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UROLITHIASIS

First European experience with LithoVue™ Elite: Multicentre end-user experience and feedback

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Introduction The LithoVue™ Elite (LVE) is a novel ureteroscope which allows measurement of intrarenal pressure (IRP) during flexible ureteroscopy (fURS). Here we report the survey of first European experience.

Material and methods A multicentric prospective analysis of end-user experience and feedback was performed for 51 consecutive patients undergoing fURS using LVE across 9 European centres involving 11 surgeons.

Results A total of 51 cases were analysed with a mean stone size of 9.9 mm (range:4–30 mm), standard ureteral access sheath used in 28 patients (54.9%), with multiple stones in 18 (35.3%) patients. The stone location was lower pole (n = 24; 47.1%), renal pelvis (n = 12; 23.5%), proximal ureter (n = 5; 9.8%), upper pole (n = 4; 7.8%), and other locations (n = 6; 11.7%). The irrigation method used for URS was manual pressure irrigation (n = 25, 49%), gravity with pressure cuff (n = 12; 23.5%), gravity with no pressure cuff (n = 9; 17.6%), and fluid management system or pump (n = 5; 9.8%). A planned pressure threshold (in mmHg) was documented by the surgeon in all cases, with a mean setpoint of ≤ 50 mmHg in 26 (51%) patients, 51–60 mmHg in 13 (25.5%) patients and above 60 mm Hg in 12 (23.5%) patients. Post-procedurally, in 48 (94.1%) cases, surgeons reported that real-time IRP monitoring influenced their surgical technique. The most common intraoperative modifications included reduced manual irrigation in 19 (37.3%), lowered irrigation bag height in 13 (25.50%), adjusted sheath positioning in 10 (19.6%), and reduced or avoidance irrigation pressure in 6 (11.8%) cases. Regarding perceived value, the pressure-sensing scope was rated as highly desirable in 28 procedures (54.9%), and moderately desirable in 16 (31.4%) procedures, yielding a combined desirability rating of 86.3%. Importantly, all 11 surgeons (100%) indicated an intention to continue using LVE, particularly in high-risk patients or complex procedures.

Conclusions Real time IRP measurement influenced intraoperative technique in majority of cases with surgeons adopting real-time strategies to reduce IRP. The LVE scope was rated as desirable by most users and was universally endorsed for continued use, especially in higher-risk scenarios. These findings support the integration of IRP monitoring as a valuable adjunct in endourologic practice.

Key Words: kidney calculi ‹› LithoVue Elite ‹› intrarenal pressure ‹› flexible ureteroscopy ‹› survey ‹› kidney stones

INTRODUCTION

Ureteroscopy often considered as the gold-standard treatment for renal stones less than 2 cm. However, despite its widespread adoption worldwide, increasing attention has been directed towards a key procedural limitation: the need for continuous irrigation to maintain adequate visibility and working space. Increased irrigation can create an imbalance between inflow and outflow, leading to a rise in IRP, potentially triggering adverse events [1]. Indeed, elevated IRP has been associated with pyelovenous backflow, collecting system rupture, postoperative pain, and infectious complications up to urosepsis [2].

To address these challenges, novel technologies have been developed to allow real-time monitoring of IRP during flexible ureteroscopy, including pressure-sensing guidewires, pressure-sensing flexible navigable access sheath (FANS) systems, and pressure-sensing ureteroscopes, providing surgeons with immediate feedback on intrarenal pressure dynamics [3]. Technological development is particularly relevant in modern endourology, where there is trend in treating larger stone burdens, with longer operative durations, and using modern high-power laser systems which increase the likelihood of sustained pressure elevation and unrecognized pressure peaks [4, 5].

Among the new technology, pressure-sensing flexible ureteroscopes have emerged as a promising innovation, enabling direct intrarenal pressure measurement at the operative field. LithoVue™ Elite (LVE) represents the first commercially available platform integrating real-time IRP sensing into a single-use digital ureteroscope, with the potential to improve intraoperative awareness and promote safer fluid management strategies [6]. However, while early single-centre experiences are encouraging, robust real-world evaluation across multiple institutions remains limited.

