Original Article

Comparison of portable blood-warming devices under simulated pre-hospital conditions: a randomised in-vitro blood circuit study

A. Weatherall,[1,2] **M. Gill,**[3] **J. Milligan,**[4] **C. Tetlow,**[4] **C. Harris,**[5] **A. Garner**[6] and **A. Lee**[7]

1 Anaesthetist and Retrieval Specialist, 4 Retrieval Specialist, 6 Emergency Physician and Retrieval Specialist, CareFlight, Sydney, NSW, Australia
2 Clinical Lecturer, Faculty of Medicine, University of Sydney, NSW, Australia
3 Perfusionist, Department of Perfusion, 5 Staff Specialist and Head of Department, Department of Haematology, Children's Hospital at Westmead, Sydney, NSW, Australia
7 Professor, Department of Anaesthesia and Intensive Care, Chinese University of Hong Kong, Hong Kong

Summary

Pre-hospital transfusion of blood products is a vital component of many advanced pre-hospital systems. Portable fluid warmers may be utilised to help prevent hypothermia, but the limits defined by manufacturers often do not reflect their clinical use. The primary aim of this randomised in-vitro study was to assess the warming performance of four portable blood warming devices (Thermal Angel, Hypotherm X LG, °M Warmer, Buddy Lite) against control at different clinically-relevant flow rates. The secondary aim was to assess haemolysis rates between devices at different flow rates. We assessed each of the four devices and the control, at flow rates of 50 ml.min^{-1}, 100 ml.min^{-1} and 200 ml.min^{-1}, using a controlled perfusion circuit with multisite temperature monitoring. Free haemoglobin concentration, a marker of haemolysis, was measured at multiple points during each initial study run with spectrophotometry. At all flow rates, the four devices provided superior warming performance compared with the control ($p < 0.001$). Only the °M Warmer provided a substantial change in temperature at all flow rates (mean (95%CI) temperature change of 21.1 (19.8–22.4) °C, 20.4 (19.1–21.8) °C and 19.4 (17.7–21.1) °C at 50 ml.min^{-1}, 100 ml.min^{-1} and 200 ml.min^{-1}, respectively). There was no association between warming and haemolysis with any device ($p = 0.949$) or flow rate ($p = 0.169$). Practical issues, which may be relevant to clinical use, also emerged during testing. Our results suggest that there were significant differences in the performance of portable blood warming devices used at flow rates encountered in clinical practice.

Correspondence to: A. Weatherall
Email: andrew.weatherall@careflight.org
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Twitter: @AndyDW_

Introduction

Trauma is a leading cause of death with approximately five million people worldwide dying from traumatic injury each year [1]. Early trauma-related death is associated with haemorrhage in approximately 30% of cases, and although it is vital to arrest haemorrhage, resuscitation with blood products, including red cell transfusion and increasingly plasma, are commonly used therapeutic options in many advanced pre-hospital systems [2, 3].

A contributing factor to haemorrhage after trauma is acute traumatic coagulopathy, which is both common in this setting and an independent predictor of mortality [4]. Key

factors in the development of acute traumatic coagulopathy include: injury severity; hypothermia; hypocalcaemia; acidosis; ongoing bleeding with consumption of clotting factors; haemodilution from non-blood resuscitation; and activation of fibrinolysis [5]. A simpler way of grouping these factors is to refer to the trauma triad of death – coagulopathy, acidosis and hypothermia [6].

As red cells for pre-hospital blood transfusion are required to be maintained between 2–6 °C under local guidelines, there is a significant risk of promoting hypothermia with transfusion without warming the blood. Previous studies have shown that the rapid infusion of similar volumes of cold crystalloid fluids caused a drop in core body temperature of approximately 1.3 °C [7].

