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Prospective Randomized Comparison of Standard Hand Pump Infuser Irrigation vs an Automated Irrigation Pump During Percutaneous Nephrolithotomy and Ureteroscopy: Assessment of Operating Room Efficiency and Surgeon Satisfaction

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Abstract

Introduction: The objective of this study was to determine if use of an automated irrigation pump (AIP) during ureteroscopy (URS) and percutaneous nephrolithotomy (PCNL) affects circulating nurse labor, irrigation-related issues, and surgeon and nurse satisfaction when compared to manual hand pump (HP) irrigation.

Methods: Eighty consecutive adult patients undergoing unilateral URS or PCNL were prospectively randomized to irrigation with the HP or AIP. Preoperative pump setup time, intraoperative pump maintenance time, total pump time (setup+maintenance), and the number of irrigation-related concerns verbalized by the surgeon intraoperatively were recorded; postoperatively, surgeons and nurses rated their satisfaction with the irrigation system (1 = highly dissatisfied to 10 = highly satisfied).

Results: Eighty patients were enrolled (39 AIP and 41 HP); 51 patients underwent URS and 29 patients underwent PCNL. On univariate analysis, the AIP resulted in a significantly reduced total pump time for URS (2.9 vs 5.9 minutes) and PCNL (4.6 vs 33.9 minutes; $p < 0.001$). The number of irrigation-related concerns was significantly lower in the AIP group during URS (1.2 vs 2.8, $p < 0.001$), but not during PCNL (1.9 vs 4.0, $p = 0.07$). The AIP was associated with significantly higher nurse satisfaction during URS (9.2/10 vs 6.5/10, $p < 0.001$) and PCNL (9.4/10 vs 4.4/10, $p = 0.001$). There was no significant association between pump type and surgeon satisfaction. On multivariate analysis of URS cases controlling for body mass index and number of stones, use of the AIP was a predictor of total pump time < 5 minutes (odds ratio 25.8, 95% confidence interval [CI] 4.0–165.4; $p < 0.001$) and favorable (8–10/10) nurse satisfaction rating (odds ratio 25.4, 95% CI 4.1–164.0; $p < 0.001$). Operative time, stone-free rate, and liters of irrigant used with the HP and AIP were similar.

Conclusions: During URS and PCNL, the AIP was associated with a significant reduction in irrigation pump time and higher nurse satisfaction.

Keywords: irrigation, percutaneous nephrolithotomy, ureteroscopy, urolithiasis, endoscopy

Introduction

DURING ENDOUROLOGICAL STONE procedures, consistent irrigation flow is essential for optimizing the endoscopic view. The use of an automated irrigation pump (AIP) provides more consistent flow than irrigation devices that rely on pressure from external compression, such as pressure infusion sleeves that are inflated manually.^{1,2} Manual hand pump (HP) infuser irrigation systems do not maintain steady pres-

sure and flow continuously, as compression from the pressurized sleeve decreases as irrigation fluid leaves the infusion bag. In addition to a suboptimal endoscopic field of view, this inconsistent pressure and resulting drop in flow may result in circulating nurses' expending excess time and physical effort in trying to maintain the irrigation flow.

Prior studies have characterized the performance of a variety of manual^{3–5} and automated^{2,6–8} endoscopic irrigation systems used in endourology, but have failed to examine the

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labor and operating room (OR) efficiency associated with these different irrigation systems. The potential for enhanced OR efficiency is notable, given that OR procedures account for an estimated 40% of hospital costs and generate over 60% of hospital revenue.⁹

The objective of this study was to determine if the use of an AIP during ureteroscopy (URS) and percutaneous nephrolithotomy (PCNL) favorably affects circulating nurse labor, intraoperative irrigation-related issues, and surgeon and nurse satisfaction compared to a manual HP irrigation system.