Therefore, the present study reports the first European multicentre end-user experience with LVE, focusing on intraoperative pressure monitoring behaviour, surgeon feedback, and perceived clinical utility during flexible ureteroscopy for treating stone disease.

MATERIAL AND METHODS

Study design and participants

A multicentric prospective analysis of end-user experience and feedback was performed for 51 consecutive patients undergoing fURS using LVE across 9 European centres. (France, UK, Spain, Italy, Denmark, Germany, Ireland) between March and July 2025. The following preoperative data were prospectively collected: stone location, stone diameter, planned sheath usage, irrigation method, and pressure threshold set on the StoneSmart Connect Console at the beginning of the procedure. Table 1 contains the questions included in the survey.

LithoVue™ Elite

The LithoVue™ Elite (Boston Scientific) is the first FDA and CE approved commercially available single-use digital flexible ureteroscope, with the capability of real-time IRP monitoring. The pressure sensor is positioned laterally at the distal tip of the ureteroscope, enabling pressure measurement directly at the point of interest within the collecting system. Prior to insertion, a calibration step is required using the StoneSmart Connect console, by immersing the ureteroscope tip in sterile saline for approximately 15 seconds.

The LVE features a distal tip diameter of 7.7 Fr and an overall shaft diameter of 9.5 Fr, with a 3.6 Fr working channel. It provides a maximum deflection angle of up to 270 degrees (Figure 1 A, B).

During flexible ureteroscopy, continuous IRP monitoring provides real-time feedback on pressure dynamics and may support intraoperative decision-making. However, careful manipulation of the ureteroscope is recommended, as transient contact between the distal sensor and the urothelium may generate sudden pressure spikes that do not necessarily reflect true intrarenal pressure changes. In addition, caution should be exercised during la-

Table 1. *Questions included in the survey*

Step	Question	Answer
1	Did the IRP information influence your technique to maintain desired pressure range or threshold?	Yes / No
2	(if answered YES at 1) How did pressure monitoring impact surgical technique?	Free text
3	(if answered NO at 1) Was pressure monitoring used to validate your pre-op plan and technique?	Yes / No
4	How desirable is using a flexible ureteroscope with pressure monitoring capabilities?	Likert scale (low → high desirable)
5	How long did the procedure take? (start: cystoscope insertion; end: bladder drainage)	Time (minutes)
6	Do you intend to continue using this product after evaluation?	Yes / No + Free text explanation
7	explain how you intend to utilize LithoVue™ Elite going forward (e.g., case selection, patient selection, etc.) or why not	Free text

ser lithotripsy, as the distal sensor may be vulnerable to mechanical damage.

At present, evidence supporting the accuracy and clinical performance of LVE remains limited, with a lack of large multicentre validation studies, and even more limited data are available for other pressure-sensing ureteroscope platforms. The system incorporates a built-in alarm function, with a preset safety threshold of 30 mmHg. When the infrarenal pressure exceeds the surgeon-determined preset threshold, which, when exceeded, the pressure display changes to red, providing an immediate visual warning to the operating surgeon [7].

Evaluation criteria

The main outcome was the impact of real-time IRP monitoring on intraoperative surgeon behaviour and perceived clinical utility of LVE, according to the above-mentioned survey criteria.

Statistical analysis

Statistical analysis was performed using descriptive methods. Categorical variables were reported as frequencies and percentages, while continuous variables were summarized as mean values with ranges. No inferential statistical testing was undertaken, as the study was designed to describe end-user experience and feedback.

Bioethical standards

Ethical approval was not required for this as it involved physician perspective of LVE only.

RESULTS

A total of 51 cases were analysed, with a mean stone size of 9.9 mm (range: 4–30 mm). A standard ureteral access sheath was used in 28 patients (54.9%), and multiple stones were present in 18 cases (35.3%). Stone location was most commonly the lower pole (n = 24; 47.1%), followed by the renal pelvis (n = 12; 23.5%), proximal ureter (n = 5; 9.8%), upper pole (n = 4; 7.8%), and other locations (n = 5; 9.8%).

The irrigation method used during ureteroscopy was manual pressure irrigation in 25 cases (49.0%), gravity irrigation with a pressure cuff in 12 (23.5%), gravity irrigation without a pressure cuff in 9 (17.6%), and a fluid management system or pump in 5 (9.8%).

