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Effect of pre-warming on paediatric patients presenting for magnetic resonance imaging under general anaesthesia

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

Johannesburg, 2020

Declaration

I, Emily Mathilda Bezuidenhout, declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

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24 March 2020

Abstract

Background

The combination of anaesthesia and environmental factors in the magnetic resonance imaging (MRI) suite increases patient susceptibility to hypothermia. Pre-warming patients with a forced-air warmer prior to anaesthesia has been shown to decrease the incidence of peri-operative hypothermia. This study aimed to determine whether pre-warming paediatric patients presenting for MRI under general anaesthetic prevented them from developing hypothermia.

Methods

A prospective, quasi-experimental research design was followed. A total of 102 patients were enrolled during the 4-month study period and were divided equally into pre-warmed and control groups. Inclusion criteria were patients aged 6 months to 6 years, ASA physical status I or II and with written informed consent from a caregiver. The pre-warmed group received 30 minutes of active warming with a forced-air warmer. The MRI examination was conducted using a volatile-based general anaesthetic. Tympanic temperatures were measured at baseline, pre-scan and post-scan.

Results

The pre-warmed group received an average (SD) of 34.8 (4.3) minutes of warming. The median (IQR) time spent inside the MRI unit was 60 (50 to 77) minutes. The incidence of hypothermia was 1.96%. The pre-warmed group had a statistically significant increase of 0.3°C in core body temperature (CBT) compared to the control group following the pre-warming period ($p=0.0001$). There was a statistically significant difference in CBT between the pre-warmed and control groups (0.15°C; $p=0.0001$). A weak negative correlation between patient weight and temperature change ($r=-0.220$, $p=0.026$) and between length of time of pre-warming and temperature change ($r=-0.268$, $p=0.006$) was found.

Conclusions

The effect of pre-warming to prevent hypothermia under general anaesthetic in the MRI unit could not be established due to the low incidence of hypothermia. Pre-warming patients for a period of 30 minutes prevented a statistically significant decline in CBT compared to the control group, however, this finding was not clinically significant.

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Abbreviations

ASA	American Society of Anesthesiologists
ATP	Adenosine triphosphate
CBT	Core body temperature
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
CHBAH	Chris Hani Baragwanath Academic Hospital
ECG	Electrocardiogram
FAW	Forced-air warming
IQR	Interquartile range
MAC	Minimum alveolar concentration
MMED	Masters of Medicine
MRI	Magnetic resonance imaging
NICE	National Institute for Health Care Excellence
RF	Radiofrequency
SAJAA	Southern African Journal of Anaesthesia and Analgesia
SAR	Specific absorption rate
SASA	South African Society of Anaesthesiologists
SD	Standard deviation
TTM	Targeted temperature management

Statement

The Research Report consists of a literature review, draft article, study proposal and appendices. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article may differ from the rest of the Research Report in order to comply with the author guidelines of the Southern African Journal of Anaesthesia and Analgesia (SAJAA), the journal to which it is intended to be submitted.

Section 1: Review of the literature

1.1 Introduction

Magnetic Resonance Imaging (MRI) scans are increasingly used as a diagnostic modality (1). Patients are required to remain still for the duration of the scanning process in order to obtain high quality images. Paediatric patients can often not comply with this requirement and are therefore sedated or anaesthetised to minimise movement (2). The MRI environment poses a significant challenge for thermal control due to low ambient temperatures required for scanner operation, the possibility of radiofrequency heating, limitations of remote monitoring and MRI incompatibility of most warming devices (3–5). This situation is then further compounded by sedation or anaesthesia that limits intrinsic thermoregulation (6,7). Inadvertent hypothermia under anaesthesia has well documented adverse effects (8–11).

This literature review will address the physiology of thermoregulation with the emphasis on differences in the paediatric population. The physiological effects of hypothermia and hyperthermia will be summarised. The effects of general and regional anaesthesia on temperature control will be discussed. Temperature monitoring, warming methods and relevant research on pre-operative warming will be overviewed.

The physical principles of MRI, the challenges of the MRI environment with particular emphasis on anaesthetic monitoring and temperature control will be reviewed.

1.2 Physiology of thermoregulation

Thermoregulation is the mechanism the body uses to maintain a constant temperature and this is mainly regulated by the hypothalamus. Mammals are

homeothermic and require a near constant body temperature and this is regulated within a narrow range. The core temperature is usually maintained within 0.4°C of a normal temperature set point of 37°C (12,13). This is known as the interthreshold range, the temperature range above and below the norm which does not trigger a thermoregulatory response. When the core temperature deviates by more than 0.4°C, autonomic thermoregulatory responses are activated to normalise the temperature (12,13).

1.2.1 Temperature distribution

Body temperature is heterogeneously distributed between the core body temperature and skin surface temperature. The core accounts for about two thirds of the body heat content and comprises the trunk, organs and brain. The core temperature is tightly regulated in order to maintain cellular enzyme function. The peripheral compartment comprises the skin, subcutaneous tissues and limbs and represents about one third of the total heat content of the body. The peripheral compartment can withstand wide fluctuation in temperature and there exists a 2 to 4°C gradient between the core and periphery (14).

1.2.2 Thermoregulation

Normal thermoregulation depends on the interaction of afferent thermal sensors, central regulation and efferent responses (13,14).

Afferent input

Thermal information is registered by warm and cold sensitive cells, distributed in cutaneous and visceral tissues around the body (14). Cold signals generally travel via the A-delta fibres and they discharge maximally between 25 and 30°C. Warm signals travel via unmyelinated C-fibres and discharge maximally between 45 and 50°C (12,15). Afferent temperature information ascends via the spinothalamic tracts in the anterior spinal cord (12).

Central control

Central structures, in particular the pre-optic area of the anterior hypothalamus, are responsible for the integration and regulation of thermal input (12,14,16).The posterior hypothalamus, reticular formation, medulla and spinal cord also contains neurones that are sensitive to thermal stimuli. The posterior hypothalamus integrates cold afferent signals from the periphery and compares them to a threshold temperature for each thermoregulatory response, following which it instigates an effector response (13,17). Central control involves autonomic and behavioural responses. Behavioural responses are largely determined by input from the skin surface and autonomic responses from thermal input from core structures. Core receptors contribute 80% of autonomic responses and skin input only 20% (6,14).

Efferent responses

These are either behavioural or autonomic in nature. Behavioural regulation is quantitatively the most important effector mechanism in conscious people but has no role to play under anaesthesia (14). Efferent responses are designed to either increase metabolic heat production or alter environmental heat loss and are employed when the core body temperature reaches the threshold temperature (6,17). Autonomic responses include cold defences, such as cutaneous vasoconstriction of arterio-venous shunts, piloerection, non-shivering thermogenesis and shivering, and heat defences, such as sweating and active vasodilatation (14,16).

Each thermoregulatory response is characterised by a threshold temperature, gain and maximum intensity. The threshold temperature is where a response becomes activated, the gain is the rate of response to a given stimulus and maximum intensity is where no further increase in response occurs despite further deviations in core temperature (13,14).

1.3 Thermoregulation under anaesthesia

Heat is transferred through the mechanisms of radiation, convection, conduction and evaporation. Radiation and convection are clinically the most significant, with the majority of heat loss occurring via the skin surface (18,19). The main reasons for intra-operative hypothermia are a cold operating room environment and impaired thermoregulation due to the anaesthetic agents themselves (20).

1.3.1 General anaesthesia

All general anaesthetic agents so far tested, impair autonomic thermoregulatory control in a dose-dependent fashion and increase the interthreshold range (13,21). The warm responses are better preserved than the cold responses; the cold responses also being less effective when triggered. Under anaesthesia warm response thresholds are elevated whereas cold-response thresholds are markedly reduced, therefore widening the interthreshold range to 2 to 4°C (8,12,14,20).

General anaesthesia is associated with three recognisable patterns of hypothermia following induction of anaesthesia namely a phase of rapid decline, followed by a slow linear decline and ultimately a plateau phase (21).

The rapid decline in core temperature by 0.5 to 1.5°C occurs within the first hour of anaesthesia and is primarily due to thermal redistribution (21,22). The peripheral body temperature can be between 2 to 4°C cooler than the core. Normally this temperature gradient is maintained by vasoconstriction, but under anaesthesia the threshold for vasoconstriction is reduced, arteriovenous shunts open and vasodilatation occurs with heat flowing from the core to the periphery (22). This rapid decline is almost solely due to redistribution and very little heat is lost to the environment, i.e. there is no net loss of body heat during this phase (6,13,20).

A slow linear decline occurs over the next 1 to 2 hours and is due to heat loss to the environment exceeding metabolic heat production (8,13,14) . Core temperature usually reaches a plateau after 3 to 4 hours of anaesthesia. A thermal steady state is achieved where heat loss equals metabolic heat production. There may be some effect of peripheral vasoconstriction, which is triggered when the patient becomes sufficiently hypothermic (core temperature 33 to 35°C). This means that heat is retained at the core and its transmission to the peripheries is diminished (16,20).

1.3.2 Neuraxial anaesthesia

Neuraxial anaesthesia also impairs autonomic thermoregulation at both a central and peripheral level, but to a lesser degree than general anaesthesia. Neuraxial anaesthesia decreases the cold sensitive thresholds, above the level of the block, by about 0.6°C (14,20). Hypothermia under neuraxial blockade is not often consciously recognised by the patient, who may be shivering and have core hypothermia, but denies feeling cold. The reason that core hypothermia is undetected by the patient is because subjective thermal perception is triggered by afferent input from the skin rather than by core temperature. The vasodilatation resulting from regional anaesthesia increases skin temperature and leads to a sensation of warmth, despite core hypothermia and shivering (6,14,16).

Additionally, with neuraxial blockade, the thermal input from the legs is abolished, this is typically cold information. The brain therefore receives less cold information than usual from the peripheries and interprets this as relative warming, with reduced vasoconstriction and shivering thresholds. If neuraxial blockade is supplemented by sedation or general anaesthesia, the cold responses are further inhibited and severe hypothermia may result. The interthreshold range for neuraxial blockade is about 0.9°C (14).

The cooling patterns observed under general anaesthesia differ when neuraxial blockade is administered. The rapid decrease in core temperature is still observed, but is because of peripheral inhibition of tonic vasoconstriction (rather than central inhibition as seen with general anaesthesia). The rapid decrease in temperature may not be as precipitous as that occurring in general anaesthesia because the redistribution is confined to the lower half of the body. Under neuraxial anaesthesia, hypothermia tends to progress and the thermal steady state and plateau phase do not occur. The mechanism for thermal steady state, namely triggered vasoconstriction, can only occur cephalad to the level of the block and is insufficient to counterbalance the effects of vasodilatation below the level of the block(14,16).

