

## Preventing hypothermia during continuous veno-venous haemodiafiltration: a randomized controlled trial

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**Background.** Continuous veno-venous haemodiafiltration is a common form of dialysis used in intensive care units. Unfortunately, patients often experience hypothermia as a side-effect of the therapy because of the necessity for extracorporeal blood flow. Intensive care nurses aim to prevent hypothermia developing. Intravenous fluid warmers are sometimes added to the dialysis circuit in an attempt to maintain patient temperature. However, the efficacy of this method has not been previously studied.

**Aim.** This paper reports a study to investigate whether intravenous fluid warmers prevent hypothermia during continuous veno-venous haemodiafiltration.

**Method.** A prospective randomized controlled trial was carried out in the intensive care unit of a metropolitan, tertiary-referral, teaching hospital. After Ethics Committee approval, 60 circuits in continuous veno-venous haemodiafiltration mode (200 mL/minute blood flow, 1 L/hour countercurrent dialysate, 3 L/hour pump-controlled ultrafiltration and prefilter fluid replacement of 1.72.0 L/hour) were studied. Circuits were randomized to have either an intravenous fluid warmer set at 38.5°C on the dialysate and 1 L/hour of replacement fluid lines or no fluid warmer. Patient core temperature was recorded at baseline and then hourly. Hypothermia was defined as a core temperature <36.0°C.

**Results.** Mean core temperature loss did not vary between circuits with or without a fluid warmer (0.92°C vs. 1.11°C,  $P = 0.339$ ). Survival analysis found no difference in hypothermia incidence between groups (log rank = 0.47, d.f. = 1,  $P = 0.491$ ). Lower baseline temperature (RR 0.142, 95% CI 0.044, 0.459,  $P = 0.001$ ) and female gender (RR 0.185, 95% CI 0.060, 0.573,  $P = 0.003$ ) were significant risks for hypothermia.

**Conclusions.** Intravenous fluid warmers used as described do not prevent hypothermia during continuous veno-venous haemodiafiltration. Female patients and those with a lownormal baseline temperature are most likely to become hypothermic during this form of dialysis. Further research is needed to address effective ways of preventing hypothermia in critically ill patients receiving continuous renal replacement therapies.

### **What is already known about this topic**

Hypothermia is a common complication of continuous renal replacement therapies in critically ill patients.

Hypothermia is an undesirable condition with negative physiological sequelae.

Continuous veno-venous haemodiafiltration is a frequently used form of continuous renal replacement therapies.

### **What this paper adds**

The first data on the efficacy of an intervention (intravenous fluid warmers) to prevent hypothermia in patients receiving continuous veno-venous haemodiafiltration.

Information and quantification regarding risk factors for hypothermia in continuous veno-venous haemodiafiltration.

### **Background**

Up to 25% of intensive care unit (ICU) patients develop acute renal failure (ARF) (de Mendonca et al. 2000). Only a small number of these patients have primary renal disease with the majority developing ARF secondary to sepsis and septic shock (Silvester et al. 2001). Typically, ARF resolves when the underlying diseases abate, but until then patients who are unable to remove their own fluid and solute waste, require renal dialysis. ICU patients lack the haemodynamic stability necessary to undergo the traditional forms of dialysis, which involve the exchange of large amounts of fluids over short periods of time. A better result, with fewer complications, is achieved through the use of continuous renal replacement therapy (CRRT), which involves a slower exchange of fluids over a continuous 24-hour period (van Bommel et al. 1994, Holt et al. 1996).

During CRRT, as with other forms of haemodialysis, the patient's blood must leave the body and travel over a filter membrane via plastic tubing. This blood is exposed to the cooler ambient environment and CRRT fluids, returning to the patient's bloodstream at a lower temperature. Experimental work has identified a 1.95.5°C drop in blood temperature between the arterial and venous circuit lines of one mode of CRRT (continuous veno-venous haemodialysis), with temperature loss increased by faster dialysate and/or slower blood flows (Yagi et al. 1998).

