



Cross sectional retrospective assessment of safety of retrograde intrarenal surgery with laser lithotripsy in management of upper urinary tract calculi

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Abstract

Context: The utility of Retrograde Intra Renal Surgery (RIRS) with laser lithotripsy has gained wider acceptance in management of upper tract stones. RIRS is associated with fewer complications. This study aims to assess complication rate of RIRS with laser lithotripsy, severity of complication using modified Clavien-Dindo classification system (MCCS), factors predicting complications and grade of complications.

Materials and Methods: This was a retrospective cross-sectional study involving 33 patients with a diagnosis of upper tract stone less than 20mm. Patients had retrograde intrarenal surgery with laser lithotripsy for ureteric stone using a semi rigid ureteroscope (9.5Fr Karl Storz) with a Holmium YAG laser machine, in combination with 274um laser fiber, and a flexible ureterorenoscope was used for renal stones with a ureteral access sheath (UAS).

Results: Thirty-three patients were involved in this study, with a mean age of 43.70+/- 11.44 years. Males accounted for 18 (54.5%) of the study population. Mean duration of admission was 2.5+/-1.6 days. The median stone size was 10.55(IQR=0.42-85.0), while mean stone density measured in Hounsfield unit (HU), was 817+/-285.5. Intraoperative and postoperative complication rate was 12.1% and 21.2% respectively. Severity of complication using the MCCS include 47.6%,28.6%, 19.0%, 4.8% for grades I, II, III and, IV respectively. Age (p=0.364), gender (p=0.843), stone size (p=0.143) and, ureteric stones or emergency interventions (p=0.151) were not associated with complications or grade of complications. In a multivariate regression analysis, there were no predictors of complications, or grade of complications.

Conclusion: The complication rate of RIRS with laser lithotripsy in this study was moderate, with most patient having minor complications Clavien-Dindo I and II.

Keywords Calculi, Clavien-Dindo Classification, Complications, Laser Lithotripsy, Retrograde intra renal surgery, Safety, Ureteroscope

Introduction

Urinary stones are a growing health challenge. The lifetime prevalence of renal stones range from 1-15% with variations based on age, sex, race and geographic location.¹ Refinement in endoscopic device has made ureteroscopic stone surgery the most common approach to treat urinary stones.² It has become the treatment of choice in upper urinary tract stones <2cm.^{3,4} Retrograde intrarenal surgery (RIRS) with laser lithotripsy is commonly considered a safe procedure with few complications.⁵ The unfulfilled need for

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effective treatment modalities with minimal morbidity motivated the invention of novel techniques like RIRS, as alternatives to shock wave lithotripsy (SWL) and percutaneous nephrolithotomy PCNL.⁶

Among the complications following RIRS with laser lithotripsy, the most prevalent is fever, urinary

infections with an incidence ranging from 0.2% to 15%, and sepsis, which can be fatal and is a major cause of postoperative mortality. Other commonly reported complications include discomfort from ureteral stent, injuries to the ureteral wall and migration of fragments.⁷ Another major complication reported in the literature include severe bleeding, which may require transfusion.⁶ Complication classification system for surgical procedures are imperative as this helps to define the safety profile of these procedures and also serve as basis for comparing complication rates between procedures for similar pathologies and a means of standardization between centers. Several scoring systems have been developed for surgical procedures, amongst which are the modified Clavien classification system (MCCS) and the modified Stava classification system (SCS), which are most commonly used for postoperative and intraoperative complications respectively.^{8,9}

The adoption and development of minimally invasive surgery for upper tract stone management in Nigeria particularly RIRS and Laser lithotripsy is on the rise, however, there is dearth of study evaluating safety and complication rate of this emerging technology. The aim of this study therefore was to assess complication rate, the severity of complications using modified clavien classification system and factors predicting complications associated with RIRS with laser lithotripsy in our center.

Materials and methods

Study setting: This study was carried out in Urology unit, Department of Surgery, University of Benin Teaching Hospital (UBTH), Benin City, Edo State, south-south, Nigeria. A multi- specialty tertiary health care facility, attending to the needs of patients in Edo State and other neighboring states like Delta, Bayelsa, Ondo and Kogi States. It has over 900 bed capacity.¹⁰

Study design: This is a retrospective descriptive cross- sectional study.