1.4 Paediatric thermoregulation

Paediatric patients are more susceptible to peri-operative hypothermia. This is due to a combination of decreased heat production and increased heat loss under anaesthesia (19). Paediatric patients undergoing general anaesthesia experience a 20% decrease in metabolic rate (23), which is comparable to that seen in the adult population. In neonates however, approximately half the oxygen consumption and therefore heat generated can be attributed to the work of respiration. When under general anaesthetic and mechanically ventilated, this source of heat production is largely removed (24). Other factors contributing to the increased risk of hypothermia are central thermoregulatory inhibition and redistribution of heat, similar to that in adults, but with an increased slope in each phase (25).

An adaptation specific to neonates is non-shivering thermogenesis, a metabolic process that occurs in brown fat. ATP synthesis is uncoupled from oxidative phosphorylation, which results in heat production (14). Volatile anaesthetics (halothane, enflurane and isoflurane), at clinically relevant concentrations, inhibit non-shivering thermogenesis (26,27).

Infants have a greater surface area to weight ratio compared to adults and also have less insulation in the form of subcutaneous adipose tissue. These factors increase thermal conductance and heat loss through the skin (19,21). Warmer ambient temperatures are required to prevent them from exhausting their compensatory mechanisms and they will become hypothermic at 22°C.

Neonates and infants are most vulnerable to the adverse effects of hypothermia. Cold stress causes increased sympathetic activity with increased oxygen consumption and substrate utilisation (19).

1.5 Hypothermia

Hypothermia is defined physiologically as greater than one standard deviation below the mean core temperature for that mammal, under resting conditions in a thermoneutral environment. In humans, it is generally accepted as occurring at 36.4°C (16). The clinical anaesthetist's working definition of mild hypothermia is 34 to 36°C and is the approximate temperature at which mild organ dysfunction begins to develop (7,12)

1.5.1 Benefits

Mild hypothermia provides some protection against cerebral ischaemia and hypoxia (28), reduces oxygen consumption and blunts the effect of malignant hyperthermia (9,12). This neuroprotective effect of hypothermia is utilised during cardiac surgery or deep hypothermic arrest (29). Therapeutic hypothermia or targeted temperature management (TTM) has only shown some clinical benefit in out of hospital cardiac arrest with return of spontaneous circulation (30,31) and in neonatal patients with hypoxic-ischaemic encephalopathy (31).

1.5.2 Complications

Unintentional perioperative hypothermia is known to have many adverse outcomes (19,32). Hypothermia reduces cardiac output, increases systemic vascular resistance, increases the occurrence of arrhythmias and causes ECG changes such as prolonged PR, widened QRS and prolonged QT intervals (19,33).

Thermal discomfort can induce physical stresses such as an elevation of blood pressure, heart rate and plasma catecholamines, which presumably contribute to the morbidity seen with mild perioperative hypothermia (6,20,33). Hypothermia causes a left shift in the oxyhaemoglobin dissociation curve, thus reducing the available oxygen at tissue level. The combination of increased myocardial oxygen demand and reduction in myocardial oxygen supply may result in ischaemia (19).

Cerebral metabolic rate decreases by 7 to 10% for every 1°C drop in temperature (24). Hypothermia decreases cerebral blood flow and ultimately induces loss of consciousness at 28 to 30°C (32). Hypothermia reduces hypoxic ventilatory drive and attenuates hypoxic pulmonary vasoconstriction (34). It decreases renal blood flow and glomerular filtration rate and induces a cold diuresis (24). Hypothermia also reduces hepatic blood flow (hepatic artery more than portal vein), increases liver size and decreases metabolic and excretory functions (32).

Hypothermia is associated with a cold-induced defect in platelet functioning. This is the most important coagulation abnormality seen in mild perioperative hypothermia and is related to local temperature, not core temperature (6,19,35). In addition to a qualitative reduction in platelet function, there is also a reduction in circulating numbers as platelets become sequestered in the enlarged hypothermic liver. Enzymes of the coagulation cascade are impaired; this may not be seen in routine laboratory tests as these are carried out at 37°C (36). Fibrinolysis is enhanced with hypothermia, this leads to unstable clots and increased risk of bleeding (19). Blood transfusion requirements increase in proportion to the

decrease in temperature and duration of hypothermia (37). Viscosity also increases by 2 to 3% for every 1°C drop in temperature (18).

Drug metabolism markedly decreases with perioperative hypothermia (6,19). A 2°C drop in core temperature more than doubles the duration of action of vecuronium (38). This may be due to the reduction in hepatic metabolism seen in hypothermia. The twitch strength is also reduced by core hypothermia, irrespective of neuromuscular blockade (19). The minimum alveolar concentration (MAC) is reduced by 5% for every 1°C drop in temperature and at 20°C no anaesthesia is required to prevent movement in response to a skin incision (39).

Hypothermia increases the incidence of surgical site infections (40). Several mechanisms may be responsible including impaired antibody production and neutrophil function, impaired chemotaxis and phagocytosis (32). Vasoconstriction also reduces blood flow and therefore oxygen supply to healing tissues (19,20). A RCT involving 200 patients undergoing colorectal surgery found a 19% incidence of wound infections in the hypothermia group compared to 6% in the normothermic group (40).

Hypothermia leads to an increase in length of hospital stay and delay in discharge from the anaesthetic recovery room (32,40). Patients experience an increase in thermal discomfort and shivering (16,41) with a resultant increase in oxygen consumption.

1.6 Hyperthermia

Hyperthermia is defined as a core body temperature of > 37.5°C and is much less common in the peri-operative period (42). It can result from excessive or prolonged heating with warming systems, prevention of heat loss, the administration of warmed fluids or lavage solutions and excessive heat production (22).

Fever is defined by an increase in the internal thermostat set point and is regulated by the hypothalamus in response to circulating inflammatory cytokines (29). Causes of fever in the perioperative period include infections, transfusion reactions and medication (neurolept malignant syndrome, serotonergic syndrome) or anaesthetic (malignant hyperthermia) side effects. Hyperpyrexia is a core temperature ≥ 40°C and results in life-threatening multi-organ failure when temperature exceeds 41.5°C (43). The potential complications include pulmonary oedema, acute respiratory distress syndrome, renal failure, hepatic dysfunction, neurological deficits and seizures, rhabdomyolysis and diffuse intravascular coagulation (43).

1.7 Temperature monitoring

According to the SASA practice guidelines core temperature monitoring is regarded as a minimum requirement for the safe conduct of anaesthesia (44). The Association of Anaesthetists of Great Britain and Ireland's recommendations for standard monitoring during anaesthesia considers temperature monitoring a minimum requirement for any anaesthetic longer than 30 minutes in duration (45).

Temperature monitoring devices vary according to the transducer type and monitoring site. The most commonly used transducer types are thermistors and thermocouples (9,20). Newer developments include tympanic thermometers that use infrared emission to measure temperature, liquid crystal sensors used to measure skin temperature (20) and fibre-optic sensors that can function in an environment with high radiofrequency and microwave interference (46).

Core temperature is the best indicator of body temperature and all temperature measurements at peripheral sites need to be assessed by their ability to accurately reflect the core temperature (8,14,20). Techniques that measure core temperature to within 0.5°C accuracy, should be used under general anaesthesia

(21). Core temperatures are measured at the pulmonary artery, distal oesophagus, tympanic membrane, nasopharynx and bladder (20). Pulmonary artery catheter temperature measurement (via a thermistor) is regarded as the gold standard for core temperature measurement but because of cost and invasiveness are not employed on a regular basis (14). Intra-operatively, core temperature is ideally measured by an oesophageal probe, positioned at the point of maximal heart sounds (14). This method is low risk and low cost and provides the most accurate assessment of core temperature when compared to pulmonary artery catheter measurements (19). Nasopharyngeal probes should be inserted at least 10cm past the nares to obtain core temperature and are probably only accurate in patients who are not breathing through their nostrils (14,21).

Tympanic temperature measurement is believed to be a reliable measure of core temperature because the hypothalamus and tympanic membrane share their arterial blood supply from the carotid artery (47,48). Readings are affected by the presence of debris in the ear and incorrect technique, where the external auditory canal temperature is measured instead (21). The presence of acute otitis media can increase the tympanic temperature measurement with a mean of 0.5°C while cerumen can decrease the temperature with 0.6°C (47). Non-suppurative otitis media, fluid in the middle ear, perforation of the tympanic membrane and grommets do not affect the measured temperature (47,48).

Near core temperatures such as that obtained at the axilla, rectum, bladder (with low urine flow) and oral cavity are more commonly used during regional anaesthesia and in the peri-operative period. These measurements are easier to obtain but are affected by the ambient temperature and changes in regional skin blood flow (19).

1.8 Temperature management

The National Institute for Health Care Excellence (NICE) published guidelines on the prevention and treatment of peri-operative hypothermia (49). Their target core

body temperature during anaesthesia and surgery is 36.5°C and temperature management should commence in the pre-operative phase. Temperature can be managed by passive methods, mainly aimed at minimising cutaneous heat loss and active warming or cooling methods, which actively transfer heat to and from the body (8,20).

1.8.1 Passive warming

Heat lost via radiation accounts for approximately 60% of total heat loss during surgery. Operating room temperature is the main determinant of the rate at which heat is lost, mainly through radiation and convection from the skin surface and evaporation from surgical sites. Operating room temperatures above 23°C are needed to maintain a normal temperature and is therefore not a practical way of keeping patients warm (50).

A single layer of insulation reduces heat loss by approximately 30% (7,8). Thermal insulators include cotton blankets, surgical drapes, plastic sheeting and reflective materials. The insulation material is less important as the insulation is actually provided by the layer of still air trapped under the blanket. Adding additional layers does not reduce the amount of heat lost further (14).

1.8.2 Active warming

Active warming methods minimise heat loss from convection and are most effective in preventing hypothermia (8). Forced-air warmers, resistive heating blankets and circulating water garments are available and are equally effective (51,52).