The phenomenon of CRRT-related hypothermia is well acknowledged (Ronco 1993, Bellomo & Ronco 1999) but little studied. This may be because the therapy is relatively new, or because hypothermia is not perceived as a serious complication. Although in our setting, temperatures below 36.0°C are interpreted as hypothermia

and treated, there is no internationally recognized definition and others consider lower temperatures acceptable, for example, 35.0°C (Danzl & Pozos 1994, Curley 1995).

The limited research that does exist about hypothermia during CRRT focuses on incidence rather than prevention, and is difficult to compare because of the many different models of CRRT in use. Arterio-venous CRRT therapies have largely been replaced over the past decade by the veno-venous modalities of continuous veno-venous haemodiafiltration (CVVHDF), continuous veno-venous haemofiltration (CVVHF) or continuous veno-venous haemodialysis (CVVHD) (Holt et al. 1996, Silvester et al. 2001).

The incidence of hypothermia in patients receiving CRRT has been measured during a variety of arterio-venous and veno-venous modalities at 25.5%, although definitions used for hypothermia have varied (Matamis et al. 1994, Yagi et al. 1998). In one report, veno-venous modes were found to have almost twice the incidence of hypothermia of arterio-venous regimes (Yagi et al. 1998). No data have been published on the incidence of hypothermia specifically in CVVHDF; however, it is likely to be as high as or higher than that quoted for other CRRT regimes, because of the larger volume of fluid exchange. Other factors identified in prospective clinical research as associated with an increased risk for hypothermia during CRRT include an increased ultrafiltration rate and the use of muscle relaxants (Matamis et al. 1994).

Although hypothermia is reported to be associated with various forms of CRRT, it is surprising that there have been no published evaluations of any of the many preventative methods employed. CRRT circuits differ between modes (and even for the same mode between hospitals), as do beliefs about appropriate methods to preventing and treating CRRT-related hypothermia.

One method used in an attempt to prevent hypothermia is the incorporation of an intravenous fluid warmer into the CRRT circuit. These fluid warmers are designed for use in intravenous therapy and blood transfusions. However, because the necessary tubing can be fitted into CRRT circuits, the practice has gained support from many clinicians. Intravenous fluid warmer use with CRRT has never been evaluated for effectiveness. However, use on the arterio-venous fistulae of extracorporeal circuits has been found effective to treat non-CRRT-related hypothermia (Gentilello et al. 1990, Gentilello & Moujaes 1995).

### **Significance**

The need to prevent hypothermia in patients receiving CRRT is repeatedly stated in the literature (Ronco 1993, Bellomo & Ronco 1999). However, we could find no published data on effective ways to achieve this. In our institution, and others, intravenous fluid warmers were used semi-regularly but haphazardly and often in conjunction with other heating systems in the belief that they might prevent CVVHDF-induced hypothermia. As there was no evidence on the efficacy of this practice, the following research project was undertaken.

The study Go to: ChooseTop of pageWhat is already known abo...What this paper addsBackgroundThe study <<SampleResultsDiscussionConclusionsAuthor contributionsFundingAcknowledgementsReferences

**Aims**

The aim of the study was to test whether fluid warmers prevent hypothermia in patients receiving CVVHDF.

**Design**

A prospective, randomized controlled clinical trial was conducted.

**Research setting**

The study was undertaken in the 18-bed intensive care unit of a 700-bed metropolitan, tertiary-referral, teaching hospital. The unit has its own nursing staff, a large number of whom have ICU qualifications. Over 1400 patients are admitted per annum, and have an average length of stay of 4 days.

**Sample size**

A power calculation determined that the minimum sample size required to detect 0.5°C difference in temperature loss between the two groups, with 80% power at the 0.05 significance level was 2530 per group. The analysis used data from our historical records of a mean temperature loss of 1.0°C in patients undergoing CVVHDF, regardless of the presence or absence of a variety of heating therapies

**Sample**

Sixty CVVHDF circuits were enrolled into the study. A sequential sampling method was used to recruit all patients who met the following inclusion criteria: prescribed continuous renal replacement therapy according to the unit protocol, at least 18 years of age, and a baseline temperature of 36.0-39.5°C. Patients were not enrolled if they met any of the following exclusion criteria: malignant hyperthermia, receiving any form of heating or cooling therapy, or a diagnosis of burns.

