Performance Characteristics of Fluid Warming Technology in Austere Environments

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ABSTRACT

Resuscitation of the critically ill or injured is a significant and complex task in any setting, often complicated by environmental influences. Hypothermia is one of the components of the "Triad of Death" in trauma patients. Devices for warming IV fluids in the austere environment must be small and portable, able to operate on battery power, warm fluids to normal body temperature (37°C), and perform under various conditions, including at altitude. The authors evaluated four portable fluid warmers that are currently fielded or have potential for use in military environments.

KEYWORDS: *intravenous fluids; fluid warming; resuscitation; hypothermia*

Introduction

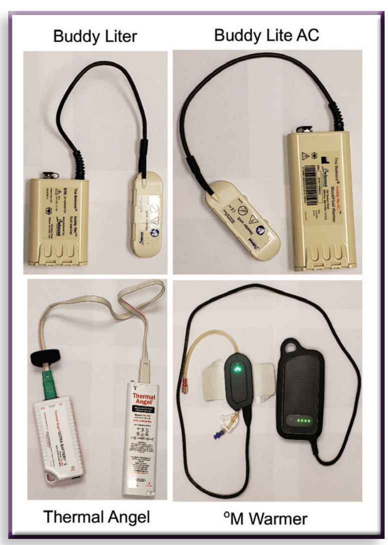
Resuscitation of the critically ill or injured is a significant and complex task in any setting, often complicated by environmental influences. Hypothermia is one of the components of the "Triad of Death" in trauma patients, frequently seen in the prehospital setting, and often exacerbated by resuscitation efforts.[1,2–4] Studies have shown that the incidence of hypothermia in the prehospital setting can reach 43%.[5] Most guidelines classify hypothermia as mild, 35°C to 32°C; moderate, 32°C to 28°C; or severe, <28°C.[6–9] Warming of intravenous (IV) fluids is recommended for the mitigation and treatment of hypothermia in prehospital trauma patients.[10] The US military has many of the same needs as civilian prehospital caregivers but operates under unique conditions. Many casualties require fluid resuscitation and simultaneous treatment of hypothermia in the field. Far forward deployed military units do not have ability to warm large quantities of IV fluids due to weight and cube constraints.[4] Devices for warming IV fluids in this environment must be small and portable, able to operate on battery power, warm fluids to normal body temperature (37°C), and perform under various conditions, including at altitude. We evaluated four portable fluid warmers that are currently fielded or have potential for use in military environments.

Methods

The study evaluated four portable fluid warming devices: Buddy Liter™ and Buddy Lite AC™ (Belmont Instrument Corp.; https://belmontmedtech.com/portable-iv-pump), Thermal Angel™ (Estill Medical Technologies; https://thermalangel.com/), and M Warmer™ (MEQU; https://mequ.dk/product/#mwarmer). These devices are shown in Figure 1. The devices were evaluated using two different fluids and flows. Room temperature normal saline (NS) was run at a nonemergent flow of 125mL/h (2.1mL/min) for 1 hour via an Alaris Medsystem III™ infusion pump (Becton, Dickinson and Company; http://www.bd-products.com/products/ivsets/product.php?ID=334) and using a pressure bag inflated to 300mmHg to represent an emergent flow, infusing 1L of fluid. These flow rates were chosen as extremes that may be encountered in far forward and transport military operations based on experience of one of the authors (JF). During high flows under pressure, flow was calculated by infusing a measured 1L volume of NS, running the fluid through each warmer using the pressure bag, and measuring the time in seconds to infuse the fluid. Flows for the Buddy Liter, Buddy Lite, M Warmer, and Thermal Angel were 278mL/min, 278mL/min, 222mL/min, and 232mL/min, respectively. Only one such measurement was made per device.

Expired, iced packed red blood cells (PRBCs) were run under identical conditions as the NS with the exception of using 2

FIGURE 1 *The four devices evaluated in the study.*



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units of PRBCs infused simultaneously at the emergent flow instead of 1L. These tests were done at ground level and at 8,000- and 16,000-ft simulated altitude in an altitude chamber. The ambient temperature inside the altitude chamber was maintained at 24°C to approximate room temperature in our laboratory (23.9 ± 0.4°C) in which ground level testing was completed. Two of each device were used in the study and two tests with each device were completed at each condition. All devices were operated on battery power, and the Buddy Liter and Buddy Lite AC were also operated on alternating current (AC) power. The Thermal Angel and M Warmer do not offer the option of operating from AC power.

