Perioperative Risk Factors for Intraoperative Hypothermia in Adult Patients Undergoing Elective Surgery at Jigme Dorji Wangchuk National Referral Hospital, Bhutan: a Prospective Observational Study

Kinley Zangmo

A Thesis Submitted in Partial Fulfillment of the Requirements for the

Degree of Master of Science in Health Sciences
Prince of Songkla University
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Author	Miss Kinley Zangmo
Major Program	Health Sciences

Major Advisor	**Examining Committee**
……	……...…….Chairperson
(Dr. Sunisa Chatmongkolchart)	Assoc. Prof. Kaweesak Chittawannarat
	.....Committee (Dr. Pasuree Sangsupawanich)
	.....Committee (Dr. Sunisa Chatmongkolchart)

The Graduate School, Prince of Songkla University, has approved this thesis as partial fulfillment of the for the Master of Science Degree in Health Sciences

.....
(Prof. Dr. Damrongsak Faroongsarng)
Dean of Graduate School

This is to certify that the work here submitted is the result of the candidate's own investigations. Due acknowledgement has been made of any assistance received.

.....Signature
(Dr. Sunisa Chatmongkolchart)
Major Advisor

.....Signature
(Miss Kinley Zangmo)
Candidate

I hereby certify that this work has not been accepted in substance for any degree, and is not being currently submitted in candidature for any degree.

……...…..……..……Signature

(Miss Kinley Zangmo)
Candidate

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ABSTRACT

BACKGROUND: Intraoperative hypothermia is commonly encountered in anesthetic practice. It is related to several risk factors and can lead to various adverse events. It is important to detect it early and prevent the complications related to it. Thus, this study was done to identify the incidence and perioperative risk factors for intraoperative hypothermia at a National Referral Hospital in Bhutan.

METHODS: A prospective observational study was conducted in adult patients who underwent elective surgery lasting more than 30 minutes at the National Referral Hospital in Bhutan from August 2017 to November 2017. Patient characteristics, incidence of hypothermia, and any interventions for treatment of hypothermia during operation were recorded. Hypothermia was defined as core body temperature less than 36°C measured with an esophageal probe.

RESULTS: Data were obtained from 91 patients with the mean (SD) age of 42.3 (17.2) years (range 18–75 years) and ASA scores of 1 and 2 in 57 and 34 of the patients, respectively. The patients underwent elective surgery with a mean (SD) duration of 73.2 (48.1) minutes and a mean (SD) duration of anesthesia of 80.9 (49.2) minutes. The incidence of intraoperative hypothermia was 61.5% (56/91). Preoperative heart rate more than 80 bpm (hazard ratio [HR] 0.45, 95% confidence interval [CI], 0.26–0.77) was a protective factor and duration of anesthesia more than 60 minutes (HR 1.82, 95% CI, 0.98–3.38) was a risk factor for intraoperative hypothermia. Hypothermic patients were managed with cotton blankets,air forced warmer and warmed IV fluids.

CONCLUSIONS: Patients undergoing elective surgery lasting more than 30 minutes with preoperative heart rate less than 80 beats per minute and undergoing duration of anesthesia more than 60 minutes should be assessed properly from the preoperative period. Furthermore, the core body temperature of these patients should be continuously monitored throughout the operation period to detect intraoperative hypothermia and to intervene early.

Keywords: Intraoperative, Hypothermia, Perioperative, Risk factors, Monitoring, Body temperature

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CHAPTER 1
INTRODUCTION

1. Background

1.1. Background information

Intraoperative hypothermia (defined as core body temperature less than 36℃) is a common problem encountered in anesthetic practice. The incidence has been reported as high as 27% to 40.[1-3] Intraoperative hypothermia is associated with complications, such as postoperative shivering, intraoperative bleeding, delayed wound healing, wound infection and delayed awakening from anesthesia.[4-11] In severe cases it can cause cardiovascular complications which are life threatening.[9] Thus, it is important to identify intra operative hypothermia early and prevent these complications.

The cause and effect of inadvertent intraoperative hypothermia has been extensively studied and many guidelines have been developed as well.[12-14] These guidelines suggest to continuously monitor the core body temperature of all patients undergoing surgery. In a survey study authors found that hypothermia is recurrent in anesthetic surgical procedures, neither being neither valued, nor treated as it should.[15] Although guidelines are developed for proper management of hypothermia, its implementation is still a problem. It is not a standard of care in many settings in the world.[15-16]

Bhutan is a high altitude country located at 2,000 to 3,000 metres above the sea level and has a cold climate. We postulated that patients undergoing surgery at this altitude and cold climate may be more vulnerable to intraoperative hypothermia. We, therefore, conducted this study to identify an incidence and the perioperative risk factors of intraoperative hypothermia in adult patients undergoing elective surgery lasting more than 30 minutes in Bhutan.

1.2. Mechanisms of intraoperative hypothermia

The core body temperature decline rapidly by 0.5 to 1℃ in the first hour of operation and after that it decreases gradually.[17-19] General anesthesia causes hypothermia from the anesthetic agents such as volatile agents which result in vasodilation and redistribution of core body temperature to the peripheral parts of the body. The anesthetic effect also inhibit the tonic thermoregulatory vasoconstriction thereby resulting in arteriovenous shunt dilation.[18] Anesthesia also reduces the metabolic rate by 20% to 30%. In regional anesthesia autonomic thermoregulation is impaired. It decreases the threshold to trigger vasoconstriction and shivering.

Heat is also lost in various ways during surgery such as through exposure of internal organs to cold environment and by evaporation, while in laparoscopic surgery due to insufflation of abdominal cavities with carbon dioxide. The infusion of cold intravenous fluids and bleeding during the surgery further contributes to the development of intraoperative hypothermia.

1.3. Perioperative risk factors

Many factors related to patient, surgical and anesthesia have been found to be associated with the development of intraoperative hypothermia.[20-26] We studied risk factors; age, sex, body weight, body mass index, preoperative body temperature, preoperative blood pressure, preoperative heart rate, type of case, type and duration of operation, type and duration of anesthesia, operating room temperature and infusion of cold intravenous fluid for intraoperative hypothermia. Many authors discussed preoperative core body temperature as the most important risk factor for intraoperative hypothermia.[21-22, 25] We also thought the cold climate in our country might influence patient's preoperative core body temperature in the preoperative period and may result in intraoperative hypothermia.

1.4. Prevention of intraoperative hypothermia

Intraoperative hypothermia is a common avoidable complication during surgery. This can be prevented by proper assessment and optimizing those patients who are at risk of developing intraoperative hypothermia by prewarming in the preoperative period.

Prewarming of the patients in the preoperative period was found effective in lowering the incidence of intraoperative hypothermia especially in the first hour of surgery.[28-31]

The body temperature of the patients who receive anesthesia should be monitored throughout the perioperative period so to detect intraoperative hypothermia early.

Warming methods such as blankets or air forced warmer, warm intravenous fluids and optimum room temperature should be maintained to maintain normothermia.

2. Literature review

2.1. Incidence

Table 1: Incidence of intraoperative hypothermia

First Author	Design	Title	Subjects	Total patients	Result
Yi J[1], 2015	Cross-sectional, multicenter study in China (24 hospitals)	Incidence of Inadvertent Intraoperative Hypothermia and Its Risk Factors in Patients Undergoing General Anesthesia in Beijing: A Prospective Regional Survey.	Patients who underwent elective surgery under GA >30 min	830	39.9% 17.1% (<2 hr) 44.8% (>2 hr)
Frisch[2], 2016	Retrospective study (2 hospitals)	Intraoperative Hypothermia During Surgical Fixation of Hip Fractures.	Patients who underwent knee or hip arthroplasty	2,397	37%
Kim[3], 2014	Prospective descriptive research	Preoperative factors affecting the intraoperative core body temperature in abdominal surgery under general anesthesia: an observational cohort.	Patients who underwent elective abdominal surgery under GA	147	34.7% in 1 hr 46.3% in 2 hrs 54.4% in 3 hrs

GA: General anesthesia, hr: hour

2.2.Complications

Table 2: Complications from intraoperative hypothermia

First Author	Design	Title	Subjects	Total patients	Result
Rajagopalan [4], 2008	Systematic review	The effects of mild perioperative hypothermia on blood loss and transfusion requirement.	Trials that reported blood loss, transfusion requirement or both as an outcome.	Blood loss (1219) Transfusion (985)	Normothermia is associated with significantly lower blood loss and reduced need for transfusion compared to hypothermia.
Eberhart[7], 2005	Observational one center trial	Independent risk factors for postoperative shivering.	Patients who underwent GA (RA not included)	1,340	Moderate to severe Shivering -11.6% 95 CI 9.7%-13.7 Associated with core temperature (per℃) P<0.0001 OR 0.63 (0.49-0.81)
Lenhardt[8], 1997	RCT	Mild Intraoperative hypothermia prolongs post anesthetic recovery.	Elective abdominal surgery	150	- Discharge from PACU ~40 min longer in hypothermia group.
Kurz[30], 1996	RCT Hypothermia (34.5℃) Normothermia (36.5℃)	Perioperative normothermia to reduce the incidence of surgical wound infection and shorten hospitalization.	Elective colorectal resection for cancer or IBD.	200	- Infection (6 vs 18) P= 0.009 - Shivering (59% vs few) - Days of hospitalization (11.8±4.1 vs 13.5±4.5) P=0.01
Winkler[31], 2000	RCT Aggressive warming to maintain normothermia	Aggressive warming reduces blood loss during hip arthroplasty.	Primary unilateral cement free total hip arthroplasty.	150	- Core temperature remained significantly higher in the aggressive warming group at 3 hr (37.1 ± 0.9 vs 36.8 ± 0.6℃ P = 0.005)

GA: General anesthesia, hr: Hour, RCT: Randomized controlled trials, ER: Exponential risk, RR: Relative risk, vs: versus, RA: Regional anesthesia, CI: Confidence interval, OR: Odds ratio, PACU: Post anesthetic care unit, min: Minute

2.3.Guidelines

Table 3**:** Guidelines for intraoperative body temperature management

10. National Collaborating Centre for Nursing and supportive care Commissioned by National Institute for Health and Clinical Excellence (NICE). Clinical practice Guideline	Each patient should be assessed for their risk of inadvertent perioperative hypothermia and potential adverse consequences before transfer to the theatre The patient's temperature should be measured and documented before induction of anaesthesia and then every 30 minutes until the end of surgery.
11. Standards and Practice Parameters. Standards for Basic Anaesthetic Monitoring.	Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.
12. American Association of Nurse Anesthetists. Standards for Nurse Anesthesia Practice.	When clinically significant changes in body temperature are intended, anticipated, or suspected, monitor body temperature in order to facilitate the maintenance of normothermia.

2.4. Perioperative risk factors

Table 4: Perioperative risk factors for intraoperative hypothermia

First Author	Design	Title	Subjects	Total patients	Risk factors	Result
Wetz[15], 2016	Analysis of prospective studies (7 studies)	Unexpectedly high incidence of hypothermia before induction of anesthesia in elective surgical patients.	Patients who underwent variety of elective surgical procedures including head and neck.	493	- BMI, Weight Adipose ratio, ASA classification, Height, Lean body weight, Age, sex	- Age (>52 years) - Sex female
Yang[16], 2015	Observational study	Risk factors for hypothermia in patients under general anesthesia: Is there a drawback of laminar airflow operating rooms? A prospective cohort study.	Patients who underwent Surgeries> 90 min, and ASA 1 to 3	1,840	- Gender - Age - operating room airflow - Type of surgery	- Age (>60 years) - Operating room laminar airflow
de Brito Poveda[17], 2009	Prospective descriptive, correlational study	Factors associated to the development of hypothermia in the intraoperative period.	Patients who underwent elective surgery at least 1 hour.	70	- blood transfusion Type and duration of anesthesia, Duration of surgery, BMI, OR temperature, Gender Age, Chronic condition	- Type of anesthesia - Duration of anesthesia - BMI - Mean OR temperature
Fernandes[19], 2012	Observational study	Comparison of peri-operative core	Female patients who	20	- Obesity - BMI (18.5-	Incidence of

First Author	Design	Title	Subjects	Total patients	Risk factors	Result
		temperature in obese and non-obese patients.	underwent elective abdominal gynecological surgery of at least 120 min.		35 kg/m^2)	hypothermia – Obese - 10% Non obese - 60%

OR: Odd ratio, BMI: Body mass index, ASA: American Society of Anesthesiologists physical classification, min: minute, GA: General anesthesia.

