COMPARISON OF INTRAOPERATIVE TEMPERATURE MONITORING BY ZHF DEVICE AND NASOPHARYNGEAL TECHNIQUES IN PEDIATRIC PATIENTS: A PROSPECTIVE, OBSERVATIONAL STUDY

THESIS

Submitted to

All India Institute of Medical Sciences, Jodhpur
In partial fulfillment of the requirement for the degree of
DOCTOR OF MEDICINE (MD)
(ANAESTHESIOLOGY AND CRITICAL CARE)

JULY 2020 **DR NAVIN VINCENT**

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DECLARATION

I here declare that thesis titled "**COMPARISON OF INTRAOPERATIVE TEMPERATURE MONITORING BY ZHF DEVICE AND NASOPHARYNGEAL TECHNIQUES IN PEDIATRIC PATIENTS: A PROSPECTIVE, OBSERVATIONAL STUDY**" embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

The submitted thesis "**COMPARISON OF INTRAOPERATIVE TEMPERATURE MONITORING BY ZHF DEVICE AND NASOPHARYNGEAL TECHNIQUES IN PEDIATRIC PATIENTS: A PROSPECTIVE, OBSERVATIONAL STUDY"** has been evaluated on iThenticate software platform and the report reads that the submitted thesis has no similarity in the discussion and introduction section.

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CERTIFICATE FROM THE SUPERVISORS

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Institutional Ethics Committee

No. AIIMS/IEC/2021/3486 **Date: 12/03/2021**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3321**

Project title: **"Comparison of intraoperative temperature monitoring by ZHF device and nasopharyngeal techniques in pediatric patients: A prospective, observational study"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr. Navin Vincent**
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On behalf of Ethics Committee, I wish you success in your research.

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Member Secretary

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intro

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ACKNOWLEDGEMENT

"Acknowledge all of your small victories. They will eventually add up to something great"

-Kara Goucher

First and foremost, I offer my gratitude to The Almighty **God** for blessing me for completing my thesis project. Nothing can be possible without the good guidance of teachers, by saying these words, I would like to express my deep and sincere gratitude to

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Dr. NAVIN VINCENT

ABBREVIATIONS

IV	Intra Venous
ZHF	Zero Heat Flux
MAC	Minimum Alveolar Concentration
Min	Minutes
GA	General Anaesthesia
ASA	American Society of Anaesthesiologist
OT	Operation Theatre
ECG	Electrocardiogram
NIBP	Non-invasive Blood Pressure
LA	Local Anesthetic

SUMMARY

BACKGROUND

Perioperative Hypothermia is one of the adverse effects of General Anaesthesia, especially in the pediatric age group, which may lead to undesirable effects. The Pulmonary Artery Thermistor is the gold standard for core temperature monitoring. But the usage of the gold standard modality might not be a feasible option in the pediatric age group, especially in the case of patients undergoing non-cardiac or minor surgeries. On the other hand, the Zero Heat Flux devices are well tolerated by awake pediatric patients and are purely non-invasive. Hence, we planned this study to compare the ZHF sensor with the Nasopharyngeal probe in children undergoing General Anesthesia.

METHOD

In this prospective, observational study, pediatric patients aged 1 to 12 years, who were to undergo surgeries under General Anaesthesia were enrolled. Intraoperative core temperature monitoring was done using both the ZHF device and the Nasopharyngeal probe simultaneously. Core temperatures from both devices were recorded every 15 minutes.

RESULTS

In this study, the ZHF device is showing a statistically significant difference in temperature reading when compared to the Nasopharyngeal probe till 90 minutes, but there is no clinically significant difference. Core temperature readings after 90 minutes are not showing any statistical or clinically significant difference in both devices. The correlation coefficient between the ZHF and the Nasopharyngeal device is 0.928, showing that the ZHF sensor is having an acceptable accuracy for usage in clinical settings.

CONCLUSION

We conclude that for perioperative core temperature monitoring in pediatric patients undergoing General Anaesthesia, the Zero Heat Flux sensor showed a significant agreement with the Nasopharyngeal probe.

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INTRODUCTION

INTRODUCTION

General Anaesthesia can impair the thermoregulatory response and may contribute to perioperative hypothermia, more so in children. Intraoperative monitoring of core body temperature is thus recommended in General Anaesthesia lasting more than 30 min.[1] Maintenance of core body temperature in the intraoperative period is a great challenge in the paediatric population, who are quite vulnerable to temperature variations due to various reasons. When compared to adult patients, paediatric patients lose a disproportionate amount of the core temperature via conduction and radiation. Due to their thin skin and the fact that children have a higher body surface area than adults, evaporative losses are also substantial. [2]

Inadvertent hypothermia during the perioperative period is associated with complications such as impaired coagulation, greater blood loss, increased cardiac morbidity, higher incidence of wound infections, and patient discomfort. Hence, adequate perioperative measurement of core temperature is a prerequisite.[3]

The Pulmonary artery catheter is the gold standard for intraoperative core temperature monitoring. Alternative sites for core temperature measurements include the tympanic membrane, the esophagus, the nasopharynx and the bladder.[4] Except for pulmonary artery catheter which is an invasive technique, all the other methods mentioned are semi-invasive techniques. The monitoring of core temperature prior to anaesthesia induction is rarely possible with any of these devices. Non-invasive methods, such as sublingual devices, can be used on conscious individuals and offer rather excellent accuracy, but they usually won't enable continuous monitoring.[5]

Zero heat flux (ZHF), which was developed in 1973 and has been compared with other sensors, is a unique method of monitoring core temperature from the surface of the skin.[1,6] The ZHF system is based on the concept that as long as the core temperature is higher than the skin temperature, heat will transfer from the core to the skin surface. The sensor used by the ZHF system is composed of a thermometer that is fixed directly to the skin's surface, an insulation layer placed over it, a second thermometer, and finally a servo-controlled heater.[1,10] The heater is programmed in such a way that the temperature difference measured by the two

thermometers is maintained as zero. In this ZHF system, since there is no temperature gradient, we can infer that the subcutaneous temperature is identical to the surface temperature that was measured, and we use this temperature as a proxy for the core body temperature[1]

The present study aims to compare the ZHF sensor with the Nasopharyngeal probe with respect to their correlation, accuracy and precision in paediatric population undergoing surgery under General Anaesthesia.

AIMS & OBJECTIVES

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AIM

To assess and compare the intraoperative core temperature monitoring by Zero Heat Flux (ZHF) device and Nasopharyngeal probes in children

OBJECTIVES

- PRIMARY : To compare the methods of temperature monitoring between ZHF and Nasopharyngeal temperature monitoring devices.
- SECONDARY: To monitor any side effects

REVIEW OF LITERATURE

REVIEW OF LITERATURE

1. **West n et al (2019)** conducted the study on Zero-heat-reflux core temperature monitoring system: an observational secondary analysis in adult population to evaluate agreement with naso-/oropharyngeal probe during anaesthesia. Data were collected in 194 patients with procedures lasting 120 (89-185) min. The ZHF measurements had a mean bias of -0.05°C with 95% limits of agreement within -0.68 to +0.58 degree Celsius. They concluded that core body temperature obtained with Bair Hagger ZHF – based monitoring system demonstrated moderate agreement with temperature from standard naso-/oropharyngeal temperature probes.

2. **Carvalho H et al (2019)** conducted a prospective study on Intraoperative temperature monitoring with cutaneous zero -heat -flux thermometry in comparison with oesophageal temperature in paediatric population. Esophageal temperature probe and SpotOn sensor were placed after induction of anaesthesia. Temperature was then recorded in pairs per 1-minute intervals. The study concluded that SpotOn has been shown to be as accurate as oesophageal temperature probe when estimating central core temperature.

3. **Iden T et al (2015)** conducted an observational study in adult population were they aimed to evaluate the new temperature sensor (3M SpotOn) and compare it with sublingual and nasopharyngeal sensors in terms of correlation, accuracy and precision. Among one hundred and twenty patients enrolled, analysis of 83 data sets revealed that 3M SpotOn temperatures were almost identical to that of nasopharyngeal temperatures and little lower than sublingual temperatures. Thus the study arrived at a conclusion that 3M SpotOn sensor using the ZHF method is an adequate, non-invasive, single-use device for temperature monitoring.

