Original Article

Comparative evaluation of forced air warming and infusion of amino acid-enriched solution on intraoperative hypothermia in patients undergoing head and neck cancer surgeries: A prospective randomised study

ABSTRACT

Background: Inadvertent core hypothermia is a common occurrence during general anaesthesia. Forced air warming (FAW) is the most effective perianaesthetic warming system, but it may lead to thermal discomfort. Amino acids (AAs) have been used to prevent hypothermia, but no study has compared the effect of AA infusion with FAW systems. We have conducted this study to compare the effects of external heating (FAW system) and internal heat generation (AA infusion) in preventing hypothermia during anaesthesia.

Methods: After institutional review board approval, 80 American Society of Anesthesiologists Grade I/II adult patients admitted for head and neck cancer surgeries lasting more than 2 h under general anaesthesia were included. The patients were randomly divided into two groups using computer-generated codes to receive AA infusion at 3 mL/kg/h, Group AA ($N = 40$), or normal saline at 3 mL/kg/h with FAW, Group FA ($N = 40$) till the end of surgery. Standard anaesthetic technique and monitoring was used in all the patients.

Results: The baseline mean temperature in both the groups was comparable. The core temperature was similar in the two groups at 30 min (35.6 ± 0.54 vs 35.5 ± 0.54), 60 min (35.5 ± 0.63 vs 35.3 ± 0.60), 90 min (35.5 ± 0.79 vs 35.2 ± 0.66), 120 min (35.6 ± 0.93 vs 35.2 ± 0.78), 150 min (35.7 ± 0.88 vs 35.3 ± 0.89) and 180 min (35.8 ± 1.01 vs 35.3 ± 0.95) in Groups FA and AA, respectively ($P > 0.05$). However, the core temperature was significantly higher in Group FA at 210 min (35.8 ± 1.0 vs 35.3 ± 0.85; $P = 0.01$), 240 min (35.9 ± 1.0 vs 35.4 ± 0.90; ($P = 0.001$), 270 min (35.9 ± 1.12 vs 35.6 ± 0.97; $P = 0.002$) and 300 min (36.0 ± 1.12 vs 35.6 ± 1.02; $P = 0.002$), respectively. Clinically relevant hypothermia (at least one measurement <35.5°C) was comparable between the two groups.

Conclusion: The AA infusion can be used as an alternative to FAW in preventing intraoperative hypothermia under general anaesthesia especially in places where FAW system is unavailable.

Key words: Amino acid infusion; forced air warming; general anaesthesia; head and neck cancer surgery; hypothermia

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Nishkarsh Gupta, Sachidanand Jee Bharti, Vinod Kumar, Rakesh Garg, Seema Mishra, Sushma Bhatnagar

Department of Onco-Anesthesiology and Palliative Medicine, DRBRAIRCH, AIIMS, Delhi, India

Address for correspondence: Dr. Nishkarsh Gupta, 437, Pocket A, Sarita Vihar, New Delhi - 110 076, India.
E-mail: drnishkarsh@rediffmail.com

Introduction

Perioperative hypothermia may result from multiple mechanisms including the cold environment of the operating room (OR), absence of the behavioural response and altered thermoregulatory mechanisms due to anaesthesia.[1] The occurrence of even mild intraoperative hypothermia can lead to myocardial ischemia, coagulopathy, prolonged drug effects, increased incidence of wound infections and delayed healing.[2-5] Hence, preventive measures for intraoperative hypothermia and the associated adverse outcomes are necessary.

Several devices like circulating water garments, forced air warming (FAW), resistive heating devices, radiant heaters and negative pressure water warming systems have been used to prevent perioperative hypothermia. Most of them may not be effective and may cause burns and have limited warming capacity.[6,7] FAW is known to be the most effective perioperative warming modality.[6,7] However, FAW can lead to thermal discomfort, disrupt the air flow in the theatre and may increase the risk of wound contamination.[8] Moreover, it might not be economically viable for all healthcare set-ups, or the equipment might suffer a downtime at times.

Nutrients are known to induce thermogenesis, and amino acids (AAs) have the highest thermogenic effect. AA increases the metabolic rate by 30 kcal/100 kcal (whereas carbohydrates and fat increase it by 6 and 4 kcal, respectively).[9-11] AA infusion has been proven to reduce hypothermia under anaesthesia.[12,13] However, a recently published Cochrane review and meta-analysis on nutrient-induced thermogenesis suggested that most of the evidence was of moderate to low quality.[13,14] The AAs are safe and are used routinely in intensive care unit without associated side effects.

