ORIGINAL ARTICLE

Prospective Review of Safety Incidents Reported in the iMRI OT (Intraoperative Magnetic Resonance Imaging Operating Theatre)

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ABSTRACT

Introduction: The purpose of this study was to determine the types of incidents that occurred in the iMRI OT over a nineteen-month period in our institution. We aim to prevent any future avoidable incidents from happening in this potentially hazardous environment.

Methods: This is a single centre prospective non-anonymous observational study conducted from February 2009 to September 2010 on surgeries performed in the iMRI OT. Safety incidents specific to the iMRI OT such as violation of safety protocols and equipment failures were reported as well as any other safety incidents resulting in potential or actual adverse safety outcomes. The outcomes of the incidents were included and the data analysed at the end of the study period.

Results: Of 271 cases that were operated in the iMRI OT, 43 incidents were reported by the staff involved in the care of the patient. Of the 43 incidents, 14 incidents (32.6%) were classified as staff/personnel error and were preventable. Incidents resulted in either delayed surgery or cancellation of the surgery. There were no major adverse incidents that led to patient harm.

Conclusion: Many of the incidents were preventable and measures have been instituted to prevent the recurrence of such incidents. Staff training, safety protocols and stringent maintenance of equipment are paramount to safe and efficient use of the iMRI operating theatre.

Keywords: Anaesthesia, Hazards, Neurosurgery, Intraoperative MRI

INTRODUCTION

The iMRI operating theatre was set up at the Singapore General Hospital (SGH) in 2008 under the conjoint efforts of the neuro-anaesthetists, neuro-surgeons and the radiology department. Singapore is the first country in Southeast Asia with such a facility[1].

Intra-operative magnetic resonance imaging (iMRI) plays a vital role in modern neurosurgery. It provides superior high resolution and three-dimensional images as well as information on the function and metabolism of the brain. Real time acquisition of the image also means that surgeons are able to accurately demarcate difficult tumours, allow for adequate resection without repeated surgeries and protect normal parts of the brain. This will invariably translate to better clinical outcomes, patient care and cost savings[2–6].

The BrainSUITE® iMRI (Fig. 1) is a sophisticated operating theatre in a self-contained environment. This includes a Siemens MAGNETOM® symphony 1.5 Tesla MRI, a navigation and data management system, a radiofrequency-shielded operating room cabin, operating lights, a ceiling mounted microscope and basic magnetic resonance (MR) compatible anaesthesia equipment. The BrainSUITE® uses a rotating operating table that also serves as an MR tray. During MR scanning, the table is rotated 180° and the patient's head is positioned in the centre of the scanner. After the scan, the table returns to its original position

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Fig. 1. The induction room showing the MRI scanner.

with the patient's head outside the 5-Gauss line. This allows minimal movement of the patient and anaesthetic equipment and significantly reduces the time to and from the MR scanner.

Despite many advantages of iMRI, the hostility and isolation of the magnetic field environment (this is continuously turned on) pose significant safety issues to both patients and personnel involved in patient care[7,8].

The danger of ferrous objects being brought into the prohibited parts of the operating theatre with high-intensity magnetic field is real and every step has been taken to prevent this. There is also danger that patients who should not be allowed into the MRI field for various reasons, are accidentally allowed in.

All personnel entering the iMRI OT have to undergo a compulsory video training program and sign a personal declaration and screening form declaring the absence of any contraindications to enter the MRI environment. Safety checklists for patients scheduled to enter the iMRI OT are performed at various stages of patient movement and by various people from the ward to the operating theatre. Special MR-compatible equipment are necessary in the iMRI OT and regular checks and maintenance are done to prevent malfunction. This is especially important in this unique environment where access to patient and retrieving them, when things go wrong, is awkward. There is also the effect of high-intensity magnetic field on equipment. This includes displacement, malfunction, thermal injury to the patient, current induction in long cables and degradation of MR image quality.