2.5. Prewarming

Table 5**:** Effectiveness of prewarming patients for prevention of intraoperative hypothermia

First Author	Study Design	Title	Subjects	Total patients	Result
Horn[24], 2012	RCT (Passive insulation - Active forced air warming)	The effect of short time periods of preoperative warming in the prevention of peri-operative hypothermia.	Patients who underwent elective surgery under GA 30 to 90 min.	200	- Core temperature of patients who were not prewarmed declined more than with prewarming despite active warming.
Torossian [25], 2015	Clinical Practice Guideline (Germany)	Preventing inadvertent perioperative hypothermia. Clinical Practice Guideline.	Systematic review of literatures	_	- Prewarming for 10 to 30 min (Recommendation grade A) All patients undergoing anesthesia >30 min should be actively warmed intra operatively.
Andrzejowski[26], 2008	RCT (Prewarmed	Effect of prewarming on	Adult patients	76	- Significantly smaller decrease in core

First Author	Study Design	Title	Subjects	Total patients	Result
	group for 60 min - Non prewarmed group)	post-induction core temperature and the incidence of inadvertent perioperative hypothermia in patients undergoing general anesthesia.	undergoing GA for elective spinal surgery.		temperature in the prewarmed group at 40, 60 and 80 min.

RCT: Randomized controlled trials, GA: General anesthesia, min: minute

3. Rationale

Prevention of intraoperative hypothermia is an important measure to prevent various complications associated with an intraoperative hypothermia. Thus, this study will help to identify some perioperative risk factors for intraoperative hypothermia to manage it better. This will help to provide additional care for those patients at risk of developing intraoperative hypothermia. It will also help to reduce a huge cost spend on treating hypothermia and its complication.

4. Research question

What are the perioperative risk factors for intraoperative hypothermia in adult patients undergoing elective surgery lasting more than 30 minutes at a national referral hospital in Bhutan?

5. Objectives

General objectives

To find the peri-operative risk factors for intraoperative hypothermia in adult patients undergoing elective surgery lasting more than 30 minutes duration.

Specific objectives

Primary objective

To find the peri-operative risk factors for intraoperative hypothermia in adult patients undergoing elective surgery lasting more than 30 minutes duration.

Secondary objective

To find an incidence of intraoperative hypothermia in adult patients undergoing elective surgery lasting more than 30 minutes.

6. Endpoints and assessments

Primary endpoint

- The incidence of intraoperative hypothermia in adult patients undergoing elective surgery lasting more than 30 minutes.
- The perioperative risk factors for intraoperative hypothermia in adult patients undergoing elective surgery lasting more than 30 minutes.

Safety assessments

Intraoperative hypothermia (core body temperature less than 36℃) and its associated complications such as shivering, bleeding and delayed awakening from anesthesia.

CHAPTER 2

METHODS

7. Conceptual framework

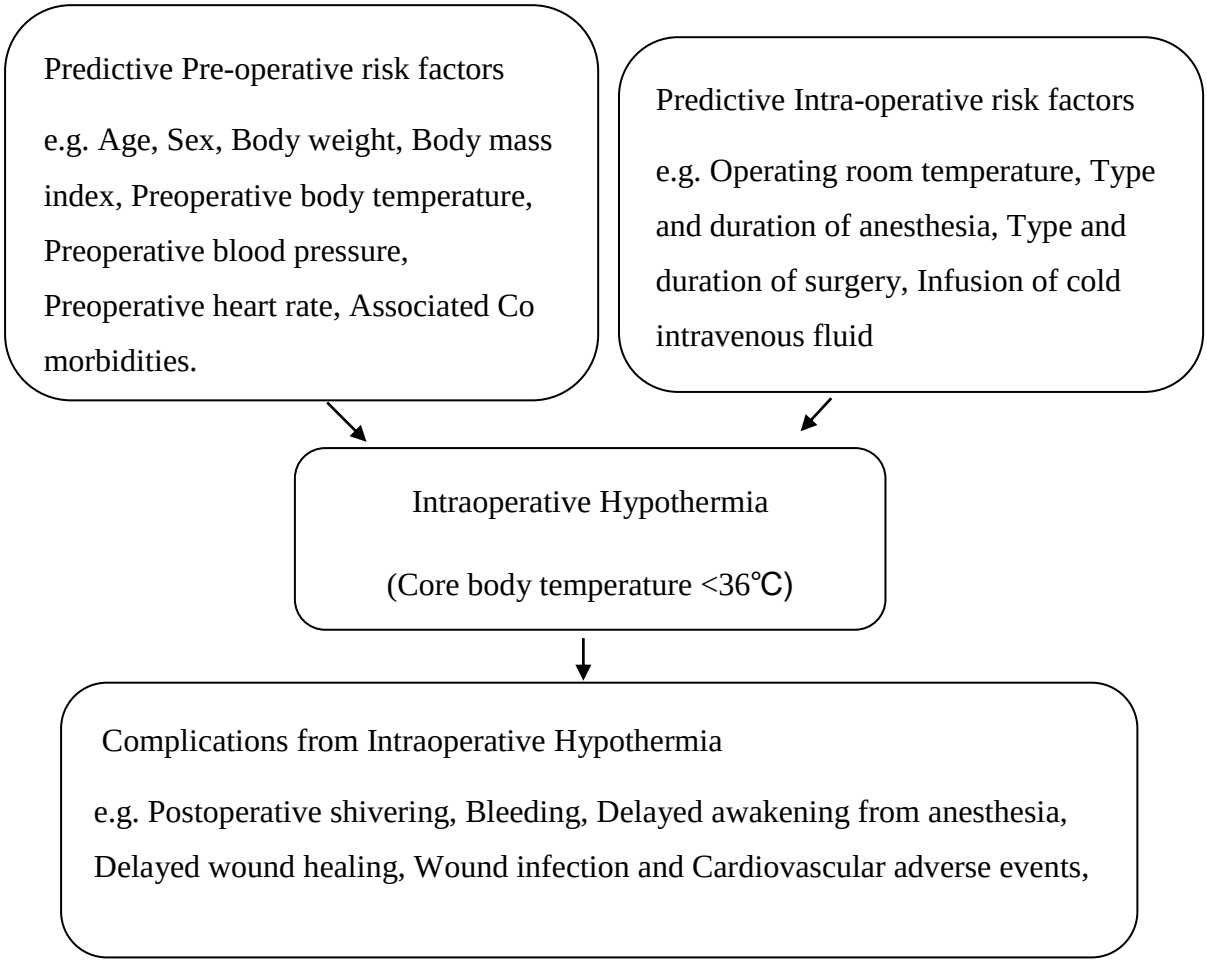

Figure 1 Conceptual framework

8. Methodology

8.1. Study design

This was a prospective observational case control study.

8.2.Study setting

The study was conducted at Jigme Dorji Wangchuk National Referral Hospital, Thimphu, Bhutan, a tertiary-care 300 bedded university hospital. The hospital has 8 operating rooms. The commonly performed surgeries are general (Urology, oncology, cholecystectomy), orthopaedics, ENT and gynaecological cases. All patients who need extensive major surgery are referred from other parts of country to this hospital.

8.3.Study period

This study was conducted between August 11, 2017 and November 4, 2017.

8.4.Study population

Adult patients between 18 to 75 years old who underwent elective surgery lasting more than 30 minutes.

8.5.Study sample

Inclusion criteria

1. Both genders
2. Age 18 to 75 years
3. ASA 1 to 3
4. Surgeries lasting more than 30 minutes

5. Undergoing any type of anesthetic procedure

Exclusion criteria

1. Emergency cases

2. Patients with medical conditions such as thyroid disease and muscular diseases

3. Patients with thermoregulation abnormalities such as malignant hyperthermia and neuroleptic malignant syndrome

4. Pre-operative temperature >37.5℃ (infections and central fever)

5. Prisoners

6. Any patient having difficulty to assess temperature measuring site

8.6.Sample size

The formula for two proportions was used for the sample size calculation with study power 80%, alpha 0.05 and $\mathscr{B}$ 0.2. 95% Confidence interval = 1.96

$$N = \frac{\left\{ Z\,\alpha/2\,\sqrt{2P\,(1-P)} + Z\beta\,\sqrt{P1\,(1-P1) + P2\,(1-P2)} \right\}^2}{(\,P1-P2\,)^2}$$

Based on the findings from the previous studies, 5 risk factors were used to calculate the sample size (Annexure 5). Although the highest sample size required for the study was 434 participants, due to the feasibility and lack of time, the sample size which used preoperative core body temperature as a risk factor (174) was used for this study.

Variables	Total number of patients
Preoperative core body temperature	174
Age	420
Duration of operation	434
Type of surgery	136
Preoperative blood pressure and heart rate	168

8.7. Study procedure(s)/stage(s)

8.7.1. Preoperative period

Patients who met the study criteria were selected from the OT list on the day prior to surgery. The principal investigator visited the selected patients in the ward on the preoperative day prior to surgery. Patients were given a participant information sheet which explained about the study and were explained verbally in detail as well. After the detailed explanation of the study, informed written consent was taken.

During the preoperative period the preoperative body core temperature was measured with tympanic temperature measuring thermometer Medcare, preoperative blood pressure and heart rate was measured with digital monitor (mindrey) and body weight and height were measured with the measuring scale. The vital signs were measured every 2 hourly in the ward and the final value was the average of 4 values.

Any patient who developed hypothermia in the preoperative period was managed with normal blankets if patient was clinically cold.

Preoperative measurement was done by the principal investigator and the respective ward nurses on duty.

8.7.2**.** Intraoperative period

General anesthesia was induced with 5mg/kg to 7mg/kg of thiopental for induction, 2 mcg/kg to 3 mcg/kg of fentanyl for analgesia and 0.4 to 0.5 mg/kg of atracurium for muscle relaxant. Regional anesthesia was done with the spinal needle and heavy

Marcaine 0.5%. All anesthetic and surgical procedures were done as per the routine schedule. The most commonly performed surgery was the general surgery (44%) followed by orthopaedic surgery (28%) and then gynaecological surgery (19%).

In the Intraoperative period patient's core body temperature, blood pressure and heart rate were recorded at the time of induction of anesthesia and start of operation. Intraoperative vital signs were monitored with Mindray, Beneview T8. Core body temperature was measured with an esophageal probe. The room temperature was measured with room thermometer (KIJ, Thermo meter, Max-Min Thermometer, Thailand).

The intraoperative recordings were done every fifteen minutes in the first hour of operation, then every thirty minutes after first hour till the end of operation and patient was sent to recovery room. Intraoperative recordings and management was mostly done by the principal investigator and in some cases were done by other anesthesia residents and anesthetic nurses who were already taught about the procedure and instruments.

During the intraoperative period patients whose body temperature dropped below 36 degree Celsius were first covered with cotton blankets, if there was no improvement we used the air forced warmer to warm the patients as the air forced warmer blanket was already put on the patient at the start of operation. Furthermore, the operating room temperature was increased to keep the patients warm. If there was no improvement with the above mentioned manoeuvres, warmed intravenous fluids and plastic cover was used to cover patient's head area wherever appropriate.

8.8. Study instrument(s) and outcome measurement(s)

1. Ward

Core body temperature: ear thermometer (Med care) (Medicare infrared ear and forehead thermometer Model HW-1, China)

Blood pressure: digital monitor (Mindray, vital signs monitor, VS-800, 2013-11, China)

Heart rate: digital monitor (Mindray, vital signs monitor, VS-800, 2013-11, China)

Body weight: weighing scale machine

Height: height measuring scale

Body mass index: using the formula weight/ (height) 2 kg/cm2

2. Operation Theatre

Core body temperature:

Esophageal temperature: Esophageal probe, Mindray monitor MR402B, China

Tympanic membrane temperature: ear thermometer (Med care) (Medicare infrared ear and forehead thermometer Model HW-1, China)

Intraoperative Blood pressure and Heart rate: Mindray monitor MR402B, China

Air forced warmer: Gaymar Thermacare, Covidien Warmtouch

Record form

Recording form was divided into 2 parts: the first part was for the general information of patient. The second form was to record the variables and vital signs of the patient. It also included the details of surgery and anesthesia

8.9. Variables of the study

8.9.1. Dependent variable

Dependent variable- Outcome

Intraoperative hypothermia: defined as intraoperative core body temperature less than 36℃ measured with an esophageal probe.

