Research, Society and Development, v. 13, n. 12, e10131247376, 2024
(CC BY 4.0) | ISSN 2525-3409 | DOI: http://dx.doi.org/10.33448/rsd-v13i12.47376

Complications of retrograde intrarenal surgery for the treatment of large renal stone burdens: A prospective observational study

Complicações da cirurgia intrarrenal retrógrada para o tratamento de grandes cargas de cálculos renais: Um estudo observacional prospectivo

Complicaciones de la cirugía intrarrenal retrógrada para el tratamiento de grandes cargas de cálculos renales: Un estudio observacional prospectivo

Received: 10/31/2024 | Revised: 11/20/2024 | Accepted: 11/23/2024 | Published: 11/26/2024

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Abstract
Objective: Retrograde intrarenal surgery (RIRS) is a less invasive method of treating renal calculi. Despite its widespread use, there is little research on RIRS safety address large renal stone burdens (≥21 mm). This study sought to evaluate the perioperative complications associated with RIRS. Methodology: A prospective evaluation of stone characteristics and perioperative outcomes was conducted on 55 patients each having a stone burden of ≥21 mm and treated with RIRS between November 2019 and October 2021. Patients were divided into three groups according to stone burdens (21–30 mm, 31–40 mm, and >40 mm). Chemoprophylaxis and surgery were performed according to standard procedures. All of these patients were followed up on for a minimum of three months. Results: The mean stone burden was 32.36 ± 10.20 mm. The mean cumulative endoscopy time was 142.0 ± 74.7 min. The overall stone-free rate (SFR) was 78.2%, with an average of 1.58 sessions of RIRS. The majority of the post-operative complications were minor (Clavien-Dindo I and II). Clavien-Dindo IIIa complications reported in 9%. Conclusions: RIRS is a safe treatment alternative with low morbidity for addressing large renal stone burdens in a subset of patients who are unfit for other therapeutic options.
Keywords: Retrograde intrarenal surgery; Flexible ureteroscopy; Large renal stone burdens; Holmium laser lithotripsy.

Resumo
Objetivo: A cirurgia retrógrada intrarrenal (CRIR) é um método menos invasivo para tratar cálculos renais. Apesar de seu uso generalizado, há poucas pesquisas sobre a segurança da CRIR para tratar cargas elevadas de cálculos renais (≥21 mm). Este estudo buscou avaliar as complicações perioperatórias associadas à CRIR. Metodologia: Foi realizada uma avaliação prospectiva das características dos cálculos e dos desfechos perioperatórios em 55 pacientes, cada um com carga de cálculos ≥21 mm, tratados com CRIR entre novembro de 2019 e outubro de 2021. Os pacientes foram divididos em três grupos de acordo com as cargas de cálculos (21–30 mm, 31–40 mm e >40 mm). Quimioprofilaxia e cirurgia foram realizadas conforme os procedimentos padrão. Todos os pacientes foram acompanhados por no mínimo três meses. Resultados: A carga média de cálculos foi de 32,36 ± 10,20 mm. O tempo médio acumulado de endoscopia foi de 142,0 ± 74,7 minutos. A taxa geral de eliminação completa de cálculos (TEC) foi de 78,2%, com

uma média de 1,58 sessões de CRIR. A maioria das complicações pós-operatórias foi menor (Clavien-Dindo I e II). Complicações Clavien-Dindo IIIa foram relatadas em 9%. Conclusões: A CRIR é uma alternativa de tratamento segura, com baixa morbidade, para tratar grandes cargas de cálculos renais em um subconjunto de pacientes inelegíveis para outras opções terapêuticas.
Palavras-chave: Cirurgia retrógrada intrarrenal; Ureteroscopia flexível; Grandes cargas de cálculos renais; Litotripsia a laser de holmio.

Resumen
Objetivo: La cirugía intrarrenal retrógrada (CIR) es un método menos invasivo para tratar los cálculos renales. A pesar de su uso generalizado, hay poca investigación sobre la seguridad de la CIR para tratar cargas grandes de cálculos renales (≥21 mm). Este estudio tuvo como objetivo evaluar las complicaciones perioperatorias asociadas con la CIR. Metodología: Se realizó una evaluación prospectiva de las características de los cálculos y los resultados perioperatorios en 55 pacientes, cada uno con una carga de cálculos ≥21 mm, tratados con CIR entre noviembre de 2019 y octubre de 2021. Los pacientes fueron divididos en tres grupos según la carga de cálculos (21–30 mm, 31–40 mm y >40 mm). La quimioprofilaxis y la cirugía se realizaron siguiendo procedimientos estándar. Todos los pacientes fueron seguidos durante un mínimo de tres meses. Resultados: La carga promedio de cálculos fue de 32,36 ± 10,20 mm. El tiempo promedio acumulado de endoscopia fue de 142,0 ± 74,7 minutos. La tasa global de eliminación completa de cálculos (TEC) fue del 78,2%, con un promedio de 1,58 sesiones de CIR. La mayoría de las complicaciones postoperatorias fueron menores (Clavien-Dindo I y II). Las complicaciones Clavien-Dindo IIIa se informaron en el 9%. Conclusiones: La CIR es una alternativa de tratamiento segura, con baja morbilidad, para abordar grandes cargas de cálculos renales en un subconjunto de pacientes no aptos para otras opciones terapêuticas.
Palabras clave: Cirugía intrarrenal retrógrada; Ureteroscopia flexible; Grandes cargas de cálculos renales; Litotricia láser de holmio.

