Preventive Care in Nursing and Midwifery Journal 2018; 8(4): 16-22

The Effect of Warm Intravenous Fluid on Postoperative Pain: A Double-Blind Clinical Trial

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Received: 1 Dec 2019 Accepted: 9 Feb 2020

Abstract

Background: Hypothermia is likely to cause enormous dangers for patients undergoing cesarean section.

Objectives: This study aims to comparison between the effect of using two different temperatures of IV fluids (37.5°C versus 21-22°C) in body temperature drop and the post-operative pain.

Methods: This experimental study was double-blind clinical trial, conducted in 2017 (April, 2017 to January, 2018). The method of sampling was simple random sampling. The randomly selected mothers, undergoing cesarean section, were assigned into two groups of equal number (the hexagonal blocks of A and B) in this clinical trial. The experimental and control group participants received IV fluid at the operation room temperature (25°C) and the IV fluid of 37.5°C, respectively. The core intraoperative body temperature was measured by Microlife Infrared Tympanic-IR100 thermometer. Severity of the experimental and control group patients' post-operative pain was also measured and compared for 24 hours (since when the patients were discharged from the recovery ward) by the VAS (0-10).

Results: A total of 80 patients underwent this study. The demographic information of the two group members showed no difference of significance (p>0.05). The average intraoperative body temperature of the experimental group participants was higher in the level (p=0.001) of significance than that of the control group members. There was no difference of significance (p=0.41) between the mean severity of pain of both groups' participants in the first 24 hours.

Conclusion: The intraoperative IV fluid warming seems not to have any tranquilizing effect in the post-surgery pain.

Keywords: cesarean section, temperature, fluid warming, pain

Introduction

Hypothermia is defined as a fall in core body temperature below 36°C during surgical procedures. [1] This pathological phenomenon occurs during operation. Various reasons are at work such as cold temperature of the operation room; using fluids at the operation room temperature; insufficient covering of the patients; the surgical position left uncovered and many other factors. [2] More than 60% of mothers undergoing cesarean section are reported to suffer hypothermia [3-6].

Growing cardiac work load, carbon dioxide generation, lactate levels, delayed surgical wound healing, prolongation of hospitalization and development of metabolic acidosis in human body should be considered as complication of hypothermia [3,7]. Furthermore, hypothermia can cause shivering, subsequently leading to several times increase in metabolism [8].

Literature has proposed different methods for hypothermia control. In general, the methods are classified into the active (like using warmed IV sera, forced air warming and conduction mattress warming) and the passive (such coverings as blanket or clothe) methods. [8,9] Compared to others, the warm IV is taken the most acceptable and available method of use in the operation room [9,7]. Horn et al. studied pre-anesthesia warming of patient and its supportive effects avoiding hyperthermia hitting patients during surgery [10]. Latest studies show that the fluid warming methods might prompt postoperative sever pain but unfortunately there are very limited, insufficient and incomplete clinical evidence supporting the claim [10,2]. Therefore, present study tried to investigate effects of using the intravenous fluid in falling core body temperature and the severity of pain in the area of surgery of the cesarean section patients.

Methods

This study, which is a double-blind randomized clinical trial, was done in 2017 (April, 2017 to January, 2018) after getting approval of the Research Ethics Committee of Semnan University of Medical Sciences (ir.semums.1395.157) and receiving the Clinical Trial Code (Irct2017020232361N1) from the International Center for Clinical Trials Registration of Iran, which is a member of the international centers distinguished by the World Health Organization. The present study was performed in Amiralmomenin Educational Hospital in Semnan, Iran. The study population consisted of women undergoing cesarean section through the spinal anesthesia method. There were 80 participants based on results of a pilot study. The criteria for selection of the group were the class 1 and 2 patients of American Society of Anesthesiologists (ASA) (those not suffering systematic diseases) who underwent cesarean section on spinal anesthesia. The patients addicted to narcotic drugs (like opium) or alcohol, those suffering diabetics thvroid diseases. candid infection. or gynecological surgical background in the past one month and also those with a record of temperatures of below 36°C and above 38°C before surgery were discarded from this study. The participant was omitted from this study if receiving any blood.

The participants were briefed on goals of this study and informed consent was thus received. To randomize the participants, the hexagonal blocks of A and B were used. The availability and randomized sampling methods were used. Once entering the operation room, the participants received an intravenous route on their arm. An (non-invasive) automatic blood pressure measuring cuff was put on other arm of the patients. Pulse oximetry and hemodynamic monitoring precede anesthesia induction, well proceeding up to recovery. Core body temperature of the patients were measured using Microlife IR100 (infrared tympanic) thermometer placed in one of their ears. To evaluation reliability (r>0.8) of the measuring, the test was repeated three times on either of the patient's ears and then the average core body temperature was estimated . Spinal anesthesia was injected to patients in the sitting position and in the level of L2 to L4. Two anesthesiologists carried out the injection, using 26-27 gauge needles with 10 mg of hyperbaric bupivacaine. Just following the anesthesia injection, the participants were put in the supine position. Using alcohol cotton, the researchers could measure every minute the level of nerve block elevation. This went on until getting ensured that the level of nerve block is fixed (left unchanged). Following spinal injection the blood pressure of the participants was checked every two minutes. The surgery was conducted once the anesthesia level reached the T5 point while the hemodynamic conditions were stabilized. Upon entering the operation room, the control group participants also received fluid being at the operation room temperature. The control group members also received IV fluid upon entering the operation room. The experimental group members, however, received 37.5°C warm fluid as they entered the operation room. The fluid was heated by HOTLINE® Blood and Liquid Heaters (Smith's medical company's level 1 model). The warm fluid injection continued up to recovery. The data, thus collected, included: Demographic