Battery life was measured under two conditions with each device: nonemergent flow of 125mL/h using room temperature NS as described above and using a pressure bag inflated to 300mmHg using iced NS. Each device was operated until the low battery indicator was activated and measured temperature decreased by >1°C.

Devices were set up per manufacturer's instructions. The infusion pump had preventive maintenance and calibration performed before the study began. Device batteries were charged for a minimum of 24 hours before use. Standard IV tubing was used for all nonemergent flows with the infusion pump and pressure bag, and standard blood tubing was used for testing with PRBCs. A three-way stopcock was placed at the entrance to and directly after the heater unit of the device being tested, and a J-type thermocouple (Omega Engineering, https://www.omega.com/en-us/thermocouple-types) was placed in each of the stopcocks' open port and sealed with silicone. The thermocouples were attached to a data acquisition system (National Instruments, https://www.ni.com/en-us.html), and temperature data were continuously recorded at 1-second intervals. The Buddy Liter and Buddy Lite use disposable cartridges inside the reusable heater unit, and the Thermal Angel and M Warmer use disposable heater units. All the cartridges/heater units except the Thermal Angel had tubing before and after the heater units. These are the points at which the preheater and postheater temperatures were measured. A 9-inch IV extension tubing supplied with the Thermal Angel was placed on the output side of the heater so that measurements could be taken in the same location with all devices and would simulate the temperature at which the warmed fluid would enter a patient's circulation. After priming, each warmer was turned on, and fluid flow and temperature measurements were started simultaneously.

The measurements of interest for this study were mean temperature, time to reach mean temperature, change in temperature from inlet to outlet, proportion of time the temperature was ≥32°C and ≥35°C, and battery life.

Statistical Analysis

Temperature differences at specified conditions, NS and PRBCs, emergent flow and nonemergent flow rate, and altitude differences were compared for each device. Mean and SD were used to summarize data. Comparisons were made using the general linear model univariate analysis to create contrasts that tested specified custom hypotheses. This method was preferred to avoid testing all pairwise comparisons, as comparisons were set a priori. Post hoc analysis was completed by comparing the change in temperature prewarmer to postwarmer, and time to reach mean temperature was created with each device at all conditions using the Student *t*-test. Devices were compared to each other at all conditions and compared to themselves using altitude as the independent variable, to determine if altitude had an effect on device performance. Statistical significance was determined at $\alpha = .05$, two-tailed, and SPSS® Statistics 25 was used for data analysis.

