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APPARATUS

The air elimination capabilities of pressure infusion devices and fluid-warmers

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Summary

Pressurised infusion devices may have only limited capability to detect and remove air during pressurised infusions. In order to assess pressure infusion systems with regard to their actual air elimination capabilities four disposable pressure infusion systems and fluid warmers were investigated: The Level 1® (L-1), Ranger ® (RA), Gymar® (GY), and the Warmflo® (WF). Different volumes of air were injected proximal to the heat exchanger and the remaining amount of air that was delivered at the end of the tubing was measured during pressurised infusions. Elimination of the injected air (100–200 ml) was superior by the RA system when compared to L-1 ($p < 0.01$). The GY and WF systems failed to eliminate the injected air. In conclusion, air elimination was best performed by the RA system. In terms of the risk of air embolism during pressurised infusions, improvements in air elimination of the investigated devices are still necessary.

Keywords *Equipment*: pressure infusors. *Intraoperative complications*: air embolus.

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Peri-operative hypothermia has been shown to be associated with an increase in oxygen consumption [1] and blood loss [2], and in a higher incidence of surgical-wound infections [3]. Therefore, the peri-operative maintenance of normothermia can reduce the incidence of cardiac events [4]. In the past, fluid warming devices have made a major contribution in maintaining patients in a normothermic state during surgery [5].

Pressure infusion devices promote the administration of large volumes of fluid over a short period of time, which has made the management of major haemorrhage, as well as the administration of warm fluids much easier. However, there are important safety concerns relating to the use of forced pressurised rapid infusion devices, most notably with regard to the potential risk of causing significant air embolism. Many fluid-warmers and pressurised infusion devices may have only limited, if any, capability to detect and remove air during pressurised infusions [6–8]. In dogs it has been shown that a minimum of 7.5 $ml.kg^{-1}$ of rapidly injected air was necessary to cause death [9]. In humans, the lethal volume of injected air is not actually known, but it is believed to be in the region of 100–300 ml of air [10–14]. In cases of cardiac right-to-left shunt much smaller volumes of gas could be deleterious [15]. This fact is of great importance since approximately 25% of the population demonstrate a functionally patent foramen ovale.

This laboratory investigation was performed in order to compare and assess different pressure infusion devices and fluid warmers (Level 1®, Ranger®, Gymar® and Warmflo®) with respect to their air elimination capability.

Methods

Four different systems were investigated: (1) Level 1® (L-1), Level 1 Technologies Inc., Rockland, USA, including disposable tubing D-100, volume load 65 ml, see Fig. 1. (2) Ranger® (RA), Augustine Medical GmbH, Trittau, Germany, including disposable tubing 'High Flow', volume load 150 ml, see Fig. 2. (3) Gymar® (GY), B + P Beatmungsprodukte GmbH,

Figure 1 The Level 1® including disposable tubing. Gas vent including gas-permeable membrane is shown on the right.

Figure 2 The Ranger® including disposable tubing 'High Flow'. Gas vent is demonstrated in detail on the right.

Figure 3 The Gymar® including disposable tubing 'High-Flow'. Gas vent is shown on the left.

Neunkirchen-Seelscheid, Germany, including disposable tubing 'High-Flow', volume load 79 ml, see Fig. 3. (4) Warmflo® (WF), Tyco Healthcare/Mallinckrodt Medical GmbH, Hennef, Germany, and the disposable tubing system WF-100, volume load 50 ml, see Fig. 4. All measurements were performed at a constant room temperature of 20 °C.

The disposable infusion systems were primed according to the manufacturers' instructions using normal saline (Combiflac®, B Braun Melsungen, Germany) with the drip chamber half filled and all air removed from the fluid pathway. Maximal flow rates (ml.min^{-1}) were repeatedly measured (six times), using a pneumatic pressure infuser at a set pressure (300 mmHg, Level 1®, Level 1 Technologies Inc., Rockland, USA), a standardised 1000 ml bag of normal saline (Combiflac®, B Braun Melsungen, Germany) with air removed and connected to the disposable IV spike and a stop watch. The final temperature of the 'infused' fluid was measured for at least 30 s of flow at the distal end of the disposable tubing using a rapid-response thermometer (Celsimeter®, Spirig, Switzerland), once at maximal flow and again after an equilibration time of 30 s.