The data, thus collected, included: Demographic information; core body temperature; total volume of fluid the participants received; and the information on the post-operative pain. The participants' body temperatures were measured during application of anesthesia, 15 minutes after injection of anesthesia; 30 minutes later, 60 minutes later, at the end of the cesarean section, early in the begging of recovery and at the end of the recovery stage. The patients' blood pressure and heart beat, displayed on the monitoring systems of the operation room and recovery ward, were recorded every 15 minutes. To prevent any hypothermia in the routine care method, blankets were used in the recovery ward. The postoperative pain severity was assessed every six hours in the first 24 hours based on the Visual Analogue Scale (VAS) criteria. A 10-degree calibrated ruler was used for the purpose of the VAS assessment of pain severity. To blind the study, any link between the intervening nurses and the assessor was cut and due to the same reason the type of intervention in the case of the patient could not be

distinguished by the assessor. To analyze the statistical quantitative data at the 0.05 level of significance, the SPSS software version 16 was used. The data were analyzed and interpreted through the T-Test, Mann-Whitney and Repeated Measurement tests accordingly.

Results

On the whole, this study consisted of 80 participants, divided into two groups of 40 members each. The mean age of the participants in the control group (31.5 ± 4.4) and the experimental group (30.07 ± 5.08) showed no difference of significance (P=0.18). None of the participants did receive pre-anesthesia medicine. The amount of different kinds of analgesics, that the two groups of control and experimental received during this study, did not show any difference of significance (p> 0.05) (Table 1).

Variable Duration of operating room (min)		Control Group (n=40)		Test Group (n=40)		Devolues
		SD 62.8	Mean 153.3	SD 45.7	Mean 157.9	P value 0.32
NPO time		2.4	9.5	2.4	9.8	0.51
Gestation (weeks)		0.6	38	0.7	37.8	0.2
Operating room temperature (C)	Beffor surgery	25.4	1.5	25.1	1.5	0.41
	After surgery	25.8	1.3	25.3	1.5	0.07
	Patients who received ephedrine (n)	6		7		0.5
Antipyretic drugs	Morphin (mg)	1.2	0.6	1	0.6	0.70
	Supp (N)	2.2	0.9	2.1	0.9	0.87
	Midazolam (mg)	1.6	0.7	1.4	1.05	0.40

Table 1: Surgical and Spinal Anesthesia Data

BMI: Body mass index. *Significant results.

Changes in the core body temperature of the participants at the time of assessment are well illustrated (Figure 1). The mean fall in the core body temperatures of both control and experimental group participants in different time periods compared to that in the beginning of the cesarean section are shown (Table 2).

Variable		Control Group (n=40)		Test Group (n=40)		Devalue
		SD	Mean	SD	Mean	P value
Mean temperature drop(°C) ^{**}	15 min later	0.5	0.3	+ 0.8	0.3	+0.6
	30 min later	0.4	0.4	- 0.2	0.4	- 0.2
	60 min later	0.5	0.5	- 0.2	0.5	- 0.3
	End of surgery	0.01^{*}	0.6	- 0.2	0.5	- 0.6
	Entry to Recovery	0.003*	0.5	- 0.2	0.4	-0.6
	End of recovery	0.05	0.5	- 0.1	0.5	- 0.3
Pain(hours after OR)	0	0.23	3.1	4.1	2.9	4.9
	6	0.29	3.1	5.5	2.7	6.2
	12	0.78	2.6	5.8	2.3	6
	18	0.97	2.6	4.6	2.8	4.6
	24	0.34	2.5	3.5	2.4	3.1

 Table 2: temperature drop and pain data in patients undergoing surgery who received warmed

 IV fluids (the Experimental Group) or IV fluids at room temperature (The Control Group)

*Significant results.

** Average temperature drop from the base line (Induction of anesthesia)

Temperature trend from anesthesia induction to end of recovery



Figure 1: Diagram of core body temperature changes since before anesthesia induction up to end of recovery 1. Before anesthesia induction 2. 15 minutes later 3. 30 minutes later 4. 60 minutes later 5. At the end of surgery 6. At entry to recovery 7. At the end of recovery

The mean body temperature of the experimental group participants were measured in all junctures, being higher level of significance (p=0.001, F=5.4) compared to the control group. The highest amount of difference in the body temperatures of the patients in the experimental and control groups was observed at the moment of recovery (p=0.004). The mean of pain severity difference in both control and experimental

groups in the first 24 hours was not significant (p=0.41, F=0.94). Table 2 separately shows the mean pain severity of the participants in the first 24 hours.

