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RESEARCH METHODOLOGY: INSTRUMENT DEVELOPMENT

Development and validation of a questionnaire evaluating patient anxiety during Magnetic Resonance Imaging: the Magnetic Resonance Imaging-Anxiety Questionnaire (MRI-AQ)

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Abstract

Aim. To develop and validate a new instrument measuring patient anxiety during Magnetic Resonance Imaging examinations, Magnetic Resonance Imaging- Anxiety Questionnaire.

Background. Questionnaires measuring patients' anxiety during Magnetic Resonance Imaging examinations have been the same as used in a wide range of conditions. To learn about patients' experience during examination and to evaluate interventions, a specific questionnaire measuring patient anxiety during Magnetic Resonance Imaging is needed.

Design. Psychometric cross-sectional study with test-retest design.

Methods. A new questionnaire, Magnetic Resonance Imaging-Anxiety Questionnaire, was designed from patient expressions of anxiety in Magnetic Resonance Imaging-scanners. The sample was recruited between October 2012–October 2014. Factor structure was evaluated with exploratory factor analysis and internal consistency with Cronbach's alpha. Criterion-related validity, known-group validity and test-retest was calculated.

Results. Patients referred for Magnetic Resonance Imaging of either the spine or the heart, were invited to participate. The development and validation of Magnetic Resonance Imaging-Anxiety Questionnaire resulted in 15 items consisting of two factors. Cronbach's alpha was found to be high. Magnetic Resonance Imaging-Anxiety Questionnaire correlated higher with instruments measuring anxiety than with depression scales. Known-group validity demonstrated a higher level of anxiety for patients undergoing Magnetic Resonance Imaging scan of the heart than for those examining the spine. Test-retest reliability demonstrated acceptable level for the scale.

Conclusion. Magnetic Resonance Imaging-Anxiety Questionnaire bridges a gap among existing questionnaires, making it a simple and useful tool for measuring patient anxiety during Magnetic Resonance Imaging examinations.

Keywords: anxiety, instrument development, magnetic resonance imaging, nurse, nursing, reliability, validity

Why is this research needed?

- Magnetic Resonance Imaging is an important diagnostic method with the possibility to evaluate different diseases. The narrow tunnel and the loud noise are demanding for the patients.
- As there is no existing questionnaire evaluating patients' feelings of anxiety while being scanned in the tunnel of the Magnetic Resonance scanner, a new one is needed.

What are the key findings?

- The questionnaire could preferably be used as a two-factor solution.
- Cronbachs alpha showed high internal consistency ($\alpha = 0{\cdot}90$).
- The questionnaire detected a higher level of anxiety in patients that were subjected to Magnetic Resonance Imaging of the heart compared with Magnetic Resonance Imaging of the spine.

How should the findings be used to influence policy/practice/research/education?

- Magnetic Resonance Imaging-Anxiety Questionnaire could be used to evaluate different kinds of interventions to alleviate anxiety.
- In nursing, patients' subjective experience is of great value to know.
- The additional knowledge provided by this questionnaire enables Magnetic Resonance Imaging radiographers to avoid early unnecessary interruption of examinations thus enhancing the diagnostic yield for patients and reducing cost for society.

Introduction

Magnetic Resonance Imaging (MRI) has emerged as an important diagnostic method in health care and is used for evaluating a wide range of disorders, including coronary artery disease (von Knobelsdorff-Brenkenhoff & Schulz-Menger 2012). It does not expose the patients to radiation, it has high signal-to-noise and contrast-to-noise ratios, and high spatial resolution (Nandalur *et al.* 2007, Greenwood *et al.* 2012). MRI examinations are non-invasive and painless but may nevertheless be demanding on the part of the patient. In particular, the narrow tunnel at times creates problems with claustrophobia. During the examination, a loud, high-pitched noise is heard, requiring hearing protection. To enable communication between staff and the patient throughout the examination, intercom is used (McRobbie *et al.* 2007). The scanning procedure is familiar to MRI staff, but for the patient the narrow tunnel may provoke a wide range of feelings, such as nervousness, anxiety, claustrophobia and uncontrolled panic (Munn & Jordan 2011). Magnetic Resonance Imaging–Anxiety Questionnaire (MRI-AQ) was developed to evaluate patient anxiety during MRI examinations.

