Temperature Changes in Paediatric Patients Undergoing Magnetic Resonance Imaging: A Red Cross War Memorial Children's Hospital Experience

By

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ABBREVIATIONS

ASA	American Society of Anesthesiologists
HREC	Human Research Ethics Committee
MMED	Masters of Medicine
MRI	Magnetic resonance imaging
RCWMCH	Red Cross War Memorial Children's Hospital
SAR	Specific absorption rate
SAJAA	Southern African Journal of Anaesthesia and Analgesia
SD	Standard deviation

DECLARATION

I, Zahnne Fullerton, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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ABSTRACT

TEMPERATURE CHANGES IN PAEDIATRIC PATIENTS UNDERGOING MAGNETIC RESONANCE IMAGING: A RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL EXPERIENCE

ABSTRACT

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Background: Magnetic resonance imaging (MRI) scanning places paediatric patients at risk of both hypothermia and hyperthermia. The aim of this study is to determine primarily if paediatric patients gain or lose heat during MRI scanning, and secondarily to examine potential risk factors for any such change.

Methods: A prospective audit was conducted from February 2015 until April 2015 involving 200 children aged five days to 12 years. Tympanic temperatures were recorded pre- and post-MRI scan. Variables including age, height, weight, head circumference, area scanned, length of time in the scanning room and duration of scan were recorded. The type of anaesthetic management was decided by the anaesthetist and recorded.

Results: Tympanic temperature decreased in 111 patients, with a loss of greater than 0.5°C in 29% of patients (n=58) and a range of decrease from 0.1°C to 1.9°C. Hypothermia, defined as a core temperature of less than 36°C for this study, occurred in 13.5% (n=27) patients. A total of 23 patients had no change in pre- and post-scan temperature, and 66 recorded a higher temperature post-scan. The range of gain in temperature was 0.1°C to 1.5°C, with 14.5% (n=29) of patients' temperatures increasing by 0.5°C or more. The mean pre-scan temperature was 36.603 °C ± 0.512°C (range: 35.5 – 38.70 °C) and the mean post-scan temperature was 36.442°C ± 0.615 (34.80-40.0 °C). Overall, the mean post scan temperature was 0.16°C ($P<0.001$) less than the pre-scan temperature. Linear regression analysis identified sedation and general anaesthesia as signficant risk factors for heat loss.

Conclusion: Overall paediatric patients tend to have a minor decrease in temperature during MRI scanning. Individually, each paediatric patient may have an increase or decrease in temperature, or no change. A significant proportion of paediatric patients are at risk of hypothermia post MRI scan, and almost half are at risk of an increase or decrease in temperature of a minimum of 0.5°C. These factors are clinically significant and may be associated with adverse outcomes. For these reasons, temperature monitoring and active temperature management should be implemented during MRI scanning in paediatric patients.

Keywords: Magnetic Resonance Imaging (MRI), paediatric, anaesthesia, sedation, temperature.

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CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

Introduction

Magnetic Resonance Imaging (MRI) is a non–invasive imaging modality that uses non-ionizing radiation to generate very detailed images of the anatomical area scanned.[1] There are certain challenges to performing a MRI scan. Firstly the duration of the scan may be in excess of an hour, during which time the patient needs to lie completely still. Loud noises produced by the MRI scanner, which may be louder than 90 decibels, may be experienced as very unpleasant or frightening to a child. [2] Many adults are able to withstand the noise (with the aid of protective ear covers) and are able to lie still for the duration of the investigation. This is often not the case in paediatric patients who often require general anaesthesia or sedation for a MRI scan.

MRI scanners create radiofrequency energy, which may cause local or systemic heat gain.[3] Paediatric patients are at increased risk of heat loss during MRI scanning due to cold ambient temperatures, their unique physiology, anaesthesia-induced heat loss and due to the lack of adequate MRI compatible temperature monitoring and warming devices. Therefore, during an MRI scan, paediatric patients are at risk of both hyperthermia and hypothermia.

A paediatric patient at Red Cross War Memorial Children's Hospital (RCWMCH) developed significant hypothermia (33°C) during a MRI scan, complicated by hypotension and bradycardia. This case was presented at an anaesthetic departmental morbidity and mortality meeting, and sparked interest in the subject of temperature changes in paediatric patients undergoing MRI. This has formed the basis for the question to be answered in this Masters of Medicine (MMED) paper.

Literature Review

The following review will highlight important topics regarding this subject and will expand on the concepts as summarized in the introduction. The review will include the following topics:

- Relevant paediatric physiology and thermoregulation.
- Sedation and general anaesthesia and the effects thereof in paediatric patients.
- Physiological effects of hypothermia and hyperthermia.

- Physics of MRI scanning, particularly relating to temperature.
- Unique challenges of MRI scanning relating to paediatric patients, temperature control and temperature measurement.
- Relevant previous research in the field of temperature and paediatric MRI.

Paediatric Physiology

When exposed to a cold environment, paediatric patients are more likely to become hypothermic compared to adults. The risk of hypothermia is increased in smaller and younger children compared to older and bigger children.[4] There are many physiological differences that explain this risk of hypothermia. Numerous physiological and behavioural mechanisms allow humans to generate and retain heat. Adults are able to maintain their core temperature in cold environments up to 0°C. Neonates, on the other hand, overwhelm these compensatory mechanisms at warmer ambient temperatures and will start to become hypothermic at 22°C.[4] Children have a proportionally larger skin surface area and their skin is thinner with less subcutaneous tissue. This encourages heat loss via convection, conduction, evaporation and radiation.[4,5] Children also have less effective heat generating mechanisms, with suboptimal shivering and non-shivering thermogenesis and vasoconstriction.[4,5]

Effects of Anaesthesia on Temperature

The risk of hypothermia is exacerbated under anaesthesia. The hypothalamus is responsible for maintaining normal temperature. As core temperature drops, warming is activated via behavioural responses, vasoconstriction and shivering and non-shivering thermogenesis. When it rises, cooling is activated via sweating and vasodilation. The comparative points at which these processes occur are termed the interthreshold range, which is very narrow in the non-anaesthetized patient.[4,6-8] Anaesthesia interferes with hypothalamic function resulting in a very wide interthreshold range, with compensatory warming mechanisms only being activated at lower temperatures.[4,7,8] Under anaesthesia temperature drops rapidly in the first hour (phase1), then the rate slows (phase 2) and reaches a steady state (phase 3). The reduction in temperature is primarily from heat redistribution from the core to the periphery, which encourages heat loss to the environment. Anaesthesia also reduces heat generation by slowing metabolism and muscle movement.[4,7,8] Behavioural responses to cooling are not possible under anaesthesia.

Effects of Hyperthermia and Hypothermia

The clinical effects of hypothermia may be significant and have been associated with much morbidity and even mortality.[4,7-10] These effects may be significant for mild hypothermia. Perioperative hypothermia is usually defined as a core temperature of less than 36°C,[4,10] however some define it as a core temperature of less than 36.5°C.[7] The effects of hypothermia are numerous: mild hypothermia is associated with minimal physiological derangement while more profound hypothermia is associated with significant physiological derangement, ultimately leading to death. The following problems have been associated with hypothermia: [4,7-10]

- Myocardial ischaemia
- Cardiac rhythm disturbances
- Abnormal coagulation with increased blood loss and need for blood transfusion
- Activation of the sympathetic nervous system
- Acidosis
- Delayed drug metabolism – especially muscle relaxants and propofol
- Delayed emergence
- Surgical site infection
- Poor surgical site healing
- Renal impairment
- Rhabdomyolysis
- Discomfort
- Post-operative shivering
- Longer hospital stays (due to complications)

In attempt to avoid the above-mentioned complications, normothermia is targeted during anaesthesia. The National Institute for Health and Care Excellence (NICE) guidelines suggest that a target core temperature of 36.5°C should be aimed for in patients undergoing surgery. Temperature monitoring is routine practice and patients are actively warmed with the aid of warm fluids, warm ambient temperatures, forced-air warmers, warm intravenous fluids and heat-moisture exchangers.[4,7,8]

Hyperthermia (>37.5°C) is far less common during anaesthesia but it is a risk during MRI (see later). The effects of hyperthermia are also significant, and severe untreated hyperthermia can result in significant organ dysfunction and death, with more significant effects occurring

at temperatures greater than 38.5°C.[4,11,12] The following are potential complications of hyperthermia: [4,11,12]

- Pulmonary oedema and acute respiratory distress syndrome
- Kidney dysfunction
- Liver dysfunction
- Abnormal clotting and thrombus formation
- Neurological deficit, confusion and seizures
- Muscle break down: rhabdomyolysis
- Dehydration

Physics of MRI

In order to understand the effect of MRI on temperature, the physics of MRI is reviewed.

