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Enhanced Pressure Management Using an Upgraded Vacuum-Assisted Ureteroscopic System: Experimental Validation and Predictive Modeling

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Title Page

Title: Enhanced Pressure Management Using an Upgraded Vacuum-Assisted Ureteroscopic System: Experimental Validation and Predictive Modeling.

Running head: Vacuum-Assisted Ureteroscopy: Pressure Management & Modeling.

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Abbreviations

1. VA-URS - Vacuum-Assisted Ureteroscopy
2. T-URS - Traditional Ureteroscopy

Abstract

Introduction: To evaluate the pressure-control performance and irrigation efficiency of an upgraded vacuum-assisted ureteroscopic system (VA-URS) compared with traditional ureteroscopy (T-URS) using an in vitro kidney model.

Methods: An artificial renal pelvis model was used to simulate ureteroscopy under varying irrigation pressures (50, 100, 150 cmH_2O) and flow rates (30–50 mL/min). Intrapelvic pressure and effective irrigation flow rates were continuously recorded. Three-way ANOVA assessed the influence of surgical method, irrigation pressure, and flow rate, while multiple regression models quantified pressure–parameter relationships.

Results: VA-URS consistently produced lower intrapelvic pressures than T-URS across all settings. At 50 cmH_2O with 30 mL/min, pressures were −21.47 ± 1.86 cmH_2O versus 24.73 ± 1.56 cmH_2O ($P < 0.01$). At 150 cmH_2O with 50 mL/min, values were 50.13 ± 2.14 cmH_2O versus 61.53 ± 1.27 cmH_2O ($P < 0.01$). Effective irrigation flow was also higher with VA-URS (24.50 ± 0.79 vs. 20.40 ± 0.70 mL/min at 50 cmH_2O/30 mL/min; $P < 0.01$). Regression modeling demonstrated strong predictive accuracy ($R^2 = 0.984$ for VA-URS) and distinct pressure–flow dynamics compared with T-URS.

Conclusions: The upgraded VA-URS system significantly enhances intrapelvic pressure management and irrigation efficiency compared with T-URS in this in vitro model. These bench findings support further translational evaluation; however, animal and clinical studies are required to confirm clinical benefit and safety.

Keywords: Vacuum-assisted ureteroscopy; intrapelvic pressure; irrigation flow; in vitro model; pressure prediction

Introduction

Semi-rigid ureteroscopy is a widely used minimally invasive technique for diagnosing and treating urinary tract disorders [1]. However, one major concern is the increase in intrarenal pressure during procedures, which can lead to serious complications such as sepsis, kidney injury, and urine extravasation [2-5].

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The treatment of ureteral stones, particularly impacted ones, involves various techniques, each with distinct advantages and limitations. While shock wave lithotripsy offers a non-invasive approach, it often requires multiple sessions and shows limited efficacy for larger stones[6]. Flexible ureteroscopy provides high stone-free rates but involves significant equipment costs[7, 8]. Semi-rigid ureteroscopic lithotripsy remains a primary treatment option, particularly in resource-conscious settings, yet it faces challenges with stone retropulsion and elevated renal pelvic pressure[9-13].

Our earlier studies introduced a vacuum-assisted ureteroscopic system using a basic F5 ureteral catheter and tee joint configuration that effectively reduced intrarenal pressure while maintaining adequate visualization[14-16]. In a recent editorial comment in Urology, this novel technique was highly commended for its cost-effectiveness, efficiency, reduced complications, and significantly improved stone-free rates[17]. However, limitations in device stability and operability presented challenges for widespread adoption.

In response to these challenges, we developed an upgraded integrated vacuum suction catheter incorporating three key improvements—(i) a stainless-steel stabilizing tube for secure scope attachment, (ii) a sealed reinforcement cap for improved fixation and sealing, and (iii) an adjustable valve for precise regulation of vacuum suction—as described in our published study [18]. These modifications were designed to overcome the technical limitations of the original prototype while preserving its clinical benefits.