1. Introduction

Retrograde intra-renal surgery (RIRS) or percutaneous nephrolithotomy (PCNL) are the usual treatments for large renal calculi. Nevertheless, the use of these techniques must be chosen cautiously. Although PCNL has a greater stone-free rate (SFR), complications potentially exist. (Turk et al., 2016; Taylor et al., 2012). RIRS is less invasive, has fewer side effects, and is particularly helpful for patients with bleeding diathesis, complex renal anatomy, and those using anticoagulants. (Prabhakar, 2010; Demirbas et al., 2016).

The American Urological Association (AUA) and the European Association of Urology (EAU) both advocate PCNL as the first-line treatment for stone loads larger than 20 mm because of its high SFR and reduced need for auxiliary treatments (AUA/EAU: Strong recommendation). Staged-RIRS is recommended as a second-line treatment if PCNL is not appropriate (EAU: Strong recommendation). (Assimos et al., AUA 2016; Türk et al., EAU 2000).

Despite the introduction of mini-PCNL and technological developments in RIRS, there is a lack of clinical data assessing the safety of RIRS for treating substantial renal stone loads. In order to address substantial renal stone burdens, the purpose of this study is to prospectively assess the perioperative complications of RIRS.

2. Methodology

An epidemiological research of a qualitative and quantitative nature and a statistical study were carried out (Toassi & Petri, 2021). The Institutional Review Board gave its approval to the study (RAJH/SRC/DNB/037). Patients undergoing RIRS for renal stone loads of ≥21 mm between 1/11/2019 and 31/20/2021 were prospectively included. Multiple co-morbidities and patient preference were common indications for RIRS. Stag-horn stones and renal anomalies were excluded. Three groups have been generated from the patients' stone burdens (21–30 mm, 31–40 mm, and >40 mm). Stone burden was calculated using the cumulative linear diameter of the stones as measured by preoperative computed tomography (CT) or X-ray. Preoperative antibiotics were administered 30 minutes prior to surgery in accordance with the sensitivity for positive urine cultures, or Cefoperazone (1 g) with Sulbactum (0.5 g).

The patient was positioned in a lithotomy, and RIRS was performed under either spinal or general anesthesia. Following a formal cystoscopy, we cannulated the ureter under fluoroscopy guidance using a hydrophilic guidewire (0.038 inches). In order to visually dilate the ureter and evaluate any concurrent ureteric calculi or diseases, a semi-rigid ureteroscope (6 Fr. tip) was performed. Over a ureteral access sheath (UAS, 9.5/11.5 Fr, or 12/14 Fr), a flexible ureteroscope (tip/shaft; 4.9/7.95 Fr) was inserted. The calculi were fragmented using a Ho:YAG laser. At the conclusion of RIRS, we routinely implanted a double-J ureteric stent, which we removed two to four weeks later. The follow-up period following surgery was three months. SFR was defined as the lack of residual stones in the CT, X-ray, or ultrasonography follow-up scans. The results included endoscopic time, perioperative complications, and overall SFR.

The statistical analysis was conducted using IBM SPSS version 20.

3. Results

RIRS was performed on 55 individuals who had a substantial renal stone burden (≥21 mm). 54 ± 11 years was the mean age. Table 1 summarizes the clinical and demographic data. The two most prevalent co-morbidities were diabetes (41.8%) and hypertension (38.1%), respectively. Fourteen patients (25.5%) required pre-stenting, 7 for pyelonephritis, 4 for AKI, 1 each for infected hydronephrosis, post-URS, and as a routine.

Table 1 - Demographic and clinical data.

	Group	**Number**	**Percentage**
Sex	Male	35	64.0%
	Female	20	36.0%
Comorbidities	Present	31	56.3%
Presenting symptoms	Pain	38	69.1%
	Fever	8	14.5%
	Hematuria	6	10.9%
	Dysuria	2	03.6%
	Incidental	11	20.0%

Source: Authors.

