

Attitude towards MRI safety during pregnancy

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Magnetic resonance imaging (MRI) has been in clinical use for more than two decades. At the time of introduction of this important diagnostic tool, there were many concerns about its safety and the effects of the different types of magnetic fields utilized in MRI on the body tissues. Safety of MRI in pregnancy, however, was and still is one of the important concerns. There is an extensive body of literature on the issue of safety of MRI during pregnancy¹ and overall the results indicate that there is no significant evidence of harm or injury to the fetus from exposure to a magnetic field during MRI. However, there is at the same time no proof of safety and further research in this area is still needed to reach a solid conclusion.¹ It is not easy to ascertain safety of MRI during pregnancy or otherwise with retrospective or prospective data because there are a near infinite number of possible combinations of factors that influence the risk, such as static magnetic field strength, gradient magnetic field and radiofrequency energy variability, and scan time.² Furthermore, confounding factors responsible for the high rate of spontaneous abortion in humans are not possible to control throughout pregnancy when studying exposure to magnetic field in early pregnancy.

With the growing indications for MRI during pregnancy, there is a real necessity for an established institutional policy controlling exposure of pregnant patients to a magnetic field. Such a policy should provide appropriate medical care to the mother and fetus and avoid exposure of the unborn fetus to undue risk.² We studied the attitude of radiology staff in Saudi Arabia towards safety issues concerning MRI during pregnancy.

Methods

We surveyed the MR facilities in the Kingdom of Saudi Arabia using a questionnaire that addresses issues concerning policies and procedures as well as the practice of exposure of pregnant patients and pregnant health workers to a magnetic field, including questions about screening, consent, use of MR contrast agents, and follow-up of babies exposed to MR in utero. The information was collected by direct telephone calls or by having the person in-charge in each MR facility fill out the questionnaire. Health workers included physicians, MR technicians, nurses, receptionists, porters, and cleaners.

Results

A total of 48 MRI facilities in different parts of the Kingdom were contacted and 41 (85%) responded to our survey (41% governmental, 59% private). The number of monthly exams done in these facilities was less than 100 in 14 (34%), between 100 and 200 in 12 (29%), and more than 200 exams in 13 (32%) of the facilities (Table 1). The remaining two facilities (5%) refused to release information about patient load. The majority of facilities (70%) use high field magnets. Table 2 shows the attitude of the surveyed facilities staff towards MRI safety issues

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*Accepted for publication
July 2006*

Ann Saudi Med 2006;26(4):306-309

during pregnancy. Only one third of the MRI facilities have a written policy on exposure of pregnant patients to magnetic fields. On the other hand, a few (10%) had a written policy on exposure of pregnant health workers to magnetic fields. Four centers (10%) have no screening form for MRI, but they use only verbal screening. Eleven centers (27%) do not ask about pregnancy prior to MRI examination in their screening procedure. In 12 (29%) centers MR contrast agents are given to the pregnant patients when needed, while the remaining 29 (71%) centers do not administer such agents to pregnant patients. None of the responded facilities do regular follow-up for babies exposed to the magnetic field in utero, but about half of them require special consent for MRI during pregnancy. The persons requested to sign this consent are the patient herself (59%), the husband (44%), the referring doctor (34%), and the attending radiologist (15%). The majority (68%) conditionally allow pregnant patients to go for MRI examination. Only 6 (14%) centers do not allow pregnant patients to go for MRI examination. Twenty-three (56%) of the respondents allow pregnant health workers to work in the MRI Unit. Sixteen (39%) of them allow the pregnant health worker to go inside the magnet room while actual scanning is not conducted, 12 (29%) allow the pregnant health worker to go inside the magnet room while actual scanning is conducted, and same number allow the pregnant health worker to go inside the magnetic bore.