4. **Morettini E et al (2019)** conducted a prospective study in children aged <18yrs undergoing urological surgeries on Intraoperative core temperature monitoring to assess the accuracy and precision of ZHF controlled servo sensor compared with esophageal temperatures. Data analysis have shown that the ZHF temperature probe has demonstrated an acceptable clinical concordance compared to esophageal probe and can possibly replace the

esophageal probe for core temperature measurements in patients undergoing elective urologic and abdominal major surgeries.

5. **Boisson M et al (2018)** conducted a prospective observational study on Intra-operative cutaneous temperature monitoring with ZHF technique in comparison with oesophageal and arterial temperature in adults undergoing major abdominal surgeries. Statistical analysis showed that the esophageal temperature bias and limits of agreement for ZHF temperatures were 0.1+/- 0.5 degree Celsius during slow core temperature changes periods and 0.6+/-1.8 degree Celsius during RCTC periods. When compared to Arterial temperatures, these values were 0.1+/-0.4 and 0.5+/-1.7 degree celsius. The study concluded that – A SpotOn sensor using ZHF method is reliable for core temperature monitoring during abdominal surgery when the variations in temperature are slow rather than rapid.

6. **Conway A et al (2020)** conducted a systemic review and meta analysis among adults on Accuracy and precision of ZHF temperature measurements with the 3M Bair Hugger Temperature monitoring system. 16 studies were included in the meta analysis having data from 952 participants with 3,14,137 paired measurements. The systematic review was suggestive that the ZHF temperature monitoring device has temperature readings as much as 1 degree Celsius higher or lower than core temperature.

7. **Jack JM et al (2019)** conducted a study in patients aged over 18 years to determine the accuracy of zero-flux and ingestible thermometers in peri-operative settings. 30 patients were then recruited to the study, data analysis done showed mean+/- SD duration per subject was 84+/-46 min, with a total of 2511 measurements made with both devices. The study concluded that ZHF device is to be a reliable, practical and accurate continuous measure of core temperature during elective surgeries that could potentially be used for awake patients as it is a non-invasive technique.

8. **Brajkovic D et al (2005)** conducted a study which evaluated a zero heat flux non-invasive temperature probe for the in-vivo measurements of resting muscle temperature of 8 male subjects for up to 2cm below the skin surface. They concluded that ZHF probe will not provide an absolute measurement of thigh muscle temperature up to 2cm below the skin surface.

9. **Yamakage M et al (2005)** conducted a study among adult population undergoing general anesthesia on deep temperature monitoring using a ZHF method . The study evaluated and considered regarding the application of a thermal insulator over a large area of the skin surface might be more effective than the smaller area of the current version in bringing the surface temperature close to that of deep tissues. They concluded that the non-invasive deep temperature thermometer using the zero-heat-flow method enables measurement of the deep body temperature indirectly from intact skin surface.

10. **Pesonen E et al (2018)** conducted a study on The focus of temperature monitoring with zero-heat-flux technology (3M Bair-Hugger): a clinical study with patients undergoing craniotomy. The temperature readings obtained 15 min post induction for nasopharyngeal probe was 36.1+/-0.5 degree Celsius and corresponding ZHF temperature was 36.5+/-0.4 degree Celsius. Gradually the ZHF temperature declined and approximately 45min after anaesthesia induction, it was almost similar to that of nasopharyngeal temperature readings. The study concluded that the Bair Hugger ZHF system operates with good agreement with other modalities of core temperature monitoring.

11. **Tachibana S et al (2019)** conducted a pilot study on temperature monitoring in adults undergoing general anesthesia using the Blair Hugger system in neck and chest regions. 30 female patients were included in the study and the participants were then divided into three groups- the forehead group, neck group and anterior chest group according to different sites of attachment of BHTMS sensor. Study concluded that it is possible to monitor core body temperature seamlessly with the BHTMS in the neck region.

12. **Sessler DI et al (2008)** conducted a study on temperature monitoring and perioperative thermoregulation in adults undergoing general anesthesia and concluded that core temperature, while by no means completely characterizing body heat content and distribution ,is the best single indicator of thermal status in humans

13. **Nemeth M et al (2020)** conducted an observational study in 100 infants and young children to assess the reliability of zero-heat-flux thermometry when compared to esophageal temperature probe. Data analysis showed that ZHF system had a mean bias of +0.26 degree Celsius(95% CI +0.22 degree Celsius to +0.29 degree Celsius) when compared with the standard esophageal probes used for core temperature monitoring . The study concluded

that the risk of perioperative hypothermia may be underestimated and at the same time, the risk of hyperthermia may be overestimated.

14. **Sang BH et al (2022)** did a prospective comparative analysis of noninvasive body temperature monitoring using zero heat flux technology(SpotOn sensor) compared with esophageal temperature monitoring in pediatric surgery patients. 49 patients aged 1-8 years with ASA I/II were recruited. Pearson rank correlation between esophageal and axillary pairs gave a correlation coefficient (r) of 0.89 (95% CI 0.87 -0.91). They came to a conclusion that SpotOn sensor showed high correlation with the esophageal probe in pediatric patients.

15. **Bräuer A et al (2020)** A prospective, observational study was done comparing core temperatures measured with Zero heat flux thermometer and bladder catheter against blood temperature in 50 critically ill patients. They concluded that the zero-heat-flux and bladder temperatures were almost identical, thus suitable for clinical use.

16. **Hart D et al (2020)** A prospective observational quality improvement project was done comparing non-invasive zero-heat-flux with traditional core temperature measurements in the emergency department. 268 patients were included in the study and the mean temperatures were 36.6 degree Celsius for T_{core} and 36.3 degree Celsius for $T_{ZHF.}$ Study concluded that temperature variations increased with increase in body temperature.

17. **Kollmann Camaiora A et al (2018)** conducted a comparative study for validation of Zero-heat-flux thermometer with esophageal core temperature in major gynecological surgeries in monitoring intraoperative core temperature.70 patients were recruited for the study and 66 patients data were analysed. They concluded that there is a high overall correlation between the SpotOn and the esophageal probes.

18. **Aksu Erdost H et al (2021)** conducted an observational study comparing Zero heat flux technology with tympanic and esophageal temperatures for intraoperative temperature monitoring. They concluded that the zero heat flux method provided temperature measurements comparable with esophageal temperature measurements.

19. **Shell Chaple HM et al (2018)** conducted a prospective observational study comparing Forehead core temperatures using SpotOn with rectal & bladder temperatures. 38 patients were recruited to the study and the differences in temperatures were within +/- 0.5 degree Celsius in both groups. The study concluded that the SpotOn system has good agreement and can be considered as potential alternative for non-invasive monitoring of core temperature.

20. **Dahyot Fizelier c et al (2017)** did a study to compare the accuracy of zero heat flux method to esophageal temperature and arterial temperature in Intensive care patients. Bias and limits of agreement for temperature using zero-heat-flux were 0.19℃+/- 0.53℃ when compared to esophageal temperatures. They concluded that temperature measurements with cutaneous sensor using zero heat flux method is a reliable alternative measure for temperature monitoring in intensive care patients.

21. **Jack JM et al (2019)** conducted a study to determine the accuracy of zero-flux and ingestible thermometers in the peri-operative setting. Thirty patients undergoing surgical procedures under general anaesthesia were included in the study. The study concluded that zero-flux thermometer is accurate and reliable for clinical use but the ingestible sensors are not.

22. **Lauronen SL et al (2022)** conducted a study on Zero heat flux and double sensor (DS), which are non-invasive methods that measure the core temperature from forehead skin. Sixty patients were recruited and divided into two groups of thirty patients each. They concluded that the mean difference between ZHF and DS temperatures increased as the core temperature decreased.

23. **Bisonnette B (1992)** in a review article mentioned the importance of temperature monitoring in pediatric anesthesia. The article discuss regarding the major causes of perioperative hypothermia and the importance of maintenance of normothermia during intraoperative period. Article also mentioned that perioperative hypothermia can be decreased by prewarming the skin surface before induction of anesthesia, warming the operating room, humidifying the airway, and by warming intravenous fluids.