There are now an increasing number of portable blood-warming devices available in the market. We have previously demonstrated that a commercial device was more reliable than ad-hoc methods of warming cold red cells [8]. However, devices that are commercially available also specify flow rates (50–150 $ml.min^{-1}$) for optimal performance that may not reflect use in critically ill patients. Other publications reflecting use in the clinical setting suggest that flow and pressure values seen in clinical practice may exceed warming device guidelines [9, 10]. Pressure changes associated with passage of red cells through the device may also result in haemolysis. As transfusion of haemolysed red cells is associated with an increase in patient morbidity, further exploration of this problem is warranted [11, 12].

In this randomised in-vitro blood circuit study, we compared four commercially available portable blood-warming devices with control (no active warming technique employed). Our primary objective was to evaluate the warming performance of each device over a range of clinically-relevant temperatures at different flow rates. Our secondary aim was to assess whether there were differences in the incidence of haemolysis with different devices, or at different flow rates.

Methods

After gaining approval from the Sydney Children's Hospital Network Human Research Ethical Committee we conducted a prospective randomised controlled bench-test study of four commercial portable warming devices in the Perfusion Laboratory at The Children's Hospital at Westmead. We obtained units of red cell concentrate from the Australian Red Cross Blood Service and stored them in accordance with Australian National Pathology Accreditation Advisory Council Requirements for Transfusion Laboratory Practice [13].

As we wished to test devices that were lightweight and portable enough for field use by helicopter emergency medical services (HEMS), we identified devices that did not require an external power source and weighed less than 1 kg, including batteries and any required accessories. The four devices identified that met these criteria were (Table 1):

1. Thermal Angel TA-200 (Estill Medical Technologies Incorporated, TX, USA). The maximum recommended flow rate is 150 $ml.min^{-1}$.
2. Hypotherm X LG (EMIT Corporation, TX, USA). The maximum recommended flow rate is 100 $ml.min^{-1}$.
3. °M Warmer (MEQU Company, Denmark). The maximum recommended flow rate is 150 $ml.min^{-1}$.
4. Belmont Buddy Lite™ (Belmont Instrument Corporation, MA, USA). The maximum recommended flow rate is 50 $ml.min^{-1}$ (if inlet temperature < 10 °C).

We purchased Thermal Angel, Hypotherm X LG and Buddy Lite under normal commercial arrangements – no discounts were provided by manufacturers or distributors. The °M Warmer had not been certified at the time of the investigation, and hence was not available for purchase. The device tested was, therefore, a loan unit.

We compared these devices with a control group (no active warming technique employed). Each device used was set up and primed as per manufacturer's instructions. For each device, and the control group, we tested three different flow rates (50 $ml.min^{-1}$, 100 $ml.min^{-1}$ and 200 $ml.min^{-1}$). In order to replicate the performance of the device with the administration of a second unit of red cells, each test at a particular rate included the unit of red cell concentrate being recooled to 4 °C and infused through the system a second time. In each study arm, the complete test was carried out three times at each flow rate.

Table 1 Physical characteristics of the tested devices. Minimum weight includes cartridges or tubing required for function of the devices but excludes packaging.

Device	Minimum weight (g)	Energy source
Thermal Angel TA-200	255	Battery
Hypotherm X LG	450	Flameless catalytic combustion of propane/isobutane mix
°M Warmer	760	Battery
Buddy Lite	730	Battery

We randomly allocated the orders of rates and device groups using a computer-generated randomisation sequence using PASS software version 11 (NCSS, Kaysville, UT). Just before a bench test occurred, we opened a consecutively numbered sealed opaque envelope that had been prepared by a research nurse who was not involved in the in-vitro testing. The staff at the haematology laboratory reporting free haemoglobin (fHb), a marker for haemolysis, were blinded to treatment allocation.

The red cell concentrate was delivered to the warming device via a standardised circuit (Fig. 1). A pre-study, volumetrically calibrated, Stockert SIII heart-lung machine roller pump (Stockert GmbH, Munich, Germany) was used to regulate the required flow rates through the circuit, and where applicable, the warming device. Following infusion through a standardised giving set, the blood was delivered to a collection reservoir, and it was subsequently pumped through a heat exchanger to allow recooling to 4 °C. This was then recycled back to the collection bag for re-infusion at the set flow rate. After the second run at the set flow rate, the blood was discarded.