Background

In the literature, 25-37% of patients have reported experiencing a moderate to high level of anxiety during MRI examinations (Katz *et al.* 1994, McIsaac *et al.* 1998). The American Psychological Association defines anxiety as 'an emotion characterized by heightened autonomic system activity, specifically activation of the sympathetic nervous system (i.e. increased heart rate, blood pressure, respiration and muscle tone), subjective feelings of tension and cognitions that involve apprehension and worry' (Kazdin 2000, p 209). Barlow stated that anxiety is 'a sense of uncontrollability focused largely on possible future threats, danger, or other upcoming potentially negative events, in contrast to fear, where the danger is present and imminent' (Barlow 2000, p.1249). It is a state of helplessness, depending on a perceived inability to control desired outcomes in a personal situation (Barlow 2000). During MRI examinations, the loud noise and the experience of losing control contribute to the feeling of anxiety (Tornqvist *et al.* 2006b, Funk *et al.* 2014). In addition, fear of pain and of the unknown, and apprehension about the result (Quirk *et al.* 1989, Katz *et al.* 1994) may enhance the experience of anxiety, inducing a first attack of claustrophobia. This claustrophobic experience may be generalized to other enclosed situations as well (McIsaac *et al.* 1998, Radomsky *et al.* 2001). Severe anxiety during MRI scanning may cause patient motion, inducing image artefacts (Tornqvist *et al.* 2006a) that can decrease the diagnostic value of the examination. In the study of Murphy and Brunberg as many as 134 (14·3%) of 939 patients required either oral or intravenous sedation or general anaesthesia (Murphy & Brunberg 1997).

The manufacturers have tried to improve patient comfort by making the tunnel wider and shorter (Dewey *et al.* 2007), but several issues that affect the level of patient anxiety remain. Previous studies have attempted to predict (Harris *et al.* 2004) or measure patient anxiety (Kilborn & Labbé 1990, Katz *et al.* 1994, Enders *et al.* 2011). The findings showed remaining problems, suggesting a need for additional intervention (Tornqvist *et al.* 2006b, Tischler *et al.* 2008, Tazegul *et al.* 2015) to minimize adverse patient experience. It is thus important to support patients

psychologically to facilitate a successful scan. To learn about the anxiety patients experience during examination and evaluate different kinds of interventions, a specific questionnaire measuring patient anxiety during MRI is needed. A literature review showed that previously used questionnaires in MRI are identical to those evaluating anxiety in a wide range of conditions (Spielberger & Gorsuch 1983, Bjelland *et al.* 2002). Given the gap in knowledge, it would be helpful to develop a new questionnaire evaluating patient anxiety in the very specific situation of being examined with an MRI scanner.

The study

Aim

To develop and validate a new instrument measuring patient anxiety during Magnetic Resonance Imaging examinations, Magnetic Resonance Imaging-Anxiety Questionnaire.

Methodology

This study was conducted in two phases; an initial scale development step followed by a psychometric evaluation step.

Scale development

To create the items of the Magnetic Resonance Imaging-Anxiety Questionnaire, the findings from a hermeneutic phenomenological study was used (Tornqvist *et al.* 2006b). Nineteen patients (22-73 years old) were interviewed, thus illuminating 'patient's lived experience' (Tornqvist *et al.* 2006b) during an MRI examination. Physical expressions of anxiety were e.g. tachycardia, palpitation, difficulties breathing and dizziness. The participants with anxiety expressed fear and an irresistible urge to get out of the scanner. When apprehensive, they felt a strong need for detailed information about the planned procedure. To endure, they tried to think about something pleasant. Other important supporting factors were reliance and confidence in the staff and a channel of communication with the operator. From the interviews, 22 items, for example, 'I was afraid', 'I needed to come out from the scanner' and 'I had difficulty breathing', were created.