Sampling technique: A convenience sampling method was used based on availability of records, since it was a retrospective study. Therefore, participant's records were abstracted consecutively, till all available data were collated.

Study Population: The study involved all patients

with renal and ureteric calculi less than 2cm, who had retrograde intrarenal surgery and laser lithotripsy over a 2 year period, from November, 2021 to December, 2023. Their data were retrieved from their case notes, electronic medical records [EMR] and operative records. Patients whose records were incomplete were excluded. Data were collected with a pro forma. The study was approved by our institution's research and ethics committee.

Study Procedure: Patients had preoperative computed tomography, urine microscopy, culture and sensitivity (MCS), Full blood count (FBC) and Electrolyte, urea and creatinine (E/U/Cr) prior to the procedure. Stone size was assessed based on the widest diameter measured in millimeters(mm).

Preoperative antibiotics were administered after administration of epidural anesthesia or induction of general anesthesia. With patients in Lithotomy position, a semi-rigid ureteroscopy (9.5 Fr Karl Storz ureterorenoscope with a 5Fr working channel) was performed routinely to passively dilate the ureters and to place a hydrophilic safety guidewire (0.038- inch) that was advanced to the renal pelvis with fluoroscopic assistance where the stones were renal. If the stones were ureteric, after passing the semi rigid ureteroscope, stone fragmentation were done with a holmium- YAG laser using laser machine (Quanta system, Litho machine 35W model) in combination with 274um laser fiber. For renal stones, a ureteral access sheath (UAS) was passed via the hydrophilic safety guide wire, a flexible ureterorenoscope (9.5Fr with a 3.6Fr working channel) was inserted into the renal pelvis via UAS or the calices. Kidney stones were fragmented with a holmium -YAG laser using laser machine (Quanta system, Litho machine 35W model) in combination with 274um laser fiber. The laser settings include for fragmentation: high energy (1-2J), low frequency (3-5Hz); dusting: low energy(0.2-0.5J), high frequency(10-20Hz); Pop-corn effect: high energy(1J), high frequency (10-20Hz). However, larger stone fragments were extracted using nintinol stone basket catheter. Flexible ureterorenoscope was used to reassess for residual fragment after the procedure and findings were documented as perceived stone clearance. Following lithotripsy, a 5/26 or 6/26 double J(JJ) stent were placed for 2-3 weeks, unless there was a complication in which case the double J stent is

placed for 4-6 weeks, to allow smaller fragments pass with ease and allow antegrade flow of urine despite post – operative edema. Post operatively, plain x-ray of kidney ureter and bladder (KUB), was done to confirm stent position and assess residual stone fragments. Four weeks post-operatively, plain x-ray, abdominopelvic ultrasonography or non-contrast computed tomography was used to assess residual fragments.

Statistical analysis: Data were analyzed using SPSS version 25.0. Categorical data were summarized as frequencies and percentages while continuous data were presented as mean $\pm$ standard deviation when normally distributed and summarized as median and inter-quartile range when not normally distributed. Pearson correlation coefficient was used to establish the correlation between calcium and stone size and density. Fishers' exact or chi square was used to assess factors determining complications and grade of complications of laser retrograde intrarenal surgery (RIRS) with laser lithotripsy using modified Clavien-Dindo classification where appropriate and independent predictors of complications and grade of complications were determined using multivariate regression analysis. P-value less < 0.05 was considered significant.

Results

In Table 1, showing socio-demographic characteristics of respondents, Eleven (33.3%) study participants were aged 50 to 59 years while 9 (27.3%) were between 40 – 49 years. The mean $\pm$ standard deviation age of the study participants was 43.70 ± 11.44 years. More than half, 18 (54.5%) of the study participants, were males while 15 (45.5%) were females.

Twelve (36.4%) study participants had secondary level of education, while 20 (60.6%) had tertiary level of education

Using the international standard classification of occupation, 11 (33.3%) persons belonged to class 1 while 15 (45.5%) belonged to class 3.