Hence, we conducted this study to compare the effect of external heating (FAW system) and internal heat generation (AA infusion) in preventing hypothermia during anaesthesia.

Methods

After the Institutional Ethics Committee approval, this prospective, randomised study was conducted in 80 American Society of Anesthesiologists Grade I/II adult patients undergoing head and neck cancer surgeries under general anaesthesia, lasting more than 2 h. This study was approved by the Institutes Ethics Committee (IEC/NP-386/2013 RP-09/2013), and written informed consent was obtained from all subjects participating in the trial. The trial was registered prior to patient enrollment at ctri.nic.in (REF/2014/02/004389; principal investigator: Nishkarsh Gupta; date of registration: 07/02/2014). Patients undergoing emergency surgery, those with known hepatic or renal disease, clinical hypothyroidism or hyperthyroidism, known allergy to the drugs used in the study and those with a body mass index <20 kg/m^2 or >30 kg/m^2 were excluded from the study.

All patients underwent a thorough preanaesthesia checkup including a detailed history, complete physical examination and standard preoperative investigations. A written informed consent was obtained from every patient and an intravenous (IV) line was established. All patients were administered an IV fentanyl dose of 2 μg/kg body weight, 15 min before induction, and were randomly divided into two groups of 40 each: Group AA received AA infusion at 3 mL/kg/h (celemin 10% solution; Claris Lifesciences, Sanand, Ahmedabad, Gujrat, India) and Group FA received normal saline at 3 mL/kg/h with FAW. The randomisation was done using computer-generated codes that were maintained in sequentially numbered, sealed, opaque envelopes. It was not possible to do perioperative blinding for the anaesthesiologist due to difference between the two methods of warming used; however, the patients and the person analysing the data were blinded to group allocation.

The OR had a controlled laminar airflow system and its temperature was set at 21°C. Ringer's lactate was warmed using Ranger™ Standard Flow (Model 24200; Arizant Healthcare, MN, USA) to 37°C and was administered throughout the surgery at 7 mL/kg/h through an infusion pump (Infusomet™; B Braun, Melsungen AG, Melsungen, Germany). In the OR, standard monitors were attached and all the patients were covered with a warming blanket. The anaesthesia was induced using IV propofol 2 mg/kg, and a measured length of the temperature probe (tip of the nose to tragus) was lubricated with normal saline and inserted into the nasopharynx to monitor the core temperature (Tc). Three minutes after induction, the airway was secured with a cuffed endotracheal tube, 3 min after the administration of vecuronium bromide at a dose of 0.1 mg/kg. In the FA group, the FAW blankets were inflated with a Bair Hugger blower unit (Model 750; Arizant Healthcare) with the temperature set to "high" (43°C), whereas in Group AA a continuous IV infusion of a mixture of AAs was administered at the rate of 3 mL/kg/h. In Group FA, additional normal saline at the rate of 3 mL/kg/h was administered using an infusion pump. The exposed body parts were covered with surgical drapes to minimise the heat loss from the surface. After induction of anaesthesia, arterial and central venous lines were established. The anaesthesia was maintained using

sevoflurane with O_2:N_2O to maintain 1.2 minimum alveolar concentration (MAC) and the ventilation was adjusted to maintain normocapnia. In addition to above-mentioned fluids, a bolus of 2 mL/kg Ringer's lactate was administered in case of a fall in mean arterial pressure to less than 70 mm Hg or an increase of >20% from the baseline, or a urine output of less than 1 mL/kg/h. The blood loss was replaced with blood (1:1) as required at room temperature.

Core temperature (Tc), heart rate, systolic blood pressure, diastolic blood pressure and mean blood pressure (MBP) were recorded at baseline and every 10 min until the end of surgery. Blood urea nitrogen and serum proteins (total, albumin and globulin) were also recorded before induction, at the end of surgery and 24 h after surgery.

Perioperative variables including operative time, the total volume of blood products infused, total fluids infused and perioperative complications (if any) were recorded.

Statistical analysis

All data were presented as mean [standard deviation (SD)]. The analysis was performed using SPSS 20 for Windows (IBM Inc., Chicago, IL, USA). The patient characteristics in the two groups were compared using Chi-square test.

