

UNIVERSITY of RWANDA

COLLEGE OF MEDECINE AND HEALTH SCIENCES SCHOOL OF MEDICINE AND PHARMACY DEPARTMENT OF ANESTHESIA, CRITICAL CARE AND EMERGENCY

INCIDENCE, RISK FACTORS AND OUTCOME OF PERIOPERATIVE HYPOTHERMIA IN PAEDIATRIC PATIENTS AT KIGALI UNIVERSITY TEACHING HOSPITAL

A dissertation submitted as partial fulfilment of the requirements for the award of the Degree

1

of Master of Medicine in Anesthesiology

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KIGALI, August, 2019

DECLARATION

Dr UWIMANA Jean Claude

I hereby declare thap this dissertation has been submitted with my approval as the supervisor

) Date 9th May 2019 (Bimas) Signed ...

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Di UWINEZA Jeun Bonaventure

DEDICATION

To my parents,

To NYAGAHANGA BENEBIKIRA Congregation especially Sister Aurélie,

To UWIMANA Angélique,

To MAHORO Annonciata,

To HABUMUREMYI Etienne, TWAGIRAMARIYA Louise and MANIRIHO Beatrice,

To my fellow residents,

TO KUTH anesthesia providers,

I dedicate this work.

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May the Almighty God bless all of you.

ABBREVIATIONS

ASA: American Society of Anesthesiologists IV: Intravenous IRB: Institutional Review Board KUTH: Kigali University Teaching Hospital OR: Operating Room PACU: Post Anesthesia Care Unit. CMHS: College of medicine and health sciences

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ABSTRACT

Background: To maintain normal temperature in pediatric patients is problematic. Hypothermia can cause physiological derangements including coagulopathy, decreased drug metabolism and vasoconstriction. Patients who develop perioperative hypothermia, are prone to severe complications including impaired wound healing ,postoperative infections, increased bleeding with blood transfusions, cardiac disorders and prolonged hospital stay. Since inadvertent perioperative hypothermia is a modifiable condition, understanding its risk factors may help prevent hypothermia and its associated complications.

Objective: The aim of this study was to determine the incidence of perioperative hypothermia, factors associated with intraoperative hypothermia and outcome of perioperative hypothermia in pediatric patients operated at KUTH.

Methods: a prospective observational study was conducted. Selected pediatric patients undergoing surgery in theatre between June 2018 and August 2018 were eligible for the study. Temperature was taken on arrival in theatre, immediately after induction of anesthesia, then after every hour until the procedure finished. The postoperative temperature was taken every 30 minutes up to 2 hours considering that patients stay in the postoperative care unit for 1-2 hours. Data were entered and texted using Microsoft word, cleaned with SPSS version 22.0. Tables and graphs were made using Microsoft excel. The quantitative variables were analyzed with "t" test and chi square was used for qualitative variables. Logistic regression was used to test each factor with the dependent variable and variables were carried to multi variant analysis. P value of <0.05 was a cutoff point to test for significance of associations.

Results: 103 pediatric patients were enrolled to the study of whom 28 females and 75 males. Incidences of preoperative, intraoperative and postoperative hypothermia were 67%, 71.7% and 67.7% respectively. Female patients, use of general anesthesia, elective surgery, not using a warmer perioperatively and low operating room temperature ($22-24^{\circ}C$) were associated with intraoperative hypothermia. Hypothermic patients had increased transfusion requirements compared to the ones with normothermia. Hypothermic patients had longer PACU stay compared to normothermic patients.

Conclusion: Perioperative hypothermia is common in our hospital. Warming patients, continuous temperature monitoring and management of operating room temperature should be done during anesthesia and in PACU.

CHAP I. INTRODUCTION

I.1 BACKGROUND

To maintain normal temperature in pediatric patients is problematic. [1] Unintended hypothermia is mostly encountered in children. [2, 14] Hypothermia can be divide into mild, moderate and severe when core temperature measurement is 35 to 35.9°C, 34 to 34.9° C and $\leq 33^{\circ}$ C respectively. [5, 9]

Patients can lose heat through different ways. The major one is radiation. That is loss of heat from the body surface to a cooler solid surface not in direct contact, but in relative proximity. The second way of is convection which is flow of heat from body surface to cooler air. The third one is conduction. That is loss of heat from the body surface to cooler surfaces in direct contact. The fourth way of heat loss which occurs by humidification and warming of inspired air, is evaporation. [5, 9, 10] After induction of anesthesia, there is a reduction in core temperature due to loss of core-periphery temperature gradient. [14]

Hypothermia can cause physiological derangements including coagulopathy, decreased drug metabolism and vasoconstriction.[3,4].Patient who develop perioperative hypothermia, are prone to severe complications including impaired wound healing ,postoperative infections, increased bleeding with blood transfusions, cardiac disorders and prolonged hospital stay[3]

