EFFECTIVENESS OF HYPOTHERMIA PREVENTION PROTOCOL AMONG PATIENTS SUBJECTED TO MAJOR SURGERIES AT KMCH, COIMBATORE.

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A DISSERTATION SUBMITTED TO THE TAMILNADU

Dr. M. G. R. MEDICAL UNIVERSITY CHENNAI, IN

PARTIAL FULFILMENT OF REQUIREMENT

FOR THE DEGREE OF MASTER OF

SCIENCE IN NURSING

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CERTFICATE

This is to certify that the Dissertation entitled **"Effectiveness of Hypothermia Prevention Protocol among patients subjected to major surgeries at KMCH, Coimbatore"** is submitted to the faculty of Nursing, **The Tamilnadu Dr. M. G. R. Medical University, Chennai** by **Reg. No. 301510454** in partial fulfilment of requirement for the degree of Master of Science in Nursing. It is the bonafide work done by her and the conclusions are her own. It is further certified that this dissertation or any part thereof has not formed the basis for award of any degree, diploma or similar titles.

Prof. DR. S. Madhavi, M.Sc (N), Ph.D.,

Principal,

KMCH College of Nursing,

Coimbatore- 641014,

Tamil Nadu.

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APPROVED BY DISSERTATION COMMITTEE ON AUGUST 2016

1. RESEARCH GUIDE: _____

Prof. DR. S. Madhavi, M.Sc. (N), Ph.D.,
Principal
KMCH College of Nursing,
Coimbatore – 641014

2. CLINICAL GUIDE: _____

Prof. DR. P. Akila, M.Sc. (N), Ph.D.,
Department of Medical and Surgical Nursing,
KMCH College of Nursing,
Coimbatore – 641014

3. MEDICAL GUIDE: _____

Dr. N. Selvarajan, MD., AIIMS.,
Head of Department of Anaesthesiology
Kovai Medical Center and Hospital,
Coimbatore – 641014.

A DISSERTATION SUBMITTED TO THE TAMIL NADU Dr. M. G. R. MEDICAL UNIVERSITY CHENNAI, IN PARTIAL FULFILMENT OF REQUIREMENT FOR THE DEGREEOF MASTER OF SCIENCE IN NURSING

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LIST OF ABBREVIATIONS

S. NO	ABBREVIATION	ACRONYMS
1.	Air Conditioner	AC
2.	American Association of Nurse Anaesthetists	AANA
3.	Analysis of Variance	ANOVA
4.	Association of periOperative Registered Nurses	AORN
5.	American Society of Anesthesiologists	ASA
6.	American Society of PeriAnesthesia Nurses	ASPAN
7.	Body Mass Index	BMI
8.	Content Validity Index	CVI
9.	Content Validity Ratio	CVR
10.	Inadvertent Perioperative Hypothermia	IPH
11.	Intravenous fluids	IV FLUIDS
12.	National Institute for Clinical Excellence	NICE
13.	Operation Theatre	OT
14.	Post Anaesthesia Care Unit	PACU
15.	Standard Deviation	SD
16.	Statistical Package for the Social Science	SPSS
17.	Whole Blood Cell	WBC

CHAPTER - I
INTRODUCTION

Core temperature is the temperature of the central circulatory system. It is one of the most closely maintained physiological parameters as enzyme systems in the body have narrow temperature ranges in which they function optimally. Strict temperature control is important for normal organ, enzymatic, and cellular function. Temperature control is tightly regulated by the body within 0.2 ºC. This is referred to as the inter threshold range (Insler, 2006). Within this range, active methods of heating or cooling are not triggered. In addition, a set point temperature exists in which the body maintains steady changes in core body temperature (0.5-1.0 ºC) based on circadian rhythms (Horosz, 2013). Temperature tends to be decreased during sleep and increased with physical activity. Under normal conditions, the human body would initiate mechanisms to preserve or create heat. Balance of heat production and loss by thermoregulation is the essential mechanism of maintaining normal body temperature that optimizes the patient's chances of avoiding postoperative complications (Buggy & Crossley, 2000).

Hypothermia refers to the cooling of the body below the normal temperature range. Usually, a lower limit of 36°C is accepted. Below this value, dysfunction of various homeostatic mechanisms set in. This hypothermia is important in a perioperative setting for various reasons.

While there is no universally accepted definition for perioperative hypothermia or normothermic core body temperature, according to the American Society of Peri Anaesthesia Nurses (ASPAN), a temperature < 36°C (96.8°F) is used to define perioperative hypothermia (Hooper et al 2009). According to the United States National Library of Medicine, a temperature within 36.1°C-37.2°C (97-99°F) is used to designate a normothermic core body temperature. Hypothermia is defined as a body temperature of <36°C (96.8F) and may be classified as mild (35.0°C-35.9°C), moderate (34.0°C-34.9°C) and severe (≤ 33.9°C) (Burns 2009). Temperatures between 35.0°C to around 35.9°C are considered mildly hypothermic (Brock et al., 2013).

Perioperative hypothermia, is a common consequence among patients undergoing surgery with core temperature below 36.0 °C, due to disruption of thermoregulation during general anaesthesia. It decreases the heat production (inhibited vasoconstriction) while at the same time increases heat loss (induced vasodilatation), as in a result, causing a decrease of body temperature. The reported incidence of hypothermia varies from 6-90% of surgical procedures (Monzón et al., 2013). One recent source suggests as many as 50-70% of all surgical patients experience IPH (Roberson et al., 2013). This number is alarming to the perioperative care physician who deals with the deleterious complications of hypothermia. This implies the fact that research directed towards evidence-based practice for maintaining normothermia and prevention of IPH is warranted.

Risk factors for hypothermia includes , extremes of age (infants, children and elderly), thin patients and patients with large body surface area, preoperative hypothermia (patient in sepsis), prolonged duration of surgeries, surgeries with large amounts of fluid shifts, body cavity surgeries (open thoracic, abdominal, uro-gynaecological procedures), unregulated operating room temperature, reluctance to routine temperature monitoring & warming strategies, anaesthesia in patients with central regulatory depression, more area of body exposed during surgery, more amount of intravenous, irrigation fluids used.

The body reacts with thermoregulatory mechanisms such as cutaneous vasoconstriction and shivering. Hypothermia can result with undesirable effects during intra and postoperative period. Established complications of hypothermia include patient discomfort, increased sympathetic drive, increased incidence of myocardial events (Frank et al., 1997), impaired immune function (Beilin et al., 1998), wound infection (Kurz et al., 1996), coagulopathies, blood loss (Schmied, 1996), increased duration of ICU and hospital stay (Sessler et al., 2000). There are various factors which cause drop in body temperature of an anaesthetized patient. Impaired heat regulation from the higher centers (Sessler, 2000), transfer of core body heat to the peripheries, reduced metabolism under anaesthesia, exposure of the body cavities to the environment, cold operating room temperature are all the causes of intraoperative hypothermia Patients undergoing major procedures including body cavity surgeries, surgeries involving major fluid shifts and pediatric patients are at risk of dangerous levels of hypothermia (Forstot, 1995).

In addition, symptoms such as tachycardia, tachypnea, hypovolemia and coordination disturbances like ataxia, apathy appear. Moderate hypothermia, or temperatures between 34.0°C and 34.9°C, cause respiratory depression (hypoventilation) slow pulse (bradycardia), decreased blood pressure (hypotension), reflex suppression (hyporeflexia), enlarged pupils and an ever-increasing loss of consciousness and seizures. Shivering ceases. At even lower temperatures, severe hypothermia, the human organism reacts with circulatory and respiratory collapse (Bräuer 2006, Wartzek 2011, McCullough 2004, Stanhope 2006). Hence it becomes important in maintaining normothermia during the perioperative period.

The effective perioperative temperature management begins with accurate temperature measurement. The body temperature of the patients will be measured every 5 minutes after 33 when they are admitted to the operating theatre department. The body temperature will be measured by tympanic thermometer at the tympanic membrane. Findings have shown that the core temperature of surgical patients usually drops by 0.5°C to 1.5°C at the first hour of anaesthesia (Purssell, 2009).

International Journal of Evidence Based Healthcare (2011) reported that 50% to 90% of surgical patients had perioperative hypothermia. In local setting all patients underwent abdominal surgery experienced hypothermia. Shivering was observed in almost half of the patients postoperatively. Hypothermia causes shivering which in controlled settings can increase the metabolic rate up to 5 times the basal rate (Eyolfson, 2001). Increased metabolism, minute ventilation, and activation of the sympathetic system make avoidance of shivering necessary (De Witte 2002). Hypothermia is also associated with up to a 250% increase in minute ventilation, which may be detrimental in certain subsets of patients such as those with underlying lung disease (Marion, et.al 2009). The body's natural ability to warm itself is disrupted by anaesthetic agents (Torossian, 2015). General anesthesia causes tonic vasoconstriction of the peripheral vasculature, which causes vasodilation; thus, the patient's core temperature can decrease during the surgical procedure (Kurz, 2008).

In addition to causing discomfort for the patient, hypothermia may contribute to myocardial events, no increase in the use of vasopressors, arrhythmias (other than sinus bradycardia), myocardial ischemia, or myocardial infarction most likely due to an increase in the amount of circulating catecholamines. However, adverse cardiac

events have been demonstrated only in patients with probable coexisting coronary atherosclerotic disease (CAD) (Frank, 2003).The authors further hypothesized that with adequate adrenergic blockade, even patients with a history of CAD would suffer a low incidence of cardiac events when cooled (Todd 2005 & Nguyen 2010). Furthermore, postoperative cardiac events occur at a higher rate; although it is unclear whether this is due to increased oxygen consumption or norepinephrine levels.

Hypothermia can also induce coagulopathy and inhibit platelet function which may lead to an increase in the amount of surgical bleeding, and potentially leading to greater transfusion requirements. Patient with a mean temperature of 35.6°C was likely to lose 16% more blood and was 22% more likely to receive a blood transfusion (Rajagopalan, 2008). Therefore, based on the available evidence, hypothermia should be permitted only when clinically indicated for neuro protection. Also, to be consistent with the American Heart Association's guidelines for the induction of hypothermia, ongoing bleeding should be controlled before decreasing temperature (Peberdy, 2010).

Hypothermia in the post-operative period is thought to be a risk factor for surgical site infections (SSI) and delay wound healing and may result in a longer hospital stay. Infectious complications are more likely associated with an increased duration of hypothermia (Badjatia, 2009). Hypothermia causes the blood vessels to constrict, decreases blood flow to tissues and decreases oxygenation of surgical wounds, allowing a more favourable environment for bacterial growth. Recently, a large retrospective study found that documented adherence to postoperative normothermia in patients undergoing colorectal surgery. The results implied that there is an association with an increase in infectious complications involving hypothermia outside of the operating room (Shiozaki, 2001).In 1996, a randomized controlled trial reported that patients who were hypothermic at the end of surgery experienced a three-fold increase in the incidence of SSI.

Hypothermia may also affect pharmacokinetics and prolong postoperative recovery times and hospital length of stay. It alters medication metabolism, causing metabolic acidosis, hypokalemia, and nitrogen imbalance. Hypothermia has been linked to additional adverse outcomes such as prolonged time to recovery from general anaesthesia. Drug effects are prolonged because of decreased metabolism and

increased potency secondary to decreased body temperature. The clearance of midazolam and vecuronium is reduced approximately 11% for every degree Celsius drop in body temperature. Similarly, the metabolism of remifentanil is reduced by approximately 6% for every one degree Celsius drop in temperature. Likewise, the metabolism of fentanyl and propofol are reduced (Fritz, et al., 2005).

When a temperature of 36°C was added to discharge criteria, discharge time was prolonged by 90 minutes (Hooper 2010). A randomized controlled trial demonstrated that hypothermic patients (average intraoperative temperature 34.8°C) took approximately 40 minutes longer to meet discharge criteria from the post anaesthesia care unit compared to normothermic patients (average intraoperative temperature 36.7°C) (Cattaneo, 2000). Factors such as the patient's age, weight, and health conditions can contribute to unplanned hypothermia. In addition, (Kurz, 2008 & Sessler, 2000) environmental factors specific to the OR, including low room temperatures, lack of clothing on the patient, administration of room-temperature IV and irrigation fluids, evaporation of skin preparation solutions, and air movement, can contribute to heat loss and a decrease in core body temperature.

Perioperative hypothermia is a multidisciplinary/multispecialty problem. Management of this nursing and medical diagnosis requires the coordinated efforts of anaesthesia providers, surgeons, and perioperative, peri-anaesthesia, and critical care nurses. Inadvertent perioperative hypothermia is a common but preventable complication. Currently, there are multiple warming methods used during and after the surgical operations for prevention and treatment. One effective strategy for maintaining normothermia involves warming the patient preoperatively. This strategy has been shown to significantly attenuate, and prevent, hypothermia from redistribution of blood from the patient's core to periphery while under general anesthesia (Horn, 2012).

NEED FOR STUDY

Perioperative hypothermia is a condition that affects most surgical patients and may lead to an increase in recovery time, length of hospital stay and costs, and also, a decrease in patient satisfaction. In order to combat perioperative hypothermia, many prevention strategies have been examined. With respect to temperature, it is easier to

prevent temperature changes than to treat undesirable changes; However, prevention of hypothermia is relatively effective, assuming that suitable devices are available and properly used (Moola, 2011). Maintaining normothermia can be achieved by adopting various warming strategies which includes usage of patient warming devices. Various methods of patient warming during preoperative, intraoperative and postoperative settings have been introduced and are in clinical practice (Welch 1994). They work on different mechanisms like conduction, convection or radiation. Different studies give different results on the efficacy of various warming strategies in maintaining normothermia in the patient. The choice of the warming device is dependent on the availability, efficiency of the device, cost issues, nature and duration of the surgery and anaesthesiologist's preferences. Different studies give different conclusions on the efficiency of these warming devices in various settings (Russell et al., 1995)

The recommended practice for the prevention of unplanned perioperative hypothermia is "pre-warming the patient for a minimum of 15 minutes immediately prior to induction of anesthesia or warming should be started before the patients being transferred to the operating table or provision of a minimum of 30 minutes of preoperative warming [American Society of Perianesthesia Nurses] (ASPAN, 2009).Few studies conclude that forced air warming is more efficient than circulating water mattress in maintaining normothermia because of the larger body surface area exposed to forced air (Chiharu Negishi 2003). However other studies conclude that circulating water mattress is more efficient in heat transfer and maintaining normothermia (Taguchi, et al., 2004).

Active and passive cutaneous warming are likely the most common and aim to both warm and prevent heat loss; many consider active warming a standard of care for surgeries over one hour. During surgical anaesthesia, approximately 90% of the patient's body temperature loss occurs from the skin to the environment. Active warming systems such as forced-air system, blankets, warming blankets, circulating water mattresses and garments, and radiant warming system are commonly used to prevent hypothermia during anaesthetic/surgical procedures. The use of cotton blankets (warmed or not) and surgical drapes (tissue or adhesive) are passive methods. Today, evidence exists that indicate that the use of active warming methods (warmed air or water) is more effective to maintain patients' body temperature in the

perioperative period (Kumar 2005, Kurz 2008, Galvao 2010). Patients also experience a greater level of comfort, and avoid postoperative shivering and the unpleasant sensation of feeling cold.

Bair hugger is a device which blows heated air into a blanket on which the patient lies. It usually consists of three values of preset air temperature which can be selected based on the requirement. Since it blows unsterile air into the surgical field, a few studies have reported increased incidence of postoperative infection in using forced air warmer (Baker, 2002). Blanketrol II circulating water mattress consists of a mattress into which water of preset temperature circulates. Blanketrol II also has an auto mode, whereby patient's temperature is sensed by the machine with the help of a temperature probe and water is heated or cooled to maintain the patient's temperature at the set point. This auto mode is easier than the manual adjustment of set temperature in forced air warmer or the circulating water mattress according to the patient's temperature.

Intravenous nutrients have also been examined to boost metabolic heat production. Additionally, pharmacologic agents that induce vasoconstriction have been studied with the goal of minimizing heat loss. Considering the operating room temperature, the loss of energy in the form of heat through exposed skin is always substantial; the greater the difference in the skin and surrounding temperatures, the bigger the loss (Galvao, 2010). The patient’s heat reserve decreases during surgery, predominantly via the loss through the skin, the expenditure of energy used for vaporisation from the surgical site and for the warming of transfused intravenous fluids, and through the airway. Because the surgical site cannot be altered, hypothermia can be effectively prevented only by the prevention of heat loss through the skin and by transfusion of pre-warmed fluids. Warmed infusion fluids can inhibit the heat escape or even enable its supply to the body, but only under certain circumstances. “Warming intravenous (IV) fluids should be considered only if large volumes (i.e., more than two litres/hour for adults) are being administered. Warming IV fluids to near 37 degrees Celsius (98.6 degrees Fahrenheit) prevents heat loss from the administration of cold IV fluids and should be considered as an adjunct to skin surface warming. When less than two litres of volume is given, fluid warming is of limited value because fluid induced cooling is minimal (Denver, 2010).

A decrease in core temperature by 0.5 to 1.0° C was observed after transfusion of 500 mL of cold blood, and massive transfusions were found to be associated with marked hypothermia and a high risk of sudden cardiac arrest (SCA). To increase the temperature of 1 kg of water by 1°C, 1 kcal of energy is needed (the heat capacity of water is 1 kcal); thus, the body needs 16 kcal of energy to "warm" 1 litre of crystalloids from room temperature (21°C) to body temperature (37°C) (assuming that their heat capacity equals that of water). Based on the above data, to warm 3.7 litres of crystalloids from room temperature, the anaesthetised patient's body has to use the energy it produces during one hour of anaesthesia using substitutive ventilation (approximately 60 kcal h–1 ~ 70 W). The transfusion of 1 litre of full blood at 4° C requires approximately 30 kcal of energy for warming; the transfusion of 2 litres is likely to decrease the core temperature by 1–1.5°C (Oshvandi, 2014).

The desirable temperature of crystalloids and colloids should depend on the clinical situation; there are, however, reports about the safe supply of crystalloids of 54°C (Campbell 2015). However, despite the tremendous effort of improvement, the incidence of postoperative hypothermia is still high in many hospital settings. All active warming methods prevent the loss of body heat; however, some are more effective than others, with circulating water garments and the forced-air system being the most effective methods.

Water has a markedly higher heat capacity than air, it can be potentially assumed that when water circulates in the warming system, the amount of heat supplied can be large. The only condition is the provision of direct contact with the largest possible skin surface; thus, specially shaped covers filled with warm water were designed in which the limbs and intraoperatively available trunk parts are wrapped. Such a system was found to be more effective than forced-air and electric systems Hasegawa, (2012).

Forced-Air warming systems operate by forcing warmed air through the warming device to the container, which is in direct contact with the patient's skin, (usually a two-layer blanket). The blanket shape is tailored to the needs, i.e., it contacts the largest possible surface of the body, depending on the patient's position and location of the operative field. The air forced inside escapes through the pores of blanket fabric, forming a specific, warm microclimate around the individual being

warmed. The lack or reversal of the temperature gradient between the environment (warming blanket) and the skin inhibits heat loss through radiation as well as overheating Chung, (2008). The effectiveness of these systems also depends on the gradient of temperatures between the blanket and skin surface. The higher the gradient in favour of the warming blanket (air warmer than the skin), the bigger the heat flow to the body surface. In an article published by Lista, et al., (2012) it was concluded that use of simple measure like use of warmed fluids, limiting the area exposed to surgical site alone, forced air warming improved clinical outcomes, patient comfort and recovery following surgery. They also showed an association between the perioperative hypothermia and the deleterious outcomes like cardiac injuries, wound infection and impaired wound healing.

Patient safety is paramount in perioperative practice. Prevention of unplanned hypothermia is among the main patient-safety concerns for perioperative nurses. Perioperative team members should receive education about hypothermia, including clinical signs and symptoms of hypothermia and preventive measures. In the existing literature, there are numerous reports exploring the effectiveness of different interventions in maintaining the patients' body temperature. Despite these multiple strategies, hypothermia continues to be a problem and a common consequence of the perioperative period. It is a big challenge for perioperative nursing staff to maintain normal body temperature of the patients in perioperative setting. One of the duties of nurses is to maintain the patient's body temperature within the normal range. A methodological trend that has been gaining momentum is the temperature monitoring. Regular measurement and recording of temperature is the key to prompt identification and its management with prevention and management of hypothermia. Anaesthesiologists are expected to be proactive in recognizing and managing temperature derangements throughout the perioperative period. (National Quality Measures Clearinghouse, 2007).

The purpose of this paper is to review and update policies and procedures related to hypothermia. In turn address components of perioperative assessment for hypothermia, disruption of temperature regulation by anaesthesia and perioperative environment, the consequences of hypothermia, and the methods for hypothermia prevention and treatment, consistent temperature measurement through all phases of

care, use of warming equipment according to manufacturer's instructions, and competency requirements related to hypothermia prevention. Working as a collaborative team, perioperative nurses and other health care providers in the preoperative, intraoperative, and postoperative recovery phases can minimize, if not eliminate, unplanned hypothermia, resulting in optimal outcomes for their patients.

STATEMENT OF THE PROBLEM

Effectiveness of Hypothermia Prevention Protocol among patients subjected to major surgeries at KMCH, Coimbatore.

OBJECTIVES

The objectives of the study were to,

- assess the incidence and extent of hypothermia among patients subjected to major surgeries.
- determine the effectiveness of hypothermia prevention protocol among patients subjected to major surgeries.
- associate the demographic variables, clinical variables and risk factors of hypothermia with core body temperature among patients subjected to major surgeries.

OPERATIONAL DEFINITIONS

1. HYPOTHERMIA

It refers to various degree of subnormal core body temperature as measured using reusable tympanic membrane thermometer on arrival in and transfer out from holding area, operation theatre and PACU. The subnormal core body temperature was classified as

- Mild hypothermia (35 ºC - 35.9 ºC)
- Moderate hypothermia (34 ºC -34.9 ºC)
- Severe hypothermia (≤ 33.9 ºC).

2. MAJOR SURGERY

It refers to surgical procedure either open or laparoscopic surgical procedures extending more than one hour.

3. HYPOTHERMIA PREVENTION PROTOCOL

It refers to the implementation of management strategies for the patient's with normothermia or hypothermia followed by intra and post-operative assessment of risk factors, signs & symptoms, and vital parameters.

HYPOTHESIS

There will be a significant reduction in occurrence of hypothermia among patients subjected major surgery after implementation of hypothermia prevention protocol.

ASSUMPTION

- Core body temperature is the physiologic indicator of thermoregulation.
- The duration of surgery may influence the core body temperature.
- Anaesthesia given during surgery induces hypothermia

CONCEPTUAL FRAMEWORK

Conceptual framework refers to interrelated concepts or abstract those are together in same rational scheme by virtue of their relevance to a common theme (Polit & Hungler, 1999).

The conceptual framework for this study was developed by applying Ludwig Von Beralanffy's (1968) general system theory. According to the general system theory a system consists of a set of interaction components. There are two types of general system that is closed and open.

A closed system does not exchange every matter or information with its environment. It receives no input from the environment and gives no output to the environment. In an energy, matter of information move into and output to the system.

Open system consist of the input, throughout and output process. According to theorist view the information matter, and energy that the system receives, transforms the input in a process called as throughout and releases information, matter and energy as output that returns to the system as input is called feedback, which may be positive, negative or neutral.

In this present study the investigator considered the following concepts which possessed through the systems of input, throughput and output.

INPUT

The input included the demographic variables - age, sex, education status, dietary pattern. clinical variables -ASA classification, co-morbidity, nature of surgery, BMI and type of procedure, risk factors of hypothermia - duration of stay, type of anaesthesia and agents used for anesthesia, blood loss during surgery, volume of IV fluid administration, ambient room temperature, humidity of theatre, signs and symptoms of hypothermia - shivering, pilorection and cold extremities, risk factors of hypothermia, signs & symptoms among subjects in perioperative period.

THROUGH PUT

It included the observation of hypothermia and normothermia management routines by using hypothermia prevention protocol by the investigator.

Pretest assessment on monitoring vital parameters such as core body temperature, heart rate, respiratory rate, blood pressure & SPO_2 in time sequences of every 30 minutes on arrival to each area (holding area, OT and PACU). The core body temperature was measured by using infrared tympanic thermometer (model DL8740, 2016. Philips) it gives the measurement within 2-4 seconds after placing thermometer into ear canal. Before using the infrared tympanic thermometer, the investigator was explained the procedure to the patient and obtained verbal consent. To monitor temperature, cleaned the ear with cotton buds and inserted the ear speculum into ear canal by pulling ear pinna backward, up and out. The thermometer probe was left in place until patient's temperature appears on digital display then carefully removed from auditory meatus and cleaned the speculum lens with the alcohol swab. Documented the displayed temperature. Assisted the patient in assuming a comfortable position and Performed hand hygiene.