A planned intrarenal pressure threshold was documented in nearly all cases, with a setpoint of ≤50 mmHg in 26 cases (51.0%), 51–60 mmHg in 13 (25.5%), and >60 mmHg in 12 (23.5%).

Following the procedure, 48 surgeons (94.1%) reported that real-time intrarenal pressure monitoring influenced their intraoperative technique. The most common modifications included reducing manual irrigation (n = 19; 37.3%), lowering

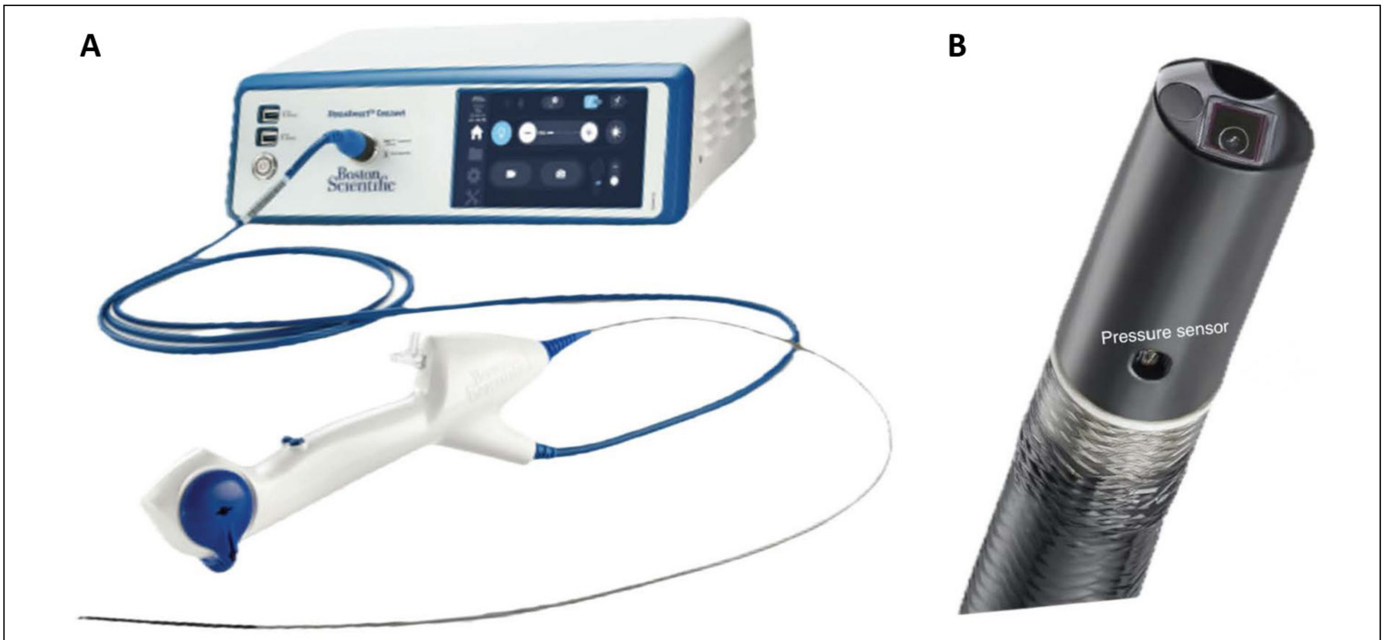

Figure 1. *LithoVueTM Elite.* **A)** *Flexible ureteroscope system with integrated pressure monitoring console.* **B)** *Distal tip of a flexible ureteroscope.*

fURS – flexible ureteroscopy; IRP – intrarenal pressure; LVE – LithoVueTM Elite; UAS – ureteral access sheath irrigation bag height (n = 13; 25.5%), adjusting sheath positioning (n = 10; 19.6%), and reducing or temporarily stopping irrigation pressure (n = 6; 11.8%).

Regarding perceived clinical value, 28 surgeons (54.9%) rated the pressure-sensing ureteroscope as highly desirable and 16 (31.4%) as moderately desirable, resulting in a combined desirability rating of 86.3%. All surgeons (n = 51; 100%) reported an intention to continue using the LVE platform, particularly in high-risk patients and complex procedures. All results are resumed in Table 2.