Children under 1 year of age are considered to be at high risk of perioperative hypothermia as their thermoregulatory capacity is not well developed and can lose heat due to large surface area to body weight ratio and less subcutaneous fat. [3, 11, 13]. Infants 'response to hypothermia is enhanced by vasoconstriction and nonshivering thermogenesis. The latter can be present up to 2 years of age. However, it can be inhibited by anesthetic agents and can lead to intraoperative hypothermia. [2, 13] With cold stress in neonates, noradrenaline release, oxygen and substrate consumption are increased. Therefore, there is increased pulmonary vascular resistance, increased right to left shunting, decreased peripheral perfusion, oxygen delivery and acidosis. [1]

Administration of cold intravenous fluids and evaporation from the surgical field to pediatric patients expose them to perioperative hypothermia. Hypothermia can still occur during the recovery phase and in the postoperative period. Therefore, postoperative rounds by anesthesia providers is mandatory. [2]

Since inadvertent perioperative hypothermia is a modifiable condition, understanding its risk factors may help prevent the hypothermia and its associated complications. Therefore, We have conducted present study in order to ascertain the incidence of perioperative hypothermia and its risk factors in paediatric patients.

I.2 LITERATURE REVIEW

The pulmonary artery catheter can be used to get the best measurement of the core temperature, the best indicator of thermal status in humans. Though the high cost and invasiveness of the pulmonary catheter limits its use. Esophageal temperature monitor can also be used to measure accurately the core temperature. However humidified gases, neuraxial blocks can influence it measurement. Tympanic membrane temperature is preferable in the perioperative period as it is noninvasive .In addition, the tympanic membrane is nearest to the carotid and the hypothalamus. And help to get the correct measure of core temperature. The axillary temperature cannot estimate well the core temperature if the probes are not placed well in the axillary region or if the room temperature is low or the infusing intravenous IV fluids is in the same extremity as the axillary temperature. Despite being used to get correct core temperature measurements, the rectal temperature cannot be used if the probe is enclosed with feces or when it is exposed to cool venous blood. It cannot be used when the child has imperforate anus, and it may not be used when there is inflammatory bowel disease, rectal tumors, neutropenia, thrombocytopenia and coagulopathy. The bladder temperature can be used to accurately measure the core temperature when there is a high urine flow. When urine flow is not high, the measurement of the bladder temperature is close to the rectal temperature. [5]

Evidence shows that it is both clinically and cost effective to keep warm patients at increased risk of unplanned perioperative hypothermia and morbid cardiac event for all procedures, and to keep warm all other patients who will be under anaesthesia for more than 30 minutes. [7]

A study done by Bridget Pearce, Robert Christensen and Terri Voepel-Lewis on perioperative hypothermia in the pediatric population at the University of Michigan Health System found that 52% experienced intraoperative hypothermia and hypothermia was more common in older children and in those undergoing longer, invasive procedures and was associated with greater blood loss and blood transfusion.[3]

A review by Sukhminder Jit Singh Bajwa and Swati on diagnosis, prevention and management of perioperative hypothermia in pediatric patients recommends preoperatively keeping the child warm, increasing ambient OR temperature to 23°-25°C, use of warm intravenous fluids, passive insulation and use of forced air warming devices.[2]

In their study, on perioperative hypothermia prevention in pediatric patients undergoing posterior spinal fusion for idiopathic scoliosis at children's national health system in Washington, DC T Shah, K Thomson, SR Pestieau, J Patel found that active pre-warming for patients undergoing posterior spinal fusion may contribute to significant reduction in the amount of intraoperative hypothermia. [4]

A multidisciplinary quality improvement on pediatric perioperative hypothermia conducted at Nationwide Children's Hospital in United States of America found a 10% incidence of hypothermia. And the Implementation of the temperature management bundle resulted in a sustained 50% reduction in hypothermia. [5]

In 2015, Yi J et al. conducted a study on Incidence of inadvertent intraoperative hypothermia and its risk factors in patients undergoing general anesthesia in Beijing and revealed a high incidence of inadvertent hypothermia in a sample with a relatively high incidence of hypothermia in patients undergoing major-plus surgery, receiving more than 1L of un-warmed intravenous fluid, and undergoing lengthy procedures. [6]

In their survey study on perioperative temperature monitoring and patient warming conducted in Turkey in 2013, Meyancı Köksal et al. found deficiencies in practice for techniques used to prevent perioperative hypothermia.

A cross-sectional study conducted by Mulat Mossie in 2016 at Tikur Anbessa specialized hospital, revealed that -intraoperative and postoperative hypothermia is common. The incidence of postoperative hypothermia being 78.9% of all pediatric patients. [12]

I.3 RATIONALE

Perioperative hypothermia is a common problem that occur during surgery. Pediatric patients are exposed to cold air, hence they are at risk of hypothermia before operation. The administration of cold IV fluids, administration of anesthetics and exposure of body cavity to cold operative room environment will further make them to loss heat.

Hypothermia affects pharmacokinetics of anesthetic drugs and cause both hepatic and renal flow decrease that will in turn decrease drug metabolism and excretion.