Hypothermia management strategies was implemented based on vital parameters especially the core body temperature. If the patient's temperature is within the normothermic range (i.e., 36° C to 37° C [96.8° F to 98.6°F]), the passive body warming measures were instituted, including maintaining the patient's temperature and the ambient room temperature, minimizing skin exposure by providing woolen blankets, stocking and head coverings in holding as well as in PACU area, draping was applied only in operation theatre.

If the patient is within the hypothermic temperature range (i.e., <36° C [<96.8° F]), then active warming measures were instituted. In holding area, forced air warming devices and inline warming devices, cabinet warming devices were applied. In intraoperative area, forced air warming devices, circulating hot water mattress, cabinet warming devices, inline warming devices, fluid warm irrigation were instituted. In PACU, forced air warming devices, cabinet warming and inline warming devices were instituted.

Post-test assessment on monitoring vital parameters such as core body temperature, heart rate, respiratory rate, blood pressure & SPO_2 in time sequences of every 30 minutes on exit from each area (holding area, OT and PACU).

OUTPUT

The expected outcome was the prevention of hypothermia or non maintenance of normal body temperature of 36ºC- 37ºC prior to discharge from PACU among patients.

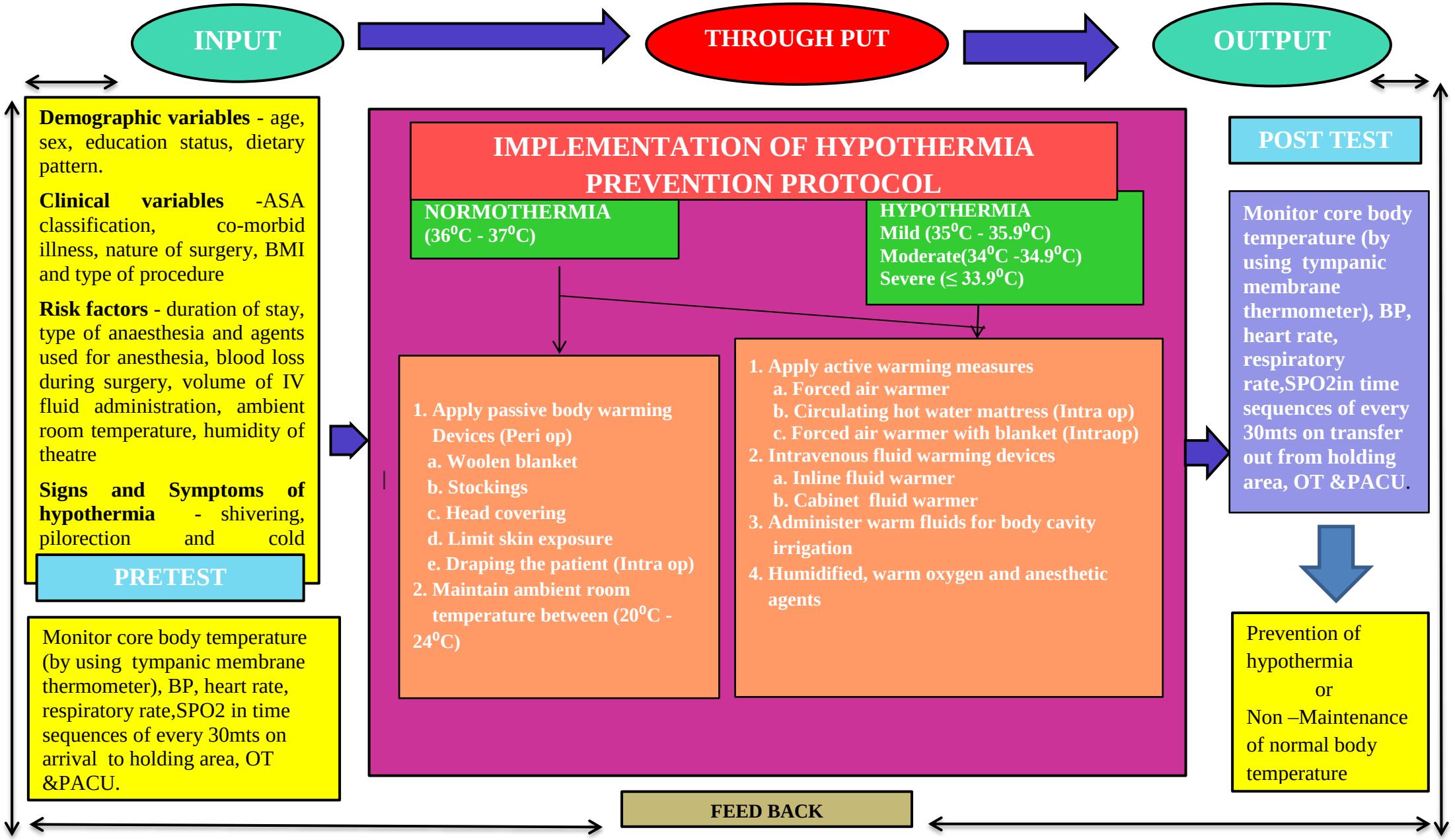


Figure 1: MODIFIED LUDWIG VON BERTALANFFY'S GENERAL SYSTEM THEORY, 1968

CHAPTER - II

REVIEW OF LITERATURE

This chapter deals with the information gathered from various research articles and unpublished thesis, related to present study. Indian literature on management and prevention of perioperative hypothermia are very few. An extensive review was made to strengthen the present study in order to lay down the foundation. It is familiarizes the investigator with previous investigation related to ones field of interest and various methods and procedure which can be pursued.

The literature reviewed for this study is presented as follows,

- Risk factors associated with perioperative hypothermia
- Prevention and management of perioperative hypothermia by active and passive warming device

Risk factors associated with perioperative hypothermia.

Hypothermia, which is defined as having a core body temperature of less than or equal to 36 degrees Celsius or 96.8 degrees Fahrenheit, is associated with several complications and an increased risk of death. Perioperative hypothermia can result in:

- Three times the incidence of surgical site infection
- Increased bleeding and increased need for blood transfusions
- Three times the risk for cardiac complications
- A higher risk for developing pressure ulcers
- Prolonged recovery after surgery

According to Fry, et al., (2007) the primary line of defences against infection is intact skin. A surgical incision exposes the body to exogenous and endogenous pathogens. The primary defense against surgical pathogens is oxidative killing by neutrophils. Hypothermia triggers vasoconstriction, which decreases tissue oxygenation and perfusion, thus significantly increasing the risk for SSIs. Increased

infection rates have been associated with surgical procedures that last longer than four hours.

Andrea Kurz, et al., (2008) published a study involving 200 colorectal surgery patients; 100 were randomly assigned to undergo surgery with warming and the other 100 without warming. For those who did not receive warming, the final mean intraoperative core temperature was 34.7ºC degrees Celsius. The final mean temperature for those who were warmed was 36.6 ºC degrees Celsius. Surgical wound infections were found in 19 percent of the hypothermic group and in six percent of the normothermic group. The study concluded that intraoperative core temperatures about two degrees Celsius below normal increase the incidence of wound infection threefold and prolong hospitalization by about 20 percent.

Melling, et al., (2001) conducted a study of wound infection rates following surgery. The random controlled trial included 421 patients and resulted in a four percent infection rate among patients who received local warming and 15 percent among those who were not warmed growth. One study found that dissolved oxygen (pO2) is a strong predictor of infection. Measuring levels of subcutaneous oxygen in post-surgical patients, he found that none with an oxygen tension greater than 90 mmHg developed a SSI whereas 43 percent of patients with an oxygen tension between 40 and 50 mmHg did develop a SSI.

The study conducted by Daniel Sessler, et al., (2008) found that less than one degree of hypothermia is enough to increase blood loss by about 16 percent and increase the need for intraoperative transfusion by about 22 percent. Normothermia, however, was associated with a reduced chance of blood loss and a reduced need for transfusion. Similarly, an earlier study by Schmied, (1996) also found that mild hypothermia can increase blood loss and the need for transfusion during surgery.

Frank, et al., (2013) revealed that a greater number of hypothermic patients (36 percent) experienced myocardial ischemia compared with normothermic patients (13 percent). The incidence of angina postoperatively was also greater among the hypothermic group (18 percent) compared with the normothermic group (1.5 percent). All 100 subjects in the study underwent a vascular reconstruction procedure. It is important to recognize the difference between unintended hypothermia that leads to

cardiac conditions, and the growing practice of therapeutic, induced hypothermia in cardiac patients. Unintentional hypothermia (perioperatively or otherwise) can lead to an unusually slow or irregular heart rate, which manifests as a weak or slow pulse or other arrythmias.16 Therapeutic hypothermia is an evidence-based intervention that attempts to lower core temperatures to around 33 degrees Celsius for 24 hours after a cardiac event for the purpose of improving neurological outcomes.

Sun, et al., (2015) in a recent large retrospective study of non-cardiac surgeries that attempted to determine whether mild hypothermia leads to increased blood loss and transfusions. The study had given inconsistent results, that a median patient temperature of 35.6 ºC resulted in increased blood loss (4%-26%) and an increased relative risk of transfusion (3%-37%). However, transfusion requirements increased in proportion to the decrease in temperature and the increased duration of hypothermia. Potential causes for increased blood loss include hypothermia-induced platelet dysfunction and coagulation cascade enzyme dysfunction. To evaluate coagulopathy, prothrombin time (PT) and partial thromboplastin time (PTT) were measured at different temperatures. For a given blood sample, PT and PTT increased from 11.8 ± 0.3 s and 36.0 ± 0.7 s to 12.9 ± 0.5 s and 39.4 ± 1.0 s, respectively, as the temperature of the sample decreased from 37 to 34 ºC. Both PT and PTT continued to increase as temperature further decreased. It is important to note that blood samples are warmed to 37 ºC prior to performing the lab tests. Therefore, laboratory values may not reflect what is occurring physiologically in the patient.

Although most studies show that hypothermia contributes to increasing length of hospital stay and PACU recovery time, results are not consistent. A large study published by Kurtz 1996 in colorectal surgery patients found that hypothermia (34.7 ± 0.6 ºC) at the end of surgery delayed patients' ability to tolerate solid food and suture removal by one day compared to patients with normothermia. Hospital length of stay also increased 20% (2.6 d) and length of stay was prolonged even after correcting for the increased risk of infection in the hypothermic group. Lenhardt, et al., (1997) PACU discharge times are also impacted by hypothermia. Discharge from the PACU was observed to significantly increase by 40 min in hypothermic patients based on a modified Aldrete and Kroulik scoring system. If discharge criteria included normothermia, then recovery was prolonged over 2hrs. The twitch tension starts to

decrease 16% per 1ºC once the temperature of the adductor pollicis muscle is below 35.2 ºC. With moderate hypothermia to 3 ºC, morphine also has decreased potency, clearance, and volume of distribution; although, its concentration is elevated in the plasma and cerebral spinal fluid. Notably, the efficacy of neostigmine and naloxone seems to be preserved during hypothermia.

Prevention and management of perioperative hypothermia by active and passive warming device.

Hong-xia, et al., (2010) conducted a Quantitative study Randomized clinical trial with general aim is to evaluate the efficacy of warm fluids in maintaining core temperature during the intraoperative period and in preventing post anaesthetic shivering. Administration of warm IV fluids at 37ºC (Hotline system) Vs Administration of intravenous fluids at room temperature (24ºC) among patients, 30 participants: control group (n=15); test group (n=15). The study concluded that the administration of warm IV fluids in abdominal surgeries is effective in maintaining core temperature (nearly normothermia) and may decrease the incidence of postaneasthetic shivering. Authors advocate the association of this IV fluid warming system with other techniques to minimize the occurrence of hypothermia. The additional cost of the fluid warming system - Hotline - is low. Moreover, its effectiveness in preventing perioperative hypothermia has been confirmed.

Galvao, et al., (2010) conducted a study Quantitative method, with general aim is to identify the effectiveness of different types of cutaneous warming systems in temperature control for patients undergoing elective surgery. Active warming methods among participants, Out of the 329 studies initially identified, 23 were selected (n=23); the study concluded that Circulating water garments (CWG) are more effective in maintaining temperature in people undergoing surgery and improving hypothermia prevention than forced-air, radiant heat or carbon-fibre warming systems. However, forced-air warming systems (convection) are more effective than passive warming systems and the radiant heat or carbon-fibre warming systems. The above mentioned aspect is enough to confirm the cost-effectiveness of forced-air systems in relation to passive warming systems, such as blankets, but not enough to demonstrate the advantage of CWG.

Bernardis, et al., (2009) conducted a Quantitative study with general aim to assess the efficacy of using a forced-air blanker in different periods as a method to prevent intraoperative hypothermia. The secondary objective is to assess the adverse effects of using a forced-air blanket at 38ºC. Warming method (s) under study was Forced-air blanket at 38ºC among 60 participants: Gcont (n=15) – patients were not warmed with a forced-air blanket; Gpre (n=15) – forced-air blanket for 30 min. before anaesthetic induction; Gintra (n=15) – forced-air blanket after anesthetic induction up to 120 minutes; Gtotal (n=15) – forced-air blanket before and after anaesthetic induction. The study concluded that the forced-air blanket is effective to prevent intraoperative hypothermia in orthopedic surgeries when applied for a period ranging from 30 min before anaesthetic induction to 120 min after anesthetic induction; under the conditions of the study, no adverse events were observed as a result of using a forced-air blanket at a moderate intensity (38ºC).

Pagnocca, et al., (2009) conducted a Randomized clinical trial with general aim to assess the efficacy of the association of conductive and convective warming methods in the prevention of hypothermia and its effects during postoperative recovery. Warming method (s) under study was Circulating water mattress at 37ºC Vs Circulating water mattress associated with warm air blanket at 42ºC among 43 participants: n=24 – circulating water mattress, on the back (Conduction); n=19 – circulating water mattress associated with warm air blanket over the thorax and upper limbs (Conduction + Convection). The study concluded that the effectiveness in preventing hypothermia in the intraoperative period by associating conductive and convective methods was greater than that achieved by the isolated use of the conductive method, thus delaying the onset of hypothermia and reducing the intensity of its adverse condition. In addition, only the association of both methods was able to prevent the onset of hypothermia in the post-anaesthetic recovery period.

Andrzejowski, et al., (2010) conducted a Randomized clinical trial with general aim to verify whether differences were found between the core temperatures of patients receiving fluids warmed with in-line devices and those of patients receiving warming cabinet fluids and to verify the incidence of postoperative hypothermia in patients receiving warmed fluids and those receiving fluids at room temperature. Warming method (s) under study was Administration of warmed

intravenous fluids *Vs* administration of IV fluids at room temperature among n=76; participants were divided into 3 groups, one group received 1L of crystalloid at room temperature, another received 1L of crystalloid warmed using an in-line warming device, and the other was pre-warmed in a warming cabinet. The study concluded that the administration of warmed fluids results in higher postoperative temperatures and a lower incidence of hypothermia. In addition, pre-warmed fluids in a warming cabinet are comparable to those used in the in-line system. This study reinforces the NICE guidelines, according to which all IV fluids should be warmed before administration to minimize the incidence of perioperative hypothermia.

Kadam, et al., (2009) conducted a randomized clinical trial with general aim to evaluate the efficiency of two warming methods (forced-air and radiant warming systems) in preventing hypothermia during elective laparoscopic cholecystectomy. Warming method (s) under study was Forced-air Vs Radiant warming devices. All administered fluids were warmed at 41ºC among N=29; 15 used forced-air and 14 used radiant warming devices. The study concluded that No statistically significant difference was found in temperature between both warming methods. This study demonstrates that both the forced-air and the radiant warming systems are effective in maintaining the patient's intraoperative temperature, thus in preventing perioperative hypothermia.

Adriani & Moriber, (2013) conducted a Quasi-experimental study with general aim to investigate if preoperative warming with a patient adjustable warming system combined with intraoperative warming is more effective in the prevention of hypothermia compared with traditional intraoperative warming alone with the Bair Hugger blanket. Warming method(s) under study was Pre-warmed group: Forced-air warming gown (Bair Paws); at least 30 minutes (mean: 51 minutes); temperature controlled by patient with handheld device. Both groups: forced-air warming blanket (Bair Hugger) initiated at anesthesia provider discretion, warmed IV fluids for all patients among n=60, Female adults 18-85 years (mean age prewarmed: 49 years non-prewarmed: 47 years) undergoing general anesthesia with an endotracheal tube, ASA class I-III. The study concluded that prewarming plus intraoperative warming is more effective in the prevention of hypothermia than intraoperative warming alone.

Hoove, (2011) conducted a study Quasi-experimental with general aim to determine whether the patients who received preprocedure warming maintained normothermia throughout the perioperative period, indicated by a normothermic tympanic temperature reading (96.8-100.4°F) upon arrival to the PACU. Preoperative Warming Device; Duration; Temperature Prewarmed group: Beginning March 2008, all colorectal patients received prewarming with forced air-warming gown (Bair Paws); 60 minutes; temperature of warming device not listed and Intraoperative Warming for Both Groups all colorectal patients received standard perioperative care which did not include prewarming (specific perioperative standards of care not listed) among n=149 Adults (mean age 64 years) undergoing general anesthesia, preoperative temperature of less than or equal to 38°C. The study concluded that Preoperative temperatures prior to prewarming differed significantly between the groups (p= 0.008).

Negishi, et al., (2003) studied 24 patients undergoing elective open abdominal surgery divided in three groups based on the warming strategy- resistive warming, circulating water and forced air warming systems. Tympanic temperature was measured intraoperatively which was the primary outcome of the study. They concluded that resistive heating and forced air warmers are comparatively effective and far better than circulating water mattress which are nearly ineffective. Core temperature in circulating water warmer group continued to decrease in linear fashion along the length of the surgery, as low as upto 34^{o}C.

Matsuzaki, et al., (2003) randomly assigned 24 patients undergoing laparoscopic cholecystectomy to three groups (1) circulating water mattress, 38^{o}C (2) Forced air warming (set to medium) or carbon fibre resistive warming (38^{o}C). Warming was applied during anaesthesia and surgery throughout. Conclusions were resistive heating as well as forced air warming maintains core body temperature better than circulating water, in which group, the core body temperature continued to decrease.

Taguchi, et al., (2004) compared heat transfer, regional heat distribution, the rewarming caused by the forced air warmer with that of the circulating water heating garment in nine volunteers. The volunteers were anaesthetised and actively cooled to oesophageal temperature of 34^{o}C with a forced air cover set and subsequently warmed with one of the two randomly assigned methods. Overall the heat balance was

calculated from the difference between the thermal loss from skin and metabolic production (indirectly from oxygen consumption). Data analysis concluded that the circulating water garment transferred more heat than air warmer and this is attributed to the posterior aspect of body warming which increases the heat transfer.

Grocott, et al., (2004) conducted a randomized control trial to compare temperature maintaining abilities of the Arctic Sun® Temperature Management System (a servo-regulated system that circulates temperature-controlled water through unique energy transfer pads adherent to the patient's body) with conventional temperature control methods (control group; increased room temperature, heated IV fluids, convective forced air warming system) in 24 patients undergoing off-pump coronary artery bypass surgery. Hypothermia was defined by a temperature 36°C or less. The circulating water system significantly reduced intraoperative hypothermia during surgery. Importantly, this was achieved in the absence of any other temperature modulating techniques, including the use of IV fluid warming or increases in the ambient operating room temperature.

Zangrillo, et al., (2006) conducted a prospective randomized control trial to evaluate the performance of Allon Thermo Wrapping Thermoregulation system, a circulating water garment and to compare it with a conventional forced air cover system in reducing the incidence of perioperative hypothermia during Off-pump coronary artery bypass graft surgery in thirty one patients. Rectal temperatures were recorded every thirty minutes and at intensive care unit arrival. Fewer patients in the study group (2/15 patients, 13.3%) suffered perioperative hypothermia than in the forced air warmer group (13/16 patients, 81.3%) which is statistically significant (P=0.0006). No differences in the outcomes were noted. The conclusion was Allon circulating water garment maintained normothermia, especially after the first two hours of the surgery, and it was not associated with surgical field disturbance

Wadhwa, et al., (2007) took up seven healthy male volunteers who participated in the study on three different days at least 48 hours apart from each study day. They were anaesthetized and actively cooled till their mean skin temperature decreased to 31^{o}C. Then they were rewarmed by one of the three strategies (1.Kimberly Clark energy transfer pads, 2.Allon circulating water garment, 3.Bair hugger forced air warming) which was randomly assigned earlier for that

particular study day. The rewarming rate was planned as the primary outcome and assessed with repeated measures analysis of variance (ANOVA). In conclusion, the warming rate with Kimberly Clark system was 25% faster than with Allon system and twice as fast as Bair Hugger. Both newer circulating warming systems were more effective in rewarming anaesthetized volunteers than forced air.

Siew-Fong Ng, et al., (2003) studied 300 patients who underwent unilateral total knee replacement and were randomized equally to three groups: (a) the two-cotton-blanket group (b) the one-reflective-blanket with one cotton- blanket group (c) the forced-air-warming with one-cotton-blanket group. Tympanic temperature readings were taken before surgery in the induction room, on arrival at the recovery room, and at 10-min intervals until discharge from the recovery room. On arrival at the recovery, the forced-air warming group had significantly higher temperatures (adjusted for sex, age, and patient's induction room temperature) of 0.577°C _ 0.079°C (95% confidence interval [CI], 0.427– 0.726; $p < 0.001$) and 0.510°C _ 0.08°C (95% CI, 0.349 – 0.672; $p < 0.001$) more than the reflective-blanket and two-cotton- blanket groups, respectively. The forced-air warming group took a significantly shorter time of 18.75 min to achieve a temperature of 36.5°C in the recovery room as compared with 41.78 min and 36.43 min for the reflective blanket and two-cotton-blanket groups, respectively. The reflective technology was less effective than using two cotton blankets and the forced-air warming was most efficient in maintaining perioperative normothermia.

Moola & Lockwood, (2011) conducted a literature review to find out the most effective and efficient strategies to prevent perioperative hypothermia in the surgical arena. The authors used a three-step search plan to find the most relevant and high quality evidence for their review. The inclusion criteria were adult patients over 18 years of age who underwent various types of surgery. The type of interventions included in the review process was any type of cover or linen blanket, forced air warming devices, fluid warming devices, and aluminium foil wraps. The reviewers considered, in addition, prospective studies using randomization and/or with a control group. The increase or decrease in the core body temperature was the primary outcome focus. The results from 19 studies that met the inclusion criteria included a total of 1451 patients. The authors concluded that there were significant benefits

related to using a forced air warming device such as increased patient comfort and increased core temperatures in the intraoperative and postoperative phases as well as decreased adverse outcomes associated with Inadvertent Perioperative Hypothermia (IPH) in the surgical patient.

To study the effects of preoperative warming for the prevention of IPH, Horn, et al., (2012) conducted a randomized control trial with 200 patients to study the effects of active skin surface pre-warming for short periods of time for the prevention of PH and shivering in the postoperative period with the control group who were not pre warmed. The authors randomly assigned patients to one of the four treatment groups scheduled to undergo general anaesthesia for 30-90 minute elective surgical procedures to receive forced air skin warming or passive insulation (cotton blankets or space blankets) for 10, 20, or 30 minutes respectively in the preoperative period. All patients included in the study were classed ASA 3 or less and greater than 18 years of age. The surgery types included laparoscopic cholecystectomy, breast surgery, inguinal hernia repair, and minor orthopedic surgeries. The forced air device blanket was covered with a regular blanket, and temperature was set at 44^{o}C then adjusted to patient comfort as needed. The device blanket was left in place when patient was transferred to the operating room. The main findings of the study were that a mere 10 minutes of pre-warming was adequate to prevent hypothermia when compared with patients who were not pre-warmed. Furthermore, the non-prewarmed patient group had reduced core temperatures upon arrival to the PACU despite intraoperative warming during the surgery.

In an article published by Lista, et al., (2012) it was concluded that use of simple measure like use of warmed fluids, limiting the area exposed to surgical site alone, forced air warming improved clinical outcomes, patient comfort and recovery following surgery. They also showed an association between the perioperative hypothermia and the deleterious outcomes like cardiac injuries, wound infection and impaired wound healing.