Figure 4 The Warmflo® including disposable tubing system WF-100. Gas vent is shown on the right.

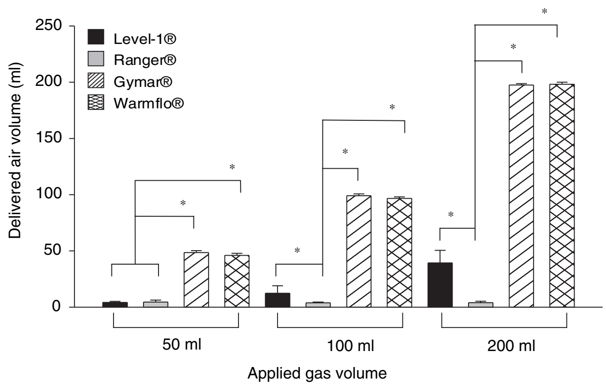

Figure 5 Volumes of delivered gas after 50-, 100-, and 200 ml of injected air (mean ± SD). (Level-1® = L-1; Ranger® = RA; Gymar® = GY; Warmflo® = WF). Significance is described as * when $p < 0.01$.

Different volumes of air were injected proximally to the heat exchangers using a luer-locked three-way-tap. Three different boluses of air (50, 100, 200 ml) were injected manually at 10 $ml.s^{-1}$. Air injection was repeatedly performed, six times in a row, using standard large volume syringes (50 ml volume, B Braun Melsungen, Germany). Fluids and air were collected at the terminal end of each disposable tubing by attaching luer-locked transfusion bags (Medos Medizintechnik AG, Germany). The amount of air and fluid thus obtained in the transfusion bag was then measured by aspiration using a standard syringe (B Braun Melsungen, Germany).

The data is shown as mean and standard deviations. Statistical analysis was performed using statistical software (NCSS®, NCSS Statistical Software, USA). The data was analysed for differences between the groups using the Mann–Whitney *U*-test. Significance was defined at $p < 0.05$.

Results

None of the investigated systems could detect air nor totally prevent the risk of an air embolism occurring. The volumes of residual air are shown in Fig. 5. With an injected air volume of 50 ml, the L-1 and RA systems both filtered out 91% of the air. In contrast, the WF and GY systems only managed to filter out 8% ($p < 0.01$) and 3% ($p < 0.01$) of the air, respectively, whilst the amounts of eliminated gas by WF were slightly greaterer than those eliminated by GY ($p < 0.05$). The RA system was the most effective in the elimination of gas at volumes between 100 and 200 ml (96% and 98%, respectively). Compared to the RA system, the L-1, WF, and GY systems were much less effective in this category of air elimination. However, the L-1 system (80% and 88%, respectively, $p < 0.01$) was still performing significantly better than the WF (1% and 3%, $p < 0.01$) and GY systems (1% and 1%, $p < 0.01$).

Maximal flow rates and the final infusion temperatures achieved by the different devices are shown in Table 1. The maximal flow rates of the L-1 system were superior when compared to the other systems. The maximal flow rates were lower in the RA (20%, $p < 0.01$), WF (42%, $p < 0.01$), and the GY (60%, $p < 0.01$) systems. Despite the lower maximal flow rate, the highest final temperature of fluids was achieved using the GY system. We found that the final temperatures during maximal flow rates to be significantly lower when the L-1 (12%, $p < 0.01$), WF (15%, $p < 0.01$), or RA (20%, $p < 0.01$) systems were used.

Discussion

In the present laboratory study analysing the air elimination capability of four different fluid warmers during pressurised infusions, the RA system was superior in eliminating injected air in volumes between 100 and 200 ml. In the category of 50 ml air injections, air elimination capability of the L-1 system was comparable to that of RA. The L-1 system also demonstrated the highest maximal flow rate associated with superior fluid-warming capability when compared to RA. In contrast to RA and L-1, both WF and GY systems failed to eliminate air altogether (independent of the volumes injected). However, none of the investigated devices could detect air nor could have totally prevented a gas embolus in a comparable clinical setting.