We measured the temperature of the infusate at three different points in the system using Capiox® Leur Thermistors (Terumo Corporation, Tokyo, Japan). The location of the first thermistor was immediately distal to the collection bag (Site 1), the second thermistor in the infusion circuit proximal to the inline blood-warming device (Site 2) and the third thermistor was just distal to the blood-warming device (Site 3) (Fig. 1). The third thermistor represented the temperature at which blood would usually enter the patient's circulation.

The temperature was continuously displayed on the Sockert SIII. The temperature data were recorded by continuous video recording of the display throughout each study run. We transcribed the measurements after examination of the video record. The temperature measurements at all three temperature sensors were recorded every 30 s after declaration of time zero as the moment at which red cells appeared distal to the warming device, following commencement at the study flow rate. However, we modified the timing for time zero for the Hypotherm X LG device as the device provided warming via ignition of a butane–propane mix. Priming of this system required both that the device itself was upright during the ignition phase and with a small amount of fluid running through the device over a period of 45 s. As such, time zero for this device was recorded as the moment that full ignition was complete.

As there was some variability in the volume of red cell units, run durations were not of uniform length. The final temperature measurement for each run was recorded only at the final 30-s mark before the flow was ceased at the end of the unit.

Free haemoglobin (fHb) concentrations, a marker of haemolysis, were measured only after the first use of a red cell concentrate unit (i.e. not after the blood had been recooled). The first recorded measurement was from the unit before commencement of the study run. A further measurement was taken at a point distal to the warming device, an equivalent point in the fluid giving set for control runs. Samples distal to the warming device were taken at 1 min into the study run, and immediately before the cessation of flow at the completion of the unit. We measured fHb concentrations using a spectrophotometer (Shimadzu UV-1700 spectrophotometer, Kyoto, Japan; wavelength 578 nm).

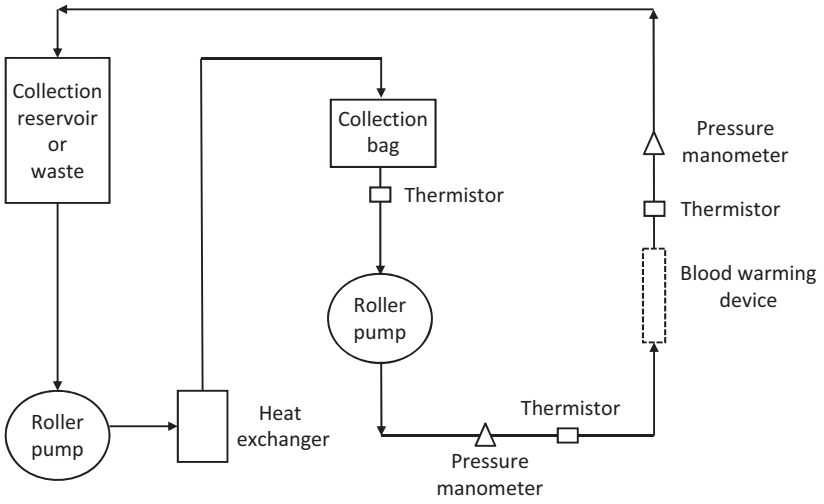

Figure 1 Standardised collection circuit.

The sample size was limited by available resources, with four devices and one control (no device) assessed at three different flow rates, repeated three times (total 45 runs); we considered this to be a realistic, achievable experiment. In the power analysis, a single-factor, repeated measures design with a sample of five devices, measured at three time-points, will achieve 100% power to detect a contrast using a multivariate T^2 test at a 0.050 significance level, assuming a standard deviation across devices at the same time-point to be 2.0. We assumed that the pattern of the covariance matrix would have all correlations equal, with a correlation of 0.20 between the time-point measurements. The value of the contrast applied to the hypothesised mean change was set at 14 °C based on a pilot run using crystalloids. We performed the sample size calculation using PASS software version 14 (NCSS, Kaysville, UT).