Our centre uses the Aestiva/5 MR imaging anaesthesia machine (GE Healthcare, Madison, WI, USA) as it has been validated for use in the MRI environment of up to 300 Gauss and has a magnetic field strength monitor (Fig. 2). The machine accepts TEC 5 and 7 vaporisers. The InVivo Precess (Research Parkway, Orlando, FL, USA) physiological monitor allows monitoring of central venous, intra-arterial and intra-cranial pressures. The Precess uses wireless ECG and pulse oximetry monitoring thereby obviating the need for lengthy cables that may interfere with image quality or may get in the way during rotation of the MR table. Total intravenous anaesthesia is widely practiced for neurosurgical procedures. We used the Medfusion 3500 syringe pump (Smiths Medical, Carlsbad, CA, USA) which is capable of withstanding up to 150 Gauss.

Fig. 1. The anaesthetic machine, infusion pumps and monitor in the iMRI OT.

MATERIALS AND METHODS

After obtaining approval from the hospital Institutional Review Board (IRB), this prospective non-anonymous observational study was conducted in Singapore General Hospital. The study date was from February 2009 to September 2010. All the neuro-anaesthetists in SGH were briefed before the commencement of the study. The anaesthetic assistants, nurses and radiographers were apprised of the study and told to inform the anaesthetists should any safety incidents occur.

Within the MRI environment, the introduction of ferrous objects could be disastrous. We paid attention to safety incidents which violated existing safety protocols that safeguards accidental introduction of ferrous objects into the iMRI OT. Particular attention was paid to the failure to conduct or complete safety checklists on patients entering the iMRI premises, as well as having untrained personnel entering the iMRI OT. Equipment used in the iMRI OT is highly specific and we reported any safety incidents relating to equipment failure or malfunction. In addition, non MRI related safety incidents were included in the study. The outcome of the incidents were also reported and analysed at the end of the study period.

The incident details obtained included the patient's information, procedure performed, the neuro-anaesthetist involved, a contemporaneous account of the description of the incident and how it impacted on safety.

At the end of the study period, the data was collected and reviewed. The total number of cases performed in the iMRI were gathered from a pre-existing logbook located in the iMRI OT. All the reported cases were vetted and any queries regarding the description or outcome of the incident were directed to the reporting anaesthetist. The cases were reviewed within one month after conclusion of the study and any queries were sorted out at the end of the review. We chose to approach the reporting anaesthetist in person regarding incidents that required clarification.

The results were subsequently tabulated using Microsoft Excel and analysed. No statistical analysis was required for this study.

RESULTS

Two hundred and seventy-one operations (n=271) were performed in the iMRI OT from February 2009 to September 2010. The distribution of the type of surgeries that required iMRI is illustrated in Fig. 3.