8.9.2. Independent variables

Independent variables-Risk factors

a) Continuous variable - Preoperative core body Temperature, Intraoperative room temperature, Weight, Height, Body mass index

b) Discrete variable - Age, Preoperative blood pressure, Preoperative heart rate, Duration of surgery, Duration of anesthesia

c) Nominal - Type of case (Outpatient or Inpatient), Type of surgery, Type of anesthesia

d) Dichotomous variables- Gender, Infusion of unwarmed intravenous fluids

Independent variables

1. Age was recorded in years, and was divided into $\leq$60 years and >60
2. Gender was defined as male or female.
3. Body weight was divided into $\leq$50 kg and >50 kg
4. Body mass index was divided into 25-50 kg/m^2 and >50 kg/m^2
5. Preoperative core body temperature $\leq$36℃ and >36℃
6. Preoperative systolic blood pressure $\leq$140 mm Hg and >140 mm Hg
7. Preoperative heart rate $\leq$80 beats/minute and >80 beats/minute
8. Case was defined as outpatient or in patient

9. Type of surgery was defined as general surgery, orthopaedic, gynaecological, ENT and others

10. Duration of surgery was divided into ≤60 minutes and >60 minutes

11. Type of anesthesia was divided into general anesthesia, regional anesthesia or combined general and regional anesthesia.

12. Duration of anesthesia was defined as time from induction to the time of extubation and was divided into ≤60 minutes and >60 minutes

13. Intra operative room temperature was divided into ≤23℃ and >23℃

14. Infusion of un warmed intravenous fluid was defined as either yes or no

8.10. Definitions and measurement

1) Intraoperative hypothermia

   Intraoperative core body temperature less than 36℃ at any point of intraoperative period measured with an esophageal probe connected to a monitor.

   Esophageal probe length was measured from the submental to subcostal region and inserted into the esophagus. The placement was further confirmed with checking the probe inside the oral cavity. Esophageal probe was inserted after the induction of anesthesia.

2) High preoperative blood pressure: Systolic blood pressure ≥140mmHg, diastolic blood pressure ≥90mmHg.
   Blood pressure was measured by placing the blood pressure cuff on either of upper arm and measured with digital monitor.

3) High preoperative heart rate: >80 beats/minute
   Heart rate was measured with the digital monitor

4) High body mass index: >25kg/m2
   Body mass index was calculated using the formula;
   Body weight (kg) / (Height) ^{2} (m)

5) Low preoperative core body temperature: Preoperative core body temperature less than 36 degree Celsius measured with tympanic membrane thermometer. The average of 4 preoperative readings in inward patient and at least 2 readings in outpatient was taken as the final value of preoperative core body temperature.

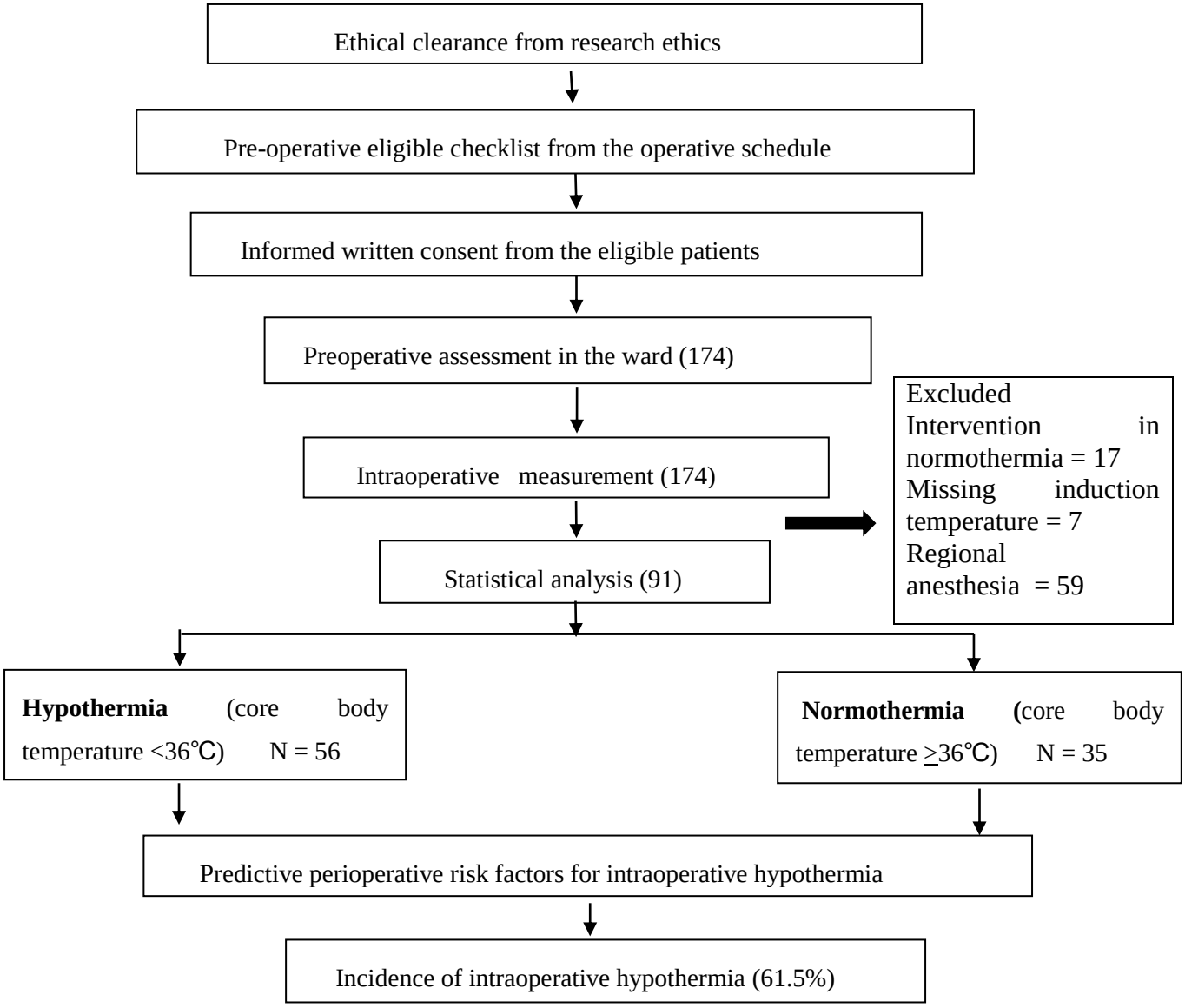

Figure 2 Flow diagram of the study

8.11**.** Data processing and analysis

8.11.1 Data entry

All data were entered in EpiData 3.1 by double entry, validated and checked for accuracy.

8.11.2. Data analysis

Data were analysed with the R program (version 3.1.2, R Development Core Team [2008]. R: A language and environment for statistical computing. R Foundation for Statistical Computing,Vienna, Austria. ISBN 3-900051-07-0, URL http: //www.R-project.org.)

9. Data safety monitoring

Safety assessments consisted of monitoring and recording the vital signs which included the routine standard ASA monitoring such as core body temperature, blood pressure, heart rate, pulse oxymetry, operating room temperature and other anesthetic monitoring.

Patients who developed intraoperative hypothermia were managed with warming blankets, warmed intravenous fluid and increasing the room temperature. The data safety monitoring was mostly done by the principal investigator (Dr. Kinley Zangmo) under the supervision of the advisor (Dr. Sunisa Chatmongkolchart).

10. Statistical methods

Survival analysis was done to find the time to hypothermia for the patients who developed hypothermia and for the patients who did not develop intraoperative hypothermia we included the time till the end of operation.

Descriptive data were summarized as percentages and proportion. Continuous data were summarized as mean and standard deviation, or median and interquartile range as appropriate. Univariate analysis was done using Logrank test. Final model was predicted with multivariate cox proportional hazards regression model. Multi Co linearity was checked using variance inflation factor (VIF).

11. Ethical consideration

We conducted the study after being reviewed and approved by The Human Research Ethics Committee, Faculty of Medicine, Prince of Songkla University, Thailand (60-181-19-6) dated 10th August 2017 and Research Ethics Board of Health, Ministry of Health, Bhutan (Number: 2017/048). It was also registered in Thai Clinical Trials Registry (number TCTR20170819002 dated 2017-08-18.) before the enrolment of the patients. All the participants provided written informed consent prior to the conduct of study.

CHAPTER 3

RESULTS

12. Results of the study

Final analysis was done for 91 adult patients who had their core body temperature measured with an oesophageal probe.

The mean (SD) age was 42.3 (17.2) years (range 18–75 years) and ASA scores of 1 and 2 in 57 and 34 of the patients, respectively. The patients underwent elective surgery with a mean (SD) duration of 73.2 (48.1) minutes and a mean (SD) duration of anesthesia of 80.9 (49.2) minutes. The incidence of intraoperative hypothermia was 61.5% (56/91). The median time to intraoperative hypothermia was 45 minutes. The characteristics of the patients are presented in Table 1.

12.1. Characteristics of patients

Comparison of background characteristics and clinical variables of the two groups are shown in Table 6.

Table 6: Baseline characteristics of the patients**.** IQR, interquartile range; SD, standard deviation; y, year; ASA, American Society of Anesthesiologists; SBP, systolic blood pressure; HR, heart rate; min, minute

Characteristics	**Normothermia =35**	**Hypothermia =56**
Age (y), median (IQR)	38.0 (27.5, 57.0)	39.5 (25.0, 58.2)
Sex		
Male	13 (37.1)	23 (41.1)
Female	22 (62.9)	33 (58.9)
Body mass index (kg/m^2),mean (SD)	24.4 (4.7)	23.0 (4.1)
ASA classification		
1	21 (60.0)	36 (64.3)
2	14 (40.0)	20 (35.7)
Preoperative temperature (°C),mean (SD)	36.5 (0.4)	36.4 (0.3)
Preoperative SBP (mm Hg), mean (SD)	117.6 (10.6)	121.6 (11.1)
Preoperative HR (beat/min), mean (SD)	84.4 (6.9)	79.8 (9.6)
Case		
Outpatient	1 (2.9)	0 (0.0)
Inpatient	34 (97.1)	56 (100.0)
Type of anesthesia		
General anesthesia	32 (91.4)	54 (96.4)
Combined	3 (8.6)	2 (3.6)
Type of surgery		
General surgery	6 (17.1)	27 (48.2)
Gynaecology	7 (20.0)	4 (7.1)
Orthopaedics	10 (28.6)	12 (21.4)
ENT	4 (11.4)	6 (10.7)
Others	8 (22.9)	7 (12.5)
Intraoperative room temperature (°C), mean (SD)	22.9 (1.5)	23.1 (1.4)
Duration of operation (min), median (IQR)	50 (35.0, 67.5)	65 (53.8, 101.2)
Duration of anesthesia (min), median (IQR)	55 (40.0, 77.5)	70 (63.8, 110.0)
Infusion of unwarmed IV fluid	35 (100.0)	54 (96.4)

12.2. Perioperative risk factors for intraoperative hypothermia

Table 7: Univariate analysis of the Perioperative Risk Factors**,** HR, hazard ratio; CI, confidence interval; SBP, systolic blood pressure; IV, intravenous.

