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Bhojani N, Miller LE, Bhattacharyya SK, Chua WJ, Tailly T, Eisner B, Chew BH

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Review Article

Continuous Intrarenal Pressure Monitoring during Endourological Procedures for Stone Disease: A Canary in the Coalmine for Optimizing Patient Safety

Naeem Bhojani, MD[a], Larry E. Miller, PhD, PStat[b]; Samir K. Bhattacharyya, PhD, MS, MSc[c], Wei Jin Chua, MBChB[d], Thomas Tailly, MD, PhD[e], Brian Eisner, MD[f], Ben H. Chew, MD[g]

[a]Division of Urology, Centre Hospitalier de l'Université de Montréal, Montréal, Québec, Canada. naeem.bhojani@gmail.com
[b]Department of Biostatistics, Miller Scientific, Johnson City, TN, United States. larry@millerscientific.com
[c]Health Economics and Market Access, Boston Scientific, Marlborough, MA, United States. samir.bhattacharyya@bsci.com
[d]Department of Urology, National University Hospital, Singapore. surcwj@nus.edu.sg
[e]Department of Urology, University Hospital Ghent, Ghent, Belgium. Thomas.tailly@uzgent.be
[f]Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA. beisner@mgh.harvard.edu
[g]Department of Urologic Sciences, University of British Columbia, Vancouver, BC, Canada. ben.chew@ubc.ca

Short title: Continuous Intrarenal Pressure Monitoring

Correspondence
Larry E. Miller, PhD, PStat
Department of Biostatistics
Miller Scientific
3101 Browns Mill Road, Ste. 6, #311
Johnson City, TN 37604, United States
larry@millerscientific.com

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Abstract

Background: Ureteroscopy is a widely used minimally invasive procedure for treating kidney stones. While ureteroscopy is generally safe and effective, it carries risks of complications that may be associated with elevated intrarenal pressure (IRP) during the procedure. This paper discusses the importance of monitoring and managing IRP during endourological procedures to mitigate the risk of complications.
Summary: We conducted a review on IRP during endourological procedures, combining systematic and narrative approaches, to examine complications, clinical implications, and IRP monitoring practices. Preclinical and clinical studies have demonstrated strong associations between elevated IRP during endourological procedures and complication risk. Further, cumulative IRP exposure, which considers pressure magnitude and duration, may be a stronger predictor of complication risk than mean or peak IRP values alone. Surveys indicate that while many urologists acknowledge the clinical importance of monitoring and managing IRP, there remains a lack of awareness of real-time IRP monitoring technologies that can alert surgeons to elevated pressures and prompt immediate procedural modifications to mitigate complication risks.
Key Messages: Based on current evidence, IRP monitoring should be considered for patients at high risk for pressure-related complications during endourological procedures, which includes a significant proportion of the patient population due to the prevalence of risk factors such as older age, female sex, diabetes mellitus, and obesity. A coordinated effort across the urological community is recommended to generate additional high-quality data to further our understanding of the potential benefits of real-time monitoring technologies.

Introduction

Kidney stone disease is a prevalent condition, affecting approximately 10% of adults in the United States [1]. Ureteroscopy (URS) has emerged as an indispensable minimally invasive intervention for managing various urinary tract conditions, particularly stone disease, and is the most common treatment for stone disease in many countries, including the United States and Canada [2, 3]. Advances in patient selection protocols, procedural techniques, and device technologies have substantially improved the efficacy and safety of URS [4]. Consequently, the American Urological Association (AUA) and European Association of Urology (EAU) recommend URS to treat stones with a low probability of spontaneous passage or those associated with pain or complications [5-7].

Despite its advantages, URS is associated with certain risks. Approximately 50% of postoperative complications following URS are infectious in nature [8]. While fever and urinary tract infection are typically minor and require no intervention, urosepsis occurs in approximately 5% of cases [9, 10]. This is particularly concerning as sepsis carries significant morbidity and mortality risks, and more than doubles the total healthcare expenditures associated with stone treatment [11]. Thus, strategies are critically needed to identify high-risk patients and mitigate the associated sepsis risk.

Standard patient monitoring during URS involves basic vital sign assessment, which provides limited insight into the dynamic physiological changes occurring within the kidney during the procedure. In particular, these parameters do not capture fluctuations in intrarenal pressure (IRP), which can have significant implications for patient safety. Elevated IRP can cause pyelovenous and pyelolymphatic backflow, potentially resulting in the translocation of bacteria from the renal collecting system into the systemic circulation, which is hypothesized as a key precipitating event for the development of urosepsis [12, 13]. Furthermore, as significant infectious complications such as postoperative pyelonephritis and urosepsis often present after the patient has left the operating room, current real-time monitoring of vital signs is rarely useful for prediction and prevention of infectious complications.

