EFFICACY OF EDUCATIONAL PROGRAM ON ANXIETY OF THE PATIENT UNDERGOING MAGNETIC RESONANCE SCAN

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ABSTRACT

Anxiety related issues are common for those who are undergoing for MRI scan. This may happen because of the anticipation about the Misaim is to study the efficacy of patient education program to reduce the anxiety of patients undergoing MRI scan. The Study Design is Randomized Controlled Trial. Three groups involved in this study are: (1) Intervention group (2) Placebo group (3) wait-listed group. Sample size: 25 patients in intervention and placebo group and 30 in wait-listed group. Tools used in the study: Anxiety Scale, Pulse Oximeter. Study Procedure: In this phase, data collection was done based on guidelines on randomized controlled trial. Sequence generation was done using a computer based program. Allocation concealment was achieved using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) to avoid deciphering. The participants were blinded regarding the arm to which they were allocated. Informed Consent and socio-demographic data was obtained from the participant Comparison of the pre and post anxiety of patients in intervention and placebo group indicates that there is a significant decrease in anxiety levels of patients in intervention Compared to that of placebo group.Comparison of pre and post pulse of patients in intervention and placebo group indicates that there is no statistically significant change in the pulse readings. Comparsion of pre and post oxygen saturation level in patients in intervention and placebo group which indicates that there is no statistically significant change in the oxygen saturation level after intervention group as compared to placebo group.

KEYWORDS: magnetic resonance scan, educational program and anxiety

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INTRODUCTION

MRI is a scanning procedure that makes use of a strong magnetic field and pulses of radio waves to help create and visualize pictures of organs and structures present within the body. Because of its peculiar sensitivity and most importantly, its property of using non-ionizing radiation for imaging, MRI is emerging as the gold standard in Medical Imaging with its advancements being introduced at a rapid pace[1]. To enclose in a nutshell the procedure that occurs during the MRI scan, it involves imaging of hydrogen nuclei (protons) heavily abundant in the body in form of water and fat, using the influence of a strong magnetic field[1]. To begin with, a patient is positioned within a bore that contains a strong magnet which in turn creates the strong magnetic field .This magnetic field can range from 0.5 T up to 9.4 T (most recent, however not yet clinically adapted).[1]The possible behavioral problems in the MRI patients are anxiety, stress and claustrophobia effects.[2]Charles c. poling had done qualitative studies which were conducted in MRI anxiety. To understand the patients' experience better, they explored the psychological basis of anxiety and asked them to describe their imaging experiences. Some of the patients commented about MR as: "I had some butterflies even before I got there", "I was very apprehensive. I'd never had anything done like that before". They felt like they were in a coffin. Some of them assumed that it was like being in a room with a tiger. The common symptoms they felt were rapid heart rate, sweating, trembling or even shaking, sensation of a weight pressing on the chest, shortness of breath and nausea.[3]Anxiety can present itself in other forms of medical examinations such as dental anxiety[6] surgical anxiety, nuclear medicine and mammography anxiety.[3]Anxiety related issues are common for those who are undergoing for MRI scan. This may happen because of the anticipation about MRI scan and the introduction of a patient into a confined tube with a limited field of vision. Among the disadvantages is the expense, artefacts, and diminished speed. A particularly common artefact is image degradation due to patient motion. Some patients get anxious because of them being scheduled for an MRI scan.[4] Anxiety is "a future-oriented mood state in which one is ready or prepared to attempt to cope with upcoming negative events".[5]he causes of voluntary patient motion during MRI scanning were high patient anxiety. Excessive anxiety during scanning compromises the patient's level of self-control, thus reducing his or her ability to remain still in the scanner[8,9]. Motion artefacts result from excessive patient movement during the data acquisition phase and typically cause the signal to be mis-registered during reconstruction. Mis-registration in effect disperses portions of the image, causing overlap between regions or loss of portions of the image altogether. Therefore, imaging features not only become blurred but also may appear as superimposed ghosts on adjacent or regional voxels[10,11,12] Patients who are not anxious during the scanning period exhibit less motion, and lower anxiety during MRI scanning improves image quality[13,14] Increasing patient education and patient staff interaction before an MRI examination can result in reduced motion artefact, not only by reducing anxiety[15,16]Anticipatory anxiety is a common discomfort. The forthcoming events in which we have our own predictions where we don't know what will happen, and we keep guessing and fabricating our imagination can be a cause of anxiety. This may cause elevation in heart rate, increase pulse, cause rapid breathing and increase tension, as well as cause headaches and sweating when we think about the upcoming event. So this anticipatory anxiety had been classified as a negative affect state that is accompanied by both somatic symptoms and appraisals of one's abilities to cope with potentially negative events.[7]Anticipatory anxiety was thus seen both as a consequence of experiencing panic attacks as well as one important antecedent of further panic attacks. The conclusion is that MRI examination is a gold standard examination comparing to other radiological examination where anxiety is commonly felt by the patients. Comparing the risks and benefits, it is not possible to avoid an MRI scan only because of the anxiety related issues. The aim and objective of this first every study in India is to study the efficacy of patient education program to reduce the anxiety of patients undergoing MRI scan.