Variables	**crude HR (95% CI)**	**P value**
Age (years); >60	1.08 (0.57, 2.05)	0.814
Sex; Female	0.85 (0.50, 1.46)	0.566
Body mass index (kg/m^2); >25	0.67 (0.36, 1.23)	0.199
Preoperative body temperature (℃); >36	1.31 (0.47, 3.65)	0.597
Preoperative SBP (mmHg); >140	1.71 (0.61, 4.73)	0.305
Preoperative Heart rate (beat/min); >80	0.48 (0.28, 0.81)	0.006
Type of surgery (Reference; General surgery)		
Gynaecology	0.26 (0.09, 0.76)	0.013
Orthopaedic	0.58 (0.29, 1.15)	0.119
ENT	0.76 (0.31, 1.87)	0.558
Others	0.45 (0.19, 1.05)	0.066
Duration of operation (min); > 60	1.06 (0.62, 1.82)	0.827
Type of anesthesia;(Reference; General Anesthesia(GA)		
Combined GA and RA	0.44 (0.11, 1.81)	0.250
Duration of anesthesia (min); > 60	1.69 (0.92, 3.13)	0.093
Intraoperative room temperature (°C); >23	1.12 (0.92, 1.35)	0.277
Unwarmed IV fluid	1.77 (0.43, 7.29)	0.429

12.3**.** Final analysis

Preoperative heart rate more than 80 beats per minute (hazard ratio [HR] 0.45, 95% confidence interval [CI], 0.26–0.77) was a protective factor and duration of anesthesia more than 60 minutes (HR 1.82, 95% CI, 0.98–3.38) was a risk factor for intraoperative hypothermia (Table 8).

Table 8: Multivariate cox proportional hazards regression model. HR, hazard ratio; CI, confidence interval

Risk factors	**HR (95%CI)**	**P value**
Preoperative heart rate ; > 80 beats/minute	0.45 (0.26, 0.77)	0.003
Duration of anesthesia ; > 60 minutes	1.82 (0.98, 3.38)	0.05

The median time to intraoperative hypothermia was 60 minutes in patients with preoperative heart rate more than 80 minutes compared to median time of 30 minutes in patients with preoperative heart rate less or equal to 80 beats per minute (figure 3).

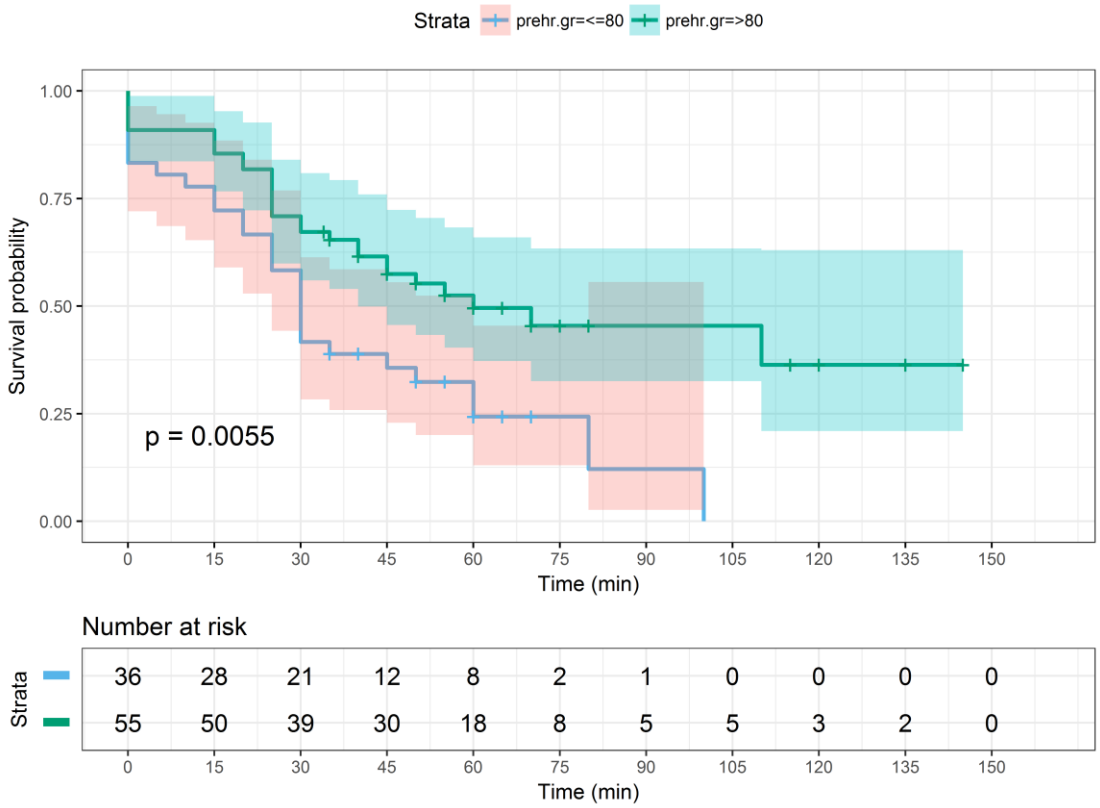

Figure 3. Preoperative heart rate and time to intraoperative hypothermia.

Duration of anesthesia more than 60 minutes was a risk factor for intraoperative hypothermia with a median time of 35 minutes to develop intraoperative hypothermia compared to the patients with duration of anesthesia less than 60 minutes (figure 4).

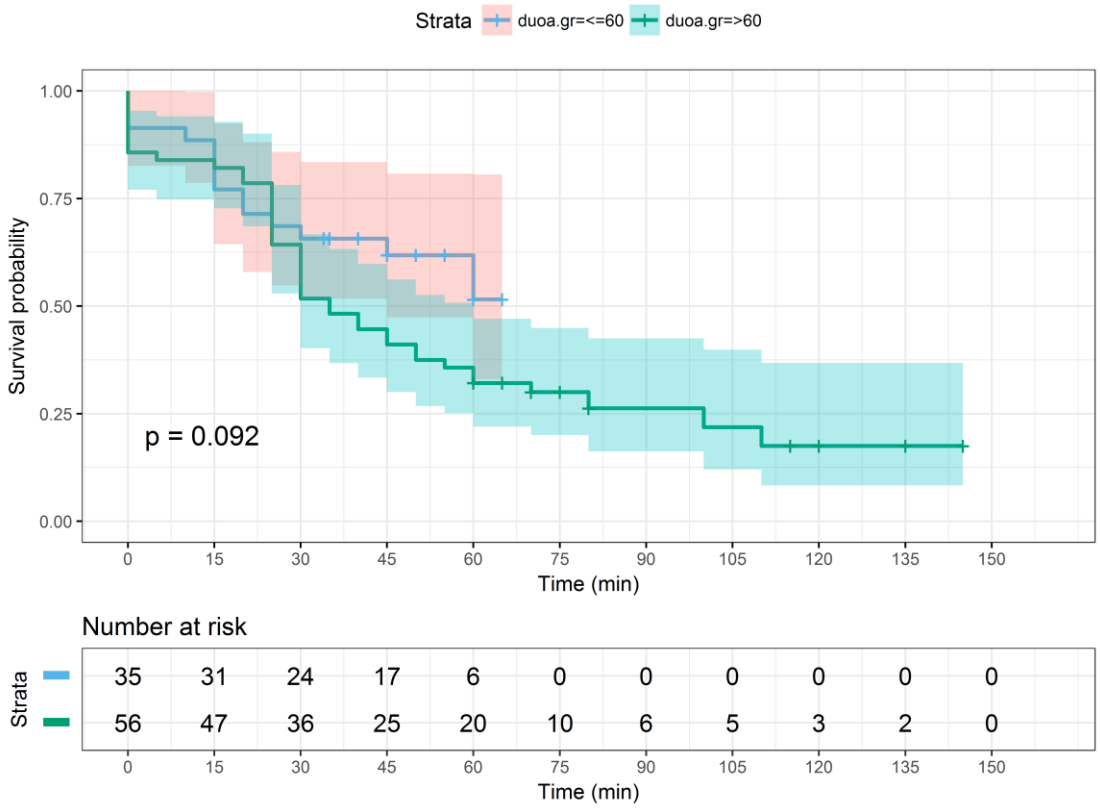

Figure 4. Duration of anesthesia and time to intraoperative hypothermia

CHAPTER 4

DISCUSSION

13. Discussion of study design

This was a non-randomised observational case control study done to find the perioperative risk factors for intraoperative hypothermia.

14. Discussion of results

The incidence of intraoperative hypothermia in adult patients undergoing elective surgery lasting more than 30 minutes under general anesthesia was 61.5%. Preoperative heart rate more than 80 beats per minute (hazards ratio [HR] 0.45, 95% confidence interval [CI], 0.26–0.77 was a protective factors for intraoperative hypothermia. Duration of anesthesia more than 60 minutes (HR 1.82, 95% CI, 0.98–3.38) was statistically significant risk factor for intraoperative hypothermia.

14.1.Incidence of intraoperative hypothermia

The incidence of intraoperative hypothermia in our patients was 61.5% which is quite high compared to other studies.[1-3] Due to the cold climate and high altitude of our country we predicted high incidence of intraoperative hypothermia. Furthermore since we analysed only those patients who underwent general anesthesia, the effect of general anesthesia on the thermoregulation response could have led to the high incidence of intraoperative hypothermia.

14.2.Perioperative risk factors for intraoperative hypothermia

14.2.1. Duration of anesthesia

We found that duration of anesthesia more than 60 minutes was a risk factor for intraoperative hypothermia.

Similar findings were explained by other authors[1,3,22] who also showed longer duration of anesthesia as a risk factor for intraoperative hypothermia. The rapid decline in the core body temperature in the first hour of surgery was due to the vasodilation and redistribution effects of an anesthetic agent used.[28-29] During anesthesia, it was demonstrated heat production decreased and cutaneous heat loss increased by 7% [29-31]. Prolong anesthesia also increase the exposure time to the cold environment of operating room. It is also associated with bleeding and increase use of un warmed intravenous fluids and blood component, all of which contributes to the development of intraoperative hypothermia.

14.2.2**.** Preoperative heart rate

Patients were less likely to develop intraoperative hypothermia if the preoperative heart rate was more than 80 beats per minute.

A study by Kim and others revealed that the low preoperative heart rate was a risk factor for intraoperative hypothermia.[3] Kasai and colleagues explained that the sympathetic nervous system plays a role in preventing hypothermia.[23] An increased level of catecholamine causes the shunting of heat from the internal organs to the skin. They showed the association of higher preoperative blood pressure and heart rate with a lower incidence of intraoperative hypothermia. However, our study and the study by Kim and others [3] found an association of higher preoperative heart rate with lower incidence of intraoperative

hypothermia but could not find an association with higher preoperative blood pressure.

14.2.3. Other factors

Knowing the fact that intraoperative core body temperature drops rapidly in the first hour of surgery, preoperative core body temperature is one of the important predictive factor for intraoperative hypothermia. Kim and all demonstrated that patients with a lower preoperative core body temperature contributed to a high incidence of intraoperative hypothermia.[3] This factor had stronger influence over intraoperative core body temperature at 1 hour and 2 hours of operation time. Other reports also explained the thermoregulatory changes in the first hour of surgery and the effect of preoperative core body temperature on intraoperative core body temperature.[25-26] Due to the geographical setting and the cold climate in Bhutan we thought that preoperative core body temperature might be one of the important predictive factor for intraoperative hypothermia in our patients as well.

Although lower preoperative core body temperature, old age, female sex, and low body mass index have been demonstrated as risk factors for intraoperative hypothermia,[3,20-27] the present study did not find an association with these factors. The type of surgery also did not show any association with intraoperative hypothermia in our study. Maintenance of warm operating rooms has also been shown to reduce the incidence of intraoperative hypothermia.[28] The different findings in our study might be due to the study population. All of the patients in our study were American Society of Anesthesiologists physical classification 1 or 2 who were mostly young healthy patients (79.1%) below 60 years. Furthermore, the dress code of the patients during the preoperative

period possibly influenced the study results because Bhutanese people usually wear warm clothes.

15. Strengths of the study

The strength of this study is that we studied multiple predictive factors for intraoperative hypothermia and patients were continuously monitored throughout the study period.

This is the first study conducted on intraoperative hypothermia in our hospital in Bhutan and this will give a baseline data for future studies related to intraoperative hypothermia in our setting.

16. Limitations of the study

This study has some limitations;

Sample size was possibly not large enough to generate significant associations with all the risk factors studied. The sample size that was required to find associations between some factors and intraoperative hypothermia was high.

Although we measured intraoperative core body temperature in all 174 patients undergoing both general anesthesia and regional anesthesia, we analysed only the patients who underwent general anesthesia and developed hypothermia from an esophageal probe. Thus it might have caused some bias to the results of the study.