Hydrogen atoms contain a single proton with a positive charge, which spins along its axis, in a random direction. This spinning creates a miniscule magnetic field. When the proton is placed in a magnetic field, the spinning axis aligns parallel (lower energy state) or antiparallel (higher energy state) with the applied magnetic field. The protons constantly move between the two directions (or energy states), with a slight excess in the parallel state. It is this difference between parallel and antiparallel that creates the energy for detection and image creation. The larger the external magnetic force, the larger the difference and the greater the amount of energy available for image creation. Magnetic force is measured in Tesla units, with most MRI scanners using 0.5-4 Tesla forces (which are 10 000 to 80 000 times stronger than the earth's magnetic force).[1,2,13,14]

If a second magnetic force, or radiofrequency pulse is applied perpendicular to the static magnetic field, the protons absorb energy and change the direction of their spins by 90 degrees. When the pulse is stopped, the protons return to their original alignment, retransmitting the absorbed energy, which creates a signal. This signal is detected and integrated and plotted into a grayscale image by the detector and computer.[1,2,13,14]

Clinical Challenges of MRI Scanning for Paediatric Anaesthetists

In order to facilitate a motionless field during MRI scanning of paediatric patients, general anaesthesia or sedation is often required.[2] Anaesthesia for MRI scanning presents a multitude of unique challenges that can be very daunting for the paediatric anaesthetist. Besides challenges of remote anaesthesia and paediatric anaesthesia, there are challenges that relate

especially to temperature measurement. These include the following and each will be discussed in more detail:

- Anaesthesia equipment and patient monitors (including temperature)
- Potential temperature changes during MRI

Anaesthesia Equipment and Patient Monitors

As a result of static and dynamic magnetic forces (the radiofrequency pulses), the MRI environment is potentially hazardous. This strong magnetic force will attract any ferromagnetic material which may result in normal non-MRI compatible equipment and objects transforming into hazardous flying missiles. These airborn missiles may cause serious injury or death if a person is in the trajectory pathway. Tissue damage or death may result from internal ferromagnetic implants such as pacemakers or vascular clips becoming magnetised.[1,2,13-15]

In order to ensure safety, different MRI safety zones have been created by the American College of Radiology. Each zone is within a specific distance of the magnet and has a list of safety requirements and checks (table A).[16] No ferromagnetic material is allowed in zone three and zone four.[16] Thus all equipment and patient monitors used in zone three and four need to be non-ferromagnetic and clearly deemed MRI-safe. Most anaesthetic equipment can be specifically manufactured to meet these requirements, or should be safely secured to the wall or ground. Alternately, this equipment may be placed outside the MRI room in zone 1 or 2, but this presents problems of accessibility.

Table A: MRI safety zones

Zone	Description
1	Outside the MRI area, general public access.
2	Closer to MRI – pre-scan room, recovery, reception. Public only allowed access with supervision.
3	Area just outside magnet room. Strict access and screening for ferromagnetic objects - essential to prevent injury.
4	Area with magnet, potentially very dangerous if ferromagnetic objects in this area.

The need for non-ferromagnetic material is not the only limitation on anaesthetic equipment and patient monitors. The forces created by the MRI machine can also cause interference with patient monitors, making them potentially unreliable.[13,15] The electric field from monitors and cables may also cause inferior image production.[13] Radiofrequency from the MRI machine in conjunction with cables and monitors may induce eletrical current. This current can cause

burns and fires and may trigger nerve and muscle cells, resulting in movement and in severe cases resulting in life-threatening arrhythmias.[14,15] In essence, there are numerous factors limiting the safe use of anaesthesia equipment and monitors in the MRI suite.

The prevention, dectection and treatment of hypothermia during anaesthesia is essential and is a well-established practice, supported by the South African Society of Anaesthesiology 2012 (2013 Update) Practice Guidelines.[17] The American Society of Anesthesiologists, in accordance with their basic standards (which includes temperature monitoring), also supports the use of monitoring, but in their MRI guidelines they do acknowledge that not all monitors are suitable for use in the MRI scanning room.[18] Only recently have MRI-safe forced air warmers and temperature probes been developed and validated, [19] but access to them is very limited due to cost and availability. Prevention of hypothermia is actively and routinely practised, but temperature monitoring or active warming with forced air warmers does not take place at RCWMCH, due to lack of compatible equipment.

Potential Temperature Changes During MRI

For a number of reasons, relating to the MRI scanner, unique paediatric physiology and the effects of anaesthesia, paediatric patients are at risk of both hyperthermia or hypothermia during MRI scanning.

The radiofrequency emitted can be absorbed by the tissues resulting in local or systemic heating. Local heat gain, if large enough, can cause thermal burns. Systemic heating may result in progressive hyperthermia, which, as discussed earlier, has many potential deleterious effects. The amount of heat absorbed by tissues is known as specific absorption rate (SAR), and is measured in watts per kilogram. SAR depends on the strength of the magnet, the number of sequences used, the type of radiofrequency pulse, the part of the body exposed and other factors. [1,3,13,15,16] The SAR is monitored by the radiographer and when a predefined value is reached, the scan is terminated. This may result in incomplete scans or may necessitate a repeat scan.[1,3] It is advised that a maximum temperature gain of 1°C should be allowed, but for patients at higher risk of the effects of hyperthermia, such as infants, the gain should be no more than 0.5°C.[20]

Alternatively, the magnets require a cool ambient room temperature to ensure optimal function.[1,21] The cool environment can encourage heat loss, which is compounded by the unique physiology of the paediatric patient and the use of anaesthetic agents.

Current Literature: Paediatric Temperature in MRI

From the above discussion, it is clear that paediatric patients undergoing MRI scans are at risk of both hyperthermia and hypothermia. A literature search was conducted using PubMed, Google Scholar and QXRead data bases. The criteria were to include any published articles that dealt with temperature measurement in paediatric patients undergoing MRI scan under general anaesthesia or sedation. The keywords used were "MRI", "paediatric/pediatric" and "core temperature". A total of seven articles that matched the criteria were found, including one case report and six prospective observational studies, ranging from 2004 - 2014. Two of the papers are available in abstract format only. An additional two articles that measured temperature during MRI as a secondary outcome were found and for completeness, will be discussed.

The results are heterogeneous with three papers reporting hyperthermia, two showing mixed or inconclusive results and two showing a trend towards hypothermia. The two articles measuring temperature as a secondary outcome also show a trend towards heat loss.

The first paper to report hyperthermia was a case report by Kussman et al.[22] in 2004. A 16 month-old infant underwent a 95 minute cardiac MRI scan under general anaesthesia. She was covered in a single warmed blanket. Her pre-scan temperature was 35.6°C and increased to 38°C post scan, returning to baseline 3.5 hours later. Signs of hyperthermia were also present; she had a tachycardia, was flushed and irritable which necessitated overnight admission. The authors suggested that the hyperthermia may be related to length of the scan, insulation of the body and a larger portion of the body inside the radio-frequency coils. They suggested that the usual cooling effect of general anaesthesia may have been mitigated by her severe congential heart disease because of low cardiac output and peripheral vasoconstriction. This case report suggests that despite the usual tendency towards hypothermia because of paediatric physiology as well as the effect of general anaesthesia, some children are at risk of hyperthermia for other reasons, particularly related to length of scan and co-morbidities.

This report led to the next two prospective observational studies in 2006 and 2009, which both reported hyperthermia as their primary outcome. The first of these is by Bryan et al.[23] in 2006. In this study 30 children for brain MRI between the ages of two to 33 months, were enrolled. The environmental conditions and the covering of the children were standardized. All the children received sedation with chloral hydrate and the temperature was measured at the tympanic membrane. Overall they found a statistically significant increase in temperature of 0.5°C (95% confidence interval (CI) 0.3-0.7°C, $P<0.001$). However, not all children had an increase in temperature – two had no change and four had minor decreases in temperature of

0.1 to 0.3°C. Of the 24 children who had increases in temperature (range 0.1to 1.3°C), five had clinically significant increases of >1°C. The only significant covariate was lower pre-scan temperatures, which predicted a higher gain of temperature. The other covariates such as weight or length of scan were not statistically significant.

The results of this study by Bryan et al.[23] do suggest an increase in temperature but there are a number of limitations. The sample size is small and the power of the study sample size is not mentioned. The authors also recognize that local radiofrequency heating to the head may have resulted in higher tympanic membrane temperatures, which may not truly reflect whole body temperature. The children were also sedated with choral hydrate, which may not have the same negative effect on thermoregulation as general anaesthesia. This may potentially cause an imbalance of heat loss and gain, favouring radiofrequency heat gain.