Results

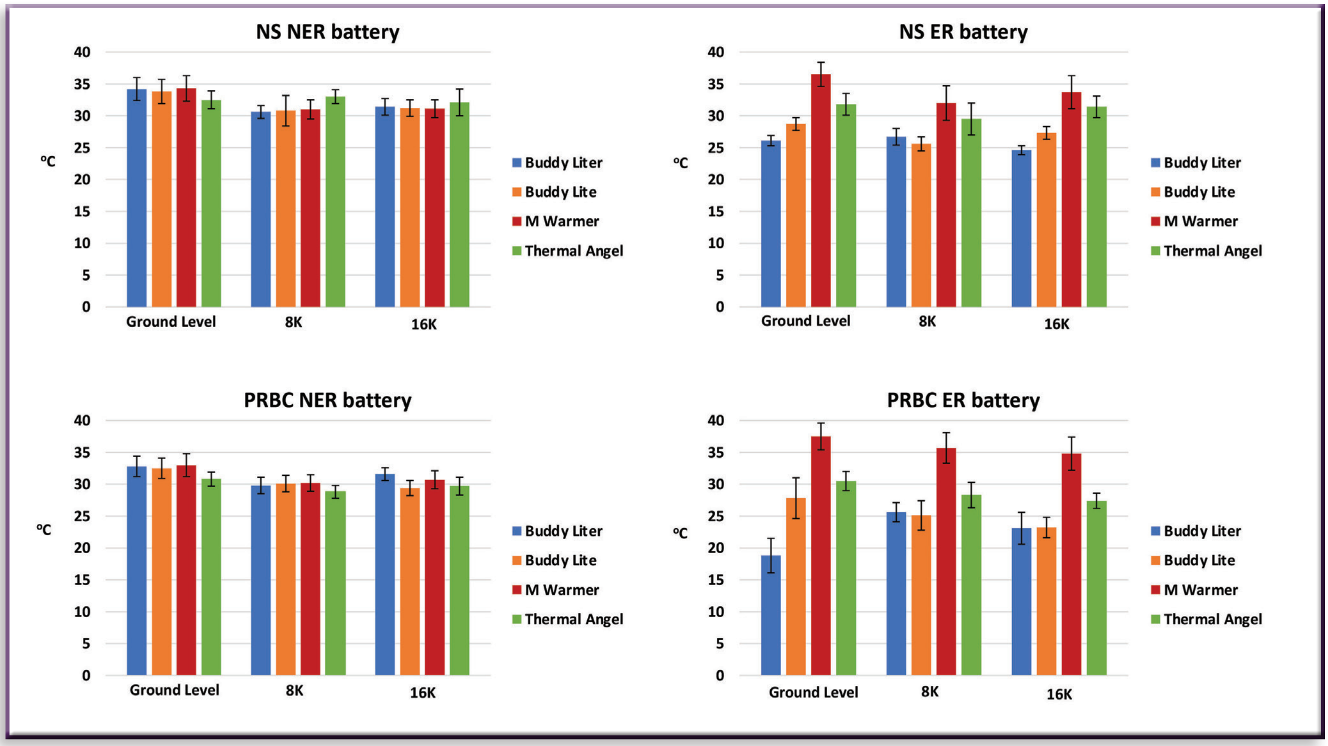
Table 1 shows the physical and operational characteristics of the devices. There was no distinct size or weight advantage of one device over the others. The stated maximum flows were much higher for the Thermal Angel and M Warmer. None of the devices were able to heat NS or cold PRBCs to a mean temperature equal to normal human body temperature (37°C) at either flow tested. Analysis of the differences in overall temperature profiles produced by the devices at all conditions was statistically significant ($p < .01$) except for the Buddy Liter versus the Buddy Lite at ground level on AC power, at the nonemergent flow using room temperature NS ($p = .42$), and the same devices at 16,000-ft altitude on AC power at the nonemergent flow, using cold PRBCs ($p = .24$). Figure 2 shows the mean (SD) temperatures for all devices on battery power. The M Warmer produced the highest mean temperatures at the emergent flow using NS and cold PRBCs. Differences in mean temperature between devices at the nonemergent flow using both NS and PRBCs were within 3°C at each of the altitude conditions, although the temperatures were somewhat lower at altitude compared to ground level. Figure 3 shows the mean (SD) temperatures for the Buddy Liter and

TABLE 1 *Physical and Operational Characteristics for Each Fluid Warming Device*

	Buddy Liter	Buddy Lite AC™	Thermal Angel	M Warmer
Dimensions (in) (L × W × H)				
Battery housing	4.92 × 3.33 × 1.36	7.26 × 3.33 × 1.36	6.4 × 3.2 × 1.7	7.09 × 3.54 × 1.38
Heater unit	5.2 × 1.5 × 0.87	15.2x 1.5 × 0.87	9.0 × 2.9 × 0.95	3.94 × 1.97 × 0.79
Weight (lb)				
Battery and heater unit	1.09	1.46	1.83	1.68
AC power supply	2.64	2.64	N/A	0.55
Power requirement	AC, battery	AC, battery	Battery	Battery
Temperature set point (°C)	38 ± 2	38 ± 2	38 ± 3	39 ± 3
High temperature alarm	Yes	Yes	LED only	LED only
Low temperature/no heat alarm	Yes	Yes	LED only	LED only
Maximum flow rate (mL/min)	30 @ 20°C 20 @ 10°C	80 @ 20°C 50 @ 10°C	150 @ 20°C	150 @ 4°C – 37°C