17. Conclusion

Core body temperature measurement in the intraoperative period is important, as any other vital sign. All patients should be monitored for intraoperative hypothermia regardless of duration of operation. Patients with a preoperative heart rate less than 80 beats per minute and undergoing duration of anesthesia more than 60 minutes should be assessed from the preoperative period and these patients should be continuously monitored throughout the intraoperative period to detect intraoperative hypothermia and for early intervention.

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Annex 1: Record form 1

Study Title: **Perioperative Risk factors for intraoperative hypothermia in Bhutanese patients undergoing elective surgery.**

ID No:……. Date: _____
(dd / mm /yyyy)

Name:……

Age/Sex:…….....Weight/Height……

Contact address…….
Email:……

Contact No: Tel:.....Cell:.....

Occupation:…….. Education level:…….

Diagnosis –

Operation –

Past medical problems-

Past surgery-

Anaesthetic history-

History of Food/drug Allergy-

ID……...

Annex 2: Record form 2

Pre-operative Factors

1. Age [ ] [ ] Years	1. age [ ] [ ]
2. Sex ☐ 1. male ☐ 2. female	2. sex [ ]
3. weight [ ] [ ] [ ] (kgs)	3. bw [ ] [ ] [ ]
4. Height [ ] [ ] [ ] (cms)	4. ht [ ] [ ]
5. BMI [ ] [ ].[ ] (Kg/m2)	5. bmi [ ] [ ].[ ]
6. ASA classification ☐ 1 ☐ 2 ☐ 3	6. asa [ ]
Underlying condition	
☐ 1. None	7. udnil [ ]
☐ 2. DM	8. dm [ ]
☐ 3. Hypertension	9. hyper [ ]
☐ 4. Psychiatric illness	10. psychiat [ ]
☐ 5. Others ……	11. udot [ ]
	12.udcoth .....
Hypothermia ☐ 1. Yes ☐ 2. No	13. hypother [ ]
7. Preoperative Vitals (In WARD)	
Time 1st [ ] [ ].[ ] [ ] hrs	14. timepre1 [ ] [ ].[ ] [ ]
1st Preop temperature [ ] [ ].[ ] °C	15. pret1 [ ] [ ].[ ] °C
Preop SBP1 [ ] [ ] [ ]	16. presbp1 [ ] [ ] [ ]
Preop DBP1 [ ] [ ] [ ]	17. predbp1 [ ] [ ] [ ]
Preop HR1 [ ] [ ] [ ]	18. prehr1 [ ] [ ] [ ]

Time 2nd [ ] [ ].[ ] [ ] hrs	19. timepre2 [ ] [ ].[ ] [ ]
2nd Preop temperature [ ] [ ].[ ] °C	20. pret2 [ ] [ ].[ ] °C
Preop SBP2 [ ] [ ] [ ]	21. presbp2 [ ] [ ] [ ]
Preop DBP2 [ ] [ ] [ ]	22. predbp2 [ ] [ ] [ ]
Preop HR2 [ ] [ ] [ ]	23. prehr2 [ ] [ ] [ ]
Time 3rd [ ] [ ].[ ] [ ] hrs	24. timepre3 [ ] [ ].[ ] [ ]
3rd Preop temperature [ ] [ ].[ ] °C	25. pret3 [ ] [ ].[ ] °C
Preop SBP3 [ ] [ ] [ ]	26. presbp3 [ ] [ ] [ ]
Preop DBP3 [ ] [ ] [ ]	27. predbp3 [ ] [ ] [ ]
Preop HR3 [ ] [ ] [ ]	28. prehr3 [ ] [ ] [ ]
Time 4th [ ] [ ].[ ] [ ] hrs	29. timepre4 [ ] [ ].[ ] [ ]
4th Preop temperature [ ] [ ].[ ] °C	30. pret4 [ ] [ ].[ ] °C
Preop SBP4 [ ] [ ] [ ]	31. presbp4 [ ] [ ] [ ]
Preop DBP4 [ ] [ ] [ ]	32. predbp4 [ ] [ ] [ ]
Preop HR4 [ ] [ ] [ ]	33. prehr4 [ ] [ ] [ ]
Final preop temperature [ ] [ ].[ ] °C	34. finalpre [ ] [ ].[ ] °C
Final preop sbp [ ] [ ] [ ]	35. finalsbp [ ] [ ] [ ]
Final preop dbp [ ] [ ] [ ]	36. finaldbp [ ] [ ] [ ]
Final preop hr [ ] [ ] [ ]	37. finalhr [ ] [ ] [ ]
8. Type of Case ☐ 1. OPD ☐ 2. In-patient	38. case [ ]

Intra-operative Factors

1. Type of Anesthesia

☐ 1. GA ☐ 2. RA ☐ 3. GA+RA — 39. anes [ ]

2. Anesthetic medications induction agent

- ☐ 1. Propofol — 40. propof [ ]
- ☐ 2. Thiopental — 41. thiopen [ ]
- ☐ 3. Gases — 42. gases [ ]
- ☐ 4. Others …… — 43. inducot [ ]
  44. inducoth ……

3. Muscle relaxant

- ☐ 1. Succinylcholine — 45. succin [ ]
- ☐ 2. Atracurium — 46. atra [ ]
- ☐ 3. Vecurionium — 47. vecur [ ]
- ☐ 4. Others …… — 48. musot [ ]
  49.musoth ……

4. Use of Vasopressor — 50. vaso [ ]
  51.vasooth ……

- ☐ 1. None
- ☐ 2.Ephedrine
- ☐ 3. Nosadrenaline
- ☐ 4. Others ……..

5. Type of surgery

- ☐ 1. General surgery (Abdomen) — 52. gensurg [ ]
- ☐ 2. Gynaecological — 53. gynaeco [ ]
- ☐ 3. Orthopaedic — 54. ortho [ ]

☐ 4. Extremities	55. extremit [ ]
☐ 5. Eye	56. eye [ ]
☐ 6. ENT	57. ent [ ]
☐ 7. Laparoscopic	58. laparo [ ]
☐ 8. Others ……	59. sxot [ ]
	60.sxoth ……
6. Blood Pressure	
Time [ ] [ ].[ ] [ ] hrs	61. timeindu [ ] [ ].[ ] [ ]
At the start of induction (mmHg)	
SBP [ ] [ ] [ ]	62. indusbp [ ] [ ] [ ]
DBP [ ] [ ] [ ]	63. indudbp [ ] [ ] [ ]
7. Heart rate	
At the start of induction [ ] [ ] [ ]	64. induchr [ ] [ ] [ ]
8. Intraoperative temperature (°C)	
Time [ ] [ ].[ ] [ ] hrs	65.timeintra [ ] [ ].[ ] [ ]
At the start of operation [ ] [ ].[ ] °C	66. induct [ ] [ ].[ ] °C
9. **<u>1st hour (every 15 minutes)</u>**	
Time1 [ ] [ ].[ ] [ ] hrs	67. time1 [ ] [ ].[ ] [ ]
Intraop temp1 (Oesophageal) [ ] [ ].[ ] °C	68. intrato1 [ ] [ ].[ ]
Intraop temp1 (Tympanic) [ ] [ ].[ ] °C	69. intrat1 [ ] [ ].[ ]
SBP1 [ ] [ ] [ ]	70. intsbp1 [ ] [ ] [ ]
DBP1 [ ] [ ] [ ]	71. intdbp1 [ ] [ ] [ ]
Inraop HR1 [ ] [ ] [ ]	72. inthr1 [ ] [ ] [ ]

Inraop room temp1 [ ] [ ].[ ] °C	73. intrt1 [ ] [ ].[ ]
Time2 [ ] [ ].[ ] [ ] hrs	74. time2 [ ] [ ].[ ] [ ]
Intraop temp2 (Oesophageal) [ ] [ ].[ ] °C	75.intrato2 [ ] [ ].[ ]
Intraop temp2 (Tympanic) [ ] [ ].[ ] °C	76. intrat2 [ ] [ ].[ ]
SBP2 [ ] [ ] [ ]	77. intsbp2 [ ] [ ] [ ]
DBP2 [ ] [ ] [ ]	78. intdbp2 [ ] [ ] [ ]
Inraop HR2 [ ] [ ] [ ]	79. inthr2 [ ] [ ] [ ]
Inraop room temp2 [ ] [ ].[ ] °C	80. intrt2 [ ] [ ].[ ]
Time3 [ ] [ ].[ ] [ ] hrs	81. time3 [ ] [ ].[] [ ]
Intraop temp3 (Oesophageal) [ ] [ ].[ ] °C	82.intrato3 [ ] [ ].[ ]
Intraop temp3 (Tympanic) [ ] [ ].[ ] °C	83. intrat3 [ ] [ ].[ ]
SBP3 [ ] [ ] [ ]	84. intsbp3 [ ] [ ] [ ]
DBP3 [ ] [ ] [ ]	85. intdbp3 [ ] [ ] [ ]
Inraop HR3 [ ] [ ] [ ]	86. inthr3 [ ] [ ] [ ]
Inraop room temp3 [ ] [ ].[ ] °C	87. intrt3 [ ] [ ].[ ]
Time4 [ ] [ ].[ ] [ ] hrs	88.time4 [ ] [ ] [ ]
Intraop temp4 (Oesophageal) [ ] [ ].[ ] °C	89.intrato4 [ ] [ ].[ ]
Intraop temp7 (Tympanic) [ ] [ ].[ ] °C	90. intrat4 [ ] [ ].[ ]
SBP4 [ ] [ ] [ ]	91. intsbp4 [ ] [ ] [ ]
DBP4 [ ] [ ] [ ]	92. intdbp4 [ ] [ ] [ ]
Inraop HR4 [ ] [ ] [ ]	93. inthr4 [ ] [ ] [ ]
Inraop room temp4 [ ] [ ].[ ] °C	94. intrt4 [ ] [ ].[ ]

10. **>1 hour (Every 30 minutes)**

Time5 [ ] [ ].[ ] [ ] hrs	95.time5 [ ] [ ].[ ] [ ]
Intraop temp5 (Oesophageal) [ ] [ ].[ ] °C	96.intrato5 [ ] [ ].[ ]
Intraop temp5 (Tympanic) [ ] [ ].[ ] °C	97. intrat5 [ ] [ ].[ ]
SBP5 [ ] [ ] [ ]	98. intsbp5 [ ] [ ] [ ]
DBP5 [ ] [ ] [ ]	99. intdbp5 [ ] [ ] [ ]
Inraop HR5 [ ] [ ] [ ]	100. inthr5 [ ] [ ] [ ]
Inraop room temp5 [ ] [ ].[ ] °C	101. intrt5 [ ] [ ].[ ]
Time6 [ ] [ ].[ ] [ ] hrs	102. time6 [ ] [ ].[ ] [ ]
Intraop temp6 (Oesophageal) [ ] [ ].[ ] °C	103. intrato6 [ ] [ ].[ ]
Intraop temp6 (Tympanic) [ ] [ ].[ ] °C	104. intrat6 [ ] [ ].[ ]
SBP6 [ ] [ ] [ ]	105. intsbp6 [ ] [ ] [ ]
DBP6 [ ] [ ] [ ]	106. intdbp6 [ ] [ ] [ ]
Inraop HR6 [ ] [ ] [ ]	107. inthr6 [ ] [ ] [ ]
Inraop room temp6 [ ] [ ].[ ] °C	108. Intrt [ ] [ ].[ ]
Time7 [ ] [ ].[ ] [ ] hrs	109. time7 [ ] [ ].[ ] [ ]
Intraop temp7 (Oesophageal) [ ] [ ].[ ] °C	110. intrato7 [ ] [ ].[ ]
Intraop temp7 (Tympanic) [ ] [ ].[ ] °C	111. intrat7 [ ] [ ].[ ]
SBP7 [ ] [ ] [ ]	112. intsbp7 [ ] [ ] [ ]
DBP7 [ ] [ ] [ ]	113. intdbp7 [ ] [ ] [ ]
Inraop HR7 [ ] [ ] [ ]	114. inthr7 [ ] [ ] [ ]
Inraop room temp7 [ ] [ ].[ ] °C	115. intrt7 [ ] [ ].[ ]
Time8 [ ] [ ].[ ] [ ] hrs	116. time8 [ ] [ ].[ ] [ ]
Intraop temp8 (Oesophageal) [ ] [ ].[ ] °C	117.intrato8 [ ] [ ].[ ]