The second paper with trends towards increased temperature is by Machata et al.[24] in 2009. This prospective observational study aimed to detect the effect of magnet strength on temperature change in paediatric patients. The study had two groups of 38 patients (American Society of Anesthesiology(ASA) Class I and II), each exposed to a MRI scan with a different strength magnet. Higher ASA classes were excluded, as well as those requiring general anaesthesia. The study followed a strict protocol of sedation with midazolam, nalbuphine and propofol, and standardized environmental settings. The temperature was measured at both the tympanic and rectal sites. The rectal site was included to mitigate the potential confounders, and the results showed good correlation between the two sites. The sample size was calculated using a power analysis. Allocation to each group was not blinded, but rather done according to clinical need as required by the neuroradiologist. The 1.5 Tesla group had an increase in temperature in 35 of the 38 children, with a statistically significant increase of +0.2°C for both measurement sites ($P<0.001$). The highest increase was +0.9 °C in two patients. The 3 Tesla group had 37 of 38 children having higher post scan temperatures and a greater average increase in temperature of 0.5°C ($P<0.001$). The 3 Tesla group also had statistically significant longer scans. The highest increase in temperature was 1°C in three patients.

Machata et al.[24] suggest that the increase in temperature is multifactorial. Firstly, the use of sedation instead of general anaesthesia may preserve some thermoregulatory mechanisms resulting in heating. Secondly, they suggest the guidelines for SAR, which were developed in awake adults, may not apply to paediatric patients, potentially resulting in more radiofrequency heating of tissues. However, it is useful to note that the stronger magnet is associated with more heating than the 1.5 Tesla magnet. There are a number of limitations to this study. Firstly, ill children or children with signifcant co-morbidities or emergency scans

were excluded, so it is not a representative sample of all the patients presenting for MRI. Secondly, though heat gain was found with both magnets, the clinical significance of increase in temperature of 0.2°C and 0.5°C may not have much clinical impact. However, some children displayed higher temperature gains, which may be more clinically significant.

Two prospective observational studies in 2011 and 2012 published results that showed no convincing evidence to suggest that children get significantly hot or cold in the MRI scanner. The first was in 2011 by Isaacson et al.[25] where 400 patients were enrolled and they examined differences in propofol-sedated versus non-sedated children, as well as comparing 1.5 Tesla and 3 Tesla MRI scanners. This study enrolled 400 children up to the age of 21 years, and included elective and emergency scans. The overall results show no significant change in temperature between pre- and post-scan temperatures (-0.0155°C 95% CI -0.035°C to +0.064°C). Some patients displayed heat loss of more than 0.5°C (15.6% of patients) and 1°C (3.89% of patients and 13 of 15 were propofol sedated). Heat gain of more than 0.5°C was noted in 16.4% and more than 1°C in 1.81% (all not sedated). Propofol sedation resulted in heat loss (-0,26°C +/- 0.44°C) ($P<0.0001$) and no sedation tended towards heat gain (+0.24°C +/-0.42°C) ($P<0.0001$). The findings of Machata et al.[24] were echoed in this study, with statistically significant findings that the 3 Tesla magnet produced more heat gain (+0.076°C +/-0.52) as compared to the 1.5 Tesla magnet (-0.06°C +/- 0.48) ($P=0.011$). Of the contributory factors the following were found to be significant: the use of sedation, pre-MRI temperature, the protocol for the MRI, the magnet strength, and the age of the patient.

This study by Isaacson et al.[25] does not show absolute significant change in temperature, but does suggest that there may be risk factors for hypothermia, which include younger age and propofol sedation. The potential risk factors for hyperthermia may be older age, no sedation and the use of stronger magnets. However the absolute gains and losses of temperature are very small and likely to be clinically irrelevant, except for in a very small group of patients. The inclusion of larger adolescents and young adults are potential limitations in this study.

A prospective observational study in 2012 by Acar et al.[26] showed an average decrease in temperature of 0.4°C ($P<0.001$) in a group of 30 children (aged 0 to 7 years) for a head MRI under general anaesthesia. They noted that 21 children had cooler temperatures, while one had no change and eight had higher temperatures, and concluded that paediatric patients may gain or lose heat during MRI scanning. There was a statistically significant relationship between younger age and heat loss, echoing the findings of Isaacson et al.[25] The limits of this study are that it is only available in abstract form and the small sample size.

Four studies report a general finding of hypothermia, with two examining temperature as a primary outcome and two as a secondary outcome. The first of these by Patel et al.[27] was a prospective observational study involving 64 children from six months to eight years old. They found a statistically significant mean temperature decrease of 1.03°C and also found a correlation between young age and decrease in temperature. This study is also only available in abstract form, which is a significant limitation to interpreting the data obtained.

The second study that reports hypothermia was conducted by Lo et al.[28] in 2014 and was a prospective observational study. This study has the second largest sample group of 193 children aged three months to six years. The participants included all received general anaesthesia. The protocol excluded patients that were deemed unfit for general anaesthesia and those who had limitations regarding ear canal anatomy for access for temperature measurement (the only study to note this). They report hypothermia (<36°C) in 52.3% of patients post scan and an absolute decrease overall of 0.28°C +/-0.6°C. (95% CI -0.36°C to -0.19°C P <0.001), with no cases of hyperthermia. However, 64.2% of patients had a decrease in temperature, 29% had an increase and 6.7% had no change.

Of significance, the type of tympanic thermometer was changed during the study, and analysis showed that one thermometer produced higher readings. The number of blankets used to cover the children and the clothes worn were not standardized. The 3 Tesla scanner was used in 4.7% of children and the remainder in a 1.5 Tesla scanner. The general anaesthetic was lengthened in 15% of patients in order to perform extra procedures. Interestingly 42.6% of patients were hypothermic (<36°C) before the scan. These factors are all potential limitations to the study.

Tsui et al.[29] conducted a prospective observational study in 2005 investigating the recovery and discharge times of patients receiving propofol and remifentanil sedation for MRI. The secondary outcomes measured other variables including complications. A total of 56 patients were enrolled, aged 29 days to 11 years old. They found an average decrease in temperature of -0.3°C, but this was not statistically significant. No further discussion of this variable was reported on.

A retrospective observational study in 2012 by Plaisier et al.[30] examined the brain MRI records of 52 premature infants at 30 weeks gestational age. The aim was to examine the

safety of MRI scans conducted in preterm infants. They reported on a number of adverse events, including temperature change. Hypothermia (<36°C) occurred in 17.3% of the patients, with an average of -0.5°C decrease in temperature. This once again suggests that the younger and smaller patients are more at risk of hypothermia.

Review of the current evidence shows mixed results. The earlier studies show a tendency towards heat gain while the newer studies reflect the opposite, with other studies being inconclusive. It is also important to note that some results, though statistically significant, are minor and not clinically significant. Overall, the evidence suggests that younger patients under general anaesthesia are more likely to develop hypothermia, while older and/or sedated patients are likely to become hyperthermic. Most of the studies are limited in terms of sample size and exclusion criteria; many excluding patients who are ill, with higher ASA ratings or emergency/urgent scans. Some studies have failed to exclude older adolescents and young adults or have not included preterm babies and neonates. While some of the risk factors for temperature change were analyzed in the studies, none examined other risk factors such as head circumference, body surface area or length of fasting, all which may be important determinants of temperature along with the examined factors such as age, time of scan, type of anaesthesia and magnet strength.

Considering the case presented at the morbidity and mortality meeting at RCWMCH of a clinically significant case of hypothermia during MRI scan and the vast results in the current literature, a decision was made to investigate this topic at our institution.

Aims and Objectives

The **purpose** of the study was to investigate pre- and post-MRI temperatures in all children undergoing MRI at Red Cross War Memorial Children's Hospital, to determine if significant loss or gain of temperature occurs (+/- 0.5°C).

The **primary aim** was to determine if a significant change in temperature occurs in paediatric patients undergoing MRI. The **secondary aim** was to determine any factors that could lead to such a change. The factors examined included age, weight, body surface area, head circumference, co-morbidities, duration of scan, ambient room temperature, duration of pre-scan fasting and type of sedation/anaesthesia.

The **null hypothesis** stated that no significant temperature changes (+/- 0.5°C) occurred in paediatric patients undergoing MRI.

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CHAPTER 2: PUBLICATION READY MANUSCRIPT

Introduction

Magnetic Resonance Imaging (MRI) places paediatric patients at risk of a decrease or increase in temperature. Absorption of radiofrequency energy may cause heat gain, while the cold ambient environment may cause heat loss.[1,2] Paediatric patients are more likely to lose heat compared to adults because of anatomical and physiological differences. Paediatric patients also often require sedation or general anaesthesia to ensure no motion during the often lengthy and loud MRI scan. Anaesthesia is also associated with heat loss and hypothermia.