24. **Lee SY et al (2020)** conducted a study to determine the risk factors of hypothermia and to determine the effectiveness of ongoing interventions in the pediatric population. 869

patients (<16 years of age) undergoing emergency or elective surgeries were recruited in the study. Statistical analysis were done to identify the risk factors of hypothermia. The study concluded that intraoperative core temperature monitoring and active forced-air warming are ideal measures to prevent hypothermia along with occlusive dressings and maintenance of ambient OT temperature.

25. **Bindu B et al (2017)** published a review article emphasizing the importance of temperature management under General Anesthesia. The article discuss regarding the basic physiology of thermoregulation, effects of anesthesia, different temperature monitoring devices, guidelines for intraoperative temperature management and inadvertent temperature complications like hypothermia and hyperthermia.

JUSTIFICATION OF THE STUDY

Literature reveals that the Zero Heat Flux sensor has been found comparable to the Nasopharyngeal probe in adults for measurement of core body temperature intraoperatively. To the best of our knowledge, there is no single study comparing the ZHF sensor and Nasopharyngeal probe in children, hence we planned this study

MATERIALS & METHODS

MATERIALS & METHODS

STUDY SETTING:

This observational study was conducted in the Department of Anesthesiology and Critical Care, AIIMS, Jodhpur after getting approval from Institutional Ethical Committee **(**IEC Ref.No: **AIIMS/IEC/2021/3321)** and registration in CTRI **(**Reg.No:**CTRI/2021/06/034389)**. Written informed consent was obtained from parents/ guardians of children and assent was taken from children >7 years of age. Intraoperative temperature monitoring of paediatric population aged 1-12years was done with ZHF and Nasopharyngeal temperature probes simultaneously, admitted for elective surgeries under General Anaesthesia in AIIMS Jodhpur.

STUDY DESIGN:

Prospective, Observational Study

STUDY PARTICIPANTS:

INCLUSION CRITERIA:

- Paediatric patients of age 1-12 years, ASA grade I/II undergoing elective surgeries under General Anaesthesia for a period of >30min

EXCLUSION CRITERIA:

1. Refusal of informed consent/ assent
2. Fragile forehead skin.
3. Known allergy to probe adhesive or any constituent components.
4. Procedures impending proper placement of ZHF sensor (Eg: Head & Neck surgeries)
5. Coagulopathy.
6. Hemodynamic instability.
7. Neurologically impaired children with abnormal thermoregulation.
8. Emergency surgery
9. Fever or infection

METHODOLOGY

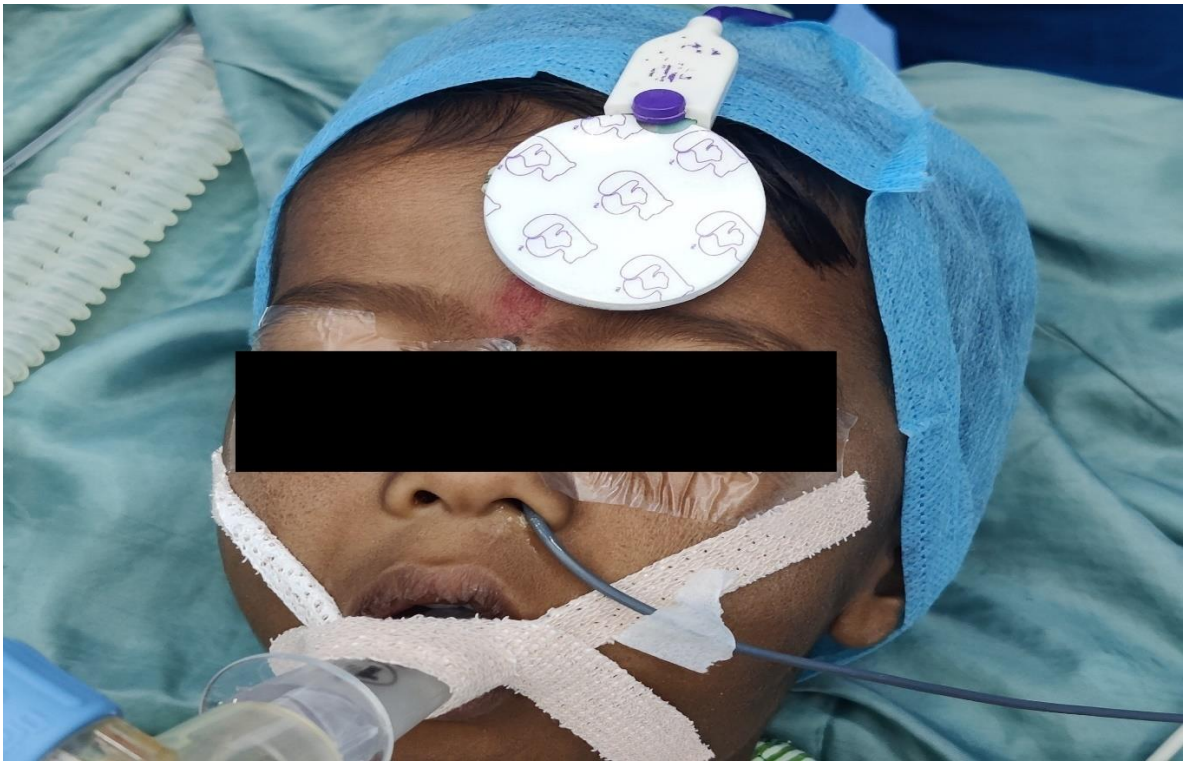
After approval from Institute's ethical committee, children of age group 1-12 years, ASA grade I/II , undergoing surgeries lasting >30min were recruited into the study. PAC (Pre Anesthetic Check-up) was done a day prior to scheduled elective surgery. After written informed consent taken from the parents or local guardian and assent from children >7 years of age, patient temperature was monitored intraoperatively with two monitoring devices:ZHF (3M SpotOn) and Nasopharyngeal probe simultaneously.

Fasting was ensured as per the Institution's protocol. All patients were taken to Operation theatre after premedication with I.V midazolam (0.025 to 0.05mg/kg) and ketamine (0.5mg/kg). OT room temperature was standardized through central AC control to 25degree Celsius. All standard ASA monitoring including electrocardiography (ECG), Pulse oximetry (SpO2), Non-invasive blood pressure(NIBP) and temperature probe was applied. Intravenous fluid was administered through fluid warmer set at a temperature of 37 degrees C. An Endotracheal tube or I gel will be inserted after induction of General Anaesthesia. Patients will be actively warmed during surgery using a forced air warming unit (3M Bair Hugger Patient Warmer-675).

After induction of anesthesia, both the probes will be applied: 3M SpotOn sensors and Nasopharyngeal probe. The data obtained will be entered in -spreadsheet and will be analyzed.

3M SpotOn sensor will be attached to the forehead after wiping the forehead with chlorohexidine using the ZHF method. Nasopharyngeal probe will be inserted through the roomier nostril after applying LA gel at its tip till it is placed in nasopharynx.

Temperature monitoring will be monitored continuously and simultaneously for both the probes. The data will be recorded in the proforma after every 15 min starting at 0, 15 min, 30 min, 45 min, 60 min, 75 min, 90 min, 105 min, 120 min, till the end of surgery. All these probes will be removed before emergence of the patient from GA.



ZHF DEVICE PLACED OVER FOREHEAD AND NASOPHARYNGEAL PROBE PLACED IN POSITION (INTRAOPERATIVE IMAGE)

SAMPLE SIZE AND STATISTICAL ANALYSIS PLAN:

The study will be time-bound, for a duration of 15 months [Jan 2021 - May 2022] conducted in the Pediatric population aged 1-12yrs undergoing General Anaesthesia in AIIMS, Jodhpur

Descriptive statistics were done using mean with standard deviation for quantitative variables, and categorical variables were presented in frequencies along with respective percentages. The statistical comparisons for quantitative variables were done using Student's *t-test* and for categorical variables, the Chi-square test was used according to the data. All statistical analyses were performed using SPSS software (Version 22, SPSS Inc., Chicago, IL, USA). All analyses were two-tailed, and results were discussed on a 5% level of significance, i.e., $P < 0.05$ was considered statistically significant. Correlations between the Zero Heat Flux device and Nasopharyngeal probe were evaluated using Pearson correlation coefficient analysis.