Discussion

The issue of MRI safety during pregnancy involves both the pregnant patient and the pregnant health worker. The later group includes technicians, nurses, physicians, physicists, porters, receptionists, and any other medical personnel working in or near the magnetic field of the MRI system. However, the exposure of the pregnant patient and pregnant health worker to MRI environmental hazards is different from several aspects. Firstly, for the pregnant patient, the sources of potential hazards include the static magnetic field, the gradient magnetic field, the radiofrequency magnetic field, any combination of these time-varying or static electromagnetic fields, and MR contrast agents.²⁻⁴ On the other hand, the pregnant health worker is exposed only to the static magnetic field unless the worker accompanies the patient into the magnetic bore during scanning as happens in cases of patients ventilated by ambu bag or non-sedated children. Our results show that 29% of the surveyed facilities do allow health workers to

Table 1. Patient load in the surveyed MRI facilities

Number of patients/month	Number of MRI facilities*
<50	6 (14.6%)
50-99	8 (19.5%)
100-149	5 (12.2%)
150-200	7 (17.1%)
>200	13 (31.7%)

* Two facilities (4.9%) refused to disclose numbers.

Table 2. Responses of the surveyed MRI facilities (n=41).

	Yes	No
Written policy on exposure of pregnant patient to MRI	13 (32%)	28 (68%)
Written policy on exposure of pregnant health worker to MRI	4 (10%)	37 (90%)
Special MRI screening form	37 (90%)	4 (10%)
Ask about pregnancy before MRI	30 (73%)	11 (27%)
MRI contrast agents are given to pregnant patient	12 (29%)	29 (71%)
Special consent for MRI during pregnancy	20 (49%)	21 (51%)
Regular assessment of babies exposed to MRI in-utero	0	41 (100%)

accompany patients into the magnetic bore during scanning. The presence of an individual in the scanning room (away from the magnet bore) during the actual scanning will not expose him/her to the gradient or radiofrequency magnetic fields but obviously will cause exposure to the static magnetic field. This is because radiofrequency and gradient magnetic fields drop off rapidly outside the magnet bore to essentially insignificant magnitudes.² The hazard from MR contrast agents is not an issue for the pregnant health worker. Secondly, the pregnant patient's exposure is short-term and the exam is seldom repeated during the same pregnancy, while the exposure of most pregnant health workers is long-term and may be repeated several times during the same pregnancy. Finally, the exposure of the pregnant patient carries a risk and has a benefit to the patient and/or the fetus, but the exposure of the pregnant health worker carries only a risk to the fetus with no benefit.

The Safety Committee of the Society for Magnetic Resonance Imaging issued Policies, Guidelines, and Recommendations for MR Imaging Safety and Patient Management in 1991 stating that "MR im-

aging may be used in pregnant women if other non-ionizing forms of diagnostic imaging are inadequate or if the examination provides important information that would otherwise require exposure to ionizing radiation (e.g., fluoroscopy, CT). It is recommended that pregnant patients be informed that, to date, there has been no indication that the use of clinical MR imaging during pregnancy has produced deleterious effects. However, as noted by FDA, the safety of MR imaging during pregnancy has not been provided.⁵ In a recent update, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) stated "There is at present insufficient knowledge to establish unequivocal guidance for the use of MRI procedures on pregnant patients. In these circumstances, it is advised that MR procedures may be used for pregnant patients only after critical risk/benefit analysis, in particular in the first trimester, to investigate important clinical problems or to manage potential complications for the patient or fetus".⁶ In 1988, a survey of 250 MRI sites in the United States showed that 36% do not perform MRI on pregnant patients, and 63% conditionally perform the exam.⁷ A survey of 207 MRI sites in the United Kingdom in 2003 showed that 91% perform MRI on pregnant patients when clinically indicated.⁴ In our survey, 68% of the sites conditionally perform MRI on pregnant patients, 14% do not allow pregnant patients go for MRI, and the remaining 18% would perform the exam without conditions. More than one third of the surveyed facilities do not screen for pregnancy prior to MRI either because they did not include pregnancy in the screening form or because they do not have a screening form at all. The current recommendation is to ask about pregnancy during pre-MRI screening.⁸

