ORIGINAL ARTICLE

Effects of line type blood-liquid warmer on two different infusion sets

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Abstract

Objective: To investigate the source of 'bubbles' in infusion sets which were caused by the 'line type' blood-liquid warmers used in operation rooms to prevent hypothermia.

Methods: The experimental study was conducted from August to September 2012 at the Thoracic Surgery Department of Dokuz Eylul University, Izmir, Turkey, by warming liquids in the operation room experimentally in a setting similar to clinical routine. Initially, 0.9% sodium chloride solution was infused using S-line blood-liquid warmers with Medisetin patients who were placed in Group M). The IPC Group had Intrafix Primeline Confortset at a rate of 350ml/hour in the operating room. The initiation time and level of bubble formation, temperatures of the operation room, infusion liquid, S-line device, line of the device, and the liquid at the outflow were recorded. Data was analysed with SPSS 15.

Result: The two groups had 10 subjects each. The temperatures of the working area, the liquid before and after being placed in the warming device, the proximal-middle and distal parts of the line and the set temperature on the screen of the device were similar and the difference between them was not statistically significant ($p>0.05$). While no bubble formation was observed in Group IPC, bubbles were formed after 9.80±0.78 minutes and the level of bubble formation was close to 3 in Group Mediset (2.80±1.03). The main difference between the two groups was di (2-ethylhexyl) phthalate content of Mediset.

Conclusion: Infusion sets containing di(2-ethylhexyl) phthalate should not be used with warming devices in order to avoid toxic effects.

Keywords: Blood-liquid warmer, Infusion set, Bubbles, Di(2-ethylhexyl)phthalate. (JPMA 65: 362; 2015)

Introduction

In operation rooms the most common method for prevention of hypothermia affecting mortality and morbidity is warming the patient, blood and liquid. While 'warm air heaters' and 'blankets' are used to warm up the patient, the most common warmers for blood products and liquid are 'rapid infusion devices' and 'line-type blood-liquid warmers'. Negative effects like infection and noise[1] from warm air heaters, burns[2] and artifact formation in electrocardiography (ECG)[3] with blankets, damage the shaped elements of blood related rapid infusion devices,[4-8] and limit their use.

Line type of blood-liquid warmers are preferred for reasons of not requiring an additional set during use, being easy to use and transport, and lack of known side effects. However, we detected 'bubble' formation while warming the liquid infusion sets with S-line (Barkey, Germany) devices which are routinely used.

The current study aimed at investigating the effects of S-line blood-liquid warmers on two sets with different chemical contents.

Material and Method

The experimental study was conducted from August to September 2012 at the Thoracic Surgery Department of Dokuz Eylul University, Izmir, Turkey. After obtaining consent from the ethics committee of Dokuz Eylul University, Turkey, the study was conducted by warming liquids in the operation room experimentally in a setting similar to clinical routine. A simple random sampling method was used to enrol subjects. Two groups were formed according to the usage of two different structured sets in S-line blood-fluid warmers. Group M: Mediset (Eczacibasi-Baxter, Istanbul/Turkey) (Figure-1A). Group IPC: Intrafix Primeline Confort (B/Braun, Melsungen AG) (Figure-1B).

After fixing S-line blood-liquid warmer on the hanger, 1000ml of 0.9% sodium chloride (NaCl) (Eczacibasi-Baxter, Istanbul/Turkey) solution was put up. One of the sets (Mediset/ IPC) was fitted with the bottle. Drop tuning kit (Flowmeter, Lacus, Ankara/Turkey) and 18G intravenous (IV) catheter (Vasofix Safety, B/Braun, Melsungen AG) were added to the tip of the set to fix the flow rate (Figure 1C). The tank (half-full) and the infusion set were filled with 0.9% NaCl with no visible bubbles. The infusion set was placed into the channel of the line of blood-liquid

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warmer. Infusion rate was set at350ml/h.

In both groups, the temperature of the working area was measured with Temperature Station (WS8610R, Precision Sensor, La Crosse, Swiss). Following operating the device, the temperature of S-line was read from the screen. The temperature of the 0.9% NaCl solution before the infusion was measured by touching the proximal, middle and distal parts of the S-Line apparatus with metal probe of the heating profile and the results were recorded. The temperature of the liquid in the bottle was also recorded. After initiation of infusion, time to visible bubble formation (min) and the level of bubbles formed (0= no bubble, 1= very low, 2= low, 3= moderate, 4=diffuse bubbles) were recorded. Infusion was stopped after one hour. The procedure was repeated for 10 times in both groups.

Data was analysed using SPSS 15). The mean of the data and standard deviations were calculated. Mann-Whitney U test was used to analyse the data, and $p<0.05$ was considered significant.

