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Clinical Evaluation of Fluido Compact®: A New Intravenous Fluid Warmer

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Abstract

Unintended peri-operative hypothermia is very common in surgical patients and is associated with adverse outcomes. Perioperative use of forced-air and intravenous fluid warmers is recommended for hypothermia prevention. This study evaluated the ease of use of Fluido® *Compact*, a new fluid warming device, and its ability to help as part of the intraoperative patient temperature management. It was used in 36 patients undergoing scheduled surgery at risk of hypothermia under regional, general or combined anesthesia, of more than one hour duration and with a predicted intravenous fluid administration of at least 1000 ml. The fluid warmer is very easy to set up. The disposable cassette has a very low (3 ml) priming volume and it is easy to handle and to place inside the warming module. Once connected to the main power outlet, it is ready to deliver fluid at target temperature in just a few seconds. Control panel is intuitive, and the one button operation system makes it safe and convenient. The combination of peri-operative patient surface warming with Mistral®-Air forced-air warming system and intravenous fluid warming with Fluido® *Compact,* that allowed the administration of IV perfusions at body temperature at the rate needed thus avoiding heat loss, helps to maintain intraoperative core temperature between 36.4˚C and 36.8˚C. A group of patients undergo a variety of surgical procedures with neuraxial, general or combined epidural-general anesthesia.

Keywords

Fluid Warming, Perioperative Normothermia, Anesthesia Equipment

1. Introduction

Unintended peri-operative hypothermia, defined as a core body temperature under 36˚C, is very common in surgical patients and is associated with adverse outcomes. Anesthetized patients are at risk of hypothermia due to absent beha-

vioral responses, inhibition of thermoregulatory control and increased heat loss to the cold environment of the operating room [1]. Complications related to peri-operative hypothermia are well documented and include thermal discomfort, morbid cardiac events, increased intraoperative blood loss and transfusion requirements, greater postoperative wound infection rates, prolonged postoperative recovery and hospital stay [2] [3].

The maintenance of peri-operative normothermia is a responsibility of the anesthesiologist. Core temperature should be measured continuously by using the same method, if possible, during surgery and in the postoperative period, to diagnose hypothermia and to guide thermal therapy [3].

Forced-air warming is the most common and extensively tested warming modality for effectiveness and for ease of use in the published literature. It outperforms passive insulation and circulating water matresses [3] [4].

In 2008, the national Institute for Health and Care (NICE) published clinical guideline addressing the prevention of accidental peri-operative hypothermia. Forced-air and intravenous fluid warmers were recommended for hypothermia prevention [5].

More recently, the German Society of anesthesiologists, together with other professional societies, have published their recommendations stating that in pediatric surgery warming infusion fluids should be always considered. In adults, fluids should be warmed by using "in-line warmers" (RL II) recommendation grade B when infusion rates are above 500 ml/h, or when blood products are transfused [6].

Intravenous Fluid Warmers

Fluid infusion, below body temperature, can be regarded as a form of active patient cooling. The intravenous administration of 1 litre of room temperature fluid (21˚C) decreases central body temperature by 0.25˚C. Fluid warming devices are designed to deliver perfusions at about body temperature, and their use has been recommended when more that 500 ml/h is considered in adults undergoing surgery [3] [4].

Warmed intravenous fluids in conjunction with heat conservation measures has been shown to reduce the incidence of peri-operative hypothermia in gynecology, abdominal and orthopedic surgery [4]. But warmed fluids do not actively warm patients, fluid warming by itself is not enough to maintain normothermia during most surgical procedures [3] [4].

Furthermore, in a trial of adult emergency department patients, infusing IV fluids warmed to body temperature was associated with improved comfort compared to room temperature fluids [7].

Intravenous fluid warming devices comprise a heater unit and a disposable that connects the bag of fluid to a cannula that is inserted in the patient's vein. Device design varies and this can influence its warming performance. The maximum flow rate at which the device will warm the fluid to the required temperature should be specified by the manufacturer. Giving warming alarms, ra-

ther than notifying the user whether the fluid temperature delivered is too warm or too low, is mandatory safety features.

There are several devices on the market and their heating methods include insulators, water bath, convective air systems, counter current heat exchange and passing intravenous tubing through heating blocks (dry warming) [4] [8]. Their ability to deliver heated fluid to the patient depends on the effectiveness of the warming method, the flow rate and the length of tubing between warmer and the patient.