Methods

Study design and subject population

This was a prospective, randomized study approved by the institutional review board; all patients provided written informed consent. Adult patients undergoing unilateral URS or PCNL were randomized to HP or AIP irrigation. The study was performed using the Karl Storz Flex Xc (Karl Storz SE and Co. KG, Tuttlingen, Germany) and dual lumen COBRA Vision (Richard Wolf Medical Instruments Corporation, Vernon Hills, IL) ureteroscopes. Two separate irrigation systems were used during PCNL: one for the ureteroscope and one for the rigid and flexible nephroscopes; only data pertaining to the nephroscope irrigation were recorded.

Irrigation equipment

The ThermoMedx® FluidSmart® Fluid Management System (Richard Wolf Medical Instruments Corporation) (Fig. 1) is an AIP that automatically regulates irrigation pressure, flow, and temperature. The ThermoMedx pump exhibits accurate flow, pressure, and temperature data.⁷ Maximum infusion pressure with this AIP is 300 mm Hg.

The HP irrigation system (Infu-Surg® Pressure Infusion Bag; SunMed/Ethox) (Fig. 2) is a method for pressurizing the irrigant. It consists of a sleeve that fits around a 3000 mL bag of irrigation fluid. The user squeezes a handheld bulb pump to inflate the bladder within the sleeve, which exerts external pressure on the bag of irrigation fluid. The pressurized fluid then flows through a separate fluid-warming device (3M™ Ranger™ Irrigation Warming System, St. Paul, MN). The HP system can reach a maximum pressure of 300 mm Hg.

Time and labor measurements

A dedicated independent observer equipped with a digital stopwatch served as the timekeeper. Operative time was recorded from the preoperative time-out to completion of closing. Preoperative pump setup time for the HP system included hanging of irrigation fluid bags on the irrigation tower, hand pumping the pressure infusion sleeves over the irrigation bags, connecting and priming the irrigation tubing, and preparing the fluid warming system. Pump setup time for the AIP included plugging the device into an electrical outlet, hanging the irrigation fluid bags, connecting and priming the irrigation tubing, and selecting the pressure setting.

Irrigation pump manipulation after the preoperative time-out and before completion of closing was recorded as intraoperative pump maintenance time (e.g., replacing irrigation fluid bags, additional hand pumping of pressure sleeves, or changing the pump pressure settings). Total pump time was calculated as the sum of the setup and maintenance times.

Surgeon and nurse satisfaction

The number of irrigation-related concerns verbalized by the surgeon during the case was recorded (e.g., complaints