DISCUSSION

This study represents the first multicentric evaluation of expert endourologists' feedback and experience with the LVE system, which was the first clinical experience of the surgeons using this device. Overall, real-time IRP monitoring influenced the surgical technique in 94% of cases, with most surgeons rating it as highly desirable.

Table 2. *Multicentre European experience with LithoVue™ Elite*

Variable		
Study cohort	Total cases analysed	51
	Mean stone size (mm)	9.9 (range: 4–30)
	Multiple stones	18 (35.3%)
	UAS used	28 (54.9%)
Stone location	Lower pole	24 (47.1%)
	Renal pelvis	12 (23.5%)
	Proximal ureter	5 (9.8%)
	Upper pole	4 (7.8%)
	Other	6 (11.7%)
Irrigation method	Manual pressure irrigation	25 (49.0%)
	Gravity + pressure cuff	12 (23.5%)
	Gravity (no cuff)	9 (17.6%)
	Pump / fluid management system	5 (9.8%)
Planned IRP threshold	≤50 mmHg	26 (51.0%)
	51–60 mmHg	13 (25.5%)
	>60 mmHg	12 (23.5%)
Impact of IRP monitoring	IRP monitoring influenced surgical technique	48 (94.1%)
Intraoperative modifications	Reduced manual irrigation	19 (37.3%)
	Lowered irrigation bag height	13 (25.5%)
	Adjusted sheath positioning	10 (19.6%)
	Reduced/closed irrigation pressure	6 (11.8%)
Surgeon desirability rating	Highly desirable	28 (54.9%)
	Moderately desirable	16 (31.4%)
	Combined desirability	44 (86.3%)
Future adoption	Intention to continue using LVE	51 (100%)

LVE – LithoVue™ Elite; UAS – Understanding America Stu

IRP monitoring during flexible ureteroscopy has increased its clinical relevance, as elevated IRP can be associated with adverse outcomes including pyelovenous backflow, pelvicalyceal extravasation, postoperative pain, and infectious complications up to urosepsis [8]. A Delphi consensus panel emphasized that any IRP above physiological levels (typically in the range of approximately 0–15 mmHg, equalling 0–20 cmH_2O [9]) should be considered high and a potential threat to patient safety, although no universally accepted threshold exists[4]. In parallel, the scoping review from the Global Research on Intra-renal Pressure Collaborative Group highlighted that IRP elevations above 30–40 mmHg were repeatedly linked with postoperative complications, particularly infectious events [10].

IRP during endourological surgery is primarily determined by the balance between irrigation inflow and outflow, and is influenced by irrigation modality, irrigation bag height, ureteroscope calibre, ureteral access sheath use/size, and suction mechanisms. Gravity irrigation generally results in lower and more stable IRP, whereas manual hand-pump irrigation produces significantly higher and more variable pressure peaks [7, 8]. Automated irrigation improves flow stability but does not fully prevent transient pressure surges, particularly when outflow is limited [11].

Real-world evidence suggests that the use of a pressure-monitoring ureteroscope such as LVE may translate into improved short-term outcomes, with significantly reduced 30-day postoperative infection rates compared to other single-use ureteroscopes without IRP monitoring [7]. This improvement is likely explained by the ability of surgeons to actively respond when IRP rises above accepted safety thresholds (30–40 mmHg), prompting real-time intraoperative modifications such as adjusting scope position, reducing irrigation flow, optimizing ureteral access sheath placement, or using suction. By translating real-time pressure feedback into immediate corrective actions, the use of LVE with pressure monitoring may enhance procedural safety [12].

In an increasingly quality and cost-conscious healthcare environment, there is an urgent need for effective and safer strategies to prevent infection and other URS related adverse outcomes. Importantly, while technological innovation is often considered a major driver of rising healthcare expenditure, it may still be justified when it delivers measurable improvements in patient outcomes and overall value, rather than cost escalation alone [13]. Indeed, following ureteroscopy, more than 10% of patients re-present to the emergency department within the first 30 days, with urinary tract infection being one of the most common reasons for readmission [14, 15]. A proportion of these infections progress to sepsis, which carries a major societal and economic impact [16].