METHODOLOGY

Hypothesis
H₁: Education program will reduce the anxiety of patients undergoing MRI scan.

Study Design
Randomized Controlled Trial. Three groups involved in this study are:
(1) Intervention group (2) Placebo group (3) Wait-listed group

Sample Size
25 patients in intervention and placebo group and 30 in wait-listed group

Sampling Technique
Random sampling technique

Study Settings
The research work was done at Kasturba Hospital (IEC68/2014)Manipal. This is a 2000 bedded tertiary care teaching and referral hospital providing specialized healthcare services to all sections of people.

Study period : 10 months
Sources of data : Patients undergoing for MRI Scan in Radio-Diagnostic and Imaging Department, Kasturba Hospital, Manipal
MRI Machine : GE 1.5 Tesla and PHILIPS 1.5 Tesla

Ethical consideration
Approved by institutional ethics committee (IEC).

Registration: Approved by Clinical Trials Registry- India (CTRI).

Sampling Criteria
Inclusion criteri
Age between 18 and 65 years
Able to read English, Kannada or Malayalam.
Patient referred for MRI scan
Conscious patient

Exclusion criteria
Patients having diagnosis of mental retardation
Patients diagnosed with psychiatric illness
Unconscious and Semi-conscious patients

TOOLS USED IN THE STUDY
Anxiety Scale
The Manipal Anxiety Inventory (MAI) developed was intended to measure the state anxiety level of the individual. The MAI is a self-report version and can also be administered to general population. The age group considered was within the limits of 18 – 65 years. MAI is a five point likert scale. MAI consisted of 14 items for assessing anxiety. The content validity of the tool was established. Various aspects of reliability were measured. MAI was found to have high internal consistency. Cronbach's Alpha score of MAI was 0.90. Test retest was conducted on a sample size of 30 and MAI was found to have high test retest reliability with Pearson correlation 0.94.

Pulse Oximeter
A pulse oximeter is an instrument which helps to measure the amount of oxygen available in the blood[41]And the heart Rate also. A healthy person has an oxygen saturation level of about 95 – 99%. And the pulsed is 72 .Pulse oximetry measures the percentage of hemoglobin in the blood, which is bound (saturated) with oxygen. This is called the oxygen saturation level, and it indicates the function of a person's heart and lung. It is very important to make sure that these devices work properly, as many patients with lung and heart problems rely on these units to be accurate.

Study Procedure
In this phase, data collection was done based on guidelines on randomized controlled trial. Sequence generation was done using a computer based program. Allocation concealment was achieved using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) to avoid deciphering. The participants were blinded regarding the arm to which they were allocated. Three groups were present in this study: Intervention group, placebo group and the Wait-listed group. Informed Consent was obtained from the participant prior to the study and Socio-demographic data were collected from the participant.