The cost of managing the complications that follows hypothermia in the perioperative setting has been studied by various authors as their primary and secondary outcomes. A meta- analysis of these studies conducted by Mahoney & Odom, (1999) showed that complications that are associated with hypothermia

increased the cost for the patient and the health care facility, ranging from $2,500 to $7,500, depending on the nature of the surgical procedure and the increased duration of hospital stay due to these adverse outcomes.

CHAPTER- III

METHODOLOGY

The study was designed to determine the effectiveness of hypothermia prevention protocol among patients subjected to major surgeries at KMCH, Coimbatore. This chapter deals with the methods adopted by the researcher such as, research design, variables, setting of the study, population, sample, sample size, sampling techniques, criteria for sample selection, development of hypothermia prevention protocol and flow chart, description of the tools, validity and reliability of the tool, pilot study, procedure for data collection, ethical consideration and statistical analysis.

RESEARCH DESIGN

The research design adopted for the study was one group pre and post-test quasi experimental design.

Table.1 Schematic representation of the research design

Group	Pre-test	Intervention	Post-test
Study (E)	O_1	X	O_2

Key:

E – Study group

O_1 - Assessment of baseline variables (demographic and clinical variables, risk factors, signs & symptoms), and Pretest assessment on monitoring vital parameters such as core body temperature, heart rate, respiratory rate, blood pressure & SPO_2 in time sequences of every 30 minutes on arrival to each area (holding area, OT and PACU). The core body temperature was measured by using infrared tympanic thermometer.

X – Observation of Hypothermia management strategies by using Hypothermia prevention protocol

O_2 - Post-test assessment on monitoring vital parameters such as core body temperature, heart rate, respiratory rate, blood pressure & SPO_2 in time sequences of every 30 minutes on exit from each area (holding area, OT and PACU).

VARIABLES UNDER THE STUDY

a) Independent variable

The independent variable in this study was hypothermia prevention protocol implementation.

b) Dependent variable

The dependent variables in this study was hypothermia

SETTING OF THE STUDY

This study was conducted in the operation theatre-II at KMCH, Coimbatore. KMCH is an 800 bedded multi-speciality hospital, having advanced facilities. The operation theatre-II comprises of seven OT's and equipped with latest gadgets.

POPULATION OF THE STUDY

The target population were patients in the age group of 21-70 years subjected to surgery for the first time. The accessible population were patients posted for surgery in Kovai Medical Center and Hospital (KMCH), Coimbatore, South India.

SAMPLE

Patients admitted to KMCH for surgery, who met the inclusion criteria during the period of the study.

SAMPLE SIZE

The sample size for the study was 50 patients and the hypothermia prevention protocol was implemented for them.

SAMPLING TECHNIQUE

Non probability convenient sampling technique was adopted for sample selection. Those who fulfilled the selection criteria and willing to participate were recruited for the study.

CRITERIA FOR SAMPLE SELECTION

a) Inclusion Criteria

Patients who were

- both male and female patients in the age group of 21 to 70 years
- patients subjected to elective or emergency open and laparoscopic & endoscopic surgeries such as gastro intestinal, plastic reconstructive, ENT and genito-urinary systems extending for more than an hour.
- met the American Society of Anesthesiologists physical status score of I,II & III.
- preoperative normothermia

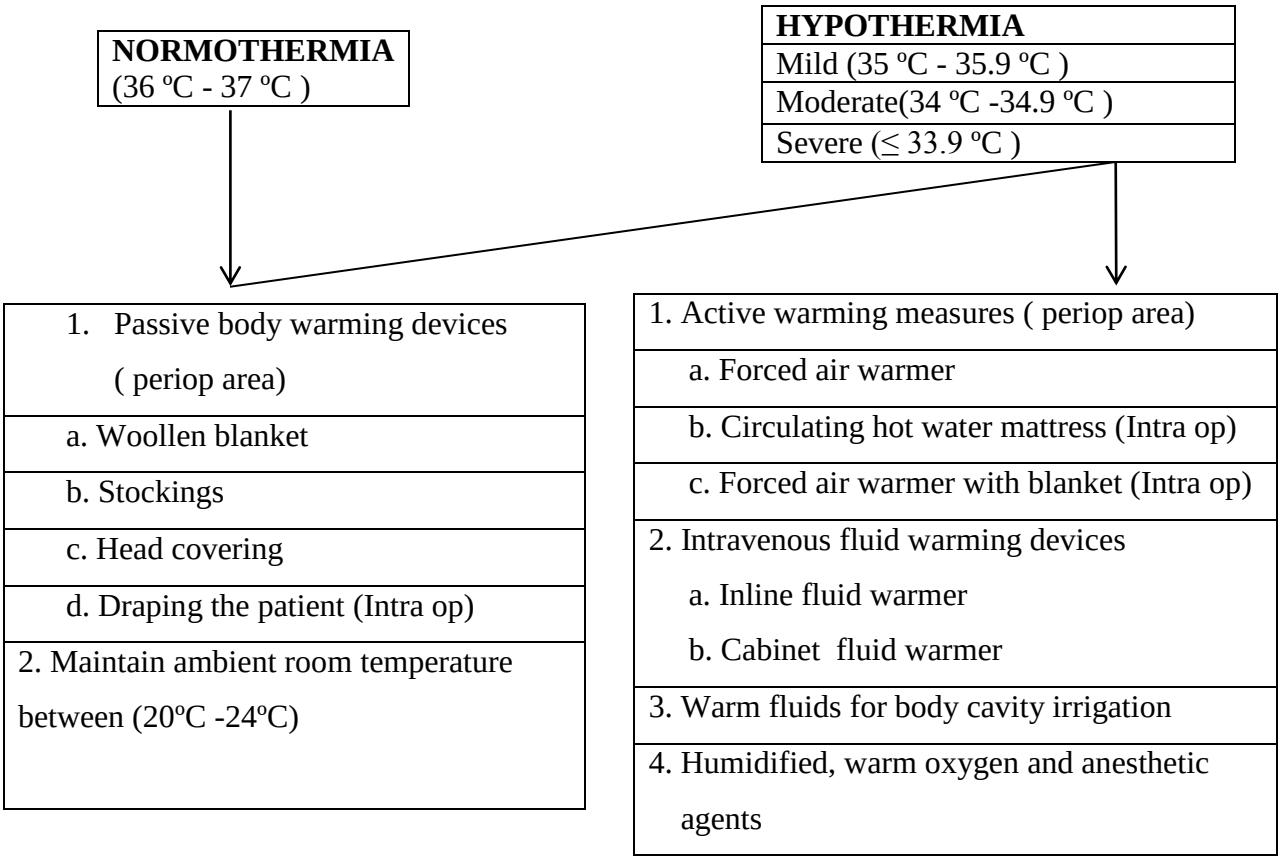
b) Exclusion Criteria

Patients who were posted for burns & orthopedic, cardio thoracic & Liver transplant surgery.

IMPLEMENTATION OF HYPOTHERMIA PREVENTION PROTOCOL

Based on the literature review, research evidence, existing management strategies, hospital facilities and equipment, the hypothermia prevention protocol was prepared and modified as per expert's guidance. The protocol covers the management strategies among patients with normothermia or hypothermia during pre, intra and post-operative period.

HYPOTHERMIA PREVENTION PROTOCOL



DESCRIPTION OF THE TOOL

Extensive review of literature, discussion and views of experts enhanced the development of the tool. The tool consisted of 4 sections. (APPENDIX-A)

Part I: Demographic Variables such as age, sex, educational status, diet pattern and unhealthy habits.

Part II: Clinical variables such as Co morbidity (Diabetes mellitus. Hypertension, Chronic kidney disease, Ischemic heart disease & Hypothyroidism), ASA classification on Level of physical status (Healthy patient (ASA – I), Mild systemic diseases (ASA- 2),Severe systemic diseases (ASA- 3), body mass index, Surgical procedures (Upper abdominal, Lower abdominal, Upper & lower abdominal, Thoracic and Extremities), nature of surgery (Elective or Emergency), Blood Investigation (Haemoglobin <10 mg / dl, WBC >11000 cells/cu mm).

Part III: Risk factors of hypothermia such as, Duration of patient stay, Volume of IV fluid administration, Type of anaesthesia, Blood loss during surgery, Blood transfusion during surgery and PACU).

Part IV: Signs and symptoms of hypothermia such as Shivering, Cold extremities & Pilorection in holding area, intra operative and PACU area.

Part V: Assessment on measurement of vital parameters such as core body temperature, heart rate, respiratory rate, blood pressure & SPO_2 every half an hourly on arrival in and transfer out from holding area, OT and PACU.

Part VI: Hypothermia prevention protocol implementation included observational checklist on measures implemented to prevent and manage hypothermia for the study subjects. The observational criteria included the passive body warming measures such as woolen blankets, stockings, head covering was used and the ambient room temperature was maintained between (20ºC – 24ºC) and core body temperature was checked every 30 minutes. Active body warming measures such as forced air warmer or circulating hot water mattress or forced air warmer with blankets were applied along with passive body warming measures, intravenous warm fluid irrigation was administered, and humidified warm oxygen and anesthetic gases was used.

VALIDITY AND RELIABILITY OF THE TOOL

All the instruments were reviewed for face and content validity by medical and nursing experts and they were pilot tested to assess the usability and ease of administration. Content validity of the tool was established by experts comprising of experts from the fields of nursing, anaesthetists (Appendix H). The researcher gave a copy of the tool and explained the purpose and objectives of the study to them individually. A panel of content experts were asked to rate the tool that measures the signs and symptoms, risk factors and core body temperature and observational checklist on hypothermia prevention protocol.

The criteria for content validity included objective based relevance of the content, language, accuracy, feasibility and clarity on a three point rating scale (0= not necessary, 1= useful, 2= essential). The average overall rating for the tool on signs and symptoms, risk factors and core body temperature and observational

checklist on hypothermia prevention protocol hypothermia prevention protocol was 4.24 out of 5 score.

To reliability of the vital parameters such as heart rate, respiratory rate, blood pressure & SPO_2 were measured through monitors. The core body temperature was measured using infrared tympanic thermometer (model DL8740, 2016. Philips). The monitors and theinfrared tympanic thermometer were calibrated and tested regularly, measured and validated according to the manufacturer's manual before use by bio medical department and the instrument was found to be valid and reliable.

PILOT STUDY

The pilot study was conducted in operation theatre II of KMCH, Coimbatore, to ascertain the feasibility of the study. Formal permission was obtained before pilot study. Pilot study has been conducted with 7 patients in study group. The collected data were analyzed. The tool was modified with the following consideration as per experts opinion:

- patients subjected to ENT surgery were excluded, as the tympanic temperature measurement was not possible

The analysis of the pilot study revealed that it was feasible and practicable to conduct the main study. The reliability of the tool was also established in pilot study and the same was approved and the investigator was permitted to proceed with the main study.

PROCEDURE FOR DATA COLLECTION

On the first day of the holding area, while subjects were comfortable or when the physician and nurse completed the routine procedure, patients who met the inclusion criteria were approached consecutively by the researcher and were explained the study purposes and procedures in detail and informed written consent was obtained individually from the subjects. The subjects were assured that they were free to withdraw during the study without any compromise in subsequent treatment. The study subjects were clearly explained about the hypothermia prevention protocol

and were asked to answer by self-reporting. Strict confidentiality was maintained throughout the process of data collection and analysis.

Patients' Demographic Variables such as age, sex, educational status, diet pattern and unhealthy habits and Clinical variables such as Co morbidity (Diabetes mellitus. Hypertension, Chronic kidney disease, Ischemic heart disease & Hypothyroidism), ASA classification on Level of physical status (Healthy patient (ASA – I), Mild systemic diseases (ASA- 2),Severe systemic diseases (ASA- 3), body mass index, Surgical procedures (Upper abdominal, Lower abdominal, Upper & lower abdominal, Thoracic and Extremities), nature of surgery(Elective or Emergency), Blood Investigation (Haemoglobin <10 mg / dl, WBC >11000 cells/cu mm) were collected by the investigator from the patient medical record.

The potential risk factors of hypothermia(Duration of patient stay, Volume of IV fluid administration, Type of anaesthesia, Blood loss during surgery, Blood transfusion during surgery and PACU), risk factors, also were collected: duration of patient stay, volume of IV fluid administration, type of anaesthesia, Blood loss during surgery, Blood transfusion), and Signs and symptoms of hypothermia such as Shivering, Cold extremities & Pilorection in Holding area, intra operative and PACU area were assessed by the investigator and recorded.

Pretest assessment on monitoring vital parameters such as core body temperature, heart rate, respiratory rate, blood pressure & SPO_2 in time sequences of every 30 minutes on arrival to each area (holding area, OT and PACU). The core body temperature was measured by using infrared tympanic thermometer (model DL8740, 2016. Philips) it gives the measurement within 2-4 seconds after placing thermometer into ear canal. Before using the infrared tympanic thermometer, the investigator was explained the procedure to the patient and obtained verbal consent. To monitor temperature, cleaned the ear with cotton buds and inserted the ear speculum into ear canal by pulling ear pinna backward, up and out. The thermometer probe was left in place until patient's temperature appears on digital display then carefully removed from auditory meatus and cleaned the speculum lens with the alcohol swab. Documented the displayed temperature. Assisted the patient in assuming a comfortable position and Performed hand hygiene.

Hypothermia management strategies was implemented based on vital parameters especially the core body temperature. If the patient's temperature is within the normothermic range (ie, 36° C to 37° C [96.8° F to 98.6°F]), the passive body warming measures were instituted, including maintaining the patient's temperature and the ambient room temperature, minimizing skin exposure by providing woolen blankets, stocking and head coverings in holding as well as in PACU area, draping was applied only in operation theatre.

If the patient is within the hypothermic temperature range (ie, <36° C [<96.8° F]), then active warming measures were instituted. In holding area, forced air warming devices and inline warming devices, cabinet warming devices were applied. In intraoperative area, forced air warming devices, circulating hot water mattress, cabinet warming devices, inline warming devices, fluid warm irrigation were instituted. In PACU, forced air warming devices, cabinet warming and inline warming devices were instituted.

Post-test assessment on monitoring vital parameters such as core body temperature, heart rate, respiratory rate, blood pressure & SPO_2 in time sequences of every 30 minutes on exit from each area (holding area, OT and PACU).

ETHICAL CONSIDERATION

Ethical clearance was obtained from the institutional ethical committee to conduct the study. Informed written consent was obtained individually from the patients participated in the research study. Permission was obtained from Head of the Department in OT and in charges of the operation theatres for conducting the main study.

Information essential for consent included description of the purpose of the study, the research activities and the usefulness of the study outcome, assurance of privacy and confidentiality to answer any questions that a potential subject has and the option to withdraw themselves from the study at any time. In intervention were restricted to observing, measuring, and recording core body temperature of the patients, whose anonymity and confidentiality were assured (Appendix-B).

STATISTICAL ANALYSIS

The data were analyzed on the basis of objectives and hypothesis. Descriptive and Inferential statistics were used for analyzing the data. Data were analyzed using the statistical package for the social sciences (SPSS version 22). The plan for data analysis as follows**:**

Table.2 Schematic representation of the data analysis plan.

Methods	**Types**	**Purpose**
Descriptive statistics.	Frequency, percentage, mean and standard deviation	Assessment of background, clinical variables, signs & symptoms, risk factors, core body temperature and hypothermia prevention strategies.
Inferential statistics	Chi square	Association between core body temperature with selected demographic & clinical variables, risk factors, signs & symptoms among patients in perioperative period.
	Paired t test and independent test.	Comparison of pre-test and post-test mean score of core body temperature in perioperative period.
	RM ANOVA	The differences in the core body temperature at various time periods in perioperative period.

CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with the analysis and interpretation of the data collected to evaluate the effectiveness of hypothermia prevention protocol among patients subjected to major surgeries at KMCH, Coimbatore. The data collected from 50 patients were carefully coded and analysed using the statistical package for the social sciences (SPSS version 22) are presented as follows.

Section A: Distribution of demographic variables among subjects.

Section B: Distribution of clinical variables among subjects.

Section C: Distribution of subjects based on presence of risk factors

Section D: Distribution of subjects based on presence of signs and symptoms of hypothermia

Section E: Distribution of vital parameters in perioperative period.

Section F: Distribution of hypothermia prevention strategies among subjects in perioperative period.

Section G: Association between core body temperature with selected demographic & clinical variables, risk factors, among subjects in perioperative period

SECTION A: Distribution of demographic variables among subjects

Table 3: Distribution of demographic variables among subjects

N=50

S. No	Demographic variables	Study group	
		No.	%
1.	**Age in years**		
	a) 21-40	17	34
	b) 41-60	17	34
	c) 61-70	16	32
2.	**Sex**		
	a) Male	24	48
	b) Female	26	52
3.	**Educational status**		
	a) No formal education	18	36
	b) Primary	02	04
	c) Secondary	16	32
	d) Higher secondary	03	06
	e) Collegiate	11	22
4.	**Diet pattern**		
	a) Vegetarian	02	04
	b) Mixed diet	48	96
5.	**Unhealthy habits**		
	a) Smoking	02	04
	b) Alcohol consumption	07	14
	c) Nil	41	82

Table 3 demonstrates the distribution of demographic variables among study subjects. The mean age of the subjects were 41.20 years where 64 years was the highest and 21years was the lowest with the mean score of 41.20 SD 14.68

With regard to gender, Male: Female ratio was 1:1. (n=24) 48% were male and (n=26) 52% were female.

Concerning with the educational status, dietary pattern & unhealthy habits majority of subjects 32% (n=16), 96% (n=48) & 82% (n=41) had secondary education and were on mixed diet they had no such unhealthy habits of Smoking & alcohol consumption respectively.

