Relative Performance of the Level 1 and Ranger Pressure Infusion Devices

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Pressure infusion devices are often used to administer fluids in the operating room, but they may rarely be associated with serious venous air embolism. We studied the performance of the Level 1 and the Ranger Pressure Infusor in the laboratory. The Ranger delivered less air and delivered fluid faster than the Level 1 but did not warm fluid or blood as well. Although the Ranger device may be safer in terms of the risk of air embolism, its inferior warming performance shows that the optimal pressure infusion device has yet to be manufactured.

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Pressure infusion devices (PIDs) such as the Level 1 (Level 1 Technologies, Inc., Rockland, MA) are widely used to maintain normovolemia and normothermia in patients experiencing large-volume blood loss. The development of these devices has allowed anesthesiologists to manage patients undergoing trauma, vascular, and other complex operations with significantly less risk of hypovolemia, hypothermia, and associated morbidity and mortality.

However, the use of PIDs is not without risk. IV fluid bags and other bags used in volume delivery (e.g., cell-saver bags) contain volumes of air sufficient to cause significant venous air embolism (VAE) (1,2). To avoid this complication, the clinician using a PID must always carefully purge all air from the bag before its placement in the device, or the PID itself must purge the air during infusion. The need to remove air from any fluid container used in the device is emphasized in the instructions for the Level 1 and Ranger (Ranger Pressure Infusor; Augustine Medical, Eden Prairie, MN) PIDs. Because these devices are often used during cases involving large-volume shifts accompanied by significant hemodynamic instability, the clinician may at times be distracted from removing the air from bags placed in the PID. Adhikary and Massey (3) reported a case of fatal air embolism resulting from the use of the Level 1 PID. Many anesthesiology departments have had such mortalities or near misses (O'Reilly M, personal communication, 2002). At the October 2002 Director's Retreat of the Anesthesia Patient Safety Foundation, Dr. O'Reilly, the session moderator, stated that until the air embolism risk has been minimized, available PIDs should be taken off the market.

Recently Augustine Medical introduced a PID, based on their Ranger blood/fluid warmer, that the company claims has superior air elimination capabilities compared with competing devices. We undertook this study to determine whether the Ranger PID eliminates air better than the Level 1 device and also to assess its abilities to deliver fluid rapidly at physiologic temperature.

Methods

In a laboratory evaluation, two different Level 1 PIDs (System H-1025; Level 1 Technologies, Inc.) owned by Strong Memorial Hospital were compared with two Ranger PIDs supplied to the hospital for evaluation by the manufacturer. All devices were evaluated for function by the hospital's medical engineering laboratory before use. Two different disposable fluid sets for the Level 1 were evaluated: the D50 and D100. Two of each of these disposables were used in each Level 1. Two Ranger high-flow fluid sets were used in each Ranger PID. All sets were new out of the box and were inspected for flaws before use. Each disposable was

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Table 1. Trial Protocol

1. Disposable placed in device according to manufacturer's directions, device turned on, and proper operating temperature achieved.
2. Disposable primed with normal saline (NS) so that drip chamber was half full, and all air removed from fluid path.
3. Distal end of disposable connected to side arm of 9F introducer sheath (Arrow 09903; Arrow International, Reading, PA).
4. Tip of introducer placed in center of 30-mL medicine cup so outflow was not obstructed.
5. Two banjo-style temperature probes (YSI 408; YSI Inc., Yellow Springs, OH; accuracy ± 0.1°C) placed in cup adjacent to but not obstructing the introducer and connected to a Philips Viridia M1205A portable monitor (Philips Medical Systems, Andover, MA).
6. A standardized[a] 1000-mL bag of NS at room temperature (21°C–23°C) with air removed was connected to the IV spike of the disposable and placed in the pressure chamber, and the chamber was pressurized with the disposable clamped.
7. The chamber was pressurized and achievement of proper operating pressure noted (300 mm Hg).
8. The disposable was unclamped and the time to deliver the full liter noted. The peak plateau temperature[b] of the delivered fluid was noted.
9. Three additional NS liters were run through the system as above, alternating between the two spikes and two pressure chambers.
10. The distal end of the disposable was disconnected from the introducer and placed under a water-filled inverted graduated cylinder immersed in water to catch any air delivered through the system.
11. A 1000-mL bag of NS containing a measured 200 mL of air was connected to one spike, placed in the chamber, and pressurized with the clamp closed.
12. Clamp open and amount of air delivered via end of disposable noted.
13. System reprimed as per 2.
14. Two 1000-mL bags of NS containing a measured 200 mL of air connected to spikes, placed in chambers, and pressurized with clamp closed.
15. Clamps open for each bag sequentially so each ran out fully before unclamping the other. Total air delivered from the two bags noted.
16. System reprimed as per 2 and connected as per 3–5.
17. A measured[c] unit of expired packed red blood cells was connected to a spike, placed in the chamber, and pressurized with clamp closed.
18. The disposable was unclamped and the time to deliver the full unit noted. The peak plateau temperature of the delivered blood was noted.
19. 17–18 repeated twice.
20. 11–15 repeated.
21. System reprimed as per 2 and connected as per 3–5.
22. 6–9 repeated, except with a total of three bags.