Ten (30.3%) study participants were from the Benin ethnic group, while 7 (21.3%) were of the Urhobo/Isoko ethnic group. Majority, 32 (97%) study participants were Christians. Fifteen (45.5%) study participants lived outside Edo State.

The Mean $\pm$ standard deviation duration of

Table 1: Socio-demographic characteristics of respondents

Variable	Frequency n = 33	Percent (%)
Age group (years)		
20 – 29	4	12.1
30 – 39	8	24.2
40 – 49	9	27.3
50 – 59	11	33.3
60 and above	1	3.0
Mean $\pm$ sd Age (years)	43.70 ± 11.44	
Sex		
Male	18	54.5
Female	15	45.5
Level of Education		
Primary	1	3.0
Secondary	12	36.4
Tertiary	20	60.6
Religion		
Christianity	32	97.0
Islam	1	3.0
Occupation		
Skill 1	11	33.3
Skill 2	5	15.1
Skill 3	15	45.5
Skill 4	2	6.0
Ethnic group		
Bini	10	30.3
Urhobo/Isoko	7	21.3
Esan	6	18.2
Igbo	6	18.2
Afemai	2	6.0
Yoruba	1	3.0
Ika	1	3.0
Residential location		
Outside Edo State	15	45
Within Benin City	11	33
Outside Benin City	7	21
Mean $\pm$ sd Duration of Admission (Days)	2.4 ± 1.5	
Minimum Duration (Days)	1	
Maximum Duration (Days)	7	

Table 2: Renal Stone Size and Density among Study Participants

Variables	Mean $\pm$ sd	
Stone Size (mm)	10.55 (IQR=0.42-85.0)*	
Stone Density (HU)	817.6 $\pm$ 285.5	
	Right Kidney	Left Kidney
Stone Size (mm)	11.8 $\pm$ 4.8	11.2 $\pm$ 3.3
Stone Density (HU)	723.2 $\pm$ 361.3	905.9 $\pm$ 379.9

*=medianAll participants had stent replacement; in Table 3

admission of study participants was 2.4 ± 1.5 days, as shown in Table 1.

Table 2, showing size and density of stone amongst study participants. The median stone size was 10.55 (IQR=0.42-85.0) mm, while the mean $\pm$ sd stone density (HU) was 817.6 ± 285.5 .

The Mean $\pm$ sd stone size (mm) was 11.8 ± 4.8 in the right kidney and 11.2 ± 3.3 in the left kidney.

The Mean $\pm$ sd stone density (Hu) was 723.2 ± 361.3 in the right kidney and 905.9 ± 379.9 in the left

Table 3: Stent Replacement and Complications among Study Participants

Variables	Frequency (%)
Stent Replacement	
Yes	33 (100.0)
No	0 (0.0)
Mean $\pm$ sd Duration of Stent (weeks)	8.6 $\pm$ 5.0

Table 4: Complications of Procedure Reported among Study Participants

Variables	Frequency (%) (n=33)
Intra op procedural complication	
Yes	4 (12.1)
No	29 (87.9)
Type of Intra-op complications (n=4)	
Hematuria	2(50.0)
Left ureteric perforation	1 (25.0)
Right ureteric perforation	1 (25.0)
Post-op procedural complication	
Yes	7(21.2)
No	26 (78.8)
Type of post-op complications* (n=7)	
Fever	6 (85.7)
Irritative symptoms	4 (57.1)
Hematuria	3 (42.8)
Sepsis	2(28.5)
Left ureteric stricture	2 (28.5)
Lower abdominal pains,	1 (14.2)
Painful micturition	1 (14.2)
Complications (intra + Post-Op)	
Yes	11 (33.3)
No	23 (66.7)
Mean $\pm$ sd Duration of Admission (Days)	2.4 $\pm$ 1.5
Minimum Duration (Days)	1
Maximum Duration (Days)	7

*Multiple responses

kidney.