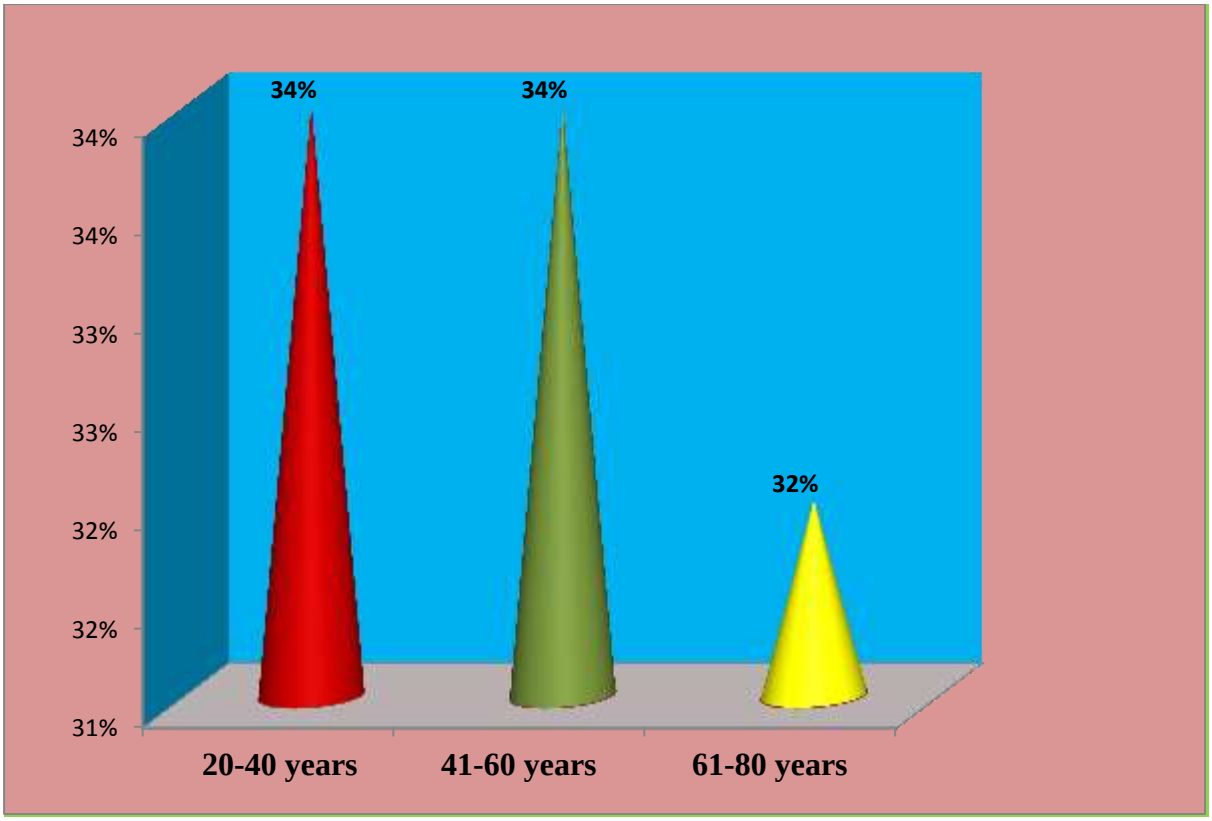


Figure 2: Distribution of age

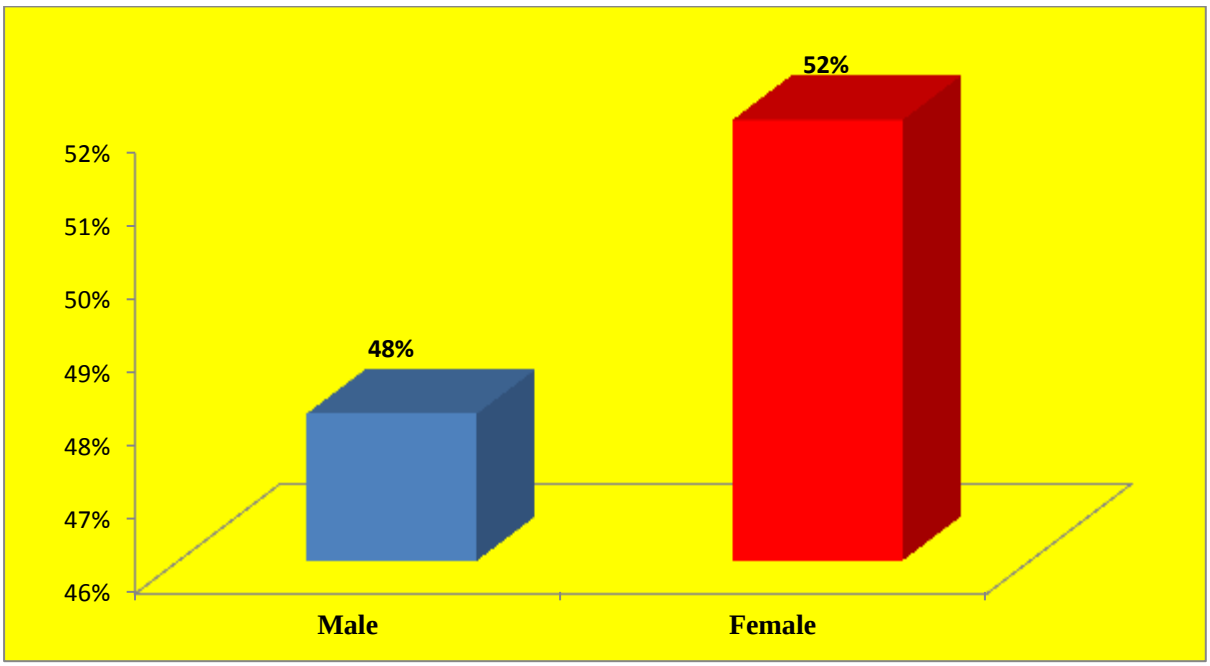


Figure 3: Distribution of sex

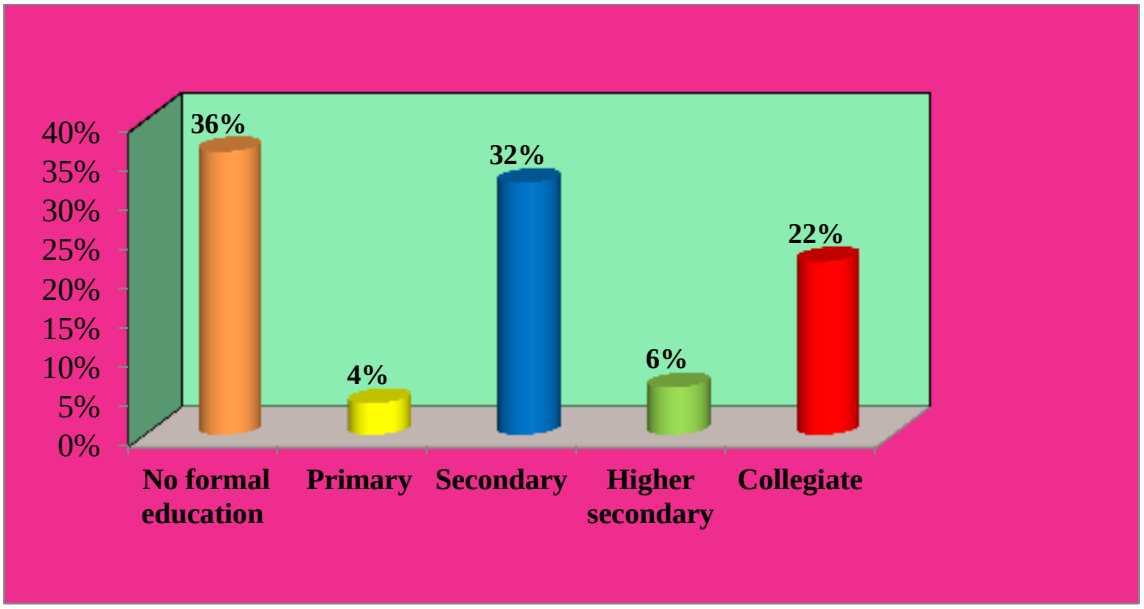


Figure 4: Distribution of educational status

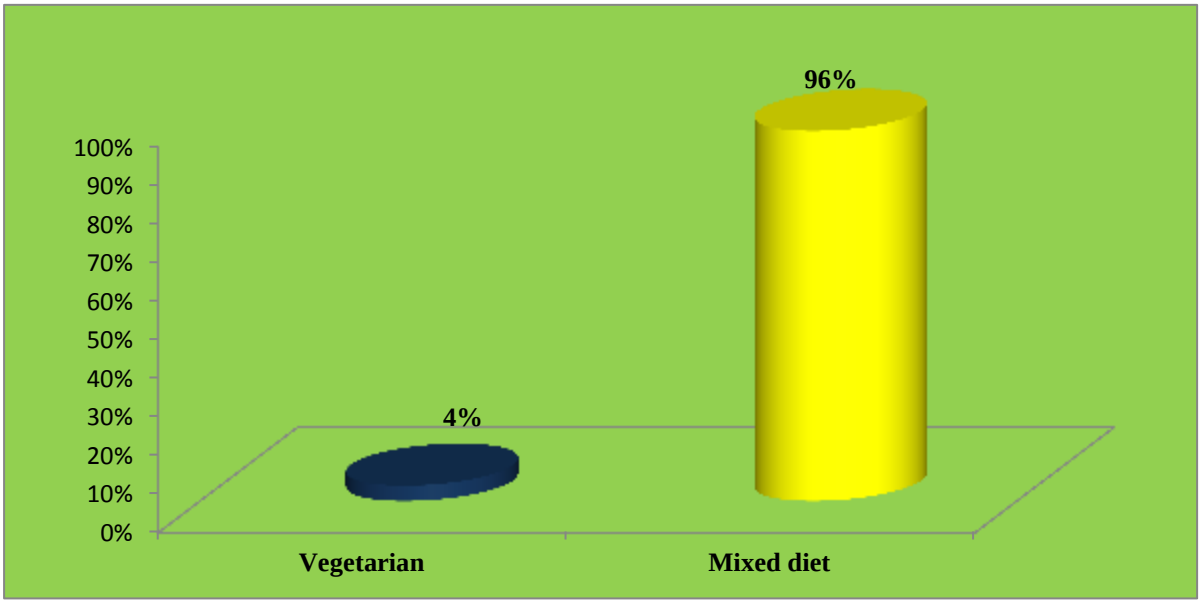


Figure 5: Distribution of diet pattern

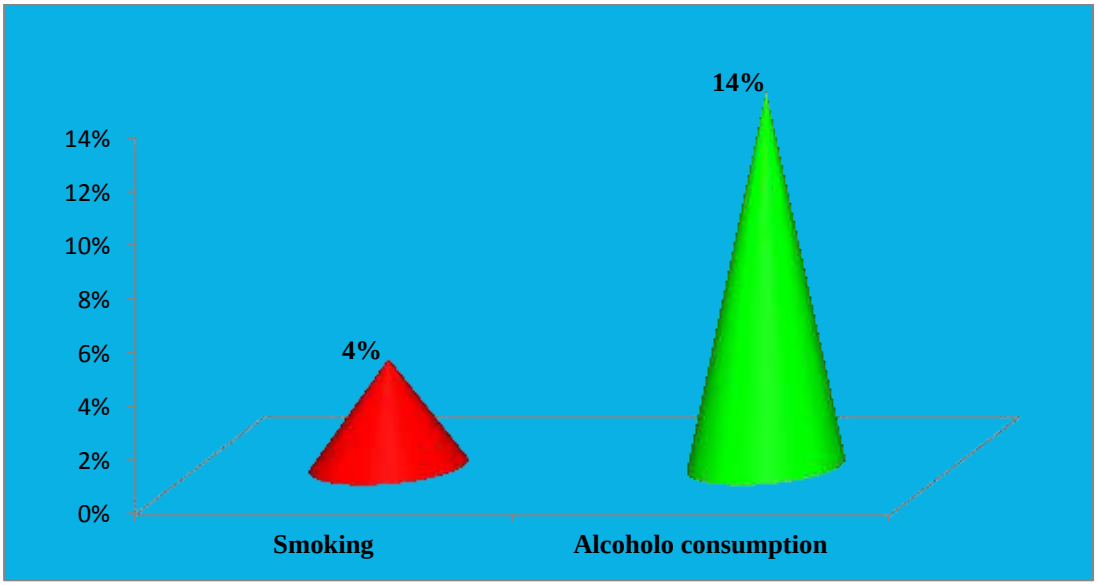


Figure 6: Distribution of unhealthy habits

SECTION B: Distribution of clinical variables among subjects in perioperative period.

Table 4: Distribution of clinical variables among subjects

N=50

S.No	Clinical variables	Study group	
		No	%
1.	**Co morbidity**		
	a). Diabetes mellitus	10	20
	b). Hypertension	20	40
	c). Chronic kidney disease	09	18
	d). Ischemic heart disease	01	02
	e). Hypothyroidism	04	08
	f). Nil	06	12
2.	**Level of physical status (acc to ASA)**		
	a) Healthy patient (ASA – I)	10	20
	b) Mild systemic diseases (ASA- 2)	31	62
	c) Severe systemic diseases (ASA- 3)	09	18
3.	**Body Mass Index (kg/m²)**		
	a) Underweight <18.5	01	02
	b) Normal 18.5- 24.99	30	60
	c) Over weight >25	05	10
	d) Obesity >30	14	28
4.	**Surgical procedures**		
	a) Upper abdominal	10	20
	b) Lower abdominal	36	72
	c) Upper & lower abdominal	01	02
	d) Thoracic	02	04
	e) Extremities	01	02
5.	**Nature of surgery**		
	a) Elective	48	96
	b) Emergency	02	04
6.	**Blood investigation**		
	a) Haemoglobin (<10 mg/dl)	05	10
	b) WBC(>11000m cells/mm)	11	22
	c) Nil	34	68

Table 4 presents the distribution of clinical variables. Majority 40% (n=20) of the subjects were hypertensive, the mean BMI of the subjects were 22.07 kg/m² where 27.4 was the highest and 17.3 was the lowest with the mean score of 22.7 SD 3.01.

All subjects were categorized according to ASA's (American Society of Anaesthesiologists) classification as level of physical status 1 to 3. 20% (n=10) were

healthy ASA grade-I, 62% (n=31) with mild systemic diseases (ASA-II), 18% (n=9) were with severe systemic diseases (ASA-III).

Concerning with the surgical procedures majority 72% (n=36) of the subjects were subjected to the lower abdominal surgery, 96% (n=48) had elective surgery.

Majority of study subjects 90% (n=45) & 78% (n=39) had normal haemoglobin& white blood cells respectively.

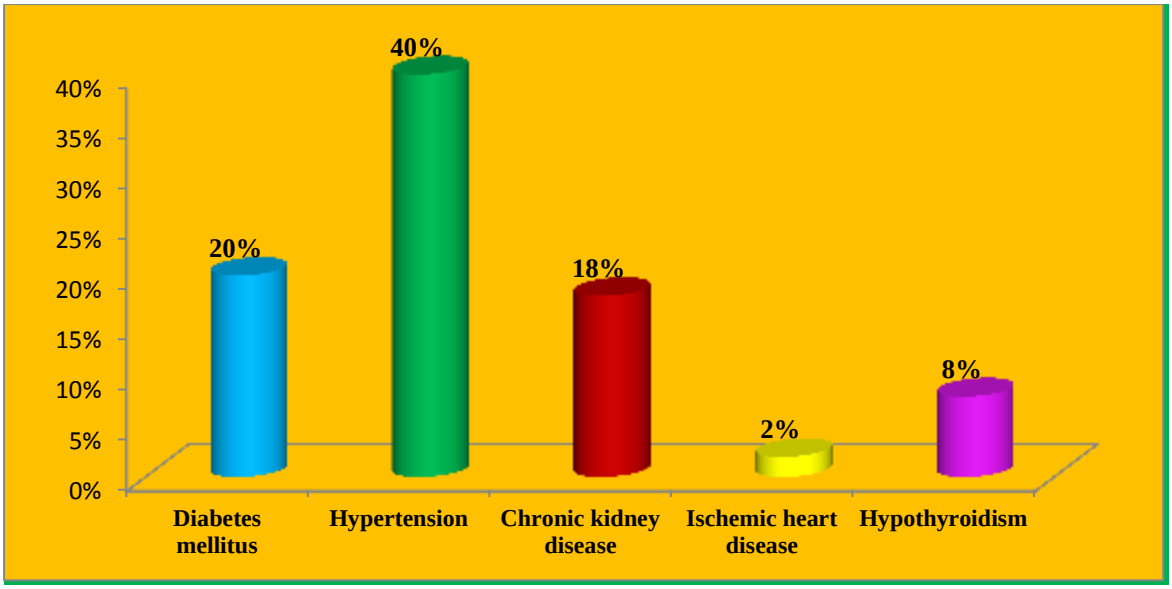


Figure 7: Distribution of comorbidity

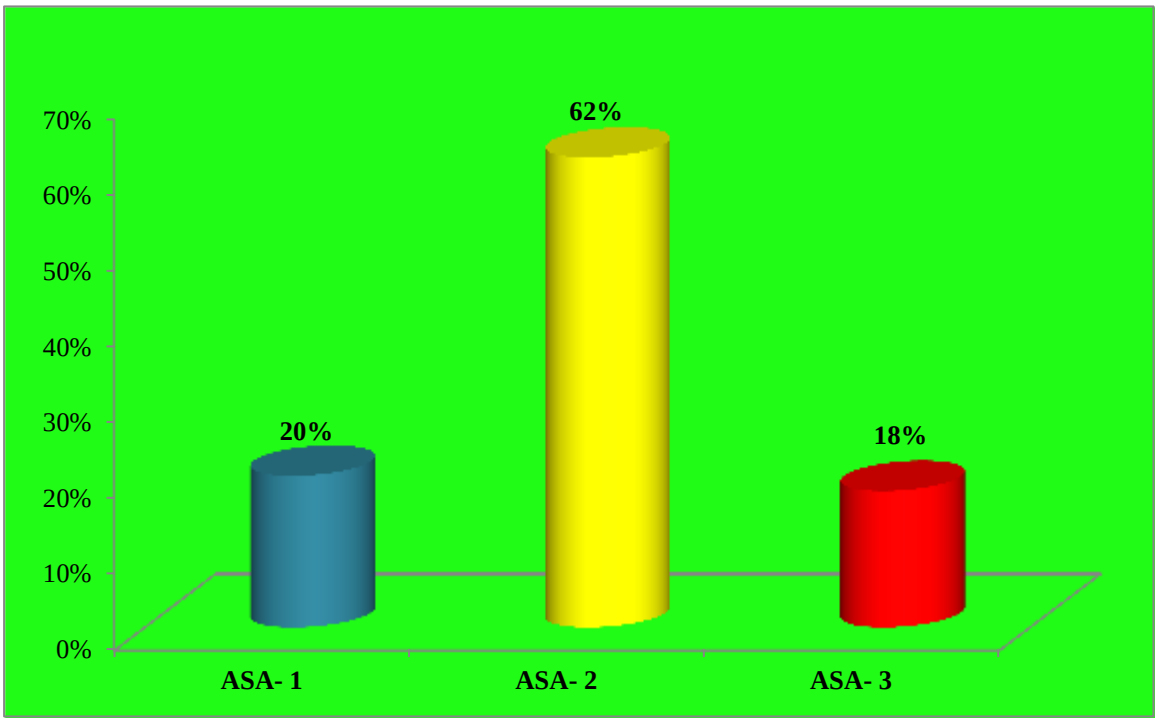


Figure 8: Distribution of ASA classification on level of physical status

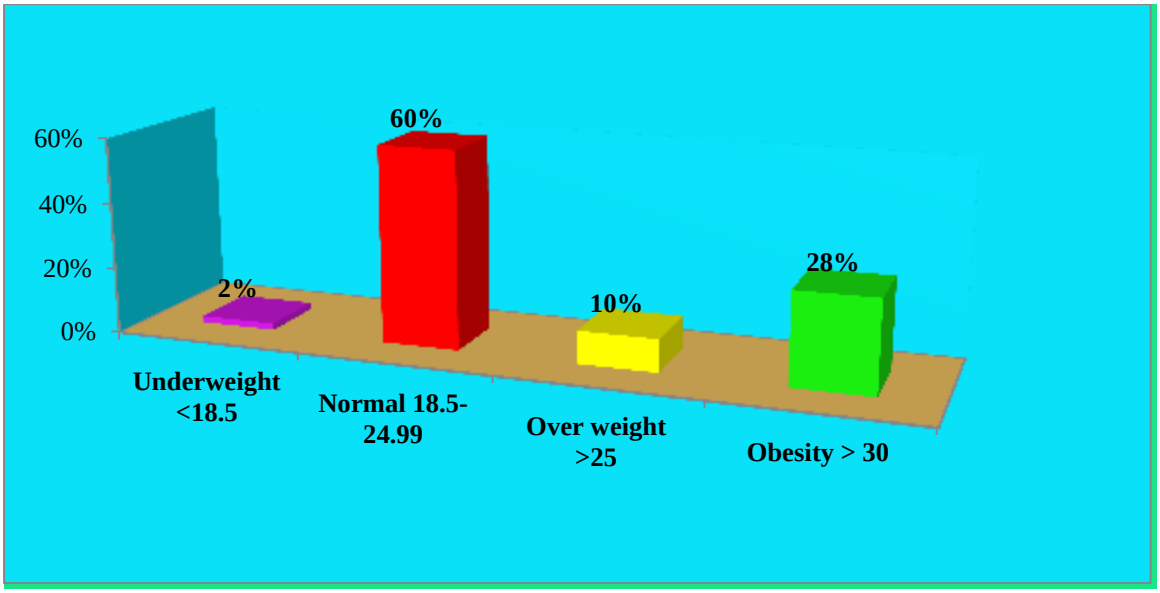


Figure 9: Distribution of body mass index

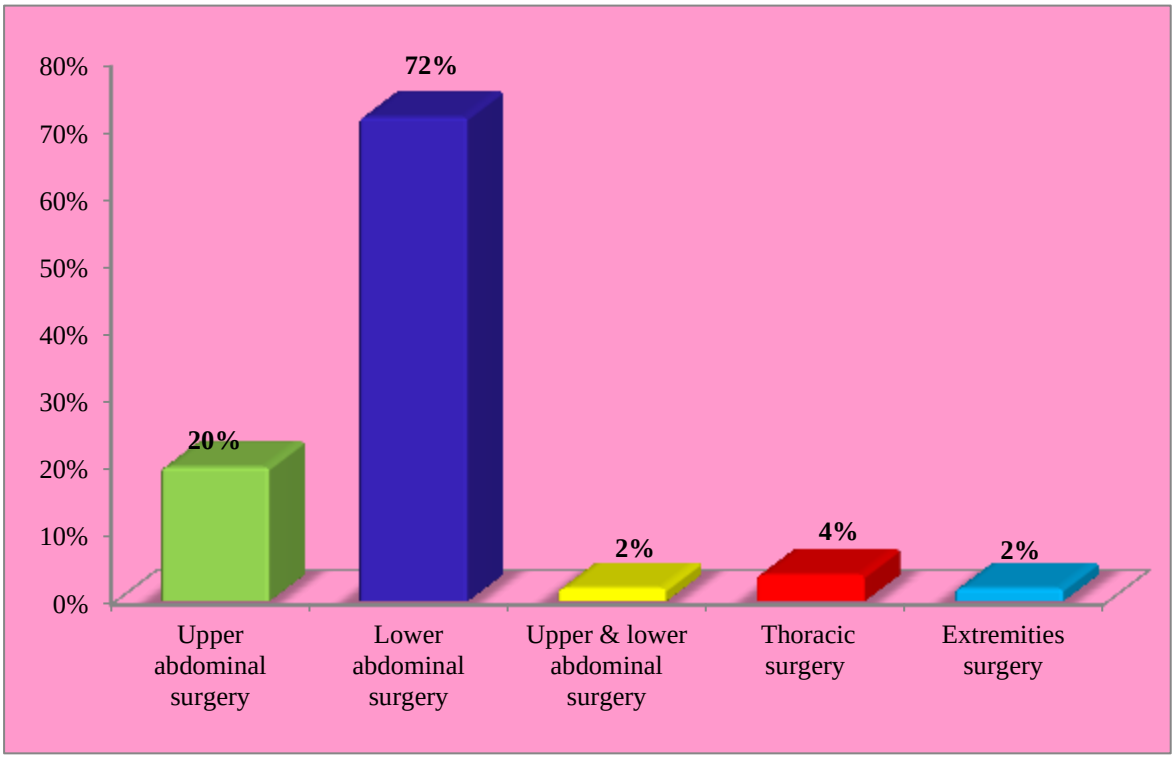


Figure 10: Distribution of surgical procedures

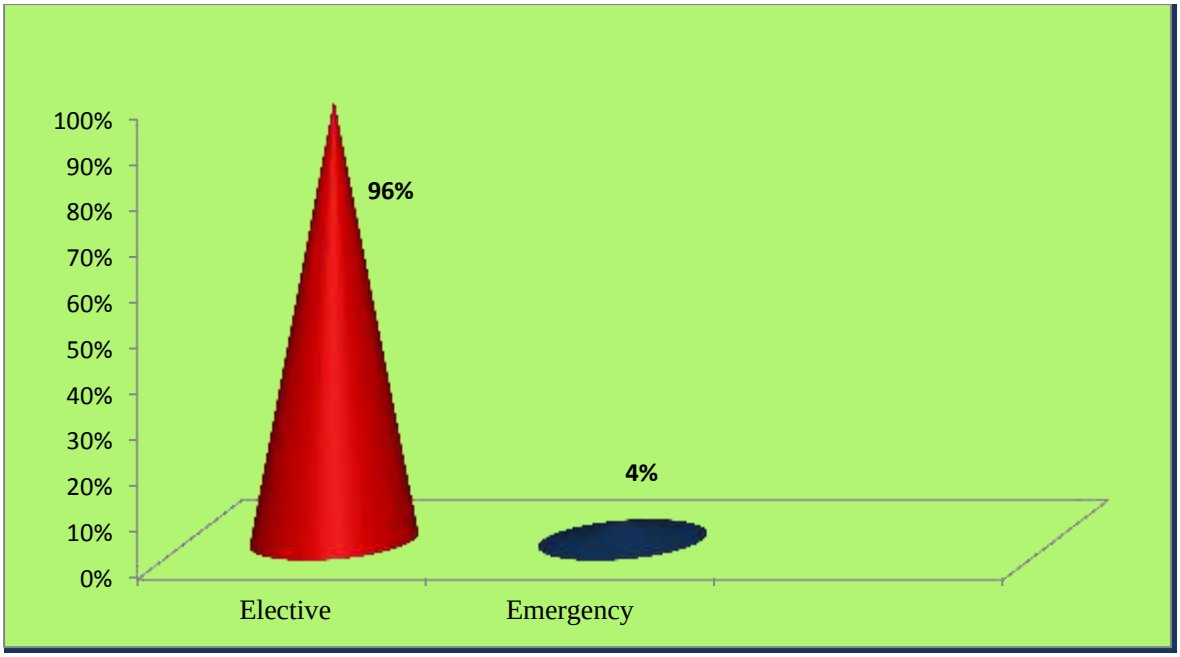


Figure 11: Distribution of nature of surgery

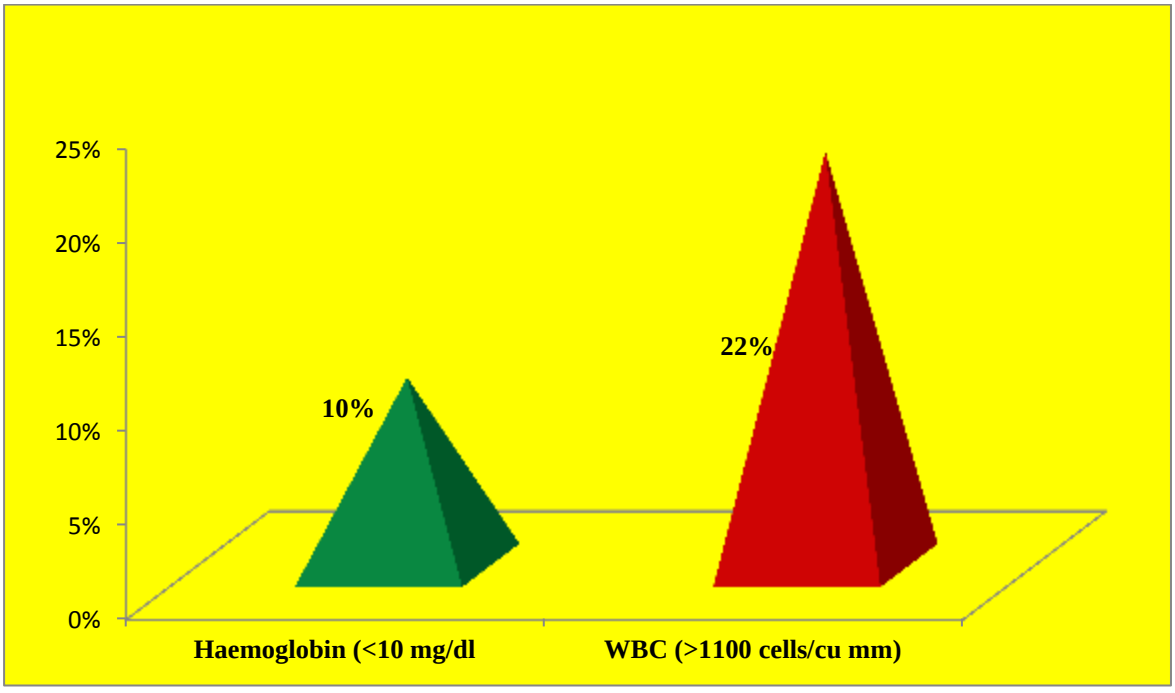


Figure 12: Distribution of blood investigations

SECTION C: Distribution of subjects based on presence of risk factors

Table 5: Distribution on duration of patient stay among patients

N=50

S.No	Criteria	Study group	
		No.	**%**
1.	**Duration of patient stay in holding area**		
	a) <1 hr	32	64
	b) >1 hr	18	36
2.	**Duration of patient stay in intraoperative period**		
	a) <2 hrs	05	10
	b) >2 hrs	45	90
3.	**Duration of patient stay in PACU**		
	a) <2 hrs	24	48
	b) >2 hrs	26	52

Table 5 denotes the duration of stay among subjects in each area during perioperative period. Duration of stay among subjects in holding area varied greatly from 15 minutes to a maximum of up to 45 minutes. The average of this time for majority 64% (n=32) of subjects was 36.5 minutes and 31.25 minutes.

The average of duration of stay in OT among majority 90% (n=45) of subjects was varied greatly from 2 hrs 30 minutes to a maximum of upto 4 hrs 40 minutes. 52% (n=26) were stayed >2 hours in the PACU.