Therefore, given the high volume of URS procedures, the significant incidence of postoperative infection, and the potentially devastating consequences of urosepsis, the integration of real-time IRP monitoring through LVE could have a transformative impact on URS patient care by decreasing infection risks and supporting cost-effective adoption of innovation.

The increased cost of a pressure-monitoring ureteroscope means that their use should be judicious through careful patient selection. Patients most likely to benefit from IRP monitoring are those at higher risk of infectious complications, particularly individuals with advanced age, diabetes, positive pre-operative urine culture, significant comorbidity burden, pre-operative stenting, or expected prolonged operative times, as these factors have been consistently associated with post-URS infection and sepsis [12].

In addition, IRP monitoring may be particularly valuable in complex stone cases, such as large stone burdens or anatomically challenging procedures requiring higher irrigation demands, where uncontrolled IRP elevation above 30–40 mmHg has been linked to postoperative pain and infectious outcomes [7, 17].

However, one of the downsides of LVE is that raw intrarenal pressure recordings may be affected by frequent artefactual pressure spikes that do not reflect true physiological changes within the collecting system. These false peaks are most commonly generated by transient contact between the distal pressure sensor and the urothelium, leading to an overestimation of actual IRP values [18]. To address this limitation, Yanase et al. proposed an AI-based artefact detection and correction framework capable of distinguishing true IRP fluctuations from measurement errors, thereby enabling more reliable quantification of mean IRP and clinically relevant pressure peaks [19].

Future directions for LVE should prioritize multicentre prospective studies with standardized IRP measurement protocols, including calibration methods, irrigation and suction techniques, and the definition of safe pressure thresholds. In parallel, structured training pathways will be essential to reduce inter-operator variability and improve the consistency and interpretability of IRP monitoring across centres and devices.

This study has several limitations. First, no clinical endpoints were assessed, as the analysis was primarily based on surgeon feedback and therefore remains subjective despite its multicentric design. There is also a potential "novelty bias", and while the study received no financial support, a few surgeons involved in the study are consultants or do educational activities for Boston Scientific. In addition, the sample size of surgeons included was limited, reflecting the current restricted availability and early adoption of this technology across European centres. Nevertheless, this work should be regarded as a preliminary evaluation of a novel pressure-sensing ureteroscope and provides an important foundation for future studies incorporating standardized outcome measures and clinical endpoints. Another limitation is the low case volume for the number of urologists involved.

CONCLUSIONS

We report on the European multi-centre use of a novel ureteroscope, which allows the monitoring of intrarenal pressure, the LithoVue Elite™ (Boston Scientific). Intrarenal pressure monitoring influenced intraoperative technique in the vast majority of cases. Surgeons adopted real-time strategies to reduce IRP, such as adjusting irrigation dynamics and sheath use. The LVE scope was rated as desirable by most users and was universally endorsed for continued use post-evaluation, especially in higher-risk patients. These findings support the integration of IRP monitoring as a valuable adjunct in endourologic practice.

CONFLICTS OF INTEREST

Guido Giusti: Boston Scientific, Coloplast, Cook Medical, Olympus, Karl Storz, Rocamed. Olivier Traxer: Boston Scientific, Coloplast, Lumenis, Olympus, Rocamed. Silvia Proietti: Boston Scientific. Oriol Angerri: Boston Scientific. Arkadiusz Miernik: Boston Scientific, Dornier, Optimed, AMX. Benjamin Turney: Consultant: Boston Scientific, EMS, Verathon. Education: Boston Scientific, EMS, Dornier, Hugemed. Oliver Wiseman: Consultant: Boston Scientific, EMS, Verathon. Education: Boston Scientific, EMS, Dornier, Hugemed. Mohammad Boulmani: Employee Boston Scientific. Bhaskar K. Somani: Boston Scientific, Pusen, HugeMed, Coloplast, Penlan. The other authors declare no conflict of interest.

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ETHICS APPROVAL STATEMENT

Ethical approval was not required for this as it involved physician perspective of LVE only.

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