**Data collection**

CVVHDF and fluid warmer protocol

Each CVVHDF circuit was randomized using a computer generated random number system to have a fluid warmer (treatment group) or not (control group). For circuits randomized to the treatment group, the 1 L/hour dialysate and 1 L/hour replacement fluid lines had warming tubing (Blood and Infusion Warmer Administration Set; Biegler Mauerbach, Austria) attached and inserted into the intravenous fluid warmer (Biegler Blood and Infusion Warmer BW 485/L, Mauerbach, Austria), according to the manufacturer's instructions. The fluid warmer had a standard preset temperature of 38.5°C. The warming tubing was attached to the dialysate and prefilter replacement fluids, not to the blood circuit, and had no impact on the length of the blood circuit. This placement was chosen as consistent with preexisting unit practice, as there were no published standards or examples of the technique. A standard CVVHDF regime was used for all patients, with a blood flow rate of 200 mL/minute, countercurrent dialysate rate of 1 L/hour through an AN69 ST (Hospal, Bologna, Italy) hollow fibre

membrane filter, controlled ultrafiltration rate of 3.0 L/hour and prefilter replacement fluids of 1.72.0 L/hour to achieve fluid loss or balance. All dialysis and replacement fluid bags (Gambro, Stockholm, Sweden), and a 0.71.0 L/hour replacement fluid line were at (air-conditioned) room temperature for patients in both groups. IMED® Gemini® infusion pumps (ALARISTM Medical Systems, San Diego, CA, USA) and a Gambro BMM-AK10 dialysis pump were used to control the fluid and blood flows respectively. Circuits were not anticoagulated. Figure 1 shows the configuration of circuits in the experimental group.