The items were discussed by an expert group (radiologist and radiographer) that decided to exclude three items, two about patients' thoughts during the examination. As a result of complaints from the patients about their difficulties to choose the right statement, one more item was excluded. After this reduction, content validity was evaluated using the content validity index (CVI). The CVI was rated by seven experts, all healthcare professionals, of whom four were medical scientists. Two were nurses with experience of patients undergoing MRI. Five of the raters had experience as radiographers working with MRI, one also had psychiatric experience of patients with anxiety.

CVI was judged for each item on a four-point scale; '1' = not relevant, '2' = somewhat relevant, '3' = quite relevant and '4' = highly relevant. The answers were dichotomized to 'not relevant' ('1' and '2') and 'relevant' ('3' and '4'). When an expert found an item to be relevant, it was given a CVI of '1' and when it was not, CVI was '0'. CVI was evaluated on item-level and scale-level. Item-level CVI (I-CVI) was calculated by summing the number of experts rating the item as relevant ('1') divided by the number of experts. With seven or more experts in the group, I-CVI is recommended to be at least 0·78 (Polit & Beck 2006), which means that the majority agree. CVI on scale-level (S-CVI) was calculated as the average proportion of items rated as relevant. According to this definition, CVI on scale-level should be at least 0·90 (Polit & Beck 2006). The findings showed that one item, 'I felt nauseous ', had not sufficient content validity', (I-CVI = 0·71). After this item was excluded, the scale CVI was very good (S-CVI = 0·99).

Together with the expert group, the authors decided to use a four-point Likert-type response scale for the items in the MRI-AQ. This is consistent with the most common instrument used for evaluating anxiety during MRI examination, for example, Spielberg State Anxiety Index–State (STAI-S) (Spielberger *et al.* 1970). The response categories were labelled as: 1 = 'Not at all', 2 = 'Somewhat', 3 = 'Moderately so', to 4 = 'Very much so'. The reversed item (n = 7) in the MRI-AQ scale was inverted before computing the sum scores. Thus, a higher score indicates a higher degree of anxiety (Appendices 1 and 2).

Psychometric evaluation

Participants

Consecutive patients referred for MRI examination of the spine or the heart were asked to participate. Patients were recruited from three radiology departments in Sweden, one in a private hospital, one in a university hospital and one in a county hospital. The sample was recruited between October 2012–October 2014.

Further requirements were being older than 18 years of age and being able to read, understand and speak the

Swedish language. Exclusion criteria were cognitive deficits and/or physical disabilities affecting the experience of the examination (e.g. patients with cancer where the disease may affect feelings of anxiety), contraindications for MRI investigations and participation in another study. It should be noted that none of the MRI examinations of the heart were performed during pharmacological stress.

According to Pett *et al.* (2003), the number of patients in the sample should be at least 10-15 times the total number of questions to display an appropriate range of responses for the factor analysis. The MRI-AQ included 18 items; therefore a total number of 180-270 participants was regarded as sufficient.

Procedure

In the letter to the patient scheduling the examination, study information and an invitation to participate were enclosed. Those who accepted filled out the consent form, which was brought to the examination. The participants were given the questionnaires after the MRI scan was completed and responded to the questions before leaving the department. The questionnaire included MRI-AQ, Spielberg State Anxiety Index-State (STAI-S), Hospital Anxiety and Depression Scale (HAD) and Magnetic Resonance Imaging Fear Survey Schedule (MRI-FSS). To evaluate the stability of MRI-AQ, 111 participants responded to the questionnaire a second time at home, one day after the examination. The form was completed on paper and was sent to the scientist by mail.