Intervention Group
In the intervention group, the physiological parameters of anxiety which is Pre pulse and pre oxygen saturation were measured first using a pulse oximeter and a pre-assessment of anxiety was measured using MAI. After obtaining the level of anxiety, a handout comprising of patient educational program to reduce anxiety of MRI patient was introduced to the patient. Post anxiety had measured with anxiety inventory after that pulse and oxygen saturation also measured using pulse oximeter.

Placebo Group
In this group, the physiological parameters of anxiety which is Pre pulse and pre oxygen saturation were measured first using a pulse oximeter and a pre-assessment of anxiety was measured using MAI. After obtaining level of anxiety, a placebo which consisted of a story "A Wonderful gesture" was introduced to the patient. Post anxiety was measured using anxiety inventory after that pulse and oxygen saturation was measured using pulse oximeter.

Wait- Listed Group
In wait-listed group, the physiological parameters of anxiety in normal population such as pulse and oxygen saturation were measured using pulse oximeter, and anxiety was measured using Manipal Anxiety Inventory which was administered to the group to analyze the level of anxiety among normal population. This group is to measure the anxiety score in normal population. It will help to compare the anxiety difference between patients undergoing for MRI scan and normal population.

Statistical Analysis
SPSS 15.0 was used for data analyses .Descriptive and inferential statistics were used for data analysis

Figure 1
Study Flow chart
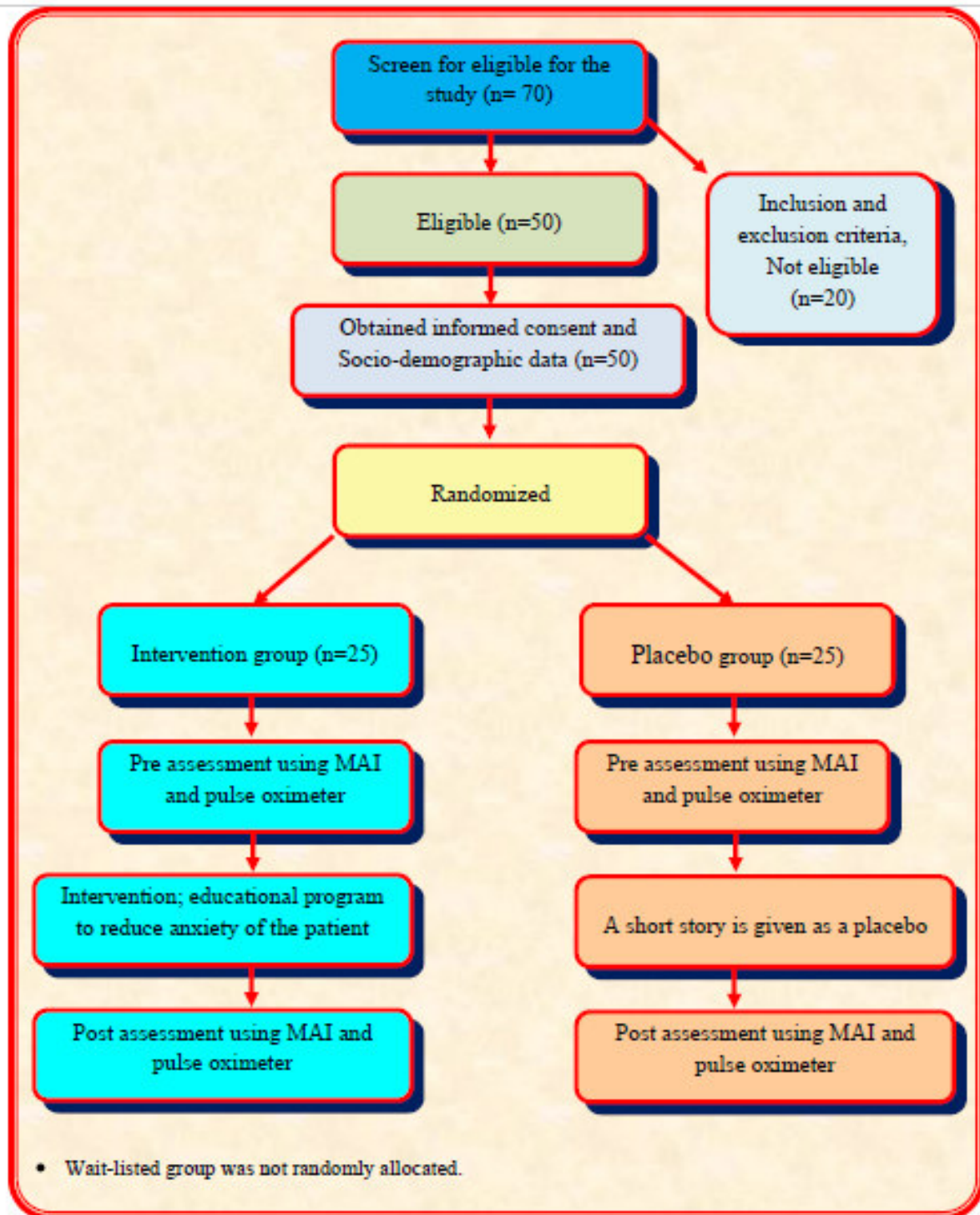
The present aim was to study the efficacy of patient education program to reduce the anxiety of patients undergoing MRI scan. The objectives were to measure level of anxiety of patients undergoing MRI scan, to develop 'patient education program to reduce anxiety 'and test its efficacy, to measure efficacy of educational program and to compare anxiety level among intervention group, placebo group and wait-listed group.