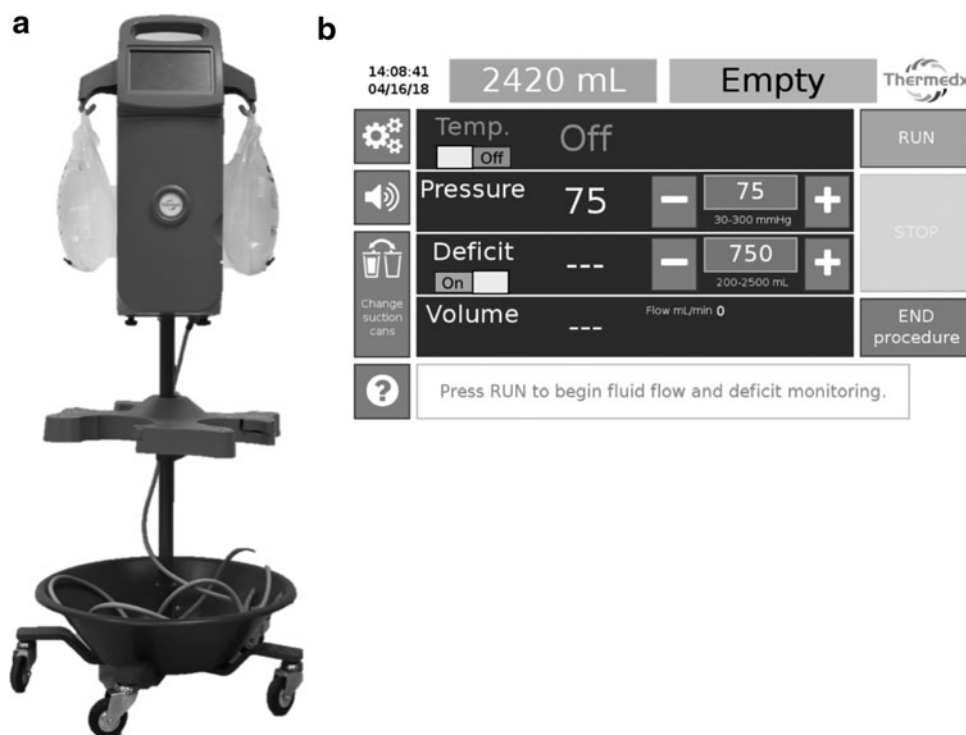


FIG. 1. (a) ThermoMedx® FluidSmart® Fluid Management System. (b) ThermoMedx touchscreen display.



FIG. 2. Hand pump infusion system (Infu-Surg® Pressure Infusion Bag; SunMed/Ethox).

about flow or requests to increase irrigation pressure). After completion of the case, the primary operating surgeon and the primary circulating nurse assigned to irrigation pump maintenance recorded his/her satisfaction with the irrigation system (1 = highly dissatisfied to 10 = highly satisfied). Surveys were completed by 6 urologic surgeons and 28 nurses. During PCNL, irrigation-related concerns and satisfaction scores pertaining only to use of the nephroscope were recorded.

Statistical analysis

Primary outcome variables included irrigation pump setup and maintenance time, total pump time, number of irrigation-related concerns verbalized by the surgeon intraoperatively, and surgeon and nurse satisfaction scores. Secondary outcome variables included operative time, liters of irrigation fluid used, and stone-free rate on postoperative computed tomography. PCNL and URS were analyzed separately. Continuous data were reported as mean $\pm$ standard deviation and were analyzed using the Welch's *t*-test and the Wilcoxon rank sum test when normally and non-normally distributed, respectively. Categorical data were compared using Fisher's exact test.

For URS, multivariate regression controlling for body mass index (BMI) and proportion of patients with >1 stone was also used. Odds ratios were reported with a 95% confidence interval (CI). Bonferroni correction was applied for outcome variables, resulting in a significance level of $\alpha < 0.01$. For all other variables, $\alpha < 0.05$ was considered statistically significant. For PCNL, no multivariate analysis was performed, as all baseline characteristics were statistically similar between the HP and AIP groups on univariate analysis. All tests were two sided. Statistical analyses were completed using RStudio version 1.1.456 (RStudio, Boston, MA).

Results

Fifty-one patients undergoing URS (26 HP, 25 AIP) and 29 patients undergoing PCNL (15 HP, 14 AIP) were included. For all URS cases, one circulating nurse was assigned to the OR. After the first two PCNL cases that were randomized to AIP irrigation, one circulating nurse was assigned for PCNL

cases randomized to the AIP, although two nurses (one of whom was solely responsible for maintaining the irrigation) were assigned for those randomized to the HP. OR staffing was not a metric included in the study protocol, but rather was established independently by the nursing team based on perceived need. There were no intraoperative complications or any case of postoperative sepsis. A cost comparison of the HP and AIP systems is summarized in Supplementary Table S1.

Ureteroscopy

Baseline characteristics for patients undergoing URS were similar between the HP and AIP groups, except for mean BMI (27.7 ± 4.5 vs 25.3 ± 3.8 kg/m², respectively; $p = 0.04$) and number of patients with >1 stone (9 [34.6%] vs 2 [8.0%], respectively; $p = 0.04$) (Table 1). The mean preoperative pump setup time was 3.7 ± 1.1 and 2.3 ± 1.2 minutes for the HP and AIP, respectively, mean intraoperative pump maintenance time was 2.3 ± 2.3 and 0.6 ± 0.5 minutes, respectively, and mean total pump time was 5.9 ± 2.6 and 2.9 ± 1.6 minutes, respectively (all $p < 0.001$) (Table 2). During URS with HP irrigation, surgeons verbalized an average of 2.8 ± 2.1 irrigation-related concerns compared with 1.2 ± 1.8 when the AIP was used ($p < 0.001$). Postoperatively, both surgeons and nurses rated their irrigation-related satisfaction higher when the AIP was used compared to the HP; this association was significant for nurses (9.2 ± 1.3 vs 6.5 ± 2.9 , $p < 0.001$). Operative time, stone-free rate, and liters of irrigation fluid used during the HP and AIP cases did not differ significantly.