The primary outcome measure was a change in temperature (°C) distal to the warming device from the temperature measured distally to the collection bag at each flow rate. The secondary outcome measure was the change in fHb concentration. We performed generalised estimating equations (GEE), with a Gaussian distribution, identity-link function, exchangeable correlation with robust standard errors, to examine the association between type of warming device and temperature, adjusting for multiple runs within a warming device at a set flow rate. Similarly, we used GEE to examine the estimated mean (SD) change in fHb concentration between Site 3 and Site 1 with Bonferroni correction for multiple comparisons. The net change (device mean change − control mean change) was also estimated with Bonferroni 95%CI adjustment. We performed statistical analyses using Stata 15.0 software (StataCorp, College Station, TX, USA), and considered a value of $p < 0.05$ to be statistically significant.

Results

We performed the randomised in vitro-blood circuit study between November 2017 and March 2018. Table 1 shows the physical characteristics of the devices tested. Usability issues that may affect pre-hospital performance of the devices became apparent during the testing process. During two initial runs of the Hypotherm X LG, the device failed to initialise. Subsequent runs required fluid to be actively circulating through the upright warmer before commencing the ignition phase. During another two runs, the Hypotherm X LG switched itself off and needed to be restarted, or seemed to run out of fuel after one min. Additionally, the Buddy Lite shut down during five out of six runs at a flow rate of 200 $ml.min^{-1}$.

We recorded 1296 temperature measurements. Two-hundred and seventy temperatures at time zero at all three sites were discarded as artefacts. The reasons were: (1) methodological timing differences between devices at Site 1 as outlined in the Methods; (2) the blood had just reached the other side of the device but the flow at the chosen rate had barely started at Site 2; and (3) the temperature represented what it was like just before the pumps started rotating at Site 3. This left 1026 temperature measurements available for analysis. As there was a significant interaction term between device and flow rate ($p = 0.042$), we have presented the estimated mean (SD) temperatures (°C) at various sites in the circuit by different warming devices stratified by flow rates (Fig. 2). Across all devices, the estimated mean (SD) temperatures (°C) at 50 $ml.min^{-1}$, 100 $ml.min^{-1}$ and 200 $ml.min^{-1}$ were 18.8 (0.2), 17.5 (0.2) and 15.7 (0.3), respectively. This association between higher flow rates and decrease in mean temperature was significant ($p < 0.001$).

At 50 $ml.min^{-1}$, there were significantly higher increased mean temperatures at Site 3 in all warming devices compared with control ($p < 0.001$) (Fig. 2). At Site 3, the estimated mean (SD) temperatures (°C) attained for control, Thermal Angel, Hypotherm X LG, °M Warmer and Buddy Lite were: 15.6 (0.5); 30.3 (0.3); 30.0 (1.7); 36.6 (0.4); and 30.5 (1.0), respectively (Fig. 2). Compared with control, the mean (95%CI) temperature (°C) increase for Thermal Angel, Hypotherm X LG and Buddy Lite were similar at 14.8 (13.6–15.9), 14.4 (11.0–17.9) and 14.9 (12.7–17.2), respectively, with the highest temperature increase seen with °M Warmer (21.1, 19.8–22.4).

At 100 $ml.min^{-1}$, there were significantly higher increases in mean temperatures at Site 3 in all warming devices compared with control ($p < 0.001$) (Fig. 2). At Site 3, the estimated mean (SD) temperatures (°C) attained for control, Thermal Angel, Hypotherm X LG, °M Warmer and Buddy Lite were: 15.1 (0.3); 29.8 (0.6); 30.7 (0.8); 35.5 (0.6); and 25.1 (0.5), respectively (Fig. 2). Compared with control, the mean (95%CI) temperature (°C) increases for Thermal Angel, Hypotherm X LG and Buddy Lite were: 14.7 (13.4–16.1); 15.6 (14.0–17.2); and 10.0 (8.9–11.0), respectively, with the highest temperature increase seen with °M Warmer (20.4, (19.1–21.8)).