Temperature monitoring and management during MRI scanning is often challenging or even impossible due to the unique MRI environment. Thus, many patients undergo MRI scanning without temperature monitoring or active warming, as would usually occur in an operating theatre.

A case of profound hypothermia post-MRI scan was presented at a morbidity and mortality meeting at Red Cross War Memorial Children's Hospital (RCWMCH). The hypothermia was complicated by hypotension and bradycardia. This case gave rise to the question to be answered in this Masters of Medicine (MMED) dissertation.

Aims and Objectives

The **purpose** of the study was to investigate pre- and post-MRI temperatures in all children undergoing MRI at Red Cross War Memorial Children's Hospital, to determine if significant loss or gain of temperature occurs (+/- 0.5°C).

The **primary aim** was to determine if a significant change in temperature occurs in paediatric patients undergoing MRI. The **secondary aim** was to determine any factors that could lead to such a change. The factors examined included age, weight, body surface area, head circumference, co-morbidities, duration of scan, ambient room temperature, duration of pre-scan fasting and type of sedation/anaesthesia.

The **null hypothesis** stated that no significant temperature changes (+/- 0.5°C) occur in paediatric patients undergoing MRI.

Materials and Methods

Study Design

The study was a prospective audit. Approval from the Human Research Ethics Committee (HREC) of the University of Cape Town was obtained prior to data collection (Appendix A). The same nurse captured pre- and post-scan temperatures, and data for the duration of the study. The consultant paediatric anaesthetist on duty for the day captured intra-scan data.

Characteristics of the Study Population

The study included all children presenting for a MRI scan at RCWMCH in Cape Town from February 2015 until April 2015. All paediatric patients from the ages of zero days up to and including 12 years old, were included. Patients 13 years and older were excluded as they are no longer considered paediatric patients as per the hospital policy.

Inclusion and exclusion criteria

In order to obtain a true reflection of the population presenting for MRI, all patients presenting for MRI were included. This is different to previous studies that used subgroups of the population and excluded certain patients. Thus the study population included:

- Any child with no, or one, or more comorbidities.
- In or outpatients, including critically ill intensive care unit patients.
- Any child on acute or chronic medication.
- Any abnormal pre-scan temperature.
- Any type of sedation, general anaesthesia or no sedation.

The exclusion criteria were as follows:

- Any child 13 years old or older.
- Any child deemed unfit for MRI in the view of the consultant anaesthetist on duty.

Number of Patients

A power calculation was done to determine the sample size. The hypothesis was that children undergoing MRI investigations will display a temperature change of at least 0.5°C. A power calculation based on a paired t-test (each subject as its own control) suggested that a sample size of 198 subjects would be sufficient to allow a reliable acceptance or rejection of the null

hypothesis. A final sample size of two hundred was obtained. A second power calculation determined that the sample size of 198 would be sufficient to examine the secondary aim.

Informed Consent

Obtaining pre- and post-scan temperatures for a scan are routine standard of practice and pose no risk to the child, likewise with the other data to be collected. For these reasons obtaining consent was waived by the HREC.

Privacy and Confidentiality

Each child was issued a study number on arrival and no personal information was recorded, thus ensuring confidentiality.

Research Procedures and Data Collection Methods

Methods for MRI scan

Each child presenting for MRI scan was assessed in the holding area pre-operatively by the consultant anaesthetist on duty. A protocol of the procedure, information to be gathered and inclusion and exclusion criteria was readily available in the MRI suite (Appendix B). The pre-scan data was filled in on the data collection sheet (Appendix C). An intravenous cannula may have been inserted at this point, depending on the choice of anaesthesia or sedation.

Temperature measurement during MRI is difficult because the probe needs to be non-ferromagnetic. The MRI compatible probes that are validated for accuracy require oesphageal placement, which is not suited for patients who do not require a general anaesthetic[3]. Thus the temperature probe needed to be accurate, user-friendly, non-invasive, fast and safe. Considering these factors, the Braun ThermoScan® PRO 4000 infrared tympanic temperature probe was used (Appendix D). Red Cross War Memorial Children's Hospital has this temperature probe and single-patient disposable ear covers available in the MRI suite.

The same ear was used for both the pre- and post-scan temperature measurement, and each measurement was taken by the same nurse throughout the study period. The right ear was used to record the temperatures, but the left ear was used if the right ear was unsuitable. Infrared ear thermometers detect infrared waves emitted from the tympanic membrane, which

receives its blood supply from a branch off the carotid artery and should reflect core temperature.[4] In order to obtain the most reliable result, the probe needs to be positioned correctly. The optimal position is to pull the ear up and back, place the tip in the ear canal and aim it in between the opposite ear and eyebrow.[4] It has been found that depth of penetration does not affect the reading.[4,5] Similarly, it has been demonstrated that minor ear surgery such as myringotomy with grommets does not affect the measured temperature.[6] In contrast, cerumen may result in a slightly lower reading of 0.2°C[4] and suppurative otitis media can cause an elevated reading of about 0.21 °C.[5] This should not affect the study because the aim is to detect a change in temperature and not absolute temperature.

Each child was issued with a standard hospital gown and was covered in a single hospital blanket. Neonates and infants up to six months of age wore a standard hospital gown, a beanie and were wrapped in two blankets; this is the usual practice in the MRI suite at RCWMCH. Routine monitoring was used during the MRI including electrocardiogram, non-invasive blood pressure and pulse oximetry as well as capnography, oxygen and gas/volatile analysis if a general anaesthetic was performed.

Each child was sedated or given a general anaesthetic as deemed appropriate by the consultant anaesthetist on duty. The drug/s, route and dosage as well as airway management were recorded. No active warming devices were used. The scan was conducted using Phillips™ 1.5 Tesla MRI machine.

Intra-scan data was collected during the scan. At the end of the scan, sedation /anaesthesia was terminated. The patient was transferred to the recovery area in a stable condition, where routine monitoring was commenced. A post-scan temperature was measured in the same ear as the pre-scan temperature on arrival (within two minutes) in the recovery suite. The vital signs were also recorded.

Data Collection

The data collected is tabulated in table I.

Table I: Data collected before, during and after the scan

Pre-scan	Intra-scan	Post-scan
Age	Body area scanned	Tympanic temperature
Gender	Time in scan room	Blood Pressure
Weight	Duration of scan	Pulse
Height	Ambient room temperature	Oxygen saturation
Head circumference	Drugs used	Any difficulties
Length of fasting	Airway device	
Co-morbidities	Maintenance of anaesthesia	
Acute Illness		
Medication		
Tympanic temperature		
Blood Pressure		
Pulse		
Oxygen saturation		

Data Safety and Monitoring

The numbered data forms were collected from the MRI suite and taken to the D23, Department of Anaesthesia in Groote Schuur Hospital in Cape Town. The data was captured by a single user on a personal password-protected computer. The data was saved on the computer and in a password-protected private cloud storage utility for backup.

Data Analysis

Data was captured on a data sheet using Microsoft Excel ©. The data is quantitative continuous numerical data with normal distribution. The data was analyzed using Statistica® (version 13.2) and includes range, median, paired students t-test. Multiple linear regression analysis was used to predict temperature changes based on the measured parameters.

Results

The data was collected over a three-month period from a total of 211 patients with 11 patients excluded. Six patients were excluded because they were older than 12 years. A further five patients were excluded because of incomplete data collection.

Descriptive Data

The demographics of the sample group are tabulated in table II, and scan data are tabulated in table III. The sample consisted of 54% male (n=108) and 46% female (n=92) patients. The mean age was 4.9 years with a range of five days to 12 years old. The mean weight, height and head circumference were 19.98kg, 105cm and 50.2cm respectively.

The areas scanned are listed in table III, with the head being the most frequently scanned area (59.5%, n=119). The mean ambient room temperature was 22.25°C, with a range of 20.1°C to 23.7°C. Sedation was the anaesthetic of choice in 83% of patients (n=166). Of these, 18 patients received an inhalation induction prior to sedation, with the remaining 148 patients receiving only intravenous or intranasal agents for sedation. Dexmedetomidine (intravenous or intranasal) was the sole agent used in 22% (n=44) with 57% (n=114) receiving a combination of propofol and dexmedetomidine. The remaining eight patients received various combinations of propofol, dexmedetomidine, midazolam, choral hydrate, alfentanil and ketamine. Inhalational induction was used in eight of the 18 patients undergoing general anaesthesia to facilitate vascular access, with the remaining ten having an intravenous induction. General anaesthesia was maintained using isoflurane/sevoflurane, oxygen and air/nitrous oxide.