Forced-air warming is the most conventional approach; heat gets distributed over a large body surface area via a two-layer blanket inflated with warmed air (32). It has limited efficacy when skin surface covering is limited due to surgical exposure. In the supine position it is more effective on the lower body and in the lateral

decubitus position yields better results on the upper body (53). Concerns exist regarding the impact of forced-air warming devices on laminar flow and subsequent infection risk. Studies done to date failed to demonstrate any effect on laminar flow and infection rates (54,55).

Circulating water garments are segmented devices that gets wrapped around a patient. Warm water is then circulated through the various segments. The device is effective at maintaining normothermia in adult and paediatric patients (56). Difficulties in handling the device, potential for water leaks and maintenance costs are prohibitive (57). Circulating water or electrical mattresses placed under a patient are ineffective in preventing hypothermia. The risk of pressure ulcers is also increased by the combination of the patient's body weight and the heat of the mattress (58).

Resistive heating blankets are comparable to forced air warming devices in maintaining normothermia (52). They consist of multiple parts connected to a central unit, are bulky, non-disposable and costly to clean.

Radiant heaters depend on proximity to the patient's skin in order for heat transfer to be effective. The risk of burns however, increases proportionally. When radiant heaters are used at a safe distance, the efficacy is less than that of forced air warming (59).

Warmed intravenous fluids (near 37°C) should be considered when large amounts of fluid are administered intra-operatively. In patients undergoing major surgery, the combination of forced air warming and warmed fluids are more effective than forced air warming alone (60). Warmed fluids used in isolation will not prevent hypothermia.

1.8.3 Pre-warming

Hypothermia following the induction of general anaesthesia mainly results from redistribution of heat from the core to the periphery (61–63). It is difficult to counter this redistribution hypothermia because heat applied to the peripheries takes considerable time to reach the core compartment. The aim of pre-warming is to increase the heat content of the peripheries, thereby minimising the core to peripheral compartment temperature gradient and subsequent heat loss (61).

Active pre-warming is usually achieved by means of forced-air warming blankets with temperature settings ranging from 38°C to 46°C, depending on the type of device used and patient thermal comfort (62,64–66). Pre-warming for 30 minutes increases the peripheral heat content by approximately 46 kcal; this amount equals the heat lost as a result of anaesthetic induced vasodilatation during the first hour of anaesthesia (61). Pre-warming increases the peripheral heat content without increasing the core body temperature (62). The optimum duration of pre-warming is not known, but time periods of 30 minutes or longer are usually targeted (61). It has been demonstrated that as little as 10 minutes of active pre-warming can result in smaller decreases in intraoperative core body temperature compared to intraoperative warming alone (67,68).

The efficacy of pre-warming is limited by patient thermal discomfort and sweating (61). Sweating occurs when skin temperature increases rapidly or with high overall skin temperatures. This only becomes problematic after 60 minutes of pre-warming or when high energy settings are employed (61,62,65).

1.9 Anaesthesia for MRI

Magnetic Resonance Imaging (MRI) produces high quality images of the body in cross section and in three dimensions and is particularly useful for the imaging of soft tissues (3). It is the preferred diagnostic modality for many neurological, cardiovascular, oncological and musculoskeletal conditions (2). The scanning

process is associated with a lot of anaesthetic challenges, including but not limited to the patient having to be immobile for the duration of the procedure, the presence of a strong magnetic field and its implications for monitoring equipment and patient safety as well as the effect of the cool environment and radiofrequency heating on patient temperature (2,69).

1.9.1 Physics of MRI

Hydrogen atoms in the human body possess an odd unpaired proton and therefore have a property called spin (2,18,70). These spinning protons create a small magnetic field known as a magnetic dipole (70). The directions of the various magnetic dipoles are randomly aligned, but when exposed to an external magnetic field, the dipoles line up with (parallel) or against (anti-parallel) the magnetic field (2,18). Once all the nuclei are aligned with the magnetic field another scanner coil emits a perpendicular pulse of electromagnetic radiation in the radio frequency (RF) range (46). The energy is absorbed by some of the parallel protons, causing them to flip their dipole in the opposite direction. These protons are now anti-parallel and in a higher energy state. When the electromagnetic pulse gets switched off, the new anti-parallel protons revert to their parallel lower energy state. During this process, they release energy in the form of small RF photons which are detected by the scanner as small electromagnetic pulses (18,69). The hydrogen atoms in effect become tiny radio transmitters, broadcasting where there is water, fat or other compounds containing hydrogen. Different tissues contain a different density of hydrogen atoms and anatomical structures can thus be reconstructed in the final image (2,69).

The exact three-dimensional position from which photons are released is found by applying additional fields during scanning, known as gradient coils. These fields make the magnetic strength vary depending on the position within the patient. The RF pulse is switched on and off repetitively during the scanning process. For each scanning position, gradient fields are applied in two dimensions, producing a cross-sectional image built up from the RF measurements made from every

position within the slice. A series of two-dimensional images are combined to reconstruct the final three-dimensional image (70).

Contrast between tissues is generated in a number of ways during MRI: varying density of hydrogen nuclei between tissues and the amount of time taken for hydrogen nuclei in different tissues to relax to their resting state. There are two distinct mechanisms of relaxation with separate time constants namely T1 and T2 weighted images (2). In a T2 weighted scan tissue with a high water content appears brighter than fat containing tissue (69). Intravenous contrast agents, most commonly chelates of gadolinium, work by shortening the T1 relaxation time of protons located nearby (70).

MRI requires strong magnetic fields between 0.5 and 3.0 Tesla, with most diagnostic scanners operating at 1.5 Tesla. This is around 30000 times the earth's geomagnetic field (2). This magnetic field is generated by a superconductor, niobium-titanium alloy coils bathed in liquid helium and cooled below -250°C (70). The magnetic field strength declines exponentially from the magnet. A safety line is usually demarcated at 5 Gauss (0.0005 Tesla) within which pacemakers will malfunction. A second line is demarcated at 30 Gauss within which all ferromagnetic objects will be attracted and risk becoming projectiles. In practice many MRI units are divided into a safe zone outside the scanner room and a controlled hazardous zone within the MRI room (69).

1.9.2 Safety considerations and challenges in the MRI unit

Static magnetic field

The strong magnetic field poses the greatest hazard related to anaesthesia and patient care in the MRI suite. The magnetic fields are able to exert large forces on any ferromagnetic materials in close proximity, may induce currents in metallic objects and can interfere with monitoring equipment (71). Ferromagnetic objects and electrical fields in close proximity to the magnet will impair the quality of MRI images produced (2,72).

The American College of Radiology has defined different MRI safety zones, determined by the distance from the MRI magnetic field (73). Zone I is outside the MRI area and is freely accessible to the general public. Zone II is usually within the MRI department and the public is only allowed access under supervision; screening questionnaires, patient examination and safety checks are conducted here. Zones III and IV are strictly access controlled and only screened patients are allowed to enter here. Zone III is the holding area or recovery room just prior to entering the MRI room and Zone IV is the MRI room containing the magnet (73).

Ferromagnetic objects within the 30 Gauss zone will experience an attractive force and torque. With most MRI scanners, the magnetic field is always on and ferromagnetic objects are at risk of becoming dangerous projectiles. All ferromagnetic, metallic or conducting materials such as needles, watches, stethoscopes, jewellery, gas cylinders, metallic trolleys, ECG electrodes etc. should be prevented from entering the MRI room. Magnetised items such as credit cards and mobile phones or SIM cards are also at risk of being damaged by the magnetic field (18,69,74).

Ferromagnetic materials present inside a patient's body such as pacemakers, defibrillators, cochlear implants, arterial clips or shrapnel are also subjected to the magnetic field and can move, malfunction or heat up with resultant morbidity or mortality (71). Most modern implantable devices are non-ferromagnetic but this must be confirmed prior to a patient being allowed to enter the MRI examination room. All patients therefore have to complete a screening questionnaire prior to MRI examination (72).

The human body contains conductive tissue and movement within the magnetic field of the MRI scanner can induce weak electrical currents. These currents can induce symptoms such as nausea, vertigo or flashing lights (74).

Acoustic noise

Rapid switching of the gradient coils induces noise levels above the 85 dB safe level and can potentially cause hearing loss with prolonged exposure. Staff and patients, whether awake or anaesthetised, should wear ear protection (2,75).

Radiofrequency heating

Radiofrequency energy gets emitted and can be absorbed by patient tissues, resulting in local or systemic heat gain (4). Local heat gain creates a risk of burns from any conductive material in contact with the patient's skin. Contact with metal in clothing, RF coils, equipment, ECG lead etc. should be avoided (2,69). Systemic heat gain and risk of hyperthermia is determined by the specific absorption rate (SAR). SAR depends on the magnet strength, the length of exposure, number of high energy sequences used, the type of radiofrequency pulse and magnitude of body surface exposure (3,4,73,76). SAR should be monitored by the radiographer and the MRI examination terminated if a maximum temperature gain of 1°C is exceeded (4).

Quenching of the superconductor

The MRI magnet coils have to be cooled to maintain their superconductor properties, this is achieved by immersion in liquid helium. In the event of a spontaneous or emergency shut down, known as a quench, there is loss of the magnetic field and the liquid helium rapidly expands to a gas. The helium gas gets vented to the outside via a quench pipe, failing which helium can accumulate in the MRI room and cause asphyxiation. All MRI suites should be equipped with oxygen sensors and the staff trained in the emergency procedures of quenching (2,74).

Restricted access

The MRI scanner is designed so that the patient is placed in the centre of the magnetic field. Access to the patient is severely restricted as a result. The MRI suite itself often located remotely within the hospital making backup or assistance from theatre less readily available (2,69).

1.9.3 Equipment and monitoring concerns

All equipment used in the MRI suite should be MRI compatible (77). A distinction needs to be made between equipment that is designated as MRI compatible and MRI safe. MRI safe implies that the particular equipment will not be a danger to patients or staff when entering the MRI room, but there is no guarantee that the equipment will function optimally or that there will be no interference with the MRI image quality (2). MRI compatible equipment is both safe and will function normally (74). MRI non-compatible equipment are all ferrous containing and may become dangerous projectiles, cause burns if in close contact with the patient or may malfunction (69,72).

Critical devices that have ferromagnetic components should be permanently fixed to the floor or wall and labelled with warning information to prevent them from being moved too close to the MRI scanner (72,74). Anaesthetic machines are modified by replacing all the ferromagnetic components with brass, aluminium or plastic. Medical gas cylinders must be constructed from aluminium. Breathing circuits require additional lengths of tubing (24,69).