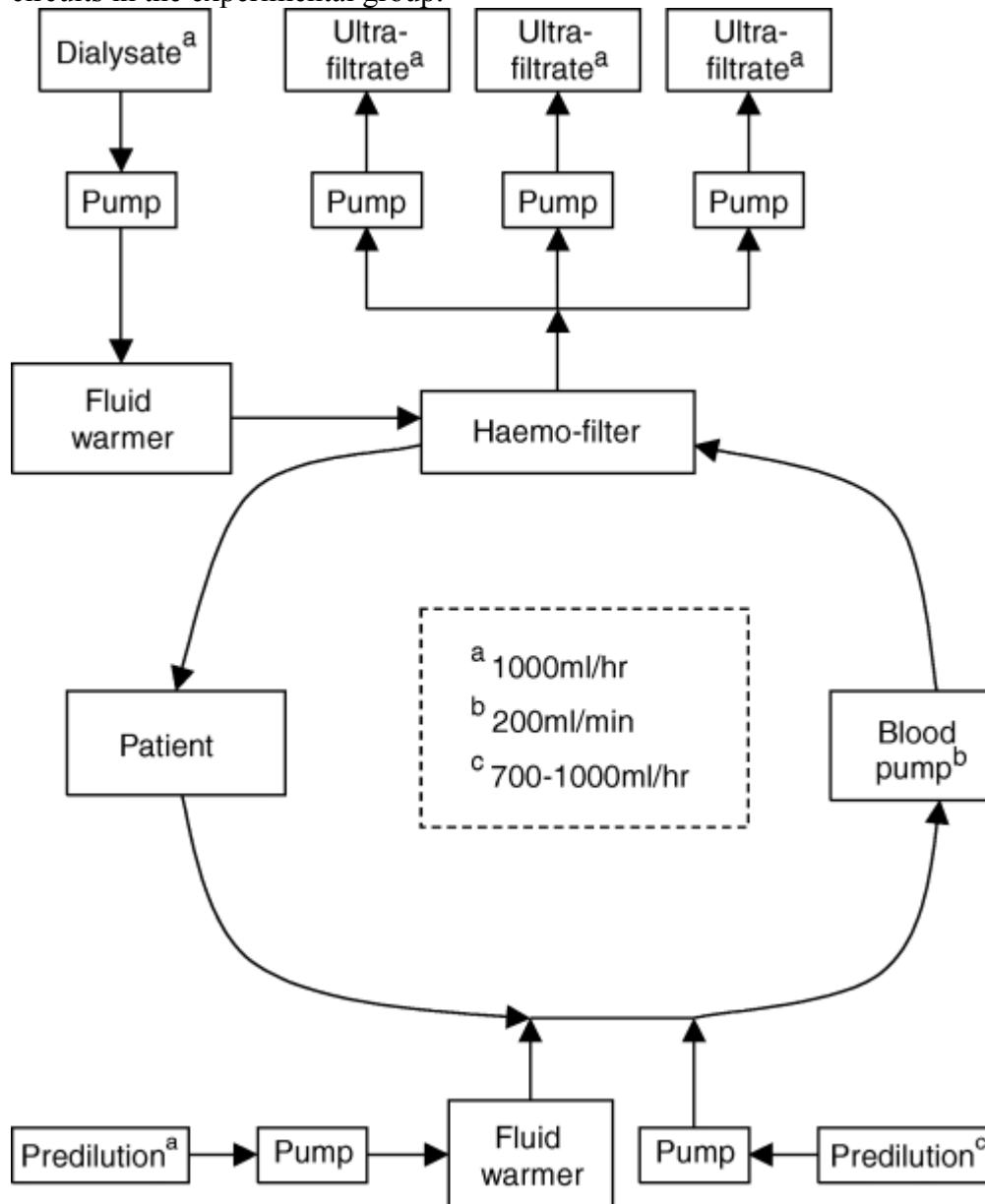


Figure 1 CRRT circuit configuration.

Patients continued on the same circuit for as long as it remained patent and they required the therapy. If the same patient required multiple circuits, then each circuit was randomized again if the patient still met all the inclusion criteria and none of the exclusion criteria, and at least 1 hour had passed between one circuit being removed and the next commencing.

### **Hypothermia data**

Patient core temperature was documented at baseline and then each hour thereafter using a rectal or oesophageal catheter probe, which was already in situ as part of standard ICU monitoring. The measurement sensitivity was 0.1°C. Patients had one cotton bed blanket but were not permitted to have any other form of heating or cooling therapy whilst in the study. The ICU was air conditioned at 22.0°C and maintained a relatively stable ambient temperature. If hypothermia occurred (defined as <36.0°C), the patient was removed from the study and actively rewarmed.

### **Demographic data**

Data were collected on the hours of CVVHDF circuit life and reason for removal (if not hypothermia). Data were also collected on patient age, gender, diagnostic group, APACHE II score on ICU admission, hours of sedation and paralysis treatment and number of CVVHDF circuits used.

### **Ethical considerations**

The Institutional Human Research Ethics Committee and the State Guardianship and Administration Tribunal approved the study protocol. The requirement for individual consent was waived in consideration of the low-risk nature of the study and the local legislative situation of the time, which precluded relatives from giving consent for research in unconscious patients. Information about the study was provided to patients' relatives, with the option to withdraw from the study without penalty. There were no requests for withdrawal.

### **Data analysis**

The primary hypothesis was that the incidence in hypothermia would not be different between patients with or without fluid warmers attached to their CVVHDF circuits. Because the circuits were used for varying lengths of time, there was also variation in the time that they were exposed to the risk of hypothermia. To account for this, the primary analysis for difference between groups over time was performed using KaplanMeier survival curves with log rank test. Survival was defined as the circuit being used for the duration of that dialysis session without the patient developing hypothermia. Each circuit was treated as an independent unit of measurement. Variables considered risk factors for hypothermia were tested for distribution between groups to assess for bias. Proportions were tested with chi-square statistic. Differences in mean scores of continuous variables were tested with t-test. Cox Regression analysis was performed to test the association of variables with time to hypothermia. Variables included use of a fluid warmer, age, gender, baseline temperature, APACHE II score, multiple circuits per patient, sedation, and muscle relaxants. A significance level of  $P = 0.05$  was used for all comparisons. All analyses were undertaken using the Statistical Package for the Social Sciences (SPSS®, Chicago, IL, USA).