Intraop temp8 (Tympanic) [ ] [ ].[ ] °C	118. intrat8 [ ] [ ].[ ]
SBP8 [ ] [ ] [ ]	119. intsbp8 [ ] [ ] [ ]
DBP8 [ ] [ ] [ ]	120.intdbp8 [ ] [ ] [ ]
Inraop HR8 [ ] [ ] [ ]	121. inthr8 [ ] [ ] [ ]
Inraop room temp8 [ ] [ ].[ ] °C	122. intrt8 [ ] [ ].[ ]
Time9 [ ] [ ].[ ] [ ] hrs	123. time9 [ ] [ ].] [ ]
Intraop temp9 (Oesophageal) [ ] [ ].[ ] °C	124.intrato9 [ ] [ ].[ ]
Intraop temp9 (Tympanic) [ ] [ ].[ ] °C	125. intrat9 [ ] [ ].[ ]
SBP9 [ ] [ ] [ ]	126. intsbp9 [ ] [ ] [ ]
DBP9 [ ] [ ] [ ]	127. intdbp9 [ ] [ ] [ ]
Inraop HR9 [ ] [ ] [ ]	128. inthr9 [ ] [ ] [ ]
Inraop room temp9 [ ] [ ].[ ] °C	129. intrt9 [ ] [ ].[ ]
Time10 [ ] [ ].[ ] [ ] hrs	130. time10 [ ] [ ].[ ] [ ]
Intraop temp10 (Oesophageal) [ ] [ ].[ ] °C	131.intrato10 [ ] [ ].[ ]
Intraop temp10 (Tympanic) [ ] [ ].[ ] °C	132. intrat10 [ ] [ ].[ ]
SBP10 [ ] [ ] [ ]	133. intsbp10 [ ] [ ] [ ]
DBP10 [ ] [ ] [ ]	134.intdbp10 [ ] [ ] [ ]
Inraop HR10 [ ] [ ] [ ]	135. inthr10 [ ] [ ] [ ]
Inraop room temp10 [ ] [ ].[ ] °C	136. intrt10 [ ] [ ].[ ]

Time11 [ ] [ ].[ ] [ ] hrs	137.time11 [ ] [ ].[ ] [ ]
Intraop temp11 (Oesophageal) [ ] [ ].[ ] °C	138. intrato11 [ ] [ ].[ ]
Intraop temp11 (Tympanic) [ ] [ ].[ ] °C	139. intrat11 [ ] [ ].[ ]
SBP11 [ ] [ ] [ ]	140. intsbp11 [ ] [ ] [ ]
DBP11 [ ] [ ] [ ]	141. intdbp1 [ ] [ ] [ ]
Inraop HR11 [ ] [ ] [ ]	142. inthr11 [ ] [ ] [ ]
Inraop room temp11 [ ] [ ].[ ] °C	143. intrt11 [ ] [ ].[ ]
Time12 [ ] [ ].[ ] [ ] hrs	144.time12 [ ] [ ].[ ] [ ]
Intraop temp12 (Oesophageal) [ ] [ ].[ ] °C	145. intrato12 [ ] [ ].[ ]
Intraop temp12 (Tympanic) [ ] [ ].[ ] °C	146. intrat12 [ ] [ ].[ ]
SBP12 [ ] [ ] [ ]	147. intsbp12 [ ] [ ] [ ]
DBP12 [ ] [ ] [ ]	148. intdbp12 [ ] [ ] [ ]
Inraop HR12 [ ] [ ] [ ]	149. inthr12 [ ] [ ] [ ]
Inraop room temp12 [ ] [ ].[ ] °C	150. intrt12 [ ] [ ].[ ]
Time13 [ ] [ ].[ ] [ ] hrs	151. time13 [ ] [ ].[ ] [ ]
Intraop temp13 (Oesophageal) [ ] [ ].[ ] °C	152. intrato13 [ ] [ ].[ ]
Intraop temp13 (Tympanic) [ ] [ ].[ ] °C	153. intrat13 [ ] [ ].[ ]
SBP13 [ ] [ ] [ ]	154. intsbp13 [ ] [ ] [ ]
DBP13 [ ] [ ] [ ]	155. intdbp13 [ ] [ ] [ ]
Inraop HR13 [ ] [ ] [ ]	156. inthr13 [ ] [ ] [ ]
Inraop room temp13 [ ] [ ].[ ] °C	157. intrt13 [ ] [ ].[ ]
11. Duration of operation [ ] [ ] [ ] (mins)	158. duo [ ] [ ] [ ]

12. Duration of Anesthesia [ ] [ ] [ ] (mins)	159. duoa [ ] [ ] [ ]
13. Room Temperature	
Max [ ] [ ].[ ] °C	160. rtmax [ ] [ ].[ ]
Min [ ] [ ].[ ] °C	161. rtmin [ ] [ ].[ ]
14. Active intra-operative warming	162. actwarm [ ]
☐ 1. Yes ☐ 2. No	
15. Type of Active warming	
☐ 1. Air forced warmer	163. air [ ]
☐ 2. Normal blanket	164. normal [ ]
☐ 3. Others ……	165. tyacwot [ ]
	166.tyacwoth ……
16. infusion of Un warmed IV Fluid	167. unwarm [ ]
☐ 1. Yes ☐ 2. No	
17. Total IV fluid [ ] [ ] [ ] [ ] ml	168. totiv [ ] [ ] [ ] [ ]
18. Blood loss [ ] [ ] [ ] [ ] ml	169. bldlos [ ] [ ] [ ] [ ]
19. Duration between Anesthesia and surgery	170.duranesx [ ] [ ][ ] []
20. At the start of operation [ ] [ ]. [ ] ℃	171. Startopt [ ] [ ].[ ]

Annex 3: Participant information sheet

Participant Information Sheet

Title of research project: Peri-operative risk factors For Intraoperative Hypothermia in Bhutanese patients undergoing elective Surgery

Name of principle investigator: Dr. Kinley Zangmo

Research site: Jigme Dorji Wangchuck National Referral Hospital, Thimphu, Bhutan

Source of fund: ***(If applicable)*** Faculty of Medicine, Prince of Songkla University, Thailand

It is important for you to know that this is a research NOT a standard procedure or treatment.

Please feel free to refuse to participate or withdraw your consent anytime.

In this document, there may be some statements that you do not understand. Please ask the principal investigator or his/her representative to give you explanations until they are well understood. To help your decision making in participating the research, you may bring this document home to read and consult your relatives, intimates, personal doctor or other doctor.

- **Introduction of the study**

(Provide a general statement of the problem area, with a focus on a specific research problem, to be followed by the rationale or justification of your study. Describe briefly why you are undertaking this study and why this study is needed.)

Hypothermia (cold body temperature less than 36℃) is a common problem in the patients undergoing surgeries. The incidence of intra-operative hypothermia has been reported as high as 40%. It is associated with complications such as postoperative shivering, bleeding, and delayed wound healing and wound infection. Anesthetic complications such as delayed awakening from anesthesia has been reported as well. In severe cases, it can cause cardiovascular complications which can be life threatening to the patients.

Therefore, it is important to prevent the intra-operative hypothermia. Many factors such as patient related, Anesthetic and surgical related factors are responsible for the development of intra-operative hypothermia. Anesthetic and surgical factors are from intra-operative procedures. But patient related factors can be identified in the preoperative period (before patients go to the operation room). Thus, this will help to prevent the development of intra-operative hypothermia and decrease the complications.

This study will be done in Bhutanese patients to find out whether the Peri-operative risk factors (Before going to the operation theatre and in the operating room) for the intra-operative hypothermia. Risk factors related to patients such as patients age, body weight, BMI, Blood pressure, preoperative core body temperature and duration and type of operation has been reported in different studies. Anesthetic procedure and type also has been shown to affect the patient's intraoperative core body temperature. Through this study it will help to find whether these risk factors are similar in our setting despite the difference in the geographical distribution and our lifestyle. If we can identify the risk factors early, we can do intervention such as Pre-warming the patients in the ward.

To my knowledge, there is no study done on intra-operative hypothermia in Bhutan and so is the Peri-operative risk factors. Therefore, this study will provide a baseline data on intra-operative hypothermia and its related risk factors.

- **Purpose of the research**

(Describe your objective(s) or research goal(s) clearly and succinctly.)

Objectives

Primary – To find the Peri-operative risk factors for intra-operative hypothermia in Bhutanese patients undergoing elective surgery lasting more than 30 minutes.

Secondary – To find the overall incidence of intra-operative hypothermia.

- **Procedures of the study**

(The purpose of this section is to provide complete description on the research methods and sequence of activities including duration of procedures. Also describe what have to be done to the samples or specimen collected, or with the research participants. Please avoid technical terms, and use lay language.)

1. Collect the list of patients undergoing surgery from the schedule list in the operation room or from the ward.

2. Patients who meet the study criteria (as per inclusion and exclusion criteria) will be recruited.

3. Visit the inward patient 24hrs prior to the surgery day and invite the patient to participate in the study after explaining about the research and its procedures.

4. Patients detailed history will be taken, mainly demographic details, past medical problems, any acute illness and allergy by the researcher or the research assistant.

5. Patients body weight, height and BMI will be measured and documented by the researcher or research assistant.

6. Body core temperature, BP and HR will be monitored as per routine practice in the ward (4 or 6 hourly) and in the morning of the operation day.

7. For the OPD patients, the researcher will visit the patients on the day when they come to see the anesthetic person. The researcher will explain about the research and its procedure and get the informed written consent.

8. The OPD patients will be requested to come about 2 to 3 hours before the operation time and monitor the BP, HR and temperature 1 hourly. The weight, Height and BMI will be measured on the same day.

9. Patients core body temperature will be measured using ear thermometer as it is reliable to check core body temperature and less invasive to the patients. Using Ear thermometer to measure core body temperature is standard and practiced in many settings.

10. The final value of Core temperature, BP and HR will be the average of the last 4 readings in Inward patients and at least 2 readings (or 3 if they come early) of outpatients before the start of induction of anesthesia.

11. Any patients found to be hypothermic (<36℃) in the Preoperative period will be managed with warming blankets and using external warmer (heater) until patients temperature is raised since there is no standard management guidelines for such problem in the hospital. In severe (<35℃ will be actively pre warmed with air forced warmer).These patients will be continuously monitored in the operation room for further decrease in temperature and do the active warming.

12. Intra operatively the routine anesthetic procedure will be carried out as per the case. Routine monitoring will be carried out as per the standard guidelines and hospital practice (No disturbance to routine practice)

13. Patients core body temperature, BP and HR will be measured and documented before the start of anesthesia.

14. Then intra operatively the Patients core body Temperature, BP and HR will be monitored every 15mins in the first hour and every 30 minutes after that till the patient is discharged to Postoperative care unit.

15. The room temperature will be measured every 15 minutes with room temperature measuring equipment that will be placed on the wall. The maximum and minimum

values from the readings will be recorded to find the optimum room temperature to prevent intraoperative hypothermia.

16. The core temperature <36℃ at any time of intra operative period will be considered hypothermia.

17. Any patient found to be hypothermic will be managed with administration of warm IV fluids, reduce the exposure of patients body (e.g. use polythene to cover the patients face), and if body temperature drop below 35℃ and no improvement with the above methods will be warmed with air forced warmer.

18. At the end of surgery the duration of Anesthesia and

Operation will be noted so to find out its association with intraoperative hypothermia.

Risk and discomforts

(Describe nature and degree of risks of possible injury, stress, discomforts, or invasion of privacy, and other side effects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires which may occur to the subject as a result of participating in the study, including prevention and treatment, medical care and other services to be provided to the study participants who may or may not be affected by any complication.)

This study will involve collection of data regarding patient's demographic details, past medical and surgical problems to find the risk factors for intra-operative hypothermia. Then monitoring of the patients for intra-operative hypothermia. It will not involve any invasive procedure or exploring patient's privacy. Therefore, this study will not involve any risk or discomforts for the participants. In case of detection of low body temperature in the ward, the necessary intervention such as warming patients with the blankets and warming the room will be done.