Measures

Spielberg State Anxiety Index (STAI) consists of two separate scales with 20 items each, measuring state (situational) and trait (baseline) anxiety. In this study, only the state anxiety scale was used (STAI-S), which measures the anxiety patients' experience at a particular moment. Patients rate their feelings on a four-point scale ranging from 'not at all' to 'very much', with a possible score range between 20-80. Higher score implies higher level of anxiety (Spielberger *et al.* 1970, Ferreira & Murray 1983, Forsberg & Björvell 1993). Cronbach's alpha in the present study was 0·91.

Magnetic Resonance Imaging Fear Survey Schedule (MRI-FSS) consists of nine statements from the Fear Survey Schedule (Wolpe & Lang 1964), defined by Lukins *et al.* (1997). These nine statements deal with fear in situations related to MRI examinations and were developed to predict fear during such examinations. This questionnaire was not available in Swedish and was therefore translated using standard forward-backward-forward translation technique (Brislin 1970, Cha *et al.* 2007). The nine statements express fear of: vacuum cleaner noise, being alone, loud noises, thunder, sirens, sudden noises, being in an elevator, enclosed places and journey by airplane (Harris *et al.* 2004). Patients rate the statements on a seven-point scale ranging from 'no fear at all' to 'terrified'. Higher scores predict higher levels of anxiety during the examination. The score ranges between 9 and 63. Cronbach's alpha in the present study was 0·80.

Hospital Anxiety and Depression Scale (HAD), measures general anxiety and depression in patients. It consists of two factors with seven questions about anxiety and seven about depression. Both are rated on a four-point scale where a higher score indicates a higher level of anxiety and depression (Zigmond & Snaith 1983, Lisspers *et al.* 1997, Bjelland *et al.* 2002). The possible score ranges between 0 and 21 for each scale. In the present study, Cronbach's alpha was 0·83 and 0·81 for anxiety and depression respectively.

Two study-specific single items about 'patient experience' and 'patient worry' during the examination were administrated. On a visual analogue scale graded from 1 = 'very good'-10 = 'very bad', the participants were asked to rate how they experienced the examination and the worry they felt throughout the examination.

Data analyses

Descriptive statistics were used to present characteristics of the participants. For each item, mean scores and standard deviations (SD) were calculated. Frequencies were used to describe missing data, score distribution and ceiling and floor effects for the item responses. If a majority of the scores were distributed at either end of the scale, floor or ceiling effects were considered (Nunnally & Bernstein 1994). The homogeneity of the scale was evaluated using item-total correlation adjusted for overlap, with an acceptance level of $r \geq 0{\cdot}30$ (Nunnally & Bernstein 1994).

To evaluate the factor structure of the instrument, an exploratory factor analysis, unweighted least squares, was conducted. Before the factor analysis, data were examined with Bartlett's test of sphericity ($\chi^2(153) = 2058{\cdot}8$, $P < 0{\cdot}001$) and Kaiser–Meyer–Olkin measure of sampling adequacy (0·896), indicating a satisfactory correlation between the items. A hot-deck multiple imputation was conducted to replace missing data. The number of factors was selected using Kaisers' criteria, eigenvalue >1·0 (Streiner & Norman 2008, Fayers & Machin 2009). The numbers of extracted factors were confirmed by Horn's parallel analysis, using the 95th percentile estimate and 500 iterations (Hoyle & Duvall 2004). Communality values were inspected to evaluate how much of the variance in each variable was explained by the extracted factors. Items with

low communality values (<0·20) and/or factor loadings (<0·40) were considered to be deleted.

To facilitate interpretation, the factors were rotated using an orthogonal rotation method (varimax). Internal consistency of the instrument was evaluated using Cronbach's alpha coefficient (Streiner & Norman 2008, Fayers & Machin 2009). An alpha value (α) $\geq$ 0·70 was considered acceptable on a group level (Fayers & Machin 2009).

Criterion-related validity was evaluated by Spearman's correlation (r_s) between the MRI-AQ, STAI-S, MRI-FSS, HAD and the two study-specific single items about experiences and worries. We hypothesized that MRI-AQ should correlate stronger with STAI-S, MRI-FSS, HAD anxiety and the patients' ratings of their experience and worry than with HAD depression.