Linear mixed model was applied to assess within and between the groups' comparison. The best covariance structure was determined based on minimum of Akaike's Information criteria (AIC); among the various covariance structures, the heterogeneous first autoregressive covariance structure was found to be optimum for these data. The interaction between time and group was not statistically significant with $P = 0.15$. However, it is not statistically significant at 5% but closer, hence there is some interaction between time and group which means difference of temperature between the groups varies across the time points. To assess the mean difference between the groups, we compared the estimated marginal mean of both the groups at individual time point and obtained *P* value which was adjusted for Bonferroni corrections. The results the difference between groups starts significant at 190 min onwards.

We considered a 0.5°C difference in body temperature between the two groups, 60 min after induction of anaesthesia as clinically significant. A sample size calculation (using G* Power 3.1) to detect a 0.5°C difference in the groups' means and an SD of 0.6°C (taken from previous study) estimated that a sample size of 32 patients would be required in each group, to achieve a 5% level of significance and a power of 90%.[15] We recruited 40 patients in each group to factor the probability of dropouts.

Results

We evaluated 100 patients for eligibility, and of these, 80 were randomised according to the study protocol [Figure 1]. The demographic characteristics were comparable between the two groups [Table 1]. All the patients were males. The mean core temperature in both the groups was comparable at 30 min (35.6 ± 0.54 vs 35.5 ± 0.54; $P = 1.0$), 60 min (35.5 ± 0.63 vs 35.3 ± 0.60; $P = 1.0$), 90 min (35.5 ± 0.79 vs 35.2 ± 0.66; $P = 1.0$), 120 min (35.6 ± 0.93 vs 35.2 ± 0.78; $P = 1.0$), 150 min (35.7 ± 0.88 vs 35.3 ± 0.89; $P = 0.36$) and 180 min (35.8 ± 1.01 vs 35.3 ± 0.95; $P = 0.08$) in Groups FA and AA, respectively [Figure 2 and Table 2], Thereafter, the core temperature was significantly higher in FA group at 210 min (35.8 ± 1.0 vs 35.3 ± 0.85; $P = 0.01$), 240 min (35.9 ± 1.0 vs 35.4 ± 0.90; $P = 0.001$), 270 min (35.9 ± 1.12 vs 35.6 ± 0.97; $P = 0.002$) and 300 min (36.0 ± 1.12 vs 35.6 ± 1.02; $P = 0.002$), respectively [Figure 2 and Table 2]. However, this difference was less than 0.5°C at all time points. Clinically relevant hypothermia (at least one measurement <35.5°C) was comparable between the two groups [Table 3]. The mean blood pressure was also comparable between the two groups [Figure 3]. The total amount of fluid transfused was comparable in the two groups ($P > 0.05$) [Table 3]. The amount of blood loss was also comparable and did not warrant blood transfusion in any of the patients ($P > 0.05$) [Table 3].

Discussion

This study was conducted to evaluate the effect of AA infusion and FAW on core temperature in patients undergoing head and neck surgery under general anaesthesia. Patients often develop hypothermia under general anaesthesia due to the cold OR environment and absence of behavioural response. Moreover, the anaesthetic agents interfere with normal thermal regulation by decreasing the metabolic rate, inhibiting vasoconstriction, altering the shivering threshold and depressing the hypothalamic regulatory mechanisms. Hypothermia occurs due to anaesthesia-induced vasodilatation, leading to the transfer of heat (46 kcal) from the trunk to the extremities, during the first hour after induction.

Table 1: Demographic parameters of the patients in the two groups

Characteristic	Group FA (*n*=40)	Group AA (*n*=40)	*P*
Age (years)	44.9 (10.3)	45.5 (9.8)	0.45
Weight (kg)	58 (11.2)	61.2 (11)	0.21
Height (cm)	162.1 (7.7)	163.68 (8.2)	0.38
Urea (mg/dL)	25.2 (8.2)	25.1 (8.7)	0.94
Urea end (g/dL)	29.5 (8.4)	35.6 (13.5)	0.2

All data are mean (standard deviation)

