube had been placed at the surgeon's discretion. In all 83 cases, the initial PCNL had concluded without undue intraoperative bleeding, therefore abortion of the surgery for bleeding was not an issue in any of these. Eleven renal units had required two accesses for stone clearance, all other procedures were accomplished through a single subcostal access (86.7%). The mean operation time was 68.6 +/- 30.3 min.

Stone free status was assessed 2 weeks from the surgery by ultrasonography, plus plain radiography or non-contrast CT scan in cases of non-opaque renal stones. Presence of any residual stone after PCNL before adjuvant therapy was recorded in 28 of these 83 patients (33.7%).

Overall, the mean size of the vascular lesion was 9.8mm (SD 6.6): For AVF 6.7mm (3-38mm) and PA 10.5 mm (4-42 mm). Forty-nine patients (59%) responded to conservative treatment and were discharged when gross hematuria ceased and the lesion was seen to shrink on control sonography. These patients were asked to return in case of recurrent hematuria, and once a week for outpatient follow up sonography until the lesion resolved. Thirty-four patients (41%) eventually required angioembolization as shown in Figure 1. The overall incidence of developing vascular lesions necessitating embolization in 4403 PCNL procedures was 0.77%. One patient required a second embolization after the failure of the first attempt to control hematuria. The final success rate for embolization was hence 100%.

Clinical findings related to PCNL and the occurrence of an intra-renal lesion are depicted in Table 1. Sample sonography of PA and AVF managed conservatively and follow up imaging of a case of pseudoaneurysm are shown in figures 2, 3 and 4 respectively.

There was no recurrence of hematuria after initial successful conservative therapy, which was predictable given serial Doppler sonographies suggestive that the lesions were regressing.

All cases diagnosed as PA or AVF by color Doppler sonography were reconfirmed at angiography, so the specificity of color Doppler sonography by an experienced uro-radiologist approached 100%.

Most patients still had a double J at the time of their second admission, and we did not replace any new ureteral catheter to allow the pyelocaliceal system to help tamponade the bleeding. Flank pain was managed with narcotics or non-opioid analgesics as required.

Univariable analysis of factors affecting the need for angioembolization:

Preadmission hemoglobin drop, units of packed cell transfused post stabilization, presence of a pseudoaneurysm, size of the lesion, history of previous open renal surgery and stone burden were predictive of the need for endovascular intervention.

Other factors including time between PCNL and re-admission for hematuria, age, sex, past medical history, history of SWL, abnormal anatomy, laterality, access size, residual fragments, and stone location did not differ significantly between the two groups as shown in **Table 1**.

Multivariable analysis: By logistic regression, predictive factors for poor response to conservative treatment and need for endovascular intervention were units transfused packed cell, presence of pseudoaneurysm, history of open renal surgery, longer interval between PCNL and second admission and size of the vascular lesion. Details of these findings are summarized in **Ta-**

Table 1. Factors predictive of the need for angioembolization, Univariable analysis.

	Factor	Subgroup responding to conservative therapy n=49	Subgroup requiring Angioembolization n=34	*P* value
Preoperative factors	Age (Mean ± SD)	43 ± 10.8	50 ± 12.8	0.1
	Sex M / F	35(71%) / 14(29%)	26(76%) / 8(24%)	0.6
	DM	6(12%)	4(12%)	0.7
	CKD	12(24.5%)	6(17.6%)	0.3
	HTN	7(8.4%)	5(6%)	0.9
	Hx of SWL	2(4%)	5(15%)	0.1
	Hx of Open renal surgery	2(4%)	10(29%)	0.003
	Laterality R/L	22(44.8%) / 27(55.2%)	16(47%) / 18(53%)	0.8
Operative	Subcostal access	43(88%)	29(85%)	0.8
	Multiple access	6(7.2%)	5(6%)	0.8
	Stone location (Pelvis and one calyx / more locations)	27(55%) / 22(45%)	14(86%) / 20(14%)	0.3
	Duration of surgery (min) (Median± SD)	50 ± 1.34	60 ± 1.38	0. 4
	Stone burden (mm) (Median± SD)	60 ± 1.60	70 ± 2.29	0.02
	Presence of any residual fragments	14(29%)	14 (41%)	0.2
Post-operative factors	Interval from PCNL to re-admission (days) (Median± SD)	5 ± 4.57	8 ± 6.30	0.06
	Duration of the second admission (days) (Mean ± SD)	8.7 ± 5.2	13 ± 6.6	0.02
	Type of vascular lesion PA (n=29)	12(24.5%)	17 (50%)	0.02
	AVF (n=54)	37(75.5%)	17 (50%)	
	Size of vascular lesion(mm) (Median± SD)	7 ± 4.02	10 ± 7.86	0.000
	Pre admission hemoglobin drops (g/dl) (Median± SD)	2.8 ± 1.69	3.8 ± 2.15	0.04
	Units of packed cell transfused after stabilization (Median± SD)	2 ± 1.60	5 ± 1.57	0.000