While our clinical studies have confirmed that the vacuum-assisted system can maintain a clear operative field while simultaneously reducing intrapelvic pressure through continuous suction, the exact mechanisms and quantitative effects of this system on intrapelvic pressure and irrigation flow dynamics have not been thoroughly investigated in a controlled setting.

This study aims to quantify the effects of the vacuum-assisted system on renal pelvic pressure using an artificial kidney model. By comparing vacuum-assisted ureteroscopic surgery (VA-URS) with traditional ureteroscopic surgery (T-URS) under various irrigation pressures and flow rates, we seek to provide a comprehensive understanding of the pressure dynamics in both systems.

Methods

We constructed an artificial kidney model using a modified bladder evacuator (Boston Scientific) to simulate the renal pelvis, designed to replicate the volume and compliance characteristics of a human renal pelvis. The model was equipped with a high-precision pressure sensor (accuracy ±0.1 mmHg) for continuous intrapelvic pressure measurement throughout the experiments.

The experimental setup consisted of a semi-rigid ureteroscope (7.5/9.8F, Schoelly, Germany) and an upgraded integrated vacuum suction catheter (inner diameter 1.2 mm, outer diameter 1.6 mm; patented product, Tangji, China). The catheter features a stainless steel stabilizing tube at the proximal end for secure attachment to the ureteroscope. The distal inlet is deliberately tapered to reduce debris obstruction, with a distal tip outer diameter of 1.4 mm and a narrowed suction lumen of 1.0 mm. A side port with an adjustable valve allows precise regulation of vacuum pressure. These upgrades were introduced to improve catheter stability, sealing reliability, and suction controllability compared with our earlier prototypes, and the detailed catheter design has been reported previously [18]. In addition, a 200-μm holmium:YAG laser fiber was introduced through the lumen of the integrated vacuum suction catheter to reach the stone site. This configuration enabled simultaneous irrigation inflow/outflow and laser lithotripsy, forming an efficient closed-loop system (Fig. 1). The setup also included an irrigation pump (JIHPUMP, Chongqing China) with adjustable pressure and flow rate settings, and a comprehensive pressure monitoring system (miniTR biological signal acquisition instrument, China) connected to a data acquisition system (miniTR biological signal acquisition and processing system, China) for real-time pressure recording (Fig. 2).

Two experimental groups were established: vacuum-assisted ureteroscopy (VA-URS) and traditional ureteroscopy without vacuum assistance (T-URS). Simulated ureteroscopy procedures were performed under varying irrigation pressures (50, 100, 150 cmH$_2$O) and flow rates (30, 40, 50 mL/min). The vacuum pressure in the VA-URS group was fixed at −150 mmHg, selected based on our prior clinical implementation of the integrated vacuum suction catheter [18] and bench pilot testing, aiming to achieve meaningful pressure reduction while maintaining stable irrigation outflow and minimizing catheter obstruction. For each irrigation pressure–flow setting, the system first underwent a 2-minute run-in (prediction) period to allow the irrigation–suction circuit to reach a quasi-steady state. Subsequently, intrapelvic pressure was continuously recorded for 5 minutes as the formal measurement window. Each setting was tested in triplicate, and the averaged values were used for analysis. Effective irrigation flow rate was defined as the actual delivered

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irrigation inflow rate measured at the irrigation source using the graduated reservoir (Fig. 2). For each trial, delivered irrigation volume (mL) was obtained from the change in reservoir volume during the 5-minute formal recording window. The effective irrigation time (min) was defined as the duration of this formal recording window (5 minutes) under each setting. The effective flow rate (mL/min) was calculated as delivered irrigation volume divided by effective irrigation time.

The primary outcome measure was intrapelvic pressure, continuously recorded at 100 Hz using the miniTR system. The secondary outcome was effective irrigation flow rate, measured at the irrigation source using the graduated reservoir and calculated as described above.