Continuous IRP monitoring during URS can detect critical pressure increases that may serve as a "canary in the coalmine", allowing the surgeon to react in real-time by decreasing irrigation or suctioning fluid out of the kidney, thereby lowering renal pelvis pressure to decrease the patient's potential risk for infectious complications. This paper examines the evidence linking IRP to complication risks during URS and other endourological procedures, explores the physiological mechanisms by which increased IRP may contribute to complications, and discusses the advantages of integrating continuous IRP surveillance into treatment protocols for appropriate patients.

Elevated Intrarenal Pressure: A Modifiable Risk Factor in Endourological Procedures

Patients undergoing URS may develop perioperative complications such as urosepsis, urinary tract infection, pain, and fever. A systematic review and meta-analysis of over 5000 URS procedures reported a 5.0% incidence of perioperative urosepsis [9]. An analysis of over 100,000 URS procedures found that 5.6% of patients developed postoperative sepsis, with an increasing incidence over time, and primary risk factors including older age, female sex, diabetes mellitus, and higher Elixhauser Comorbidity index [10]. These results highlight the persistent risks inherent to URS and the need for continued research to optimize patient safety. While these risk factors are associated with increased odds of developing postoperative complications, they are non-modifiable characteristics that are known before ureteroscopic surgery for stone removal.

Several important procedural and preparatory measures can reduce complications before and during URS. These include confirming negative urine cultures, prior ureteral stenting when indicated, appropriate antibiotic prophylaxis, strict adherence to sterile technique, and procedure suspension when purulent urine is encountered [14]. One topic receiving recent attention is IRP during URS [15, 16]. The IRP during URS depends on several factors, including ureteroscope diameter, irrigation pressure, use of a ureteral access sheath, working channel instrument occupancy, and patient factors like the degree of ureteral obstruction [17]. In healthy adults, baseline IRP ranges between 6-11 mmHg. The introduction of a ureteroscope itself elevates this baseline. During URS, mean IRP typically rises to 20-40 mmHg, with transient peaks between 100-300 mmHg commonly occurring due to intermittent increases in irrigation pressure [18, 19] (**Fig. 1**). However, *ex vivo* studies have observed pyelovenous backflow occurring as low as 10-20 mmHg, pyelolymphatic backflow at 20-30 mmHg, and forniceal rupture as low as 60-70 mmHg [17]. Moreover, a recent systematic review reported that higher IRP sustained for longer periods may increase the risk of postoperative complications [20]. Although the review included limited data that precluded formal analysis to identify a causal relationship between IRP and postoperative complications, the findings raise concern since the typical IRP during URS overlaps with pressure-duration thresholds that precipitate renal injury in preclinical models. Thus, there is a clear need for more research to identify the interrelationships among IRP, procedure time, and risk of postoperative complications.

The mechanism by which elevated IRP contributes to complications is thought to involve pyelovenous and pyelolymphatic backflow. With elevated IRP, fluid and bacteria from the renal pelvis may be forced into the renal venous and lymphatic systems, leading to systemic absorption and potentially urosepsis [12, 13]. This process is exacerbated by the presence of bacteria in the urinary tract, which is common in patients with kidney stones. Additionally, elevated IRP can cause direct damage to the renal parenchyma, leading to inflammation and further increasing the risk of infectious complications and renal dysfunction [21, 22]. In a recent study of a swine model of fluid absorption during a 1-hour URS, fluid absorption occurred at renal pelvis pressures as low as 37 mmHg, and the degree of fluid absorption and pyelovenous backflow was related to both IRP as well as the duration of procedure [23].

Ultimately, the evidence linking elevated IRP to increased complication risks remains limited, and translating specific IRP thresholds associated with injury from animal studies to human patients remains challenging. Furthermore, the complex interactions of multiple variables during URS, including patient-specific factors, stone characteristics, and surgical technique, makes it difficult to isolate the independent effect of IRP on clinical outcomes. Consequently, there is still some debate around the clinical implications of elevated IRP during URS, particularly related to safety thresholds.