Table 4, shows complications of procedure reported among study participants. Four (12.1%) participants had intra op procedural complication reported; 2 (50.0%) had initial procedure ureteric perforation; 1 (25.0%) had left ureteric perforation; 1 (25.0%) had right ureteric perforation.

Seven (21.2%) participants reported post op procedural complication; 6 (85.7%) had fever; 4 (57.1%) had irritative symptoms; 3 (42.8%) had hematuria.

Eleven (33.3%) participants had either intra-op or post-op complications.

The mean $\pm$ sd duration of Admission (Days) for study participants was 2.4 $\pm$ 1.5.

Ten (47.6%) study participants had grade 1 complications following the procedure,

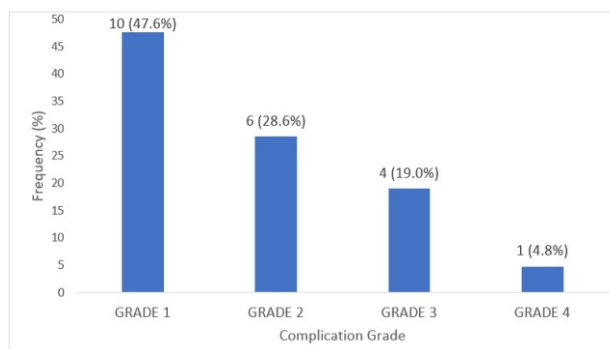


Figure 1: Grade of Complications using Clavien-Dindo Classification

while 6 (28.6%), 4 (19.0%) and 1 (4.8%) had grade 2, 3 and 4 complications respectively as shown in figure 1.

In Table 5 showing factors determining grade of complications post procedure amongst study participants, Four (66.7%) study participants aged 30 – 39 had grade 1 complication; 1 (16.7%) with grade 2 and 3 complication. This difference was not statistically significant ($p=0.364$).

Five (45.5%) male participants had grade 1 complication; 4 (36.4%) while 5 (50.0%) females also had grade 1 complication. This association between sex and complication grade was not statistically significant ($p=0.843$).

Table 5: Factors determining of Grade of Complication Post-Procedure among Study Participants

Variables	Grading of complications Freq. (%)				Test statistics	p-value
	1	2	3	4		
Age group						
20 – 29	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	Fishers exact test= 14.018	0.364
30 – 39	4 (66.7)	1 (16.7)	1 (16.7)	0 (0.0)		
40 – 49	0 (0.0)	3 (50.0)	2 (33.3)	1 (16.7)		
50 – 59	4 (57.1)	2 (28.6)	1 (14.3)	0 (0.0)		
60 and above	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Gender						
Male	5 (45.5)	4 (36.4)	2 (18.2)	0 (0.0)	Fishers exact test=1.704	0.843
Female	5 (50.0)	2 (20.0)	2 (20.0)	1 (10.0)		
Mean $\pm$ sd Stone Size (mm)	9.4 $\pm$ 5.2	22.8 $\pm$ 31.0	6.1 $\pm$ 4.4	5.5 (0)		
Mean $\pm$ sd Stone Density (HU)	698.3 $\pm$ 258.7	914.3 $\pm$ 257.7	715.0 $\pm$ 450.7	653.0 (0)		
Ureteric Stone						
Yes	8 (44.4)	6 (33.3)	4 (22.2)	0 (5.6)	Fishers exact test=5.123	0.143
No	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)		
Renal pelvis						
Yes	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	Fishers exact test=2.814	1.000
No	9 (90.0)	6 (30.0)	4 (20.0)	1 (5.0)		
Emergency intervention						
Yes	1 (16.7)	2 (33.3)	2 (33.3)	1 (16.7)	Fishers exact test=5.016	0.151
No	9 (60.0)	4 (26.7)	2 (13.3)	12 (0.0)		

Table 6: Predictors of the Grade of Complications among Study Participants

Variables	B (regression coefficient)	p-value	Odds ratio	95% C.I. for Odds ratio	
				Lower	Upper
Age (years)	0.006	0.951	1.006	0.825	1.227
Sex					
Male	-1.962	0.369	0.141	0.002	10.196
Female*			1		
Size of Stone (mm)	-0.155	0.480	0.856	0.556	1.318
Ureteric Stones					
Yes*					
No	-1.276	0.430	0.279	0.012	6.654
Emergency Intervention					
Yes*			1		
No	-2.162	0.247	0.115	0.003	4.477