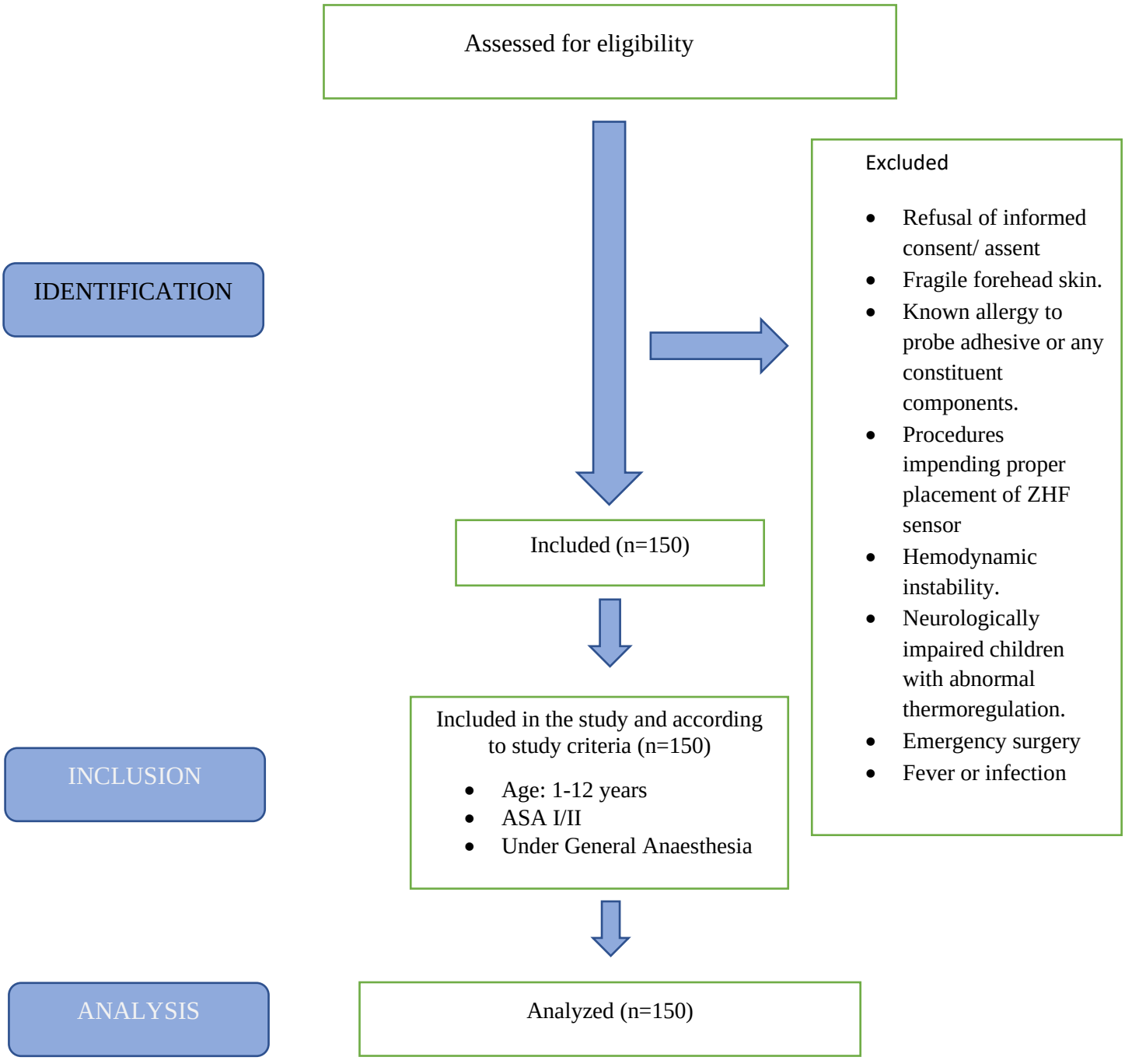
OBSERVATION

&

RESULTS

OBSERVATION & RESULTS

This prospective observational study was conducted in the Department of Anaesthesiology and Critical Care, AIIMS, Jodhpur on 150 children of age group 1 to 12 years with ASA physical status I or II of either sex.



STROBE FLOW DIAGRAM

TABLE 1: AGE & WEIGHT DISTRIBUTION OF THE STUDY GROUP

	MEAN	SD
AGE	5.27	3.49
WEIGHT	18.34	9.17

In this study, the mean age of patients is 5.27 +/- 3.49. The Mean weight of patients in the study is 18.34 +/-9.17

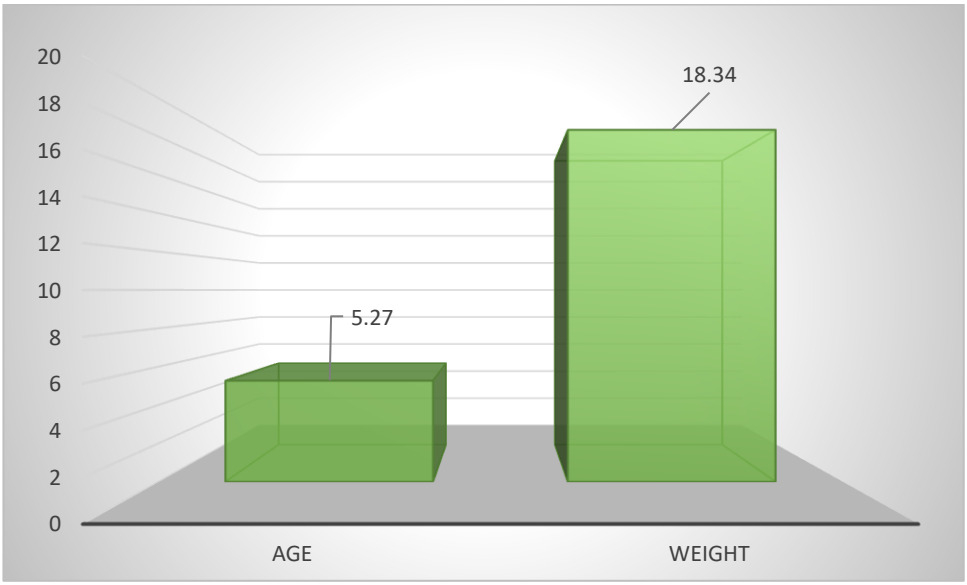


FIGURE 1: MEAN AGE & WEIGHT DISTRIBUTION

TABLE 2: GENDER DISTRIBUTION IN THE STUDY GROUP

SEX	NO.	%
MALE	131	87.33
FEMALE	19	12.66
TOTAL	150	100.00

In this study, the number of males and females enrolled in both (ZHF and Nasopharyngeal) groups were 131 (87.33%) and 19 (12.66%) respectively