Electromagnetic fields associated with the MRI can significantly affect the operation of monitoring equipment. Physiologic monitors that contain microprocessors or similar components may cause radio-frequency (RF) leaks, producing electromagnetic interference that can alter MRI images (77,78).

Wave guides, copper shielded pipes fitted into the walls to shield cables and wires from RF interference, are necessary to prevent leakage of RF pulses and the antenna effect of electrical cables and wires (24).

During the operation of the MRI, electrical currents may be generated in the conductive materials of monitoring equipment that are used as part of the interface to the patient. These currents can be of sufficient magnitude to cause excessive heating and thermal injury to the patient (2,72,78).

Electrocardiogram and heart rate

Distortion of the ECG waveform occurs because of interference caused by the static, gradient and RF electromagnetic fields. This induces an augmented T-wave amplitude and other non-specific waveform changes (71,77). Artefacts can also make observation of morphologic changes and detection of arrhythmias difficult (2,77). Carbon graphite ECG electrodes are used to lower resistance, eliminate ferromagnetism and minimise radiofrequency interference. Cables are co-axialised to avoid coiling and resultant skin burning (24,69,77).

Blood pressure

Non-invasive automated blood pressure monitoring, such as the oscillometric method, is possible if all connections are changed to plastic (77). Invasive pressure monitoring can be used if MRI compatible transducers are used with the transducer cables passing through waveguides (79).

Pulse oximetry

MRI compatible pulse oximeters use fibre-optic technology to obtain and transmit physiologic signals from the patient (72,77). The use of standard non-compatible pulse oximeters has been associated with severe extremity burns (2).

Capnography

Main stream capnography may cause interference with the MRI image quality because of the close proximity of the sensor to the magnet bore (24,77). Side stream capnography will require a longer than normal sampling tube with a resultant delay in displaying information (2).

Temperature

Body temperature may increase from heating caused by RF within the magnetic field or decrease from the cool environment necessary to protect the superconductor (55). Intermittent temperature monitoring is therefore recommended during prolonged scanning (2). Thermistors and thermocouples are not practical because of their ferromagnetic content. Skin temperature strips that use a liquid crystal display may be used but they do not reflect core temperature (77).

Fibre-optic temperature probes are MRI compatible and employ fluoroptic optical sensor technology (80). The temperature probes are not suitable for insertion into body cavities and are usually placed in the axilla. The readings they provide are therefore for peripheral and not core temperature (72,77).

Core temperature measurement during MRI can be achieved with minimally invasive thermometers inserted into the rectum or oesophagus. They are less desirable for diagnostic MRI examinations, especially in the paediatric population. Inertia and a delay in response time are additional considerations (81).

1.9.4 Temperature variation during MRI

MRI scanning requires that the patient remains still for the duration of the procedure in order to obtain high quality images. In children, sedation or general anaesthesia is often used to achieve this (3,5,82). As discussed, thermoregulation

is impaired by general anaesthesia, resulting in a decrease in core body temperature over the course of the anaesthetic. This is compounded by the cool ambient temperatures required for optimal functioning of the MRI scanner. Paediatric patients are therefore at increased risk of developing hypothermia (82).

Conversely, radiofrequency pulses emitted during operation of the MRI scanner gets absorbed by the patient resulting in local and general tissue heat gain. The potential for an increase in body temperature therefore exists (4). Children have a greater surface area to weight ratio than adults and the effect of radiofrequency heating may be greater as a result (5,83). Temperature management is further complicated by difficulty in monitoring temperature during MRI and inability to use active warming devices in the MRI suite (82).

The effect of MRI imaging when combined with general anaesthesia is relatively unknown. Two studies have observed the effect of MRI on core body temperature in sedated infants and children, with temperatures noted to increase by 0.2°C to 0.5°C (5,83). However, sedation does not impair thermoregulatory control to the same extent as general anaesthesia (5).

In a study by Ormond et al. (82) the temperature change in children undergoing MRI examination under general anaesthesia was examined. They obtained tympanic temperatures from 193 children pre- and post MRI scan. No active or passive warming measures were employed. Fifty two percent of children became hypothermic with no subjects becoming hyperthermic.

A further two studies conducted in paediatric patients undergoing MRI under general anaesthesia demonstrated a decrease in temperature in the majority of patients with only 24% (76) and 26.7% (85) experiencing an increase in temperature.

A similar study by Miti (85) demonstrated a mean temperature decrease of 0.93°C in 29 paediatric subjects undergoing MRI examination under general anaesthesia. Twenty-six of the participants (89.6%) required a warming intervention based on temperature loss and shivering. No subjects became hyperthermic.

1.10 Summary

Temperature monitoring under anaesthesia or sedation is a minimum anaesthetic requirement because of the known adverse effects of hypothermia. The MRI suite poses a unique challenge for thermal control due to the cold environment and incompatibility of most monitoring and warming devices. The majority of studies done to date on the anaesthetised paediatric population demonstrated a risk for hypothermia in the MRI suite. Safe warming methods need to be investigated and employed to reduce this risk.

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Section 2: Author's guidelines

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Cite references in numerical order in the text, in superscript format (Format> Font> Click superscript). Please do not use brackets or do not use the foot note function of MS Word.

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The following are sample references:

1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-

dimensional reconstruction by high-resolutional CT scanning. Otolaryngol Head Neck Surg. 2005 Mar;132(3):429-34.

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4. All author details (Full names, Qualifications and affiliation) must be provided.
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10. All numbers below ten, without percentages or units, must be written in words.
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Section 3: Draft article

Effect of pre-warming on paediatric patients presenting for magnetic resonance imaging under general anaesthesia

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Keywords: Pre-warming, hypothermia, paediatric patients, magnetic resonance imaging, general anaesthesia.

Abstract

Background

The combination of anaesthesia and environmental factors in the magnetic resonance imaging (MRI) suite increases patient susceptibility to hypothermia. Pre-warming patients with a forced-air warmer prior to anaesthesia has been shown to decrease the incidence of peri-operative hypothermia. This study aimed to determine whether pre-warming paediatric patients presenting for MRI under general anaesthetic prevented them from developing hypothermia.

Methods

A prospective, quasi-experimental research design was followed. A total of 102 patients were enrolled during the 4-month study period and were divided equally into pre-warmed and control groups. Inclusion criteria were patients aged 6 months to 6 years, ASA physical status I or II and with written informed consent from a caregiver. The pre-warmed group received 30 minutes of active warming with a forced-air warmer. The MRI examination was conducted using a volatile-based general anaesthetic. Tympanic temperatures were measured at baseline, pre-scan and post-scan.

Results

The pre-warmed group received an average (SD) of 34.8 (4.3) minutes of warming. The median (IQR) time spent inside the MRI unit was 60 (50 to 77) minutes. The incidence of hypothermia was 1.96%. The pre-warmed group had a statistically significant increase of 0.3°C in core body temperature (CBT) compared to the control group following the pre-warming period (p=0.0001). There was a statistically significant difference in CBT between the pre-warmed and control groups (0.15°C; p=0.0001). A weak negative correlation between patient weight and temperature change (r=-0.220, p=0.026) and between length of time of pre-warming and temperature change (r=-0.268, p=0.006) was found.

Conclusions

The effect of pre-warming to prevent hypothermia under general anaesthetic in the MRI unit could not be established due to the low incidence of hypothermia. Pre-warming patients for a period of 30 minutes prevented a statistically significant decline in CBT compared to the control group, however, this finding was not clinically significant.

Introduction

Magnetic resonance imaging (MRI) is increasingly used as a diagnostic modality.[1,2] MRI examination requires that the patient remain immobile for the duration of the investigation in order to obtain images of sufficient quality. Paediatric patients can often not comply and sedation or general anaesthesia is employed to ensure minimal movement during the MRI investigation.[2–4]

The combination of anaesthesia and environmental factors in the MRI suite increases patient susceptibility to hypothermia.[5] Inadvertent perioperative hypothermia is defined as a core body temperature (CBT) <36.0°C.[6] Perioperative hypothermia is a common anaesthetic occurrence with reported incidences ranging widely from 20% to 70%.[7–12] It is associated with a number of known adverse effects including prolonged anaesthetic recovery,[13] metabolic acidosis, cardiac events,[14] surgical site infections,[15] coagulopathy[16] and immune compromise.[17] Shivering is another common consequence of hypothermia and leads to increased oxygen consumption and patient discomfort.[18,19]

General anaesthesia impairs the normal thermoregulatory responses to hypothermia.[6,19,20] It causes internal redistribution of heat within the body, reduces metabolic heat production and increases environmental heat loss. General anaesthesia produces a 1 to 3°C decline in CBT, which follows a consistent pattern of an initial rapid decline, followed by a slower linear decline and an eventual plateau phase.[21] This decline in temperature is often exacerbated in the paediatric population because of their greater body surface area to weight ratio, reduced subcutaneous tissue and insulation, poorly developed shivering mechanism and thinner epidermal layer with increased evaporative heat loss.[22–25]

The MRI environment poses significant challenges for thermal control. Cool ambient temperatures required for proper functioning of the MRI superconductor magnet increase heat loss via conduction, convection, radiation and evaporation.[1,4,26] Besides the risk of hypothermia in the MRI environment, there is also the possibility of radiofrequency radiation with subsequent heating of tissues within the body which can potentially lead to hyperthermia.[27] Hyperthermia, defined as a CBT > 37.5°C, is much less common during anaesthesia[28] and can be complicated by life-threatening multi-organ failure when temperature exceeds 41.5°C.[29] The potential complications include pulmonary oedema, acute respiratory distress syndrome, renal

failure, hepatic dysfunction, neurological deficits and seizures, rhabdomyolysis and diffuse intravascular coagulation.[29]

Temperature monitoring and maintenance inside the MRI unit is of concern. The strength of the static magnetic field of the MRI system creates electromagnetic interference with conventional monitoring devices. Physiological monitors must, therefore, be specially adapted for use in the MRI environment. Temperature monitoring in particular is problematic because of MRI incompatibility with standard temperature probes.[30] MRI compatible fiber optic temperature probes are costly[31] and not widely available.[31–33] Monitoring devices are labeled as "MRI compatible" if the device is MRI safe, will maintain its functional integrity in the MRI environment and will not interfere with the quality of the diagnostic information.[1] "MRI safe" objects or devices must be completely non-metallic, non-conductive and not radiofrequency reactive.[4]

Warming devices utilised for active warming, such as forced-air warming blankets, are not MRI safe because of ferromagnetic components in the warming power unit. Passive insulation has limited efficiency in preventing hypothermia.[6] In the MRI environment the amount of passive insulation used needs to be limited so as not to obstruct the anaesthetist's view of the patient as most of the monitoring is done remotely.[2]

Studies have been performed to determine the effect of pre-operative warming in preventing hypothermia under general anaesthesia.[34–41] Pre-warming decreases the core to peripheral temperature gradient and can therefore minimise the initial rapid decline in temperature as a result of redistribution.[21] The optimum duration of pre-warming is not known, but time periods of 30 minutes or longer are usually targeted.[34,41,42] It has been demonstrated that as little as 10 minutes of active pre-warming can result in smaller decreases in intraoperative core body temperature compared to intraoperative warming alone. Active pre-warming is usually achieved by means of forced-air warming blankets with temperature settings ranging from 38°C to 46°C, depending on the type of device used and patient thermal comfort.[34,36,39,41] No standardised pre-warming protocol could be identified and none of the studies mentioned have been conducted in the MRI environment.