Present study will help policy makers to devise different strategies to prevent or reduce risks of perioperative hypothermia in pediatric patients.

I.4 OBJECTIVE

I.4.1 GENERAL OBJECTIVE

To determine incidence of perioperative hypothermia, factors associated with intraoperative hypothermia and outcome of perioperative hypothermia in pediatric patients operated at Kigali University Teaching Hospital (KUTH)

I.4.2 SPECIFIC OBJECTIVES

- To determine the incidence of preoperative hypothermia in pediatric patients operated at KUTH
- To determine the incidence of intraoperative hypothermia in pediatric patients operated at KUTH
- To determine the incidence of postoperative hypothermia in pediatric patients operated at KUTH
- To identify factors associated with intraoperative hypothermia in pediatric patients operated at KUTH.
- To determine outcome of perioperative hypothermia

I.6 RESEARCH QUESTIONS

Is perioperative hypothermia common in pediatric patients at KUTH? Are there factors associated with perioperative hypothermia in pediatric patients at KUTH?

I.7 HYPOTHESES

Perioperative hypothermia is not common in pediatric patients at KUTH. There are no factors associated with perioperative hypothermia in pediatric patients at KUTH.

CHAP II. METHODS

II.1 STUDY DESIGN

This is a prospective observational study. All pediatric patients who required any major surgery were eligible. Informed consent was obtained from a parent or a guardian. Hypothermia was defined as a core temperature $< 36^{\circ}$ C. Body temperature was measured using tympanic thermometer. Temperature was taken on arrival, immediately after induction, then after every hour till the procedure finished. The post-operative temperature was taken every 30 minutes up to 2 hours considering that patients stay on average in the post Anesthesia care unit for 1-2 hours.

II.2 STUDY POPULATION AND AREA

103 pediatric patients undergoing major surgery in theatre at Kigali University Teaching Hospital during the study period.

II.3 DATA COLLECTION

A designed questioner was used to collect data immediately from the patient.

II.4 DATA ANALYSIS

Data were entered, texted using Microsoft word, cleaned with SPSS version 22.0. Tables and graphs were made using Microsoft excel. The quantitative variable was analyzed with "t" test and chi square was used for qualitative variables. Logistic regression was used to test each factor with the dependent variable and variables was carried to multi variant analysis. P value of <0.05 was a cutoff point to test for significance of associations.

II.5 INCLUSION CRITERIA

The study included all pediatric patients undergoing major surgery under general anesthesia in theatre.

II.6 EXCLUSION CRITERIA

- Patients with fever
- Patients with short procedures under local anesthesia.
- Patients that bypass post anesthesia care unit
- Patients whose parents or guardians are not available to sign the consent

II.7 CONFIDENTIALITY:

The information collected from the study subjects was kept confidential and by assigning a code number to each patient.

II.8 SAMPLING AND SAMPLE SIZE DETERMINATION:

All pediatric patients undergoing surgery in theatre at KUTH during the study period were included. No sampling technique was used.

The sample size was estimated by the following formula:

$$n = \frac{(Z_{q_2})^2 \times P(1-P)D}{E^2},$$

P is the prevalence or proportion of event of interest for the study, E is the Precision (or margin of error). E will be 10% of P. For 5% level of significance, $Z\alpha/2$ is 1.96. D is the design effect and is equal to 1 for simple random sampling.

The estimate of perioperative hypothermia in pediatric patients is 78.9%(Ethiopia), and assuming 95% confidence interval or 5% level of significance and 10% margin of error, the sample size can be calculated as follow as :

(1.96)2×0.789(1-0.789) ×1

N= =103

(0.1×0.789)2

Hence, our study sample size will be 103.

II.9 STUDY VARIABLES

- Age(including postconceptional age for neonates)
- Sex
- Weight
- Height
- ASA classification
- Preoperative temperature
- Intraoperative temperature
- Postoperative temperature
- Anesthesia type
- Total intraoperative IV fluids
- Use of warm IV fluids
- Transfusion
- Massive transfusion
- Duration of anesthesia
- Operation room temperature
- Type of operation(Surgery)
- Duration of surgery
- Perioperative use of a warmer

II.10 ETHICAL CONSIDERATION

Approval was granted from IRB to help obtaining data for this study and informed consent was obtained from patients 'parent or guardian. Confidentiality of the information from the patients was assured. Data were entered using my personal computer and no other person was allowed to have an access to data.