Table II: Demographics of sample

Demographic Variable	**Range**	**Mean**	**Standard Deviation (SD)**
Age	5 days to 12 years	4.9 years	+/-3.43 years
Weight	3,6kg to 65,5kg	19.98kg	+/-11.12kg
Height	57cm to 165 cm	105cm	+/- 25cm
Head circumference	35cm to 59.5cm	50.2cm	+/- 4.05cm

Table III: MRI Scan data

Area Scanned Abdomen Arm Head/brain Head/brain and spine Leg Neck Pelvis Spine	**Number** 16 1 119 30 10 3 3 18		
Ambient room temperature	Range 20.1°C to 23.7°C, Mean 22.25°C		
Anaesthetic None (awake patient) Sedation General anaesthesia Sedation converted to general anaesthesia	Number 13 166 18 3		
Time in scanning room (minutes)	Range:14-155	Mean 50	SD +/- 19.11
Length of scan (minutes)	Range: 10-105	Mean 38	SD +/- 17.02

Outcome Measures: Overall Data

The mean pre-scan temperature was 36.60 °C ± 0.51°C (range: 35.50°C – 38.70 °C) and the mean post-scan temperature was 36.44°C ± 0.62 (range: 34.80 - 40.00 °C). Overall, the mean post scan temperature was -0.16°C (P<0.001, 95% confidence interval -0.08°C to -0.24°C) less than the pre-scan temperature. The forest plot is depicted in figure 1.

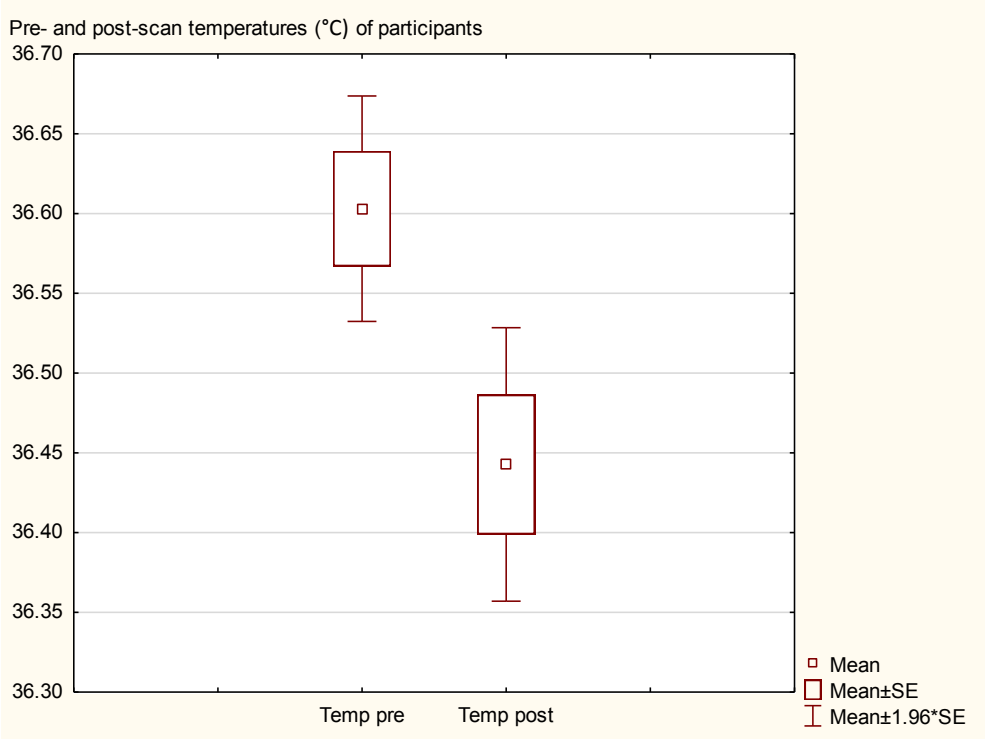

Figure 1: Box and whisker plot of pre and post scan temperatures.

Multiple regression analysis was conducted to determine any secondary factors that may be responsible for the reported change in temperature. Both sedation (r= -0.312, p=0.0358) and general anaesthesia (r= -0.429, p=0.0128) were found to be significant risk factors for a decrease in temperature. A positive correlation between length of scan and a decrease in temperature was found, but this was not statistically significant.

The other variables examined did not reveal any correlation. These included age, head circumference, weight, body surface area, ambient room temperature and duration in the scanning room. Due to inconsistent data availability, length of fasting, co-morbidities, acute illness and medications were excluded from analysis.

Outcome Measures: Subgroup Data

Despite an overall trend towards heat loss during MRI scanning, not all patients were cooler post MRI scan. Temperatures decreased in 55% (n=111) of patients, with 11.5% (n=23) remaining unchanged and 33% (n=66) increased. This is depicted in figure 2.

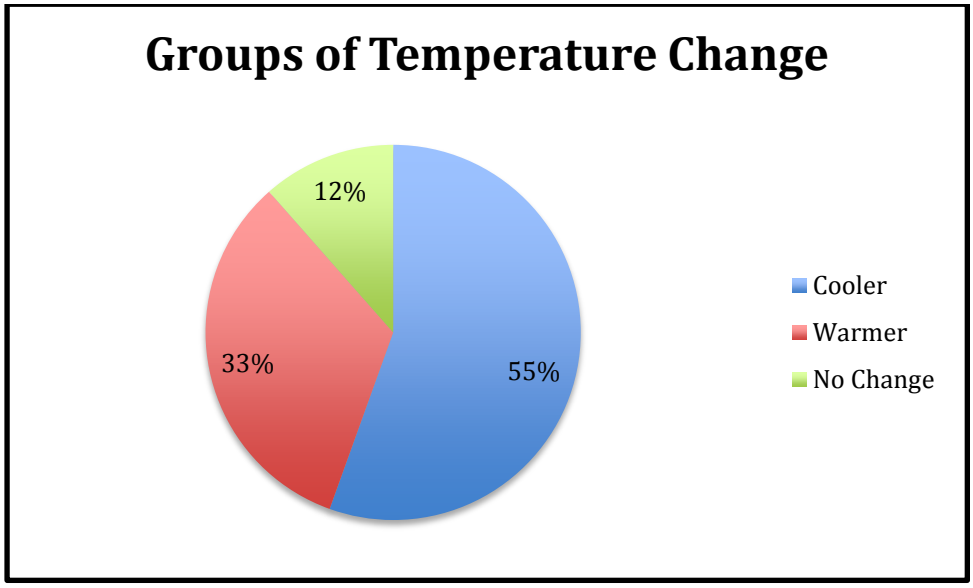

Figure 2: Subgroups of temperature change.

Tympanic temperature decreased in 55.5% (n=111) of patients with a range of loss of 0.1°C to 1.9°C. The mean decrease was 0.55°C (SD +/-0.4°C). Of this group, 19% (n=38) had a decrease in temperature between 0.5°C to 0.9°C, and 10% (n=20) had a decrease of >1°C. Thus 29% (n=58) of patients had a decrease in temperature of greater than 0.5°C.

Mild perioperative hypothermia is defined as a core temperature of less than 36°C.[7,8] Using this definition 13.5% (n=22) of the sample were hypothermic, with the range of temperatures being 34.8°C to 35.9°C. Hyperthermia (>38°C) occurred in 1.5% of patients (n=3), with a range of 38.1°C to 40°C. Of these three patients, two had pre-scan temperatures greater than 38.5°C.

A total of 11% (n=23) of patients had no change in pre- and post-scan temperature, and 33% (n=66) recorded a higher temperature post-scan. The mean gain was 0.44°C (SD +/-0.37°C) with a range of gain in temperature of 0.1°C to 1.5°C. An increase in temperature of between 0.5°C and 0.9°C was found in 11.5% (n=23) of patients, while 3% (n=6) of patients had an increase in temperature of greater than 1°C. The subgroup change in temperature is depicted in figure 3.