M, Male; F, Female; DM, Diabetes Mellitus; HTN, Hypertension; Hx, History; CKD: Chronic kidney disease, defined as the presence of glomerular filtration rate less than 90 ml/min/1.73m2 estimated by the Cockcroft-Gault equation. SWL, extracorporeal shockwave lithotripsy; L. left; R, Right. SD: Standard Deviation.

ble 2. Odds ratio was calculated on the SPSS platform by backward logistic regression for influential factors (those having a suggestive p-value below 0.2 on univariable analysis).

In univariable analysis for factors predictive of the need for endovascular intervention, greater hemoglobin drop, need for more packed cell units, presence of PA, larger size of any vascular lesion (regardless of type), history of open renal surgery on the affected kidney and larger stone burden were all found to be significant; whereas age, sex, history of diabetes, CKD, HTN, and abnormal renal anatomy were not.

Finally, in multivariable analysis, five-factors including the need for more packed cell units beyond initial sttabilizaton (Beta 1.060 and *P*-value 0.012), presence of PA (OR 0.145 and *P*-value 0.013), history of open renal surgery (OR 31.092 and P-value: 0.008), larger vascular lesion (Beta 0.314 and P-value 0.001) were statistically significant; and longer interval between PCNL and second admission (Beta: 0.117 and P-value 0.065) was concluded by the researchers to remain included until further corroboration in larger series. These were taken as predictive factors for failure of conservative treatment and the need for angioembolization. Among which, history of open renal surgery has the strongest impact with OR=31 followed by type of lesion where PA portends conservative treatment failure (OR=10).

When tested for our series, a POPVESL score below 11 was 100% specific and 81.6% sensitive in predicting success with medical management. Conversely, the POPVESL score above 16 was 100% specific but 52% sensitive for the inevitability of embolization. (Positive Predictive Value=1, Negative Predictive Value=0.75). ROC curve analysis to derive a cut-off point with optimal sensitivity and specificity, for the POPVESL score, is shown on **Figure 5**.

DISCUSSION

Based on the latest guidelines PCNL is the treatment of choice in large renal stones.[1] Complications of this modality are inevitable among which delayed hematuria from intrarenal vascular lesions is one of the most

Table 2. Predictive factors of the need for angioembolization, Multivariable analysis.

Factor	Odds Ratio	95% C.I.for OR Lower	Upper	*P* value
History of open renal surgery	31.092	2.491	388.013	.008
Number of transfused units after initial stabilization	2.886	1.264	6.590	.012
Type of lesion	1.928	.0320	.669	.013
Size of lesion(mm)	1.369	1.133	1.654	.001
Interval from PCNL to re-admission(days)	1.125	.993	1.274	.065

OR, Odds Ratio; CI, Confidence Interval

Table 3. POPVESL scoring system for calculating the likelihood of requiring vascular intervention for patients with delayed post PNL bleeding.

P	O	P	V	E
Pseudoaneurysm 3 points	Open surgery on the same kidney 5 points	Post-surgery interval (≥8.5 days) 2 points	Vascular lesion diameter (≥7.5mm) 3 points	Extra units of blood beyond initial stabilization 2 points per unit

significant.[3] Management is based on clinical course, varying from conservative treatment in cases who can be stabilized; to emergent angioembolization in hemodynamically unstable patients; to elective intervention for sustained hemoglobin drop, repeated need for blood transfusion, and prolonged hematuria despite initial improvement. Although some authors suggest early angioembolization to prevent blood transfusion,[3] one must consider the significant costs and complications of any intervention too.