Intraoperative intravenous fluid administration by anesthesiologists varies over a wide range of flow rates, from mililitres per hour in pediatric surgery to litres per minute during adult resuscitation [4]. The Fluido system, an infrared based system that varies heat delivery according to changes in flow, appears to be the most effective over the whole range of fluid flows. Is the only device that mantains a delivery temperature over a wide range of flow rates [4].

When fluid is delivered at a low flow rate, considerable heat loss occurs between the warmer and the patient. On the other side, at faster flow rates, efficacy is compromised by limited time and surface area for heat exchange as well as high resistance to flow through the warming apparatus.

When the heat exchanger is incorporated into the delivery tubing by circulating warmed water around a central delivery channel, as in the Hotline (Level 1 Technologies INC, Rockland, MA, USA), heat loss from fluid to environment at low flows is prevented [4]. But safety concerns have arised with regard to delivery fluid contamination because non sterile water that flows around can potentially contaminate the inner infusion lumen if a leak within the coaxial tubing occurs [4]. Morover they are very difficult and time consuming to be correctly cleaned.

Other ways to minimize heat loss across the tubing before reaching the patient is to reduce tubing length from the unit to the patient and building small warming devices that rest close to the patient.

2. Purpose

The purpose of the study was to evaluate the ease of use of a new fluid warming device designed for peri-operative intravenous fluid warming Fluido® *Compact* (The 37˚C Company, Amersfoort, The Netherlands) and its ability to help as part of the intraoperative patient temperature management directed towards normothermia maintenance.

3. Methods

After ethical clearance and written informed consent, Fluido® *Compact* was evaluated, from May until October 2016, in 36 patients undergoing scheduled surgery with regional, general or combined anesthesia. All surgical procedures were considered at risk of hypothermia because of large areas of surgical exposure, duration longer than one hour, a predicted intravenous fluid administration of at least 1000 ml, or that could need intraoperative blood transfusion.

Fluido® *Compact* is a small flexible "dry technology" intravenous fluid warmer, that has a coated aluminum disposable set (Figure 1) that connects to the hospital IV administration set and lodges inside the warming module, to remain in contact with the heat exchanger (Figure 2 and Figure 3). The control module attached to an IV pole, and with the warming module inside it, can be placed near the patients IV access (Figure 4 and Figure 5) or as another option, the warming module, due to its small size, can be detached from the control unit and placed on an arm board just at the side of the patients arm close to the IV catheter (Figure 6).

Figure 1. Coated aluminum disposable set.

Figure 2. Disposable set inside warming module.

Figure 3. Disposable set correctly placed inside warming module, as show by green light, and ready to use.

Figure 4. Control module. One button operating display. Warming module lodged.

Figure 5. Warming module in the control module position. Patient line connected to IV catheter. Mistral air forced air warming unit.

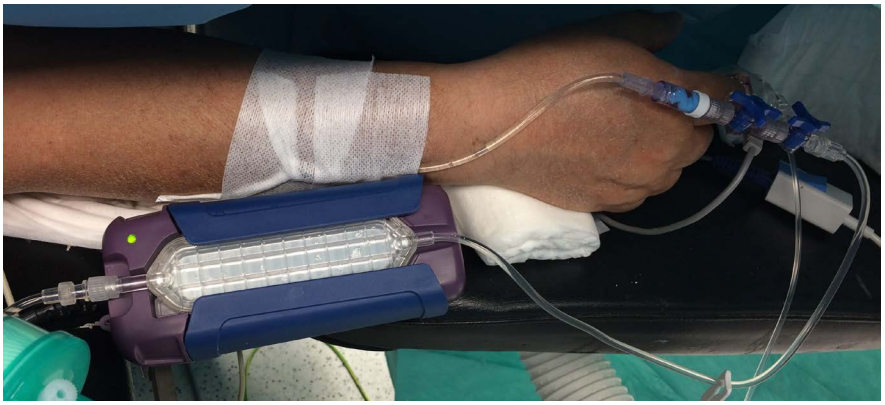

Figure 6. Warming module placed on an arm board so it is next to patients IV catheter.

The control module has a one button operation and a very simple working panel. The disposable cassette has a low prime volume of 3 ml and a 40 cm patients' line. Once connected to the power outlet, the system is ready to use at the set temperature in just a few seconds.

As per manufacturer information Fluido® *Compact* should be easy to use and warm IV fluids in a range of 39˚C ± 2˚C from 5 up to 100 ml/min.

Fluido® *Compact* was set up in the operating room and started to function right before anesthesia induction

Room temperature was kept between 20˚C and 22.5˚C, and was registered every 10 minutes.