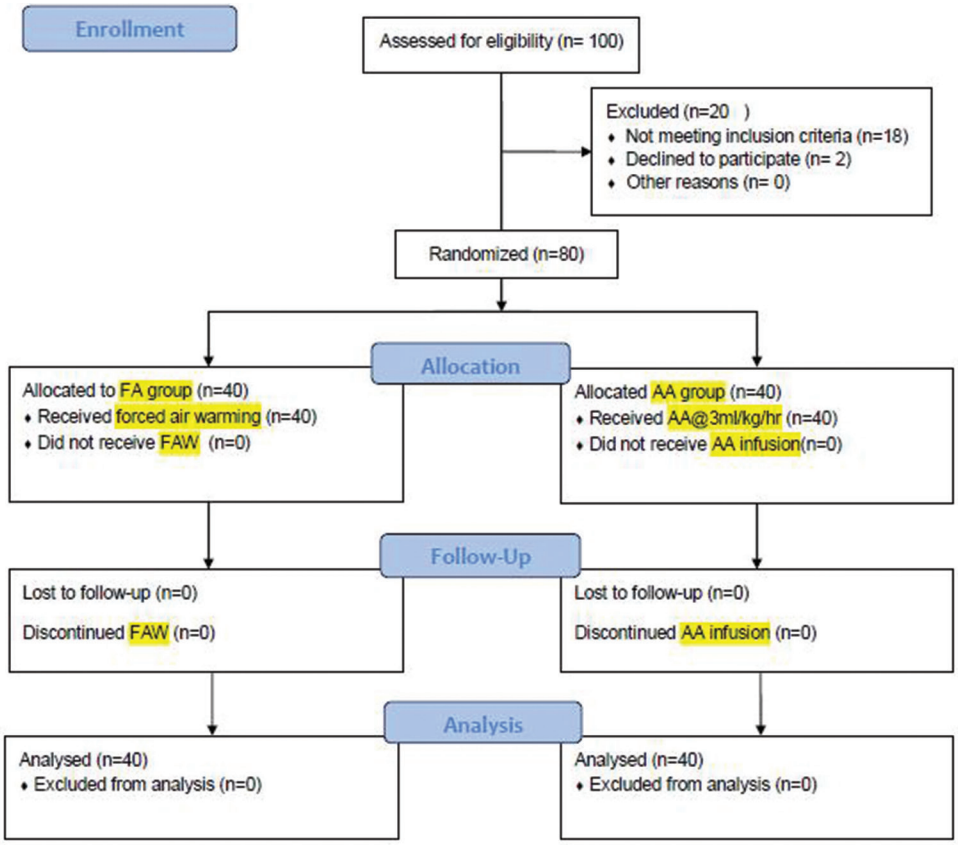

Figure 1: Consort flow diagram

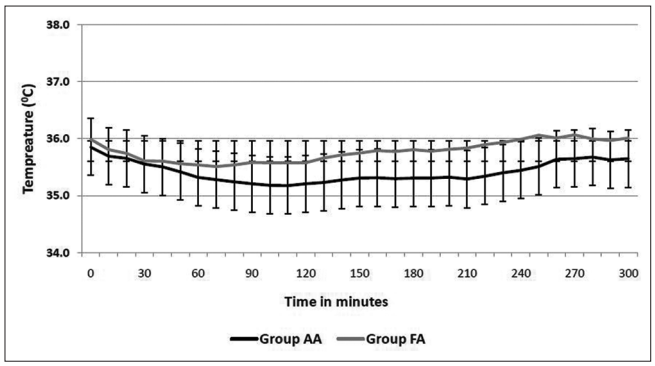

Figure 2: Core temperature at various time points in the two groups

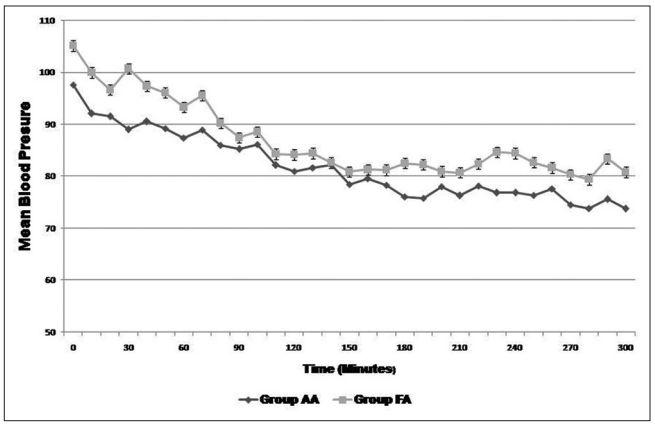

Figure 3: MBP in the two groups at various time points

Hypothermia below 35°C might adversely affect all physiological processes and cause complications including myocardial ischemia,[4] prolonged drug action, coagulopathy and shivering.[4,5] It is also reported to increase the incidence of wound infections and delay healing.[16] It might reduce the free flap survival in patients due to flap vasoconstriction, delay the time to extubation and prolong hospital stay.[16,17] Hence, it is important to prevent anaesthesia-induced hypothermia and the associated adverse outcomes.[18] Several devices have been used to prevent hypothermia in the perioperative period. Most of these are designed to minimise heat loss from the body surface.[18] Normothermia can be maintained by providing ambient temperatures greater than 26°C. However, the ORs are often much cooler (21°C in this study) to ensure the comfort of the operating team and as an infection control measure.[18] Passive insulation with blankets, surgical drapes or reflective composites is also used to reduce heat loss but is relatively ineffective.[19] Circulating water systems are newer devices that provide more heat than FAW systems since the heat capacity of water is much greater than that of dry warm air, and they provide posterior and anterior warming. However, the combination of heat and decreased local perfusion might increase the chances of pressure/heat

Table 2: Mean (SD) of core temperatures at various time points in the intraoperative period

Time	FA	AA	*P*
BL	35.9 (0.52)	35.8 (0.49)	1.000
10	35.8 (0.49)	35.7 (0.50)	1.000
20	35.7 (0.49)	35.6 (0.54)	1.000
30	35.6 (0.54)	35.5 (0.54)	1.000
40	35.6 (0.55)	35.5 (0.55)	1.000
50	35.6 (0.59)	35.4 (0.56)	1.000
60	35.5 (0.63)	35.3 (0.60)	1.000
70	35.5 (0.68)	35.3 (0.59)	1.000
80	35.5 (0.74)	35.2 (0.61)	1.000
90	35.5 (0.79)	35.2 (0.66)	1.000
100	35.5 (0.85)	35.2 (0.75)	1.000