While in the operating room any patient found to have low body temperature(less than 36℃) will be managed with warm IV fluids, reducing the exposure of the body and if not responding do active warming with air forced warmer.

Patients will be monitored continuously throughout the operating period and this will help to identify other complications as well and help to do early intervention.

- **Benefits**

(Describe the anticipated direct benefits of this research to individual subject. Declare if there is no direct benefit to individual subject but to society. Incentive does not count as benefits.)

This study will benefit individual patients during the surgery, where they will be monitored for development of intra-operative hypothermia and do early intervention. This will help to prevent the occurrence of its associated complications. It may not benefit all participants but in patients who develop hypothermia, management will be done accordingly.

For the Society. At present we don't know whether intra-operative hypothermia is a problem in our hospital with a fact that our country is a cold country. By this study, it will develop a baseline data which will help us to know more about intra operative hypothermia and its risk factors.

It will help to identify the risk factors for intra-operative hypothermia. If some risk factors which can be modified and corrected can be identified from this study, it can be used to assess the risk of intraoperative hypothermia in patients undergoing operation to prevent the development of intra-operative hypothermia.

- **Compensation**

(If participants will receive payments, service, or any other incentive for participating, provide details how much, and how it will be delivered to the subjects, for example, rated by length of participation, at the end of the study, at the beginning of the study.)

The participation of you (participants) will be truly based on your voluntarism. Therefore, no financial compensation or materialistic benefit will be provided.

- **Confidentiality**

(Investigator must ensure that the privacy and confidentiality of the participants are strictly protected. Provide details of the storage and security arrangements for personal information that will be collected within the study. Address the estimated time of retention of the personal information, security standards to be applied to the personal information, list of personnel with access to the personal information, the media or forms of the data that are to be stored. For example, electronic data on floppy disc, hard copies, cassette tapes, field samples, photographs, video tape, etc.)

The interview and questionnaire will involve only the basic demographic information and past medical and surgical problems. All of your (participants) information will be fully confidential between you and the researcher (me). But the data collected will be used to analyze and obtain results which will be further used for publications.

- **Right to refuse or withdraw**

(*Describe on when and how participants/subjects can withdraw from the study.)*

If you don't want to participate or you want to withdraw form this study, it will be accepted at any time without any litigation and procedure. There will be no difference in your management due to your non participation in the study.

- **Who to contact for further information and emergency use**

(Provide completely information following these items: name(s) of responsible person(s) or doctor(s), and contact address(es) and telephone number(s).)

1. Dr. Kinley Zangmo Tel. 66-95-6266991, Fax. 66-74-281656

2. Asst. Prof. Sunisa Chatmongkolchart Tel. 66-86-9020438, Fax. 66-74-281656

3. Assoc. Prof. Puttisak Puttawibul, Dean of Faculty of Medicine Tel. 66-74-451100, 66-74-451102, 66-74-451104

On the condition that you are not treated as indicated in this information sheet, you can contact the Chair of Human Research Ethics Committee (HREC) at the office of HREC, 4th floor, Administrative Building, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla, Thailand, 90110, Tel +66-7-4451157, E-mail: medpsu.ec@gmail.com.

Annex 4: Consent form

Informed Consent Form

This Informed Consent Form is for Bhutanese patients undergoing elective surgery lasting more than 30 minutes and who meet the inclusion and exclusion criteria *(target population for using this form)* who are invited to participate in the research entitled "Peri-operative risk factors For Intraoperative Hypothermia in Bhutanese patients undergoing elective Surgery".

(Provide briefly detail of the target population for using this Informed Consent Form by considering table below. Informed Consent Form and Informed Assent Form are required according to the following age group)

Age	***Informed Consent Form***	***Informed Assent Form***
Less than 7 yrs.	*Parent signs ICF for permission*	-
7 yrs. to less than 13 yrs.	*Parent signs ICF for permission*	*Child signs IAF*
13 yrs. to less than 18 yrs.	*Child and Parent sign the same ICF*	-
18 yrs. and over (Adult)	*Adult signs ICF*	-

I have been invited to take part in the research "Peri-operative risk factors For Intraoperative Hypothermia in patients undergoing elective Surgery". I have been told about this research as follows: *(Please provide summary of each items)*

- ***The purpose of the research*** is to

  To find the Peri-operative risk factors affecting intra-operative hypothermia in Bhutanese patients undergoing elective surgery lasting more than 30 minutes.

- ***Procedures,*** participants will be

  Participants will be those patients undergoing elective surgeries in JDWNRH (National Hospital) who are voluntarily willing to participate. The researcher (I) will visit the In-ward patients prior to the operation day and discuss about the study. Interested patients who are willing to take part will be invited if they meet inclusion. Criteria. For the outpatient, researcher will meet the patient in the Pre-anesthetic assessment period and explain about the study. Interested patients will be invited as in-ward patients. The study will involve asking some questions and monitoring of patients which will further improve patient's management. There will be no disturbances to the routine care of patients.

- ***Risks and discomforts,*** participants will be free to refuse to answer any questions that make them feel discomfort and to withdraw from the interview at any time.

  This study will involve collection of data regarding patient's demographic details, past medical and surgical problems to find the risk factors for intra-operative hypothermia. Then monitoring of the patients for intra-operative hypothermia. It will not involve any invasive procedure or exploring patient's privacy. Therefore, this study will not involve any risk or discomforts for the participants. In case of detection of low body temperature, the necessary intervention such as warming with the blanket, heating the room and air forced warmer will be used according to the degree of severity of hypothermia.

- ***Benefits*** of the research,

  It will help to identify risk factors for intra-operative hypothermia which will prevent the development of intra-operative hypothermia and its complications. It will benefit the participants since they will be monitored throughout the surgery and will help to prevent any complication other than hypothermia. The result of this study can be used to predict the same problem in other patients undergoing surgeries.

This study will provide a baseline data for the future studies on the similar topic in our country.

- ***Confidentiality*** of all information will be kept strictly confidential. Information will not be released to anyone who is not associated with the research.
- ***Contact information, for further information or any questions about the research project,*** please feel free to contact the principal investigators or the Chairperson of the Institutional Ethical Review Committee (see above).

  1. Dr. Kinley Zangmo Tel. 66-95-6266991, Fax. 66-74-281656

  2. Asst. Prof Sunisa Chatmongkolchart Tel. 66-86-9020438, Fax. 66-74-281656

  3. Assoc. Prof. Puttisak Puttawibul, Dean of Faculty of Medicine Tel. 66-74-451100, 66-74-451102, 66-74-451104

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study and understand that I have the right to withdraw from the [discussion/interview] at any time without in any way affecting my medical care.

I confirm that the individual has given consent freely.

Printed name of participant .....

Signature of participant..... Date (Day/ Month/ Year).....

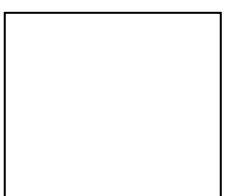
.....

If illiterate, I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Printed name of witness .....

Signature of witness .....

Date (Day/ Month/ Year) .....



Thumb print of a participant

Printed name of Researcher .....

Signature of Researcher .....

Date (Day/ Month/ Year) .....

Annex 5: Sample size calculation

Sample size calculation

Based on the findings of previous studies 5 factors are used to calculate the sample size;

1) Preoperative core body temperature

P1 = The Prevalence of patients with low Preoperative core body temperature (<36℃) in hypothermic group i.e. = 33 %

P2 = The Prevalence of patients with low Preoperative core body temperature (<36℃) in normothermic group i.e. = 20%

95% Confidence interval = 1.96

Type 1error = 5% (0.05)

Type 2 error = 20%

Power of the study = 80%

$Z\beta$ = 0.84

$$\left[N = \frac{\left\{ Z\alpha/2\sqrt{2P(1-P)} + Z\beta\sqrt{P1(1-P) + P2(1-P2)} \right\}^2}{(P1-P2)^2} \right]$$

N1 = 87 participants = N2

Total participants = 174 participants

2) Age

P1 = Prevalence of increasing age(elderly) patients in Hypothermic group is 30%

P2 = Prevalence of elderly in normothermic group is 21%

95% Confidence interval = 1.96

Type 1 error = 5% (0.05)

Type 2 error = 20%

Power of the study = 80%

$Z\beta$ = 0.8

$$\left[N = \frac{\left\{ Z\alpha/2\sqrt{2P(1-P)} + Z\beta\sqrt{P1(1-P) + P2(1-P2)} \right\}^2}{(P1-P2)^2} \right]$$

N1 = 210 = N2

Total participants = 420 participants

3) Duration of operation

P1 = Incidence of Prolonged surgery in Hypothermic group is 66%

P2 = Incidence of Prolonged surgery in normothermic group is 54%

95% Confidence interval = 1.96

Type 1 error = 5% (0.05)

Type 2 error = 20%

Power of the study = 80%

$Z\beta$ = 0.84

$$\left[N = \frac{\left\{ Z\alpha/2\sqrt{2P(1-P)} + Z\beta\sqrt{P1(1-P) + P2(1-P2)} \right\}^2}{(P1-P2)^2} \right]$$

N1 = 217 participants = N2

Total participants = 434 participants

4) Type of Surgery

P1 = Effect of major surgery (exposed large surface area of body and involving large blood loss) in Hypothermic group is 43%

P2 = In normothermic group is 25%

95% Confidence interval = 1.96

Type 1 error = 5% (0.05)

Type 2 error = 20%

Power of the study = 80%

$Z\beta$ = 0.84

$$\left[N = \frac{\left\{ Z\alpha/2\sqrt{2P(1-P)} + Z\beta\sqrt{P1(1-P)+P2(1-P2)} \right\}^2}{(P1-P2)^2} \right]$$

N1=68 participants =N2

Total participants= 136 participants

5) Preoperative Blood Pressure and Heart rate

P1 = The incidence of patients with higher BP and heart rate in hypothermic group is 17%

P2 = The incidence of patients with higher BP and heart rate in normothermic group is 33%

95% Confidence interval = 1.96

Type 1 error = 5% (0.05)

Type 2 error = 20%

Power of the study = 80%

$Z\beta$ = 0.84

$$\left[N = \frac{\left\{ Z\alpha/2\sqrt{2P(1-P)} + Z\beta\sqrt{P1(1-P)+P2(1-P2)} \right\}^2}{(P1-P2)^2} \right]$$

N1 = 84 participants = N2

Total participants = 168 participants

Annex 6: Ethical Committee Approval Letter

ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
RESEARCH ETHICS BOARD OF HEALTH
THIMPHU : BHUTAN
P.O. BOX : 726

REBH/Approval/2017/048 **28th July, 2017**

REBH Approval Letter

PI: Dr. Kinley Zangmo **Institute:** Department of Anesthesiology, Prince Of Songhkla University, Thailand	**Study Title**: Peri-operative risk factors for Intra operative Hypothermia in Patients Undergoing Elective Surgery at Jigme Dorji Wangchuk National Referral Hospital (JDWNRH), Bhutan
Co-Investigators: 1. Dr. Sunisa Chatmongkolchart, and 2. Dr. Pasuree Sangsupawanich	
Mode of Review: ✓Expedite review for version 1.1	
Decision: Approved **(Note: Abide by the conditions of approval)**	
Conditions for Approval 1. *This approval is granted for the scientific and ethical soundness of the study. The PI shall be responsible to seek all other clearances/approvals required by law/policy including permission from the study sites before conducting the study.* 2. *Report serious adverse events to REBH within 10 working days after the incident and unexpected events should be included in the continuing review report or the final report.* 3. *Any changes to the proposal or to the attachments (informed consent and research tools such as forms) should be approved by REBH before implementation.* 4. *Final report of the study should be submitted to REBH at the end of the study for protocol file closure.* 5. *This approval is valid through 27/07/2018. If the study has to continue beyond the approved period the PI has to apply for the continuing review two months before the validity of the approval expires.*	

(Dr. Tashi Tobgay)
Chairperson

For further information please contact: *REBH Member Secretary,*
msgurung@health.gov.bt/tashidema@health.gov.bt: *Tel: +975-2-322602 ext 333*

Human Research Ethics Committee

Faculty of Medicine, Prince of Songkla University

This document is a record of review and approval/acceptance of clinical study protocol.