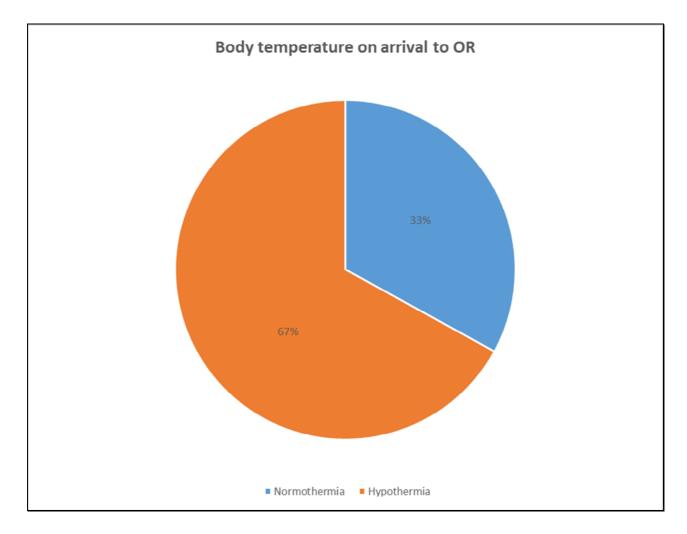
CHAP III. RESULTS

III.1. Personal and socio-demographic characteristics

Data was collected from 103 pediatric patients. Majority of participants were male (72.8%).Most of patients were ASA class I (ASAI) (64.1%). The highest number of patients 27.2% belonged to the age group of pre-school (2-5 years) followed by infants (<1 year) (26.2%) and school age children (6-12 years) (22.3%).Perioperatively a warmer was used in 34% of pediatric patients. The table below shows these and additional information.

Variables	Category	Frequency	Percentage
Age	Infant	27	26.2
-	Toddler	15	14.6
	Preschool	28	27.2
	School age	23	22.3
	Adolescent	10	9.7
	Total	103	100.0
Sex	Male	75	72.8
	Female	28	27.2
	Total	103	100.0
ASA class	Ι	66	64.1
	II	13	12.6
	III	21	20.4
	IV	3	2.9
	Total	103	100.0
Anesthesia type	General	100	97.1
	Spinal	3	2.9
	Total	103	100.0
Warm IV fluids	Yes	10	9.7
	No	93	90.3
	Total	103	100.0
Operating room	>24°C	98	95.1
temperature	22-24°C	5	4.9
	Total	103	100.0
Type of surgery	Elective	75	72.8
	Emergency	28	27.2
	Total	103	100.0
Perioperative use of a	Yes	35	34.0
warmer	No	68	66.0
	Total	103	100.0

Table 1. Personal and socio-demographic characteristics of pediatric surgical patients at KUTH



III.2. perioperative events for respondents and frequency

Figure-1 shows the preoperative body temperature distribution which implied 67% hypothermia and 33% normothermia.

Variables	Category	Normothermia	Hypothermia
Age	Infant	5(23.8%)	16(76.2%)
	Toddler	1(9.1%)	10(90.9%)
	Preschool	5(38.5%)	8(61.5%)
	School age	4(28.6%)	10(71.4%)
	Adolescent	2(20%)	8(80%)
Sex	Male	14(26.4%)	39(73.6%)
	Female	3(18.8%)	13(81.2%)
ASA class	Ι	10(25%)	30(75%)
	II	3(27.3%)	8(72.7%)
	III	4(25%)	12(75%)
	IV	0(0 %)	2(100%)
Anesthesia type	General	16(23.9%)	51(76.1%)
	Spinal	1(50%)	1(50%)
Warm IV fluids	Yes	1(11.1%)	8(88.9%)
	No	16(26.7%)	44(73.3%)
Operating room	>24°C	17(25.4%)	50(74.6%)
temperature	22-24°C	0(0%)	2(100%)
Type of surgery	Elective	11(23.9%)	35(76.1%)
	Emergency	6(26.1%)	17(73.9%)
Perioperative use	Yes	10(40%)	15(60%)
of a warmer	No	7(15.9%)	37(84.1%)

Intraoperative events for respondents, after 1 hour of surgery

Table: -2 Intraoperative events for respondents or pediatric patients who underwent surgery at KUTH

As diagrams below illustrate, the incidence of intraoperative hypothermia was greater than postoperative hypothermia, the latter being greater than perioperative hypothermia. Which implies 71.7 % for intraoperative, 67.7% for postoperative and 67% for preoperative hypothermia.

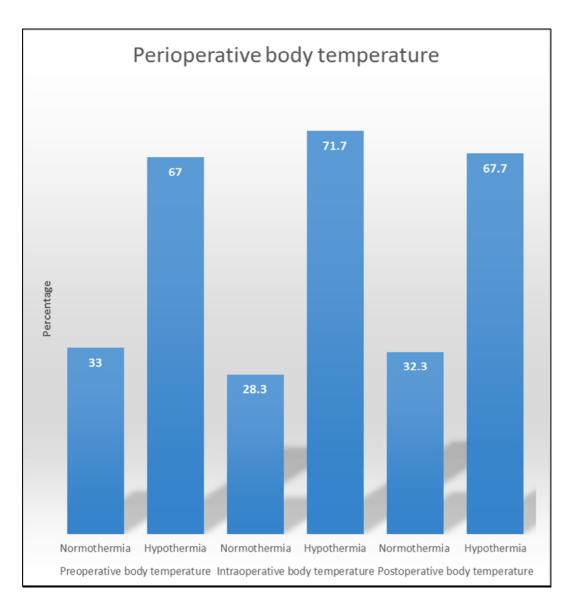


Figure: - 2 Illustrate distribution of preoperative, intraoperative and postoperative body temperature for pediatric patients who underwent surgery at KUTH