The mean cumulative endoscopic time was 142 ± 75 minutes. For stone densities >1000 HU and ≤1000 HU, the mean endoscopy time was 150.3±92.1 minutes and 141.4±63.2 minutes, respectively (p-value: 0.72).

The intraoperative complications reported in 5/55 (9%) cases were graded according to the modified Satava classification system (Table 2).

Table 2 - Intra-operative complications (modified Satava classification).

S. No	Grade	Complication	Managed with
1	1	Laser stopped working	Standby Laser
2	2a	Inaccessible calyx, acute IPA	Double-J stenting + ESWL
3	2b	Non-yielding tight ureter	PCNL
4	2b	Inaccessible lower calyx, acute IPA	Second RIRS and medical expulsive therapy
5	2b	Inaccessible lower calyx, acute IPA	mini-PCNL

IPA, Infundibulopelvic angle; ESWL, extracorporeal shock wave lithotripsy; PCNL, percutaneous nephrolithotomy; f-URS, flexible ureteroscopy. Source: Authors.

Each RIRS session required an average of 1.4 days stay in the hospital. With an average of 1.6 RIRS sessions per patient, the overall success rate in terms of SFR at three months of follow-up was 78%.

The modified Clavien-Dindo classification system was used to grade the postoperative complications (12/55) (Table 3).

Table 3 - Post-operative complications (modified Clavien-Dindo classification).

No. of cases	Grade	Complication	Managed with
5	I	Stent discomfort and/or transient hematuria	Stent discomfort - medical therapy Hematuria - spontaneously resolved
1	I	Fever	Antipyretic therapy
1	II	UTI	Intravenous antibiotics
1	IIIa	UTI, acute on CKD and stent migration	Intravenous antibiotics URS under SA
3	IIIa	Steinstrasse	URS/RIRS under SA
1	IIIa	AUR with urethral calculus	Cystolitholapaxy under SA

UTI, urinary tract infection; CKD, chronic kidney disease; URS, ureteroscopy; AUR, acute urinary retention; SA, spinal anesthesia. Source: Authors.

4. Discussion

Stone burden, stone density (HU), anatomy of the urinary system, and comorbidities are to be considered in planning the surgical treatment for large renal calculi. In 1983, Huffman and colleagues performed the first ureteroscopy to treat renal pelvic calculus (Huffman JL et al., 1983). Over time, with advances in technology, RIRS has become the routine option for the treatment of ≤20 mm renal calculi. Mini-PCNL and ultra-mini-PCNL are now comparatively less invasive choices with fewer difficulties due to advancements in PCNL technology. Despite having a good SFR, PCNL have limitations, such as being an invasive operation with a high rate of complications, morbidity, prolonged radiation exposure, a longer hospital stay, and vascular or renal parenchymal injury. A transfusion rate of 11-17.5%, fever 21-32%, pneumothorax 0-4%, urinary tract infection and sepsis of 0.2-1.5%, and colonic damage incidence of less than 1% were described in certain investigations (Michel MS et al., 2007).

Although ESWL is less invasive, it is limited by a relatively low SFR. A recent study has also shown that ESWL has the potential to cause unstable renal hemodynamic conditions by inducing vessel rupture (Clark DL et al., 2011). Schnabel et al., 2014; reported that the incidence of hematoma after ESWL was 0.53%. Lee et al., 2013; reported a 0.32% incidence of

subcapsular or perinephric hematoma after ESWL. Thus, considering the very low SFR and the potential risk of bleeding, ESWL may not be the right choice for treating large renal calculi ≥20 mm.

4.1 SFR

For renal calculi >20 mm, the overall SFR of RIRS following multiple sessions has been reported to be between 77% and 93% (Rob S. et al., 2017; Riley JM et al., 2009; Yadav Rajinder et al., 2019; Chung BI et al., 2008). The average number of RIRS procedures per patient in our study was 1.6, and the overall SFR was 78%.

4.2 Stone density (HU) can determine complications

According to Ito et al. (2015), stone density (HU) is an indicator of stone hardness. In our investigation, stones with ≤1000 HU density had a lower mean endoscopic time for RIRS (141±63 vs. 150±92 min, P-value: 0.720). All three incidents of steinstrasse were reported in >1000 HU stone densities. The reason for stone street formation may be the high density (HU) of the renal calculi, which makes the fragments comparatively more resistant to chemolysis in the postoperative period. The risk is significantly reduced by consistently breaking up a bigger remaining stone burden into tiny particles (<2 mm) and adapting the dusting technique. Thus, stone hardness plays a role in determining the perioperative complications in RIRS.