On multivariate analysis, use of the AIP was a significant predictor of decreased setup time ($\beta = -1.67$ minutes, 95% CI -2.4 to -1.0 ; $p < 0.001$), maintenance time of <1 minute (odds ratio 15.8, 95% CI 3.3–73.7; $p < 0.001$), total pump time of <5 minutes (odds ratio 25.8, 95% CI 4.0–165.4; $p < 0.001$), and favorable (8–10/10) nurse satisfaction rating (odds ratio 25.4, 95% CI 4.1–164.0; $p < 0.001$) (Table 3). The AIP was not associated with a more favorable (8–10/10) surgeon satisfaction rating (odds ratio 1.6, 95% CI 0.4–6.7; $p = 0.60$). Although fewer surgeon-generated intraoperative concerns occurred with the AIP, this association did not reach statistical significance (odds ratio 6.9, 95% CI 1.2–40.4; $p = 0.03$).

Percutaneous nephrolithotomy

Patients undergoing PCNL with use of the HP and AIP systems were similar in regard to baseline characteristics (Table 1). Mean pump setup time was 9.8 ± 4.0 and 2.2 ± 1.0 minutes for the HP and AIP, respectively, mean intraoperative pump maintenance time was 24.0 ± 29.9 and 2.5 ± 1.6 minutes, respectively, and mean total pump time was 33.9 ± 29.6 and 4.6 ± 1.3 minutes, respectively (all $p < 0.001$) (Table 2). More irrigation-related concerns (4.0 ± 3.3 vs 1.9 ± 1.2 ; $p = 0.07$) and lower surgeon satisfaction (7.3 ± 2.7 vs 8.9 ± 2.4 points out of 10; $p = 0.05$) were observed in the HP group compared to the AIP group, although these associations did not reach statistically significant levels. Circulating nurses rated their satisfaction significantly lower with the HP compared to the AIP (4.4 ± 3.5 vs 9.4 ± 1.0 points out of 10, respectively; $p = 0.001$). Operative time, stone-free rate, and liters of irrigation fluid used during HP and AIP cases did not differ significantly.

TABLE 1. BASELINE CHARACTERISTICS

Variable	Ureteroscopy			Percutaneous nephrolithotomy		
	HP (n=26)	AIP (n=25)	p	HP (n=15)	AIP (n=14)	p
Age (years)	56.8±12.2	57.8±13.2	0.70	60.1±18.0	62.4±7.2	0.70
BMI (kg/m ²)	27.7±4.5	25.3±3.8	0.04 ^a	32.1±7.2	28.7±10.2	0.30
Gender						
Female	10 (38.5%)	12 (48.0%)	0.60	9 (60.0%)	9 (64.3%)	1.0
Male	16 (61.5%)	13 (52.0%)		6 (40.0%)	5 (35.7%)	
ASA score						
1	0 (0.0%)	2 (8.0%)	0.50	0 (0.0%)	0 (0.0%)	0.50
2	17 (65.4%)	15 (60.0%)		5 (33.3%)	7 (50.0%)	
3	9 (34.6%)	8 (32.0%)		10 (66.7%)	7 (50.0%)	
Preoperative nephrostomy tube						
Yes	1 (3.8%)	1 (4.0%)	1.0	1 (6.7%)	1 (7.1%)	1.0
No	25 (96.2%)	24 (96.0%)		14 (93.3%)	13 (92.9%)	
Preoperative ureteral stent						
Yes	7 (26.9%)	6 (24.0%)	1.0	4 (26.7%)	3 (21.4%)	1.0
No	19 (73.1%)	19 (74.0%)		11 (73.3%)	11 (78.6%)	
Stone density (HU)	791.8±318.7	837.2±307.7	0.40	830.9±274.0	937.0±333.9	0.40
Stone volume ^b (cm ³)	0.4±0.4	1.2±1.8	0.20	6.7±8.9	9.3±10.9	0.30
No. of stones						
1	17 (65.4%)	23 (93.0%)	0.04 ^a	8 (53.3%)	10 (71.4%)	0.40
>1	9 (34.6%)	2 (8.0%)		7 (46.7%)	4 (28.6%)	
Ureteroscope ^c						
Single lumen (3.6F)	12 (46.2%)	9 (36.0%)	0.50	N/A	N/A	N/A
Dual lumen (3.6F)	10 (38.5%)	10 (40.0%)				
Semirigid (7.0F)	3 (11.5%)	6 (24.0%)				
None ^d	1 (3.8%)	0 (0.0%)				