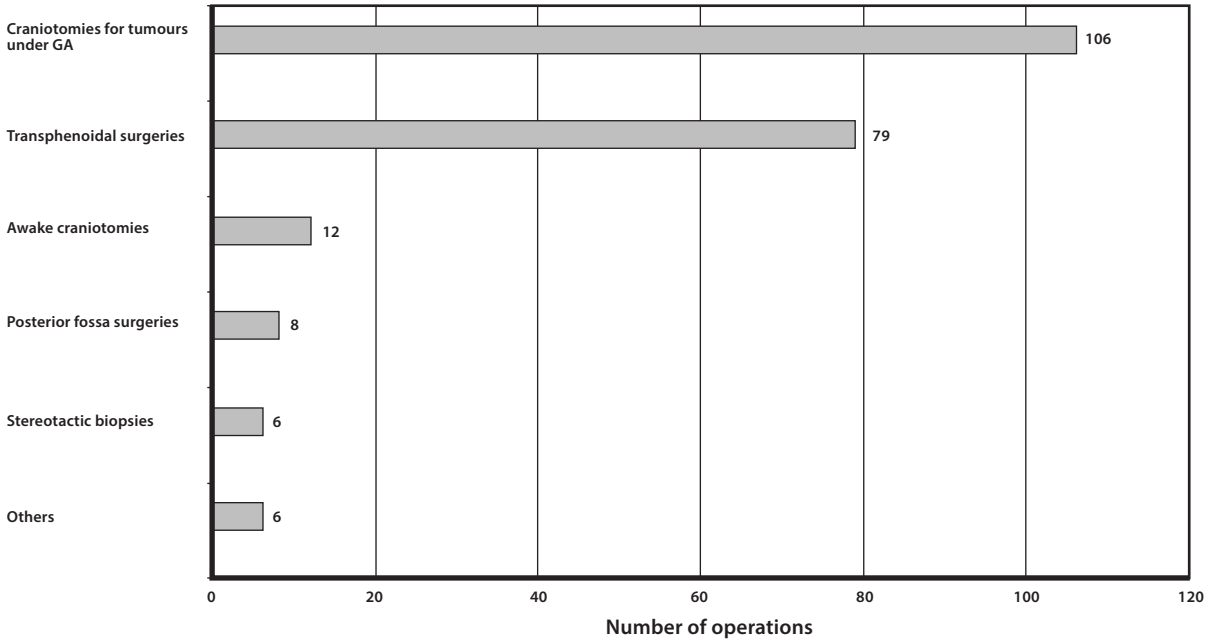

Fig. 3. Types of surgeries performed in the iMRI OT over a period of 19 months.

Forty-three incidents were reported during the period. The incidents were analysed and grouped into equipment factors, staff/personnel factors and patient factors.

Equipment Factors

These factors can be divided into either anaesthetic or operation theatre equipment-related factors (Table 1).

Non-invasive blood pressure monitoring (NIBP)

Most of the patients were induced with invasive arterial blood pressure monitoring. Blood pressure was monitored with the non-invasive NIBP cycled between 30 to 60 minutes and invasive arterial line. This allows for correlation of the arterial blood pressure with the NIBP in event of errors arising from factors inherent with the arterial line such as dampening, resonance or wrong transducer height.

With the failure of NIBP (cuff failed to inflate or to give any readings despite multiple attempts), there was no NIBP to correlate with the arterial blood pressure. Access to the patient was often restricted as both arms were tucked in and the patient was wrapped to prevent hypothermia. In such cases, the anaesthetist had to rely solely on the arterial line for haemodynamic monitoring.

Temperature probe

The cold environment coupled with the prolonged duration of operation often predisposes the patient to hypothermia. Active warming devices and full body drapes are used to protect against hypothermia. Therefore, temperature monitoring is important to safeguard against hypothermia as well as iatrogenic hyperthermia. There were two incidents where the temperature probes malfunctioned during the operation resulting in the lack of temperature monitoring. There was no replacement or backup probe available for use. The cost of the temperature probe is much higher than the standard probe and it is also not disposable and more fragile.

Pulse Oximetry

Type of equipment factors	Frequency
Anaesthesia equipment	
Non-invasive blood presure	5
Temperature probe	2
Pulse oximeter	2
Ventilator	1
Others	1
Operating theatre equipment	
Magnetic resonance scanner	5
Rotating table	4
Door	2
Others	2

Table 1. Types of equipment factors

An MR-compatible wireless pulse oximeter is used in the iMRI OT to avoid cumbersome long cables and to avoid the incidence of thermal burns due to current induction in the cable loops. Two incidents of intermittent functioning of the pulse oximeter throughout the operation were reported. The backup probes were either spoilt or not comaptible for use in both incidents respectively. Hence, a vital monitor was not available or was unreliable.

Ventilator

One incident of a circuit leak that occurred six hours into the operation was reported, which was then isolated to the ventilator. The machine had to be changed with an identical MR-compatible machine, which fortunately was readily available in the induction room.

Miscellaneous

Long intravenous fluid tubing lines (IV) of up to 6 metres in length, from the infusion pump to the patient are required. This allows for a safe distance from the magnet core to the MR conditional infusion pumps and drip stands when the patient is moved into the magnet's core. An incident where the IV tubing was caught on the side of the operating table during rotation for MRI scanning, was reported. There is also a potential risk that the tubing may get dislodged during the rotation. Conversely, it could result in the moving parts of the MRI scanner table being jammed by the long tubing. This can lead to interruption of anaesthetic drugs and the jamming of the MRI table or scanner.