The same anesthesiologist personally performed the anesthesia technique required for the procedure and selected the forced warming blanket for each surgical procedure besides fluid warming with Fluido® *Compact*

All patients were warmed intraoperatively using a Mistral®-Air forced-air warming system (The 37˚C Company, Amersfoort. The Netherlands). In addition 22 patients, received forced air warming 10 - 30 min before induction of anesthesia (pre-warming)

Patient Data

After informed consent, 36 patients were recruited for the prospective observational study, 24 were males and 12 females, ASA (American Society of Anesthesiologists patient status I (3), II (19), III (12), IV (2). In one patient undergoing a thoracotomy, urgent blood transfusion was required due to intraoperative bleeding, and data registration was not complete, so it was excluded from posterior data analysis.

Demographic patient data are shown in Table 1.

The number of patients classified by surgical specialty is shown in Table 2.

A combined epidural and general anesthesia was used in all thoracic procedures and in one patient undergoing urological surgery. General anesthesia was chosen in 12 patients and neuraxial anesthesia with intravenous sedation in 5 patients.

Patient monitoring included continuous Electrocardiogram (ECG), non invasive (NIBP) or invasive blood pressure (BP), Bispectral index (BIS®) peripheral oxygen saturation (SaO_2) and core temperature.

Table 1. Patient data.

	Mean ± SD	Range
Age(Years)	63.8 ± 12.5	(28 - 83)
Weight (kg)	76.46 ± 13.75	(49 - 101)
Height (cm)	168.4 ± 8.77	(152 - 183)
BMI kg/m^2	26.7 ± 3.84	(19.6 - 36.2)

Table 2. Surgical procedures.

Surgical Procedure	Number	%
Thoracic	18	50
Orthopedic	6	16.6
General Surgery	4	11.1
Vascular Surgery	3	8.3
Ginecology	2	5.5
Urology	2	5.5
ENT Surgery	1	2.7

Core temperature was measured in the urinary bladder using a foley catheter in 18 patients, in the distal esophagus in 8 patients, using a nasopharyngeal probe in 5 patients and a zero heat flux thermometer (Spot-On®, 3M Company. St Paul, MN, USA) was applied to the forehead of 5 patients for non-invasive core temperature monitoring.

Hemodynamic data were documented in the patients chart every five minutes. Core temperature was registered every ten minutes starting right after anesthesia induction until the end of the surgical procedure.

4. Results

Ambient temperature at the start of anesthesia was 20.8˚C ± 0.59˚C (mean ± SD) ˚C Range (19.5˚C - 22˚C), and at the end of surgery 21.7˚C ± 0.52˚C (mean ± SD) Range (20.3˚C - 23˚C).

A 16G intravenous catheter was used in 14 patients for perioperative fluid administration, and a 18 G catheter in 22 patients. Total intravenous crystalloid administration was 1128.85 ± 415.91 ml (mean ± SD) range (1000 ml - 2500 ml). In one patient undergoing a thoracotomy, urgent blood transfusion was required due to intraoperative bleeding, and data registration was not complete, so it was excluded from posterior data analysis.

Fluido® *Compact* IV fluid warmer was very easy to set up. The disposable cassette has a very low (3 ml) priming volume and it is easy to handle and to place inside the warming module. Once connected to the main power outlet it was ready to deliver fluid at target temperature in just a few seconds. Control panel is intuitive, and the one button operation system makes it safe and convenient.

Core temperature data throughout surgery from all patients were analized as a group. Mean temperatures (˚C) at each time point right after anesthesia induction (mean ± SD) and Range (minimun–maximum) are shown in Table 3 and Table 4.

Table 3. Core temperatures at each time point. Shown as mean, Standard deviation (SD) and Range (Min-Max).

time	00:00	00:10	00:20	00:30	00:40	00:50	01:00	01:10	01:20	01:30	01:40
Mean t ˚C	36.16	36.30	36.40	36.45	36.46	36.48	36.51	36.52	36.52	36.55	36.66
SD	0.67	0.55	0.50	0.47	0.49	0.49	0.48	0.46	0.45	0.50	0.51
Min t ˚C	34.5	35.1	35.3	35.5	35.5	35.5	35.5	35.5	35.5	35.5	35.5
Max t ˚C	37.5	37.5	37.6	37.6	37.6	37.5	37.5	37.4	37.4	37.5	37.5

Table 4. Core temperatures at each time point. Shown as mean, Standard deviation (SD) and Range (Min-Max).