All trials for any single disposable were run sequentially, on the same day. Total elapsed time start to finish was 1–2 h per disposable.

[a] NS bags were delivered with some variability in volume. Volume was adjusted up or down to make all tested bags within ±5 g (0.5%).

[b] Delivered fluid temperature tended to vary biphasically early in delivery and then increase slightly toward the end of each liter or unit. The peak plateau temperature recorded was the highest temperature recorded during the plateau phase, which corresponded to the middle 80%–90% of fluid delivered. Temperature variation during plateau was typically ±0.2°C–0.3°C.

[c] Expired Packed Red Blood Cells were all within 2 wk of the expiration date. Hematocrit and weight of each unit were measured and recorded.

put through an identical series of fluid-delivery trials to assess its ability to deliver fluid rapidly, warm the fluid to physiologic temperature, and purge air from the system (Table 1).

Data were analyzed with the JMP statistics package for Macintosh (SAS Institute, Inc., Cary, NC). Tukey-Kramer honestly significant difference analysis for comparison of multiple paired data was used to compare fluid and blood delivery times, temperatures, and air delivery.

Results

The Ranger device was more effective in eliminating air from the fluid set at all challenge volumes (Table 2). The Ranger PID delivered fluid at a faster rate than the Level 1 with either set, but at a lower output temperature (Table 2).

Discussion

The recent Institute of Medicine Report on Medical Errors (4) highlights the need for complex medical devices such as PIDs to be as safe as possible. Using systems solutions (i.e., making the environment, equipment, and procedures safer) to minimize risk in potentially fatal situations is mandatory when predictable human behavior (such as failure to remove air from fluid bags) may increase that risk. Currently available PIDs, such as the Level 1, are not safe if clinicians do not always take the extra steps required to de-air bags of IV fluid before placing them in the device to avoid VAE. Although appropriate de-airing may occur most of the time, case reports and anecdotal evidence suggest that clinicians occasionally omit this safety step (2,3). A better system design would include one or more mechanisms to prevent the adverse sequelae of such an oversight.

Table 2. Results

Value	L50	L100	Ranger	*P* value
Time/liter of NaCl (s)	112.0 ± 2.9	104.3 ± 3.3	96.8 ± 2.1	<0.05 R versus L100 <0.01 R versus L50
Temperature of NaCl (°C)	32.6 ± 0.7	38.4 ± 0.3	30.4 ± 0.4	<0.001 L100 versus both, <0.01 L50 versus R
Air delivered (200) (mL)	88 ± 5	68 ± 5	4 ± 5	<0.001 R versus both <0.01 L100 versus L50
Air delivered (400) (mL)	239 ± 17	200 ± 12	12 ± 9	<0.001 R versus both <0.05 L100 versus L50
PRBC time/unit (s)	110.6 ± 9.1	72.9 ± 8.9	62.2 ± 5.3	<0.01 L 50 versus both
PRBC temperature (°C)	34.4 ± 0.8	38.2 ± 0.2	30.2 ± 1.6	<0.001 R versus L100 <0.05 L50 versus both

Data are means ± SD.
L50 and L100 = Level 1 device with D50 and D100 disposable, respectively; R = Ranger; Air delivered (numbers) = initial volumes of air presented to the air-elimination portion of the disposables; PRBC = Packe Red Blood Cells.