Socio-demographic Data

Table 1
*Socio-demographic data of intervention, placebo
and wait-listed groups (n=80)*

		Intervention (n and %)	Placebo (n and %)	Wait-listed (n and %)
Gender	Male	12 (48)	18 (72)	17 (56.7)
	Female	13 (52)	7 (28)	13 (43.3)
Previous Experience In MRI	Yes	9 (36)	12 (48)	9 (30)
	No	16 (64)	13 (52)	21 (70)
Marital status	Married	21 (84)	23 (92)	18 (60)
	Single	4 (16)	2 (8)	12 (40)
Residence	Rural	13 (52)	14 (56))	19 (63.3)
	Urban	12 (48)	11 (44)	11 (36.7)

In socio-demographic data, intervention group consisted of 12 males (48%) and 13 females (52%), placebo group consisted of 18 males (72%) and 7 females (28%) and wait-listed group consisted of 17 males (56.7%) and 13 females (43.3%).The intervention group had 9 participants (36%) who had previous experiences in MRI and 16 (64%) who had no previous experience. From placebo group 12 participants (48%) had previous experiences in MRI and 13 (52%) had no previous experience. From wait-listed group 9 participants (30%) had previous experience in MRI and 21 (70%) had no previous experience.In intervention group 21 (84%) were married whereas 4 (16%) were single, placebo group 23 (92%) were married whereas 2 (8%) were single and wait-listed group 18 (60%) were married whereas 12 (40%) were single.In intervention group 13 (52%) were from rural areas while 12 (48%) were from urban areas, placebo group 14 (56%) were from rural areas while 11 (44%) were from urban areas and wait-listed group 19 (63.3%) were from rural while 11 (36.7%) were from urban areas.

Table 2
*Mean and standard deviation of age in intervention,
placebo and wait-listed group(n=80)*

Group	Mean (SD)
Intervention	39.80(12.376)
Placebo	44.48(11.128)
Wait-listed	31.83(11.597)

*The intervention group mean age was calculated 39.80 and the standard deviation as 12.376.
The placebo group mean age was found to be 44.45 whereas the standard deviation was 11.128.
The wait-listed group mean age was calculated as 31.83 and the standard deviation as 11.597.*

Table 3
*Correlation Coefficient between baseline anxiety,
pulse and oxygen saturation (n=50)*

Variables	Correlation	p. value
Anxiety and pulse	-0.112	0.322
Anxiety and oxygen saturation	0.032	0.776
Pulse and oxygen saturation	0.427	0.32