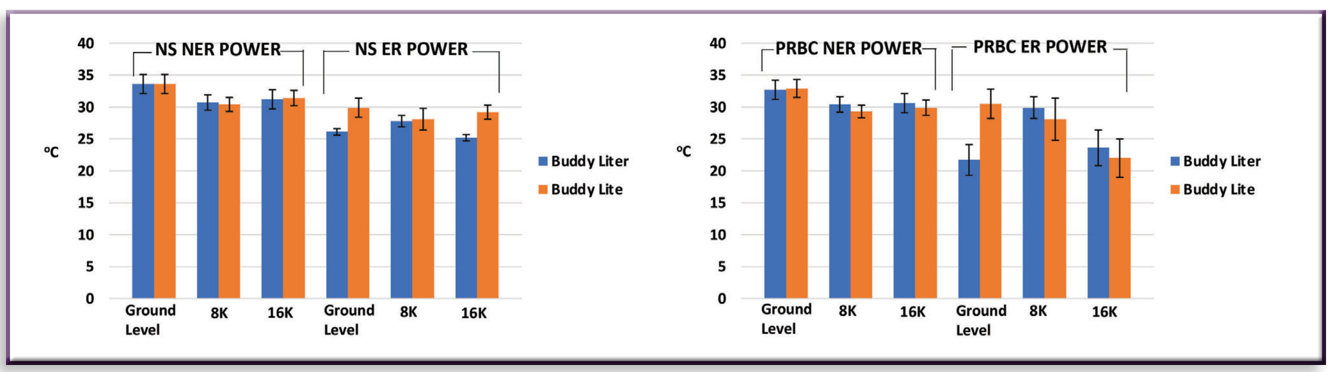
L × W × H = length × width × height, LED = light-emitting diode.

FIGURE 2 *Mean (SD) temperatures for all devices on battery power.*



NS = normal saline, PRBC = packed red blood cells, NER = nonemergent rate, ER = emergent rate, ground level = ambient barometric pressure, 8K = 8,000-ft altitude, 16K = 16,000-ft altitude.

FIGURE 3 *Mean (SD) temperatures for the Buddy Liter and Buddy Lite on AC power.*



NS = normal saline, AC = alternating current, PRBC = packed red blood cells, NER = nonemergent rate, ER = emergent rate, ground level = ambient barometric pressure, 8K = 8,000-ft altitude, 16K = 16,000-ft altitude.

Buddy Lite on AC power. The Buddy Lite produced the highest mean temperature at the emergent flow using NS and PRBCs.

Data comparing each of the devices with the change in fluid temperature from before entering the device and after leaving the warmer at the end of the extension tubing plus the time the devices took to reach the mean temperature produced by the devices at all conditions are shown in Table 2. The table also shows the device pairings that had statistically significant differences. The temperature changes varied widely between devices and, to a lesser degree, the time to reach mean temperature. Nearly all the changes in temperature between devices were statistically significant at the emergent flow using both NS and PRBCs, as were nearly 50% of the time to reach mean temperature at the emergent flow.

Using battery power at ground level, the M Warmer produced temperatures ≥35°C less than 1% of the time with cold PRBCs using the nonemergent rate (Figure 2). At 8,000 ft and 16,000 ft, the temperature produced with the device did not reach 35°C. None of the other devices were able to produce this temperature using cold PRBCs at any altitude. The percentage of time the Buddy Liter, Buddy Lite, and M Warmer reached this threshold using NS, nonemergent flow, at ground level was 61%, 41%, and 65%, respectively. Temperatures did not reach the ≥35°C threshold at 8,000 and 16,000 ft. The Thermal Angel did not reach this threshold at ground level or any altitude. Using NS and PRBCs at the emergent flow, only the M Warmer had any significant percentage of time at temperature ≥35°C. The percentage of time above this threshold was 96%, 81%, and 80% at ground level, 8,000 ft, and 16,000 ft, respectively.

TABLE 2 *Temperature Change From Inlet of Warmer to End of Outlet Tubing at All Test Conditions*

