Anesthesiology
73:173–176, 1990

Evaluation of a New High-Efficiency Blood Warmer for Children

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Because currently available blood warmers are inadequate for infants and children requiring massive transfusion, the performance of a new high-efficiency pediatric blood warmer (System 250™, LEVEL 1® Technologies Inc., Marshfield, Massachusetts) was evaluated and compared with a commonly used conventional blood warmer (Model DW1000A, American Pharmaseal, Valencia, California). Cold (5–6° C), diluted red blood cells (RBC) (Hct = 30%) were infused through the warmers over a series of flow rates, and the resulting temperatures of the infusate were measured. The flow rates of diluted packed RBC were also measured over a series of infusion pressures. At a flow rate of 225 ml/min, the output temperature of the System 250™ was 33.6° C compared with 24.6 ° C ($P < 0.05$) for the conventional warmer. Above a flow rate of 250 ml/min, however, the water bath of the System 250™ cooled significantly, resulting in a deterioration of performance and an output temperature of only 24.2° C at a flow rate of 400 ml/min. With a 16-G catheter attached, the flow rate at a pressure of 300 mmHg was 223 ml/min through the System 250™ compared with 160 ml/min ($P < 0.05$) for the conventional warmer. The System 250™ produced higher output temperatures and a lower resistance to flow compared with the conventional warmer, but flow rates of cold blood through the System 250™ should be restricted to 250 ml/min or less to ensure adequate warming. (Key words: Blood: massive transfusion. Equipment: blood warmer; countercurrent heat exchanger.)

MASSIVE HEMORRHAGE is a common occurrence in cases of trauma and radical surgical procedures, such as liver transplantation.[1] In these situations rapid replacement of blood loss is required to correct the resulting hypovolemia. Transfused blood products must be adequately warmed to prevent hypothermia. Conventional blood warmers do not meet these requirements because of their high resistance to flow and inadequate warming at high flow rates. Although devices providing efficient warming at high flow rates and low resistance have been developed for adult patients, they are not entirely satisfactory for children because of their large priming volumes.[2] In search of an appropriate blood warmer for pediatric patients requiring massive transfusion, we evaluated the performance of the System 250™ (LEVEL 1® Technologies Inc., Marshfield, Massachusetts) and compared it with the performance of a commonly used conventional blood warmer (Model DW1000A, American Pharmaseal, Valencia, California).

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Received from the Department of Anesthesia, Riley Children's Hospital, Indiana University School of Medicine, Indianapolis, Indiana. Accepted for publication March 1, 1990.

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Materials and Methods

The System 250™ was equipped with a disposable set (D50, LEVEL 1® Technologies Inc., Marshfield, Massachusetts), which contained a 70 μm blood filter, and the conventional warmer was equipped with a blood recipient set containing an 80 μm filter (Fenwal 4C2138, Travenol Laboratories, Deerfield, Illinois). Packed red blood cells (RBC) diluted with normal saline (Hct = 30%) and cooled with a countercurrent heat exchanger (HE100, Bently, Chicago, Illinois) packed in ice were infused through each warmer with a roller pump (S10KII, Sarns, Ann Arbor, Michigan) (fig. 1). The temperature of the infused blood ranged from 5.0 to 6.0° C. Roller pump calibration was confirmed with a stopwatch and a graduated cylinder and was accurate within 10 ml/min over the flow range of 0–400 ml/min. The output temperatures of each warmer were measured over a series of flow rates with a thermocouple connected to a digital meter (503-0102, Mona-therm, St. Louis, Missouri). The thermocouple was placed inside a 6-Fr catheter connected to the end of the warmer tubing sets. Thermocouple calibration was checked with a mercury thermometer and was accurate within 0.5° C over the temperature range of 0–40° C. The water bath temperature of the System 250™ was read from a digital display located on the unit. The warming plate temperature of the conventional warmer was read from an analog dial located on the unit. At each flow rate the lowest stable temperature of the warmer and the blood flowing out of the system was recorded. Output temperatures as a function of flow were fitted (ASYSTANT™, ASYST Software Technologies, Rochester, New York) to the equation for blood temperature in a channel flow device,[3] which includes the effect of cooling in the delivery tubing beyond the warmer:

$$T_d = T_r + (T_b - T_r)e^{A/F} + (T_i - T_b)e^{B/F}$$

where T_d is the temperature of the blood delivered to the patient, T_r is room temperature, T_b is the temperature of the warming plate or water bath, T_i is the temperature of the blood as it enters the warmer, F is the flow rate through the system, and A and B are time constants unique to the warmer, its tubing, and the physical properties of the fluid that is warmed. The constants A and B, which were obtained from the regression routine, are referred to as the apparent thermal clearances and represent the flow rates at which output temperature has reached 63% of its limiting value. The constant A is the apparent thermal clearance of the extension tubing alone,