Pearson correlation co-efficient was computed to find the relationship. The correlation co-efficient of anxiety and pulse was found to be -0.112 whereas p value was 0.322.The correlation co-efficient of Anxiety and oxygen saturation was calculated as 0.032 and p value as 0.776. The correlation co-efficient of pulse and oxygen saturation was calculated as 0.427 and p value as 0.32. Hence it is interpreted that variables anxiety and pulse, anxiety and oxygen saturation, pulse and oxygen saturation are not related

Comparison of Baseline Anxiety Score of Intervention and Placebo Group to Wait-Listed Group

Table 4
*Mean and the Standard deviation and p value of the pre
Anxiety in normal population and the MRI patient*

			(n=80)
	Group	**Mean [SD]**	**p value**
Pulse	MRI patient	78.54 (12.039)	.558
	Normal population	80.13 (11.212)	
Oxygen Saturation	MRI patient	96.729 (3.791)	.099
	Normal population	97.90 (.923)	
Anxiety	MRI patient	37.14 (7.467)	< .001*
	Normal population	28.37 (11.607)	

Significant (p<0.01)

Table 4 shows the results for the comparsion of anxiety score of intervention and placebo group to wait-listed group where saturation independent sample t- test was done for pulse and oxygen saturation. There is a significantly high anxiety in MRI patients than normal population but there is no significant difference in pulse and oxygen saturation in mri patients and normal population

Pre and Post Anxiety Scores

Table 5
*Mean, standard deviation and p value of the pre and post anxiety
scores of intervention and placebo group.(n=50)*

	Group	**Mean [SD]**	**p value**
Pre Anxiety	Intervention	36.96 (6.168)	
	Placebo	37.32 (8.702)	.003*
Post Anxiety	Intervention	32.44 (7.682)	
	Placebo	36.76 (8.007)	

Significant (p<0.01)

Comparsion of the pre and post anxiety of patients in intervention and placebo group indicates that there is a significant decrease in anxiety levels of patients in intervention compared to that of placebo group. Hence the research hypothesis (H_1) was accepted and the null hypothesis was rejected.

Figure2
Repeated measures profile plot of pre and post Anxiety
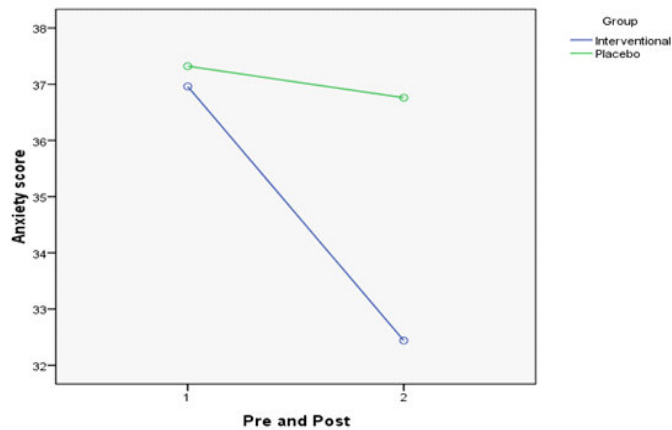

Figure 2 Represents repeated measures profile plot shows pre and post anxiety in intervention group and placebo group. In this, the intervention group had pre anxiety mean of 36.96 and placebo group of 37.32. Post anxiety mean score in intervention group is 32.44 and placebo group is 36.76. This shows that intervention group has significantly less anxiety in the post intervention comparing to placebo group.

Pre and Post Pulse Reading

Table 6

	Group	Mean[SD]	p value
Pre Pulse	Intervention	78.80(12.437)	
	Placebo	78.28(11.880)	.799
Post Pulse	Intervention	78.96(10.394)	
	Placebo	77.52(12.810)	

Comparsion of pre and post pulse of patients in intervention and placebo group indicates that there is no statistically significant change in the pulse readings after intervention group as compared to placebo group.