Data were analyzed using the built-in analysis software of the miniTR system and SPSS (version 25, IBM). Continuous variables were summarized as mean ± standard deviation and compared between VA-URS and T-URS using Student's t-test where appropriate.

In the factorial experimental design, a three-way ANOVA was performed to quantify the contribution of the assigned/controlled factors—surgical method (VA-URS vs. T-URS), irrigation pressure (50, 100, 150 cmH_2O), and flow setting (30, 40, 50 mL/min)—to the measured intrapelvic pressure, including interaction terms.

In addition, multiple linear regression models were fitted separately for VA-URS and T-URS to describe the empirical relationship between irrigation settings and intrapelvic pressure within the tested parameter range. Regression model assumptions were assessed by residual analysis (including distribution and homoscedasticity) prior to interpretation. Statistical significance was set at $P < 0.05$.

Results

The VA-URS group demonstrated consistently lower intrapelvic pressures than the T-URS group across all test conditions. At baseline irrigation pressure (50 cmH_2O) with a 30 mL/min flow setting, mean intrapelvic pressure was −21.47 ± 1.86 cmH_2O in the VA-URS group versus 24.73 ± 1.56 cmH_2O in the T-URS group. This pressure-reducing effect remained significant at higher irrigation pressures; for example, at 150 cmH_2O with a 50 mL/min flow setting, VA-URS maintained 50.13 ± 2.14 cmH_2O versus 61.53 ± 1.27 cmH_2O in T-URS (see Fig. 3A–C; Table 1).

The VA-URS group also achieved higher effective irrigation flow rates across all settings. At 50 cmH_2O with a 30 mL/min flow setting, VA-URS reached 24.50 ± 0.79 mL/min compared with 20.40 ± 0.70 mL/min in T-URS ($P < 0.01$). At 150 cmH_2O with a 50 mL/min flow setting, VA-URS achieved 48.60 ± 0.90 mL/min versus 45.97 ± 0.75 mL/min in T-URS ($P < 0.05$) (Fig. 3D–F; Table 1).

In this controlled factorial design, three-way ANOVA was used to quantify the contribution of the assigned irrigation settings (pressure and flow) and surgical method to measured intrapelvic pressure. Surgical method showed the largest contribution ($F(1,36) = 5448.811$, $P < 0.001$), followed by assigned flow setting ($F(2,36) = 1790.077$, $P < 0.001$) and assigned irrigation pressure ($F(2,36) = 958.633$, $P < 0.001$) (Table 2). Significant interaction terms indicated that the magnitude of the method effect varied across different irrigation settings.

Multiple linear regression models were constructed separately for each group to provide an empirical prediction of intrapelvic pressure from assigned irrigation pressure (X_1) and flow setting (X_2) within the tested range (Table 3). The fitted equations were: T-URS: $Y = 0.196X_1 + 0.884X_2 - 11.13$ ($R^2 = 0.978$) and VA-URS: $Y = 0.260X_1 + 2.256X_2 - 104.096$ ($R^2 = 0.984$), where Y represents intrapelvic pressure. These models showed high goodness-of-fit for the discrete experimental settings; however, coefficients and intercepts should be interpreted as model-specific empirical parameters rather than physiological constants. Given the discretized design, the models are intended for within-grid prediction and should not be extrapolated beyond the tested settings. Residual diagnostics suggested no major violations of linear regression assumptions within the tested range (residuals were approximately symmetrically distributed and residual variance appeared broadly constant across fitted values).

Discussion

Our study demonstrates that VA-URS significantly reduces intrapelvic pressure compared with T-URS in an in vitro kidney model, with reductions increasing from approximately 13.8% at baseline to 18.5% at higher irrigation pressures. Across all tested settings, VA-URS consistently maintained a lower-pressure environment than T-URS (Fig. 3A–C; Table 1), indicating that vacuum assistance becomes particularly advantageous when irrigation demands and pressure-control requirements are greatest. This finding

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supports the concept that improving outflow evacuation is central to stabilizing intrapelvic pressure during ureteroscopy in this bench model.