110	35.6 (0.90)	35.2 (0.78)	1.000
120	35.6 (0.93)	35.2 (0.78)	1.000
130	35.6 (0.95)	35.2 (0.80)	0.513
140	35.7 (0.95)	35.3 (0.85)	0.395
150	35.7 (0.88)	35.3 (0.89)	0.360
160	35.7 (0.98)	35.3 (0.91)	0.182
170	35.8 (0.99)	35.3 (0.93)	0.109
180	35.8 (1.01)	35.3 (0.95)	0.083
190	35.7 (1.01)	35.3 (0.96)	0.028
200	35.8 (1.04)	35.3 (0.92)	0.023
210	35.8 (1.04)	35.3 (0.85)	0.011
220	35.8 (1.04)	35.3 (0.86)	0.005
230	35.9 (1.05)	35.4 (0.87)	0.001
240	35.9 (1.04)	35.4 (0.90)	0.001
250	35.9 (1.15)	35.5 (0.97)	0.001
260	35.9 (1.18)	35.6 (0.96)	0.003
270	35.9 (1.12)	35.6 (0.97)	0.002
280	35.9 (1.12)	35.6 (0.99)	0.004
290	35.9 (1.16)	35.6 (1.01)	0.002
300	36.0 (1.12)	35.6 (1.02)	0.002

SD: Standard deviation

Table 3: Fluid balance, incidence of hypothermia and duration of surgery of the patients in the two groups

Characteristic	Group FA (*n*=40)	Group AA (*n*=40)	*P*
Anaesthesia time	274.8 (82.3)	276.8 (82.6)	0.91
Surgical time	235.1 (77.7)	240.6 (78.2)	0.76
Total volume of study drug (mL)	808.8 (288.8)	862.9 (284.5)	0.39
Total volume of RL (mL)	1859.8 (640.7)	2020 (645.9)	0.26
Total fluid (mL)	2668.5 (913)	2883 (927.9)	0.29
Blood loss	228.2 (41.8)	220.1 (38.5)	0.39
Incidence of hypothermia (Tcore <35°C at least for one measurement)	17 (40)	21 (40)	0.50

RL: Ringer's lactate

necrosis due to the decrease in capillary perfusion caused by the patient's weight.[20]

During the first hour of use, FAW system increases the heat in the arms and legs by up to 136 kcal and is considered as the most effective strategy to prevent hypothermia under anaesthesia.[1] However, its use might be associated with sweating and thermal discomfort. Moreover, some recent studies have raised concerns regarding the formation of convection currents by forced air warmers, which might disrupt theatre airflows and increase the risk of wound contamination.[8] Moreover, in resource-constrained countries, FAW might not be viable due to the costs involved, or the equipment might be nonfunctional at times. Hence, there is a need for a simple and cost-effective alternative to prevent hypothermia under anaesthesia.