Figure 3
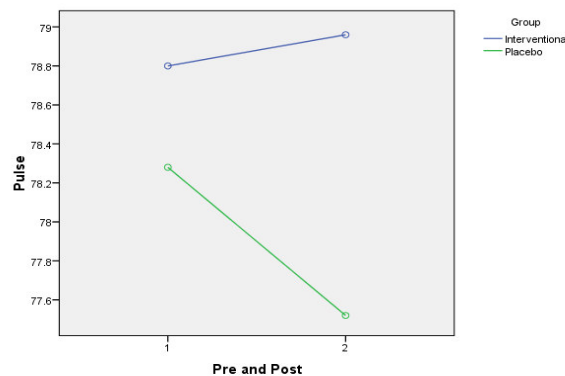*Repeated measures profile plot of pre and post pulse*

Figure 3 represents repeated measures profile plot shows pre and post pulse in intervention group and placebo group. In this, the intervention group pre pulse mean is 78.80 and placebo group is 78.28. The post pulse mean in intervention

group is 78.96 and placebo group is 77.52. This shows that intervention group has higher pulse in the post intervention comparing to placebo group. This change was not statistically significant.

Pre and Post Oxygen Saturation Reading

Table 7
Mean, Standard deviation and the p value of the pre and post oxygen saturation readings of intervention and placebo groups(n=50)

	Group	Mean [SD]	p value
Pre Oxygen Saturation	Intervention	96.60(5.148)	
	Placebo	96.84(1.675)	.216
Post Oxygen Saturation	Intervention	97.64(1.350)	
	Placebo	97.24(1.615)	

Comparsion of pre and post oxygen saturation level in patients in intervention and placebo group which indicates that there is no statistically significant change in the oxygen saturation level after intervention group as compared to placebo group.

Figure 4
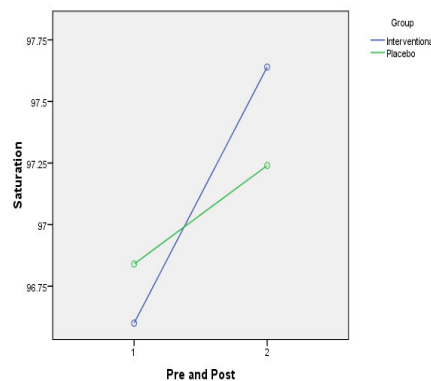*Repeated measures profile plot of pre and post oxygen saturation*

Figure 4 represents repeated measures profile plot shows pre and post oxygen saturation in intervention group and placebo group. In this, the intervention group pre oxygen saturation mean is 96.60 and placebo group is 96.84. The post oxygen saturation mean in intervention group is 97.64 and placebo group is 97.24. This shows that there are no statistically significant changes in the oxygen saturation in intervention and the placebo group.

DISCUSSION

The anxiety is a common reaction when people come to face new problems where they don't know what to expect.The present study aimed to reduce the anxiety of the patient undergoing MRI scan, as part of the first phase the researchers developed and standardized an educational program and a questionnaire called Manipal anxiety inventory (MAI). In the second phase, researcher divided the population into 3 groups: intervention, placebo and wait-listed group. After the study the researchers found that the MRI patients had significantly higher anxiety level compared to the normal population. After intervention, the intervention group had significantly less anxiety compared to the placebo group. There was no correlation between anxiety level, and pulse of the patient, as well as oxygen saturationIn the present study,

the researchers allowed the intervention group to receive the educational program to reduce anxiety of MRI patients, whereas placebo group received a normal story, and Manipal anxiety inventory (MAI) was used to measure the anxiety level of the MRI patients. The researchers found that in the post assessment there was a significantly (p<0.003) less anxiety for intervention group comparing to placebo group; and hence showed that the awareness program helped to reduce anxiety of the MRI patients. This finding was similar to a study done by Selim (2001) on anxiety in MRI patients where there were two groups - a control group and an intervention. In his study[15], the intervention group received instructions which were designed by the researcher along with routine hospital instructions whereas the control groups were given only regular hospital instructions. The State - Trait Anxiety Inventory was dispensed to both groups