The pressure-reducing effect can be attributed to the continuous suction generated by the vacuum system, which establishes a pressure gradient that promotes fluid outflow and prevents intrapelvic fluid accumulation. Regression modeling provided an empirical description of the pressure response to assigned irrigation settings in each system. The high within-range fit ($R^2 > 0.97$) supports its use as a practical predictor for parameter selection in this bench model; however, the regression coefficients and intercepts should not be over-interpreted mechanistically, and non-linear behavior may emerge outside the tested range.

The ANOVA results indicate that the use of vacuum assistance was the dominant contributor to lowering intrapelvic pressure across the tested settings, supporting the robustness of VA-URS pressure control under different assigned irrigation pressures and flow rates.

Another key finding is that VA-URS maintained higher effective irrigation flow rates across the predefined pressure–flow combinations (Fig. 3D–F; Table 1). This suggests that the system can preserve irrigation performance and visualization while simultaneously facilitating pressure control. Clinically, this dual effect is desirable because it addresses two competing goals in ureteroscopic surgery—maintaining a clear operative field and minimizing pressure-related risks—without requiring the operator to compromise one for the other.

Our bench findings are consistent with prior clinical reports suggesting that vacuum-assisted ureteroscopic techniques may reduce complications and improve outcomes[15, 16, 18]. Similar pressure- and outflow-oriented concepts have also been explored with suction-assisted strategies such as aspirating ureteral access sheaths and suction-assisted semi-rigid ureteroscopy [19]. In this controlled in vitro model, VA-URS maintained a more favorable pressure environment while preserving irrigation performance, supporting its potential as a practical approach for pressure management. Nevertheless, these data do not establish clinical superiority; they should be viewed as hypothesis-generating, and further in vivo and clinical studies incorporating clinically relevant intrarenal pressure thresholds are required to confirm translational safety and benefit.

Nevertheless, this in vitro renal pelvis model cannot reproduce key in vivo features, including collecting-system compliance, mucosal elasticity/peristalsis, and dynamic outflow resistance at the pyeloureteral junction. Potential pressure-related backflow pathways (e.g., papillary ducts and pyelovenous/pyelolymphatic routes) are not represented; thus, the measured pressures should not be interpreted as clinical threshold values. Moreover, obstruction was simplified to a proximal ureteral “stone/occlusion” scenario. Therefore, our findings should be considered mechanistic bench validation under defined settings, and in vivo studies are needed for translational confirmation.

Conclusion

This in vitro study shows that VA-URS effectively lowers intrapelvic pressure while maintaining higher irrigation flow compared with T-URS. The advantage was most evident under high-pressure and high-flow conditions, suggesting improved safety margins for ureteroscopic procedures. These findings provide quantitative bench evidence that VA-URS can improve pressure management and irrigation outflow under controlled conditions, supporting further translational evaluation rather than definitive claims of clinical superiority.

Statement of Ethics： An ethics statement was not required for this study type since no human or animal subjects or materials were used.

Conflict of Interest Statement: The authors report no conflicts of interest.

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Authors' contribution: YT Zuo, BL Qu, and P Zou: project development, data collection and manuscript writing. TZ Liu, and ZH Wu: designed research and supervision.

Data Availability Statement: The data that support the findings of this study are not publicly available due to institutional data-sharing policy and laboratory confidentiality but are available from the corresponding authors upon reasonable request.

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Figure legend:

Fig. 1: Schematic diagram of the vacuum-assisted ureteroscopic system.

The left panel shows the overall structure of the semi-rigid ureteroscope with integrated vacuum suction catheter. The right panel presents a magnified view of the working channel, demonstrating the flow dynamics of irrigation fluid (solid arrows) and the vacuum suction effect (dashed arrows) during operation.

Fig. 2: Experimental setup and key components of the vacuum-assisted ureteroscopic system.

Left: Overview of the experimental setup showing the integrated system including laptop for data acquisition, pressure monitoring device (green box), irrigation pump, and artificial kidney model with pressure sensors.