In comparison to our results, laboratory investigations of Eaton [8], demonstrated that the RA system delivered

	Level-1®	Ranger®	Gymar®	Warmflo®	
MFR (ml min^{-1})	696 (4)	558 (7)	282 (5)	404 (10)	$p < 0.01$ between L-1 and the others; $p < 0.01$ between RA and GY, WF; $p < 0.01$ between WF and GY
FT (°C)	33.3 (0.1)	30.3 (0.2)	38.5 (0.3)	32.4 (0.5)	$p < 0.01$ between GY and the others; $p < 0.01$ between L-1 and WF, RA; $p < 0.01$ between WF and RA

Table 1 Maximal flow rates (MFR) and final temperatures (FT) of pressurised infusion devices (Level-1® = L-1; Ranger® = RA; Gymar® = GY; Warmflo® = WF). Data are given as mean (SD).

less air during pressurised infusions with its heating capability being inferior, when compared to the L-1 system. The superior air elimination capability of RA seemed to be created by a gas permeable membrane, which surface area is three-fold larger when compared to L-1. In contrast to our results, they showed that the RA system delivered fluids faster than the L-1 system. Their finding could be explained by their use of the RA disposable pressure infuser, which uses higher infusion pressures (i.e. 350 mmHg) than the pneumatic infusion pressures that were used in our study (300 mmHg, Level 1®). Data on the air elimination properties of the fluid warmers WF and GY used for pressurised infusions does not exist. Our results suggest that the lack of gas elimination of WF and GY was due to the function of the gas vents distal to the heat exchanger, which failed to eliminate air (GY) or needed to be squeezed manually (WF). Therefore, in cases of unnoticed gas embolism both systems become useless. Additionally, care must also be taken that gas trapped inside the heat exchanger, may be inadvertently mobilised during subsequent infusions.

One-litre sized crystalloid IV infusion bags contain approximately 60 ml of air [6]. Plastic bottles containing hydroxyethyl-starch (HAES 6%, Fresenius Kabi, Germany), which might have first been partially emptied under non-pressurised conditions and are subsequently used for a pressurised infusion could also inadvertently deliver 60 ml of air and more. Whilst this can be avoided by following the manufacturers' instructions, a gas embolism might still be possible, particularly when considering the stress placed on all the personnel involved in the setting of a massive haemorrhage. The attention of the personnel towards the fluid resuscitation in progress can be distracted by many ongoing events and problems. Hence, from a medical perspective 50–200 ml of injected air were chosen as realistic clinical conditions for this laboratory investigation.

Alternative systems that are on the market (FMS 2000®, Belmont Instrument Corp., Billerica, MA) might offer a greater advantage in detecting and eliminating gas through a set of semiocclusive roller-head pumps including ultrasonic detectors, which can promote both, rapid and accurate infusion rates, as well as in-line air detection. Whenever air is detected, this system will immediately stop pumping and heating, with valves closing off the flow to the patient [14]. In the opinion of the authors, for the future, it would be important for comparable devices based on roller-pumps to become available and to be separately installed with air detection and air elimnation devices.

In conclusion, none of the investigated pressurised infusion devices detected or totally eliminated air, which was injected. The Ranger® system was superior in respect to air elimination capability when compared to the Level-1® device. The Gymar® and Warmflo® systems both failed to achieve satisfactory maximal infusion rates, had virtually no gas elimination capability, and did not have sufficient fluid warming capabilities during maximal flow. Whilst clinicians using such devices must always be aware of the potential risk of air embolism occurring, however, improved air filtering capabilities of these devices would still be worthwhile. One way of improving the air filtering capabilities and hence the safety of these pressure infusion devices and fluid warmers would be to install a separate device, based on roller-pumps with air detection mechanisms, which would allow the immediate cessation of the infusion.

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