It is not known whether pre-warming patients prior to MRI examination under general anaesthesia prevents hypothermia. The aim of this study was to determine if pre-warming paediatric patients at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) for a period of 30 minutes prior to entering the MRI unit would prevent them from becoming hypothermic under general anaesthesia.

Methods

A prospective, quasi-experimental research design was followed in this study. Approval to conduct this study was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand and other relevant authorities.

Patients were enrolled during the period 21 August to 21 December 2018. The study participants consisted of paediatric patients presenting for MRI examination under general anaesthesia. Inclusion criteria for the study were patients from the ages of 6 months to 6 years old, American Society of Anesthesiologists (ASA) physical status I or II and with written informed consent from a caregiver. Patients were excluded from the study if their tympanic membranes were obstructed by cerumen or foreign bodies or if their baseline tympanic temperatures were below 36°C or above 37.5°C. Tympanic temperature measurement is believed to be a reliable measure of CBT because the hypothalamus and tympanic membrane share their arterial blood supply from the carotid artery.[43,44]

A consecutive, convenience sampling method was used to allocate patients to two groups: a pre-warmed group and a control group. This was done based on the day the patients presented for their MRI scan. In consultation with a biostatistician, the reported incidence of hypothermia in a previous study[45] at Chris Hani Baragwanath Academic Hospital (CHBAH) was used to determine a sample size of 100 (minimum) patients, divided equally among pre-warmed and control groups. The study was powered to 80%, with a 95% confidence interval and margin of error of 5%.

Data (Table I) were collected by one author (EB), who provided the pre-warming and anaesthetic to all enrolled patients to standardise the care provided and ensure consistency.

Table I: Data collected

Pre-scan	Post-scan
Study number	Time of leaving MRI unit
Study/ Control group	Post-scan tympanic temperature
Ambient temperature waiting area	Thermoregulatory intervention
Ambient temperature in MRI unit	
Age (in months)	
Sex	
Weight (kg)	
ASA Classification	
Tympanic temperature waiting area	
Pre-warming time period	
Pre-scan tympanic temperature	
Time of entering MRI unit	

Ambient temperatures in the waiting area and MRI unit were measured with a calibrated whirling hygrometer in the morning prior to scan commencement. Patients were examined on arrival to the MRI waiting area and their characteristics were recorded. Otoscopic examination was carried out to exclude cerumen or foreign bodies prior to tympanic temperature measurement. Initial tympanic temperature measurements were taken with an infrared thermometer (BRAUN ThermoScan®) from the right ear. All patients wore a hospital gown and were covered with a single cotton blanket.

Patients in the pre-warmed group were warmed with a 3M™ Bair Hugger™ paediatric forced-air warming blanket for a minimum of 30 minutes prior to their MRI scan. The duration of pre-warming was chosen based on efficacy[42] while minimising impact on patient turnover in the MRI unit. The thermal output of the 3M™ Bair Hugger™ warming unit was 1600 $BTUh^{-1}$ and the temperature was set at 43°C (high setting) throughout the study. A paediatric underbody warming blanket was used and the patient positioned supine on the blanket. Distraction modalities such as mobile phone applications and videos were available to ensure patient cooperation but were necessary for two children only.

All patients had their tympanic temperatures repeated immediately prior to entering the MRI unit (pre-scan). Routine monitors (oxygen saturation, non-invasive blood pressure and electrocardiography) were attached and the patient covered with a single cotton blanket. General anaesthesia was induced via the inhalational method with a sevoflurane and oxygen mixture. Intravenous access was obtained and Ringers Lactate, at room temperature, administered to a maximum of 10 ml/kg body weight. The airway was secured with a laryngeal mask airway and spontaneous ventilation maintained. Anaesthetic maintenance was achieved with a mixture of sevoflurane in oxygen and air (50:50%). Standard ASA monitoring was instituted. The MRI scan was conducted with a Siemens™ 1.5 Tesla MRI machine.

Following completion of the MRI scan and anaesthetic emergence, all patients were transferred to a recovery area where their post-scan tympanic temperatures were recorded from the right ear together with routine vital signs. Thermoregulatory interventions were instituted if necessary. In the event that a patient became hypothermic (≤36°C), active warming with a 3M™ Bair Hugger™ forced-air warming blanket was undertaken, or if they became hyperthermic (≥37.5°C), the cotton blanket was removed.

Data were analysed in consultation with a biostatistician using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows). Categorical variables were described using frequencies and percentages. Parametric data were summarised using means and standard deviations and non-parametric data using medians and interquartile ranges. Comparisons between groups were done using a t-test or Mann-Whitney test as appropriate. Pearson's correlation coefficient was used to determine if any correlation existed between CBT change inside the MRI unit and patients' weight, age and length of time of pre-warming. A p-value of <0.05 was considered statistically significant.

Results

A total of 198 paediatric patients presented for MRI examination under general anaesthesia during the 4-month data collection period. Of these, 102 patients met the inclusion criteria and were enrolled, with 51 patients allocated to each group. No participants were excluded following enrolment. Patient characteristics were comparable between the pre-warmed and control groups and are shown in Table II.

Table II: Patient characteristics

Variable		Pre-warmed (n=51) Mean (SD)	Control (n=51) Mean (SD)	p-value
Age (months)		45.8 (23.4)	44.1 (26.0)	0.7374
Weight (kg)		16.1 (5.8)	14.8 (6.1)	0.2685
		n (%)	**n (%)**	
Sex	Male	35 (68.6)	26 (50.9)	0.1057
	Female	16 (31.4)	25 (49.0)	
ASA	I	18 (35.3)	10 (19.6)	0.1196
	II	33 (64.7)	41 (80.4)	

The initial mean tympanic temperatures for the pre-warmed and control groups were comparable. The pre-warmed group received an average (SD) of 34.8 (4.3) minutes of warming with a forced-air warming blanket prior to entering the MRI unit. Their pre-scan tympanic temperature measurements and change in CBT following pre-warming demonstrated a significant difference compared to the control group. The post-scan tympanic temperature as well as temperature change inside the MRI unit were significantly different between the pre-warmed and control groups. The tympanic temperature measurements for the pre-warmed and control groups are summarised in Table III.

The mean (SD) ambient temperature measured in the waiting area was 22.8°C (1.6) for the pre-warmed group and 21.3°C (2.6) for the control group. The difference of 1.5°C was statistically significant (p=0.0006). The mean (SD) ambient temperature in the MRI unit was 20.4°C (1.6) for the pre-warmed group and 19.3°C (2.2) for the control group. The difference in mean ambient temperature of 1.1°C was also statistically significant (p=0.0061).

Table III: Comparison of tympanic temperatures between control and pre-warmed groups

Variable	Pre-warmed (n=51) Mean (SD)	Control (n=51) Mean (SD)	p-value
Initial tympanic temperature (°C)	36.8 (0.2)	36.8 (0.3)	0.7846
Pre-scan tympanic temperature (°C)	37.1 (0.2)	36.8 (0.2)	<0.0001
Post-scan tympanic temperature (°C)	37.0 (0.3)	36.5 (0.3)	<0.0001
	Mean (Range)	**Mean (Range)**	
CBT difference between initial and pre-scan tympanic temperatures (°C)	0.3 (0.1 to 0.8)	0 (-0.3 to 0.4)	<0.0001
CBT difference between pre- and post-scan tympanic temperatures (°C)	-0.1 (-0.5 to 0.7)	-0.2 (-0.9 to 0.6)	<0.0001

The median (IQR) time spent inside the MRI unit was 60 (50 to 77) minutes for the whole group. The pre-warmed group spent a median (IQR) of 60 (42 to 75.5) minutes inside the MRI unit and the control group a median (IQR) of 63 (35 to 76.3) minutes. There was no significant difference between the two groups (p=0.8829). The longest scan duration of 172 minutes was recorded for a patient in the control group.

Thermoregulatory interventions had to be undertaken in the recovery area for 9 (8.8%) patients. The findings are summarised in Table IV.

Table IV: Thermoregulatory interventions post MRI examination

	Pre-warmed n (%)	Control n (%)	Thermoregulatory intervention
Hypothermia < 36°C	0	2 (1.96)	Forced-air warming
Shivering	0	2 (1.96)	Forced-air warming
Hyperthermia > 37.5°C	4 (3.9)	1 (0.98)	Blanket removed

A negligible relationship was found between patient age and CBT change inside the MRI unit. When subgroup analyses of different age categories were performed, no significant correlation between temperature change and age could be shown. A weak negative but statistically significant correlation was demonstrated between patient weight, length of time of pre-warming and CBT change during MRI examination (Table V).

Table V: Correlation of CBT change inside MRI unit with patient weight, age, length of time of pre-warming and time in MRI unit.

Variable	r-value	p-value
Weight (kg)	-0.220	0.026
Age (months)	-0.184	0.065
6 - 12 (n=11)	-0.411	0.209
13 - 24 (n=16)	-0.259	0.333
25 - 72 (n=75)	-0.147	0.266
Length of time of pre-warming (minutes)	-0.268	0.006
Time in MRI unit (minutes)	-0.013	0.896

Discussion

The primary outcome of this study was to determine if pre-warming patients prevented the occurrence of hypothermia. Hypothermia post-scan occurred in two (1.96%) patients, both of whom were in the control group. This is contrary to the findings of an earlier study conducted at CHBAH where 34.4% of paediatric patients in the MRI unit became hypothermic (temperature < 36°C) under general anaesthetic and all patients demonstrated a decline in CBT, with a mean temperature loss of 0.93°C.[45] The patient's ages, type of anaesthetic (volatile based general anaesthetic), MRI magnetic field strength (1.5 Tesla) and season of data collection were comparable between the studies. The median scan duration of 50 minutes was shorter than the 60 minutes for this study. The only observed difference was a higher ambient temperature in the MRI unit (mean 19.3°C) compared to the 18°C MRI unit ambient temperature measured in the CHBAH study which is unlikely to be the only contributing factor to the difference in outcome.