Results

The temperatures of the working area, the liquid before and after being placed in the warming device, the proximal-middle and distal parts of the line and the set temperature on the screen of the device were similar; the difference between them was not statistically significant ($p>0.05$) (Table-1).

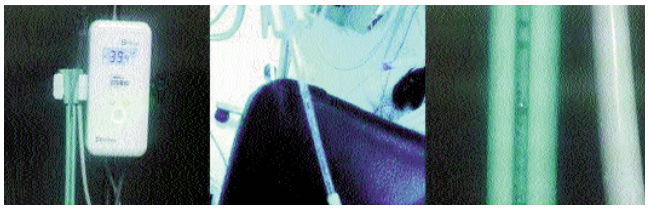


Figure-2: Bubbles in Mediset.

While no bubble formation was observed in Group IPC, bubbles were formed after 9.80±0.78 minutes and the level of bubble formation was close to 3 in Group Mediset (2.80±1.03) (Table-1) (Figures-2).

Discussion

Operation rooms, post-anaesthetic care unit (PACU) and intensive care unit (ICU) are the most common areas of hypothermia. Acid-base balance is disrupted, energy-

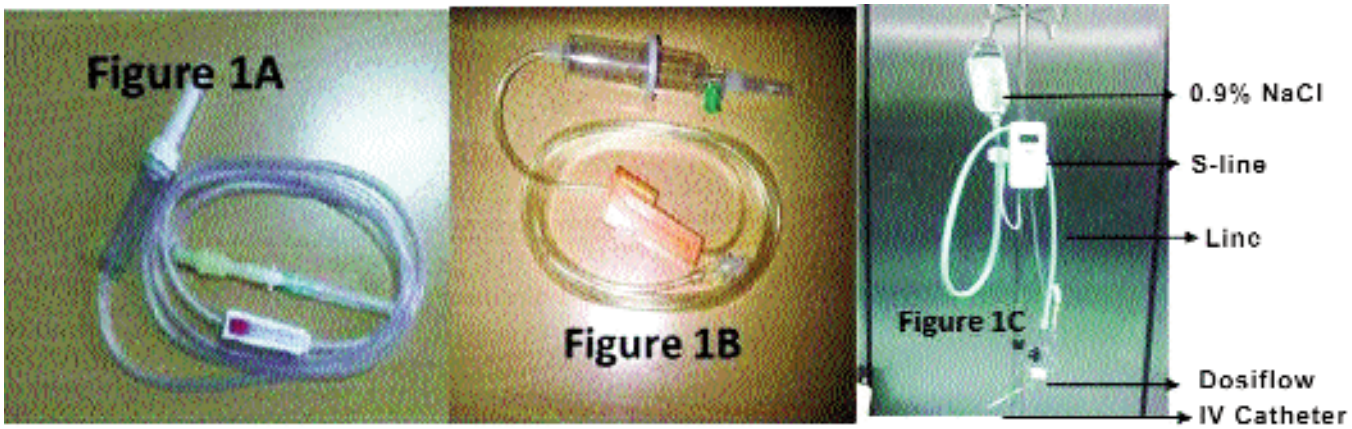


Figure 1A-1B-1C: Mediset, Intrafix Primeline Confort, Experimental setup.

Table-1: Comparison of temperatures, the level of bubble formation and duration (mean ± standard deviation).

	Group M (°C)	Group IPC (°C)	P
Temperature of the working area	22.36±1.36	21.12±0.76	0.080
Temperature of the liquid before the infusion	21.87±1.49	21.16±0.95	0.173
Temperature of the set of warmer	39.13±0.09	39.10±0.08	0.497
Temperature of the proximal part of the warming line	40.25±1,23	40.620±0.82	0.426
Temperature of the middle part of the warming line	39.92±1.32	40.64±0.69	0.288
Temperature of the distal part of the warming line	39.23±0.61	39.20±0.21	0.878
Temperature of the liquid exiting from the catheter	33.53±1,12	33.77±0.91	0.650
Duration of bubble formation (min)	9.80±0.78	No bubbles	-
Level of bubble formation (0-4)	2.80±1.03	0	-

IPC: Intrafix Primeline Confort.

oxygen consumption and the incidence of cardiac arrhythmias increase, drug metabolism slows down and wound healing is delayed in hypothermic patients. For these reasons, warming the environment, the patient, blood and liquid is important to fight against hypothermia. Blood and liquid warmers are classified according to the heating technique (water baths, electrical, microwave and magnetic heaters) and the speed of liquid infusion (slow and fast infusion systems).[1,9]

Although rapid infusion devices are life-saving, they have side effects like air embolism and damage on red blood cells (RBCs).[4-8]

S-line equipment, which was used at the study site is a blood-liquid warmer with an electrical heating method weighting 750gr. Its temperature setting is 39°C, heating profile length is 150cm, and standard blood and liquid sets can be placed into its heating profile. It has a heating capacity of 30-39°C depending on the speed of blood and liquid infusion. No side effects have been reported until now.[10] We have detected bubbles during liquid infusions with Mediset which is placed into S-line equipment's heating line. After the manufacturers were alerted, they reported that they had not received any warning from the users about bubble formation with the S-line device.