MRI scanner

The scanner required rebooting on two occasions but this did not significantly delay the surgery. However, in another incident, the scanner failed to function and required an engineer to rectify the fault, delaying the start of the operation by two hours. One operation was delayed for forty minutes as the technician was not available to load scanned images needed for navigation. Another operation was delayed for two hours when the functional MR images and anatomical MR images did not match as both were taken in different planes. All these incidents resulted in unnecessary time under general anaesthesia for the patients.

Rotating table

During the transfer of a patient out of the MRI scanner, the rotating operating table ceased functioning in one incident. This occurred in a patient who had the head pinned while in the prone position. The table had to be manually cranked down and patient manually removed from the magnet's core before being turned supine onto the transfer trolley. Fortunately, surgery had not commenced and the procedure was cancelled.

Doors

Doors that separate the operating room from the induction room have to be closed during scanning. In one incident, the closing mechanism malfunctioned and had to be closed manually before scanning could take place. In another incident, the doors opened spontaneously during MR scanning.

Staff/Personnel Factors

These factors are listed in Table 2 and can be further classified into errors relating to checklist, anaesthesia and surgical personnel.

Type of staff/personnel factors	Frequency
Checklist-related errors	
Checklist not performed	1
Items missed after performing a checklist but picked up before operation	6
Items missed after performing a checklist and not picked up until after operation	2
Anaesthesia personnel errors	
Untrained personnel allwoed to work in iMRI OT	1
Unauthorised items brought into iMRI OT	1
Unfamiliarity with MR-compatible equipment	1
Surgical personnel errors	
Untrained personnel allwoed to work in iMRI OT	1
Change of theatre after MR equipment were used	1

Table 2. Types of staff/personnel factors

Type of patient factors	Frequency
Preoperative	
Inadequate optimisation before surgery	1
Crises occurring after induction	2
Intraoperative	
Severe hypertension	1
Severe hypotension	1

Table 3. Types of patient factors

Checklist

A checklist system was implemented to ensure that patients entering the iMRI OT for procedures do not have any objects that are contraindicated in the vicinity of the high-intensity MR field. Nine incidents were reported relating to checklist error. A checklist was not done on one occasion. There were five instances where radiofrequency identification (RFID) tags were left on the patients but was picked up in the induction room before operation, while one of the RFID tag was discovered on the patient after MR scanning and was damaged. In another incident, the safety pin that was attached to the nasal airway was not picked up by the checklist but was noticed and removed in the induction room. In another incident, an auditory implant was undetected until after the operation. Fortunately it was not damaged.

Personnel – Anaesthesia

A junior doctor who did not receive safety training was wrongly assigned to the iMRI OT in one incident. A mobile phone was brought into the iMRI OT by one of the anaesthetists. In another incident, the propofol infusion pump was inaccurately set at 280 ml/hr instead of the intended 28 ml/hr. This was discovered after 14 ml was delivered and the infusion was stopped immediately.

Total intravenous anaesthesia using propofol infusion is a common method of maintaining anaesthesia in neurosurgical patients and only specialised syringe pumps that can withstand the effect of magnetic field should be used. In our iMRI OT, we use the Medfusion 3500 syringe pump (Smiths Medical, Carlsbad, CA, USA). We attributed the incident to unfamiliarity with this syringe pump.

Personnel – Surgical

One operation required the assistance of plastic surgeons who were unfamiliar with the iMRI OT environment, nor had they attended the safety video training. In another incident, the surgeons changed their minds and decided to use a conventional operating theatre after MR-compatible equipment i.e. intra-arterial line, central venous line had already been sited; this had to be changed and led to wastage.

Patient Factors

These factors are listed in Table 3 and can be further classified into incidents that happened in the pre-operative and intra-operative period. Extrication of patient for resuscitation in the iMRI OT is dangerous. High risk patients should be carefully assessed for suitability to have the operation performed in the iMRI OT.