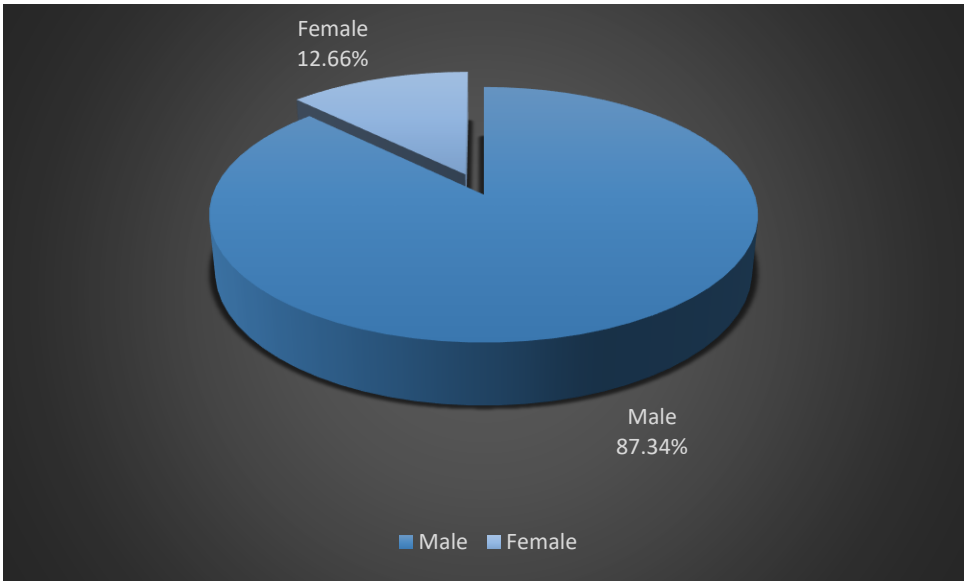


FIGURE 2: GENDER DISTRIBUTION IN THE STUDY GROUP

TABLE 3: COMPARISON OF TEMPERATURE READINGS BETWEEN THE ZERO HEAT FLUX DEVICE AND NASOPHARYNGEAL DEVICES

	Nasopharyngeal		**ZHF**	
	Mean	**SD**	**Mean**	**SD**
15 min	36.35	0.35	36.57	0.35
30 min	36.38	0.36	36.57	0.36
45 min	36.37	0.40	36.57	0.39
60 min	36.45	0.42	36.57	0.39
75 min	36.38	0.44	36.57	0.44
90 min	36.40	0.42	36.59	0.44
105 min	36.47	0.43	36.64	0.40
120 min	36.55	0.47	36.74	0.41
135 min	36.56	0.49	36.71	0.43
150 min	36.36	051	36.49	0.39
165 min	36.46	0.40	36.65	0.34
180 min	36.55	0.49	36.60	0.28
195 min	36.65	0.64	36.65	0.35

In this study, the mean difference between the readings of the Zero Heat Flux device and the Nasopharyngeal probe decreases as time progresses. The mean readings at 195th minute are almost similar for the ZHF device (36.65+/-0.64 °C) and the Nasopharyngeal probe (36.65+/-0.35).

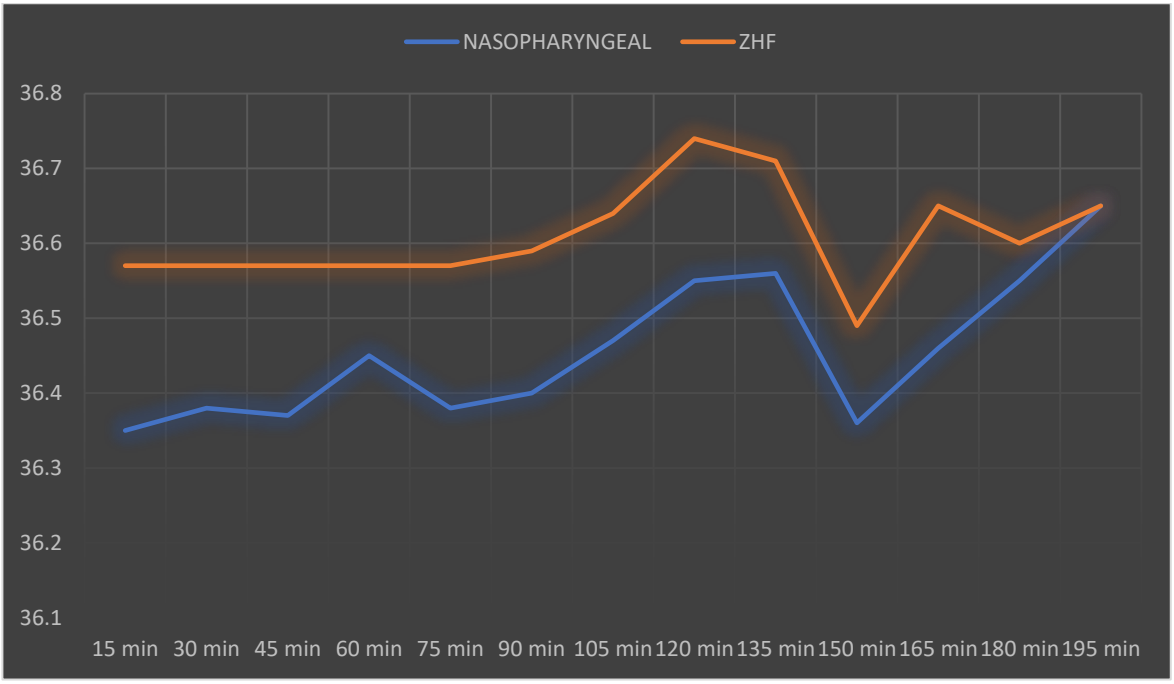


FIGURE 3: COMPARISON BETWEEN MEAN TEMPERATURE READINGS OF THE ZHF DEVICE & THE NASOPHARYNGEAL PROBE

TABLE 4: PEARSON CORRELATION COEFFICIENT (r) (95% CONFIDENCE INTERVAL)

Time (min)	NASOPHARYNGEAL and ZHF
15 min	0.9331 (-0.2414 to -0.1999)
30 min	0.902 (-0.2218 to -0.1702)
45 min	0.926 (-0.2046 to -0.1488)
60 min	0.875 (-0.1703 to -0.1154)
75 min	0.948 (-0.1533 to -0.08774)
90 min	0.948 (-0.145 to -0.06879)
105 min	0.915 (-0.1026 to -0.01736)
120 min	0.940 (-1.546 to 4.246)
135 min	0.960 (-0.04225 to 0.008919)
150 min	0.873 (-0.3381 to 0.08814)
165 min	0.845 (-0.4437 to 0.2437)
180 min	1 (-1.956 to 1.856)
195 min	1 (-2.541 to 2.541)

In this study, Analysis of the Pearson rank correlation between the Zero Heat Flux and the Nasopharyngeal pairs showed a correlation coefficient (r)of 0.928.

TABLE 5: DIFFERENCE BETWEEN MEAN TEMPERATURE READINGS OF ZHF AND NASOPHARYNGEAL PROBES

	NASOPHARYNGEAL	ZHF	DIFFERENCE
15 min	36.35	36.57	***0.22***
30 min	36.38	36.57	***0.19***
45 min	36.37	36.57	***0.2***
60 min	36.45	36.57	***0.12***
75 min	36.38	36.57	***0.19***
90 min	36.4	36.59	***0.19***
105 min	36.47	36.64	***0.17***
120 min	36.55	36.74	***0.19***
135 min	36.56	36.71	***0.15***
150 min	36.36	36.49	***0.13***
165 min	36.46	36.65	***0.19***
180 min	36.55	36.6	***0.05***
195 min	36.65	36.65	***0***

In this study, the maximum difference between the means of the ZHF sensor and the Nasopharyngeal probe is 0.22°C and the average difference between both modalities is 0.15°C