## **Results**

### **Descriptive statistics**

Sixty circuits were randomized into the study from 26 patients. Nine of the circuits were excluded from analysis because of protocol violations, one for the use of additional warming therapy during the study and eight for non-protocol CVVHDF settings, such as larger ultrafiltration rates. Thus, a total of 51 CVVHDF circuits were analysed from 24 patients. Of these, 26 circuits were randomized to have a fluid warmer attached and 25 to have no fluid warmer. The study groups were well matched, with no significant difference for age, gender, APACHE II score on ICU admission, diagnostic group and other risk factors for hypothermia (Table 1).

**Table 1** Sample characteristics

	<b>Fluid warmer</b>	<b>No fluid warmer</b>	<b>Total</b>	<b>P value</b>
Patient age (mean years) (sd)	52.6 (15.4)	53.3 (15.5)	52.9 (15.3)	0.88
Male <i>n</i> (%)	19 (73)	19 (76)	38 (75)	0.81
Female <i>n</i> (%)	7 (27)	6 (24)	13 (25)	
Study circuit use (hours) (sd)	16.7 (14.4)	15.1 (14.2)	15.9 (14.2)	0.69
Apache II (mean) (sd)	28.2 (8.3)	28.3 (8.5)	28.2 (8.3)	0.94
Paralysis ( <i>n</i> )	4	6	10	0.44
Sedation ( <i>n</i> )	19	19	38	0.81
Patients with multiple circuits ( <i>n</i> )	18	20	38	0.38
Diagnosis ( <i>n</i> )				0.77
Medical	14	13	27	
Surgical	5	3	8	
Neurological	4	5	9	
Trauma	3	4	7	

Table 1 Sample characteristics

### **Patient core temperature**

There were no significant differences between groups for mean baseline, minimum or maximum temperature or temperature loss during the study (Table 2).

	<b>Fluid warmer</b>	<b>No fluid warmer</b>	<b>Total</b>	<b>P value</b>
Baseline (mean)	37.49	37.65	37.57	0.41
Minimum (mean)	36.57	36.54	36.56	0.87
Temperature loss (mean)	0.92	1.11	1.01	0.34

Table 2 Patient core temperature data (°C)

### Reason for completing study

The study protocol involved a cessation of study involvement if hypothermia occurred. There was no difference between groups as to removal from the study for the endpoint of hypothermia or for other reasons (Table 3).

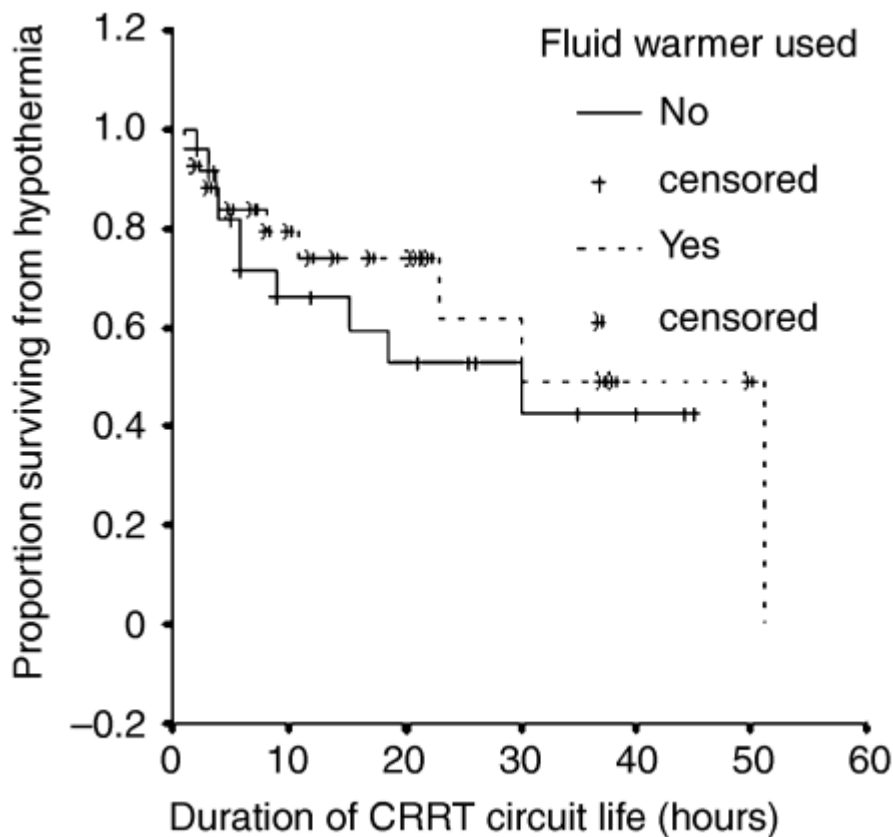
	Fluid warmer	No fluid warmer	Total
Hypothermia	9	10	19
Not required	1	2	3
Patient died	1	0	1
Circuit failure	12	9	21
Other	3	4	7