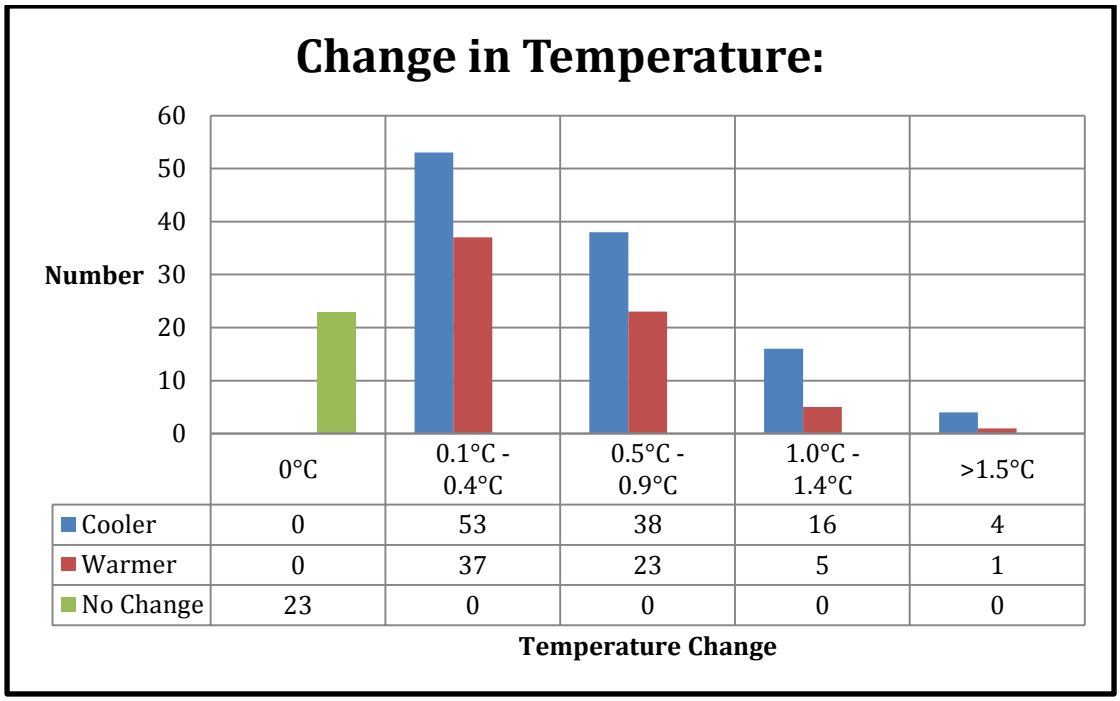

Figure 3: Magnitude of temperature change.

Overall 29 % (n=58) of patients had a decrease in temperature of greater than 0.5°C and14.5% (n=29) of patients had an increase in temperature greater than 0.5°C. Thus, a total of 43.5% (n=87) of patients had a change in temperature of at least 0.5°C. This information is reflected in figure 4.

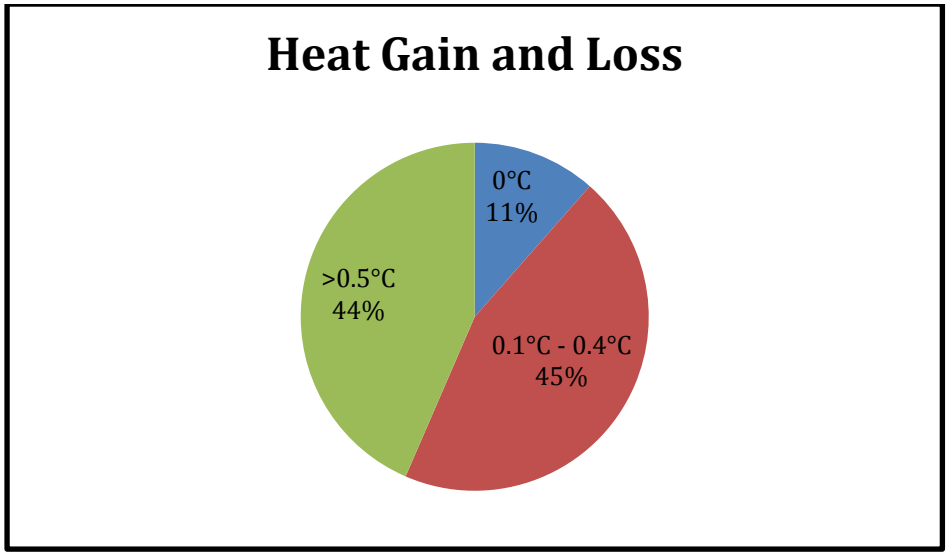

Figure 4: Overall heat gain and loss

Table IV contains the data of the 20 children who lost more than 1°C during the scan and table V contains the data of the six children who gained more than 1°C during the scan.

Gender	Head	Age	Weight	Height	BSA (m^2)	T pre (°C)	T post(°C)	T change	Area scanned	Scan room	Length	Room T (°C)	GA/sed
Male	48	3	13.2	93	0.584	37	35.1	-1.9	Head and spine	79	48	22.2	GA
Female	54	10	37	142	1.2081	36.7	34.9	-1.8	Leg	62	53	22.5	GA
Female	49	3	14.7	105	0.6548	38.2	36.6	-1.6	Abdomen	67	63	23.7	Sed
Male	49	5	13.5	93	0.5906	37.5	36	-1.5	Abdomen	70	57	23.3	GA
Male	51	10	28	132	1.0132	36.2	34.8	-1.4	Leg	77	67	22.8	Sed
Male	44	1	8.3	78	0.4241	37.2	35.8	-1.4	Head	14	10	22.1	Sed
Female	42	0.5	7.1	67	0.3635	37.6	36.3	-1.3	Head	45	25	22	Sed
Female	52	4	15	97.5	0.6374	37.1	35.8	-1.3	Head	45	33	22.3	Sed
Female	56	12	46	156	1.4119	36.9	35.6	-1.3	Head	54	47	23.4	Sed
Female	51	6	15.1	118	0.7035	37.2	36.1	-1.1	Head	77	62	22.5	Sed
Female	45	1	7.7	71	0.3897	37.1	36	-1.1	Head and spine	52	48	22.1	Sed
Female	48	1	9.4	70	0.4275	37	35.9	-1.1	Chest	38	29	21.6	Sed
Male	44	0.58	7	71	0.3716	37.3	36.2	-1.1	Head	45	32	22.3	Sed
Male	54	5	23.4	114	0.8608	36.8	35.7	-1.1	Head	38	32	22	Sed
Female	49	3	14.7	105	0.6548	38.2	37.2	-1	Abdomen	65	42	22.7	Sed
Male	50	7	17	111	0.724	37.7	36.7	-1	Head and spine	69	55	21.8	GA
Female	56	5	22.7	116	0.8552	36.6	35.6	-1	Head	61	50	22.7	Sed
Female	45	2	12.8	92	0.5719	37	36	-1	Spine	45	39	22.9	Sed
Female	52	4	21.7	105	0.7956	37.6	36.6	-1	Head	35	30	21.8	Sed
Female	50	4	16.2	101	0.6742	37.2	36.2	-1	Abdomen	43	33	22.1	Sed

Table IV: Data of patients who had a decrease in temperature of 1°C or more.

(Abbreviations: Head = head circumference (cm), Age in years, Weight (kg), Height (cm), BSA = body surface area), T = temperature, measured in °C, pre = pre-scan, post = post-scan, scan room = time in the scanning room in minutes, length = length of scan in minutes, Sed = sedation, GA = general anaesthesia)

Gender	Head	Age	Weight	Height	BSA (m^2)	T pre (°C)	T post(°C)	T change	Area scanned	Scan room	Length	Room T (°C)	GA/sed
M	50	2	15.8	97	0.6525	36.5	37.5	1	Head	37	34	22.7	Sed
F	47	2	12.5	88	0.5528	36	37.1	1.1	Head and spine	44	35	22.2	Sed
M	49	2	13.7	90	0.5852	36.2	37.4	1.2	Head	39	28	22.1	Sed
F	54	9	35	141	1.1708	36.2	37.4	1.2	Head	35	25	22.6	GA
F	51	9	25.8	140	1.0017	38.6	40	1.4	Head	41	28	22.6	Awake
F	52	11	24.3	128	0.9295	36.6	38.1	1.5	Head and spine	74	61	22.5	GA

Table V: Data of patients who had an increase in temperature of 1°C or more.

(Abbreviations: Head = head circumference (cm), Age in years, weight (kg), Height (cm), BSA = body surface area), T = temperature, measured in °C, pre = pre-scan, post = post-scan, scan room = time in the scanning room in minutes, length = length of scan in minutes, Sed = sedation, GA = general anaesthesia)

Discussion

Results

Overall, it was found that paediatric patients tend to lose heat during MRI scanning. The result of 0.16°C cooler is less than the predicted value of 0.5°C, therefore we can accept the null hypothesis. Although the decrease is statistically significant, is unlikely to pose a problem in clinical practice and is probably not clinically significant.

Comparison of our results to previous studies is difficult due to the heterogeneity of the studies and samples. Table VI depicts the key differences in the six similar studies (the case report and the studies examining temperature as a secondary outcome are not included). Nonetheless, some similarities between the studies have been found, which will be further discussed.