Discussion

The participants, receiving warmed IV fluids had less core body temperature drop during the cesarean section. The cesarean section is mainly done on condition of spinal anesthesia [3]. It is revealed that the main cause of body temperature fall is during redistribution of body temperature [11]. Intraoperative body temperature fall is in three phases [12]: 1. Sudden body temperature fall after anesthesia 2) temperature drop with less speed 3) stabilized body temperature (Plato phase) [13]. The Plato phase is in fact the outcome of physiological responses to regulation of body temperature [14,15]. The platelet phase was observed based on the study diagram around end of the cesarean section and onset of recovery. The results showed that at the end of recovery even, many of the participants had not reached their initial body temperature level at the onset of operation. Due to the same reason it seems that the body temperature of many of the participants did not reach the natural level at the end of the recovery and entry to the ward.

This study showed that compared to the passive methods (using blankets), the active methods (warm fluid injection) would more effectively prevent intraoperative temperature drop. In this vein, John et al. (2014) showed results similar to the findings of the present study [16]. The warm fluid receiving participants suffered hypothermia the least; this should not be interpreted as zero occurrence of hypothermia; rather, it should be said that compared to the control group, the experimental group suffered hypothermia the less. The study researchers do not only consider intraoperative warm fluid injection as a complete method to prevent core body temperature drop. The American Society of PeriAnesthesia Nurses (ASPAN), however, offered different suggestions in 2006 for checking core body temperature drop [17]. The warm fluid injection insignificantly raised intraoperative core body temperature of the patients. The warm fluid injection was found effective the most at the end of the cesarean section and at the onset of recovery.

The participants in this study received warm fluid injection as early as admission to the operation room (well before start of the cesarean section). Horn et al. suggest warm fluid injection to anesthetized patients 15 minutes before anesthesia injection to check any body temperature drop [10]. A study has revealed that injection of 1 liter of warm fluid could raise body temperature to the level of around 25°C [19]. Rajek et al. (2000) showed that injection of 40 mL/kg fluids at room temperature (20°C) could decrease core body temperature well by 1°C [20]. The highest level of difference in body temperature of the control and experimental group patients was recorded at the time of entry to the recovery ward. In another words, this study showed that warm (37.5°C) IV fluid injection eventually prevented core body temperature drop up to 0.27°C. This might be insignificant in numerical terms; however, clinically, it might leave multidimensional helpful effects in different body systems of the patients, which need separate surveys.

Initial hour spinal anesthesia might cause core body temperature drop of the patients up to about 0.5° C to 1°C [3]. This study observed body temperature drop of the control group patients to be about 0.3° C. Sung et al. (2012), however, reported body temperature drop in the initial hour of anesthesia to be about 0.8° C [21]. Factors such as wind severity, operation room temperature, the period the position undergoing operation left uncovered and the type of medication at the time of anesthesia might be the factors influential in difference between these amounts of temperature fall.

Different studies have proved ample links between the system for regulation of body temperature and pain control [22-26]. Pain is a vital issue for patients undergoing cesarean section. Study has shown that about 72% of the patients undergoing operation suffer severe pain [27]. The findings of this study reveal that warm IV fluid injection during the cesarean section will not cause less postoperative pain. In this vein, Benson et al. (2012) showed in a clinical trial that the patients warmed during operation did not have any difference of significance with the control group patients [23]. On the contrary, He Ma et al. (2017) showed that the orthopedic patients, receiving warm fluids, had less postoperative pain [28]. Moreover, abdominal and gynecological surgery studies have proved less pain severity among patients receiving warm fluids [29-31]. On the other hand, Benson et al. (2012) showed that warming patients will not have any effect on patients' postoperative pain severity [32]. It seems that the reason for difference in severity of pain the first postoperative period can be justified this way: Firstly, many of medicines, enzymes, neurotransmitters are temperature dependent in their production, delivery, and function [33] and secondly, body temperature drop coupled with hepatic blood flow drop could change liver metabolism of medicines (like drugs) [34,35]. The changes might have short-term effect on the feeling and severity of pain. On the other hand, the confounding factors like inadequate and imprecise methods of pain assessment can be a justifying reason for contradictory results in the study.

Limitations and Suggestions

One of the limitations of this study was measurement of temperature by ear; body temperature measured by ear would not exactly be the same as the core body temperature. Since the tympanic membrane blood sampling is done through carotid arteries, the measured temperature will be so close to the core body temperature [17,18]. However, a similar study is suggested to be made in the future to measure temperature thermometers. through pulmonary artery Moreover, another study is suggested in the future to assess patient's comfort level in the recovery ward.

Conclusions

This study's findings show that 37.5°C infusion of warm IV fluid seems to prevent drop core body temperature. However, it will not have any tranquilizing effect to postoperative pain severity.

Acknowledgments

We want to thank our friends and colleagues who helped us make this research possible. Research reported in this publication was supported by a grant [number: 1145] from the Semnan University of Medical Sciences, Semnan, Iran.

Conflict of interest

None declared.

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