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INTERVENTIONAL RADIOLOGY

TECHNICAL NOTE

Paracentesis: Faster and easier using the RenovaRP® pump

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PURPOSE
Paracentesis is commonly performed in interventional radiology practice, and large volume paracentesis (LVP) using wall suction can take up to an hour to complete, placing significant stress on room and resource time. As the number of LVP procedures performed by Interventional Radiologists continue to increase, this study was undertaken to analyze the impact of the RenovaRP® Paracentesis Management System (GI Supply) on procedure time and patient satisfaction.

METHODS
Between March 9, 2020 and May 29, 2020, procedural data and patient satisfaction was collected as part of a practice quality improvement project and retrospectively analyzed on 39 sequential paracenteses performed with wall suction prior to acquiring the RenovaRP® system and subsequently on 42 paracenteses performed with use of the device.

RESULTS
A substantially higher fluid flow rate was found using the RenovaRP® system compared to wall suction, 237.2 mL/min vs. 108.6 mL/min ($P < .001$). This resulted in a significant decrease in procedure room time from 53 min to 31 min ($P < .001$). There was associated improvement in the patient experience during paracentesis.

CONCLUSION
The RenovaRP® decreases procedure time for LVP with improvement in the patient experience during paracentesis.

Ascites commonly occurs with decompensated cirrhosis and malignancy, and can be seen with other diagnoses such as end-stage renal disease (ESRD) and lymphatic leakage.[1,2] While a variety of methods exist to treat ascites, including diuretics, transjugular intrahepatic portosystemic shunt (TIPS), Denver Shunt, tunneled peritoneal catheter placement and Alfapump® (Sequana Medical NV), paracentesis remains a widely used minimally invasive non-medical treatment. Paracentesis is commonly performed in interventional radiology, with >600 paracentesis procedures performed each year in our interventional radiology (IR) division. As these procedures are shifted from other providers to IR, there is less room time and operator involvement time available for other procedures.[3,4] In addition, there are associated facility, equipment and personnel costs that may not be recouped.[5] The RenovaRP® Paracentesis Management System is a portable pump system designed to remove fluid rapidly. It is comprised of a peristaltic pump and a disposable proprietary tubing set that ends in a T adapter, allowing for simultaneous attachment of two 1.6 L sterile reservoir bags via leur lock connectors. The purpose of this study was to investigate if use of the RenovaRP® would reduce procedure time compared to standard wall suction without increasing adverse effects such as hypotension or abdominal pain.

Methods

This study was initiated as part of a Practice Quality Improvement (PQI) project undertaken in part to justify the added expense of equipment purchase. The Institutional Review

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Board (IRB) determined that oversight for this project was not required (IRB Application #00136413). Data was recorded and maintained in a password protected HIPAA compliant database. Informed consent was obtained for all procedures. All patients >18 years of age with large volume ascites on initial ultrasound assessment, planned for therapeutic paracentesis formed the study group. Exclusion criteria were small volume ascites, paracentesis for diagnosis only, complex ascites with septations, known bowel perforation, and when performed as an adjunct to any concurrent procedure (e.g., TIPS, biliary drainage, or Denver Shunt placement). Data was collected on consecutive paracenteses performed with wall suction and then on the subsequent consecutive paracenteses performed with the use of the RenovaRP® pump. Data analysis was performed retrospectively. Paracenteses were performed by one of six interventional radiologists (experience ranging from 1 to 35 years), an interventional radiology fellow, or one of two procedural mid-level providers (9 and 3-year interventional experience). Standardized technique with real time ultrasound guidance and the multi-sidehole 5 F Centeze® Centesis Catheter (Galt Medical Corp) was used for all procedures. In the wall suction arm, 200 mmHg continuous suction was used. For the RenovaRP® arm, a power level of 60%-70% was used.