**Table 3** Reason for circuit removal

### Univariate analysis of survival from hypothermia

There was no significant difference in the incidence of hypothermia for patients with or without a fluid warmer (log rank test = 0.47, d.f. = 1, P = 0.491, Figure 2). The null hypothesis was therefore accepted. In order to assess the effect of individual patients on the study results, the analysis was also performed for the first circuit per patient only (n = 24) and for paired circuits (where an individual patient had a circuit in each of the two study groups, n = 28). The results of these analyses were consistent with the all circuit analysis, and hypothermia incidence remained not significantly different between groups.





Each + and\* is a circuit completing the study without hypothermia

Figure 2 Survival from hypothermia by fluid warmer (KaplanMeier).

### Multivariate analysis of survival from hypothermia

The final model found the two most powerful predictors of hypothermia during CVVHDF to be baseline temperature (RR 0.142, 95% CI 0.044, 0.459,  $P = 0.001$ ) and female gender (RR 0.185, 95% CI 0.060, 0.573,  $P = 0.003$ ). An increase in baseline temperature of  $1.0^{\circ}\text{C}$  decreased the risk of being hypothermic by about 86%. Alternatively, a decrease of  $1.0^{\circ}\text{C}$  in the baseline temperature increased the risk of hypothermia approximately sevenfold. Female gender increased the risk of hypothermia by a factor of 5.4. Baseline temperature by gender was not significantly different (males  $37.57^{\circ}\text{C}$ , females  $37.55^{\circ}\text{C}$ ).

Discussion Go to: ChooseTop of pageWhat is already known abo...What this paper addsBackgroundThe studySampleResultsDiscussion <<ConclusionsAuthor contributionsFundingAcknowledgementsReferences

Hypothermia is an undesirable complication in patients receiving CRRT. A variety of methods are used in attempting to prevent hypothermia, but surprisingly until now there has been no published research into which methods are effective, nor their comparative value. To our knowledge, this is the first study to evaluate the efficacy of using intravenous fluid warmers in the CRRT circuit to prevent therapy-induced hypothermia.

Our results suggest that intravenous fluid warmers do not prevent hypothermia in patients receiving CVVHDF. The practice of configuring a circuit with a fluid warmer

involves the costs of the device and the additional disposable equipment and nursing time required to undertake the procedure. The additional handling and interruption to the circuit also theoretically increases the risk of microbial contamination. If the practice of using fluid warmers is abandoned based on this study, there will be savings in equipment costs, nursing time, and environmental wastage.

Although we did not find a positive effect from the use of fluid warmers, we note that this is the first study into the phenomenon and, as such, the results may be related to the study design or sample rather than the treatment itself. The study had 80% power to detect a difference of 0.5°C between the groups at  $P = 0.05$ . It is possible that a larger study might have found a significant difference between groups, but this could only have been a difference of 0.5°C or less, which is arguably of negligible clinical value.