	RT NS SL	RT NS 8K	RT NS 16K	Cold PRBC SL	Cold PRBC 8K	Cold PRBC 16K
Emergent Flow Rate						
Time to reach mean temp at end of outlet tubing (sec)						
Buddy Liter - powered	26 ± 19	20 ± 3	10 ± 2	151 ± 31	42 ± 27	119 ± 32[e]
Buddy Liter - battery	30 ± 6[be]	23 ± 3[ab]	17 ± 16[b]	108 ± 38[bde]	37 ± 14[e]	94 ± 28[cd]
Buddy Lite AC - powered	60 ± 11	49 ± 17	36 ± 20	91 ± 23	58 ± 17	55 ± 7
Buddy Lite AC - battery	32 ± 15[e]	33 ± 4[bcd]	23 ± 2[bd]	103 ±16[b]	62 ± 20[bc]	48 ± 13[d]
Thermal Angel	47 ± 4	60 ± 13	58 ± 4[d]	28 ± 13[de]	25 ± 3[e]	61 ± 34
M Warmer	34 ± 20	24 ± 3[‡]	25 ± 2[bd]	68 ± 31[d]	25 ± 12	27 ± 7[de]
Temp change from inlet to end of outlet tubing (°C)						
Buddy Liter - powered	2.4 ± 0.3[e]	2.0 ± 0.2[e]	1.8 ± 0.1	9.0 ± 0.3[e]	13.5 ± 0.9[e]	11.3 ± 1.0
Buddy Liter - battery	1.6 ± 0.2[abce]	1.5 ± 0.2[abce]	1.4 ± 0.3[abce]	6.5 ± 0.8[abce]	9.5 ± 2.0[bce]	9.7 ± 1.5[bc]
Buddy Lite AC - powered	6.0 ± 0.3	4.7 ± 0.4	4.6 ± 0.6	18.0 ± 0.9	16.1 ± 1.6	8.6 ± 1.0
Buddy Lite AC - battery	4.5 ± 0.3[bcde]	2.9 ± 0.7[bcde]	3.0 ± 0.2[bce]	15.0 ± 0.5[bcde]	13.4 ± 2.0	10.1 ± 0.9[bc]
Thermal Angel	7.9 ± 0.3[de]	6.1 ± 0.4[de]	6.7 ± 0.4[de]	17.8 ± 0.8[d]	15.0 ± 0.6	15.4 ± 0.3[de]
M Warmer	12.7 ± 0.2[bde]	10.1± 0.6[bde]	9.9 ± 0.2[bde]	24.5 ± 0.8[bde]	22.5 ± 1.0[bde]	21.8 ± 1.2[bde]
Nonemergent Flow Rate						
Time to reach mean temp at end of outlet tubing (sec)						
Buddy Liter - powered	413 ± 71	246 ± 42	231 ± 45	252 ± 43	284 ± 43	296 ± 59
Buddy Liter - battery	252 ± 62	191 ± 38[d]	270 ± 113	283 ± 48	281 ± 42	228 ± 90
Buddy Lite AC - powered	323 ± 59	207 ± 24	195 ± 65	273 ± 58	252 ± 81	336 ± 144
Buddy Lite AC - battery	206 ± 27[bcde]	262 ± 105	235 ± 82[b]	289 ± 25	237 ± 26	304 ± 37
Thermal Angel	244 ± 13[d]	152 ± 29[d]	133 ± 38	308 ± 61	324 ± 94	332 ± 55
M Warmer	251 ± 7[d]	272 ± 66[b]	259 ± 61	325 ± 99	345 ± 148	299 ± 155
Temp change from inlet to end of outlet tubing (°C)						
Buddy Liter - powered	9.6 ± 0.1	6.0 ± 0.3	6.8 ± 0.4	8.7 ± 0.7[e]	5.6 ± 0.3[e]	6.0 ± 0.9
Buddy Liter - battery	10.2 ± 0.3[bd]	5.9 ± 0.4[bc]	6.9 ± 0.3[b]	8.7 ± 0.7[be]	5.1 ± 0.7	6.9 ± 0.4[abe]
Buddy Lite AC - powered	9.6 ± 0.1	5.8 ± 0.2	6.9 ± 0.2	9.0 ± 0.6	4.6 ± 0.3	5.3 ± 0.4
Buddy Lite AC - battery	9.7 ± 1.1	6.3 ± 0.4[be]	6.8 ± 0.6[b]	8.7 ± 0.6[bd]	5.5 ± 0.6[b]	4.9 ± 0.1[c]
Thermal Angel	8.5 ± 0.4[de]	8.4 ± 0.5[de]	8.5 ± 0.3[de]	6.7 ± 0.2[de]	4.3 ± 0.4[d]	5.9 ± 0.9
M Warmer	10.3 ± 0.5[b]	6.7 ± 0.7	6.4 ± 0.4[be]	9.1 ± 0.6[b]	5.2 ± 0.6	7.0 ± 0.9[be]

Statistical significance ($p < .5$). Legend: [a]vs Buddy Lite, [b]vs Thermal Angel, [c]vs M Warmer, [d]vs Buddy Liter AC Power, [e]vs Buddy Lite AC Power.