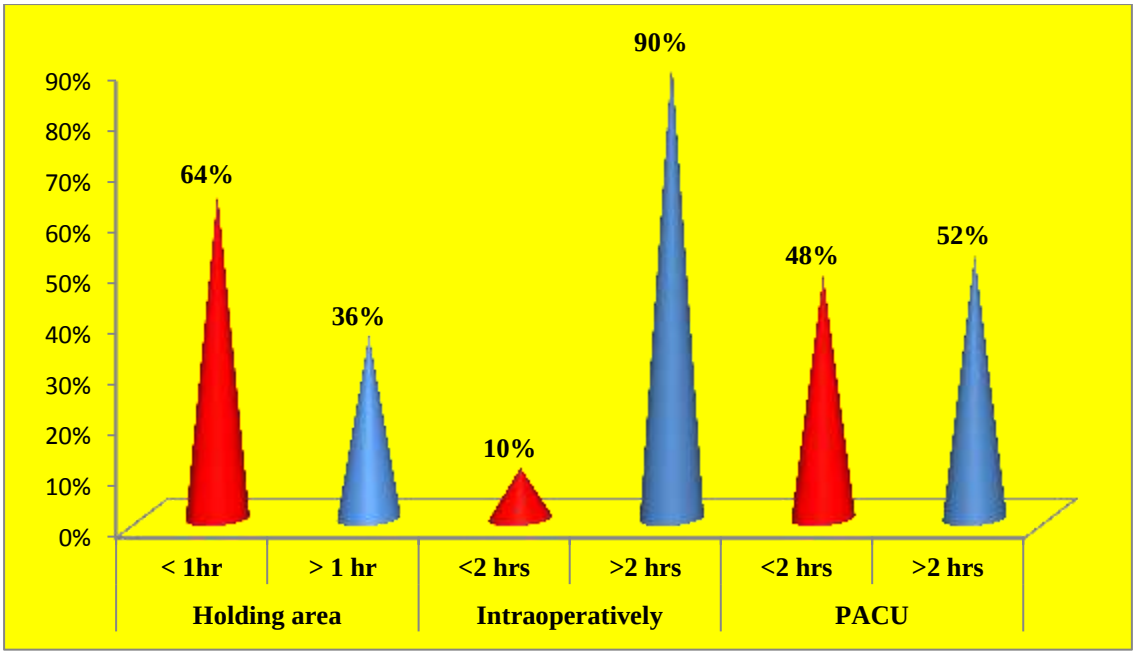


Figure 13: Distribution of duration of stay in perioperative period

Table 6: Distribution of Volume of IV fluid administration among subjects

N=50

S. No	Criteria	Study group	
		No.	**%**
1.	**Volume of IV fluid administration in holding area**		
	a) < 500 ml	35	70
	b) 500 ml - 1 litre	01	02
	c) Nil	14	28
2.	**Volume of IV fluid administration in intraoperative period**		
	a) < 500 ml	02	04
	b) 500 ml – 2 litre	29	58
	c) >2 litres	19	38
3.	**Volume of IV fluid administration in** PACU	09	18
	a) < 500 ml	35	70
	b) 500 ml - 2 litre	06	12
	c) >2 litres		

Table 6 presents the amount of intravenous fluids used in perioperative period. Majority of subjects70% (n=35) had received the average amount ie. 365 ml IV fluids in the holding area. (n=29) 58% & 70% (n=35) had IV fluid administration of 500ml to 2liters intraoperatively and in PACU respectively.

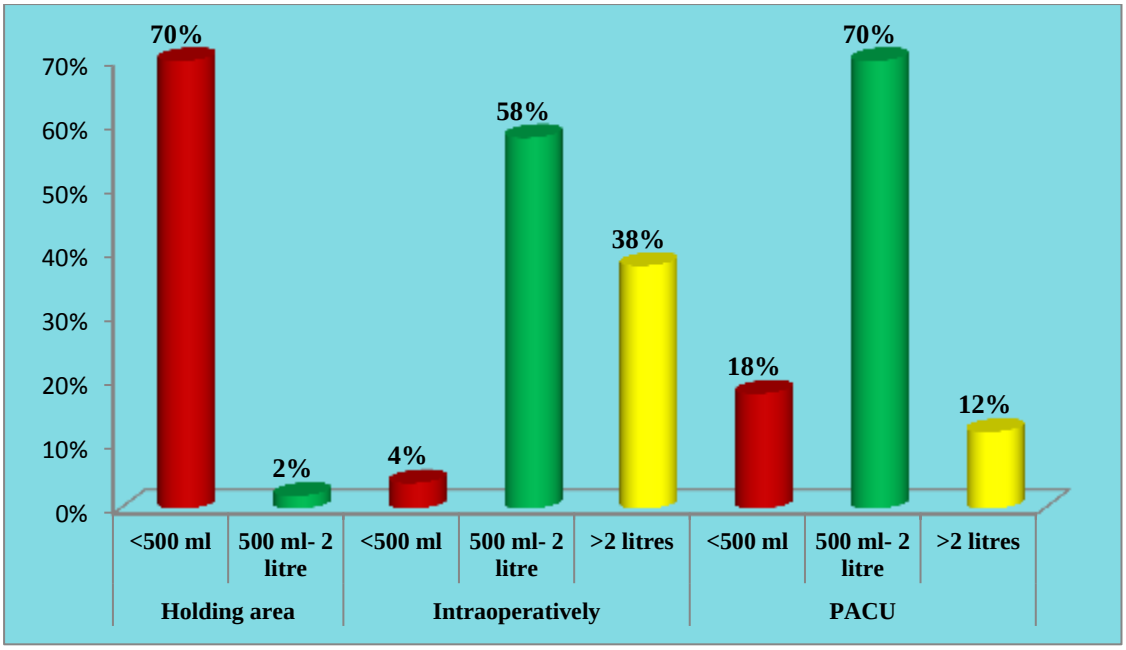


Figure 14: Distribution of volume of IV fluid administration in perioperative period

Table 7: Distribution of Type of anaesthesia among subjects

N=50

Type of anaesthesia	**Study group**	
	No.	**%**
a) GA	46	92
b) RA	03	06
c) GA & RA	01	02

Table 7 presents the type of anaesthesia among subjects Majority 92% (n=46) had general anaesthesia, 6% (n=3) had regional anaesthesia, 2% (n=1) had general and regional anaesthesia.

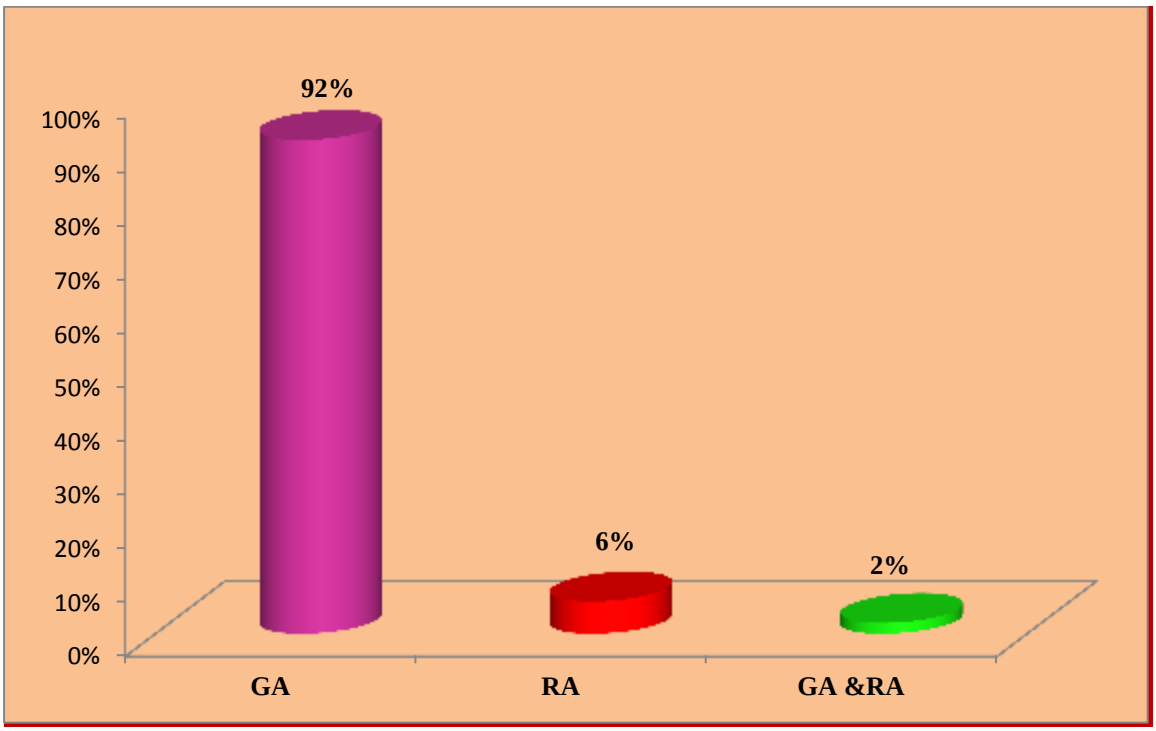


Figure 15: Distribution of type of anaesthesia in OT

Table 8: Distribution of Blood loss during surgery among subjects.

N=50

Blood loss during surgery	Study group	
	No.	**%**
a) < 100 ml	17	34
b) 100 – 200 ml	18	36
c) >200 ml	15	30

Table 8 illustrates the distribution of Blood loss during surgery among subjects. 34% (n=17) had the blood loss below 100 ml, 36% (n=18) had the blood loss 100-200ml, 30% (n=15) had blood loss above 200 ml.

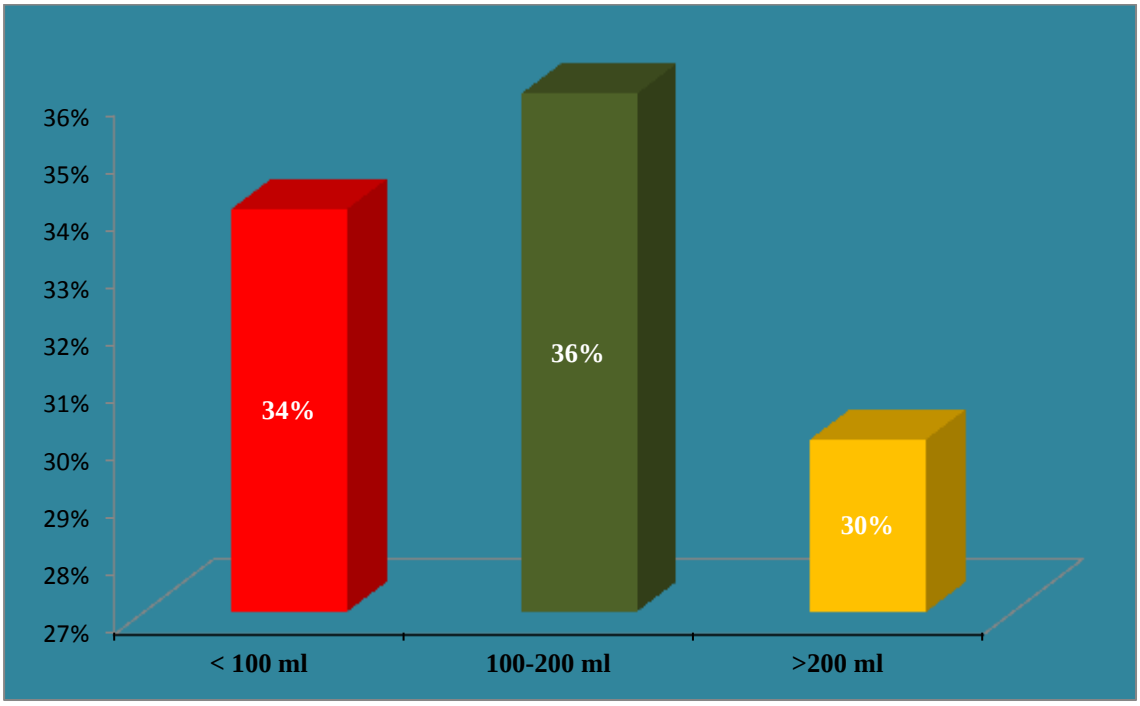


Figure 16: Distribution of blood loss during surgery

Table 9: Distribution of Blood transfusion among subjects in study group

N=50

S. No	Criteria	Study group	
		No.	%
1.	**Blood transfusion in intra operatively.** a) Yes b) No	03 47	06 94
2.	**Blood transfusion in PACU** a) Yes b) No	02 48	04 96

Table 9 describes the blood transfusion among subjects. 3 (6%) received blood transfusion during surgery, 2 (4%) received blood transfusion in the PACU.

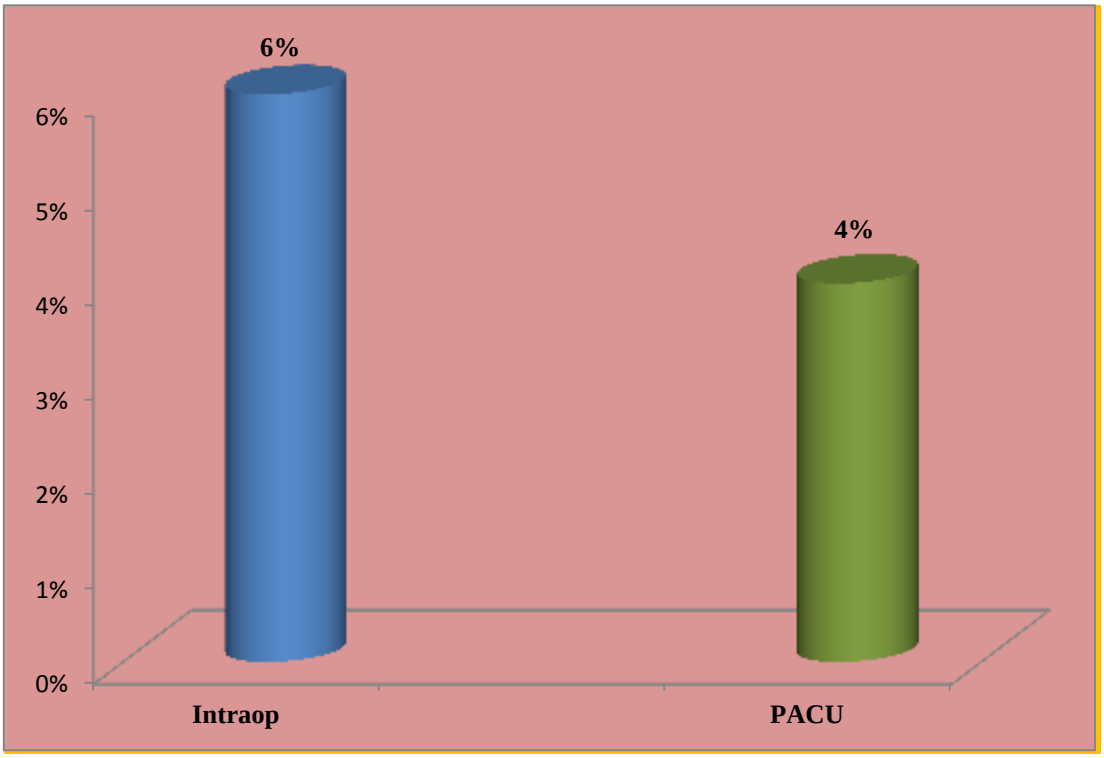


Figure 17: Distribution of blood transfusion

SECTION D: Distribution of subjects based on presence of signs and symptoms of hypothermia

Table 10: Distribution of subjects based on the presence of signs and symptoms of hypothermia

N=50

S. No	Signs and Symptoms	Study group	
		No.	%
1.	**Holding area**		
	a) Cold extremities	01	02
	b) Shivering & Cold extremities	05	10
	c) Pilorection & Cold extremities	02	04
	d) Nil	42	84
2.	**PACU**		
	a) Cold extremities	03	06
	b) Shivering & Cold extremities	05	10
	c) Pilorection & Cold extremities	03	06
	d) Nil	39	78

Table 10 explicates the frequency and percentage distribution on signs and symptoms of hypothermia among subjects in study and control group. Shivering was one of the important secondary outcomes studied because most of the ill effects of hypothermia are associated with shivering. About 10% (n=5) of subjects shivered and had Cold extremities in the Holding area and in PACU area respectively.

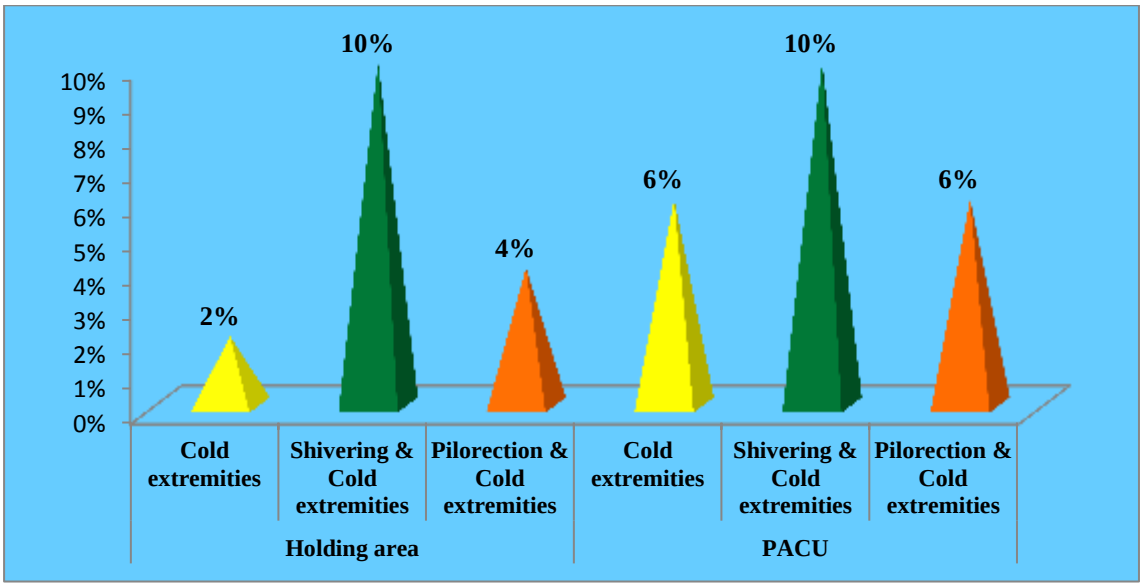


Figure 18: Distribution of subjects based on signs and symptoms of hypothermia.

SECTION E: Distribution of vital parameters in perioperative period.

Table 11: Distribution of core body temperature in perioperative period

N=50

Vital parameters	Holding area		OT		PACU	
	No.	%	No.	%	No.	%
1. Core body temperature						
a) Mild (35 ºC - 35.9ºC)	02	04	26	52	23	46
b) Moderate (34 ºC -34.9 ºC)	0	0	01	02	0	0
c) Severe (≤ 33.9 ºC)	0	0	0	0	0	0
d) Normothermia (36 ºC -37 ºC)	48	96	23	46	27	54

Table 11 demonstrates the distribution on core body temperature among subjects. The analysis shows that 4% (n=2) had mild hypothermia, 96% (n=48) had normothermia in the holding area. 52% (n=26) mild hypothermia. 2% (n=1) in had moderate hypothermia. 46% (n=23) had normothermia in the intraoperative period. 46% (n=23) had mild hypothermia. 54% (n=27) had normothermia in the PACU.

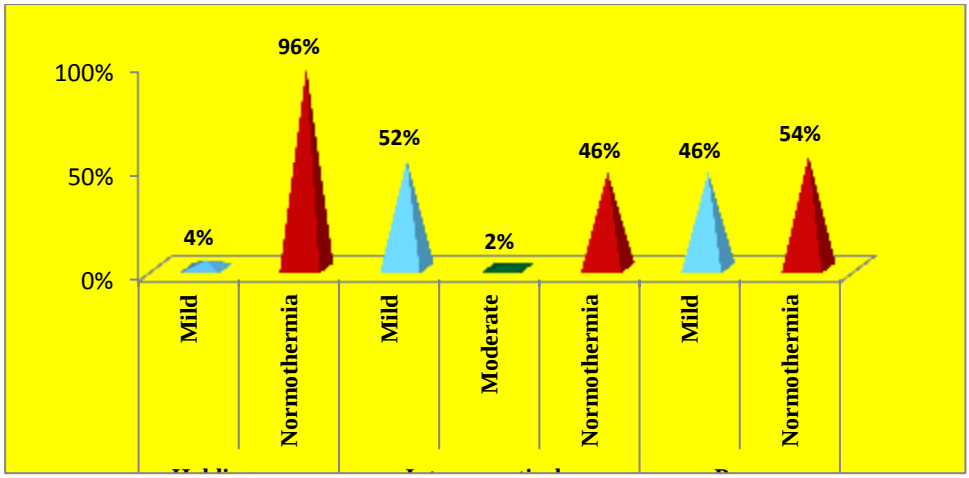


Figure 19: Distribution of core body temperature among subjects in perioperative period

Table 12: Repeated Measures ANOVA of core body temperature at various time periods in perioperative period

N=50

Time periods	Holding area		Intraoperative		PACU		F value
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
T1 (30 mts)	36.21	0.14	36.26	0.11	35.53	0.45	2.197*
T2 (1 hr)	36.19	0.11	36.18	0.30	35.32	0.39	
T3 (1 ½ hrs)	36.18	0.09	35.78	0.45	35.05	0.48	
T4 (2 hrs)	36.17	0.26	35.67	0.40	35.00	0.80	
T5 (2 ½ hrs)	36.13	0.11	35.59	0.47	35.25	0.42	
T6 (3 hrs)	36.09	0.13	35.53	0.45	36.41	0.20	
T7 (3 ½ hrs)	35.07	0.11	35.08	0.46	36.48	0.14	
T8 (4 hrs)	36.04	0.25	36.01	0.48	36.27	0.52	
T9 (4 ½ hrs)			37.00	0.21			
T10 (5 hrs)			36.05	0.08			

Table 12 presents the repeated measures ANOVA of core body temperature over a period of time in the perioperative period. There is a statistically significant difference in the mean scores of core body temperature measured at various time periods in holding area, intraoperative period and PACU at the level of $p < .05$.

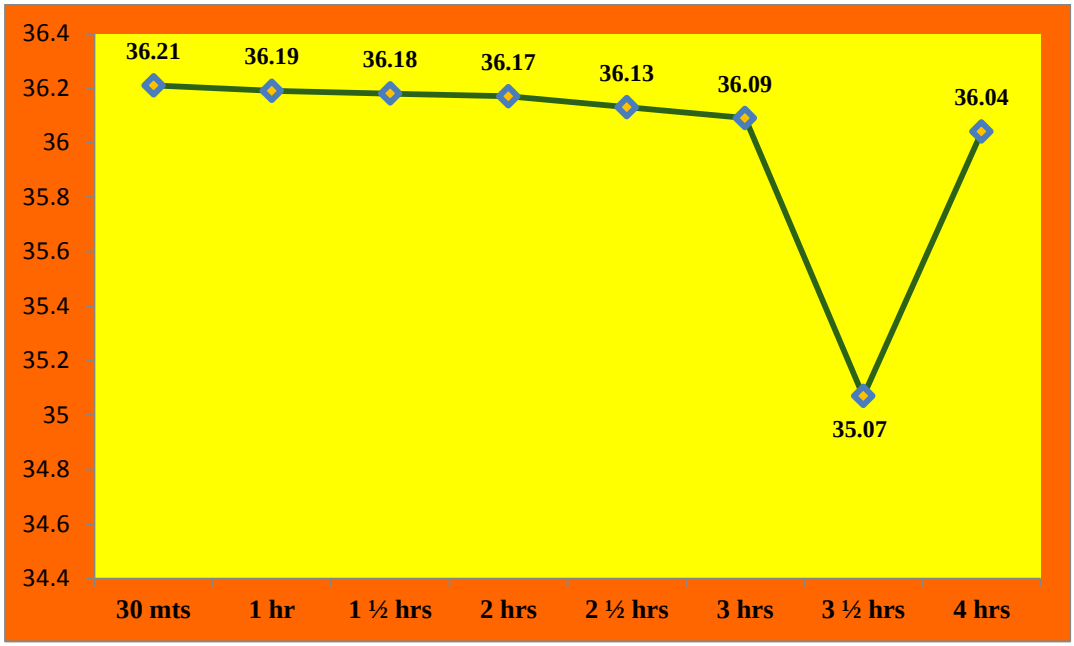


Figure 20: Mean core body temperature measurement at various time periods in holding area

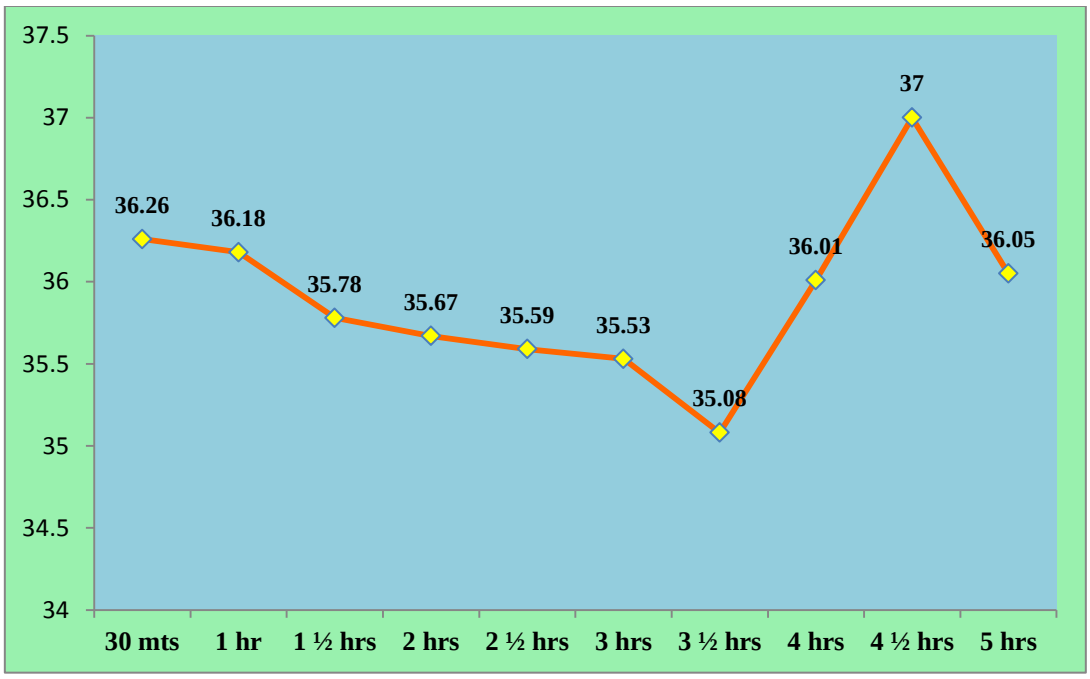


Figure 21: Mean core body temperature measurement at various time periods in intraoperative period.