Literature Review of Intrarenal Pressure and Complication Risk

The current clinical evidence on the association of IRP with complication risk during endourological procedures remains sparse, with considerable inconsistency in outcome reporting among studies that may be due to the lack of a standardized and practical method for measuring IRP. We conducted a literature review of clinical studies published over the previous 20 years (January 2004 to January 2024) evaluating the relationship between IRP and postoperative complications during endourological procedures. The primary outcome of interest was the incidence of postoperative complications. Eligible studies compared groups with higher versus lower mean procedural IRP, where the cutoff for defining higher IRP ranged from 20 to 30 mmHg among studies. We calculated the odds ratios for complication rates between patient subgroups with higher versus lower mean procedural IRP.

Our literature review identified three studies of 303 percutaneous nephrolithotomy (PCNL) procedures and no studies of URS meeting inclusion criteria [24-26]. Among the PCNL studies, higher mean procedural IRP was associated with significantly increased odds of postoperative complications (odds ratio=4.0; 95% CI=2.2 to 7.4; $p<0.001$) (**Fig. 2**). This finding suggests that patients with higher versus lower mean procedural IRP were four times more likely to experience postoperative complications. The magnitude of this association and its statistical significance highlight the clinical relevance of IRP as a risk factor for complications in endourological procedures.

However, it is important to acknowledge the limitations of this evidence synthesis. First, the included studies were observational, which limits the ability to establish a causal relationship between IRP and complications. Second, the heterogeneity in study designs, IRP cutoff values, and complication definitions may have introduced variability into the pooled analysis. The lack of standardized definitions for higher and lower IRP across studies makes it challenging to identify a precise IRP threshold above which complication risk increases. While several other clinical studies have drawn similar associations, the inconsistency in outcome reporting methods precluded their inclusion in a meta-analysis. Third, all included studies utilized PCNL, and none used URS. Inherent differences in the technical aspects and pressure dynamics between PCNL and URS may affect the generalizability of the findings to URS procedures. However, IRP is usually higher with URS than PCNL since the access significantly differs between the procedures. Finally, the small number of included studies and the modest total sample size limit the precision of the estimated effect size. As more studies with consistent outcome reporting are published on this topic, updated analyses will be able to provide more robust estimates of the association between IRP and complications. Despite these limitations, this analysis represents an initial attempt to quantitatively synthesize the emerging clinical evidence base on IRP and its relationship to complications in endourological procedures. The results corroborate prior findings primarily from preclinical models associating higher procedural IRP with an increased risk of adverse outcomes after endourological procedures.

Recent Evidence on Intrarenal Pressure and Complication Risks in Ureteroscopy

Recent studies not included in this literature review, either due to their use of non-clinical data or variations in outcome reporting, suggest that the risks associated with elevated IRP during endourological procedures may be greater than previously recognized. Lildal et al.[16] used a porcine model to demonstrate that an IRP of 21 mmHg, just slightly above physiological baseline values, resulted in retrograde flow of irrigant fluid into the renal parenchyma. This finding is noteworthy since it conflicts with the common view that maintaining IRP under 30 mmHg minimizes infection risks [20, 21]. Moreover, they reported a positive correlation between the severity of irrigant backflow and both IRP and procedure duration, suggesting that cumulative IRP exposure over time may be a more important factor in determining complication risk than simple measures of mean or peak pressures, as proposed by others [16, 20]. This finding highlights the potential importance of considering the duration of IRP elevation and the absolute pressure values rather than only peak IRP when assessing the risk of complications. As treatment of larger, more complex kidney stones during lengthier endourological procedures becomes more common [27], the issue of cumulative IRP exposure becomes increasingly relevant.

Two recent clinical studies that were ineligible for the literature review due to differences in outcome reporting have also linked high procedural IRP to an increased risk of postoperative complications. Croghan et al.[19] reported that among patients undergoing URS, the mean IRP was significantly higher in those who developed postoperative sepsis compared to non-septic patients (82 mmHg vs. 39 mmHg; $p<0.001$). Similarly, Hong et al.[28] reported higher procedural IRPs among patients requiring readmission than non-readmitted patients. These pre-clinical and clinical data provide additional support for the growing evidence base demonstrating associations between elevated IRP and subsequent complication risks during endourological procedures.