At 200 $ml.min^{-1}$, there were significantly higher increased mean temperatures at Site 3 in all warming devices compared with control ($p < 0.001$) (Fig. 2). At Site 3, the estimated mean (SD) temperatures (°C) attained for control, Thermal Angel, Hypotherm X LG, °M Warmer and Buddy Lite were: 13.1 (0.7); 23.7 (0.6); 23.5 (2.9); 32.5 (0.4); and 19.4 (1.2), respectively (Fig. 2). Compared with control, the mean (95%CI) temperature (°C) increases for Thermal

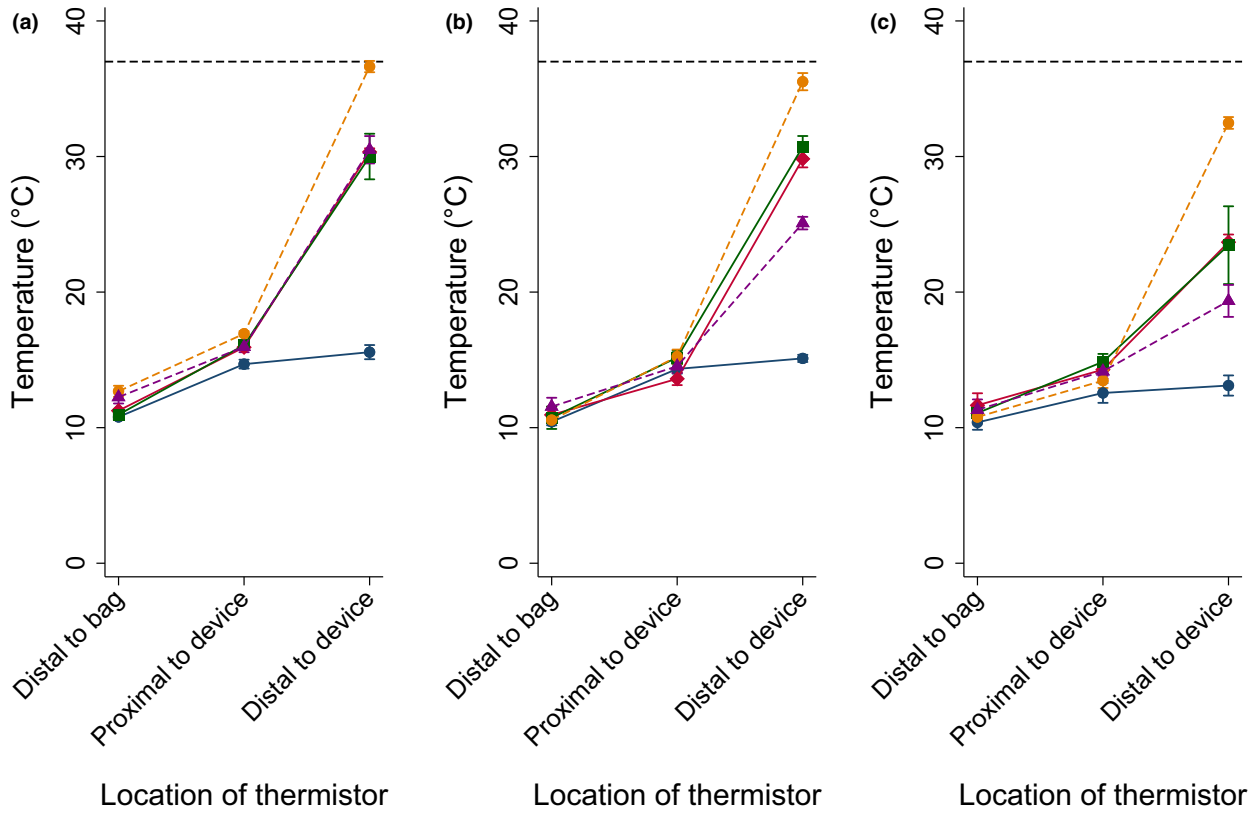

Figure 2 Temperature (°C) at various sites in the circuit by warming device at: (a) 50 ml.min^{-1}; (b) 100 ml.min^{-1} and (c) 200 ml.min^{-1}. Warming devices tested were: control (solid navy line with circle ●); Thermal Angel (solid cranberry line with diamond ◆); Hypotherm X LG (solid dark green line with square ■); °M Warmer (dashed dark orange line with circle ●) and Buddy Lite (dashed purple line with triangle ▲). Reference line (black dash) at 37 °C. Values are estimated mean (SD) from the generalised estimating equation models.

Angel, Hypotherm X LG and Buddy Lite were: 10.6 (8.7–12.4); 10.4 (4.5–16.2); and 6.2 (3.5–9.0), respectively. The highest temperature increase was seen with °M Warmer (19.4, (17.7–21.1)).

We recorded 129 fHb concentrations. Overall, there were no differences in the mean fHb between warming devices ($p = 0.949$), between sites in the circuit ($p = 0.680$), or by flow rate ($p = 0.169$). However, there were significant differences in fHb changes in devices between sites ($p < 0.001$); haemolysis occurred in the control at 200 ml.min^{-1} ($p < 0.001$), and in the Buddy Lite at 50 ml.min^{-1} ($p = 0.039$). Nonetheless, net changes in mean fHb concentrations were not different to the control for all commercial warming devices at all flow rates (Table 2).