Upper right: Magnified view of the ureteroscope tip demonstrating the internal structure near the simulated proximal ureteral stone.

Lower right: Detailed view of the vacuum-assisted system connection, showing the integration of the vacuum suction catheter with the ureteroscope.

Fig. 3: Comparison of intrapelvic pressure and effective flow rate between VA-URS and T-URS groups under different irrigation conditions.

A-C: Intrapelvic pressure comparison between VA-URS and T-URS groups at irrigation pressures of 50 cmH_2O (A), 100 cmH_2O (B), and 150 cmH_2O (C) with varying flow rates.

D-F: Effective flow rate comparison between VA-URS and T-URS groups at irrigation pressures of 50 cmH_2O (D), 100 cmH_2O (E), and 150 cmH_2O (F) with varying flow rates.

** indicates $P < 0.001$; * indicates $P < 0.05$.

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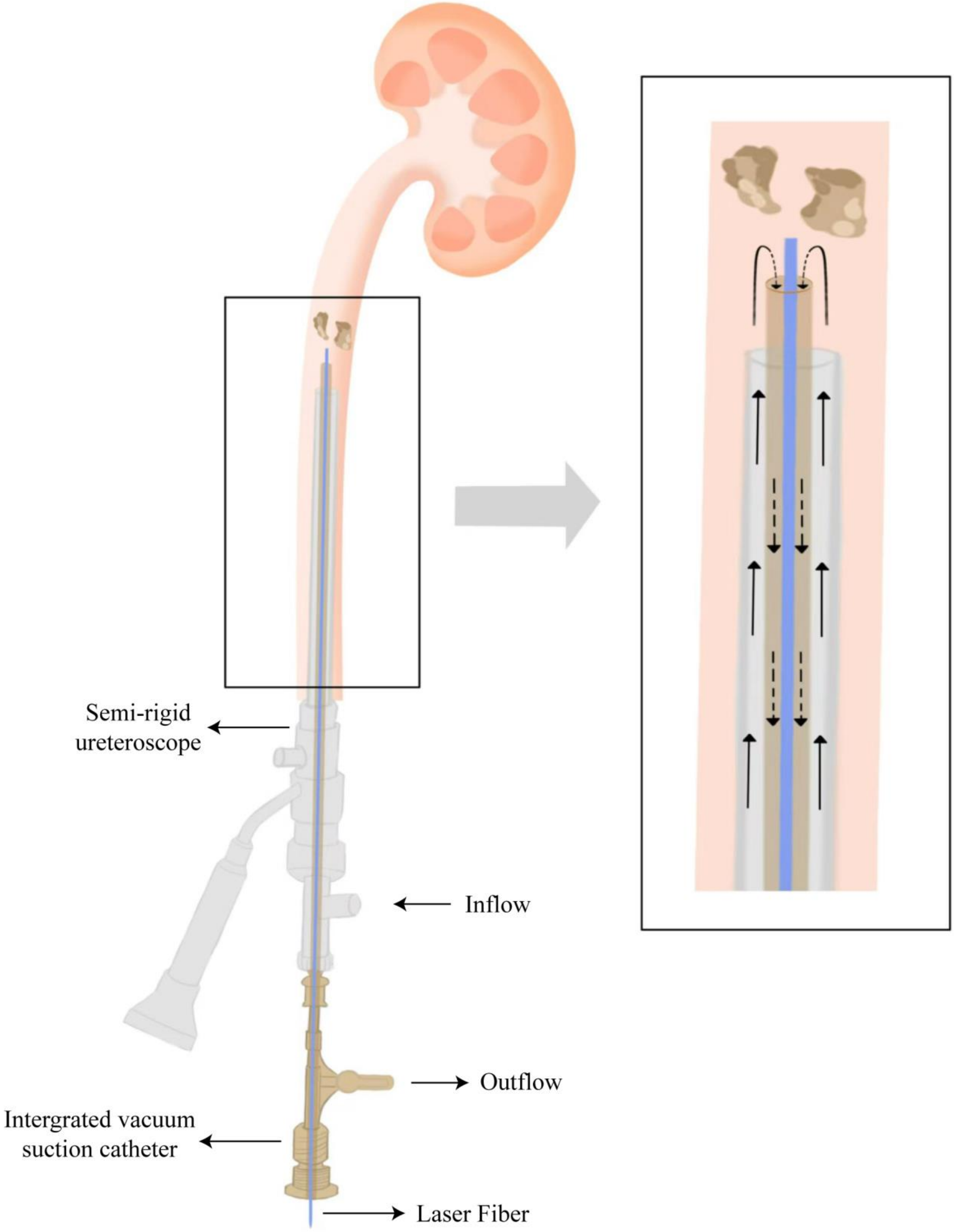