^aAlpha <0.05 considered statistically significant.^bStone volume=1×w×d×π×0.52.^cIrrigation channel diameter.^dOnly used cystoscope (distal ureteral stone).AIP=automated irrigation pump; ASA=American Society of AnesthesiologistsTM; BMI=body mass index; HP=hand pump; HU=Hounsfield units.

Discussion

In this report, compared to HP irrigation, the use of the AIP was associated with a significant decrease in the total time dedicated to preparing and maintaining the irrigation system

during both URS and PCNL. For patients undergoing URS, use of the AIP was an independent predictor of an overall pump time of <5 minutes, a decreased pump setup time, and a pump maintenance time of <1 minute. Notably, the clinical significance of the 3-minute decrease in total pump time

TABLE 2. PRIMARY OUTCOMES FOR PATIENTS UNDERGOING URETEROSCOPY AND PERCUTANEOUS NEPHROLITHOTOMY: UNIVARIATE ANALYSIS

Outcome	Ureteroscopy			Percutaneous nephrolithotomy		
	HP (n=26)	AIP (n=25)	p	HP (n=15)	AIP (n=14)	p
Pump setup time (minutes)	3.7±1.1	2.3±1.2	<0.001 ^a	9.8±4.0	2.2±1.0	<0.001 ^a
Pump maintenance time (minutes)	2.3±2.3	0.6±0.5	<0.001 ^a	24.0±29.9	2.5±1.6	<0.001 ^a
Total pump time (setup+ maintenance; minutes)	5.9±2.6	2.9±1.6	<0.001 ^a	33.9±29.6	4.6±1.3	<0.001 ^a
Intraoperative irrigation-related concerns	2.8±2.1	1.2±1.8	<0.001 ^a	4.0±3.3	1.9±1.2	0.07
Surgeon satisfaction (1–10) ^b	7.9±2.3	8.8±2.0	0.07	7.3±2.7	8.9±2.4	0.05
Nurse satisfaction (1–10) ^b	6.5±2.9	9.2±1.3	<0.001 ^a	4.4±3.5	9.4±1.0	0.001 ^a
Operative time (minutes)	69.0±35.1	76.2±42.0	0.50	140.8±81.1	131.3±56.9	0.90
Irrigation fluid used (L)	1.8±1.4	2.5±1.7	0.10	22.5±36.7	20.5±16.6	0.40
Stone-free rate ^c						
No fragments	8 (29.6%)	3 (37.5%)	0.39	6 (42.9%)	6 (42.9%)	1.0
Fragments ≤4 mm	8 (29.6%)	5 (62.5%)	1.0	7 (50.0%)	11 (78.6%)	0.24

^aAlpha <0.01 considered statistically significant after adjustment with Bonferroni correction, given comparison of five outcome variables.^bIrrigation satisfaction scoring: 1=highly dissatisfied to 10=highly satisfied.^cStone-free status based on postoperative computed tomography.