Table VI: Details of previous studies involving temperature in paediatric MRI

Study	Year	Sample Size	Age	Sedation/GA/none	Area Scanned	MRI Tesla (T)
Bryan et al.	2006	30	2-33 months	Sedation - chloral hydrate	Brain	1.5T
Machata et al.	2009	76	1 month - 6 years	Sedation	Brain	1.5T and 3T
Isaacson et al.	2011	374	0-21 years	Sedation vs None	Any	1.5T vs 3T
Acar et al.	2012	30	0-7 years	GA	Any	1.5
Patel et al.	2011	64	6 months - 8 years	GA	Any	Not recorded
Lo et al.	2014	193	3 months - 6 years	GA	Any	1.5T or 3T
Our Study	2016	200	5 days to 12 years	GA, Sedation or None	Any	1.5T

A trend towards heat loss was found in four other studies; two examined temperature as a primary outcome and two examined temperature as a secondary outcome. Patel et al.[9] demonstrated an overall decrease in temperature of 1.03°C in a prospective observational cohort of 64 children. A larger study conducted by Lo et al. in 2014[10] had an overall decrease of 0.28°C +/-0.6°C. (95% CI -0.36°C to -0.19°C P <0.001). Tsui et al.[11] examined temperature change as a secondary outcome in children receiving propofol and remifentanil sedation for MRI. They reported an overall decrease of 0.3°C, which was not statistically significant. Plasier et al.[12] examined safety outcomes in premature infants undergoing MRI. Temperature was found to decrease on average by 0.5°C.

These above mentioned reported a trend towards heat loss in paediatric patients undergoing MRI scanning and are echoed in our study. In contrast, two older studies showed heat gain during MRI scanning as the overall outcome. A case report was published by Kussman et al.[13] of clinically significant hyperthermia (38°C) in a 16-month-old child. In 2006, Bryan et al.[14] reported an average increase in temperature of 0.5°C in their study involving 30 paediatric patients. These findings were confirmed by Machata et al.[15] in 2009. The cohort consisted of 38 patients, and they found an average increase of 0.2°C and 0.5°C in core temperature in patients undergoing MRI with a 1.5 Tesla and 3 Tesla machines, respectively.

Although the entire cohort in our study had a statistically significant decrease in temperature, not all children were cooler. In fact 11.5% (n=23) had no change in temperature and 33% (n=66) were in fact warmer after the scan (see figure 2). This shows that even though the overall result is heat loss, it must be noted, that almost half (44.5%, n=89) were not cooler – but either warmer or the same temperature. This finding of mixed results was reported in a further two studies. In 2011, Isaacson et al.[16] conducted a large prospective observational study that enrolled 400 patients. Their overall finding showed no significant change in temperature (P=-0.0155°C, 95% CI -0.035, 0.064), but reported heat loss in or gain in many of their patients. These findings were echoed by a study by Acar et al.[17] in 2012. Despite finding an overall decrease in temperature of -0.4°C, they concluded that paediatric patients undergoing MRI scanning may gain or lose heat, or stay the same temperature.

Similar to our study, the results by Lo et al.[10] also reflected an overall tendency to heat loss. However not all their patients were cooler post scan. In fact, 64% were cooler, 29% were warmer and 6.7% remained unchanged. These numbers are similar to our study with 55.5% cooler, 33% warmer and 11.5% unchanged.

Subgroup analysis of the group who had a decrease in temperature (55.5%, n=111) revealed that 13.5% of the sample group were by definition hypothermic (<36°C), with the lowest recorded post-scan temperature of 34.8°C. There is a clear association of hypothermia and adverse outcomes as discussed previously [7,8,18-20]. It was also shown that the mean decrease in temperature was 0.55°C, with 29% (n=58) having a minimum decrease of 0.5°C. These results suggest that a clinically significant proportion of paediatric patients undergoing MRI are at risk of significant heat loss and hypothermia.

The warmer subgroup (33%, n=66) only had 1.5% (n=3) of patients with clinical hyperthermia, but 14.5% (n=29) patients had an increase of more than 0.5°C. In total, almost half of the study group (43,5%, n=87) had a minimum increase or decrease in temperature of 0.5°C. This is clinically relevant; paediatric patients are at risk of significant temperature change and should have their temperature monitored and actively managed during MRI scanning.

Isaacson et al.[16]found similar temperature increases and decreases, with 19.49% of patients having a decrease in temperature more than 0.5°C and 18.21% having an increase of greater that 0.5°C. In total, 37.42% had a minimum change in temperature of 0.5°C, which is less than our group, but still clinically significant.

The only factors that were found in this study to be associated (with statistical significance) with a decrease in temperature were the use of sedation and general anaesthesia; longer length of scan was associated with heat loss but was not statistically significant. Similarly, Isaacson et al.[16], found a link between the use of propofol sedation and heat loss, however their association between no sedation and heat gain was not found in our study.

Other studies have found other associations for temperature change that we did not find. The use of stronger magnets was associated with heat gain by Isaacson et al and Machata et al.[15], however this variable was not examined in our study. An association between younger age and heat loss was found by both Isaacson et al.[16] and Patel et al.[9]. Lower pre-scan temperatures were associated with lower post-scan temperatures by Lo et al.[10]

Limitations

The aim of our study was to detect temperature changes in all patients presenting for MRI scanning, as reflected in clinical practice. Therefore our exclusion criterion was limited to patients no longer defined as paediatric patients according to our institutional policy. For this reason the group demographics and intra-scan variables are heterogeneous and may have affected the analysis of contributory factors.

A number of potential contributory factors were not examined in our study. SAR was recognized to be a potential contributor to temperature changes by other authors, but we did

not record this variable during our study. Potential secondary contributory factors, such as co-morbidities, medications, acute illness and ear protection, were excluded from analysis due to poor recording; this may have been avoided if the instructions on the data collection form had been more specific.

Core temperature measurement is more accurate in paediatric patients compared to tympanic temperature measurement[21], but placement of core temperature probes is not possible in awake and sedated patients. However, infrared temperature measurement is more reliable than other less invasive measurement sites such as the mouth or axilla[21]. To decrease the chances of incorrect measurement, the same ear was used and the same observer took the measurement in a standardized manner.

Future Research

Studies to identify secondary factors that may contribute to temperature change in paediatric patients undergoing MRI scanning may help to identify which high risk patients need temperature monitoring and management during MRI scanning.

Conclusion

Overall, paediatric patients undergoing MRI scans display a decrease in temperature of -0.16°C. Clinically, this value is small and not clinically significant. Individually, each paediatric patient may have an increase or decrease in temperature, or no change. A significant proportion of paediatric patients are at risk of hypothermia post MRI scan, and almost half are at risk of an increase or decrease in temperature of a minimum of 0.5°C. These factors are clinically significant and may be associated with adverse outcomes. For these reasons, temperature monitoring and active temperature management should be implemented during MRI scanning in paediatric patients.

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APPENDIX A

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492 • **Facsimile** [021] 406 6411
Email: Sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

28 January 2015

HREC/REF: 895/2014

Prof J Thomas
Anaesthesia
D5
Red Cross Children's Hospital
Rondebosch

Dear Prof Thomas

Project Title: TEMPERATURE CHANGES IN PAEDIATRIC PATIENTS UNDERGOING MAGNETIC RESONANCE IMAGIN: A RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL EXPERIENCE (MMed-candidate - Dr Z Fullerton)

Thank you for your response letter dated 26 January 2015, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned study.

Approval is granted for one year until the 30 January 2016.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

We acknowledge that the following students:-Zahnne Fullerton is also involved in this project.

Please note that the on-going ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

"Federal Wide Assurance Number: FWA00001637.

Hrec/ref:895/2014

APPENDIX B

MRI & Temperature Study

Thank you for helping collect data for my MMED

Obtain informed consent – English/Xhosa/Afrikaans.

Inclusion criteria

- Any age from 0 days up to and including 12 years
- Any child with one or more comorbidities.
- In or outpatients, including critically ill ICU patients.
- Any child on acute or chronic medication.
- Any type of sedation, general anaesthesia or no sedation.

Exclusion criteria:

- Any child 13 years old or older
- Any child deemed unfit for MRI in the view of the consultant anaesthetist on duty.
- Refusal of consent

What information to collect?

Process

- Chose GA/Sedation/no sedation as per usual
- Each child to wear only a hospital issue gown and a single hospital issue blanket if >6 months.
- If less than 6 months old – a hospital gown, a beanie and two hospital blankets to wrap baby.

Data to collect in the prescan area:

- Age and gender
- Weight, height/length. We will calculate BSA later
- Head circumference
- Length of fasting
- Co-morbidities and chronic medications
- Acute illness and acute medications
- Right tympanic temperature. (You may use the left ear – as long as you use the same ear for both temperatures.)