Demographic and clinical data were collected including patient age, gender, diagnosis, and procedure indication. Procedural data included procedural provider, suction time, total in-room time, total volume of fluid removed. Flow rate was calculated from the total volume removed in milliliters over the suction time in minutes. Patient blood pressure was also monitored using an automated blood pressure cuff cycled every 10 minutes. The pre-procedure blood pressure and lowest blood pressure obtained throughout the procedure were recorded. The patients were asked to rate their overall level of discomfort during the procedure based on a visual analogue scale (VAS) and this was recorded. Post-procedure ultrasound was also performed estimating the amount of residual ascites (minimal/none, small, moderate, large). When return of fluid stopped, ultrasound was used to assess for residual ascites, and the catheter was repositioned to allow further drainage when indicated. The number of catheter adjustments needed during each procedure was recorded. Patients with greater than 5 L of fluid removed routinely underwent intravascular volume expansion during or immediately after the procedure with albumin using institutional protocols (25 g if ≥5 L removed and an additional 25 g if ≥10 L removed).

Main points

- A substantially higher fluid flow rate during paracentesis was found using the RenovaRP® system compared to wall suction, 237.2 mL/min vs. 108.6 mL/min ($P < .001$).
- This resulted in a significant decrease in procedure room time from 53 min to 31 min ($P < .001$).
- In centers or practices doing many large volume paracenteses, this equipment appears to offer significant time savings and may be cost effective.

Statistical analysis

Procedures performed with RenovaRP® pump were compared to those performed with wall suction. For continuous variables with a non-normal distribution a Wilcoxon rank sum tests was used. For categorical variables, a chi-square or Fisher's exact test (when any expected cell count was less than 5) was used. In addition, two sensitivity analyses to evaluate robustness of the results obtained were undertaken. A repeated measure ANOVA test was used to account for the potential confounding effects of having patients with repeated procedures. Similarly, a second repeated measures ANOVA test was performed to control for potential confounding effect of having variable numbers of procedures performed by multiple proceduralists with different characteristics. P values <0.05 were considered significant. All statistical analyses were performed using R statistical software version 3.6.1 (R foundation for statistical Computing).

Results

Of the 95 paracentesis procedures performed during the study period, 14 were excluded due to low volume paracentesis (less than 1 liter), or due to incomplete data. A total of 46 patients undergoing 81 paracentesis procedures met criteria for inclusion into the study, 22 patients and 39 paracentesis procedures in the wall suction arm followed by 30 patients undergoing 42 paracentesis procedures in the RenovaRP® pump arm. Patient age ranged from 29 to 86 years (median, 64 years) and was similar between the two groups ($P = .8$). Diagnosis or cause of ascites was most commonly cirrhosis (50 of 81 procedures) followed by malignancy (19 of 81 procedures). Malignant ascites was associated with ovarian, breast, lung, and pancreatic cancer, and lymphoma. Other causes of ascites included hepatitis,[3] lymphatic leak,[4] urine leak,[1] liver transplant failure,[1] ESRD,[1] spontaneous bacterial peritonitis,[1] and chronic heart failure.[1] The indication for paracentesis was primarily for diagnosis in 7 cases, distention/discomfort in 32 cases, and both diagnosis and distention/discomfort in 42 cases. There was no significant difference between the two groups with regard to the cause of ascites or indication for paracentesis ($P > .05$ for both). The median time of suction was 36 min in the wall suction arm and 18 min in the RenovaRP® arm ($P < .001$). The median procedure time was 53 min in the wall suction arm and 31 min in the RenovaRP® arm ($P < .001$). The median volume of ascites removed was 4350 mL in the wall suction arm and 4250 mL in the RenovaRP® arm ($P = .75$). Median flow rate was 109 mL/min in the wall suction arm and 237 mL/min in the RenovaRP® arm ($P < .001$). The median number of catheter adjustments was 1 in both groups ($P = .64$). Patients who had RenovaRP® pump reported less discomfort level (median VAS 0 vs. 1 in the wall suction arm) and this was also statistically significant difference ($P = .004$).