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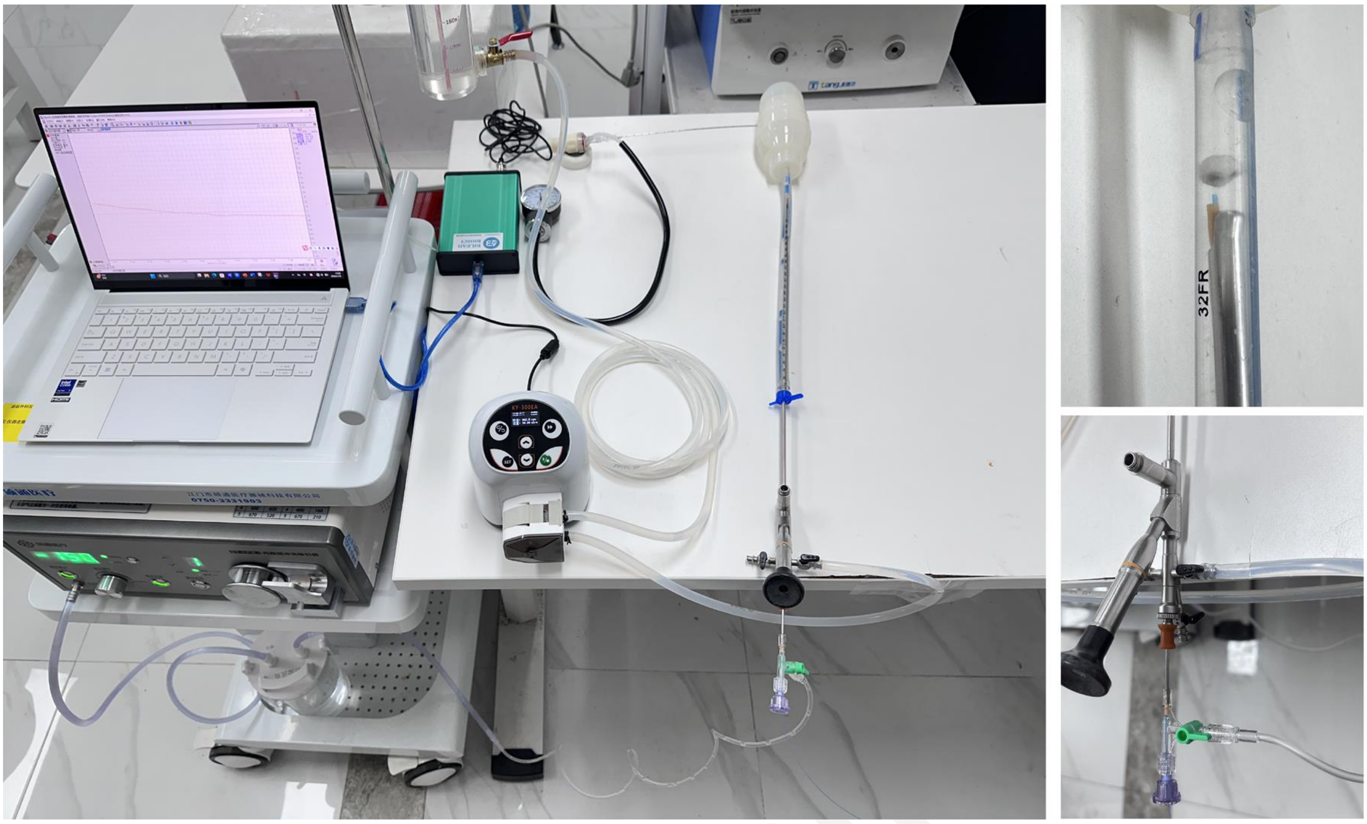