International studies on temperature change in the paediatric population in the MRI unit demonstrate conflicting results. The studies that showed a trend towards a reduction in CBT conducted their MRI examinations under general anaesthesia.[5,46,47] The studies that demonstrated an increase in CBT[2,3] or no significant change in CBT [48] used sedation as opposed to general anaesthesia. The type of anaesthetic could offer a possible explanation for the differences in outcome, with general anaesthesia affecting thermoregulation to a greater extent than sedation. The effect of differences in MRI magnetic field strength and radiofrequency radiation or differences in patient demographics and ambient temperature should also be considered. None of these studies looked at the effect of pre-warming on temperature change during MRI examination.

In this study patients were pre-warmed for an average of 34.8 minutes. The duration of pre-warming was slightly longer than the specified 30 minutes due to difficulty in predicting the exact start time of the MRI examination. The optimal duration of pre-warming is unknown but the initial recommendations by Sessler et al.[42] suggested 30 to 60 minutes. Thirty minutes of pre-warming increases peripheral heat content sufficiently to offset the amount of heat redistributed from the core to the periphery during anaesthesia. However, pre-warming for longer than 60 minutes induces sweating and thermal discomfort that limits the beneficial effect of pre-warming.[42] Shorter periods of pre-warming have been investigated showing that pre-warming patients

for only 10 or 20 minutes before general anaesthesia prevents hypothermia and reduces shivering.[36,40] The question of optimal duration of pre-warming may be addressed in future research.

The National Institute for Health and Care Excellence (NICE) guidelines [49] have described a temperature change of 0.5°C for any temperature above 36°C as being clinically significant. In our study the change in CBT was calculated on two occasions, as a difference between initial and pre-scan tympanic temperatures and as the difference between pre-scan and post-scan tympanic temperatures. The pre-warmed group had a statistically but not clinically significant increase of 0.3°C in CBT following the pre-warming period compared to no change in temperature in the control group (p=0.0001). This is contrary to the findings of Andrzejowski et al.[34] where pre-warming patients for a period of 72 minutes, limited the impact of the core to peripheral temperature redistribution under anaesthesia without significantly increasing the pre-operative CBT. This difference may in part be due to the type of forced-air warming device used. In our study a 3M™ Bair Hugger™ forced-air warmer was used compared to the Bair Paws® warming system in the study by Andrzejowski et al,[34] that delivered a lower thermal output of 1000 $BTUh^{-1}$ with the temperature set at 38°C.

The temperature change between pre-scan and post-scan measurements was statistically significant between the two groups in this study. The control group had, on average, a 0.24°C decrease in CBT under anaesthesia compared to an average decrease of 0.09°C in the pre-warmed group. The temperature difference between the groups in our study was 0.15°C and therefore not clinically significant.[49]

Five patients (4.9%) in our study became hyperthermic (temperature range 37.6 to 38.1°C), four in the pre-warmed group and one in the control group. This may be attributed to the warmer ambient temperatures in the waiting area and MRI unit for the pre-warmed group, the effect of pre-warming itself or possibly radiofrequency radiation. Radiofrequency heating is more prevalent during long scans and high-energy sequences.[50] Four of the hyperthermic patients had scan durations similar to the median time of 60 minutes, however one patient in the pre-warmed group had a scan duration of 172 minutes.

The study demonstrated a negligible correlation between patient age and CBT change. In the study by Lo et al.[5] a weak correlation between temperature change and age was found. A weak negative but statistically significant correlation between patient weight and temperature change was demonstrated in our study, no such correlation could be established in the study by Bryan et al.[2] Length of time of pre-warming and temperature change also showed a weak negative correlation.

A limitation to our study may be the difference in ambient temperature that was demonstrated between the pre-warmed and control groups. The ambient temperature in the MRI waiting area and MRI unit showed a small but significant difference between pre-warmed and control groups, with cooler ambient temperatures recorded for the control group. The effect of pre-warming could thus be partially attributed to the warmer ambient temperatures for that group.

Tympanic temperature measurement is believed to be a reliable measure of CBT but has potential limitations. Readings can be affected by incorrect technique, the presence of cerumen and acute otitis media.[43] Patients with cerumen or obstructed tympanic membranes were excluded from the study. The possibility of incorrect technique was minimised by using the same author (EB) and the right ear of study participants for all measurements.

Conclusion

The incidence of hypothermia in our study was very low. The effect of pre-warming to prevent hypothermia under general anaesthetic in the MRI unit could, therefore, not be established. Pre-warming patients for a period of 30 minutes induced a statistically significant difference in CBT compared to the control group. Pre-warming also prevented a statistically significant decline in CBT under general anaesthesia in the MRI unit. A weak negative but significant correlation between weight, length of time of pre-warming and temperature change was found.

No clinical benefit of pre-warming patients prior to MRI examination could be established and the potential for harm exists as more patients in the pre-warmed group became hyperthermic.

Conflict of interest

The authors declare that we have no financial or personal relationships which may have inappropriately influenced us in writing this paper.

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Section 4: Proposal

Effect of pre-warming on paediatric patients presenting for magnetic resonance imaging under general anaesthesia

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4.1 Introduction and Problem statement

4.1.1 Introduction

Magnetic resonance imaging (MRI) is increasingly used as a diagnostic modality (1,2). MRI examination requires that the patient remain immobile for the duration of the investigation in order to obtain images of sufficient quality. Paediatric patients can often not comply and sedation or general anaesthesia is employed to ensure minimal movement during the MRI investigation (2–4).

The combination of anaesthesia and environmental factors in the MRI suite renders a patient prone to developing hypothermia. Inadvertent perioperative hypothermia is defined as a core body temperature <36.0°C (5). Perioperative hypothermia is associated with a number of known adverse effects including prolonged anaesthetic recovery (6), metabolic acidosis, hypoglycaemia, hypoxaemia, cardiac events (7), surgical site infections (8), coagulopathy (9) and immune compromise. Shivering is another common consequence of hypothermia and leads to increased oxygen consumption and patient discomfort (10,11).

General anaesthesia impairs the normal thermoregulatory responses to hypothermia (5,11,12). It causes internal redistribution of heat within the body, reduces metabolic heat production and increases environmental heat loss. The result is a 1 to 3°C decline in core body temperature and follows a consistent pattern of initial rapid decline, followed by a slower linear decline and eventual plateau phase (13). This decline in temperature is often exacerbated in the paediatric population because of their greater body surface area to weight ratio, reduced subcutaneous tissue and insulation, poorly developed shivering mechanism and thinner epidermal layer with increased evaporative heat loss (14–17).

The MRI environment poses significant challenges for thermal control. Cool ambient temperatures required for proper functioning of the MRI superconductor magnet potentially increases heat loss via conduction, convection, radiation and evaporation (1,4,18). Besides the risk of hypothermia in the MRI environment, there is also the

possibility of radiofrequency radiation with subsequent heating of tissues within the body which can potentially lead to hyperthermia (19).
Temperature monitoring and maintenance inside the MRI is of concern. The strength of the static magnetic field of the MRI system creates electromagnetic interference with the conventional monitoring devices (1). Physiological monitors must therefore be specially adapted for use in the MRI environment. Temperature monitoring in particular is problematic because of MRI incompatibility of most standard temperature probes (20,21). Monitoring devices are labelled as “MRI compatible” if the device, when used in the MRI environment, is safe and will not significantly affect the quality of the diagnostic information, nor will its function be affected by the MRI environment. “MRI safe” objects or devices must be completely non-metallic, non-conductive and not radiofrequency reactive (1,4).

Warming devices utilised for active warming, such as forced-air warming blankets, are also not MRI compatible because of ferromagnetic components. Passive insulation has limited efficiency in preventing hypothermia (22). In the MRI environment the amount of passive insulation used needs to be limited so as not to obstruct the anaesthetists view of the patient as most of the monitoring is done remotely. A number of studies have been performed to determine the effect of pre-operative warming in preventing hypothermia under general anaesthesia (23–25). Pre-warming decreases the core to peripheral temperature gradient and can therefore minimise the initial rapid decline in temperature as a result of thermal redistribution (13). The optimum duration of pre-warming is not known, but time periods between 30 and 60 minutes are usually targeted (26). It has been demonstrated that as little as 10 minutes of active pre-warming can result in smaller decreases in intraoperative core body temperature compared to intraoperative warming alone (27). Pre-warming is achieved with forced-air warming blankets and temperature settings ranging from 38°C to 44°C, depending on type of device and patient thermal comfort (21,23,25,28). No standardised pre-warming protocol exists and none of the studies identified have been conducted in the MRI environment.

4.1.2 Problem statement

Hypothermia, as defined by a core temperature of less than 36°C, is a known adverse consequence of general anaesthesia (29–33). Hypothermia is also known to occur as a result of exposure to low ambient temperatures, as is common in the MRI unit (5).

A previous study performed by Miti (34) in 2014 at Chris Hani Baragwanath Academic Hospital (CHBAH) demonstrated a mean temperature decrease of 0.93°C in 29 paediatric patients undergoing MRI examination under general anaesthesia. Twenty-six of the participants (89.6%) required a warming intervention based on temperature loss and shivering. No patients became hyperthermic. Based on the results of this study interventions were suggested to minimise the incidence of hypothermia under MRI examination. One of the suggestions was to institute active pre-warming for a period of 30 minutes to offset phase one heat loss under general anaesthesia.

It is not known whether pre-warming paediatric patients prior to MRI examination under general anaesthesia at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) prevents hypothermia.

4.2 Aim and Objectives

4.2.1 Aim

The aim of this two group study is to determine whether pre-warming paediatric patients prior to MRI examination under general anaesthesia at CMJAH prevents hypothermia.