Six patients underwent procedures in both the wall suction and the RenovaRP® pump arms. Although the study is not powered to look at results between providers, the distribution of providers was not different in the two groups ($P = .82$). Taking into account repeated measures within individuals as well as within providers, RenovaRP® pump group sustained a statistically significant higher flow rate and lower discomfort level ($P < .05$).

Of the paracenteses performed in the wall suction arm, 7 had small residual ascites and 33 had none or minimal residual ascites. Of the 41 paracenteses performed in the RenovaRP® pump arm, 1 patient had a large amount (procedure intentionally terminated after 10 L removed), 3 had moderate, 6 had small, and 31 had none

Table 1. Summary of results

		Renova arm (n = 42)	Wall suction arm (n = 39)	*P*	Statistical test
Age (years)					
	Mean (SD)	61.5 (14.7)	62.6 (12.3)		
	Median (IQR)	64 (50, 73.8)	62 (58, 72)	.8	*Wilcoxon rank sum test*
	Range	29-86	31-80		
Suction time (min)					
	Mean (SD)	20.7 (12)	41.4 (20.8)		
	Median (IQR)	17.5 (12.2, 27)	36 (24, 58.5)	<.001	*Wilcoxon rank sum test*
	Range	6-55	13-84		
Flow rate (mL/min)					
	Mean (SD)	264.4 (170.2)	109.6 (32.2)		
	Median (IQR)	237.2 (176.7, 307.3)	108.6 (84.9, 124.7)	<.001	*Wilcoxon rank sum test*
	Range	102.3-1207.1	52.4-233.3		
Procedure time (min)					
	Mean (SD)	33.9 (13.5)	54.6 (20.9)		
	Median (IQR)	31 (22, 42.8)	53 (39.5,69.5)	<.001	*Wilcoxon rank sum test*
	Range	14-67	20-102		
Volume removed (mL)					
	Mean (SD)	4725.6 (2410.1)	4448.2 (2264.8)		
	Median (IQR)	4250 (2925, 6275)	4350 (2425, 6230)	.75	*Wilcoxon rank sum test*
	Range	1125-10,900	1100-8900		
Number of catheter adjustments					
	Mean (SD)	1.2 (1.2)	1.2 (1.6)		
	Median (IQR)	1 (0, 2)	1 (0, 2)	.64	*Wilcoxon rank sum test*
	Range	0-6	0-7		
Patient discomfort level during suction					
	Mean (SD)	0.9 (1.9)	2.2 (2.5)		
	Median (IQR)	0 (0, 0.4)	1 (0, 4)	.004	*Wilcoxon rank sum test*
	Range	0-8	0-8		
Systolic blood pressure at start of procedure (mmHg)					
	Mean (SD)	119.4 (17.3)	120.8 (14.7)		
	Median (IQR)	116 (106, 129.8)	120 (107.5, 128)	.61	*Wilcoxon rank sum test*
	Range	95-179	98-150		
Systolic blood pressure lowest throughout procedure (mmHg)					
	Mean (SD)	113.2 (16.8)	111.8 (14.1)		
	Median (IQR)	110.5 (101.5, 120)	109 (101.5, 121)	.73	*Wilcoxon rank sum test*
	Range	87-180	85-145		
Significant hypotension					
	No	42 (100%)	39 (100%)		
Indication				.08	*Fisher's exact*
	Diagnostic	4 (10%)	3 (8%)		
	Therapeutic	21 (50%)	11 (28%)		