time	01:50	02:00	02:10	02:20	02:30	02:40	02:50	03:00	03:10	03:20	03:40
Mean t ˚C	36.71	36.77	36.78	36.86	36.87	36.93	36.92	37.01	36.94	36.86	36.05
SD	0.50	0.50	0.51	0.54	0.53	0.54	0.52	0.61	0.57	0.76	0.63
Min t ˚C	35.6	35.6	35.7	35.7	35.8	35.8	35.9	35.9	35.8	35.7	35.6
Max t ˚C	37.5	37.5	37.5	37.5	37.5	37.5	37.5	37.6	37.5	37.5	36.5

5. Discussion

Peri-operative hypothermia still affects a high percentage of surgical patients, even when protective thermal measures are used. To test the effectiveness of fluid warming as an added measure to forced air warming to prevent peri-operative hypothermia, we selected a variety of surgical procedures with expected duration longer than one hour and with large body cavity exposure, all related to a higher risk of peri-operative hypothermia.

A plan for thermal management should be made before every surgical procedure, depending on patient risk factors, type and length of surgery and anticipated need of intravenous crystalloids or blood products. It should include, at least, core temperature monitoring, patient surface warming systems, intravenous fluid warmers, and warming irrigation fluids.

Intravenous administration of room temperature fluids has a cooling effect by conduction in the surgical patient. Warming IV fluids to body temperature with Fluido® *Compact* in this study avoided this effect in the patients studied even though the total amount of IV fluid delivered was very moderate: 1128.85 ± 415.91 ml (mean ± SD) range: 1000 ml - 2500 ml. This may be due to following the current recommended practice of fluid restriction in thoracic surgery, that was the most frequent surgical procedure in the study group. In one patient undergoing a right thoracotomy for tumor resection, blood transfusión of two units of packed red blood cells and one unit of fresh frozen plasma were needed due to intraoperative bleeding. The performance of Fluido® *Compact* was excellent allowing the administration of blood components at body temperature at the perfusion rate needed thus avoiding heat loss and contributing to the maintenance of intraoperative core temperature between 36.4˚C and 36.8˚C.

Patient prewarming has been documented to be effective in attenuating temperature redistribution from the core thermal compartment towards the peripheral thermal compartment just after induction of general or neuraxial anesthesia [3] [9] [10]. We did observe the effect of forced air prewarming in this study. In most of the patients that forced air warming was applied before the induction of anesthesia, core temperature was already above 35.5˚C at the start of surgery. This measure had a very important effect on intraoperative temperatures and made the maintenance of normothermia easier to achieve.

In eight patients (22.2%), intraoperative forced air warming had to be stopped and Fluido® *Compact* turned off when core temperature reached 36.9˚C, to avoid patient overheating.

In most of the studied patients intraoperative core temperature was kept consistently above 36˚C due to the combined effects of fluid warming with Fluido® *Compact* and surface body warming with Mistral® Air convective warming. This has special interest because some studies show that intraoperative forced air warming does not prevent perioperative hypothermia in all cases even when used together with fluid warming [11].

In two patients (5.5%), normothermia was not even reached at the end of surgery, this could be due to unidentified patient risk factors, insufficient body

surface covered or due to surgery lasting less than expected, not having enough time to rewarm the patient intraoperatively to reach the temperature goal.

The limitations of the study include the limited number of patients recruited, being an observational study and the variety of surgical procedures involved, even though half of them were thoracic surgeries.

Morover, central temperature was not measured in the same site in all patients, even though all sites used can be used interchangeably for perioperative temperature monitoring. Another weakness of the study is that two hypothermia prevention methods were used in combination: forced air warming and intravenous fluid warming. Fluid warming alone, will not keep patients normothermic, especially in surgeries with high hypothermia risk. So it is the combination of both methods that result in an adequate strategy for preventing perioperative hypothermia, in the cases studied, and not each one when used alone.

Further research is needed to confirm the effectiveness of Fluido® *Compact* for perioperative hypothermia prevention in the same or different surgical procedures by other authors.

6. Conclusions

The combination of peri-operative patient surface warming with Mistral®-Air forced-air warming system and intravenous fluid warming with Fluido® *Compact* allowed the maintenance of peri-operative normothermia in a group of patients undergoing a variety of surgical procedures, which included thoracic surgery, with neuraxial, general or combined epidural-general anesthesia.

Fluido® *Compact* intravenous fluid warmer is a compact, very easy to use device that, when combined with forced-air patient warming, helps in the temperature management of surgical patients aimed at maintaining peri-operative normothermia.

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