Implementing Intrarenal Pressure Monitoring

Despite accumulating evidence supporting the clinical value of IRP monitoring during URS, a gap persists between the recognition of its potential benefits and the awareness of available technologies enabling its routine integration into clinical practice. In an international survey of over 500 urologists [29], most viewed IRP as a clinically significant procedural parameter, reported actively utilizing IRP-lowering measures during cases, and felt real-time IRP monitoring could provide helpful feedback to guide surgical decision-making. However, nearly one-third of respondents were unaware of existing technology enabling continuous IRP measurement. This discrepancy highlights the need for increased education and awareness among urologists regarding the availability and potential benefits of real-time IRP monitoring.

The historical limitations of pressure monitoring devices may have contributed to this awareness gap as early systems were cumbersome, required separate instrumentation, and provided only intermittent pressure measurements. However, technology now enables direct real-time surveillance of IRP at the ureteroscope tip [18, 30]. The ureteroscope-integrated system employs advanced sensors and software algorithms to provide instantaneous pressure feedback throughout URS cases. This enables surgeons to modulate irrigation fluid flow, instrument movements, and other procedural factors such as ureteral access sheath placement to mitigate excessive IRP elevations in real time.

While many urologists currently restrict IRP monitoring to high-risk subgroups [29], reliably predicting individual patient risk remains challenging. Risk factors for endourological complications such as older age, female sex, diabetes mellitus, and higher Elixhauser Comorbidity index [9, 17, 31] are so prevalent that most patients undergoing URS present with at least one of these risk factors, diminishing their predictive utility. Additionally, traditional risk factors for infectious complications like positive urine culture [32] and struvite stones [33] may not accurately indicate the presence of bacteria or endotoxin preoperatively. Since these potential risk factors are not consistently predictive, and given the episodic and unpredictable nature of IRP fluctuations, additional research is needed to identify reliable predictors of IRP elevation during URS and associated postoperative complications. Further, other factors that warrant study include the cost effectiveness of IRP monitoring and practical guidance for interpreting and reacting to real-time IRP readings.

Conclusion

The emerging clinical evidence presented in this paper highlights the potential utility of continuous IRP monitoring during endourological procedures to enhance patient safety. The limited available evidence demonstrates significant associations between elevated procedural IRP and postoperative complications. The development of technology enabling real-time IRP measurement at the ureteroscope tip represents a significant advancement in endourology that may enable proactive identification and mitigation of excessive renal pressures during stone procedures. A coordinated effort across the urological community is recommended to generate additional high-quality data to further our understanding of the potential benefits of real-time monitoring technologies and to define safe IRP limits.

Statements

Conflict of Interest Statement
N. Bhojani is a consultant for Olympus, Boston Scientific, and Procept BioRobotics.
L. Miller is a consultant for Boston Scientific.
S. Bhattacharyya is an employee of Boston Scientific.
W.J. Chua is a consultant for Boston Scientific.
T. Tailly is a consultant for Ambu, BD, Boston Scientific, Cook Medical, Dornier, and Storz.
B. Eisner is a consultant for Boston Scientific.
B. Chew is a consultant for Boston Scientific.

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Author Contributions
N. Bhojani: Conceptualization, manuscript writing, interpretation of data
L. Miller: Conceptualization, study design, data analysis, manuscript writing, interpretation of data
S. Bhattacharyya: Conceptualization, study design, critical review, interpretation of data
W.J. Chua: Manuscript editing, interpretation of data
T. Tailly: Manuscript editing and critical review, interpretation of data
B. Eisner: Manuscript editing and critical review, interpretation of data
B. Chew: Manuscript editing and critical review, interpretation of data

All authors approved the version to be published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved,