Data to collect during the scan:

- Body area scanned
- Length of scan
- Ambient room temperature – taken at the beginning of the scan with alcohol thermometer in room
- Drugs used including route and total dose (if any)
- Airway device used (if any)
- Volume and type of fluid administered (if any)

- Maintenance of anaesthesia.
- Head devices and ear protection

Post-scan data:

- Right (or left) tympanic temperature
- Blood pressure, heart rate and pulse

Taking the temperature

Please use the right ear for both temperatures
The left ear may be used if you are unable to use the right ear.
Use a new probe cover for each child.
The ear must be gently pulled upwards and backwards, the probe placed in the canal and aimed between the opposite ear and eyebrow.
Please measure the post scan temperature as soon as possible after the scan, within 3 minutes

Please place the completed form in the box provided!

Any questions – please call me on 0820984857
Thanks! Zahnne

APPENDIX C

MRI & Temperature Study – Zahnne Fullerton **Study number:_____**

Pre-Scan Data

Age: _____ Weight:_____ Height:_____
Gender: male/female Head circ:_____ BSA: _____
BP: _____ Pulse:_____ Sats:_____
Fasting time:_____
Comorbidities and chronic medications:

_____ _____ _____
_____ _____ _____
_____ _____ _____
_____ _____ _____
_____ _____ _____

Acute illness and acute medications:

_____ _____ _____
_____ _____ _____
_____ _____ _____
_____ _____ _____
_____ _____ _____

Ear used for temperature: right/left Temperature: _____

Intra-scan Data

Areas scanned_____
Time into scan room:_____ Time out of scan room:_____
Start time of scan:_____ End time of scan:_____
Room temperature:_____
Type anaesthetic: GA/sedation/no-sedation
Gas induction: yes/no 02/N20/air/sevoflurane
Drugs used and dose

_____ _____ _____ _____
_____ _____ _____ _____
_____ _____ _____ _____
_____ _____ _____ _____
_____ _____ _____ _____

Airway device and size:_____
Fluid given and volume:

_____ _____ _____ _____
_____ _____ _____ _____

Maintenance of anaesthesia: O2/air/N20 Sevoflurane/Halothane/Isoflurane
Ear/head protection: _____

Post-scan Data

Ear used for temperature: right/left Temperature: _____
BP_____ Pulse_____ Sats_____

Comments/Difficulties

_____
_____
_____

APPENDIX D


The Braun ThermoScan®
PRO 4000 Ear Thermometer
The speed and simplicity you need for accurate, reliable temperature readings
BRAUN
WelchAllyn®
Advancing Frontline Care™

The Braun ThermoScan® PRO 4000 – patented technology to give you the speed and accuracy you need with all your patients, day or night.

- **Exclusive ExacTemp™ technology provides an active user feedback light that signals that the probe has been positioned in a stable way throughout the measurement, avoiding inaccurate measurements by handling errors**
- **Preheated probe tip minimises the cool-down effect experienced when taking repeat temperatures, improving accuracy and repeatability**
- **Probe cover detection system ensures a new probe cover is always used, improving accuracy by ensuring precise infrared heat transfer**
- **Automatic probe cover eject button for quick and easy removal of used probe covers**

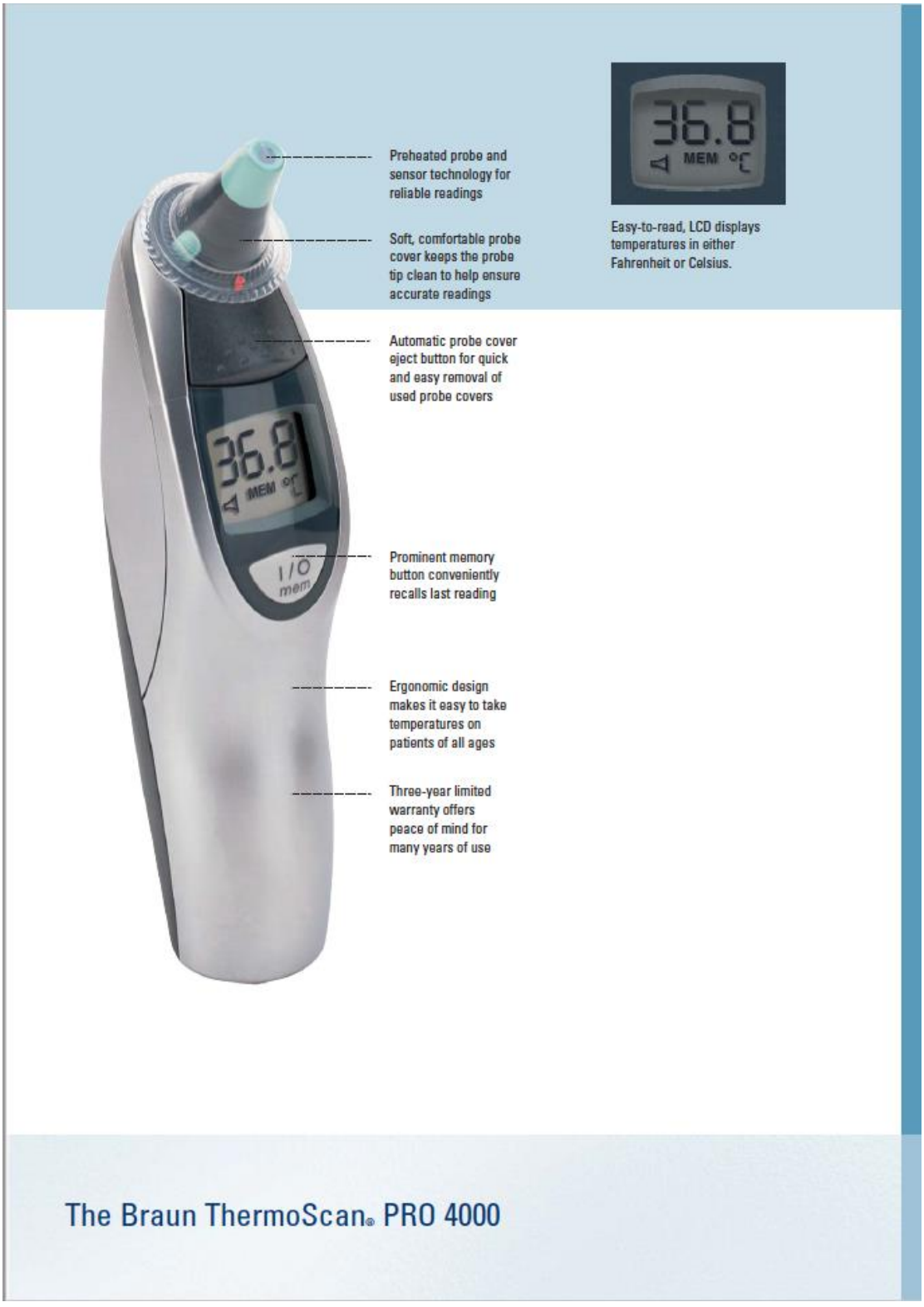
When it's time to take temperatures some patients have little patience. The ergonomically designed Braun ThermoScan® PRO 4000 ear thermometer is engineered to take temperatures easily and accurately with the click of a button.

Easy: An easy-to-read LCD display with icons that clearly communicate in any language, and an intuitive user interface and ergonomic shape.

Fast and Accurate: The only ear thermometer with a preheated probe and sensor for reliable readings. Active user feedback LED allows for fast and accurate anatomical positioning.

Safe: Patient safety is assured thanks to an automatic probe cover eject button that reduces the risk of cross-contamination.

Secure: Optional security features can reduce the occurrence of theft in hospital environments.


36.8
MEM °C
Preheated probe and sensor technology for reliable readings
Soft, comfortable probe cover keeps the probe tip clean to help ensure accurate readings
Automatic probe cover eject button for quick and easy removal of used probe covers
Prominent memory button conveniently recalls last reading
Ergonomic design makes it easy to take temperatures on patients of all ages
Three-year limited warranty offers peace of mind for many years of use
Easy-to-read, LCD displays temperatures in either Fahrenheit or Celsius.
The Braun ThermoScan® PRO 4000

The Braun ThermoScan® PRO 4000 – setting the standard of care even higher

Braun ThermoScan® PRO 4000 specifications

Calibration Accuracy	±0.2 °C for the thermometer at 35.5 - 42.0 °C
Response Time	3-7 seconds
Unit Dimensions	152 mm x 44 mm x 33 mm
Weight (without batteries)	100 grams
Ambient Temperature Range	10.0 °C - 40.0 °C
Patient Temperature Range	20.0 °C - 42.2 °C
Power Source	(2) 1.5V AA disposable batteries
Battery Life Disposable Batteries	Approx. 6 months or 1000 temperatures
Warranty	3 year limited instrument

ordering information

thermometers

04000-600 Braun ThermoScan® PRO 4000 Ear Thermometer, 3-year limited Warranty

accessories

53009-000 Replacement Alkaline Batteries

replacement probe covers

04000-800 Braun ThermoScan® PRO 4000 Disposable Probe Covers (Case of 800 probe covers)

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