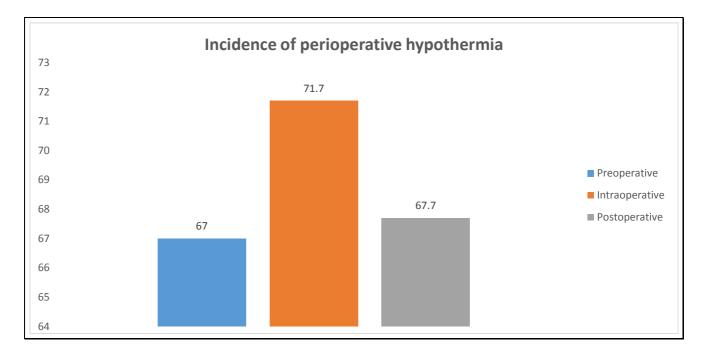


Figure 3 illustrates incidence of preoperative, intraoperative and postoperative hypothermia

The association of variables to intraoperative hypothermia

Multivariate association implied that not using a warmer perioperatively was strongly associated with intraoperative hypothermia at p value less than 0.05. The odd of developing intraoperative hypothermia for female patients was high as the odd of developing intraoperative hypothermia for male patients. The odd of developing intraoperative hypothermia for patients who underwent surgery under general anesthesia was three times high as the odd of developing intraoperative hypothermia for patients who underwent surgery under general anesthesia was three times high as the odd of developing intraoperative hypothermia for patients who underwent surgery under spinal anesthesia.

Variables	Category	p-value	Odds	95% C. I.
			ratio(OR)	
Sex	Female	0.5350	1.5556	0.3851-6.2832
	Male	*	*	*
Anesthesia type	General	0.4218	3.1875	0.1884-53.9157
	Spinal	*	*	*
Type of surgery	Elective	0.8434	1.1230	0.3552-3.5509
	Emergency	*	*	*
Perioperative use of	Yes	*	*	*
a warmer	No	0.0299	3.5238	1.1303-10.9857
Operating room	>24°C	*	*	*
temperature	22-24°C	0.7269	1.7327	0.0793-37.8782

Table: - 3 The association of variables to intraoperative hypothermia for pediatric patients who underwent surgery at KUTH

Intraoperative temperature and transfusion requirements

The diagram below illustrate that 9.60% of hypothermic patients were transfused compared to 5.90% of patients with normothermia. The table below shows that the odds of being transfused for a pediatric patient with hypothermia was 1.7 compared to the one with normothermia.

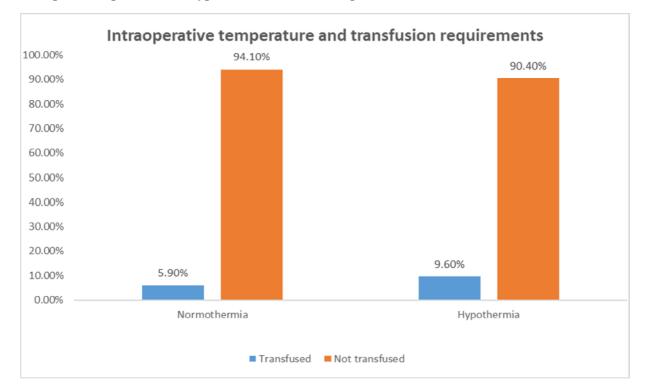


Figure 4 illustrates intraoperative hypothermia and transfusion requirements

Association of intra	operative hypot	hermia to t	ransfusion	requirements
	1 1			1

Variable	Category	p-value	Odds ratio(OR)	95% C. I.
Temperature	Hypothermia	0.6388	1.7021	0.1847-15.6839
	Normothermia	*	*	*

Table: - 4 The association of intraoperative hypothermia to transfusion for pediatric patients who underwent surgery at KUTH

The association of variables to postoperative hypothermia

Data from multivariate analysis implied that the odd of developing postoperative hypothermia for operating room temperature of between 22 to 24° C was almost 6 times as high as the odd of developing postoperative hypothermia for operating room temperature of >24°C. The odd of

Variables	Category	p-value	Odds ratio(OR)	95% C. I.
Sex	Female	0.8128	1.1818	0.2966-4.7084
	Male	*	*	*
Perioperative use	Yes	*	*	*
of a warmer	No	0.1253	2.8000	0.7506-10.4454
Operating room	>24°C		*	*
temperature	22-24°C	0.2417	5.9434	0.3008-117.4248

developing postoperative hypothermia when a warmer was not used perioperatively was almost 3 times as high as the odd of developing postoperative hypothermia when a warmer was used.