The degree of morbidity from VAE is a function of both the volume embolized and the rate at which it enters the heart. Rapid air infusion is more likely to be lethal, with <50 mL causing symptoms in adults (5) and as little as 200 mL being potentially fatal (2). A PID pressurized to 300 mm Hg (standard operating pressure in the PIDs tested) can cause delivery of this fatal dose in as little as 4 seconds.

Both Level 1 and Ranger disposables incorporate a gas-permeable membrane that allows air to leave the system without fluid leakage. The membrane in the Level 1 disposable is incorporated into a combination filter/air eliminator distal to the warming element (Fig. 1). The membrane surface area is 0.57 cm^2, less than one thirtieth of the Ranger's membrane area of 17.7 cm^2. This large difference in the area available for air purging likely explains the significant difference in performance between the two devices. Hartmannsgruber and Gravenstein (1) found that at rapid flow rates, the Level 1 allowed up to 98% of a 60-mL air bolus to pass by the air eliminator. Sixty milliliters is within the range of air volumes we typically found in unspiked IV fluid bags.

Although it would be uncommon to encounter 200 mL of air in commercially available IV fluid bags, we chose this volume for our study for four reasons: 1) it has been described as a minimal fatal dose (2), 2) it would be a more stringent test of the air-venting systems on the PIDs investigated, 3) previous studies revealed that the Level 1 air eliminator performed poorly at smaller air volumes (1), and 4) 200 mL was the maximum air volume that would fit easily into full liter bags of normal saline. Additionally, it is likely that bags filled by automated blood salvage devices contain significantly larger amounts of air, consistent with reports of fatal VAE (2). Although the Level 1 may have vented air effectively at slow flow rates, we were primarily interested in the maximum risk of VAE, so we chose to study the systems at their fastest flow rates. These flow rates are frequently used in resuscitation and also maximally stress the devices' ability to warm fluid and blood.

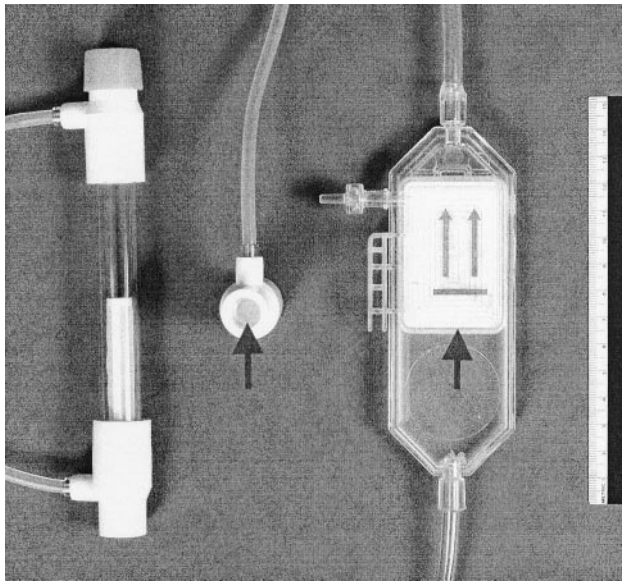

Figure 1. Air-purging elements of the Level 1 (left) and Ranger (right). Center is the Level 1 element seen end-on with the cap and filter cut away. Arrows indicate gas-permeable membranes.

According to our data, the Ranger Pressure Infusor seems to be an acceptable alternative to the Level 1, at least in terms of minimizing the potential for air embolism. However, lower delivered fluid temperature with the Ranger Pressure Infusor may place patients at risk for hypothermia.

Large-volume blood loss during surgery stresses both resuscitation equipment and the clinician, creating an environment that favors errors of omission. The need to minimize the adverse effects of these errors mandates that companies improve the design of their products to ensure that all clinicians have access to safe, reliable fluid resuscitation equipment.

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