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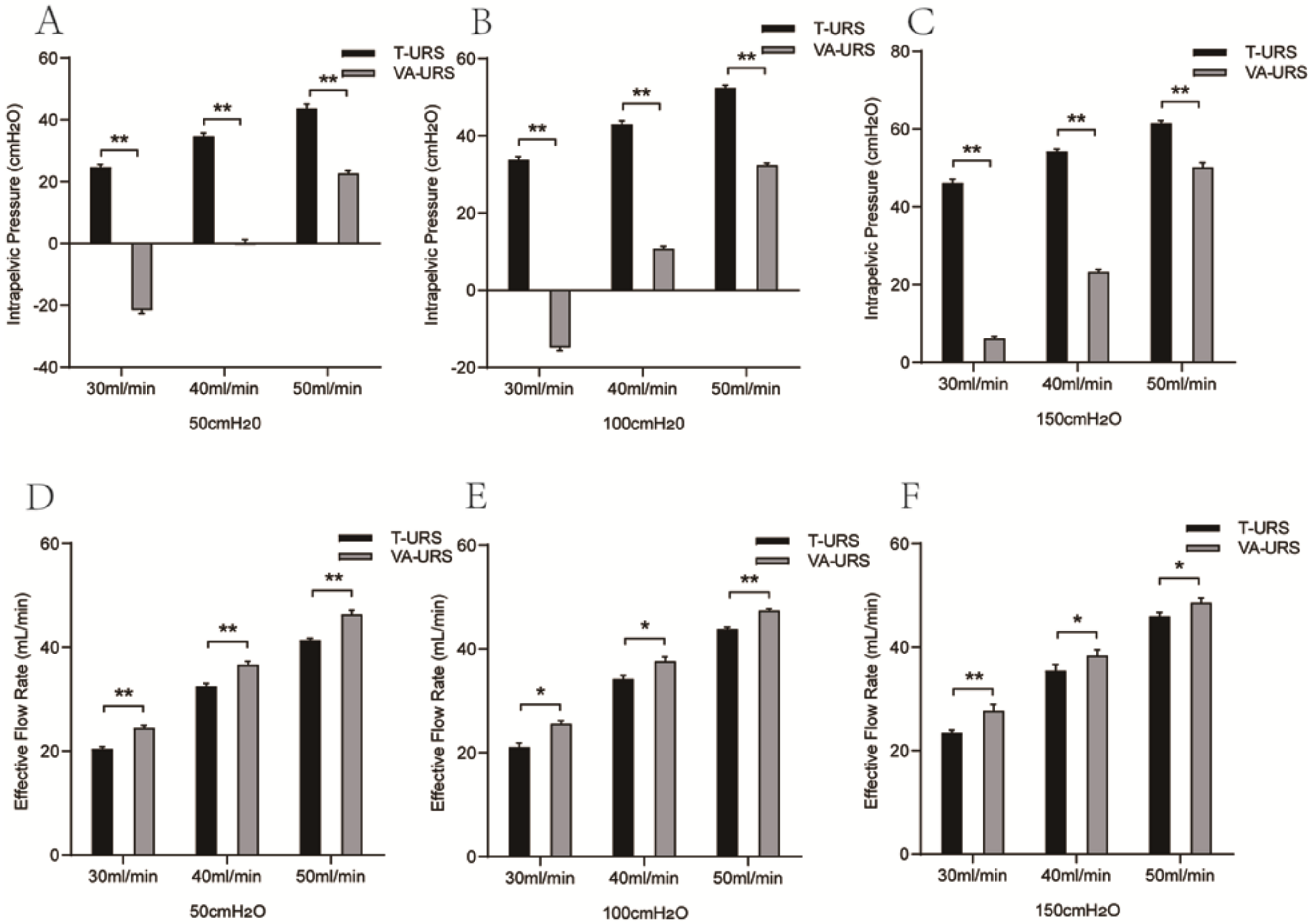