We compared S-line blood-liquid warmer and Astoflo device with Mediset to seek the answer to the questions, "can we experience the same problem with other blood-liquid warmers?" and "which problems may be caused by the bubbles?" Results showed that each device had similar capacity of warming and a similar risk of bubble formation.

In order to answer the questions, "may bubbles be caused by the sets used?" and "what is the effect of S-line blood-liquid warmers on sets which have different chemical contents?", we investigated the effects of S-line blood-liquid warmers on Mediset and IPC. No bubble formation was observed in Group IPC. We observed visible bubbles in Mediset with the use of S-line blood-liquid warmers after 9.80min. Level of bubble formation increased to 2.80. We didn't find any publications in Pubmed search if Line type blood-liquid warmers lead to any bubble formation or state the reasons for the bubbles formed. The main chemical difference between the two sets is the presence of di(2-ethylhexyl) phthalate DEHP in Mediset.[11]

Phthalates are widely used as a plasticiser to provide flexibility and durability of polyvinylchloride (PVC) type of plastic products. US Environmental Protection Agency (EPA) reports that there are 8 phthalates. Phthalates are produced in high volume, over 470 million pounds per year.[12] In western Europe phthalate production was 595,000 tons/year in 1997.[12,13] Phthalates are commonly used in medical supplies mostly such as intubation tubes, blood and liquid sets, blood bags, pneumothorax tubes, dialysis and extracorporeal membrane oxygenation (ECMO) materials. Medical devices made from PVC contain 20-40% DEHP.[12,13] Mediset, which is produced as a set of infusion, contains 25-33% DEHP. The manufacturers of Mediset have mentioned the DEHP content on the packaging. According to European Union risk assessment report[12] and FDA,[13] phthalates are carcinogenic in animals. They can cause toxic effects on the reproductive system such as foetal death, malformations, anti-androgenic effect, teratogenicity and testicular damage. Mono (2-ethylhexyl) phthalate (MEHP) is a metabolite which is more toxic than DEHP. Although there are no proven carcinogenic effects in humans, but adverse effects have been proven on the endocrine system, especially in children.[12-15]

While no MEHP occurred in stored blood at 4°C, a significant conversion was determined at 22°C.[16] The amount of lipid in the environment, heating, route of administration and duration changes the amount of exposure to DEHP and MEHP. It was reported that while the amount of soluble DEHP in plasma is 0.5g/ml at 4°C, it is about 2g/ml at 22°C.

A study[17] investigated the effects of lipid emulsions on DEHP-containing infusion sets made of PVC at different temperatures (24°C, 32°C and 37°C). It reported DEHP release in direct proportion to the increase of temperature. This finding pointed to the importance of the use of warmers to prevent hypothermia. This study showed that DEHP release may increase in direct proportion to the temperature which may be carcinogenic and can cause abnormalities in children. They stated that DEHP release is associated with the length of infusion line, pH of the infusate, flow rate, duration and lipophility of infusion.

Our study suggested that the amount of melted DEHP and MEHP would be even higher when infusion sets in S-line exposed to temperatures at 39-40°C. For this reason, we thought that the cause of bubbles formed in Mediset might be DEHP and MEHP release after warming.

We didn't aim to address the amount of DEHP and MEHP release by using Mediset. This may be the subject of another study. Determination of the amount of bubbles and side effects of these bubbles like embolism can be another subject of research.

It is obvious that a single infusion set cannot be the cause

of acute toxicity. However, accumulation may be important in patients with polytrauma who have more than one venous access, in ICU, in chronic diseases and especially in children.[13] In most of the reports, attention is drawn to the dangers of massive blood transfusions and chronic dialysis procedures in humans.[12,13,15,16,18] For this reason, manufacturers must strive to obtain new alternative non-toxic products.

Conclusion

DEHP-containing infusion sets lead to the release of DEHP and bubble formation during infusion with line type warming devices. Alternative products should be developed by taking into account the European Union Risk Assessment reports and FDA's warnings. DEHP-containing products should be avoided in order to prevent potential hazards.

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