Patients in the two study groups were well-matched and were strictly monitored for adherence to the study protocol. The only known significant difference between the two groups was the use of the intravenous fluid warmer on the CVVHDF circuits in the treatment group. Our decision to assign the unit of measurement as individual circuits rather than patients may have meant that individual patient effects were not controlled for, and it also introduced some degree of multicollinearity into our tests. However, on restricting the analysis to the first circuit per patient only, or to matched pairs (one circuit from each study group per patient), we still did not find a significant difference in hypothermia between groups, which gives some support to our method.

Probably the most important factor to consider in the interpretation of these results is the influence of the CRRT regime used, that is, CVVHDF. Matamis et al. (1994) found that an increased ultrafiltration rate significantly correlated ( $r = 0.68$ ,  $P < 0.01$ ) with hypothermia in patients receiving the non-dialytic therapies of CAVHF and CVVHF. Our ultrafiltration rate of 3 L/hour was relatively high, and the hypothermic effect of this, combined with the hypothermic effect of the dialytic counter-current, may have outweighed any small protective effect that the fluid warmer could provide. The study involved the use of one fluid warmer set at 38.5°C, which incorporated a dialysate line at 1 L/hour and a replacement line at 1 L/hour. Additional unwarmed replacement fluids were infused at 0.7 L/hour, in the context of a blood flow of 200 mL/minute and a pump-driven ultrafiltration rate of 3 L/hour. We chose this regime as it was the most clinically relevant to our practice. However, other institutions and clinicians who prefer different approaches will need to interpret the results in consideration of their circuit design and methods. It is entirely possible that some variation or variations in the fluid warmer-CRRT circuit set-up would demonstrate efficacy in preventing hypothermia, for example, multiple fluid warmers, a different brand of fluid warmer, a different temperature setting for the fluid warmer, placement of the fluid warmer on a different configuration of fluids, or direct warming of the blood tubing itself. Other preventative methods remain untested in the ICU population, for example, the microwave heating of fluids that is accepted practice during peritoneal dialysis (Armstrong & Zalatan 1992). There is much scope for future research to explore this area further.

The gender implication of results was of interest. Nine of 13 circuits from female patients (69%) were associated with hypothermia as opposed to only 10 of 38 from male patients (26%). This was despite an equivalent baseline temperature by gender

between circuits. Possibly there was a gender influence of muscle:fat ratios or body mass index. Weight data were not available for our study as patients were critically ill and bed-bound (fluid management is determined by clinical assessment). Yagi et al. (1998) performed a retrospective chart audit of 72 patients who received a variety of CRRT modalities and found that lower body weight was significantly associated with hypothermia, although the gender component of this was not discussed (Yagi et al. 1998).

The finding that baseline temperature was the most important risk factor for hypothermia was perhaps not surprising. Of the 15 patients whose baseline temperature was 37.0°C, 60% developed hypothermia. Incidence decreased to 33% of 27 patients with a baseline temperature of 37.138.0°C, and 11% of nine patients with baseline temperature of 38.1°C. No patients with a baseline temperature of 38.6°C became hypothermic. From these results and those of previous studies, it seems that CRRT patients can be expected to experience a minimum temperature loss of approximately 1.0°C, and therefore patients whose baseline temperature is below 37.0°C will need to be actively targeted for prevention and early detection of hypothermia. Fluid warmers as evaluated in this study will not be beneficial, but a multitude of other therapies remain untested and may be useful.

We found the hypothermia incidence in patients on CVVHDF to be 37%. Previous studies have reported hypothermic incidence of 55% in CAVHF/CVVHF (Matamis et al. 1994), 48% in CVVHD and 40% in CVVHF (Yagi et al. 1998). Our data are surprisingly comparable to those in earlier work considering differences in CRRT modes and regimes, as well as varying definitions of hypothermia. The dearth of studies investigating ways to prevent CRRT-related hypothermia is starkly incongruent with the high reported incidence of the phenomenon.