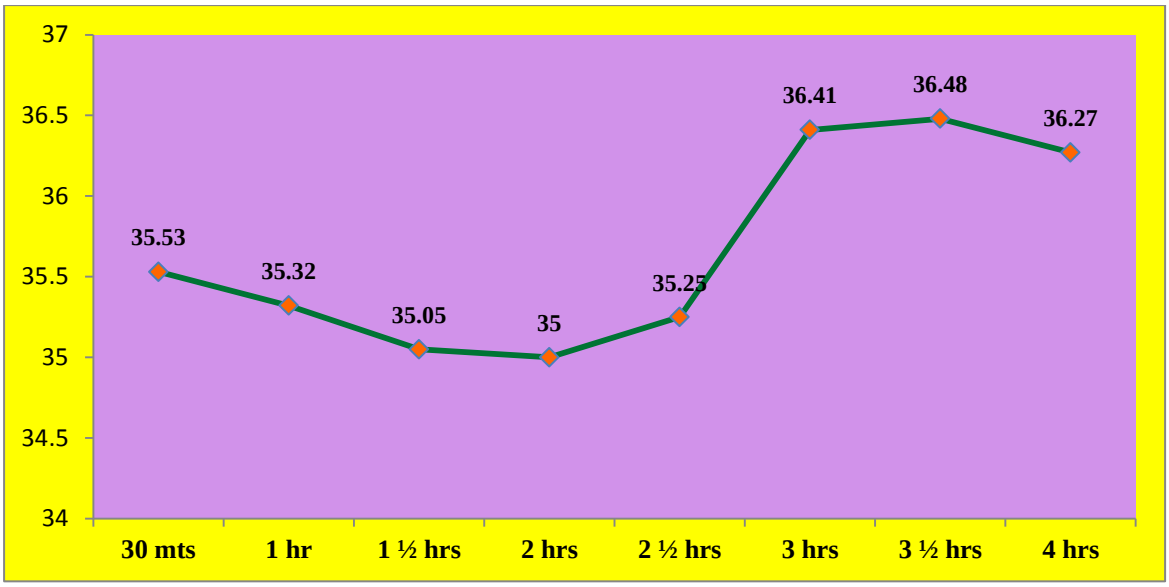


Figure 22: Mean score of core body temperature measurement at various time periods in PACU area.

Table 13: Comparison of pre-test and post-test mean score of core body temperature among subjects.

N= 50

Core body temperature	Duration of study	Mean	SD	Mean Difference	SD	't'value 'p'value
Holding Area	Pre test	36.21	0.14	0.17	0.04	4.19 0.0001***
	Post test	36.04	0.25			
Intra Operative	Pre test	36.26	0.19	0.21	0.07	2.87 .004**
	Post test	36.05	0.48			
PACU	Pre test	35.53	0.26	0.74	0.07	10.59 0.0001***
	Post test	36.27	0.42			

- p<0.01, * - p<0.001

Table13 interprets the comparison of mean score of core body temperature in the holding area in the study group during pre test & post test using paired t test. Comparison of the pre test and post test showed a statistically significant improvement in the post test mean score of core body temperature in the holding area intraoperative and the PACU than the pre test mean score of core body temperature in the holding area, intraoperative and the PACU. This is because of the fact, that the patients received a better and a quicker warming. And it is important to note that all patients remained above 36^{o}C all throughout the surgery once they reached the cut off limit at p <0.001.

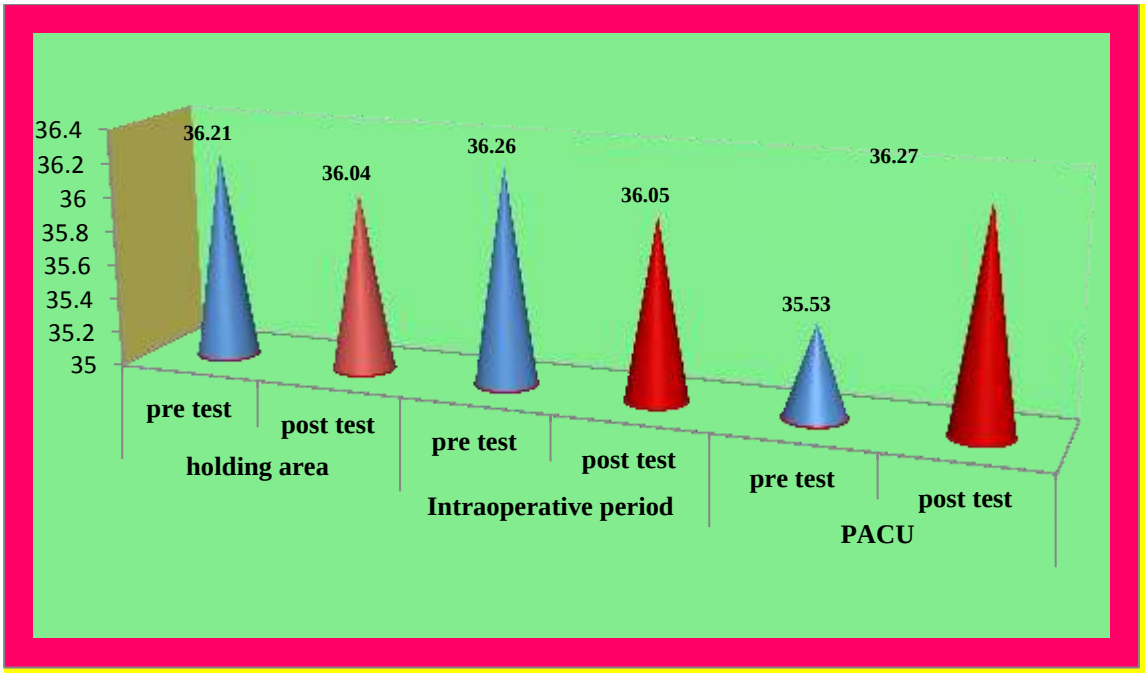


Figure 23: Comparison of pre-test & post-test mean score of core body temperature among subjects.

Table 14: Distribution of heart rate among subjects in perioperative period

N=50

Vital parameters	**Holding area**		**OT**		**PACU**	
	No.	%	No.	%	No.	%
1. Heart rate (beats/minutes)						
a) Normal – 60-100	48	96	49	98	46	92
b) Bradycardia - < 60	01	02	01	02	02	04
c) Tachycardia -> 100	01	02	0	0	02	04

Table 14 demonstrates the distribution of heart rate among subjects. The analysis shows that majority of subjects 96% (n=48), 98% (n=49) and 92% (n=46) had normal heart rate in the holding, intraoperative and PACU respectively.

Table 15: Repeated Measures ANOVA of heart rate at various time periods in perioperative period

N=50

Time periods	Holding area		Intraoperative		PACU		F value
	Mean	SD	Mean	SD	Mean	SD	
T1 (30 mts)	76.26	10.13	72.60	9.88	78.68	13.21	4.18*
T2 (1 hr)	61.82	29.93	72.46	14.76	79.92	11.78	
T3 (1 ½ hrs)	71.28	8.20	73.56	10.32	77.71	11.68	
T4 (2 hrs)	69.25	5.50	72.41	10.27	78.22	11.08	
T5 (2 ½ hrs)	65.00	1.41	72.00	10.82	76.81	12.14	
T6 (3 hrs)	65.00	4.24	74.30	11.16	81.11	12.09	
T7 (3 ½ hrs)	63.00	1.41	76.16	11.82	82.00	12.98	
T8 (4 hrs)	64.00	2.19	76.44	11.18	75.37	17.90	
T9 (4 ½ hrs)			73.17	9.87			
T10 (5 hrs)			70.90	9.62			

Table 15 presents the repeated measures ANOVA of heart rate over a period of time in the perioperative period. There is a statistically significant difference in the mean scores of heart rate measured at various time periods in holding area, intraoperative period and PACU at the level of $p < .05$.

Table 16: Comparison of pre-test and post-test mean score of heart rate at various time periods in perioperative period

N= 50

Core body temperature	Duration of study	Mean	SD	Mean Difference	SD	't'value 'p'value
Holding Area	Pre test	76.26	10.13	12.26	7.01	4.32 0.0001***
	Post test	64.00	2.19			
Intra Operative	Pre test	72.60	9.88	1.70	1.01	2.47 .004**
	Post test	70.90	9.62			
PACU	Pre test	78.68	13.21	3.31	4.10	5.59 0.0001***
	Post test	75.37	17.90			

- p<0.01, * - p<0.001

Table16 interprets the comparison of mean score of heart rate in the holding area among subjects during pre test & post test using paired t test. Comparison of the pre test and post test showed a statistically significant improvement in the post test mean score of heart rate in the holding area, intraoperative and the PACU than the pre test mean score of heart rate in the holding area, intraoperative and the PACU.

Table 17: Distribution of respiratory rate in perioperative period

N=50

Respiratory rate (bths/ mins)	**Holding area**		**OT**		**PACU**	
	No.	%	No.	%	No.	%
a) Normal – 12 to 24 b) Bradypnea -< 12 c) Tachypnea ->24	48 02 0	92 04 0	49 0 01	98 0 02	40 0 10	80 0 10

Table 17 demonstrates the distribution on respiratory rate among subjects. The analysis shows that majority of the subjects 92% (n=48) , 98% (n=49) and 80% (n=40), had normal respiratory rate in the holding, intraoperative and PACU respectively.

Table 18: Repeated Measures ANOVA of respiratory rate at various time periods in perioperative period

N=50

Time periods	Holding area		Intraoperative		PACU		F value
	Mean	SD	Mean	SD	Mean	SD	
T1 (30 mts)	17.12	4.08	13.88	2.92	17.06	4.86	4.23*
T2 (1 hr)	15.44	7.78	13.20	2.82	18.68	6.01	
T3 (1 ½ hrs)	17.39	3.36	14.12	2.49	18.78	4.54	
T4 (2 hrs)	18.50	3.33	13.99	2.66	18.85	4.67	
T5 (2 ½ hrs)	18.00	0.000	13.59	1.79	18.44	4.31	
T6 (3 hrs)	21.00	1.41	13.24	1.84	19.39	5.26	
T7 (3 ½ hrs)	21.00	1.41	13.65	2.10	18.21	4.83	
T8 (4 hrs)	21.00	1.41	13.50	2.00	20.59	7.91	
T9 (4 ½ hrs)			14.22	2.36	20.00	6.92	
T10 (5 hrs)			14.10	2.68	22.00	0.000	

Table 18 presents the repeated measures ANOVA of respiratory rate over a period of time in the perioperative period. There is a statistically significant difference in the mean scores of respiratory rate measured at various time periods in holding area, intraoperative period and PACU at the level of $p < .05$.

Table 19: Comparison of pre-test and post-test mean score of respiratory rate among patients

.N=50

Core body temperature	Duration of study	Mean	SD	Mean Difference	SD	't'value 'p'value
Holding Area	Pre test	17.12	4.08	3.88	1.23	3.97 0.0001***
	Post test	21.00	1.41			
Intra Operative	Pre test	13.88	2.92	0.22	0.04	6.83 .0001**
	Post test	14.10	2.68			
PACU	Pre test	17.06	4.86	4.94	2.11	11.52 0.0001***
	Post test	22.00	0.000			

- p<0.01, * - p<0.001

Table19 interprets the comparison of mean score of respiratory rate in the holding area in the study group during pre test & post test using paired t test. Comparison of the pre test and post test showed a statistically significant improvement in the post test mean score of respiratory rate in the holding area, intraoperative and the PACU than the pre test mean score of respiratory rate in the holding area, intraoperative and the PACU.

Table 20: Distribution of blood pressure among subjects in perioperative period

N=50

Blood pressure (mm of Hg)	Holding area		OT		PACU	
	No.	%	No.	%	No.	%
a) Normal	23	46	29	58	23	46
b) Pre HTN	13	26	17	34	16	32
c) I Stage	09	18	03	06	07	14
d) II Stage	04	08	0	0	03	06
e) Hypotension	01	02	01	02	01	02

Table 20 demonstrates the distribution on blood pressure among subjects. The analysis shows that majority 46% (n=23), 58% (n=29) and 46% (n=23), had normal blood pressure in the holding, intraoperative and PACU respectively.

Table 21: Repeated Measures ANOVA of blood pressure at various time periods in perioperative period

N=50

Time periods	Holding area		Intraoperative		PACU		F value (systolic)	F value (diastolic)
	Mean	SD	Mean	SD	Mean	SD		
T1 (30 mts)	126.50	21.56	117.04	19.72	123.58	25.28	7.185*	4.163*
	72.64	10.63	70.35	12.90	71.82	9.36		
T2 (1 hr)	109.78	53.03	118.12	21.32	127.02	18.96		
	71.26	10.85	70.28	10.84	72.44	9.65		
T3 (1 ½ hrs)	130.06	23.83	116.56	16.26	125.59	25.10		
	72.18	8.08	70.14	9.51	71.11	9.90		
T4 (2 hrs)	119.00	10.50	115.63	13.82	125.95	18.78		
	67.75	7.04	71.43	10.72	72.00	7.95		
T5 (2 ½ hrs)	119.50	2.12	114.30	13.71	126.34	17.04		
	71.00	1.41	70.50	9.31	70.03	7.48		
T6 (3 hrs)	117.0	7.07	119.33	18.12	130.10	19.38		
	65.00	4.24	70.83	10.63	70.40	9.36		
T7 (3 ½ hrs)	117.0	7.07	116.73	18.52	131.07	18.04		
	69.00	1.41	70.30	10.74	70.56	11.16		
T8 (4 hrs)	115.00	6.36	118.00	20.20	139.57	14.18		
	66.00	5.65	71.44	10.09	70.38	1.73		
T9 (4 ½ hrs)			124.56	13.63				
			71.47	8.26				
T10 (5 hrs)			125.73	26.97				
			72.09	7.47				

Table 21 presents the repeated measures ANOVA of blood pressure over a period of time in the perioperative period. There is a statistically significant difference in the mean scores of systolic blood pressure and diastolic blood pressure measured at various time periods in holding area, intraoperative period and PACU at the level of $p < .05$.

Table22: Comparison of pre-test and post-test mean score of blood pressure among patients

N=50

Core body temperature	Duration of study	Mean	SD	Mean Difference	SD	't'value 'p'value
Holding Area	Pre test	126.50	21.56	11.50	7.09	7.76 0.0001***
	Post test	115.00	6.36			
	Pre test	72.64	10.63	6.64	6.12	8.56 0.0001**
	Post test	66.00	5.65			
Intra Operative	Pre test	117.04	19.72	8.69	7.15	12.57 0.0001***
	Post test	125.73	26.97			
	Pre test	70.35	12.90	1.74	5.78	6.52 0.0001**
	Post test	72.09	7.47			
PACU	Pre test	123.58	25.28	15.19	4.78	4.67 0.0001**
	Post test	139.57	14.18			
	Pre test	71.82	9.36	1.44	1.12	7.53 0.0001**
	Post test	70.38	1.73			

- $p<0.01$, * - $p<0.001$

Table 22 interprets the comparison of mean score of systolic and diastolic blood pressure in the holding area in the study group during pre test & post test using paired t test. Comparison of the pre test and post test showed a statistically significant improvement in the post test mean score of systolic and diastolic blood pressure in the holding area, intraoperative and the PACU than the pre test mean score of systolic and diastolic blood pressure in the holding area, intraoperative and the PACU.

SECTION F: Distribution of hypothermia prevention strategies among subjects in perioperative period.

Table 23: Distribution on hypothermia prevention strategies N=50

S. No	Hypothermia prevention strategies	Study group	
		No.	%
1.	**Passive warming devices** A. Holding area & PACU area (Woollen blanket, Stocking, Head covering)	50	100
	B. Intra op area (Draping, Stocking & Head covering)	50	100
2.	**Active warming devices** A. Holding area a) Forced air warming b) Inline warming	 1 1	 2 2
	B .Intra op area a) Forced air warming b) Circulating hot water mattress c) Cabinet warming d) Inline warming e) Warm fluids for irrigation	 43 07 46 10 23	 86 14 92 20 46
	C. PACU a) Forced air warming b) Cabinet warming c) Inline warming	 23 06 21	 46 12 42

Table 23 demonstrates the distribution of hypothermia prevention strategies among patients. In holding intraoperative area and PACU. 100% (n=50) of subjects had received passive warming devices such as woollen blankets, stocking head, covering and draping(OT).

With regard to active warming devices 2% (n=1)of subject was on forced air and inline warming in holding area, 86% (n=43) were on forced air warming devices, 14% (n=7) were on circulating hot water mattress, 92% (n=46) were on cabinet warming devices, 20% (n=10) were on inline warming devices, 46% (n=23) were on fluid warm irrigation in intraoperative area. In PACU, 46% (n=23) were on forced air warming devices, 12% (n=6) had received cabinet warming and 42% (n=21) inline warming devices.

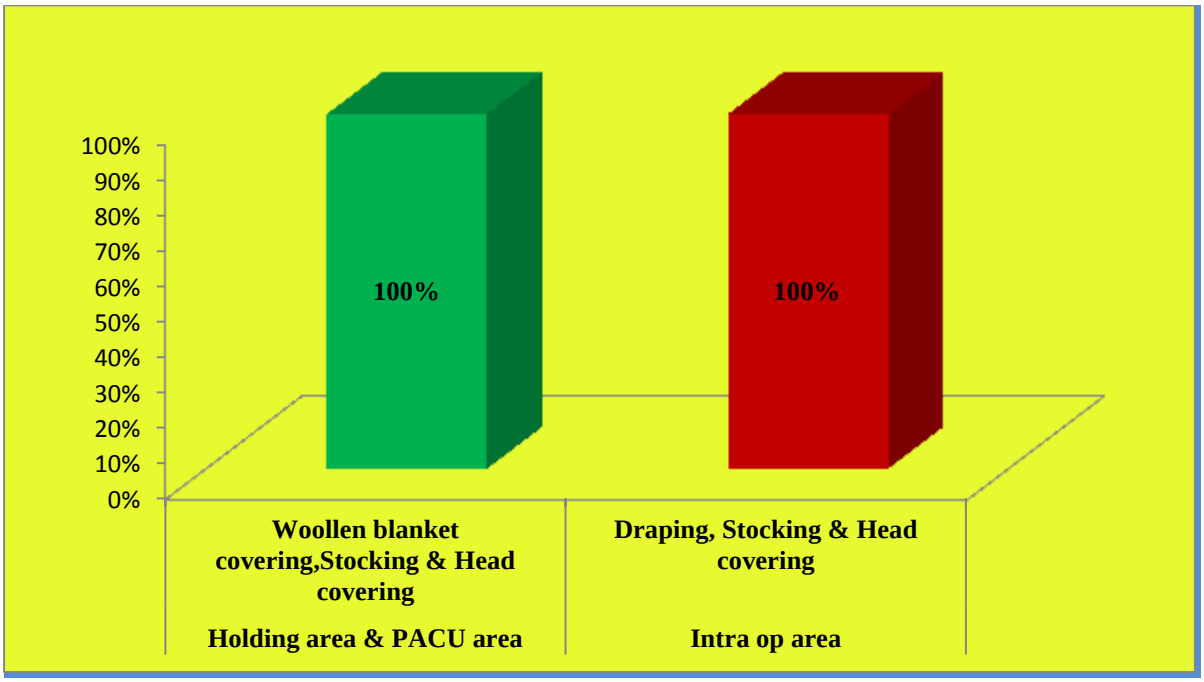


Figure 24: Distribution of passive warming devices used among subjects.

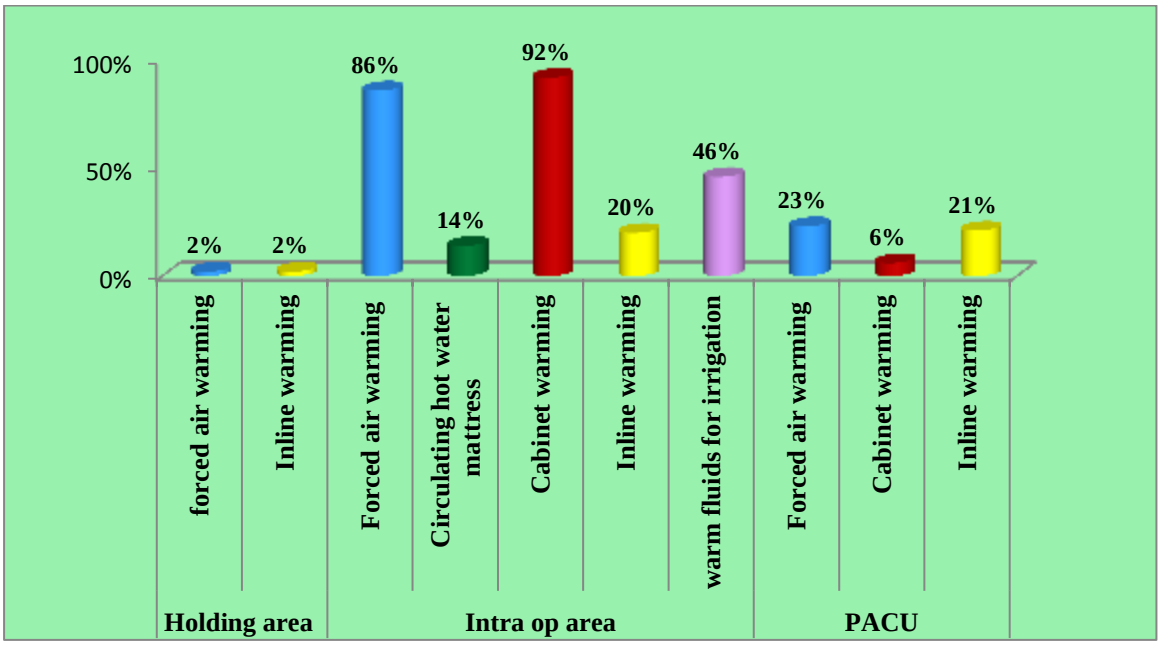


Figure 25: Distribution of active warming devices used among subjects.