4.3 Pre-stenting will lessen complications

In the present study, 25.45% required pre-stenting, and the overall complications were less in the pre-stenting group (1/14 vs. 12/41). Our study has limitations as we did not perform randomization. However, in cases that are difficult or symptomatic, including infection, AKI, or restricted ureters, preoperative stent insertion is more likely to be done. It is thought that a ureteral stent might produce more substantial outcomes if these unfavorable factors were corrected.

4.4 Prolonged endoscopy time results in complications

For 20–40 mm renal calculi, Akman et al. (2012) reported an 88.2% SFR, an average surgical duration of 58.2±13.4 minutes, and an average hospital stay of 67.4 hours. In this study, the cumulative mean hospital stay was 2.2±1.3 days, with an average of 1.4 days for single session of RIRS. According to a 2015 study by Orhan Kerakoc et al., PCNL's hospital stay was longer (4.5±2.1 days) than RIRS's (1.6±0.8 days). The hospital stay is still longer than with RIRS, even though recent studies have shown that PCNL procedures without tubes dramatically reduced hospital stays.

The infectious complications rate after RIRS was reported as 1.7% to 18.8% (Fan J et al., 2017), whereas in this study, it was 5.5% . Zhong et al., 2014; reported that large stone burden, presence of struvite stones, using small caliber UAS, and irrigation with a high flow rate were independent risk factors for systemic inflammatory response syndrome (SIRS) after RIRS. Moreover, Orsan Demir et al., 2019; reported that operative time was an independent risk factor for SIRS after RIRS. In this study, the average cumulative operative time in patients who had infectious complications was 213 min, higher than the overall average cumulative operation time of 120 min. Although a safe operative time has not been determined so far, the present findings and prior research indicate that an extended duration of RIRS is a risk factor for postoperative SIRS.

In some instances, like a tight ureter, infected hydronephrosis (which cannot be detected by a routine pre-operative urine test), and/or high perfusion pressure flow, the infected urine may flow retrograde or leak into the perinephric tissue space, leading to the occurrence of SIRS. Hence, avoiding these situations by simply placing a ureteral stent and planning a staged approach can avoid severe infectious complications.

4.5 Intra-operative complications

This study reported 9% (5/55) intraoperative complications. Inaccessible lower calyx due to long infundibulum or acute infundibulopelvic angle (IPA) was the most common intraoperative complication, reported in 3 cases. All three of these cases required an auxiliary procedure to clear the stone burden completely. Acute postoperative renal insult was not seen in any of the patients.

4.6 Post-operative complications

Postoperative complications noted in 21.8% cases (12/55). Half of the complications were Clavien-Dindo grade I, with stent discomfort and/or transient hematuria being the most common. Stent discomfort included burning urination, flank pain during early void, or transient hematuria. All the patients with hematuria had indwelling double-J stents, and all resolved spontaneously after removal of the stent. As detailed above, Steinstrasse was the second most common complication reported in 3 cases (25%). All cases with steinstrasse required a URS and/or RIRS under spinal anesthesia (Grade IIIa). No other major complications were reported except for one case of stent migration and another case of urethral calculus.

Çakıcı MÇ et al., 2020; found that infectious complications (22.9%) were significantly higher in RIRS for > 20 mm renal calculi. Aboumarzouk et al., 2012; reported a 10.1% complication rate (5.3% major and 4.8% minor) for 93.7% SFR with a median of 1.6 sessions of RIRS in treating a median stone diameter of 25 mm. Breda A et al., 2014; published 20% complications, 2 cases of gross hematuria, and one case of SIRS, which required an emergency room visit and admission. In another study, one patient had ureteric perforation, seven patients had transient hematuria, and no incidence of ureteric stricture was reported (Niwa N et al., 2019).

4.7 Limitations

Its shortcomings include a limited, single-center trial group, no randomization, and no direct comparison with PCNL. To show that RIRS is safe for treating large renal stone burdens, more multicenter studies with prospective, double-blind randomized trials with larger study groups are required

5. Conclusion

Given its minimally invasive nature, preservation of the renal parenchyma, decreased blood loss, brief hospital stay, and low overall risk of complications, RIRS is a safe therapeutic option for large renal stone burdens in properly selected patients. Staged-RIRS may be an option for patients with several comorbidities, obesity, and bleeding diathesis. Pre-stenting for the previously stated indications should not be delayed. When preparing for RIRS, stone hardness (HU) should be taken into account.

Acknowledgments

We are duty-bound to acknowledge the support of our patients for allowing us to conduct the study, Dr. Susan John for her contribution to statistical analysis, and the health care workers who supported us throughout the journey.

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