4.2.2 Objectives

The primary objectives of the study will be to:

- estimate the tympanic temperature of paediatric patients in the MRI waiting area (baseline temperature)
- estimate the ambient temperature in the MRI waiting area
- estimate the time taken for pre-warming
- estimate the ambient temperature in the MRI examination room
- compare the tympanic temperature at the beginning and end of the MRI examination
- compare the temperature change between patients in the study and control groups.

The secondary objectives of the study will be to correlate temperature change with:

- patient age
- patient weight
- length of time of pre-warming.

4.3 Research assumptions

The following definitions will be used in the study.

Normothermia: tympanic temperature in the range of 36°C to 37.5°C.

Hypothermia: tympanic temperature below 36°C.

Hyperthermia: tympanic temperature above 37.5°C.

Paediatric patient: patients aged 6 months to 6 years.

Caregiver: parent or legal guardian accompanying the patient and who takes responsibility for the patient.

4.4 Demarcation of study field

The study will be conducted in the MRI unit of CMJAH, a 1200 bed central hospital. The MRI unit is affiliated to the Department of Radiology at the University of the Witwatersrand. The MRI unit conducts on average 3000 MRI examinations annually with approximately 350 paediatric MRI examinations done under general anaesthesia.

Chris Hani Baragwanath Academic Hospital (CHBAH) will be reserved as a back-up facility to conduct the study in case the MRI scanner at CMJAH is out of commission for the duration of data collection.

4.5 Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical), the Graduate Studies Committee of the University of the Witwatersrand, the National Health Research Committee (Gauteng) and the Department of Radiology at CMJAH (Appendix I).

This is a prospective study where patients and their respective caregivers will be invited to take part. An information sheet (Appendix II) will be provided to the respective caregivers of each patient. Should they consent to the patient's participation in the study, the caregiver will be asked to sign a written consent form (Appendix III).

Confidentiality will be ensured. Data will be collected without identifying information and a study number will be allocated to each patient. A separate list with names, hospital numbers and study numbers will be kept. Only the researcher and supervisors will have access to the raw data.

There will be a study and control group. To ensure fairness, a decision will be made in advance whether all the patients for that day be allocated to the study or control

group. For example, all patients undergoing MRI examination on a Tuesday will be pre-warmed and all patients attending on a Friday will receive standard care. Patients found to have hypothermia or hyperthermia on completion of the MRI examination will have the necessary warming or cooling measures instituted to ensure that they are discharged with a tympanic temperature within the normal range.

All raw data will be stored securely in a locked cupboard for six years after completion of the study.

This study will be conducted according to the principles of the Declaration of Helsinki (16) and the South African Guidelines for Good Clinical Practice (36).

4.6 Research methodology

4.6.1 Research design

A prospective, quasi-experimental research design will be followed in this study. In a prospective study, “data about a presumed cause are first collected and then the effect or outcome is measured” (37). In this study an intervention will be instituted and data collected to compare the effect of the intervention between the study group and the control group.

Quasi-experimental is a type of interventional study where the impact of an intervention is measured on a target population without random assignment (18). In this study patients will be assigned to the study and control groups depending on the day that they present for their MRI examination.

4.6.2 Study population

The study population will include all paediatric patients presenting for MRI examination under general anaesthesia to CMJAH.

4.6.3 Study sample

Sampling method

In this study a consecutive, convenience sampling method will be used. Convenience sampling employs the use of the most readily accessible subjects in a study. Consecutive sampling is a version of convenience sampling where every available individual within an accessible population is chosen. It is the best choice of non-random sampling (19). Participants for this study will be recruited from a list of patients who are pre-booked to undergo MRI examination under general anaesthesia at CMJAH. A decision will be made whether patients presenting on the Tuesday or Friday be included in the study or control groups.

Sample size

The sample size was determined in consultation with a biostatistician using Epi-Info™ version 6. A previous study by Miti (15) demonstrated a decrease in tympanic temperature below the hypothermic threshold in 10 of the 29 patients (34.4%). Based on these findings the sample size calculated for this study will be a total of 100 patients divided equally among a study and control group. This will provide a power of greater than 80%, a 95% confidence interval with a margin of error of 5%.

Inclusion and exclusion criteria

The inclusion criteria for this study are:

- ASA I and II paediatric patients
- between the ages of 6 months and 6 years
- patients for whom the caregivers have provided consent

The exclusion criteria in this study are:

- patients with pre-scan tympanic temperatures below 36°C and above 37.5°C
- patients whose tympanic membranes are obstructed by wax or other foreign bodies.

4.6.4 Data collection

Once the relevant approvals have been obtained, patients will be enrolled for the study. Patients will be identified from a booking list kept in the MRI department. Paediatric patients for MRI examination under general anaesthesia are usually booked on a Tuesday or Friday at CMJAH. Most of the patients present as outpatients on the morning of the MRI examination.

A decision will be made in advance whether all the patients for that day be allocated to the study or control group, for example all patients attending on a Tuesday will be included in the study group and all patients on the Friday in the control group. The individual caregivers for each patient will be approached, an information sheet (Appendix II), verbal explanation and consent form (Appendix III) provided and they will be invited to take part in the study. Should the caregiver consent to the patient's inclusion in the study, the caregiver will be asked to sign a written consent form.

Standard care provided

A thorough history and physical examination will be performed as per usual anaesthetic guidelines in the waiting area of the MRI unit. The ambient temperature of the waiting area will be recorded. Demographic data will be captured on the data collection sheet (Appendix IV). An ear examination will be carried out to confirm patency of the tympanic membranes and to confirm that no obstruction to temperature assessment exists. An initial tympanic temperature measurement will be taken. Standard patient screening for ferrous material will be done. All participants will change into a hospital gown and be covered with a single cotton blanket.

Study group

Patients in the study group will be pre-warmed for a minimum duration of 30 minutes with a 3M™ Bair Hugger™ paediatric forced-air warming blanket. Immediately prior to moving into the MRI unit, the forced-air warming blanket will be removed and the patient covered with a cotton blanket. In order to improve patient compliance with

pre-warming, various distraction techniques such as mobile phone applications and videos will be employed as necessary.

Control group

This group will receive the routine passive warming with a cotton blanket only.

Study and control groups

Tympanic temperature will be measured from the right ear using an infrared thermometer (BRAUN ThermoScan®) following the manufacturer's instructions:

- a single-use lens filter will be placed on the temperature probe tip for hygiene purposes
- the temperature probe tip will be placed in the ear canal, sealing the opening to the external auditory meatus
- the scan button will be pressed for one second, released and the reading acquired.

Patients will be transferred to the MRI unit. The ambient temperature of the MRI unit and the starting time will be recorded on entering the MRI unit. Routine monitors (oxygen saturation, non-invasive blood pressure and electrocardiography) will be attached. An inhalational induction with a mixture of O_2 and incremental doses of Sevoflurane will be performed. Following loss of consciousness intravenous access will be obtained. The airway will be secured with a laryngeal mask airway and continuous monitoring of the oxygen saturation, capnography, non-invasive blood pressure and echocardiography will take place. General anaesthesia will be maintained via spontaneous inhalation of Sevoflurane in a mixture of O_2 and air (50:50%). A standard fluid regimen will be used for all patients consisting of Ringers Lactate at room temperature to a maximum of 10 ml/kg body weight. Tympanic temperature will be repeated on leaving the MRI unit following emergence from general anaesthesia. Patients will be transferred to the recovery area where they are to receive thermoregulatory interventions as follow:

- post-scan temperature ≤ 36°C – active warming with a Bair Hugger™ blanket

- shivering patients, regardless of post scan temperature – active warming with a Bair Hugger™ blanket
- post-scan temperature > 37.5°C – removal of clothing and/ or blankets and tepid sponging if necessary
- sweating patients, regardless of post scan temperature – removal of clothing and blankets and tepid sponging if necessary.

The following data will be collected and entered onto a data collection form (Appendix IV):

- patient demographics – age, sex, weight and ASA classification
- ambient temperature in the MRI waiting area
- waiting area tympanic temperature (prior to pre-warming)
- pre-warming time period
- ambient temperature in MRI unit
- pre-scan tympanic temperature
- time of entering the MRI unit
- time of leaving the MRI unit
- post-scan tympanic temperature
- thermoregulatory intervention.

4.6.5 Data analysis

All data collected will be captured using a Microsoft Excel™ spreadsheet. Data will be analysed in consultation with a bio-statistician. Data will be analysed using descriptive and inferential statistics. Categorical data will be summarised using frequencies and percentages. Continuous variables that are normally distributed will be summarised using means and standard deviations and those not normally distributed will use medians and interquartile ranges. Comparisons between groups will be done using t-tests or Mann-Whitney tests as appropriate. Correlations will be determined using the Pearson or Spearman correlation coefficient. The 95% confidence interval will be reported where appropriate. P values ≤0.05 will be considered statistically significant.

4.7 Significance of the study

Two international studies conducted on paediatric patients undergoing MRI examination under general anaesthesia have demonstrated that patients have a tendency to become hypothermic, firstly as a result of impaired thermoregulation under general anaesthesia and secondly as a consequence of the cold ambient temperatures required for scanner operation (39,40).

A study done by Miti (34) at CHBAH in 2014 echoed these findings, with 20 out of 29 patients becoming hypothermic (the temperature threshold for hypothermia in this study was 36.5°C) and a mean temperature decrease of 0.93°C across all participants.

In all these studies, passive warming methods such as hospital blankets or cotton blankets failed to prevent hypothermia from occurring.

Active pre-warming of patients with forced-air warming blankets prior to general anaesthesia have been shown to limit the redistribution hypothermia that occurs as a result of general anaesthesia (11-13). Different pre-warming periods have been investigated, ranging from 10, 20, 30 and 60 minutes or longer and there seems to be no consensus as to the optimal time period required for pre-warming (23,25,26,41). A 30 minute or longer period of pre-warming appears to be the most commonly employed.

Hypothermia as a result of general anaesthesia has known adverse consequences (22) and should a relatively simple intervention such as pre-warming of patients prevent hypothermia, this could have an important impact on the routine standard of care provided and on patient comfort.

4.8 Validity and reliability of the study

The validity of a study is the extent to which it accurately reflects the variables being measured and the reliability is the consistency and repeatability of the measures implemented (23).

Measures to ensure validity and reliability of this study are:

- the appropriate study design
- sample size calculation performed in consultation with a biostatistician
- pre-scan and post-scan temperature measurements will be made by one researcher
- the same infrared thermometer will be used for all patients, following the same technique. The thermometer is pre-calibrated by the manufacturer and no ongoing calibration will be required.
- temperature will be measured from the right tympanic membrane in all patients
- data analysis will be done in consultation with a biostatistician.