Previous studies did not focus on factors predictive of success or failure with conservative therapy. Some have looked into predicting post-PCNL bleeding, and the success rate of angioembolization.[5,6,7] These studies highlighted the effect of multiple tracts, stone burden, baseline hemoglobin level, perforation of the renal pelvis, intraoperative bleeding, history of open surgery on the affected renal unit and operation time, on the need for transfusion or intervention. Un et al studied patients who underwent angioablation for post PCNL hematuria and stated the presence of renal anomaly and stone burden as predictors.[8] Therefore, searching for more objective and practical clinical criteria for management decision, rather than waiting to be guided by the natural course of symptoms is justifiable.

One virtue of the present study is pertaining to a single high-volume referral center for urolithiasis. HKC is an academic center at which over 1000 PCNL cases are performed annually. The stone-free rate on this report is visibly below that of previous reports from our center, in which the stone-free rate after PCNL measured 2 weeks after surgery was historically reported between 89-92%.[9] Although this might owe in part to a slightly larger than institutional average stone burden in the present cohort, it is mostly the result of re-defining stone rest as the presence of any (even smaller than 2mm) fragment as residue in the present analysis.

In our 4403 patients, the incidence of intrarenal vascular insult following PCNL was 1.8 % and need for angioembolization was 0.7%. These findings are comparable to contemporary series.[10,11] Kessaris et al, reported post PCNL vascular lesions in 0.8 % of their patients.[10] El Tayeb et al, also published the result of their survey of 2892 PCNLs for which angioembolization was required in 0.5%.[11] Many centers would embolize post PCNL hemorrhage early-on. This would detract from those left to present with delayed bleeding, and explains the apparently high proportion of embolized cases in our series which is entirely composed of the high risk patients presenting with delayed gross bleeding, and diagnosed with an overt vascular lesion.

In our series, there was no significant difference between the AVF and PA in terms of demographic data and other preoperative or intraoperative variables, and none were consistently correlated with the type of lesion. However, factors including the magnitude of hemoglobin drop, number of transfused packed cell units, and duration of hospital stay at the second admission were significantly higher in the PA group. Conversely, we found a significant dominance of AVF over PA among initial responders to conservative treatment.

In suggesting a cut-off point for the size of the vascular lesion, PCNL-to-readmission time and number of units transfused after stabilization enhance the practical value of these findings and enables us to counsel patients based on predictive factors and decide between two lines of treatment. To assist with this bedside decision, based on our multivariable analysis, we propose the POPVESL score (short for Post PNL Vascular Embolization selection), wherein the risk factors recognized above are included and weighted building upon their calculated odds ratio, and fine-tuned based on expert opinion of the researchers for fidelity and the highest differentiating power, to derive a score as described in **Table 3**.

Our study suggests that conservative management and prompt intervention do differ in cost. We calculated the direct cost of each modality in our public health care system as an example, confident that the POPVESL score can be used equally well at contrasting settings where the index shall help by predicting the odds for each course of action, while local healthcare fees will be factored-in to allow patients and care givers to make an educated choice. In our academic hospital setting in this country, patients are typically covered by public health insurance. The average cost (at the exchange rate in mid-2019) for hospitalized patients managed on conservative therapy in this series was 30 USD per day, and total cost of conservative therapy amounted to 260 USD +/- 150 USD; of which patients only pay 10% out of pocket. Whereas the total hospital cost for cases requiring angioembolization was about seven times this amount, mostly owing to the coils which alone costed 1600 USD, comparable to the US price tag.[16] Due to high costs of angioembolization in our setting and its potential complications, usually in case of stable clinical status following initial resuscitation we offer both treatments to our patients. Because of the high success rate of conservative therapy and its lower cost and acceptable complications, most of them choose to be managed conservatively at the beginning.

Although representing one of the largest volumes of data for any single-center, the low overall incidence of this complication nevertheless makes sample size one of the limitations of this study, along with its retrospective nature. Future prospective studies with a larger sample size may fine-tune weight allocation to the score criteria.

CONCLUSIONS

Post PCNL intrarenal vascular lesions usually occur in the form of arteriovenous fistula and pseudoaneurysm. Patients with stable hemodynamics and less severe bleeding can be managed conservatively. Based on our results in multivariable analysis, more transfusions, presence of PA, history of open renal surgery, larger

vascular lesion and protracted interval between PCNL and second admission are independent predictive factors for angioembolization. Our findings including the proposed POPVESL score have potential implications in updating future guidelines on the management of post-PCNL bleeding.

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CONFLICT OF INTEREST

There is no conflict of interest, or any financial agreement with companies whose products may be alluded to in the paper

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