Table: - 5 illustrate the association of variables to postoperative hypothermia for pediatric patients who underwent surgery at KUTH

PACU BODY TEMPERATURE

The diagram below illustrates that a high proportion of patients with hypothermia stayed in PACU longer compared to patients with normothermia. After 30 minutes in PACU, 100% of patients with hypothermia were still in PACU compared to 77.5% of patients with normothermia. After 1 hour in PACU, 47.6% of patients with hypothermia were still in PACU compared to 42.5% with normothermia. After 2 hours in PACU, 6.3% of patients with hypothermia were still there compared to 2.5% of patients with normothermia.

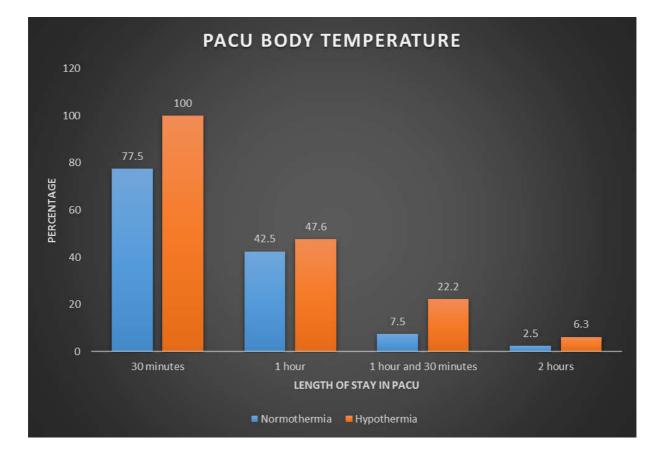


Figure 5 illustrates PACU length of stay according to body temperature in pediatric patients who underwent surgery at KUTH.

CHAP IV. DISCUSSION

In this study, perioperative hypothermia was assessed in pediatric patients. It was found that the incidence of pre, intra and post-operative hypothermia was 67%, 71.7% and 67.7% respectively. The incidence of intraoperative hypothermia is higher when compared to a study done by Pearce B et al at the University of Michigan Health System where the incidence of intraoperative hypothermia was 52% [3] and slightly higher when compared to a study done by Mulat Mossie in Ethiopia at Tikur Anbessa specialized hospital where the incidence of intraoperative hypothermia was 71.1%. [5]

A study done in 2017 in Tokyo, Japan by Yumoto M et al. on incidence of inadvertent intraoperative hypothermia with continuous air forced active warming in 16 years of age or younger patients found an hypothermia incidence of 54.5% which was lower compared to the one found in our study.[16]

A study conducted in 2016 in Ethiopia, Mulat Mossie found that the incidence of postoperative hypothermia was 78.9% [5] which was higher than the one found in our study. However, the incidence of postoperative hypothermia of our study was higher than the one found in a study done by Pearce B et al at the University of Michigan Health System where it was 52%.[3]

In 2013, Yi J, Xiang Z, Deng X, Fan T, Fu R, Geng W, et al conducted a prospective regional survey on incidence of inadvertent intraoperative hypothermia and its risk factors in patients undergoing general anesthesia in Beijing and found that high ambient temperature was protective of hypothermia which is consistent with the result of our study.[6]

In our study, We found that the use of general anesthesia increased incidence of intraoperative by more than three times (OR=3.18) as compared to the use of spinal anesthesia which is higher than the one found by Denu AZ, Semple P, Tawuye HY, Kassa AA in 2015 in their study at Gondar university hospital where the use of general anesthesia increased incidence of intraoperative hypothermia by more twice as compared to use of spinal anesthesia (AOR=2.3).[9] The same study conducted at Gondar university hospital, found that elective procedures increased incidence of intra operative hypothermia by 2.1 times.[9] which is higher than the one found in our study for which, elective procedures increased incidence of intraoperative hypothermia by 1.12 times.

In the study He conducted in 2016 in Ethiopia, Mulat Mossie found that operating room temperature was strongly associated with postoperative hypothermia and that females were three times more vulnerable for postoperative hypothermia than male pediatric patients.[5] Compared to the findings of our study, children who were operated at ambient temperature of 22-24°C were vulnerable to hypothermia than children who were operated at ambient temperature of >24°C and females were 1.18 times vulnerable for postoperative hypothermia than male pediatric patients.

An observational study done by Rosália G Páscoa in 2011 at Centro Hospitalar São João, in Portugal on postoperative hypothermia found that hypothermia was a risk factor for longer length post-anesthesia care unit stay. [17] In our study, hypothermic pediatric patients had a longer post-anesthesia care unit stay compared to patients with normothermia (100% versus 77.5% after 30 minutes,47.6% versus 42.5% after 1 hour ,22.2% versus 7.5% after 1 hour and 30 minutes and 6.3% versus 2.5%).

CHAP V. CONCLUSION AND RECOMMENDATION

V.I. CONCLUSION

This study revealed a high incidence of preoperative, intraoperative and postoperative hypothermia in operated pediatric patients.