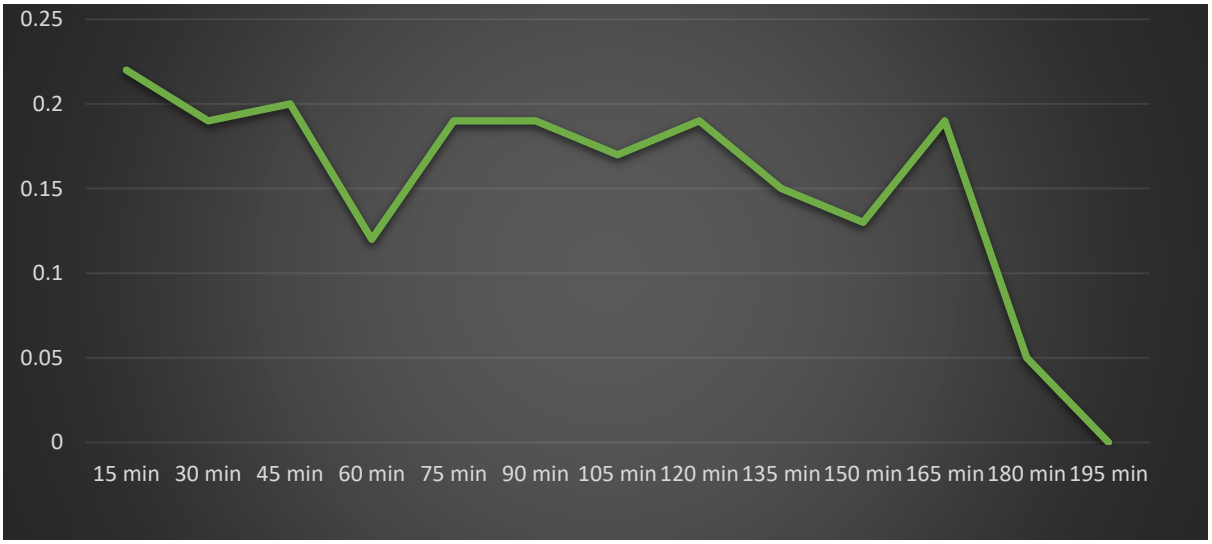


FIGURE 4: DIFFERENCE OF MEAN TEMPERATURE READINGS OF ZHF SENSOR & NASOPHARYNGEAL PROBE

TABLE 6: COMPARISON OF DIFFICULTIES FACED ON PLACEMENT OF ZHF AND NASOPHARYNGEAL DEVICES

	Number of Cases	Percentage
NO ISSUES	139	92.6
ZHF ADHESIVE ISSUE	10	6.67
ZHF SENSOR ERROR	1	0.67
Grand Total	150	100.00

In this study, no issues were encountered in 139 cases (92.6%) during the placement of either the ZHF device or the Nasopharyngeal probe. ZHF adhesive issue occurred in 10 cases (6.67%) and ZHF sensor error occurred in 1 case (0.67%) while placement of the probe.

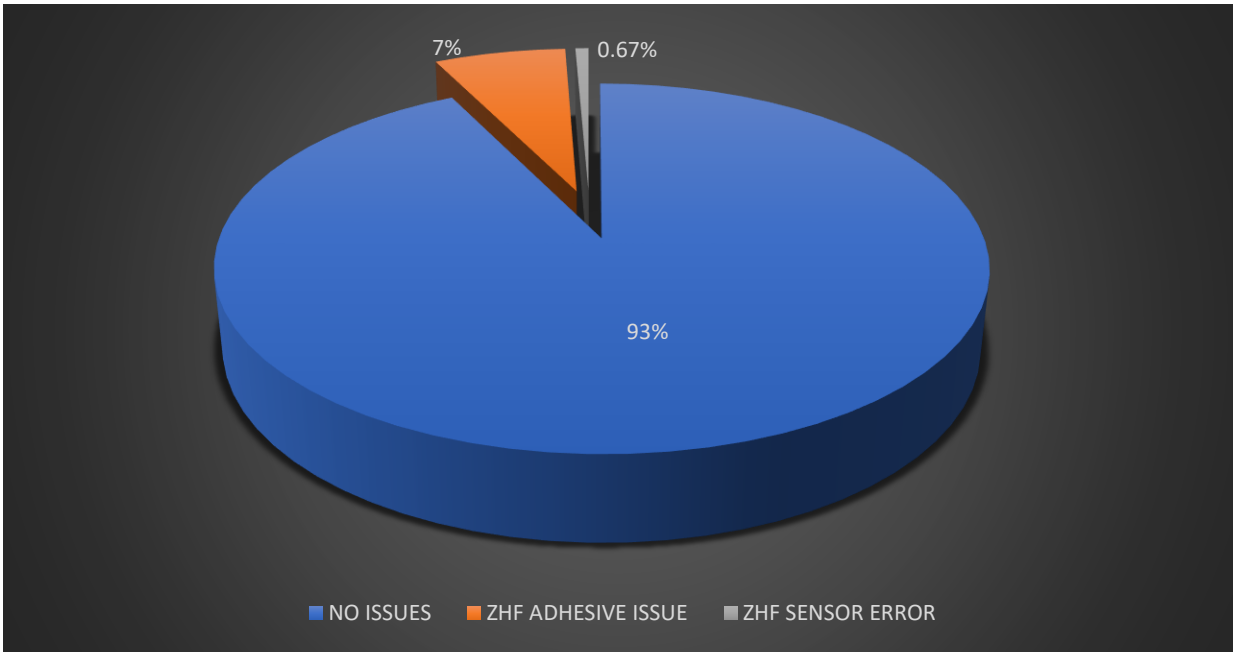


FIGURE 5: COMPARISON OF DIFFICULTIES FACED ON PROBE/ DEVICE PLACEMENT

TABLE 7: INTERRUPTIONS FACED DURING PERIOPERATIVE TEMPERATURE MONITORING

Row Labels	Number of Cases	Percentage
NONE	136	90.6
NP PROBE DISPLACEMENT	2	1.33
ZHF SENSOR ERROR	12	8.00
Grand Total	**150**	**100.00**

In this study, no interruptions were encountered during the perioperative period in 136 cases (90.6%). Nasopharyngeal probe displacement occurred in 2 cases (1.33%) and ZHF sensor error occurred in 12 cases (8%)

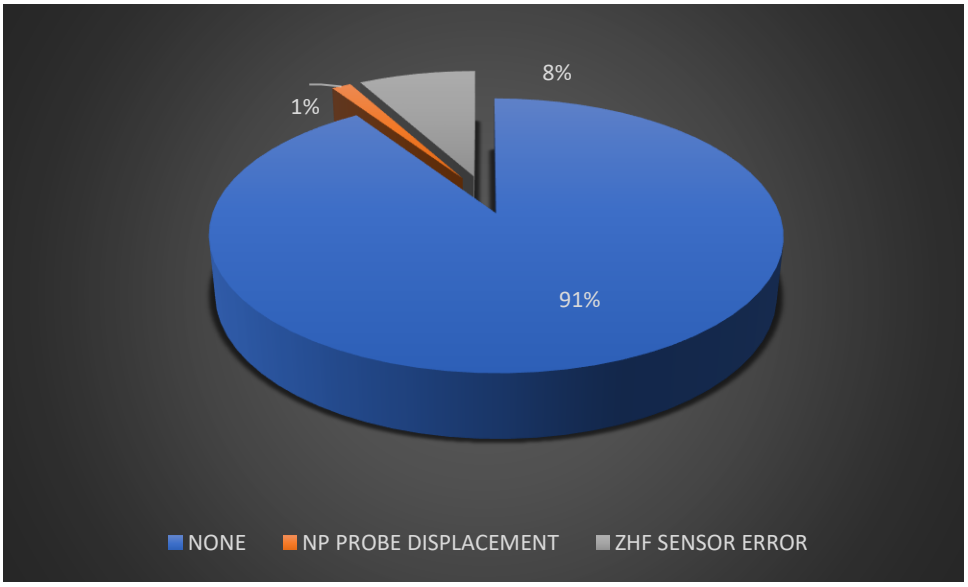


FIGURE 6: INTERRUPTIONS FACED DURING TEMPERATURE MONITORING

TABLE 8: SIDE EFFECTS / PATIENT DISCOMFORT DUE TO ZHF PLACEMENT

	ZHF
SIDE EFFECTS /ALLERGY	NIL
PATIENT DISCOMFORT FACED	NIL

In this study, no side effects/allergies were reported in any patients due to the ZHF probe placement over the forehead.

DISCUSSION

DISCUSSION

Pediatric patients undergoing General Anesthesia are more likely to experience intraoperative hypothermia when compared to adult patients. Perioperative normothermia is an essential quality indicator for pediatric anesthesia. Hence core temperature should be continuously monitored during the intraoperative period and a core temperature measurement technique needs to be precise, clinically accurate, and minimally invasive.