TABLE 3. PRIMARY OUTCOMES FOR PATIENTS UNDERGOING URETEROSCOPY: MULTIVARIATE ANALYSIS

Outcome ^a	Ureteroscopy		Estimated difference (β) (95% CI)	p
	HP (n=26)	AIP (n=25)		
Pump setup time	3.7 $\pm$ 1.1	2.3 $\pm$ 1.2	-1.67 (-2.4 to -1.0)	<0.001 ^b
Outcome ^c	HP (n=26) ^d	AIP (n=25)	Estimated odds ratio (95% CI)	p
Pump maintenance time				
<1 minute	7 (26.9%)	20 (80.0%)	15.8 (3.3 to 73.7)	<0.001 ^b
$\geq$ 1 minutes	19 (73.1%)	5 (20.0%)		
Total pump time				
<5 minutes	9 (36%)	22 (88%)	25.8 (4.0 to 165.4)	<0.001 ^b
$\geq$ 5 minutes	16 (64%)	3 (12%)		
Intraoperative irrigation-related concerns				
None	2 (7.6%)	11 (44.0%)	6.9 (1.2 to 40.4)	0.03
One or more	24 (92.4%)	14 (56.0%)		
Surgeon satisfaction ^e				
Favorable (8–10/10)	19 (73.1%)	20 (80.0%)	1.6 (0.4 to 6.7)	0.60
Unfavorable (0–7/10)	7 (26.9%)	5 (20.0%)		
Nurse satisfaction ^e				
Favorable (8–10/10)	11 (42.3%)	23 (92.0%)	25.4 (4.1 to 164.0)	<0.001 ^b
Unfavorable (0–7/10)	15 (57.7%)	2 (8.0%)		

^aLinear regression used for analysis (normally distributed data).

^bAlpha <0.01 considered statistically significant after adjustment with Bonferroni correction, given comparison of five outcome variables.

^cLogistic regression used for analysis (data not normally distributed).

^dTwenty-five patients included for pump maintenance time and total pump time.

^eIrrigation satisfaction scoring: 1=highly dissatisfied to 10=highly satisfied.

CI=confidence interval.

during URS was marginal. In contrast, for PCNL cases, the AIP provided a statistically and clinically significant drop in total pump time of 29 minutes.

These findings are of interest, given that OR turnover time is generally >20 minutes.^{10,11} Based on this study, OR turnover time and excess staffing costs, which are established metrics of OR inefficiency,^{10,12,13} are mitigated by the use of the AIP, with greater benefit seen during PCNL. Indeed, after the first two PCNL cases that were randomized to AIP irrigation, OR administrative personnel at our institution reduced OR staffing by one nurse for PCNL cases randomized to AIP; this decision was made exclusive from the study protocol and was based on administrators' perception of workload. The average hourly salary of a circulating nurse at our institution is \$57.00/hour. Thus, based on the average operative time of a PCNL in which HP irrigation was used (2.3 hours), an additional \$131.10 per case was allotted for the auxiliary circulating nurse whose sole responsibility was to maintain the irrigation intraoperatively.

For both URS and PCNL, the AIP was associated with a significantly higher nurse satisfaction rating, but was not associated with higher surgeon satisfaction or with decreased irrigation-related surgeon concerns. Taken together, these findings indicate that use of the AIP had a higher beneficial impact on the nursing team rather than for the surgeon, especially during PCNL. Indeed, a prior report of manual irrigation systems highlighted user fatigue as a primary concern with HP irrigation compared to the AIP.¹⁴ Furthermore, HP irrigation systems have been shown to exhibit a marked reduction in flow rate after the first 5 minutes of irrigation flow

compared to the more consistent flow provided by an AIP.² With HP irrigation, as fluid is used, the pressure exerted by the inflated pressure sleeve diminishes, and the irrigation flow weakens. In addition, manual systems such as handheld syringes and foot pumps provide flow in spikes, resulting in high maximal retro-pulsing forces and peak pressures that vary based on the strength of the user.^{3–5,14} Although increasing the height of the irrigation bag can increase the flow rate, this effect plateaus at a height of ~80 cm above the level of the patient.¹ In contrast, automated irrigation systems maintain steady flow without pressure peaks.⁸ Our findings indicate that automated control of irrigation pressure and flow reduces the burden of pump maintenance for nurses. In addition, when irrigation fluid levels fall below 600 mL, the ThermoRx sounds an alarm notifying circulating nurses that the fluid will soon require replacement, ensuring uninterrupted flow during procedures.