Our patients displayed an average temperature loss of 1.0°C. This figure is artificially reduced from that which would have been displayed had we not ceased their study participation once core temperature descended below 36.0°C. For example, previous studies that did not intervene when patients became hypothermic found higher average rates of temperature loss during CRRT of 1.6, 2.4 and 2.6°C (Matamis et al. 1994, Yagi et al. 1998). This variability is most likely explained by the types of CRRT treatments studied (CAVHF/CVVHF, CVVHD and CVVHF, respectively) and variation in research designs. In routine clinical (non-research) circumstances, ICU staff have been found to be particularly slow to react to hypothermia. A retrospective audit of the first admission day for 2362 ICU patients found that 25% of hypothermia cases (defined as <35.0°C) were left untreated, and not even noted in patient records as a problem (Wilson et al. 1991).

There is currently no consistently accepted definition of hypothermia. The recommended diagnostic criterion ranges from a temperature of <35.0°C (Danzl & Pozos 1994, Curley 1995) to <36.0°C (Weinberg 1993) or even <36.5°C (Elder 1984). Hypothermia has deleterious physiological effects stemming from a reduction in basal metabolic rate, and can debilitate cardiovascular, oxygenation, coagulation, renal, neurological and metabolic functioning, as well as being a subjectively unpleasant experience for the patient (Lilly 1990, Weinberg 1993). The extent and severity of organ involvement is directly related to the degree of hypothermia, with

more extreme reductions in temperature for extended periods of time correlating with an increase in mortality rate (Curley 1995).

In assessing the appropriate preventative and treatment regimes for hypothermia in patients undergoing CRRT, a decision must be made as to what patient temperature is considered acceptable. Mild hypothermia is considered relatively harmless and may even be beneficial in this population, as the natural compensatory responses to mild hypothermia include increases in systemic vascular resistance and cardiac output and a decrease in oxygen consumption (Weinberg 1993, Yagi et al. 1998). We chose the core temperature point for hypothermia diagnosis and intervention for the study protocol as  $<36.0^{\circ}\text{C}$  as this generally reflected current opinion and clinical practice in our institution. Earlier investigators in this area allowed the temperatures of 20 CVVHF/CAVHF patients to drop to a much lower mean level of  $34.8 \pm 0.8^{\circ}\text{C}$  and observed no negative sequelae in oxygenation or haemodynamic parameters (Matamis et al. 1994). The heterogeneity of opinion and practice regarding CRRT-related hypothermia reflects the current state of the literature: iatrogenic hypothermia is largely ignored in favour of prehospital accidental hypothermia leading to hospital admission. This is a potentially dangerous situation, as the morbidity and mortality risks of hypothermia are not related to aetiology but rather to the temperature itself. Iatrogenic forms of hypothermia (including CRRT-related) are known to be under-recognized, with effective prevention and treatment regimes largely unstudied (Wilson et al. 1991, Curley 1995). This is a situation for concern: iatrogenic hypothermia should be entirely preventable whilst patients are in our care.

### **Conclusions**

Intravenous fluid warmers do not prevent hypothermia in patients receiving CVVHDF. Significant factors for the risk of hypothermia are a low normal baseline temperature and female gender. The implications of abandoning the use of fluid warmers in this CRRT regime include savings in nursing time, disposable equipment costs and environmental waste. Infection risk may also be reduced because of less frequent interruption and manipulation of the CRRT circuit. Further research should be undertaken on fluid warmers as a possible preventative measure for hypothermia in different configurations and with different modes of CRRT. Use as a treatment for CRRT-related hypothermia (rather than prevention) is also an unexplored area. Other currently used thermoprotective methods also require scientific evaluation.

### **Author contributions**

CR and MH contributed to study conception and design. CR and BC contributed to data collection. CR and MM contributed to data analysis. CR contributed to drafting of manuscript. BC, MH and MM contributed to critical revisions of manuscript for important intellectual content. MM contributed to statistical expertise, CR and MH contributed to obtaining funding, BC and MM contributed to administrative, technical or material support.

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