As per previous literature, the Zero Heat Flux technique is an adequate non-invasive method for core temperature monitoring during the intraoperative period (**West et al[1] and Nemeth et al[13]).** Multiple studies are conducted comparing the ZHF system with other invasive and non-invasive core temperature monitoring modalities. But, to the best of our knowledge, there was no study directly comparing the ZHF system with the Nasopharyngeal device in pediatric patients undergoing General Anesthesia. There was a similar study by **West et al [1]** comparing the ZHF device with both the Nasopharyngeal and the Oropharyngeal devices in the adult population aged 18-85 years. In another study, **Sang BH et al [22]** compared the Zero Heat Flux technology (SpotOn sensor) with an esophageal temperature monitoring device in pediatric patients aged 1 to 8 years and mentioned the strong agreement of the ZHF probe with the Esophageal probe.

The following is a summary of the study's principal conclusions. In this study, the ZHF device is showing a significant difference in temperature readings when compared to the Nasopharyngeal probe till 90 minutes in terms of p-value and not the absolute values. But after 90 minutes, the p-value is >.05, suggesting that there is no significant statistical difference between the Zero Heat Flux device and the Nasopharyngeal devices. A low correlation existed between the SpotOn sensor and the esophageal probe at the start of the measurement. This could be because it takes some time for the ZHF technology to build an isothermic tunnel, making the surface and core temperatures equal **(Sang BH et al[22]).** There is a maximum mean difference of +/-0.22 degree Celsius between the Zero Heat Flux and the Nasopharyngeal probes. The findings are in agreement with a similar study by **Nemeth M et al [13],** in his study comparing the 3M Bair Hugger™ Temperature Monitoring System to a well-accepted reference for measuring temperature in the distal esophagus revealing a mean bias of +0.26 °C (95%-CI +0.22 °C to +0.29 °C). With these findings, one might draw the conclusion that the

two measurement techniques (ZHF device and Nasopharyngeal probe) have clinically acceptable accuracy.

The ZHF temperature readings are higher than the Nasopharyngeal probe, until they approximate the latter as time progresses. There is a mean bias of +0.15 °C and a maximum bias of +0.22 °C in ZHF readings. Nemeth M et al. mentioned similar findings in their study, with a mean bias of +0.26 °C in ZHF readings. As a result of this evident bias in ZHF readings, the chance of hypothermia may be understated while the risk of hyperthermia may be overstated.

Although there is a statistically significant difference between the ZHF device and the Nasopharyngeal device till 90 minutes, with a maximum mean difference of +/-0.22 degrees Celsius, this difference is not clinically significant. For the purpose of measuring body temperature, temperatures within limits of 0.5 °C are typically considered to show clinically significant agreement **(Sessler et al [12] and West et al [1])**.

In this study, the correlation coefficient between the Zero Heat Flux and the Nasopharyngeal probe was 0.928, showing an acceptable correlation between the two devices. **Sang BH et al[22]** in his study had a similar finding with a correlation coefficient of 0.93 between the SpotOn and esophageal probes. In view of these findings, it can be said that the ZHF sensor has acceptable accuracy to measure core body temperature in pediatric patients undergoing General Anaesthesia.

No issues were faced during probe placement in 139 cases (92.6%). The ZHF probe adhesive issues were faced in 10 cases (6.67%) and ZHF sensor issues in 1 case (0.67%) (Table 5). Probe adhesive issues were mostly seen with probes that were used multiple times and the same applies to the sensor error. Sensors were changed in all the above-mentioned cases. On the other hand, no difficulty was encountered in probe placement with the Nasopharyngeal probe.

During the perioperative period, no interruptions occurred in temperature monitoring in 136 patients (90.6%). Nasopharyngeal probe displacement occurred in 2 cases (1.33%) and ZHF sensor error in 12 cases (8%) (Table 6). The ZHF sensor issues were resolved once the defective sensors were replaced and most of these were related to the multiple uses of these sensors. In this study, compared to the ZHF device, issues during probe placement and interruptions in perioperative temperature monitoring were fewer with the Nasopharyngeal probe. Although very few issues were encountered with the use of Nasopharyngeal probes in this study, they

are not risk-free either; for instance, nasal probes have been linked to nasal bleeds and might not be a good option for people with coagulation abnormalities **(West et al [1])**

In this study, no side effects were observed with the placement of the ZHF device in pediatric patients (Table 7). Patient discomfort was not reported in the immediate postoperative period with the placement of the ZHF device over the forehead and no local/ systemic reactions were observed in the perioperative and postoperative periods (Table 8). Findings are in agreement with the previous study by **West et al [1]** who observed that the ZHF sensor is simple to use and is well accepted by conscious patients before and after surgery. The findings signify that the ZHF probes can be used safely in the pediatric age group. A non-invasive device like the ZHF sensor will be better tolerated than other invasive core temperature monitoring modalities, especially in awake patients belonging to the pediatric age group.

CONCLUSION & RECOMMENDATION

CONCLUSION

We conclude that the Zero Heat Flux sensor demonstrated a strong correlation with the Nasopharyngeal probe for perioperative core temperature monitoring in pediatric patients undergoing surgery under General Anesthesia. With no side effects observed, ZHF can be considered a better alternative to the Nasopharyngeal for intraoperative core temperature monitoring in pediatric patients.

RECOMMENDATION

Zero Heat Flux (3M SpotON) sensor can be used as a single-use, non-invasive device for core temperature monitoring in pediatric patients undergoing General Anesthesia.

LIMITATION

1. We did not correlate the ZHF device with a gold standard core temperature monitoring device
2. Patients in this study were not subjected to various levels of hypo/hyperthermia, which is a crucial component in evaluating a core body temperature monitor.

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BIBLIOGRAPHY

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ANNEXURES

ANNEXURE 1

All India Institute of Medical Sciences
Jodhpur, Rajasthan
Informed Consent Form

Title of Dissertation : **COMPARISON OF INTRAOPERATIVE TEMPERATURE MONITORING BY ZHF DEVICE AND NASOPHARYNGEAL TECHNIQUES IN PEDIATRIC PATIENTS: A PROSPECTIVE , OBSERVATIONAL STUDY**

Name of PG Student : Dr.Navin Vincent
Telephone no : 8921920414

Patient/Volunteer Identification No. : _____

I, _____ F/o or M/o _____
R/o_____
give my full, free, voluntary consent for my child to be a part of the study "**COMPARISON OF INTRAOPERATIVE TEMPERATURE MONITORING BY ZHF DEVICE AND NASOPHARYNGEAL TECHNIQUES IN PEDIATRIC PATIENTS: A PROSPECTIVE , OBSERVATIONAL STUDY**"
the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my child's participation is voluntary and I am aware of my right to opt out of the study at any time without giving any reason.
I understand that the information collected about my child and any of my child's medical records may be looked at by responsible individual from AIIMS Jodhpur or from regulatory authorities. I give permission for these individuals to have access to my child's records.

Date : _____ _____
Place : _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.
Date : _____ _____
Place : _____ Signature of PG Student

Witness 1
Signature
Name: _____
Address : _____

2. Witness 2
Signature
Name: _____
Address : _____

ANNEXURE 2

ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साईंसिस

जोधपुर, राजस्थान

सूचित सहमति प्रपत्र

थीसिस / निबंध का शीर्षक: **पेडियेट्रिक रोगियों में ZHF डिवाइस और नासोफेरींजल तकनीक द्वारा इंट्राऑपरेटिव तापमान निगरानी की तुलना:एक संभावित, अवलोकन संबंधी अध्ययन "।**

पीजी छात्र का नाम: डॉ। नवीन विंसेंट
टेली No : 8921920414
रोगी / स्वयंसेवक पहचान संख्या: _____

मैं, _____ एस / ओ या डी / ओ _____

आर / ओ _____

अध्ययन के एक भाग होने के लिए मेरी पूर्ण, स्वतंत्र, स्वैच्छिक सहमति दें " **पेडियेट्रिक रोगियों में ZHF डिवाइस और नासोफेरींजल तकनीक द्वारा इंट्राऑपरेटिव तापमान निगरानी की तुलना:एक संभावित , अवलोकन संबंधी अध्ययन**"
प्रक्रिया और प्रकृति जिसकी मुझे स्वयं में समझाया गया है मेरी पूरी संतुष्टि के लिए भाषा मैं पुष्टि करता हूं कि मुझे प्रश्न पूछने का अवसर मिला है।
मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मुझे किसी भी कारण दिए बिना किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार की जानकारी है।

मैं समझता हूं कि मेरे और मेरे मेडिकल रिकॉर्ड के बारे में एकत्रित की गई जानकारी को _____ (कंपनी नाम) या विनियामक प्राधिकरणों से जिम्मेदार व्यक्ति द्वारा देखा जा सकता है।
मैं इन लोगों के लिए मेरे रिकॉर्डों तक पहुंच की अनुमति देता हूं

तारीख : _____

जगह: _____

हस्ताक्षर / बाएं अंगूठे का छाप

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त की गई है

तारीख : _____

जगह: _____ पीजी छात्र के हस्ताक्षर

गवाह 1	गवाह 2
हस्ताक्षर	हस्ताक्षर
नाम:	नाम:
पता:	पता :

ANNEXURE 3

PATIENT INFORMATION SHEET

1. Risks to the patients: No interventions or life-threatening procedures will be done.

2. Confidentiality: Your participation will be kept confidential. Your medical records will be treated with confidentiality and will be revealed only to doctors/ scientists involved in this study. The results of this study may be published in a scientific journal, but you will not be identified by name.