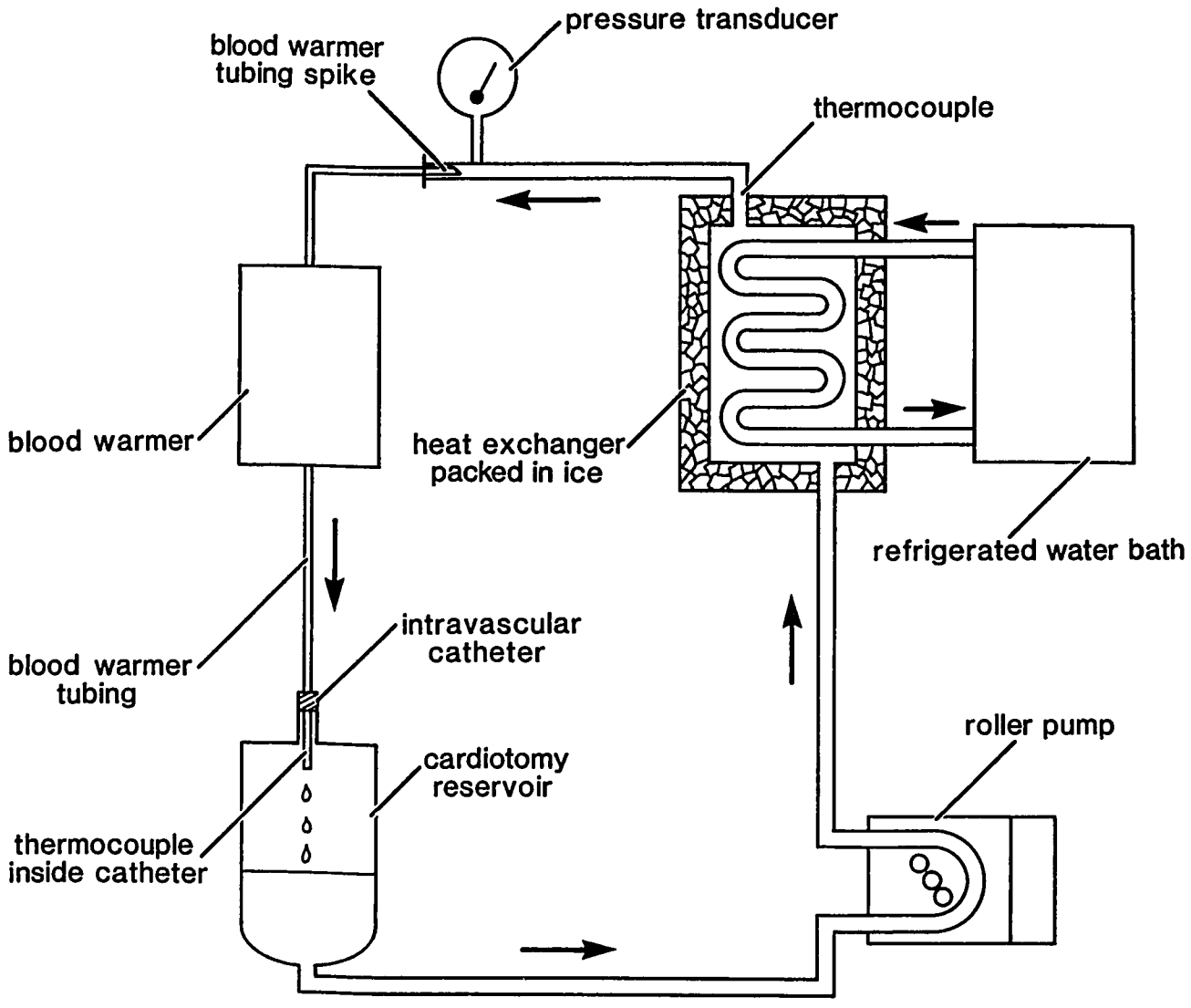

FIG. 1. Diagram of the test apparatus.

and B is the apparent thermal clearance of the warmer and extension tubing combined. The temperature *versus* flow curves thus obtained for each device were compared with a one-way nonlinear analysis of covariance.[4] The level of significance was $P < 0.05$ for all statistical tests.