All nutrients increase energy expenditure by the tissues and the AAs have the highest thermogenic effect (30 kcal for every 100 kcal).[9-12] In contrast, carbohydrate and fat metabolism produce only 6 and 4 kcal for every 100 kcal, respectively.[9] AA infusion (at 100 mL/h) has been shown to reduce hypothermia and hasten recovery from neuromuscular blockade produced by vecuronium bromide.[21] In the conscious state, this hyperthermic response due to the protein metabolism is contained due to the inhibitory action of the central thermosensors. During anaesthesia, thermoregulation is impaired; hence, AA-induced thermogenesis is exaggerated.[11,22] In this study, we showed that AA infusion increased thermogenesis and prevented hypothermia (<35.5°C) as effectively as FA. AA infusion may increase the metabolic rate and the nitrogen load that needs to be cleared by the kidneys. In our study, blood urea values before and after surgeries were similar in both the groups. But we had excluded patients with preexisting hepatic and renal disease and the results may be different in these subsets of patients.

A recently published Cochrane review on nutrient-induced thermogenesis suggested that most of the evidence was of moderate to low quality.[13] This was due to errors in assigning participants to the treatment groups and in blinding the investigators assessing the outcomes. Another meta-analysis also highlighted the role of AA in increasing the temperature and suggested that more studies are necessary to validate their effect further. Our study is the first study conducted on a homogeneous group of patients (head and neck cancer) and with controlled variables that can influence intraoperative hypothermia (ambient temperature, age, sex, total fluids administered and the duration of surgery). Moreover, all patients were adult males; thus, the differences due to age and gender were unlikely.

Most previous studies used AAs in doses of 2 mL/kg/h, and some recent meta-analysis highlighted that AAs increase the core temperature, but their effectiveness might be better by increasing the dose.[4,13]

In our study, AA at the dose of 3 mL/kg/h was effective in maintaining temperature for the first 90 min, but after 90 min FA was better in preventing hypothermia [Figure 2]. However, the number of patients developing clinically significant hypothermia (core temperature <35.5°C) was comparable. The AAs are safe and were used in doses that are routinely used in intensive care. We did not find any of the side effects with the use of AAs. Also, extensive literature search did not show any side effects.

In our country, the cost of AAs is 500 Rs. (two bottles of 500 mL at 250 Rs./bottle were used, and the remaining AA solution was discarded and not used in other patients). This is much economical than the cost of a disposable blanket (cost to hospital 1100 Rs.) in Group FA without factoring for the additional cost of the equipment. This further reinforces the importance of AA in preventing hypothermia especially in the developing countries, where the cost and availability of the equipment might hinder the regular use of FAW systems. There were a few limitations in our study. First, we used AA at a dose of 3 mL/kg/h based on previous literature and our experience. A higher dose might prove to be more effective. Second, this study was conducted among patients with head and neck cancer who were covered and draped below the nipple line. Thus, the results of this study cannot be generalised to patients undergoing other surgeries such as abdominal surgeries where the heat loss might be higher. Third, the degree of hypothermia might be more in patients with cancer, those with poor nutritional status and with less muscle mass. The results might be different in noncancer surgeries. Also, the presence of a control group would have highlighted the role of AA better. But we decided against a control group because we considered withholding modalities for perioperative warming unethical. Finally, we have tested one dose of one formulation of AA in preventing intraoperative hypothermia and compared with FAW. The results may be different with other doses and/or formulation of AA used.

Conclusion

AA infusion is an economical and effective alternative to FAW in preventing hypothermia under general anaesthesia, especially in situations where a FAW system is not available or not functional. However, further studies with higher doses of AAs are necessary, to ascertain the optimum doses for preventing anaesthesia-induced hypothermia.

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Conflicts of interest

There are no conflicts of interest.

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