3. Provision of free treatment for research-related injury. Not applicable.

4. Compensation of subjects for disability or death resulting from such injury: Not Applicable

5. Freedom of the individual to participate and to withdraw from the research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.

6. You have complete freedom to participate and to withdraw from the research at any time without penalty or loss of benefits to which you would otherwise be entitled.

7. Your participation in the study is optional and voluntary.

8. The copy of the results of the investigations performed will be provided to you for your record.

9. You can withdraw from the project at any time, and this will not affect your subsequent medical treatment or relationship with the treating physician.

10. Any additional expense for the project, other than your regular expenses, will not be charged from you.

ANNEXURE 4

रोगी सूचना पत्रक

1.रोगियों के लिऐ कोइ हस्तक्षेप या जीवन धमकी प्रक्रिया नहीं की जाएगी।

2. गोपनीयता: आपकी भागीदारी को गोपनीय रखा जाएगा। आपके मेडिकल रिकॉर्ड को गोपनीयता के साथ इलाज किया जाएगा और केवल इस अध्ययन में शामिल डॉक्टरों और वैज्ञानिकों को पता चलेगा। इस अध्ययन के परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित हो सकता है, लेकिन आपको नाम से पहचाना नहीं जाएगा।

3. अनुसंधान संबंधी चोट के लिए नि: शुल्क उपचार की व्यवस्था लागू नहीं।

4. ऐसी चोट से उत्पन्न विकलांगता या मृत्यु के लिए विषयों का मुआवजा लागू नहीं है।

5. किसी भी समय दंड या लाभों के नुक़सान के बिना किसी भी समय भाग लेने के लिए व्यक्ति को स्वतंत्रता लेने और अनुसंधान से वापस लेने के लिए स्वतंत्रता, जिसके तहत विषय अन्य धाहकदार होगा।

6. आपको जुर्माना या लाभ के नुक़सान के बिना भाग लेने और अनुसंधान से वापस लेने की पूरी आज़ादी है, जिस पर आप अन्य धाहकदार होंगे।

7. अध्ययन में आपकी भागीदारी वैकल्पिक और स्वैच्छिक है।

8. प्रदर्शन की जांच की परिणामों की प्रति आपको रिकॉर्ड के लिए आपको उपलब्ध कराई जाएगी।

9. आप किसी भी समय परियोजना से वापस ले सकते हैं, और यह आपके बाद के चिकित्सा उपचार या उपचार चिकित्सक के साथ संबंध को प्रभावित नहीं करेगा।

10. परियोजना के लिए कोई भी अतिरिक्त व्यय, आपके नियमित खर्चा के अलावा, आपसे शुल्क नहीं लिया जाएगा।

ANNEXURE 5

ASSENT

Thesis Title: **COMPARISON OF INTRAOPERATIVE TEMPERATURE MONITORING BY ZHF DEVICE AND NASOPHARYNGEAL TECHNIQUES IN PEDIATRIC PATIENTS: A PROSPECTIVE, OBSERVATIONAL STUDY**

Investigator: Dr. Navin Vincent

We are doing a research study about COMPARISON OF INTRAOPERATIVE TEMPERATURE MONITORING BY ZHF DEVICE AND NASOPHARYNGEAL TECHNIQUES IN PEDIATRIC PATIENTS: A PROSPECTIVE, OBSERVATIONAL STUDY

A research study is a way to learn more about people. ***You know about the procedure, things that take time, other risks, discomforts, etc.*** Not everyone who takes part in this study will benefit. A benefit means that something good happens to you.

If you do not want to be in this research study, we will tell you what other techniques of anaesthesia there are for you**.**

When we are finished with this study we will write a report about what was learned. This report will include your name & that you were in the study. You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

(signature of patient) (Date)

Signature of PG Student

Witness 1
Signature
Name: _____
Address : _____

Witness 2
Signature
Name: _____
Address : _____

ANNEXURE 6

अनुमति

थीसिस शीर्षक: **पेडियेट्रिक रोगियों में ZHF डिवाइस और नासोफेरींजल तकनीक द्वारा इंट्राऑपरेटिव तापमान निगरानी की तुलना:एक संभावित ,अवलोकन संबंधी अध्ययन**
जांचकर्ता: डॉ नवीन विंसेंट

हम पेडियेट्रिक रोगियों में ZHF डिवाइस और नासोफेरींजल तकनीक द्वारा इंट्राऑपरेटिव तापमान निगरानी की तुलना:एक संभावित ,अवलोकन संबंधी अध्ययन "।

एक शोध अध्ययन लोगों के बारे में अधिक जानने का एक तरीका है। आप प्रक्रिया, चीजें जो समय लेते हैं, अन्य जोखिम, असुविधा आदि के बारे में जानते हैं। इस अध्ययन में भाग लेने वाले हर किसी को लाभ नहीं होगा। एक लाभ का मतलब है कि आपके साथ कुछ अच्छा होता है।

यदि आप इस शोध अध्ययन में नहीं रहना चाहते हैं, तो हम आपको बताएंगे कि आपके लिए संज्ञाहरण की अन्य तकनीकें क्या हैं। जब हम इस अध्ययन के साथ समाप्त हो जाते हैं तो हम जो कुछ सीखा था उसके बारे में एक रिपोर्ट लिखेंगे। इस रिपोर्ट में आपका नाम शामिल होगा और आप अध्ययन में थे। अगर आप नहीं बनना चाहते हैं तो आपको इस अध्ययन में होना जरूरी नहीं है। यदि आप शुरू करने के बाद रुकने का फैसला करते हैं, तो यह भी ठीक है। आपके माता-पिता भी अध्ययन के बारे में जानते हैं। यदि आप तय करते हैं कि आप इस अध्ययन में रहना चाहते हैं, तो कृपया अपना नाम साइन करें।

मैं, _____, इस शोध अध्ययन में होना चाहता हूं।

(रोगी के हस्ताक्षर) (तिथि)

पीजी छात्र के हस्ताक्षर

साक्षी 1. . साक्षी 2. हस्ताक्षर.
हस्ताक्षर

नाम. नाम:

पता. पता :

ANNEXURE 7

PROFORMA

S.No. Date:

Thesis Title **: COMPARISON OF INTRAOPERATIVE TEMPERATURE MONITORING BY ZHF DEVICE AND NASOPHARYNGEAL TECHNIQUES IN PEDIATRIC PATIENTS: A PROSPECTIVE , OBSERVATIONAL STUDY**

IPD Serial no/Sticker:

Age : Sex: Weight:

Ambient OT temperature:
Type of Anaesthesia :
Type of Surgery :
Duration of surgery :
Temperature of IV fluid :
Warmer : Yes/ No Set Temperature of warmer:

Monitoring started at : Temp:

	3M SpotON	Nasopharyngeal
15min		
30min		
45min		
60min		
75min		
90min		
105min		
120min		

Difficulties faced in device/probe placement :
Any interruption faced during monitoring :
Any side effects / adhesive allergy due to probe/device placement:
Patient discomfort reported if any :

ANNEXURE 8: MASTER CHART