In a separate set of measurements, resistance to blood flow through the warmer circuits was tested. Infusing pressures were measured over a series of flow rates through each warmer by a pressure transducer (53-DTS-260, American Edwards Laboratories, Irvine, California) located at the inlet of the warmer tubing set. These measurements were made with 6-Fr I.D., 10 cm long pediatric introducer sheaths (AK-09601, Arrow, Reading, Pennsylvania) connected to the ends of the warmer circuits and were repeated with 16-G I.D., 5 cm long intravenous (iv) catheters (38-2814-1, Deseret, Sandy, Utah) attached. The tips of the cannulae, which drained into a cardiotomy reservoir, were at the same gravitational level as the warmer inlet and the pressure transducer. The highest flow rate tested for each device was the rate at which the inlet pressure was ≥300 mmHg. Flow was assumed to be turbulent for both devices because flow did not increase linearly with pressure. Under these conditions flow as a function of pressure is given by an equation of the form:

$$F = AP^{1/B}$$

where F is the flow rate through the system, P is the pressure driving flow, and A and B are constants unique to that particular system.[5] Flow and pressure were fitted to a linear transformation of this equation using linear regression. These curves were then compared with analysis of covariance.[6]

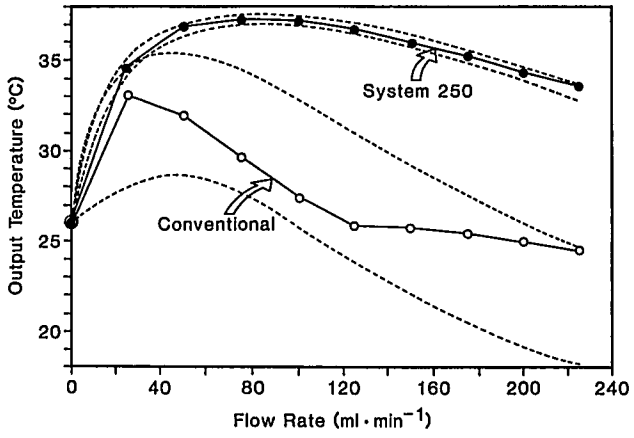

FIG. 2. Comparison of the output temperatures of diluted red blood cells (Hct = 30%) infused at 5–6° C. System 250™ (●), conventional warmer (O), (– – –) 95% confidence limits of the predicted values from the regression of temperature *versus* flow.

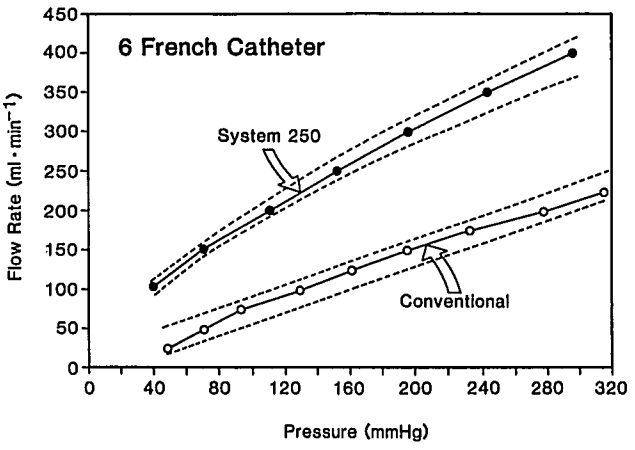

FIG. 4. Comparison of the flow rate of diluted red blood cells (Hct = 30%) infused through a 6-Fr ID catheter. System 250™ (●), conventional warmer (O), (– – –) 95% confidence limits of the predicted values from the regression of flow *versus* pressure.

Results

The output temperature from the System 250™ was higher than that from the conventional warmer above a flow rate of 40 ml/min (fig. 2). At a flow rate of 225 ml/min, the output temperature of the System 250™ was 33.6° C, whereas that of the conventional warmer was only 24.6° C. However, the bath temperature of the System 250™ fell at flow rate greater than 250 ml/min, causing a deterioration of warming performance and an output temperature of only 24.2° C at a flow rate of 400 ml/min (fig. 3).

For every infusion pressure flow rates through the System 250™ were higher compared with the conventional warmer with either the 6-Fr or 16-G cannula attached (figs. 4 and 5). At an infusing pressure of 300 mmHg, the flow rate through the System 250™ with a 6-Fr catheter attached was 400 ml/min compared with 214 ml/min through the conventional warmer. With a 16-G catheter attached, the flow rate at this pressure was 223 ml/min through the System 250™ compared with 160 ml/min for the conventional warmer.