Pre-operative

An episode of cardiac arrest at induction and an incident of severe bronchospasm at induction resulted in postponement of these operations. An operation was postponed as the patient was not adequately assessed and optimised prior to the operation. This patient had a second degree heart block, atrial fibrillation and bifasicular block.

Intraoperative

One incident reported severe hypotension during MR scanning that required the scan to be stopped for blood pressure rescue. One reported incident described a patient having hypertension intra-operatively during a transphenoid resection of pituitary tumour that was refractory to multiple anti-hypertensives. For transphenoidal operations, intra-nasal adrenaline-containing local anaesthetics are injected routinely by the surgeon to aid haemostasis during surgery. However this often results in hypertension and tachycardia that may be difficult to control, unless pre-emptive treatments are instituted early, e.g. using a higher volatile concentration or increasing the infusion of intravenous opioids such as remifentanil are effective in blunting the effect of the adrenaline. There was no adverse outcome in this incident.

DISCUSSION

As a result of advancement of neuro-surgical techniques and the need for surgical precision, we have seen an increase in the use of the iMRI OT. The provision of anaesthesia in the MRI environment is not new. Due to the longer scan time and the need to remain still during MR imaging, anaesthetists have been providing sedation or general

anaesthesia for patients who are unable to tolerate the noisy and potentially prolonged procedure.

Safety issues in the MR environment invariably concern the magnetic core and its effect on ferrous objects. Even when the MRI is not acquiring scans, its magnetic properties are still present. Careful safety planning to develop guidelines and education is therefore needed to deal with the challenges of working within the iMRI environment[9].

There have been case reports of projectile gas cylinders, drip poles, chairs or even hairpins being dragged into the magnetic core with resultant injury to the patient/staff or damage to the magnet. A study by Chaljub *et al.* reported five accidents over a 13-year period involving projectile tanks of anaesthetic nitrous oxide or oxygen[10]. One patient sustained facial fractures and was awarded legal compensation. The cost of repairs for damage to the MR machine ranged between $32,000 to $50,000. Damaging the machine also renders it unusable. Unfortunately just after the study by Chaljub *et al.* was published, a 6-year old boy died from blunt force trauma to the skull after a metal oxygen tank hit him during a MRI scan[11].

In February 2008, The Joint Commission published a Sentinel Event Alert for preventing accidents and injuries in the MRI suite[12]. The types of injuries that can and have occurred during MRI scanning process included projectile injuries from ferromagnetic objects, injuries related to dislodged ferromagnetic implants, burns from objects that may heat up during the MRI scanning, injury or complication related to equipment or device malfunction caused by the magnetic field. Injury due to failure to attend to patient during MRI, acoustic injury, adverse events from administration of MRI contrast agents and adverse events related to cryogen handling are some other resultant injuries.

Recommendations that were made included imposing restricted access to the MRI scanner only to trained personnel or patients who have passed screening for safe entry into the MRI, having detailed checklists administered by trained personnel, a complete set of medical history available to the personnel and regular safety education about MRI environment to all medical and ancillary staff.

In our institution, all medical and ancillary staff undergo safety education training before they are allowed to work in the iMRI OT. This consists of safety video and written guidelines easily accessible from the department's intranet. The iMRI OT has restricted access to personnel via a biometric fingerprint scanner. Lockers are available and personnel entering the iMRI OT are reminded to remove all ferromagnetic objects such as mobile phones, name tags, keys or wallet. To clearly identify personnel working in the iMRI OT, they are required to wear a special yellow-coloured cap at all times.

The administration of the MRI safety checklist is conducted at ward level, entry to main operating complex and again within the iMRI OT premises by trained staff. With the introduction of the RFID tag device to monitor patient movement in our hospital, we had five incidents where the RFID was not removed prior to entry into iMRI OT. The checklist was subsequently revised to account for this. Patients who are unable to communicate should be physically checked and even x-rayed to confirm the presence of metal implants.