SECTION G: Association between core body temperature with selected demographic variables, clinical variables and risk factors of hypothermia in perioperative period

Table 24: Association between core body temperature with selected demographic variables, clinical variables and risk factors of hypothermia in holding area

N = 50

S.No	Demographic variables	No	Mild (n=2)	Normothermia (n=48)	Chi square 'p' value
1.	**Age in years**				
	a) 21-40	17	1	16	0.98
	b) 41-60	17	1	16	0.61
	c) 61-70	16	0	16	(NS)
2.	**Sex**				
	a) Male	24	1	23	0.00
	b) Female	26	1	25	0.95
					(NS)
3.	**Educational status**				
	a) No formal education	18	0	18	4.42
	b) Primary	02	0	02	0.35
	c) Secondary	16	2	14	(NS)
	d) Higher secondary	03	0	03	
	e) Collegiate	11	0	11	
4.	**Diet pattern**				
	a) Vegetarian	02	0	02	0.08
	b) Mixed diet	48	2	46	0.76
					(NS)
5.	**Unhealthy habits**				
	a) Smoking	02	0	02	
	b) Alcohol consumption	07	0	07	0.45
	c) Smoking & alcohol consumption	0	0	0	0.79 (NS)
	d) Nil	41	2	39	
6.	**Co morbidity**				
	a) Diabetes mellitus	10	0	10	3.56
	b) Hypertension	20	1	19	0.61
	c) Chronic kidney disease	09	0	09	(NS)
	d) Ischemic heart disease	01	0	01	
	e) Hypothyroidism	04	0	04	
	f) Nil	46	1	05	

7.	**Level of physical status** (acc to ASA)				
	a) Healthy patient- ASA 1	10	1	09	1.36
	b) Mild systemic diseases - ASA 2	31	1	30	0.50 (NS)
	c) Severe systemic diseases-ASA 3	09	0	09	
8.	**BMI (kg/m^2)**				
	a) Underweight <18.5	01	0	01	0.64
	b) Normal 18.5- 24.99	30	1	29	0.88
	c) Over weight >25	05	0	05	(NS)
	d) Obesity >30	14	1	13	
9.	**Surgical procedures**				
	a) Upper abdominal	10	0	10	0.81
	b) Lower abdominal	36	2	34	0.93
	c) Upper & lower abdominal	01	0	01	(NS)
	d) Thoracic	02	0	02	
	e) Extremities	01	0	01	
10.	**Nature of surgery**				
	a) Elective	48	2	46	0.08
	b) Emergency	02	0	02	0.76 (NS)
11.	**Blood investigation**				
	a) Haemoglobin (<10 mg/dl)	05	0	05	1.05
	b) WBC (>11000m cells/mm	11	1	10	0.59 (NS)
	c) Nil	34	1	33	
12.	**Duration of patient stay**				
	a) <1 hr	32	0	32	3.70
	b) >1 hr	18	2	16	0.05*
13.	**Volume of fluid administration**				
	a) < 500 ml	35	2	33	0.89
	b) 500 ml - 1 litre	01	0	01	0.64
	c) Nil	14	0	14	(NS)

NS- Non Significant, p*<0.05

Table 24 shows that there is a statistically significant association between core body temperature and duration of stay at p<0.05. There is no statistical significant association between core body temperature with selected demographic variables and clinical variables in holding area.

Table 25: Association between core body temperature with selected demographic variables, clinical variables and risk factors of hypothermia intraoperative period.

N=50

S.No	Demographic variables	No.	Mild (n=26)	Moderate (n=1)	Normo thermia (n=23)	Chi square 'p' value
1.	**Age in years**					
	a) 21-40	17	07	0	10	5.52
	b) 41-60	17	12	0	05	0.23
	c) 61-70	16	07	1	08	(NS)
2.	**Sex**					4.44
	a) Male	24	16	0	08	0.10
	b) Female	26	10	1	15	(NS)
3.	**Educational status**					
	a) No formal education	18	08	1	09	
	b) Primary	02	02	0	0	9.19
	c) Secondary	16	11	0	05	0.32
	d) Higher secondary	03	0	0	03	(NS)
	e) Collegiate	11	05	0	06	
4.	**Diet pattern**					
	a) Vegetarian	02	02	0	0	1.92
	b) Mixed diet	48	24	0	23	0.38 (NS)
5.	**Unhealthy habits**					
	a) Smoking	02	0	0	02	
	b) Alcohol consumption	07	06	0	01	5.73
	c) Smoking & alcohol Consumption	0	0	0	0	0.22 (NS)
	d) Nil	41	20	1	20	
6.	**Co morbidity**					
	a) Diabetes mellitus	10	04	0	06	
	b) Hypertension	20	12	0	08	9.81
	c) Chronic kidney disease	09	05	0	04	0.45 (NS)
	d) Ischemic heart disease	01	01	0	0	
	e) Hypothyroidism	04	02	0	02	
	f) Nil	06	02	1	03	
7.	**Level of physical status (acc to ASA)**					6.54
	a) Healthy patient ASA-1	10	04	0	06	0.16
	b) Mild systemic diseases ASA-2	31	14	1	16	(NS)
	c) Severe systemic diseases ASA-3	09	08	0	01	

8.	**BMI (kg/m^2)**					
	a) Underweight <18.5	01	01	0	0	
	b) Normal 18.5- 24.99	30	15	1	14	1.75
	c) Over weight > 25	05	03	0	02	0.94
	d) Obesity > 30	14	07	0	07	(NS)
9.	**Surgical procedures**					
	a) Upper abdominal	10	04	0	06	
	b) Lower abdominal	36	21	0	15	28.23
	c) Upper & lower abdominal	01	0	0	01	0.0001***
	d) Thoracic	02	0	1	01	
	e) Extremities	01	01	0	0	
10.	**Nature of surgery**					1.92
	a) Elective	48	24	1	23	0.38
	b) Emergency	02	02	0	0	(NS)
11.	**Blood investigation**					
	a) Haemoglobin (<10 mg/dl)	05	02	0	03	2.85 0.58
	b) WBC (>11000m cells/mm)	11	09	0	03	(NS)
	c) Nil	34	12	1	23	
12.	**Duration of patient stay**					
	a) < 2 hrs	05	0	0	05	6.52
	b) > 2 hrs	45	26	1	18	0.03*
13.	**Type of anaesthesia**					
	a) GA	46	22	1	23	4.01
	b) RA	03	03	0	0	0.40
	c) GA & RA	01	01	0	0	(NS)
14.	**Blood loss during surgery**					
	a) < 100 ml	17	8	0	9	3.37
	b) 100 – 200 ml	18	9	0	9	0.49
	c) >200 ml	15	9	1	5	(NS)
15.	**Blood transfusion**					0.57
	a) Yes	03	01	0	02	0.75
	b) No	47	25	1	21	(NS)
16.	**Volume of fluid administration**					
	a) < 500 ml	02	0	0	02	6.80
	b) 500 ml - 1 litre	29	18	0	10	0.10
	c) >2 litres	19	08	1	11	(NS)

NS- Non Significant, *-p<0.05, ***-p<0.001

Table 25 shows that there is a statistically significant association between core body temperature with duration of stay at ($p < 0.05$) and surgical procedures ($p<0.001$). There is no statistical significant association between core body temperature with selected demographic variables and clinical variables in intraoperative period.

Table 26: Association between core body temperature with selected demographic variables, clinical variables and risk factors of hypothermia in PACU.

N=50

S.No	Demographic variables	No.	Mild (n=23)	Normo thermia (n=27)	Chi square 'p' value
1.	**Age in years**				
	a) 21-40	17	10	07	8.38
	b) 41-60	17	03	14	0.01*
	c) 61-70	16	10	06	
2.	**Sex**				1.34
	a) Male	24	09	15	0.24
	b) Female	26	14	12	(NS)
3.	**Educational status**				
	a) No formal education	18	08	10	
	b) Primary	02	0	02	5.75
	c) Secondary	16	08	08	0.21
	d) Higher secondary	03	03	0	(NS)
	e) Collegiate	11	04	07	
4.	**Diet pattern**				
	a) Vegetarian	02	01	01	0.01
	b) Mixed diet	48	22	26	0.90
					(NS)
5.	**Social habits**				
	a) Smoking	02	01	01	
	b) Alcohol consumption	07	03	04	0.04
	c) Smoking & Alcohol consumption	0	0	0	0.97 (NS)
	d) Nil	41	19	22	
6.	**Co morbidity**				
	a) Diabetes mellitus	10	05	05	5.96
	b) Hypertension	20	12	08	0.310
	c) Chronic kidney disease	09	02	07	(NS)
	d) Ischemic heart disease	01	01	0	
	e) Hypothyroidism	04	01	03	
	f) Nil	06	02	04	
7.	**Level of physical status (acc to ASA)**				
	a) Healthy patient ASA-1	10	06	04	2.90
	b) Mild systemic diseases ASA-2	31	15	16	0.23 (NS)
	c) Severe systemic diseases ASA-3	09	02	07	

8.	**BMI (kg/m^2)**				
	a) Underweight <18.5	01	0	01	1.17
	b) Normal 18.5- 24.99	30	15	15	0.79
	c) Over weight > 25	05	02	03	
	d) Obesity > 30	14	06	08	(NS)
9.	**Surgical procedures**				
	a) Upper abdominal	10	04	06	
	b) Lower abdominal	36	17	19	4.21
	c) Upper & lower abdominal	01	0	01	0.37
	d) Thoracic	02	02	0	(NS)
	e) Extremities	01	0	01	
10.	**Nature of surgery**				
	a) Elective	48	21	27	2.44
	b) Emergency	02	02	0	0.11
					(NS)
11.	**Blood investigation**				
	a) Haemoglobin (<10 mg/dl)	05	03	02	0.82
	b) WBC (>11000cells/cumm)	11	04	07	0.66
	c) Nil	34	16	18	(NS)
12.	**Duration of patient stay**				0.29
	a) <2 hrs	24	12	12	0.58
	b) >2 hrs	26	11	15	(NS)
13.	**Blood transfusion**				0.01
	a) Yes	2	1	1	0.90
	b) No	48	22	26	(NS)
14.	**Volume of fluid administration**				
	a) < 500 ml	09	02	07	9.50
	b) 500 ml - 1 litre	35	20	15	0.06
	c) >2 litres	06	01	5	(NS)

NS- Non Significant, *-p <0.05

Table 26 shows that there is a statistically significant association between core body temperature and age group at p*<0.05. There is no statistical significant association between core body temperature with selected demographic variables and clinical variables in PACU.

CHAPTER - V

DISCUSSION, SUMMARY, CONCLUSION, IMPLICATIONS, LIMITATIONS AND RECOMMENDATION

This chapter deals with discussion, summary and conclusion drawn from the study. The study limitations, implications and recommendations in different areas of nursing practice, nursing administration, nursing research and nursing education in the future are considered here.

Perioperative hypothermia induces several adverse effects and leads to life threatening causes. The mechanism of hypothermia under anaesthesia, monitoring temperature and the various methods of maintaining intraoperative normothermia has been discussed in detail earlier. Predictors for post-operative hypothermia include preoperative core temperature, extent of the procedure, intraoperative fluid turnover and the post-operative severity of condition. Most of the times, hypothermia goes unnoticed because of reluctance to monitor temperature. Only if the temperature is monitored, the dangerous hypothermia will be revealed. ASA guidelines advices routine temperature monitoring in all cases and is a must for cases with duration more than one hour. Hypothermia when diagnosed earlier can be managed adequately before if progresses to critically low levels of body temperature

Awareness of the anaesthesiologist and health care personnel about the hypothermia is very important in order to prevent it and if necessary to intervene. Empirical evidence and few studies have shared that even simple measures like covering the patient with a single layer of insulator, especially the head and upper body if possible can significantly prevent heat loss up to 30%. Unfortunately additional layers do not provide proportional benefits. Limiting the area of the body exposed, switching on the AC after draping the patient are simple measures, which involves no extra cost, but gives productive results.

Proper regulation of operating room environment has a pivotal role because it is the gradient between the human body and the ambience that decides the rate of heat loss from the body. Room temperature monitor should be available in every theatre and should be monitored at regular intervals to make necessary adjustments to the air conditioner. All these are passive methods to prevent heat loss from the body. In spite of these precautions, patient may still continue to drop the body temperature. In such

instances, anaesthesiologist has to adopt one of the active warming strategies. The choice of warming device is at the discretion of the anaesthesia care provider who chooses the mode of warming considering the availability, nature of the surgery, risk of hypothermia, and effectiveness of the warmer. They also opine about the various secondary outcomes like the side effects associated with the warmers, incidence of post-operative complications associated with hypothermia etc. However they all insist, in common, that hypothermia prevention and management has become a routine standard of care but how far this protocol being effectively implemented in the perioperative period is a nursing challenge experienced by the investigator. With this focus this quasi experimental one group pre and post-test design is attempted to assess the effectiveness of hypothermia prevention protocol among patients subjected to major surgeries at KMCH, Coimbatore. The study was conducted among 50 patients.

The data was collected using Non probability convenient sampling technique from Operation Complex-II of Kovai Medical Center and Hospital, Coimbatore. The intervention on hypothermia prevention protocol was implemented. The protocol was restricted to observing, risk factors of hypothermia, signs & symptoms and hypothermia management by using the checklist and measuring and recording vital parameters for every 30 minutes in the Holding area, Intraoperatively and Post Anaesthesia Care Unit.

The first objective of the study was to assess the incidence and extent of hypothermia among patients subjected to major surgeries.

The analysis shows that (n=2) 4% had mild hypothermia, (n=48) 96% had normothermia in the holding area. 26 (52%) mild hypothermia. (n=1) 2% in had moderate hypothermia. (n=23) 46% had normothermia in the intraoperative period. (n=23) 46% had mild hypothermia. (n=27) 54% had normothermia in the PACU. The results are substantiated by Frank et.al, (2007) that the risk factors for hypothermia includes Extremes of age (elderly), age related changes may alter the temperature regulation. The mean age of the subjects in the present study were 41.20 years where 64 years was the highest and 21years was the lowest with the mean score of 41.20 SD 14.68. The results of the present study showed that there is a statistically significant association between core body temperature and age of patients at $p < 0.001$ as majority of the elderly patients had mild hypothermia in PACU.

With regard to gender, Male: Female ratio was 1:1. (n=24) 48% were male and (n=26) 52% were female. The results of the present study revealed there is a statistically significant association between core body temperature and age group at $p<0.05$.

Patients with extremes in body weight or condition (e.g., thin, obese, malnourished) are at risk for hypothermia because of body surface area to weight ratios. BMI of the study subject showed that there were 30 patients with normal BMI had mild hypothermia out them 26 (80.6%) had mild hypothermia these findings are consistent with the report of World Health Organization, 1995 showed that the greater the BMI the higher the patient body temperature. In the present study majority the mean BMI of the subjects were 22.07 kg/m^2 where 27.4 was the highest and 17.3 was the lowest with the mean score of 22.7 SD 3.01 as per results of previous study Frank et.al,(2007) thin patients and patients with large body surface area are the risk factors of hypothermia.

All subjects were categorized according to ASA's (American Society of Anaesthesiologists) classification as level of physical status 1 to 3. 20% (n=10) were healthy ASA grade-I, 62% (n=31) with mild systemic diseases (ASA-II), 18% (n=9) were with severe systemic diseases (ASA-III). 40% (n=20) of the subjects were hypertensive. The study substantiated b similar study done by Xiong et.al, It is well established that thermoregulation is disrupted during general anaesthesia for hypertensive patients. For example, while normal thermoregulation leads to shivering and vasoconstriction when the core body temperature falls 0.2°C, during general anaesthesia this threshold is increased to 2°C to 4°C, leaving hypertensive patients vulnerable to significant abnormal cooling.

The results of the present study revealed that there is a statistically significant association between core body temperature with duration of stay at ($p <0.05$) and surgical procedures ($p<0.001$) in the intra operative period. Duration of stay among patients in holding area varied greatly from 15 minutes to a maximum of up to 45 minutes. The average of this time for majority 64% (n=32) of patients was 36.5 minutes and 31.25 minutes. The average of duration of stay in OT among majority 90% (n=45) of patients was varied greatly from 2 hrs30 minutes to a maximum of upto 4 hrs 40 minutes. 52% (n=26) were stayed >2 hours in the PACU. Although most studies shows that hypothermia contributes to increasing length of hospital stay

and PACU recovery time, results are not consistent. A large study published by Kurtz 1996 in colorectal surgery patients found that hypothermia (34.7 ± 0.6 ℃) at the end of surgery delayed patients' ability to tolerate solid food and suture removal by one day compared to patients with normothermia. Hospital length of stay also increased 20% (2.6 d) and length of stay was prolonged even after correcting for the increased risk of infection in the hypothermic group. Lenhardt, et al., (1997) PACU discharge times are also impacted by hypothermia. Discharge from the PACU was observed to significantly increase by 40 min in hypothermic patients based on a modified Aldrete and Kroulik scoring system. If discharge criteria included normothermia, then recovery was prolonged over 2hrs. The twitch tension starts to decrease 16% per 1ºC once the temperature of the adductor pollicis muscle is below 35.2ºC. With moderate hypothermia to 3ºC, morphine also has decreased potency, clearance, and volume of distribution; although, its concentration is elevated in the plasma and cerebral spinal fluid. Notably, the efficacy of neostigmine and naloxone seems to be preserved during hypothermia.

A literature review Durel, et al., (2000) showed that OR temperature is a major factor of intraoperative heat loss because low room temperatures lead to increased heat loss by radiation from the patient's skin to the environment and also procedures that last more than one hour and that expose large patient body cavities to room air and cool irrigation fluids place the patient at risk for hypothermia. Hypothermia is more commonly seen in long surgical procedures because body temperatures drop more markedly within the first 40 to 60 minutes after the start of anesthesia. During intraoperative period 26 patients (52%) more than of the half of the patient with mild hypothermia. ie., the longer the duration of surgery, the lower the patient's body temperature.

Majority of subjects70% (n=35) had received the average amount ie.365 ml IV fluids in the holding area. (n=29) 58% & 70% (n=35) had IV fluid administration of 500ml to 2liters intraoperatively and in PACU respectively. These results are in consistent with the amount of blood loss during surgery where 34% (n=17) had the blood loss below 100 ml, 36% (n=18) had the blood loss 100-200ml, 30% (n=15) had blood loss above 200 ml out of which 3 (6%) received blood transfusion during surgery, 2 (4%) received blood transfusion in the PACU. Sun et al (2015), in a recent large retrospective study of non-cardiac surgeries that attempted to determine whether

mild hypothermia leads to increased blood loss and transfusions. The study had given inconsistent results, that a median patient temperature of 35.6 ºC resulted in increased blood loss (4%-26%) and an increased relative risk of transfusion (3%-37%). However, transfusion requirements increased in proportion to the decrease in temperature and the increased duration of hypothermia.

In an article published by Lista e al., (2012), it was concluded that more area of body exposed during surgery, more amount of intravenous, irrigation fluids used could be the risk factor for hypothermia during intra and post operative period. Use of simple measure like use of warmed fluids, limiting the area exposed to surgical site alone, forced air warming improved clinical outcomes, patient comfort and recovery following surgery.

Second objective was to determine the effectiveness of hypothermia prevention protocol among patients subjected to major surgeries

As per the results of the previous study by Brauer, et al., (2006) it was concluded that although the hypothermia in post-operative patients runs between 41 and 60%, temperature is measured in only one in four patients undergoing general anaesthesia in European hospitals. For regional anaesthesia, it is only one in six patients. The present study attempted to determine the incidence of hypothermia by monitoring the core body temperature in variety of time periods in each area ie holding, intra operative and PACU area. The repeated measures ANOVA of core body temperature over a period of time in the holding area revealed that there is no statistically significant difference in the mean scores of core body temperature measured at various time periods in perioperative period at the level of $p>.05$.

The difference between the mean temperatures in the perioperative period approximately was $0.3^{o}C$ and approaches to $0.5^{o}C$ at around one hour. This degree of difference in mean temperature goes on increasing till about 2½hours and then decreases. This is because of the fact, that the patients received a better and a quicker warming. And it is important to note that all patients remained above $36^{o}C$ all throughout the surgery once they reached the cut off limit. This shows that the quality and quickness of this warming device is better in preventing hypothermia. This indirectly tells us about the effectiveness of these warming devices in preventing the temperature drop from baseline but still a statistically significant difference in the

mean temperature remains at various time periods throughout the perioperative period.

In the present study, comparison of the pre test and post test showed a statistically significant improvement in the post test mean score of core body temperature in the holding area intraoperative and the PACU than the pre test mean score of core body temperature in the holding area. This is because of the fact, that the patients received a better and a quicker warming. And it is important to note that all patients remained above 36^{o}C all throughout the surgery once they reached the cut off limit at $p < 0.001$. As there is a statistically significant reduction in occurrence of hypothermia among patients subjected major surgery after implementation of hypothermia prevention protocol , the hypothesis is accepted.

In holding intraoperative area and PACU 100% (n=50) of patients had received passive warming devices such as woollen blankets, stocking head, covering and draping (OT). 2% (n=1) patient had received active & inline warming in holding area, 86% (n=43) were on forced air warming devices, 14% (n=7) were on circulating hot water mattress, 92% (n=46) were on cabinet warming devices, 20% (n=10) were on inline warming devices, 46% (n=23) were on fluid warm irrigation in intraoperative area, In PACU, 46% (n=23) were on forced air warming devices, 12% (n=6) had received cabinet warming and 42% (n=21) inline warming devices. Hong-xia, X et.al 2010, conducted to evaluate the efficacy of warm fluids in maintaining core temperature during the intraoperative period and in preventing post anaesthetic shivering. Administration of warm IV fluids at 37ºC. The study concluded that the administration of warm IV fluids in abdominal surgeries is effective in maintaining core temperature (nearly normothermia) and may decrease the incidence of postaneasthetic shivering. Authors advocate the association of this IV fluid warming system with other techniques to minimize the occurrence of hypothermia.

Bernardis, et al., (2009) conducted to assess the efficacy of using a forced-air blanker in different periods as a method to prevent intraoperative hypothermia. The study concluded that the forced-air blanket is effective to prevent intraoperative hypothermia in surgeries when applied for a period ranging from 30 min before anaesthetic induction to 120 min after anesthetic induction, Under the conditions of the study, no adverse events were observed as a result of using a forced-air blanket at a moderate intensity (38ºC).

Andrzejowski, et al., (2010) the study concluded that the administration of warmed fluids results in higher postoperative temperatures and a lower incidence of hypothermia. In addition, pre-warmed fluids in a warming cabinet are comparable to those used in the in-line system. This study reinforces the NICE guidelines, according to which all IV fluids should be warmed before administration to minimize the incidence of perioperative hypothermia.

Adriani & Moriber, (2013) the study concluded that prewarming plus intraoperative warming by active warming devices is more effective in the prevention of hypothermia than intraoperative warming alone. The nurse should plan to implement all methods of temperature maintenance and preservation available for these patients. Perioperative nurses should collaborate with the surgeon and anesthesia care provider to determine the advisability of increasing the OR temperature, using warm irrigation fluids, and instituting forced-air warming. By instituting all these measures the nursing challenge of perioperative hypothermia can be rectified.

SUMMARY

- The mean age of the subjects were 41.20 years where 64 years was the highest and 21years was the lowest with the mean score of 41.20 SD 14.68
- With regard to gender, Male: Female ratio was 1:1. (n=24) 48% were male and (n=26) 52% were female.
- Concerning with the educational status, dietary pattern & unhealthy habits majority of subjects 32% (n=16), 96% (n=48) & 82% (n=41) had secondary education and were on mixed diet they had no such unhealthy habits of Smoking & alcohol consumption respectively.
- Majority 40% (n=20) of the subjects were hypertensive, the mean BMI of the subjects were 22.07 kg/m² where 27.4 was the highest and 17.3 was the lowest with the mean score of 22.7 SD 3.01.
- All subjects were categorized according to ASA's (American Society of Anaesthesiologists) classification as level of physical status 62% (n=31) with mild systemic diseases (ASA-II).
- Majority 72% (n=36) of the subjects were subjected to the lower abdominal surgery, 96% (n=48) had elective surgery.

- Duration of stay among subjects in holding area varied greatly from 15 minutes to a maximum of up to 45 minutes. The average of this time for majority 64% (n=32) of patients was 36.5 minutes and 31.25 minutes. The average of duration of stay in OT among majority 90% (n=45) of patients was varied greatly from 2 hrs30 minutes to a maximum of upto 4 hr 40 minutes. 52% (n=26) were stayed >2 hours in the PACU.
- Majority of subjects70% (n=35) had received the average amount ie. 365 ml IV fluids in the holding area. (n=29) 58% & 70% (n=35) had IV fluid administration of 500ml to 2liters intraoperatively and in PACU respectively.
- Majority 92% (n=46) had general anaesthesia, 6% (n=3) had regional anaesthesia, 2% (n=1) had general and regional anaesthesia.
- 34% (n=17) had the blood loss below 100 ml, 36% (n=18) had the blood loss 100-200ml, 30% (n=15) had blood loss above 200 ml.3 (6%) received blood transfusion during surgery, 2 (4%) received blood transfusion in the PACU.
- Shivering was one of the important secondary outcomes studied because most of the ill effects of hypothermia are associated with shivering. About 10% (n=5) of patients shivered and had Cold extremities in the Holding area and in PACU area respectively.
- The repeated measures ANOVA of core body temperature, heart rate, respiratory rate, blood pressure and SPO2 over a period of time revealed that there is a statistically significant difference in the mean scores of core body temperature heart rate, respiratory rate, blood pressure and SPO2 measured at various time periods in perioperative period at the level of $p<.05$.
- Comparison of the pre test and post test showed a statistically significant improvement in the post test mean score of core body temperature, heart rate, respiratory rate, blood pressure and SPO2 in the holding area intraoperative and the PACU than the pre test mean score of core body temperature heart rate, respiratory rate, blood pressure and SPO2 in the holding area, intraoperative and the PACU.
- In holding intraoperative area and PACU 100% (n=50) of patients had received passive warming devices such as woollen blankets, stocking head, covering and draping(OT).