Figure 4 shows the percentage of time the devices produced temperatures ≥32°C at all conditions on battery power. As shown, the percentage of time the M Warmer produced fluid temperatures that reached this threshold was significantly higher than for the other devices using NS and PRBCs at the emergent flow, at all altitudes. The Buddy Liter and Buddy Lite failed to produce temperatures that reached this threshold at any altitude. At ground level using NS at the nonemergent rate, all the devices reached this threshold >90% of the time. At this condition, percentages above this threshold were significantly less for all devices at 8,000 ft and 16,000 ft except for the Thermal Angel at 8,000 ft (97%). At ground level using PRBCs at the nonemergent flow, all devices except the Thermal Angel reached the ≥32°C threshold >90% of the time. At 8,000 ft and 16,000 ft, the percentage of time at the threshold was less.

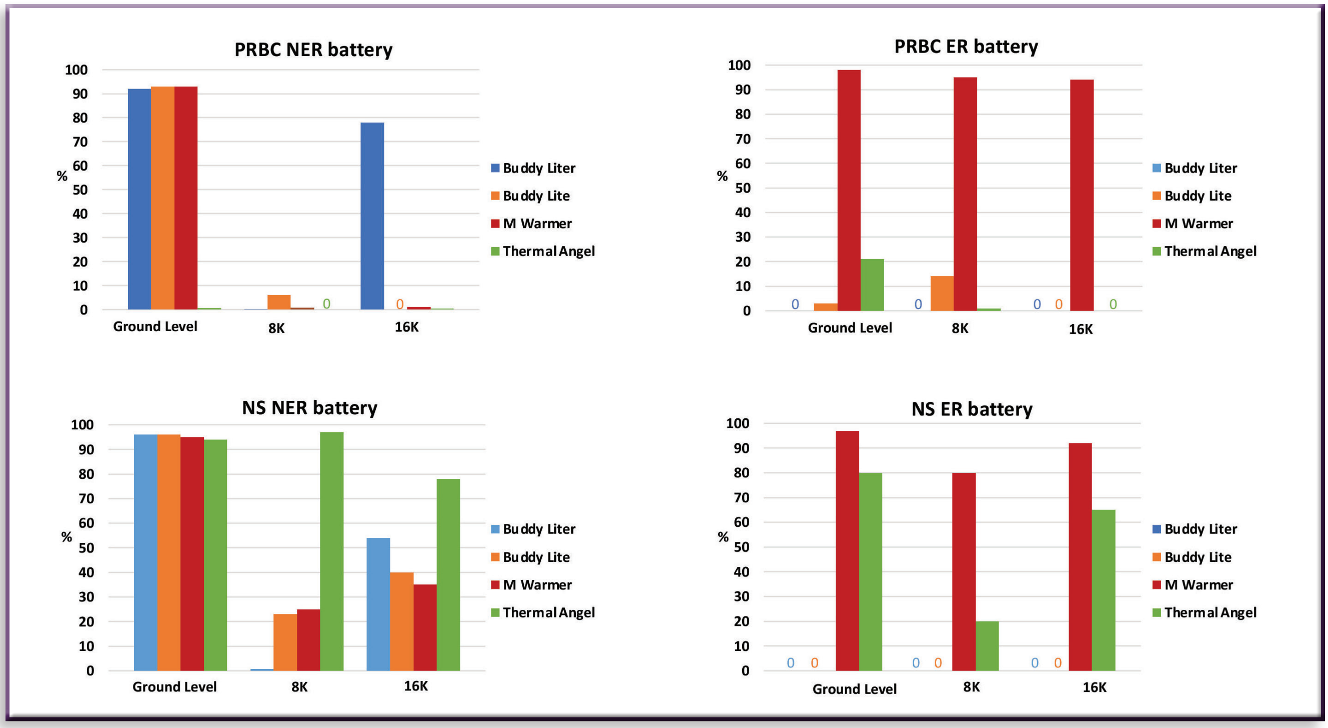
The Buddy Liter and Buddy Lite were the only two devices that had the capability to use AC power in addition to battery power, so these data were analyzed separately. Nearly all the differences in changes in temperature between these two devices were statistically significant and less than half of the time to mean temperature differences were significant. The majority of the significant differences were when comparing ground level to 16,000-ft altitude (Figure 3).