Magnetic resonance-compatible wireless electrocardiogram electrodes and pulse oximetry are used in order to reduce the need for long cables and to prevent thermal injuries if these wires are accidentally coiled up. These specialised components are difficult to replace once they malfunction. Stringent maintenance of the active and spare devices should be carried out regularly and checked prior to use. This is especially important in iMRI OT where patient accessibility is often difficult and during MR scanning, almost impossible.

Patients who are medically unwell or haemodynamically compromised may not be suitable candidates for surgery in iMRI OT since accessibility is limited and much time is needed in trying to retrieve a patient whose head is pinned to the operating table in the magnetic coil. Cardiopulmonary resuscitation is difficult in the vicinity of the MRI machine. Drills to deal with such events are routinely conducted to enhance response time and to avoid harm to patient or rescue personnel during a crisis situation. The anaesthetic induction room also serves as an area to evacuate a collapsed or unstable patient for resuscitation. It allows more skilled help to assist without fear of presence of ferromagnetic objects on them.

We appreciate the need for effective communication between the neurosurgeons, neuro-

anaesthetists, MRI technicians and OT ancillary staff. The details of operation should be discussed early and if other specialties are involved, advance notice should be given so that adequate training can be provided. Surgical planning and knowing the patient's condition would help avoid last minute removal of patient to a conventional operating theatre, since some equipment may have to be changed, resulting in added cost and delays.

Since the reported incidents, our institution made various changes to improve safety in the iMRI OT. Besides updating the checklist, we conduct half yearly training for new medical and nursing personnel joining the iMRI team. With time and experience, patient selection by the neurosurgeons for iMRI operations are more stringent and the neuroanaesthetist called upon early to help optimise the patient for operation. We also identified and categorised all the equipment in the iMRI OT as MR compatible, MR conditional or MR unsafe. These equipment are clearly labelled for easy identification by our staff. We await future safety audits to determine if such interventions reduce safety incidents in iMRI OT.

Various lessons can be drawn from this study. Equipment maintenance must be performed regularly and MR-compatible replacements made available at all times. After all, anaesthetic equipment do fail during anaesthesia and the unique and costly features of the MR-compatible equipment make unplanned replacement difficult. Even more important would be maintenance of the iMRI operating equipment and table. Sudden failure especially with a patient trapped inside the magnetic bore, can be potentially life threatening. Similarly, the software for imaging and image navigation must be regularly maintained as failure results in delays and unnecessarily prolongs keeping a patient under anaesthesia. Protocols and checklists should be revised regularly to keep up to date with new medical devices or implants that may not be MR-compatible such as deep brain stimulators. Since staff turnover is quick, there must be regular in-service training of nurses who are chief users running through the checklists. Despite having the biometric system to restrict unauthorised access, it is still possible for unauthorised staff to gain access into the iMRI OT with the help of others. We believe that having dedicated medical, nursing and ancillary staff working in the iMRI not only enhances team work and communication, it also helps identify new staff entering the iMRI OT quickly.

As the reported incidents were only analysed at the conclusion of the study, earlier incidents may face recall bias when certain queries were raised to the principal anaesthetist. In addition, the reported incidents are subjected to underreporting.

CONCLUSION

While it was fortunate that no major mortality or morbidity occurred during the study period, we should not neglect the minor consequences that, though small, still lead to significant wastage of resources. Poor patient selection for suitability of iMRI OT may not only harm the patient, but also deny another patient the valuable slot for surgery. Technical and equipment issues that result in a delay in starting the operation subject patients to the unnecessary risks associated with prolonged general anaesthesia.

The study was concluded after 19 months of data collection. However, it remains important that such incident reporting continues, with regular reviews to prevent similar mishaps. Currently, major incidents that resulted in morbidity and mortality are flagged for discussion at departmental level.

We hope this study has provided additional insights into the possible safety issues that may occur in the iMRI OT as well as increased awareness to the multitude of safety issues concerning the iMRI OT.

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