Of note, we used a ureteral access sheath (UAS) in the majority of URS (76%) and PCNL (97%) cases; UAS utilization and UAS size were similar between the HP and AIP groups. This offers one possible explanation for the similarity in surgeon satisfaction and intraoperative irrigation-related concerns, as the UAS enhances irrigation fluid outflow from the ureter and the renal collecting system, which improves the endoscopic view.^{15,16} In addition, there were no cases of postoperative sepsis as defined by the Sequential Organ Failure Assessment (SOFA) scoring system¹⁷; this was likely attributable to the high rate of UAS utilization and our departmental mandate for a documented sterile urine culture before URS or PCNL. Pressurized irrigation

increases intrarenal pressure, which is a risk factor for post-operative infectious complications after PCNL¹⁸ and URS,¹⁹ especially if the intrarenal pressure exceeds 30 to 45 mm Hg^{20,21}; however, placement of a UAS significantly decreases intrarenal pressure.^{15,16,22,23} We utilized pump pressure settings ranging from 70 to 250 mm Hg and 100 to 250 during URS and PCNL, respectively, dependent upon the presence of an instrument in the working channel.

We did not observe a significant difference in liters of irrigation fluid used, operative time, or stone-free rate between the HP and AIP cases during URS or PCNL. In a single-surgeon experience comparing an automated irrigation-suction pump to HP irrigation during flexible URS, Lechevallier and colleagues also reported a similar amount of irrigation fluid used, although they did observe a statistically significant 53% reduction in URS time, which was measured from the time of placement of the ureteroscope at the ureteral orifice to the end of the case.⁶ In contrast, we measured operative time from the end of the preoperative time-out to completion of closing for both URS and PCNL, which allowed for the clear distinction between pump setup time and pump maintenance time.

There are several limitations to this study. First, surgeon and nurse irrigation-related satisfaction were assessed with a subjective survey. However, *post hoc* analysis showed that a similar cohort of surgeons and nurses responded to the survey for HP and AIP cases (Supplementary Table S2). Second, given that an additional nurse was assigned to PCNL cases in which HP irrigation was used, the true time allotted to irrigation-related matters may have been biased in favor of the HP irrigation system. Finally, this is a single-center experience; the outcomes reported in this study are subject to factors, including institutional resources and protocols. For example, institutions that do not allocate two nurses for standard PCNL cases may not experience the cost savings that we experienced. Nevertheless, the ability to allocate an additional circulating nurse at our institution served to demonstrate the extent to which the pump type affected OR efficiency.

Conclusions

During URS and PCNL, use of the AIP resulted in a significant decrease in total irrigation pump management time. In addition, the AIP was associated with significantly improved nurse satisfaction during both URS and PCNL.

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Authors' Contributions

F.A.J.: study design, data collection, data analysis, and article writing. J.M.S.: study design, data collection, data analysis, and article writing. L.L.: data analysis and article review. S.L.: data collection and article review. C.M.C.: data collection and article review. S.T.: data collection and article review. R.M.P.: study design and data collection. R.V.C.: study design, data collection, and article review. J.L.: study design, data analysis, data collection, and article review.

Author Disclosure Statement

J.L.: paid speaker for Richard Wolf Medical Instruments Corporation. All other authors have no competing financial interests exist.

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Supplementary Material

Supplementary Table S1
Supplementary Table S2

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Abbreviations Used

AIP = automated irrigation pump

BMI = body mass index

CI = confidence interval

HP = manual hand pump infuser

NIH = National Institutes of Health

OR = operating room

PCNL = percutaneous nephrolithotomy

UAS = ureteral access sheath

URS = ureteroscopy