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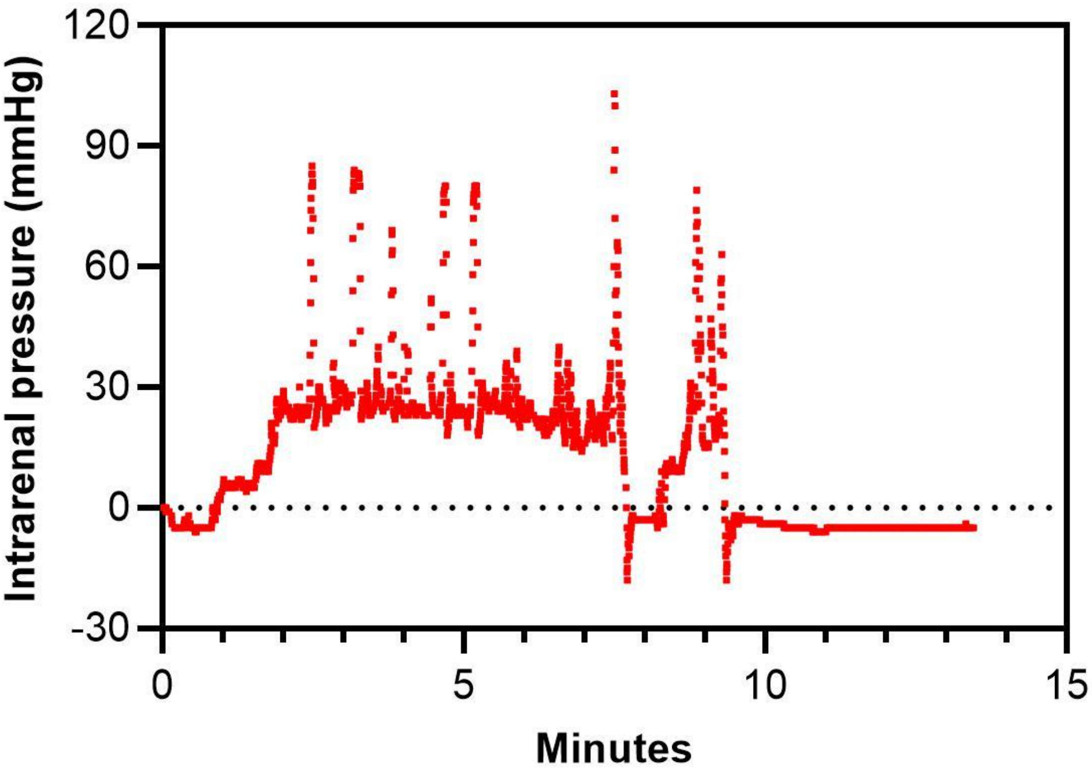
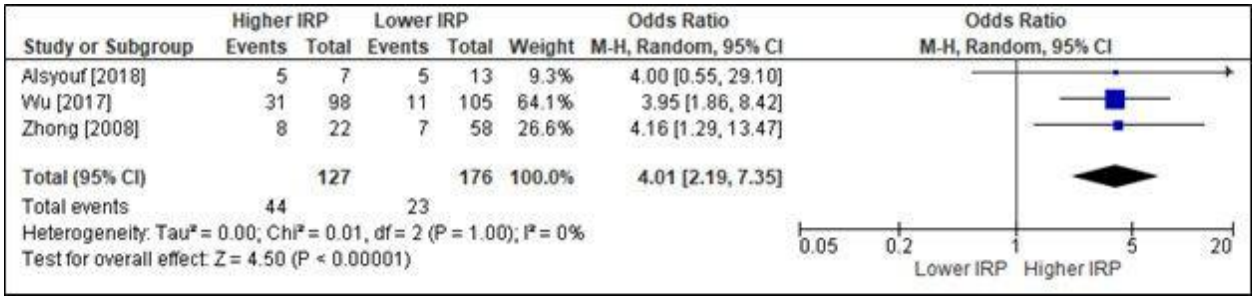
Figure Legends

Figure 1. Data generated from flexible ureteroscope with real-time intrarenal pressure (IRP) sensing. Key data include procedure time of 13.5 minutes, mean IRP of 12 mmHg, peak IRP of 103 mmHg, and 65 seconds spent at IRP > 30 mmHg.

Figure 2. Forest plot of complication risk comparing patients with higher vs. lower mean intrarenal pressure during percutaneous nephrolithotomy. Patients with higher mean intrarenal pressure had four times higher odds of a perioperative complication than those with lower intrarenal pressure (p<0.001).


120
90
60
30
0
-30
Intrarenal pressure (mmHg)
0
5
10
15
Minutes


Higher IRP
Lower IRP
Odds Ratio
Odds Ratio
Study or Subgroup
Events
Total
Events
Total
Weight
M-H, Random, 95% CI
M-H, Random, 95% CI
Alsyouf [2018] 5 7 5 13 9.3% 4.00 [0.55, 29.10]
Wu [2017] 31 98 11 105 64.1% 3.95 [1.86, 8.42]
Zhong [2008] 8 22 7 58 26.6% 4.16 [1.29, 13.47]
Total (95% CI) 127 176 100.0% 4.01 [2.19, 7.35]
Total events 44 23
Heterogeneity: Tau² = 0.00; Chi² = 0.01, df = 2 (P = 1.00); I² = 0%
Test for overall effect: Z = 4.50 (P < 0.00001)
0.05
0.2
1
5
20
Lower IRP
Higher IRP