Battery life and mean temperature varied widely among devices under the extremes of conditions. All differences were statistically significant ($p < .001$) except mean temperatures using the nonemergent flow ($p = .5$). Using the nonemergent flow, mean battery life differed widely between all devices (774.9 ± 256.9 minutes). Mean temperatures were 33.7 ± 1.0°C between all devices but were not statistically significant or clinically important. The Buddy Lite had the longest battery life under this condition. Mean battery life differed widely between all devices (35.0 ± 28.6 minutes) as did mean temperatures (19.9 ± 7.3°C) when using the emergent flow. The Buddy Liter had the longest battery life under this condition. Table 3 shows the mean battery life and mean temperature with each device at both conditions.

Discussion

This study showed there were large differences in the temperature profiles between devices on battery power using emergent flow with both NS and PRBCs. There were also differences among devices using nonemergent flow, although they were much smaller (Figure 2). The M Warmer produced the highest mean temperature at all conditions. The change in temperature from the inlet of the warmers to the end of the outlet extension tubing was used to determine the devices heating

FIGURE 4 *Proportion of time as a percentage that temperature at the end of the outlet tubing was ≥32°C for all devices on battery power.*



NS = normal saline, PRBC = packed red blood cells, NER = nonemergent rate, ER = emergent rate, ground level = ambient barometric pressure, 8K = 8,000-ft altitude, 16K = 16,000-ft altitude.

TABLE 3 *Mean Battery Life (minutes ± SD) and Mean Temperature (°C ± SD) With All Emergent Flow Rate Using Pressure Bag With Iced NS*

	Buddy Liter	Buddy Lite AC	M Warmer	Thermal Angel
Battery life (min) nonemergent rate	634 ± 31	1,177 ± 25	890 ± 14	503 ± 7
Mean temperature (°C)	34.1 ± 0.5	33.8 ± 0.7	34.3 ± 0.4	32.5 ± 0.6
Battery life (min) emergent rate	74 ± 9	47 ± 4	9 ± 2	10 ± 0.1
Mean temperature (°C)	12.3 ± 2.4	15.5 ± 2.4	30.5 ± 3.3	21.5 ± 3.5

ability and is a more accurate indicator of performance due to the differences in the time to warm the fluids to the mean temperature.

Contrary to the study by Dubick et al., time to mean fluid temperature was not a good indicator of device performance due to inconsistencies with change in temperature within each device type and between devices.[12] This may be due to the very low and high flows used in the present study. The M Warmer consistently produced the highest mean temperature and temperature change but often did not have the fastest time to mean temperature. The reason for these inconsistencies could be attributed to the higher temperature change produced by the M Warmer, which may have resulted in a longer time to reach the mean temperature, and because the mean temperature was always higher than with the other devices.

Warming cold PRBCs at the emergent flow and, to a lesser degree, NS at the same flow, clearly showed the differences in heating ability of the devices under extreme conditions. Temperature differences were not as great at the nonemergent flow, which may be attributed to the flow (125mL/h) being sufficiently low that the temperature exiting the devices was cooled toward ambient temperature by the time the measurement was made at the end of the extension tubing on the exit side of the warmers. We did not measure the temperature immediately exiting the warmer due to lack of clinical relevance. We believe the fluid temperature at the point at which it would enter a patient's circulation is clinically relevant and therefore a better measure of capability.

A literature review revealed three relevant studies that evaluated battery operated, portable fluid warmer technology.[13–15] These studies included the Buddy Lite in the evaluations. Consistent with these studies, our study showed that the warming capability of the Buddy Lite decreased with increases in flows as did the Thermal Angel in studies performed by Weatherall et al. and Dubick et al.[13,12] Dubick et al. also found that device performance decreased significantly when using cold fluids at both high and low flows.

Battery life is an important consideration for deploying any device in prehospital and austere environments when electrical power is unavailable. Battery life with the warmers in this study varied widely among each brand and within brands depending on the testing profile used. As shown in Table 3, when using the nonemergent flows with room temperature NS, the temperatures produced with each type of device showed a small variance although none of them produced mean temperatures ≥35°C, and battery life differences were highly significant ($p < .001$). Under this condition, the Buddy Lite had a much longer battery life than the other devices. This can be attributed to the extremely low flow, which allowed the warmed fluid exiting the warmers to cool while traveling through the extension tubing to the measurement point, simulating entering a patient's circulation. Using the emergent flow with iced NS produced statistically significant differences in battery life and mean temperatures ($p < .001$). This testing scheme evaluated the warming ability of the different devices under the most extreme conditions possible—very high flows combined with very cold fluids. These are conditions that may be encountered in prehospital and austere environments due to use in cold weather conditions and/or blood administration. As shown in Table 3, the Buddy Liter had the longest battery life but also produced the lowest temperatures. Conversely, the M Warmer had the shortest battery life but was much more effective at warming the cold fluid. There was an inverse relationship between battery life and warming ability under this condition. Similar results were shown in a study by Lehavi et al. with the Buddy Lite fluid warmer.[14]