[Correction added on 9 May 2019, after first online publication: p value in between sites in the circuit updated.]

Discussion

All devices warmed the blood relative to the control sample at all flow rates tested. However, there were significant differences between devices, which became more marked as flow rates increased. The °M Warmer was the only device to achieve a mean temperature greater than 35 °C when measured at 50 ml.min^{-2} and 100 ml.min^{-2}, and more than 32 °C at a flow rate of 200 ml.min^{-2}. Performances of the Hypotherm X LG and the Thermal Angel were similar to each other, and the performance of the Buddy Lite was comparatively less effective. None of the devices tested appeared to produce significant haemolysis, even at higher flow rates.

Factors that may affect usability of the devices in the field were also observed during the testing process. The Hypotherm X LG required vertical positioning with fluid flowing through the device, otherwise it would not initialise. Although this was a minor inconvenience in the laboratory, ensuring these conditions are met during field operations while resuscitating critically ill patients would add additional cognitive load for clinicians, which was not required with the battery-operated devices. Additionally, the Buddy Lite

Table 2 Free haemoglobin concentration (mg.100 ml^{-1}) at various sites in the circuit by warming device and flow rate. Values are estimated mean (SD) from the generalised estimating equation models. The 95%CI are Bonferroni adjusted for mean and net changes.