Discussion

The System 250™ incorporates a single-channel countercurrent heat exchanger warmed to 40° C by a circulating water bath. This is a more efficient method of warming blood than that employed by the conventional warmer. This is demonstrated by a thermal clearance of 427 ml/min for the System 250™ compared with 183 ml/min for the conventional warmer. Although the Sys-

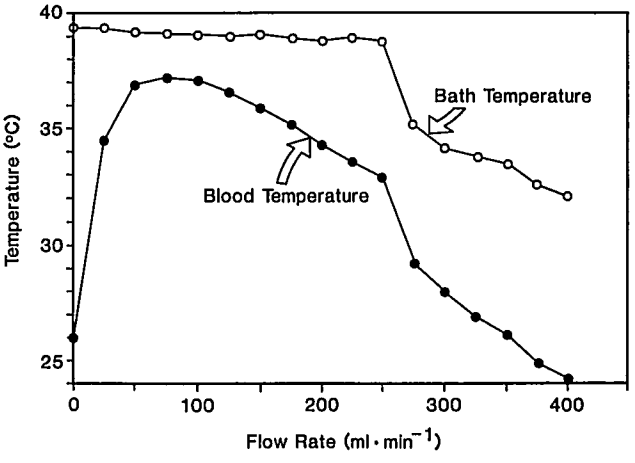

FIG. 3. Output temperature (●) and bath temperature (O) of the System 250™.

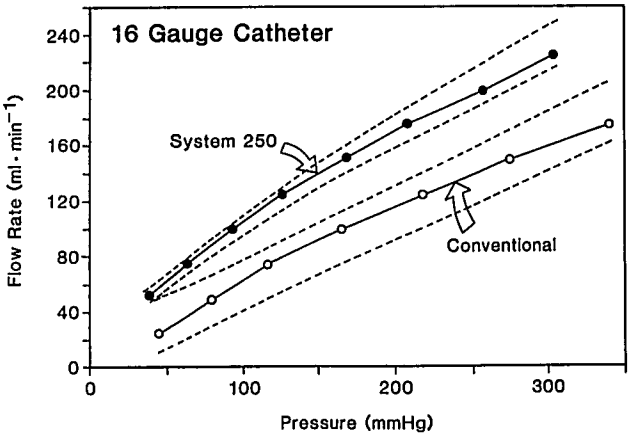

FIG. 5. Comparison of the flow rate of diluted red blood cells (Hct = 30%) infused through a 16-G ID catheter. System 250™ (●), conventional warmer (O), (– – –) 95% confidence limits of the predicted values from the regression of flow *versus* pressure.

tem 250™ is a more efficient warmer, there was no statistically significant difference in the temperature of blood delivered at low flow rates (<40 ml/min). This occurred because blood cooled[7] as it passed through the length of tubing (System 250™ = 188 cm, conventional warmer = 170 cm) exposed to room air that connects the warmer to the patient (fig. 2). At higher flow rates, however, the delivered temperatures were different. This is important because massive infusion of blood cooler than 30° C is associated with ventricular fibrillation and cardiac arrest, especially if blood is infused directly into the heart through a central vein.[8] This critical temperature was reached at a flow rate of 275 ml/min through the System 250™ compared with a flow rate of only 75 ml/min through the conventional warmer. It follows that flow rates through the System 250™ should be limited to 250 ml/min or less, which is probably adequate for most pediatric patients.

Because the peak flow rate delivered to the patient is dependent on the resistance to flow through both the blood warmer and the iv catheter attached to it, we measured flow through the warmers with two commonly available types of catheters appropriate for use in a pediatric patient requiring rapid transfusion. The resistance to flow through the System 250™ was less than that through the conventional warmer with either catheter type tested. However, there was no advantage to infusion through the 6-Fr catheter because this permitted flow rates that exceeded the capacity of both devices to warm blood adequately. Although flow resistance was less through the System 250™, flow was also more turbulent as demonstrated by the greater departure from linearity of the flow *versus* pressure curves for this device (figs. 4 and 5). This was probably the result of the rifling present in the channel of the countercurrent heat exchanger, which promotes mixing and heat exchange in the column.

Although the System 250™ produces greater warming and lower resistance to flow, it is also more expensive. The System 250™ warmer costs $2,500 compared with $495 for the conventional warmer. Disposable sets for the System 250™ are $25 each compared with $8.38 for the conventional warmer. Because the conventional warmer disposable set does not contain a blood filter, a blood administration set, which costs $2.80, is also needed, bringing the total cost for disposables to $11.18 for the conventional warmer.

We conclude that the System 250™ provided greater warming and lower resistance to flow compared with the conventional warmer above flow rates of 40 ml/min, but flow rates of cold blood through the System 250™ should be restricted to 250 ml/min because warming was inadequate above this flow rate.

The authors wish to thank Dr. Gopal Krishna and Dr. Wiltz W. Wagner, Jr., for helpful criticism of the manuscript.

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