4.9 Potential limitations of the study

Limitations are those restrictions or problems that reduce the assumptions that can be made from the findings of a study (42).

The study is contextual as participants will receive their MRI investigation at one hospital. The results of the study may not be generalised or extrapolated to other institutions as conditions may be different. There may be a difference in the magnetic field strength of the MRI scanner (1.5T or 3T) used, different ambient temperatures for operation of the MRI unit, patients may be scanned under sedation rather than general anaesthesia and the provision of passive insulation (blankets) may differ between facilities.

Convenience sampling may be a limitation however consecutive, convenience sampling as is used in this study, is the strongest form of such sampling.

Quasi-experimental studies are subject to concerns of internal validity, because the intervention and control groups may not be comparable at baseline.

4.10 Project Outline

4.10.1 Time frame

	Nov 2017	Dec 2017	Aug 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018	April 2019	May 2019	June 2019	July 2019	Aug 2019
Proposal													
Chapter 1-3													
Proposal submission													
Ethics approval													
Post graduate committee approval													
CMJAH CEO approval													
Data collection													
Data analysis													
Draft article													
Editing													
Submission													

4.10.2 Financial plan

The Department of Anaesthesiology will bear the cost of printing and paper. The 3M™ Bair Hugger™ Warming Unit and disposable Bair Hugger™ Paediatric underbody blankets will be sponsored by Augustine Medical® (Appendix V). The BRAUN Thermoscan® tympanic thermometer and disposable lens filters will be funded by the researcher.

	Unit price	Units	Total
Paper and printing	R1	1300	R1300
Grand total			R1300

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4.12 Appendices

Appendix I: Approval from Head of Department of Radiology at Charlotte Maxeke Johannesburg Academic Hospital

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF DIAGNOSTIC RADIOLOGY

29 November 2017

Dear E. Bezuidenhout

Re: Request to conduct a study in the Radiology MRI department at CMJAH and to do prospective comparative two group study with data collection commencing in May 2018.

Study title: Effect of pre-warming on paediatric patients presenting for magnetic resonance imaging under general anaesthesia.

Dr E. Bezuidenhout is granted permission to conduct her study in the Paeds MRI unit.

Please liaise with the relevant Consultant and Radiography department manager in charge of the Paeds MRI with regard to the logistics and practical aspects of conducting the study.

I hope you find the above in order.

Yours faithfully,

Victor Mngomezulu MB BCh (Wits), FC Rad Diag (SA), MBA (Wits)
Adjunct Professor and Academic Head
Division of Diagnostic Radiology
University of the Witwatersrand and Charlotte Maxeke Johannesburg Academic Hospital

Diagnostic Radiology: Department of Radiation Sciences
7 York road, Parktown, 2193, South Africa | Tel: +27 11 488-3368/4590 | Fax2Email: +27 86-238-9963 | E-mail: diagnostic.radiology@wits.ac.za

Appendix II: Information letter – parent/ caregiver

Dear parent/ caregiver,

My name is Emily Bezuidenhout and I am a doctor at Charlotte Maxeke Johannesburg Academic Hospital. I will be responsible for making your child sleep during the MRI scan. In order for the MRI machine to take proper pictures, your child must be able to lie still for 15 to 90 minutes. It will therefore be necessary for your child to be put to sleep during the scan. This sleep is called a general anaesthetic. Your child will be made to sleep by breathing gas through a mask held to his/ her face. Once asleep a drip will be put into his/her arm or hand and a breathing pipe inserted into his/her throat. This breathing pipe will be connected to a machine that will keep your child asleep by giving him/her a mixture of anaesthetic gas, air and oxygen.

It is known that children get cold during the scan because the MRI room must be kept cold for the machine to work. The anaesthetic we give also prevents children from keeping themselves warm. We usually only use a hospital blanket inside the MRI room and have found that this is often not enough to keep a child warm for the long time that they have to lie still. The MRI room makes it difficult for us to check your child's temperature and also to keep him/her warm because almost all the equipment we usually use contains metals that will affect the magnet inside the MRI machine. This can either cause damage to the MRI machine or affect the quality of the pictures taken by the machine.

I hereby request your permission for your child to participate in a study where I will find out if warming a child in a different way *before* going into the MRI room will prevent him/her from getting cold during the scan. Your child will be put into one of two groups. The difference between the two groups will be that children in the first group will receive a hospital blanket to keep themselves warm and the children in the second group will be warmed for at least 30 minutes with a plastic blanket filled with hot air from a machine before going into the MRI room. In both groups your child's temperature will be measured from the ear when they arrive in the waiting

area, just before going into the MRI room and again on leaving the MRI room. The scan will be done exactly the same for both groups.

If your child becomes too cold during the MRI scan, we will make sure that he/she is warmed up before leaving to go home. If your child becomes too hot during the MRI scan, we will cool him/her down before going home.

Your child's MRI scan will be done in the same way whether you give permission for the study or not. If you do not want your child to be part of the study, the treatment and care he/she gets will not change in any way.

The study will be anonymous and confidentiality will be maintained. No names will appear in any of the results of the study.

If you are willing to allow your child to take part in the study, you will need to sign a consent form.

Please understand that you do not have to agree for your child to take part in this study. You can also withdraw your child at any time without having to give a reason. Withdrawing your child from the study will not disadvantage him/her in any way.

Before giving permission, please make sure that you understand what we are going to do during the study. If you are unsure we can arrange for someone to explain the process to you in your home language. Please feel free to ask any questions at any time.

Ethics approval to conduct this study has been obtained. If you have any further questions or concerns, please contact:

Chair Person Human Research Ethics Committee Medical: 011 717 1234

Emily Bezuidenhout: 011 488 4344

Thank you.

Emily Bezuidenhout

Appendix III: Consent Form

Research title: Effect of pre-warming on paediatric patients presenting for magnetic resonance imaging under general anaesthesia

I, _____ grant permission for my child _____ to take part in the above study. I understand that my child's temperature will be measured from the ear in the waiting area of the MRI room, at the beginning and at the end of the MRI scan. I understand that my child will be assigned to one of two groups; the first group will receive warming with a hospital blanket and the second group active pre-warming with a special warming blanket for a minimum time of 30 minutes. I understand the reasons for the study and my questions have been answered. I understand that I can withdraw from the study without notice and my child will not be disadvantaged.

_____
Parent/ Caregiver name

_____
Parent/ Caregiver signature

_____
Date

_____
Researcher name

_____
Researcher signature

_____
Date

Appendix IV: Data Collection Sheet

EFFECT OF PRE-WARMING ON PAEDIATRIC PATIENTS PRESENTING FOR MAGNETIC RESONANCE IMAGING UNDER GENERAL ANAESTHESIA

Study number	
Study/ Control group	
Age (in months)	
Sex	
Weight	
ASA Classification	
Ambient temperature waiting area	
Tympanic temperature waiting area	
Pre-warming time period	
Ambient temperature in MRI unit	
Pre-scan tympanic temperature	
Time of entering MRI unit	
Time of leaving MRI unit	
Post-scan tympanic temperature	
Thermoregulatory intervention	

Appendix V: Funding approval from Augustine Medical®

Cindy Tamboer
to emily.bezuidenhout@gmail.com

Wed, Nov 29 04:49 PM

RE: Bair Hugger Loan Unit

Dear Emilly

As confirmed telephonically, Augustine Medical is pleased to be sponsoring your study with the loan of a Bair Hugger and 50 paediatric blankets.

I look forward to meeting with you and being of any assistance you may need when you are ready to go ahead with your study.

Wishing you well over the festive season and the best of luck with the birth of your baby.

Warm regards
Cindy Tamboer

Cell: 082 078 2567
Tel: (021) 702 7850
Fax: (021) 702 7870
Email: cindyt@augmedsa.com
BBBEE: Level 2 contributor

NOTICE - This message contains privileged and confidential information intended only for the use of the addressee named above. If you are not the intended recipient of this message, you are hereby notified thay you must not dissemble, copy or take action in reliance on it. If you have received this message in error, please notify Augustine Medical South Africa (Pty) Ltd immediately. Any views expressed in this message are those of the individual sender, except where the sender specifically states them to be the view of Augustine Medical South Africa (Pty) Ltd.

Section 5: Annexures

5.1 Ethics approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Emily Bezuidenhout

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180134

NAME: (Principal Investigator)	Dr Emily Bezuidenhout
DEPARTMENT:	Anaesthesiology Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Effect of Pre-warming on Paediatric Patients Presenting for Magnetic Resonance Imaging under General Anaesthesia
DATE CONSIDERED:	26/01/2018
DECISION:	Approved Unconditionally
CONDITIONS:	
SUPERVISOR:	J. Scribante and H. Perrie
APPROVED BY:	Professor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	30/07/2018

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **January** and will therefore be due in the month of **January** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 30/07/2018

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.2 Graduate studies approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

17 August 2018
Person No: 461278
PAG

Dr EM Bezuidenhout
37 Lyncon Road
Carlswald
Midrand
1682
South Africa

Dear Dr Bezuidenhout

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Effect of pre-warming on paediatric patients presenting for magnetic resonance imaging under general anaesthesia* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

5.3 CEO approval CMJAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. N. Mzila
Office of the Clinical Director
Tell: (011): 488-4812
Email: Nolwazi.Mzila@gauteng.gov.za
16th August 2019

GP_201903_009

Dear Dr. E. M. Bezuidenhout

STUDY TITLE: The Effect of Pre-Warming on Paediatric Patients Presenting for Magnetic Resonance Imaging under General Anesthesia

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic Hospital will not anyway incur or inherit costs as result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or sister in charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported / ~~not supported~~

Dr. M.I. Mofokeng
Clinical Director
DATE: 22/05/2018

(Approved) not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 28-05-2018

5.4 Turnitin report



UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

20th September, 2019

The Chairperson
Graduate Studies Committee
Faculty of Health Sciences
University of the Witwatersrand

Dear Madam,

Re: M Med: **Effect of pre-warming on paediatric patients presenting for magnetic resonance imaging under general anaesthesia**

Dr Emily Bezuidenhout, student number: 461278, has submitted her research report to Turnitin which revealed a similarity index of 19%. These similarities appear not to be plagiarism but mainly the use of common terminology and phrases specific to the topic of the research.

Yours sincerely,

Juan Scribante
Supervisor

461278:Turnitin_document.docx

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