- With regard to active warming devices 2% (n=1)of subject was on forced air and inline warming in holding area, 86% (n=43) were on forced air warming devices, 14% (n=7) were on circulating hot water mattress, 92% (n=46) were on cabinet warming devices, 20% (n=10) were on inline warming devices, 46% (n=23) were on fluid warm irrigation in intraoperative area. In PACU, 46% (n=23) were on forced air warming devices, 12% (n=6) had received cabinet warming and 42% (n=21) inline warming devices.

CONCLUSION

The effective perioperative temperature management begins with accurate temperature measurement. The body temperature of the patients was measured every 30 minutes. The body temperature was measured by tympanic thermometer at the tympanic membrane.

The repeated measures ANOVA of core body temperature over a period of time revealed that there is a statistically significant difference in the mean scores of core body temperature measured at various time periods in perioperative period at the level of $p<.05$. The average of duration of stay in OT among majority 90% (n=45) of patients was varied greatly from 2 hrs 30 minutes to a maximum of upto 4 hrs 40 minutes. 52% (n=26) were stayed >2 hours in the PACU. (n=29) 58% & 70% (n=35) had IV fluid administration of 500ml to 2 liters intraoperatively and in PACU respectively. 30% (n=15) had blood loss above 200 ml. 3 (6%) received blood transfusion during surgery, 2 (4%) received blood transfusion in the PACU.

There is a statistically significant association between core body temperature and duration of stay, and the type of surgical procedures and elderly age group at $p<0.05$. Working as a collaborative team, perioperative nurses and other health care providers in the preoperative, intraoperative, and postoperative recovery phases can minimize, if not eliminate, unplanned hypothermia, resulting in optimal outcomes for their patients.

NURSING IMPLICATIONS

- The study has implication in different areas in the nursing mainly, nursing practice, nursing education, nursing administration and nursing research.

Nursing practice

- Preoperative nurse should intervene, depending on the patient's preoperative temperature, to normalize or maintain the patient's temperature before surgery.
- The nurse should provide passive warming measures before surgery (eg, head coverings, socks) to maintain the patient's temperature and plan for warming measures in the OR to prevent inadvertent hypothermia (eg, forced-air warming, warmed irrigation and IV fluids, reduced body exposure to room air, elevated OR temperature).
- The nurse should plan to implement all methods of temperature maintenance and preservation available for these patients.
- Perioperative nurses should collaborate with the surgeon and anesthesia care provider to determine the advisability of increasing the OR temperature, using warm irrigation fluids, and instituting forced-air warming.

Nursing education

- The perioperative educator ensures that the health care providers in the perioperative responsible need to be trained on tympanic membrane temperature monitoring.
- Nursing students should be taught about the risk factors for hypothermia in Operation theatre and its preventive strategies
- Nursing curriculum should include session on hypothermia prevention among patients posted for surgery.

Nursing administration

- Standardized protocol Prevention hypothermia can be implemented. Policies and procedures should be made clear to the recovery room nurses in Operation Theatre about hypothermia prevention
- Nurse administrator should plan and organize continuing nursing education on prevention hypothermia or non –Maintenance of normal body temperature

which includes maintaining the patient's temperature, providing pain control, and ensuring hydration. Increasing ambient room temperature, providing warm blankets, and minimizing skin exposure.

- Nurse administrators can organize educational programs such as short term course, refresher course, seminar, workshop and conferences in collaboration with Members of the multidisciplinary team to update the nurses in order to ensure effective patient care.

Nursing research

- Nurses can use this study results for the implementation of protective actions against hypothermia may have a strong impact on patient safety and eliminate perioperative hypothermia.
- Better understanding of factors associated to the development of hypothermia provides evidences to support nurses' decision making to implement interventions for hypothermia prevention or treatment.

LIMITATIONS

- Study was limited to a small setting without randomization.
- The result cannot be generalized to other hospital OT's.
- As sample size are small, the results cannot be generalized.

RECOMMENDATION

- A study can be replicated involving large population and sample for a longer period. So that, the findings can be generalized.
- A similar study can be done in other hospital settings.

ABSTRACT

Hypothermia is a significant risk factor for perioperative complications. Whatever method is used for maintaining or promoting normothermia, first and foremost, it should be remembered that careful and thoughtful actions directed at maintaining normothermia can significantly affect the course of the patient's perioperatative experience. With this focus the present study entitled "Effectiveness of hypothermia prevention protocol among patients subjected to major surgeries at KMCH".

Objectives:

The objectives of the study were to,assess the incidence and extent of hypothermia among patients subjected to major surgeries, to determine the effectiveness of hypothermia prevention protocol among patients subjected to major surgeries and to associate the demographic variables, clinical variables and risk factors of hypothermia with core body temperature among patients subjected to major surgeries.

Methodology:

The methodology adopted for this study was a Quasi experimental one group pre test and post test design. Modified Ludwig Von Beralanffy's (1968) general system theory was applied. Data was collected for six weeks period of time after obtaining ethical clearance from concerned authorities. The basic characteristic such as Demographic variables, Clinical variables, risk factors of & signs and symptoms of hypothermia were collected. The core body temperature, heart rate, respiratory rate, blood pressure and SPO2 were monitored and in time sequences of every 30 minutes on arrival in and transfer out from holding area, OT and PACU. Hypothermia prevention management strategies (active and passive warming as per core body temperature) were implemented and it was observed by using Hypothermia prevention protocol checklist by the investigator. Both descriptive and inferential statistics were used to analyse the data.

Results:

The repeated measures ANOVA of core body temperature, heart rate, respiratory rate, blood pressure and SPO2 over a period of time revealed that there is a statistically significant difference in the mean scores of core body temperature heart rate, respiratory rate, blood pressure and SPO2 measured at various time periods in perioperative period at the level of $p<.05$.

The average of duration of stay in OT among majority 90% (n=45) of patients was varied greatly from 2 hrs 30 minutes to a maximum of upto 4 hrs 40 minutes. 52% (n=26) were stayed >2 hours in the PACU. (n=29) 58% & 70% (n=35) had IV fluid administration of 500ml to 2 liters intraoperatively and in PACU respectively. 30% (n=15) had blood loss above 200 ml. 3 (6%) received blood transfusion during surgery, 2 (4%) received blood transfusion in the PACU.

There is a statistically significant association between core body temperature and duration of stay, and the type of surgical procedures and elderly age group at $p<0.05$.

Conclusion:

Nurses play a crucial role in the prevention or treatment of perioperative hypothermia. Maintaining normothermia can reduce costs to the hospital and patients and, more importantly, reduce risk of complications. As there is a statistically significant reduction in occurrence of hypothermia among patients subjected major surgery after implementation of hypothermia prevention protocol , the hypothesis is accepted.

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APPENDIX - A

PART I

DEMOGRAPIC VARIABLES

1. IP.NO :
2. Age in years :
3. Sex :
4. Education status :
5. Dietary pattern :
6. Unhealthy habits :

Part II

CLINICAL VARIABLES

1. Diagnosis :
2. Surgical procedures :
3. Co-morbidity :
   - i) Diabetes Mellitus : Yes / No
   - ii) Chronic Kidney Disease : Yes / No
   - iii) Hypertension : Yes / No
   - iv) Ischemic Heart Disease : Yes / No
   - v) Thyroid disorder : Yes / No
     if yes, hypothyroidism / hyperthyroidism
4. Nature of surgery : Elective / Emergency
5. ASA classification :
6. BMI ((kg/m^2) :
7. Blood investigation
   - a) Haemoglobin :
   - b) WBC count :
8. Pre-medication given :
9. Border line vital signs : a) Temperature : b) Heart rate :
   c) Respiration : d) BP :
   e) SPO_2 :

PART III

RISK FACTORS OF HYPOTHERMIA

S. No	RISK FACTORS					HOLDING AREA	INTRA -OP	PACU
1.	Duration of patient stay							
2.	Duration of patient stay							
3.	Type of Anaesthesia	a. GA	b. RA	c. LA	d. GA & RA			
4.	Total duration of anaesthesia							
5.	Blood loss during surgery							
6.	Blood Transfusion							
7.	Ambient room temperature							
8.	Humidity of theatre							
9.	Volume of fluid administration							

PART IV

SIGNS AND SYMPTOMS OF HYPOTHERMIA

S. No	SIGNS AND SYMPTOMS	HOLDING AREA	INTRA -OP	PACU
1.	Shivering			
2.	Pilorection			
3.	Cold extremities			

PART V

VITAL PARAMETERS OBSERVATION CHECKLIST FOR EVERY 30 MINUTES

Time (Holding area)																
Temperature (ºC)																
HR (beats/min)																
RR (breaths/min)																
BP (mm of Hg)																
SPO_2 (%)																
Time (Intra-op)																
Temperature (ºC)																
HR (beats/min)																
RR (breaths/min)																
BP (mm of Hg)																
SPO_2 (%)																
Time (PACU)																
Temperature (ºC)																
HR (beats/min)																
RR (breaths/min)																
BP (mm of Hg)																
SPO_2 (%)																

PART VI

HYPOTHERMIA PREVENTION PROTOCOL CHECKLIST

S.No	MANAGEMENT	HOLDING AREA	INTRA OP	PACU
1.	Passive body warming devices			
	a.Woollen blankets			
	b. Stocking			
	c. Draping the patient			
	d. Head covering			
2.	Active body warming devices			
	a. Forced air warmer (Holding area & PACU)			
	b. Circulating hot water mattress (intra op)			
	c. Forced air warmer with blankets(Intra op)			
3.	Fluid warming devices			
	a. Inline fluid warmer			
	b. Cabinet warmed fluids			
4.	Warm fluids for irrigating body cavity			
5.	OT Temperature between (20^{o}C -24^{o}C)			
6.	Humidified and gases (anaesthetic)			

APPENDIX- B

COPY OF PERMISSION LETTER FROM ETHICAL COMMITTEE

KMCH ETHICS COMMITTEE
KOVAI MEDICAL CENTER AND HOSPITAL LIMITED
Post Box No. 3209, Avanashi Road, Coimbatore - 641 014. INDIA
✆ : (0422) 4323800, 4323619 Fax : (0422) 4270805
E-mail : ethics@kmchhospitals.com
EC Reg. No : ECR / 112 / Inst / TN / 2013

Ref: EC/AP/526/03/2017
13.03.2017

APPROVED

To
Prof.P.Akila
KMCH college of Nursing
Coimbatore-641014
Tamilnadu, India.

Dear Prof.P.Akila,

The proposal entitled **"Effectiveness of Hypothermia Prevention Protocol among patients Subjected to major surgeries at KMCH, Coimbatore"** Submitted by **Ms.S.Sonia,** under your guidance was reviewed by the Ethics Committee in its meeting held on 11.03.2017 and permission is granted to carry out the study at Kovai Medical Center and Hospital Ltd, Coimbatore, India.

Thanking you,

Yours faithfully,

Dr. P. R. Muthuswamy
Chairman, KMCH Ethics Committee

Dr. P. R. MUTHUSWAMY,
MA.,MBA. FDPM(IIM-A)Ph.D.,
Chairman
Ethics Committee
Kovai Medical Center and Hospital
Avanashi Road,
COIMBATORE-641 014.

Copy to:
Medical guide:
Dr.N.Selvarajan,M.D.,
Head - Dept. of Anaesthesiology
Kovai Medical Center and Hospital
Research guide:
Prof. Dr.S.Madhavi, M.Sc(N).,Ph.D.,
Principal
KMCH college of Nursing

APPENDIX- C

REQUISITION FOR CONTENT VALIDITY

From

II year M.Sc , Nursing,

KMCH College Of Nursing,

Coimbatore.

To

Through

The Principal,

KMCH College Of Nursing,

Coimbatore.

Respected Madam,

Sub: Seeking Expert Opinion and Content Validity Regarding

I am the student of KMCH college of Nursing. As a part of partial fulfilment of my post graduate programme, I wish to undertake a study titled **"Effectiveness of hypothermia prevention protocol among patients subjected to major surgeries at KMCH, Coimbatore."** It will be of immense help to me if you could peruse the proposal and the research tool. Here with I am enclosing the copy to the same. Kindly do the needful.

Thanking You,

Yours Obediently,

SONIA.S

Place:

Date:

APPENDIX -D

PARTICIPANT INFORMATION AND CONSENT FORM

Project title: To assess the Effectiveness of Hypothermia Prevention Protocol

INTRODUCTION

You are being asked to participate in a research study to be conducted by S. Sonia at the KMCH College of nursing in Coimbatore. The purpose of this study is to determine the effectiveness of hypothermia prevention protocol among patients subjected to major surgeries in Operation theatre. This will involve in this research at KMCH, and your participation will last till returning back to ward or ICU.

PROCEDURE

Data will be collected for six weeks period of time after obtaining ethical clearance from concerned authorities. The basic characteristic such as Demographic variables, Clinical variables, risk factors of & signs and symptoms of hypothermia will be collected.

The core body temperature will be monitored by using tympanic membrane thermometer in time sequences of every 30 minutes on arrival in and transfer out from holding area, OT and PACU. Hypothermia prevention management strategies (active and passive warming as per core body temperature) will be implemented and it will be observed by using Hypothermia prevention protocol checklist.

There is no chance to arise any problems due to this interventions which is aimed to Only maintaining normal core body temperature. You are free to withdraw during the study without any compromise in subsequent treatment.

I certify that I have explained the nature and purpose of this study, and I have discussed the potential benefits and risks of this study participation. The have discussed the potential benefits and risks of this study participation. The questions the individual had about this study have been answered, and we will always be available to address future questions.

Investigator Name
Sonia. S

Signature: **Date:**

APPENDIX-E

VOLUNTARY CONSENT BY THE PARTICIPANT

I have read in my first language, and I understand information

Version _____ Dated _____

I freely agree to participate in this project according to the conditions in the participant information. In signing this document I am willing to give my consent to participate in this research work to be conducted by S. Sonia at the KMCH College of Nursing in Coimbatore. I understand that, I will be a part of the research study that will focus on assess the incidence and extent of hypothermia among patients subjected to major surgeries and providing interventions.

I have read this consent from (or it has been read to me) and I fully understand the contents of this document. I have not been forced to participate as a subject in this research work. I have been informed that the participation is entirely voluntary and that even after the investigation begin I have all the rights to refuse the intervention at any point. The investigator entrusted strictly confidentiality to me thoroughly. As per the information given to me, assessment will take till the patient leave from the PACU.

All my questions concerning this study have been answered. If I have any questions in the future about this study they will be answered by investigator. I understand that this consent ends at the conclusion of this study. I understand that the study will promote my health and maintain normothermia in OT.

Contact address with phone number: **Date:**

Sonia. S

Participant's Name _____ **Signature Date:**

Name of witness to participant's Signature _____

APPENDIX- F

PARTICIPANT INFORMATION AND CONSENT FORM (TAMIL)

ஆராய்ச்சியில் பங்கு பெற சம்மதம் தெரிவித்ததின் சான்றிதழ்

மேலே குறிப்பிட்ட நபருக்கு இந்த ஆராய்ச்சியில் பங்கு பெறுவதின் நன்மைகள், விளைவுகள், தன்மை, குறிக்கோள் ஆகியவற்றை விரிவாக விளக்கியுள்ளேன். இந்த ஆராய்ச்சியைப் பற்றிய கேள்விகளுக்கு நான் சரியான விடை அளித்துள்ளேன். என்னை கீழ்கண்ட முகவரியிலும், தொலைபேசியிலும் தொடர்பு கொள்ளலாம்.

முகவரி

ஆராய்ச்சியில்பங்கேற்பவரின் கையொப்பம்

ஆராய்ச்சியாளரின் பெயர்

ஆராய்ச்சியாளரின் கையொப்பம்

APPENDIX-G

VOLUNTARY CONSENT BY THE PARTICIPANT (TAMIL)

ஆராய்ச்சியில் பங்கு பெறுபவரின் சம்மதம்

நான் இங்கு கொடுத்திருக்கும் தகவல்களை முழுவதுமாக படித்து புரிந்து கொண்டுள்ளேன். இந்த ஆராய்ச்சியில் பங்கெடுப்பதற்கு நானாகவே முன்வந்து சம்மதம் தெரிவிக்கிறேன். இந்த ஆராய்ச்சியைப் பற்றிய எல்லா சந்தேகங்களுக்கும், கேள்விகளுக்கும் விடை அளிக்கப்பட்டது. எதிர்காலத்தில் இந்த ஆராய்ச்சியைப் பற்றிய கேள்விகளுக்கு ஆராய்ச்சியாளர் விடையளிப்பார். இந்த விபரத்தின் இன்னொரு படிவம் எனக்கு கொடுக்கப்பட்டது. இந்த ஆராய்ச்சியில் பங்கு பெறுவதற்கான சம்மதத்தை இந்த படிவத்தில் கையெழுத்திடுவதின் மூலம் தெரிவிக்கிறேன்.

தேதி :

ஆட்சியாளர் பெயர்	பங்கேற்பாளரின் பெயர்
கையொப்பம்	கையொப்பம்
கைரேகை	கைரேகை

APPENDIX -H

LETTER FOR EXPERT'S GUIDANCE

KMCH COLLEGE OF NURSING
(Approved by the Government of Tamil Nadu & The Tamil Nadu Nurses & Midwives Council, Chennai.
Recognized by the Indian Nursing Council, New Delhi and Affiliated to the Tamil Nadu Dr. M.G.R. Medical University, Chennai)
KMCH Campus, Avinashi Road, Coimbatore – 641 014. INDIA
Ph: (0422) 4323740, 2369321 Telefax : (0422) 2627525 Website: kmchcon.ac.in E-mail: nursing@kmch.ac.in

Ref No: KMCT/6022/01/17 **30th January 2017**

To

Dr.N. Selvarajan., M.D.,(AIIMS)
Consultant
HOD of Anesthesiologist
Kovai Medical Center and Hospital,
Coimbatore – 14

Dear Sir,

Greetings to you.

I submit that one of our M.SC(N) final year students by name Ms. Sonia .S specializing in Medical Surgical Nursing in our College desires to conduct a study titled **"Effectiveness of Hypothermia prevention protocol among patients subjected to major surgeries at KMCH, Coimbatore"**, as a part of her M.Sc (N) curriculum.

As she is in need of Medical Expert to complete the study, I request you to kindly guide the student.

Thanking you,

Yours Truly,

Prof. DR. S. Madhavi, M.Sc(N)., Ph.D.,
Principal.

The Principal,
K.M.C.H. College of Nursing,
P.B. No : 3209, Avanashi Road,
Coimbatore - 641 014.

O.K. Thanks -
31/2/2017

Dr. N. SELVARAJAN, M.D.,
Head of the Dept. of Anesthesiology
Kovai Medical Center & Hospital Ltd,
Coimbatore-641 014

Administrative Office :
Kovai Medical Center Research and Educational Trust
No.940/1A&B, Kovai Estate, Kalapatti Road, Coimbatore - 641 048. INDIA
Ph : (0422) 2369321 E-mail : info@kmch.ac.in

APPENDIX –I

CERTIFICATION OF CONTENT VALIDITY

This is to certify that, I have pursued the research proposal submitted by Sonia. S that **"EFFECTIVENESS OF HYPOTHERMIA PREVENTION PROTOCOL AMONG PATIENTS SUBJECTED TO MAJOR SURGERIES AT KMCH, COIMBATORE".** I found that the methodolgy and instruments are appropriate.

Place: Coimbatore
Date: 16/11/16

Signature & Seal:

Dr. N. SELVARAJAN, M.D.,
Head of the Dept. of Anaesthesiology
Kovai Medical Center & Hospital
Coimbatore-641 014

CERTIFICATION OF CONTENT VALIDITY

This is to certify that, I have pursued the research proposal submitted by Sonia. S that **"EFFECTIVENESS OF HYPOTHERMIA PREVENTION PROTOCOL AMONG PATIENTS SUBJECTED TO MAJOR SURGERIES AT KMCH, COIMBATORE".** I found that the methodolgy and instruments are appropriate.

Place: Coimbatore
Date: 17/11/16

Signature & Seal:

Dr. Subbiah Ekambaram, M.D., FRCA.
Consultant Anaesthetist
Reg. No : 47174

CERTIFICATION OF CONTENT VALIDITY

This is to certify that, I have pursued the research proposal submitted by Sonia. S that **"EFFECTIVENESS OF HYPOTHERMIA PREVENTION PROTOCOL AMONG PATIENTS SUBJECTED TO MAJOR SURGERIES AT KMCH, COIMBATORE".** I found that the methodolgy and instruments are appropriate.

Place: Coimbatore
Date: 9/11/16

Signature & Seal:

Dr. D. Arunkumar MD., FICA.
Consultant Anaesthetist
Reg. No : 60875

CERTIFICATION OF CONTENT VALIDITY

This is to certify that, I have pursued the research proposal submitted by Sonia. S that **"EFFECTIVENESS OF HYPOTHERMIA PREVENTION PROTOCOL AMONG PATIENTS SUBJECTED TO MAJOR SURGERIES AT KMCH, COIMBATORE".** I found that the methodolgy and instruments are appropriate.

Place: Coimbatore
Date: 12/11/16

Signature & Seal:

CERTIFICATION OF CONTENT VALIDITY

This is to certify that, I have pursued the research proposal submitted by Sonia. S that **"EFFECTIVENESS OF HYPOTHERMIA PREVENTION PROTOCOL AMONG PATIENTS SUBJECTED TO MAJOR SURGERIES AT KMCH, COIMBATORE".** I found that the methodolgy and instruments are appropriate.

Place: Coimbatore
Date: 12/11/16

Signature & Seal:

CERTIFICATION OF CONTENT VALIDITY

This is to certify that, I have pursued the research proposal submitted by Sonia. S that **"EFFECTIVENESS OF HYPOTHERMIA PREVENTION PROTOCOL AMONG PATIENTS SUBJECTED TO MAJOR SURGERIES AT KMCH, COIMBATORE".** I found that the methodolgy and instruments are appropriate.

Place: Coimbatore
Date: 11/11/16

Signature & Seal:

APPENDIX-J

CONTENT VALIDITY EVALUATION FORM

S. No.	Criteria	Not necessary (0)	Useful (1)	Essential (2)
1.	Content - Consistent with objectives			
2.	Language - Simple and clear			
3.	Accuracy - Information could contribute to achieving personal, professional goals.			
4.	Clarity – Relevant and appropriate for intended patients			
5.	Feasibility - Information could be applied to practice.			
Total score				

Suggestions:-

Signature

APPENDIX-K

LIST OF EXPERTTS

1. **Prof. DR. S. Madhavi, M.Sc. (N), Ph.D.,**

Principal

Department of Medical and Surgical nursing,

KMCH College of Nursing,

Coimbatore – 641014

2. Dr. N. Selvarajan, M.D., AIIMS.,

Head of Department of Anaesthesiology

Kovai Medical Center and Hospital,

Coimbatore – 641014.

3. **Dr. Subbiah Chelliah., D.A., FRCA.,**

Consultant Anaesthetist,

Kovai Medical Center and Hospital,

Coimbatore – 641014.

4. **Dr. D. Arunkumar, M.D., FRCA.,**

Consultant Anaesthetist,

Kovai Medical Center and Hospital,

Coimbatore – 641014.

5 **Prof. DR. Akila, M.Sc. (N), Ph.D.,**

Department of Medical and Surgical nursing,

KMCH College of Nursing,

Coimbatore – 641014

6. **Prof. DR. Balasubramani, M.Sc (N), Ph.D.,**

Department of Medical and Surgical nursing,

KMCH College of Nursing,

Coimbatore – 641014

7. **Prof. DR. Viji, M.Sc (N), Ph.D.,**

Department of Medical and Surgical nursing,

KMCH College of Nursing,

Coimbatore – 641014

8. **Prof. P. Kuzahanthaivel, M.Sc (N).,**

Department of Medical and Surgical nursing,

KMCH College of Nursing,

Coimbatore – 641014