*Reference category. R² (coefficient of determination) = 15.2% to 21.2%

The mean $\pm$ sd Stone Size (mm) was 9.4 ± 5.2 for participants with grade 1 complication; 22.8 ± 31.0 with grade 2; 6.1 ± 4.4 with grade 3. This difference was not statistically significant ($F=1.047$, $p=0.397$). The mean $\pm$ sd stone density (hu) was 698.3 ± 258.7 for participants with grade 1 complication; 914.3 ± 257.7 with grade 2; 715.0 ± 450.7 with grade 3. This difference was not statistically significant ($F=0.709$, $p=0.561$).

Two (50.0%) participants who had multiple lithotripsies with grade 1 complication compared with 8 (4 7.1%) without multiple stones. This difference was not statistically significant ($p=1.000$).

Eight (44.4%) participants who had ureteric stone with grade 1 complication compared with 2 (66.7%) without ureteric stones. This difference was not statistically significant ($p=0.143$).

One (10.0%) participants with a renal pelvis stone had grade 1 complications compared with 9 (90.0%) without a renal pelvis stone. This difference was not statistically significant ($p=1.000$).

One (16.7%) participant with a previous emergency intervention had a grade 1 complication compared with 9 (60.0%) without a previous emergency intervention. This difference was not statistically significant ($p=0.151$), as shown in Table 5.

There was no significant predictor of the grade of complications among study participants (table 6)

Discussion

The growing concern about Urolithiasis and the reported rising incidence and prevalence,^{11,12} is paralleled by the expanding scope of RIRS with laser lithotripsy as procedure of choice in surgical treatment of stones less than 2cm.^{3,4} This trend has been mirrored in a study carried out in southern

Nigeria.¹³ This makes it imperative to assess its safety and efficacy in Nigeria. The peak age of incidence of upper tract stone in this study is between the age of 40-59 years, and is corroborated by previous studies.¹¹⁻¹³ The mean duration of hospital stay in this study was 2.4 ± 1.5 days, considered to be short in keeping with studies in Cochrane data base.¹⁴ The median stone size was 10.55mm. This is keeping with the guidelines for the management of stones which recommend RIRS for stones less than 20mm.^{3,4} All participants had stent placement post procedure and the mean duration of stent placement was 8.6 weeks. There is no consensus on duration of ureteral stenting, it varies from 72 hours to 6 weeks depending on whether there is ureteral damage.¹⁵

The complication rate deduced from this study was 33.3%, with intra operative and post-operative complications accounting for 12.1% and 21.2% of complications respectively. Studies put the overall complication rate for RIRS between 9-25%,¹⁶ this perhaps shows a wide range of variation in complication rate. Classification tools for complications of ureteroscopy and Laser lithotripsy are imperative in standardization of procedure complications, this helps in defining presence of a complication and assessing severity, helping in homogeneity of reporting in the literature.¹⁷ Clavien grade I and II were the most common complications seen as documented in the literature,¹⁸ in consonance with findings in this study in which Clavien grade I and II accounted for 76.2% of the complications, only 4.8% of participants (1 patient) had Clavien grade IV complication. A study conducted in southern part of Nigeria on management of urinary calculi using Holmium laser lithotripsy had a complication rate of 29.2%,¹³ This is similar to findings in this study though our study was solely to determine safety of RIRS with laser lithotripsy. Oguz et al also described a complication rate of 30.4% while assessing per-operative complications in 230 patients that underwent RIRS using modified Satava classification system (SCS),⁶ and this finding corroborates, findings in our study. Ozden et al reported that intraoperative and post-operative complication rates in 706 RIRS procedures in their study was 30.5% and 26.9% respectively higher than the values recorded in this study and in some literature. Most frequent intraoperative and post-