We chose the thresholds for the percentage of time that each device heated fluid to ≥32°C and ≥35°C based on work by Jurkovich et al. and Dubick et al.[12,16] The authors reported a 40% mortality in trauma patients if core temperature was <34°C, 69% if core temperature was <33°C, and 100% if core temperature was <32°C. Based on these data, the ideal goal for fluid warmers should be to deliver fluid temperatures >34°C; therefore, we chose the threshold of ≥35°C. The M Warmer was the only device we tested that was able to reach this threshold ≥80% of the time at the emergent flow using both NS and PRBCs, which were the most challenging conditions. This is an important finding in that core body temperature decreases approximately 0.25°C for every unit of cold PRBCs and 1L of ambient temperature fluids administered, and maintaining/increasing core body temperature is an important consideration with fluid administration.[17] We chose the threshold of ≥32°C as the absolute acceptable minimum for two reasons: core temperature <32°C is when shivering, the human body's mechanism for raising core temperature, ceases.[18,19] Additionally the reported mortality rate below this threshold is 100%. The Buddy Liter and Buddy Lite failed to reach this threshold using NS at the emergent flow and reached it <15% of the time using PRBCs at the emergent flow (Figure 4).

Temperatures produced by the warmers using the nonemergent flows of 125mL/h were lower than expected, especially when warming cold PRBCs. This can be attributed to the slow flow (~2mL/min) allowing the fluid to cool toward room temperature after exiting the warmer while flowing through the extension tube to the postwarmer temperature measurement. The extension tubing provided with the warmers was a minimum of 15cm in length. The minimum reported tubing length to maintain postwarmer fluid temperature >32°C is <10cm.[18] Using the shortest IV tubing possible between the warmer and the patient may help to increase the delivered fluid temperature.

Limitations

Per operator's manuals, maximum output temperature for the devices vary: Buddy Liter and Buddy Lite were 38 ± 2°C; Thermal Angel was 38 ± 3°C; and M Warmer was 39 ± 3°C. The devices lack a temperature readout so there was no way of knowing the actual operating temperature for each test condition. The emergent flow using a pressure bag was greater than the maximum flow published for each device, but this method of rapidly infusing fluids or PRBCs is common practice in the face of resuscitation following hemorrhage and would likely be encountered in clinical practice. The accuracy of the thermocouples and the data acquisition system was 0.9°C and 1°C, respectively, which may explain some of the differences in temperature. However, the same thermocouples and data acquisition system were used for the entire study, so any variation in measurement was consistent throughout the evaluation.

Conclusions

Although none of the devices warmed fluids to normal body temperature (37°C), likely due to the high flows used, the M Warmer was the only warmer tested that heated NS and PRBCs to ≥32°C and PRBCs to ≥35°C more than 80% of the time at the emergent flow. The M Warmer and, in some cases, the Thermal Angel performed better at the higher flows, whereas the Buddy Liter and Buddy Lite did not. Altitude appeared to have a small effect on the output temperatures in some testing scenarios, but the differences were not clinically important. Future evaluation of the devices at altitude, within the documented operational flow range for each device, may show more accurate warming differences. Future studies should evaluate presence of hemolysis created by infusing PRBCs under pressure through the warming devices.

Disclosure

The authors have no financial relationships related to this article to disclose.

Conflicts of Interest

The fluid warming devices evaluated in the study were purchased with funding provided by the United States Air Force Research Laboratory. The authors have not relationships to disclose with the manufacturers or sellers of the devices.

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Author Contributions

DR, RB, and MP developed the study concept. DR and RB created the proposal and study protocol. TB and JF completed the study procedures and collected data. DR, RB, and TB analyzed the data. TB wrote the first draft of the manuscript, and all authors read and approved the final manuscript.

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