The intravenous MR contrast media currently used are chelates of gadolinium. By chelating gadolinium ion its toxicity and biological half-life are substantially reduced allowing for clinical use. After intravenous injection, gadolinium-based MR contrast agents cross the placenta, accumulate in the urinary bladder of the fetus, and are then passed into the amniotic fluid. The material is then filtered from the swallowed amniotic fluid by the fetal kidneys and again passed into the amniotic fluid and the cycle is repeated several times. Because the rate of clearance of the gadolinium-based MR contrast agents from this cycle is presently unknown and general paucity of information supporting the safe use of these agents in pregnant patients, intravenous injection of such agents to a pregnant patient is contraindicated,

unless there is a compelling clinical reason for their use.^{2,9,10} According to ICNIRP, large doses of MR gadolinium-based contrast agents have been shown to cause postimplantation fetal loss, retarded development, increased locomotive activity, and skeletal and visceral abnormalities in experimental animals. Such agents should only be used during pregnancy if the potential benefit justifies the risk to the fetus.⁶ If administration of such agents is thought to be essential for a particular pregnant patient an informed consent should be obtained that specifically indicates the unknown risk associated with administration of MR contrast agents.³

Pregnant health workers chronic exposure to the static magnetic field should be controlled by clearly stated policies because unlike the exposure of a pregnant patient, the risk of exposure to a pregnant health worker is borne by the fetus only with no benefit to the fetus or mother.² Similar to our results, previous studies showed remarkable variability in policies controlling such exposure, ranging from no policy to exclusion from the magnet room to unrestricted activities.^{2,4} More than one quarter of the sites in our survey allow pregnant health worker to go inside the magnetic bore during scanning. In 1990, a survey of 1915 female health workers in MR units in the United States retrospectively compared spontaneous abortion rates, offspring gender, infertility rates, low birth weight incidence, and premature delivery rates from this group from before employment as MR imaging workers to after their employment.¹⁴ This study demonstrated no statistically significant association between these two populations and any of these five categories studied, indicating that there does not seem to be deleterious effects from exposure to at least the static component of an MR imaging system.² Based on this, it seems reasonable to permit pregnant health workers to enter the scanning room while actual scanning is not conducted. However, they should not be allowed to go inside the magnetic bore or stay in the scanning room while actual scanning is being conducted. This recommendation is not based on suspicion or indications of adverse effects, but rather on the concern that there are still insufficient data regarding the safety of the time-varying electromagnetic field components to justify such unnecessary exposure.² In addition, despite the lack of evidence of cumulative effect, there is still a need for further studies to prove the safety of such exposure, particularly with the growing trend to use stronger magnets (3 Tesla or higher) and more powerful gradients in clinical applications to shorten

scan time.^{1,12} The American College of Radiology (ACR) white paper on MR safety updated in 2004 stated "Pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy. Acceptable activities include, but are not limited to, positioning patients, scanning, archiving, injecting contrast, and entering the MR scan room in response to an emergency. Although permitted to work in and around the MR environment, pregnant health care practitioners are requested not to remain within the MR scanner bore or Zone IV during actual data acquisition or scanning".¹¹ Zone IV is synonymous with the MR scanner magnet room itself.

Under the feeling that clinical MRI is inherently a safe procedure, there was no interest in publishing "negative results" pertaining to MR safety. This, when it comes to setting up regulations and guidelines, led to the lack of a substantial body of scientific data to justify such regulations.¹⁵ In a case-control prospective study of 74 pregnancies exposed to MRI several times using 0.5 Tesla magnet after the 20th

week of gestation, the investigators failed to detect intrauterine growth restriction following this exposure.¹⁶ The authors are conducting a 10-year follow-up study for infants imaged in utero.¹⁶ In another study, pediatric assessment at the age of 9 months in infants exposed to MRI in the second half of pregnancy showed no gross abnormality likely to be related to such exposure.¹⁷ However, the investigators noticed subtle increases in motor function and height reduction in the exposed children that may warrant further studies.¹⁷

In conclusion, the current practice of exposure to MRI during pregnancy in many centers in Saudi Arabia needs modification to follow the international recommendations. There should be an effort to spread awareness about this issue among both staff and patients. Hospital policies and procedures should adequately address this issue.

We thank Dr. Janet De Wilde from Heriot-Watt University, UK for reviewing the manuscript.

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