Female patients, use of general anesthesia, elective surgery, not using a warmer perioperatively and low operating room temperature $(22-24^{\circ}C)$ were associated with intraoperative hypothermia. Female patients, not using a warmer perioperatively and low operating temperature $(22-24^{\circ}C)$ were associated with postoperative hypothermia.

Patients with hypothermia had increased transfusion requirements compared to patients with normothermia.

Hypothermic patients had longer PACU stay compared to normothermic patients.

V.II. RECOMMENDATION

Based on the finding of this study, the following recommendations are proposed

- Perioperative use of a warmer is paramount
- Patients should be warmed preoperatively
- Hypothermia should be prevented in pediatric wards
- Operative room temperature should be maintained at least above 24°C
- Monitoring PACU temperature should be done.

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CHAP VII. ANNEXES

VII.1. QUESTIONNAIRE

Instruction: For each of the questions, please circle the number of alternative(s) that fit the response or fill the blank space provided. If not applicable, skip the question and answer the next question.

No	Question	Answer
1	Age(including postconceptional age for neonates)	ryears or months or weeks or days
2	Sex	1.Male 2. Female
3	Weight	Kgs
4	Height	Cms
5	ASA classification	
6	Body temperature	
	On arrival to OR	°C
	After induction	°C
	After 1 hour of procedure	°C
	After 2 hours of surgery	°C
	After 3 hours of surgery	······°C
	After 4 hours of surgery	°C
	30 minutes after arrival in PACU	°C
	1 hour after arrival in PACU	°C
	1 hour and 30 minutes after arrival in PACU	°C
	2hours after arrival in PACU	°C
7	Anesthesia type	1. General
		2. Spinal
0		3. Nerve block
8	Total intraoperative IV fluids	ml
9	Use of warm IV fluids	1. Yes
10		2. No
10	Transfusion	1. Yes

		2. No
	If yes, number of units	
11	Massive transfusion	1. Yes
		2. No
12	Duration of anesthesia	minutes
13	Operation room temperature	°C
14	Type of operation(Surgery)	1. Elective
		2. Emergency
15	Duration of surgery	minutes
16	Perioperative use of a warmer	1. Yes
		2. No

VII. 2 INFORMATION SHEET AND CONSENT FORM for the study entitled "incidence, risk factors and outcome of Perioperative hypothermia in pediatric patients at Kigali University Teaching Hospital"

AMAKURU N'ICYEMEZO CYO KUGIRA URUHARE MU BUSHAKASHATSI

Researcher identification: *Umwirondoro w' umushakashatsi*

UWIMANA Jean Claude, MD, Resident in Anesthesiology at the University of Rwanda UWIMANA Jean Claude, Umuganga uri kwiga gutanga ikinya muri Kaminuza y'u Rwanda

Purpose of the Research project: Impamvu y'ubushakashatsi

The aim of this study is to determine the incidence of perioperative hypothermia and identify factors associated with intraoperative hypothermia in pediatric patients operated at Kigali University Teaching Hospital (KUTH). The results of this study will be used by policy makers at KUTH to come up with strategies to prevent or reduce the risks of perioperative hypothermia.

Intego y'ubu bushakashatsi ni ukureba ubukana bw'ubutita igihe kibanziriza kubagwa, igihe cyo kubagwa n'igihe cya nyuma yo kubagwa hamwe no kumenya impamvu zishobora gutera ubutita mu bana babagirwa ku bitaro bya KUTH .Ibisubizo bizava muri ubu bushakashatsi bizafasha ubuyobozi bwa KUTH gushyiraho uburyo bwo kwirinda cyangwa kugabanya ibitera ubutita mu gihe kibanziriza kubagwa, mu gihe cyo kubagwa ndetse no mu gihe gikurikira kubagwa.

How long will I take part of this research?

Igihe ubushakashatsi buzamara

The study will take around 5 months from April 2018 to September 2018. *Ubushakashatsi buzamara amezi 5.*

Benefits, Risk or Discomfort

Ibyago n'inyungu zo kuba muri ubu bushakashatsi

There will be no direct benefit to study participants. But the result of this study will be used for further improvement of the service. There will be no risk of participating in this study.

Nta nyungu z'ako kanya uzabona muri ubu bushakashatsi, ariko amakuru y'ubu bushakashatsi azakoreshwa mu kunoza serivisi duha abarwayi. Nta byago duteganya igihe waba uri muri ubu bushakashatsi.

Participation is voluntary *Kwitabira ni ku bushake*

Confidentiality:

Ibanga:

The information collected from the study subjects will be kept confidential and by assigning a code number to each patient. The name of your child will not be recorded or used in any report. When the study is completed and the data have been analyzed, this list will be destroyed.

Amakuru yose utanga muri ubu bushakashatsi azagirwa ibanga. Ayo makuru azahabwa inumero y'ibanga. Nta hantu na hamwe amazina yawe azakoreshwa. Ubu bushakashatsi niburangira, ayo makuru yose azahanagurwa.