before and after the MRI examination. The patients who received the designed instructions reported a significantly lower level of anxiety than the controls. Their findings also implied that 60% of the total sample had used prayers to reduce their anxiety[15]. The anxiety decreased in the present study which showed that prior information about MRI procedure helped to reduce anxiety in MRI patientsIn the present study we had three groups of MRI patients in which intervention group received the educational program and placebo group received the placebo. The study found that there was a significant (p<0.003) reduction in anxiety in intervention group comparing to placebo group which supported the statement that it was possible to reduce anxiety of the MRI patients without pharmacological techniques. According to the study done by Kolesos in (2013) where he had done a randomized study on the dental anxiety and assigned the efficiency of the relaxation therapy and cranial electrotherapy stimulation in the management of dental anxiety among 40 patients. In their study, the patients were divided into intervention group and the placebo group and their results also showed a significant reduction of anxiety in intervention group comparing to placebo group. They also proved that it was possible to reduce anxiety of the patients without pharmacological techniques. The anxiety reduced in both studies which showed that prior information about MRI and relaxation procedure helped to reduce anxiety in MRI patients.In the present study, found that heart rates and oxygen saturation levels showed no significant differences in the two subgroups – intervention and placebo where we measured the physiological parameters of anxiety- pulse and oxygen saturation level in both intervention and placebo group. Our results showed that in post pulse, the pulse increased in intervention group and decreased in placebo group. Our findings were similar to that of a study done by Maria Shindova, Ani Belcheva (2013) based on dental anxiety in children where the aim of the study was to evaluate effect of parental presence on dental anxiety in children aged 6-12 years during clinical examination measuring subjective and objective parameters of stress. Their study was conducted on forty-eight 6-12-years-old children where a convenient sample of children was randomly selected from patients who were treated at their department and were divided into two groups. One was where the children's parents were present during the intra oral clinical examination and the other group where children's parents was absent during the same procedure. They investigated two physiological parameters of stress - heart rate and oxygen saturation, which were measured with a pulse oximeter. Their results showed that in the two subgroups the mean heart rate of the child was lowest on the dental chair before the start of examination, but the anxiety was high during the clinical examination which was

determined to be a statistically significant difference between the two intervals (p<0.001). There was no statistically significant difference in oxygen saturation levels between any of the other groups and also between different intervals. The heart rate and oxygen saturation levels showed no significant differences between the two subgroups[6]. The reason was that the placebo acted only as a mind distraction in our study which did not help to reduce the anxiety of patients .We also found that there was also no correlation between anxiety and pulse as well as the oxygen saturation.In the present study, when we compared the anxiety level between normal population and the MRI patients the results showed that there was a significant (p< .001) anxiety difference between normal population and the MRI patients. We also found that the educational program for MRI patients helped to reduce the anxiety of the MRI patients and thus would be useful for both anxious and the claustrophobic patients. A study based on claustrophobia in MRI patients was conducted by Sarji, Abdullah, Kumar, Tan, & Narayanan (1998) where the aim of the study was to evaluate if an open or a short-bore magnetic resonance (MR) scanner was superior in relieving patients' claustrophobia. Their study was done on 174 patients where they used a Claustrophobia questionnaire to measure claustrophobia. They were assigned randomly so as to obtain their evaluation to be done by open or by short-bore MR. A follow-up was conducted after seven months of the MR imaging where the primary outcomes were incomplete MR examinations due to a claustrophobic event. The results obtained indicated the occurrence of 33 claustrophobic events in short-bore group and 23 in open bore but the difference was found to be non-significant (p>0.08)[9].

CONCLUSION

This study aimed to reduce the anxiety before an MRI scan. For this, we developed an anxiety inventory called Manipal anxiety inventory (MAI) to measure the anxiety and an Educational program for patients undergoing for MRI to reduce anxiety before scan. This study proved that MRI patients have more anxiety than normal population, so there should be some technique to reduce the anxiety of patients undergoing MRI scan. After the intervention, we found that the educational program and relaxation technique significantly reduced anxiety in patients. But there were no significant changes in physiological parameters like pulse and oxygen saturation. We also found that the intervention which was used for the present study can also be use in routine practice for patients undergoing for MRI to reduce anxiety level.

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