		Location on the circuit				
Device	**Flow rate ($ml.min^{-1}$)**	**Below collection bag (Site 1)**	**Before device (Site 2)**	**Distal to device (Site 3)**	**Mean change (95%CI)a**	**Net change (95%CI)b**
Control	50	83.4 (7.2)	91.1 (6.6)	83.4 (10.4)	0 (−8.9 to 9.0)	–
	100	66.1 (4.8)	70.3 (2.5)	69.5 (1.9)	3.4 (−12.1 to 18.8)	–
	200	36.4 (1.5)	50.7 (1.3)	43.2 (1.4)	6.8 (2.8 to 10.9)	–
Thermal angel	50	56.8 (9.7)	60.2 (10.9)	66.3 (9.5)	9.4 (−1.2 to 20.1)	9.4 (−5.3 to 24.1)
	100	37.7 (8.0)	45.1 (9.9)	51.8 (14.6)	14.1 (−6.5 to 34.7)	10.7 (−16.7 to 38.1)
	200	64.7 (14.3)	77.7 (6.7)	73.4 (4.5)	8.7 (−20.4 to 37.7)	1.8 (−29.3 to 32.9)
Hypotherm X LG	50	81.5 (17.3)	71.5 (10.6)	81.8 (12.6)	0.4 (−11.7 to 12.4)	0.3 (−15.6 to 16.2)
	100	45.4 (10.3)	44.2 (10.4)	55.6 (5.6)	10.2 (−3.0 to 23.4)	6.9 (−14.7 to 28.4)
	200	60.5 (7.4)	56.5 (6.0)	63.2 (9.6)	2.7 (−3.2 to 8.6)	−4.1 (−11.7 to 3.4)
°M Warmer	50	107.7 (51.6)	72.6 (20.8)	73.4 (24.4)	−34.3 (−104.9 to 36.4)	−34.3 (−109.9 to 41.3)
	100	33.9 (0.9)	30.9 (6.4)	37.5 (2.5)	3.6 (−0.7 to 7.9)	0.2 (−16.8 to 17.3)
	200	72.7 (7.4)	65.5 (10.8)	75.1 (10.4)	2.4 (−17.1 to 21.8)	−4.5 (−25.6 to 16.6)
Buddy lite	50	49.0 (26.1)	62.2 (21.9)	67.0 (20.0)	18.0 (0.6 to 35.4)	18.0 (−2.8 to 38.8)
	100	62.4 (5.7)	83.3 (14.3)	74.4 (10.3)	12.0 (−0.5 to 24.5)	8.6 (−12.5 to 29.7)
	200	59.0 (15.1)	56.4 (18.0)	37.0 (4.4)	−22.0 (−58.9 to 14.9)	−28.8 (−68.2 to 10.6)

[a]Temperature at site 3 minus site 1. 95%CI are Bonferroni adjusted.
[b]Device at specified flow rate minus corresponding control device at same flow rate.

appeared to shut down at higher flow rates on most occasions during our testing.

Our results are similar to a recent study which also compared the performance of pre-hospital fluid-warming devices utilising normal saline as the test fluid [14]. Two of the four devices in this prior study were also investigated in the present study, however, the other two devices which weighed more than 1 kg were excluded. The results reported in this previous study using the Buddy Lite and the Thermal Angel when heating saline from 10 °C, were similar to our results using the same devices when warming refrigerated red cell concentrates. We also noted in our present study that the temperature output of the Buddy Lite was unstable during the initial 30 min of use, with heating provided intermittently. This behaviour may have accounted for our observation that the Buddy Lite appeared to cease functioning, particularly at higher flow rates. This observation may have aligned with one of the periods of absent warming, resulting in the impression that the device had shut down, and it is possible that heating may have been again observed had the experiment continued for a longer period of time. Other authors have also noted poorer performance of the Buddy Lite compared with other warmers at flow rates of 100 $ml.min^{-1}$ or greater [15, 16]. We believe our study is the first to evaluate the comparative performance of the Hypotherm X LG or the °M Warmer devices.

The testing was conducted under laboratory conditions, with an average ambient temperature of 23 °C. It is possible that a different temperature gradient between the exposed tubing and the environment would produce greater or lesser degrees of heating than observed in our study by affecting the input temperature to the warmer. Flow was maintained through the warmer using roller pumps. In real-world pre-hospital practice, manual pumping that is pulsatile in nature is the most common method of providing high flow rates. We did not test flow produced by manual pumping in this study due to the inherent difficulty in maintaining constant conditions, to enable a valid comparison between devices. We are unable to determine from our data whether manual pumping would produce different results. As we did not consider the release of aluminium ions into red cell concentrate units, a potential safety issue recently highlighted with uncoated aluminium heating plates in some warming devices for balanced crystalloid solutions [17], its implication in transfusion management is unclear. Additionally, we made a pragmatic decision to test only devices that weighed less than 1 kg due to the requirement to carry the devices in our backpacks. This a priori weight cut-off was arbitrary and for

other services heavier devices may also be acceptable. The °M Warmer device tested by us was a pre-release version before CE certification. The manufacturer has indicated that the device as tested by us is identical to the device that has since gained CE certification.

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