operative complications were Satava grade 1 and Clavien grade 1 similar to findings in this study.¹⁹ Also, Koras et al reported similar findings with intraoperative events reported as 16.1% while post-operative complications were 12.6%, total per operative complication rate was extrapolated at 28.7%, in their study the SCS and MCCS classification system was used for intra-operative events and post-operative events respectively.²⁰ Alazaby et al in their series of 42 patients reported no major complication, the complication rate was 16.6%. Using the Clavien- Dindo classification complications were recorded as minor complications (grade I and II).²¹ Bai et al also recorded complication rate of 14%.²² Though wide variation was noted in complication rate, the complication rate in this study may have been attributed partly to the learning curve as RIRS with lithotripsy is a new innovation in our center, the inclusion of stent complications in this study may also have contributed to the increase in complication rate.

In our study, febrile complications were the commonest post-operative complication occurring in 6 patients. Overall, it is also noted to be the commonest complication of RIRS with lithotripsy, this finding is not farfetched as it correlates to findings in existing literature.²³⁻²⁵ Two patients developed intraoperative ureteric perforation. Despite stenting they still developed ureteric stricture necessitating open surgery afterwards. Only 4.8% of patients had Clavien grade IV complication. Similar to study by Xu et al that recorded complication rate of 2.4% for Clavien Dindo IV complications.²⁶

Several risk factors have been adduced to complications following ureteroscopy in the literature, some are patient related, such as the presence of stones in the kidney or proximal ureter, sex, older age, comorbidity, stone size (50% complication rate for stone size >10mm), impacted stone and non-elective procedures.²⁷ Other factors are operator-related, such as the experience of the surgeon, general anesthesia and operative time.²⁷⁻²⁹ In a univariate analysis using Fishers exact, no independent variable such as age, gender, stone size, stone density, location of stone in the upper tract or emergency intervention prior to procedure was statistically significant in their association with

complication or grade of complication using the Clavien-Dindo classification in this study. a multivariate analysis was also done to assess factors predicting complications and grade of complication, independent variables as age, stone size, stone density, location of stones either ureteric or renal including emergency intervention like stenting or percutaneous nephrostomy insertion prior to RIRS with laser lithotripsy were not statistically significant predictors of the grade of complications. This may have been due to small sample size. However, previous studies by Bas et al³⁰ revealed that stone diameter, number of stones and presence of congenital renal anomalies were associated with complications while the presence of congenital renal anomaly was the only independent predictor of complications in a multivariate analysis. This finding was at variance with the outcome of this study. Ozden et al, reported that presence of solitary kidney and residual stones were the two factors associated with complications.¹⁹ In a study by Fan et al, univariate analyses indicated that pyuria, stone size, operative duration and infectious stones were risk factors for infectious complications following flexible ureteroscopy (FURS), while multivariate logistic regression analyses indicated that pyuria, operative duration and infectious stones are independent predictors of infectious complications.³¹ These findings also do not agree with outcome of this study, this may have been due to small sample size of this study.

The limitations of this study lie in its retrospective nature and small sample size.

Conclusion

Retrograde intrarenal surgery with laser lithotripsy is increasingly being utilized in management of upper tract stones and expectedly not complication free. Findings in this study has a complication rate of 33.3%, most complications were termed as minor using the validated modified Clavien-Dindo classification system. Therefore, it is termed a safe procedure, with few major complications and no mortality in our series. It is recommended that more centers in Nigeria should adopt this technology and expertise in management of growing renal stone burden.

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Author contributions

Contributor 1: Concepts, design, definition of intellectual content, literature search, clinical studies, data acquisition, data analysis. Statistical analysis, manuscript preparation. manuscript editing, manuscript review, Guarantor.

Contributor 2: Definition of intellectual content, clinical studies, data acquisition, manuscript editing, manuscript review

Contributor 3: Clinical studies, data acquisition, data analysis, manuscript editing

Contributor 4: Clinical studies, manuscript review

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Availability of data and materials

Available when asked from the corresponding author after approval from our institution

Declarations**Ethics approval**

The study was approved by the ethical and research committee of University of Benin Teaching Hospital

Competing interests

The authors declare they have no competing interests.

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