REC:	60-181-19-6
Protocol Title:	Peri-operative Risk Factors for Intra operative Hypothermia in Patients Undergoing Elective Surgery at Jigme Dorji Wangchuk National Referral Hospital (JDWNRH), Bhutan
Principal Investigator:	Dr.Kinley Zangmo
Affiliation:	Department of Anesthesia, Faculty of Medicine Prince of Songkla University
Advisor:	Sunisa Chatmongkolchart, M.D
Affiliation:	Department of Anesthesia, Faculty of Medicine Prince of Songkla University
Co-Advisor:	Pasuree Sangsupawanich, M.D
	Department of Pediatrics ,Faculty of Medicine Prince of Songkla University

Approved documents:

1. Submission form version 2.0 date August 10, 2017
2. Study protocol version 2.0 date August 10, 2017
3. Information sheet and consent form 2.0 date August 10, 2017
4. Clinical record form version 2.0 date August 10, 2017
5. Curriculum Vitae

have/has been reviewed and approved by Human Research Ethics Committee, Faculty of Medicine Prince of Songkla University in full compliance with International Guidelines for human research subject protection such as Declaration of Helsinki, Belmont Report, CIOMS Guideline and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

This review is documented in the meeting minutes of the meeting 24/2017, panel 3

Please submit the Progress Report every 12 months. (Renewal must be submitted at least 30 days prior to expired date.)

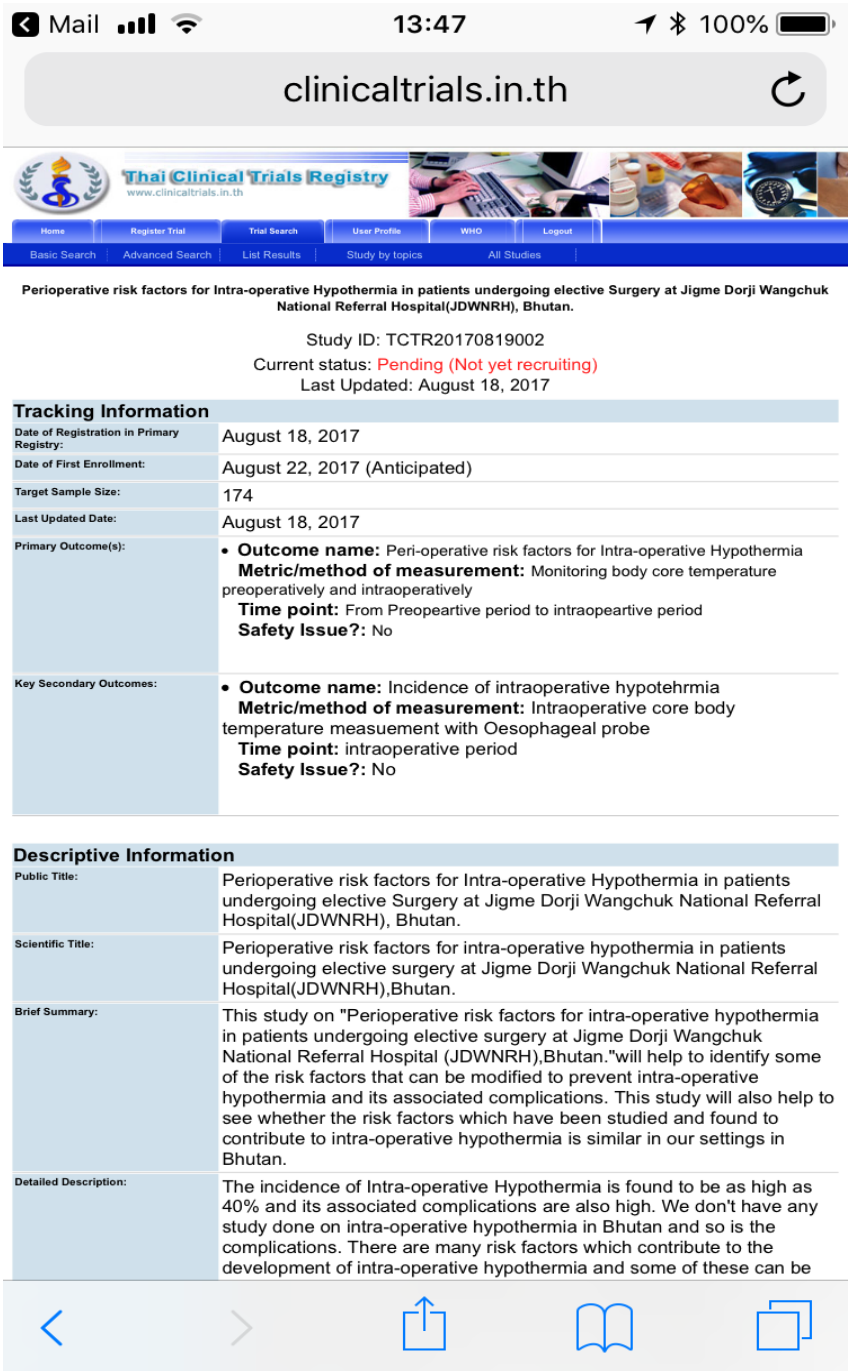
(Associate Professor Boonsin Tangtrakulwanich, M.D. PhD.)
Chairman of Human Research Ethics Committee

Date of Approval: August 11, 2017

Date of Expiration: August 10, 2018

Human Research Ethics Committee
Faculty of Medicine, Prince of Songkla University
15 Kamchanavanich Road, Hat Yai, Songkla 90110, Thailand
Tel. 66 7445-1149, 66 7445-1157 Fax: 66 7421-2900

Annex 7: Clinical Trials Registration



Mail 13:47 100%

clinicaltrials.in.th

Thai Clinical Trials Registry
www.clinicaltrials.in.th

Home | Register Trial | Trial Search | User Profile | WHO | Logout

Basic Search | Advanced Search | List Results | Study by topics | All Studies

Perioperative risk factors for Intra-operative Hypothermia in patients undergoing elective Surgery at Jigme Dorji Wangchuk National Referral Hospital(JDWNRH), Bhutan.

Study ID: TCTR20170819002

Current status: Pending (Not yet recruiting)

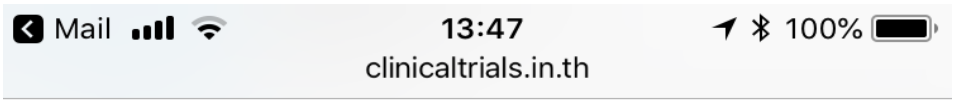
Last Updated: August 18, 2017

Tracking Information

Date of Registration in Primary Registry:	August 18, 2017
Date of First Enrollment:	August 22, 2017 (Anticipated)
Target Sample Size:	174
Last Updated Date:	August 18, 2017
Primary Outcome(s):	• **Outcome name:** Peri-operative risk factors for Intra-operative Hypothermia **Metric/method of measurement:** Monitoring body core temperature preoperatively and intraoperatively **Time point:** From Preopeartive period to intraopeartive period **Safety Issue?:** No
Key Secondary Outcomes:	• **Outcome name:** Incidence of intraoperative hypotehrmia **Metric/method of measurement:** Intraoperative core body temperature measuement with Oesophageal probe **Time point:** intraoperative period **Safety Issue?:** No

Descriptive Information

Public Title:	Perioperative risk factors for Intra-operative Hypothermia in patients undergoing elective Surgery at Jigme Dorji Wangchuk National Referral Hospital(JDWNRH), Bhutan.
Scientific Title:	Perioperative risk factors for intra-operative hypothermia in patients undergoing elective surgery at Jigme Dorji Wangchuk National Referral Hospital(JDWNRH),Bhutan.
Brief Summary:	This study on "Perioperative risk factors for intra-operative hypothermia in patients undergoing elective surgery at Jigme Dorji Wangchuk National Referral Hospital (JDWNRH),Bhutan."will help to identify some of the risk factors that can be modified to prevent intra-operative hypothermia and its associated complications. This study will also help to see whether the risk factors which have been studied and found to contribute to intra-operative hypothermia is similar in our settings in Bhutan.
Detailed Description:	The incidence of Intra-operative Hypothermia is found to be as high as 40% and its associated complications are also high. We don't have any study done on intra-operative hypothermia in Bhutan and so is the complications. There are many risk factors which contribute to the development of intra-operative hypothermia and some of these can be



Descriptive Information	
Public Title:	Perioperative risk factors for Intra-operative Hypothermia in patients undergoing elective Surgery at Jigme Dorji Wangchuk National Referral Hospital(JDWNRH), Bhutan.
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Detailed Description:	The incidence of Intra-operative Hypothermia is found to be as high as 40% and its associated complications are also high. We don't have any study done on intra-operative hypothermia in Bhutan and so is the complications. There are many risk factors which contribute to the development of intra-operative hypothermia and some of these can be modified to prevent the development of intra-operative hypothermia such as Preoperative core body temperature and room temperature.This study will help to find out some of the risk factors for intra-operative hypothermia in our setting and it will help to provide a baseline data for similar projects in future.
Study Design:	**Allocation:** N/A **Control:** N/A **Study Endpoint Classification:** Bio-availability Study **Intervention Model:** No Intervention **Number of Groups:** 1 **Masking: (Masked Roles:)** **Primary Purpose:** Prevention **Study Phase:** Phase 1
Health Condition(s) or Problem(s) Studied:	Intra-operative Hypothermia
Study Groups:	• **Group**: 1 Group Name: Patients undergoing elective surgery Descriptions: All patients who are undergoing elective surgery lasting more than 30 minutes and those who meet inclusion and exclusion criteria will be recruited for this study.

Recruitment Information	
Recruitment Status:	Pending (Not yet recruiting)
Estimated Enrollment:	174
Study Start Date (First enrollment):	August 22, 2017
Primary Completion Date:	October 31, 2017
Inclusion Criteria:	**Inclusion Criteria** **Gender**: Both **Age Limit**: Minimum 18 Years : Maximum 75 Years 1 Both gender 2 Age 18 to 75 years 3 ASA 1 to 3 4 Surgeries lasting more than 30 minutes 5 Undergoing any type of anesthetics procedure 6 Elective Surgeries

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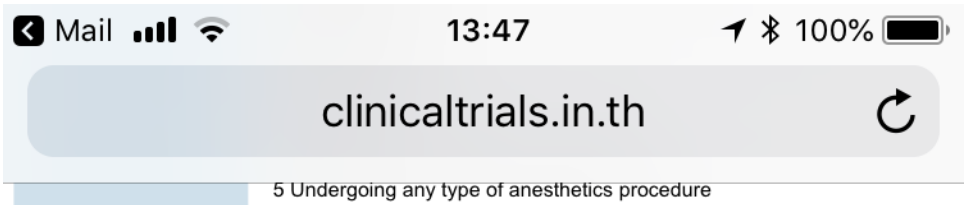
Countries of Recruitment	Bhutan
Contact for Public Queries:	Contact for Public Query's Name: Kinley Zangmo Degree: MBBS Phone: 660956266991 Email: gtkinley@gmail.com Postal Address: Jigme Dorji WAngchuk National Referral Hospital, Thimphu State/Province: Thimphu **Postal Code:** 11001 Country: Bhutan

Administrative Information

Primary Registry Site:	Thai Clinical Trials Registry
Trial Identification Number:	TCTR20170819002
Secondary Identifying Numbers:	Nil known
Source(s) of Monetary or Material Supports:	Prince Of Songkla University
Study Primary Sponsor:	Prince Of Songkla University
Study Secondary Sponsor:	1.) RGOB
Contact for Scientific Queries:	Contact for Scientific Query's Name: kinley Zangmo Degree: MBBS Phone: 660956266991



5 Undergoing any type of anesthetics procedure

6 Elective Surgeries

Exclusion Criteria

1 Emergency cases

2 Patients with medical conditions such as thyroid disease and muscular diseases

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Track changes

VITAE

Name Miss Kinley Zangmo

Student ID 5910320003

Educational Attainment

Degree	Name of Institution	Year of Graduation
Bachelor in Medicine and Bachelor in Surgery (MBBS)	Kelaniya University, Sri lanka	2014

Work – Position and Address

Doctor at Lhuentse Hospital, Bhutan