Table 1. Summary of results (Continued)					
		Renova arm (n = 42)	Wall suction arm (n = 39)	*P*	Statistical test
	Diagnostic and therapeutic	17 (40%)	25 (64%)		
Cause of ascites				.25	*Chi-square*
	Cirrhosis	23 (55%)	27 (69.2%)		
	Malignancy	13 (31%)	6 (15.4%)		
	Other	6 (14%)	6 (15.4%)		
Amount of residual ascites				.17	*Fisher's exact*
	None/minimal	31 (74%)	33 (85%)		
	Small	7 (17%)	6 (15%)		
	Moderate/large	4 (9%)	0 (0%)		
Interventionalist				.82	*Fisher's exact*
	Attending	12 (28.5%)	14 (36%)		
	Fellow	5 (12%)	5 (13%)		
	Mid-level	25 (59.5%)	20 (51%)		

SD, standard deviation; IQR, interquartile range.

Figure 1. An example of the RenovaRP® system.

or minimal of residual ascites. The amount of residual ascites was not statistically significant between groups (*P* = .17). There were no cases of >30% drop in blood pressure in either group. To the authors' knowledge, no patient suffered from clinically significant hypotension within 72 hours after the procedure. Table 1 shows a summary of results.

Discussion

There was more than a 2-fold increase in flow rate provided by the RenovaRP® pump vs. standard wall suction which allowed for significant time savings during paracenteses. Total non-suction procedure room time was about four minutes longer for wall suction. This may have been due to several uncontrolled variables, although does imply no added time requirement for set up or take down of the RenovaRP® system. Although patient reported level of discomfort was lower in the RenovaRP® group, this small difference may not be clinically significant (median VAS score of 0 vs 1). Although the study is not powered to look directly at measures among individual patients, several patients anecdotally expressed their partiality to the RenovaRP® pump due to improvement in perceived level of discomfort and shorter duration of procedure. No patient in either group developed any symptoms of hypotension necessitating escalation of care.

One of the parameters that was set prior to initiating the study to eliminate variability between the two groups was level of suction in each arm. Discussion among providers concluded it would be best to use 200 mmHg of wall suction, as it was felt that higher levels might cause more issues with catheter suction adherence to omentum or bowel that might impact flow rate or require

more catheter adjustments. It was decided to use 60%-70% power level on the RenovaRP® to be consistent with not using the maximum setting in either arm. It is conceivable that flow rates might be even higher using the RenovaRP® at higher settings.

The RenovaRP® pump is simple to use and requires little staff training. The device is portable, requiring only a grounded electrical outlet, and can be used to perform paracenteses outside of IR. In addition, the system is entirely self-contained, avoiding the potential exposure to body fluids that may occur during exchange of wall-suction canisters. A picture of the RenovaRP® pump is shown in Figure 1. The average unit cost per device is around $7500. The average cost of the tube set and 1.6 L reservoir bags are approximately $60.00 and $10.00, respectively. For wall suction procedures, the Centeze catheter was attached to standard vinyl connection tubing (average cost of ~$25) and to 1 L reservoir canisters (average cost of $2). Therefore, the additional cost of RenovaRP® supplies for the average volume removed in our study is calculated to be ~$65 (1 tubing kit and 3 reservoir bags vs. standard vinyl connecting tubing). These costs are reported as average and may differ between facilities. In certain high-volume centers where paracentesis procedures are performed frequently, the RenovaRP® pump can be expected to provide superior through-put with relatively minimal added procedural costs. At our facility, the increase in supply costs was thought to be more than compensated for by decrease in staffing costs and the freeing up of additional IR room time and operator involvement time. The added efficiency may have variable impact in this regard depending on the number of procedures performed per day, individual practice cost responsibilities, and the reimbursement structure within each department if performed in a hospital or institutional setting, but could potentially free up an additional hour of room time and operator involvement time each day.

The RenovaRP® pump offers providers and patients substantially faster procedure times without adverse outcomes. The added cost of equipment/supplies may be offset by increased patient through-put and work-flow efficiency. In centers doing many large volume paracenteses, this equipment appears to be cost and time effective.

Financial disclosures

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Conflict of interest disclosure

The authors declared no conflicts of interest.

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