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Irrigation Pressure （cmH$_2$O）	Irrigation Flow Rate (mL/min)	Intrapelvic Pressure（cmH$_2$O）		*P*	Effective Flow Rate (mL/min)		*P*
		T-URS	VA-URS		T-URS	VA-URS	
50	30	24.73±1.56	-21.47±1.86	<0.001	20.40±0.70	24.50±0.79	0.003
50	40	34.67±1.90	0.23±1.66	<0.001	32.53±0.91	36.70±1.11	0.007
50	50	43.73±2.35	22.73±1.45	<0.001	41.37±0.64	46.37±1.32	0.004
100	30	33.80±1.49	-14.77±1.47	<0.001	21.07±1.5	25.57±1.03	0.013
100	40	42.97±1.75	10.73±1.22	<0.001	34.23±1.17	37.70±1.30	0.026
100	50	52.40±1.25	32.43±0.97	<0.001	43.90±0.56	47.37±0.61	0.002
150	30	46.10±1.90	6.17±0.96	<0.001	23.43±0.57	27.67±1.32	0.007
150	40	54.20±1.10	23.23±1.17	<0.001	35.47±1.15	38.40±1.14	0.035
150	50	61.53±1.27	50.13±2.14	0.001	45.97±0.75	48.60±0.90	0.018

Table 1. Comparison of intrapelvic pressure and effective irrigation flow between VA-URS and T-URS groups under different irrigation pressures and flow rates (Mean ± SD).

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	SS	df	MS	F	P
Irrigation Pressure	4753.397	2	2376.699	958.633	<0.001
Irrigation Flow Rate	8876.13	2	4438.065	1790.077	<0.001
Method	13509.015	1	13509.015	5448.811	<0.001
Irrigation Pressure × Flow Rate	36.723	4	9.181	3.703	<0.001
Irrigation Pressure × Method	119.258	2	59.629	24.051	0.013
Flow Rate × Method	1700.298	2	850.149	342.904	<0.001
Irrigation Pressure × Flow Rate × Method	32.984	4	8.246	3.326	<0.001
Error	89.253	36	2.479		
Total	71380.29	54			

Table 2. Three-way ANOVA results for effects of irrigation pressure, flow rate, and method on intrapelvic pressure.

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Group	R	R²	Adjusted R²	SE	F	P-value	Durbin-Watson
VA-URS	0.992	0.984	0.982	2.909	721.301	<0.001	1.124
T-URS	0.989	0.978	0.977	1.698	524.728	<0.001	2.335

Table 3-1. Model Summary

Group	Variable	B	SE	Beta	t	P-value	Collinearity Statistics	
							Tolerance	VIF
VA-URS	Constant	-104.1	3.117	-	-33.4	<0.001		
	Pressure	0.26	0.014	0.495	18.969	<0.001	1	1
	Volume	2.256	0.069	0.859	32.906	<0.001	1	1
T-URS	Constant	-11.13	1.819	-	-6.118	<0.001		
	Pressure	0.196	0.008	0.734	24.447	<0.001	1	1
	Volume	0.884	0.04	0.663	22.087	<0.001	1	1

Table 3-2. Regression Coefficients

Table 3. Multiple linear regression analysis results of irrigation pressure and intrapelvic pressure in VA-URS and T-URS groups.

Note: SE = Standard Error; B = Unstandardized Coefficients; Beta = Standardized Coefficients

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