Right to refusal or withdraw

Igihe wahagarikira uruhare rwawe muri ubu bushakashatsi:

Study subjects will have full right to refuse from participating in this research without penalty.

Ushobora guhagarika uruhare rwawe muri ubu bushakashatsi igihe icyo aricyo cyose kandi nta gihano

Persons to contact

For any questions or concerns you can contact the principal investigator using the following addresses:

Niba ufite ibibazo bijyanye n'ubu bushakashatsi, binyuze kuri aba bakurikikira:

Name: Dr UWIMANA Jean Claude Phone: 0782752037/0728752037 E-mail:uwijenclau9@gmail.com Name: Dr UWINEZA Jean Bonaventure Phone: 0788493096 E mail:uwinezajeanbonaventure@gmail.com

STUDY SUBJECTS CONSENT FORM

Kwemera kugira uruhare mu bushakashatsi

As a parent or adult guardian of this child, I agree to take part in this study described above .Assent for the child is also needed/if he can talk.

Nk'umubyeyi cyangwa undi muntu uhagarariye uyu mwana, ndemera kugira uruhare muri ubu bushakashatsi nasobanuriwe.

Parent/Guardian Signature:		Date:
Umukono	w'umubyeyi/Umuhagarariye:	
Itariki:		

VII.3 CMHS IRB APPROVAL



COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 12th /02/2018

Torona lana di tari di su di sutata an

Dr UWIMANA Jean Claude School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 057 /CMHS IRB/2018

Your Project Title "Incidence, Risk Factors And Outcome Of Perioperative Hypothermia In Pediatric Patients At Kigali University Teaching Hospital" has been evaluated by CMHS Institutional Review Board.

			Involved in the decision		
			No	(Reason)	
Name of Members	Institute	Yes	Absent	Withdrawn from the proceeding	
Prof Kato J. Njunwa	UR-CMHS		X		
Prof Jean Bosco Gahutu	UR-CMHS	X			
Dr Brenda Asiimwe-Kateera	UR-CMHS	X			
Prof Ntaganira Joseph	UR-CMHS	X			
Dr Tumusiime K. David	UR-CMHS	X	1. 1.		
Dr Kayonga N. Egide	UR-CMHS	X		A CONTRACTOR OF THE	
Mr Kanyoni Maurice	UR-CMHS	X	12 2 2 2 2		
Prof Munyanshongore Cyprien	UR-CMHS	X			
Mrs Ruzindana Landrine	Kicukiro district		X		
Dr Gishoma Darius	UR-CMHS	X			
Dr Donatilla Mukamana	UR-CMHS	X			
Prof Kyamanywa Patrick	UR-CMHS		X		
Prof Condo Umutesi Jeannine	UR-CMHS		X		
Dr Nyirazinyoye Laetitia	UR-CMHS	X			
Dr Nkeramihigo Emmanuel	UR-CMHS	X			
Sr Maliboli Marie Josee	CHUK	X			
Dr Mudenge Charles	Centre Psycho-Social	X			

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 12th March 2018, **Approval has been granted to your study**.

EMAIL: researchcenter@ur.ac.rw P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/ www.ur.ac.rw

Please note that approval of the protocol and consent form is valid for 12 months.

You are responsible for fulfilling the following requirements:

- 1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
- 2. Only approved consent forms are to be used in the enrolment of participants.
- 3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
- 4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
- 5. Failure to submit a continuing review application will result in termination of the study
- 6. Notify the IRB committee once the study is finished
- .

Sincerely,

Date of Approval: The 12th March 2018

Expiration date: The 12th March 2019

Professor Kato J. NJUNWA Chairperson Institutional Review Board, College of Medicine and Health Sciences, UR



Cc:

- Principal College of Medicine and Health Sciences, UR

- University Director of Research and Postgraduate Studies, UR

EMAIL: researchcenter@ur.ac.rw P.O. Box: 3286. Kigali. Rwanda WEBSITE: http://cmhs.ur.ac.rw/www.ur.ac.rw

VII.4 KUTH ETHICS COMMITTEE APPROVAL



CENTRE HOSPITALIER UNIVERSITAIRE UNIVERSITY TEACHING HOSPITAL

Ethics Committee / Comité d'éthique

April 09th, 2018

Ref.: EC/CHUK/566/2018

Review Approval Notice

Dear Uwimana Jean Claude,

Your research project: "Incidence, risk factors and outcome of perioperative hypothermia in Paediatric patients at CHUK."

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 09/04/2018 to evaluate your protocol of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your protocol.

You are required to present the results of your study to CHUK Ethics Committee before publication.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,



Dr. Rusingiza Emmanuel The President, Ethics Committee,

University Teaching Hospital of Kigali

<< University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations>>>.

B.P.: 655 Kigali- RWANDA www.chk.rw Tél. Fax: 00 (250) 576638 E-mail: chuk.hospital@chukigali.rw