Known-group validity was evaluated by comparing MRI-AQ scores between patients examining the spine and the heart, using unpaired *t*-test. We hypothesized that the heart group would score significantly higher levels on MRI-AQ compared with the spine group. The stability of the items in MRI-AQ was evaluated by a test-retest between scores from day one and two, using weighted Kappa coefficient (K_w). Strength of agreement was defined as follows: ≤0·20 poor, 0·21-0·40 slight, 0·41-0·60 moderate, 0·61-0·80 good and 0·80-1·00 very high (Altman 1991). Intraclass correlation (one-way random model, ICC1,1) and Lin's concordance correlation coefficient (CCC) were used to evaluate the correlation for the total scale and for the factors between day one and two. Data were analysed using STATISTICA version 10 (StatSoft, Inc., Tulsa, USA), MedCalc (MedCalc Software, Mariakerke, Belgium) and Factor 10·3 (Rovira i Virgili University, Tarrgona, Spain). The level of statistical significance was set at $P < 0·05$.

Ethical considerations

The study followed the Declaration of Helsinki (World Medical Association 2001) and the principles of Good Clinical Practice (Group 1996). Approval was obtained from the Regional Ethical Review Board and all patients gave written informed consent after a full explanation of the planned procedure.

Result

In total, 881 patients referred for an MRI examination of either the spine (n = 781) or the heart (n = 100) were invited to participate, of whom 247 accepted and filled in the questionnaires (response rate 28%).The participants were significantly older (54·7 SD 14·3 years, P = 0·001) than the non-participants (51·1 SD 15·4). Of the patients included in the study; 193 had a spine scan and 54 had a heart examination. There were no significant age differences (−1·01 (d.f.) = 245, P = 0·315) between the two groups. Gender distribution differed significantly between the groups (4·69 (d.f.) = 1, P = 0·030); 63% in the spine group were women, compared with 46% in the heart group (Table 1).

Item statistics

Of the 247 participating patients, 216 (87%) answered all items. Among the 31 who did not, missing data varied between one and six items. The mean score for the items in MRI-AQ varied between 1·17 and 2·10. Floor effect was reached for all items while there were no ceiling effects. Missing data for each item varied between 0-5 (0·0-2·0%) and were equally distributed across the instrument. Item-total correlation varied between 0·44-0·78, except for the last three items where it ranged between -0·11-0·22. Alpha if item deleted ranged between 0·86-0·89 (Table 2).

Factor structure

The factor analysis identified two factors with eigenvalues >1·0. These findings were also supported by the parallel analysis. The unadjusted (reduced correlation matrix) and adjusted eigenvalues (parallel analysis) for the two first factors were 6·80/1·70 and 7·24/2·23 respectively. This two-factor model explained 52·6% of the total variance. No item demonstrated multiple loadings in the rotated factor

Table 1 Distribution of sample size, age, gender, and type of Magnetic Resonance Imaging examination.

Variables	Spine-MRI	Heart-MRI	Total
Agreed to participate, *n*	193	54	247
Gender male/female, *n*	72/121	29/25	101/146
Age in years, mean ± SD (min-max)			
All	55·2 ± 13·9 (22-82)	52·9 ± 15·7 (20-80)	54·7 ± 14·3 (20-82)
Male	58·2 ± 14 (30-81)	50·9 ± 15·0 (21-80)	56·1 ± 14·6 (21-81)
Female	53·7 ± 13·6 (22-82)	55·3 ± 16·3 (20-77)	53·7 ± 14·1 (20-82)
Sedation male/female, *n*	4/2	1/5	5/7

Table 2 Data quality and item-total correlation.

Item	Mean ± SD	Item-total correlation.	Alpha if deleted	Item score distribution *n* (%)				Missing data *n* (%)
				1	2	3	4	
1	1·46 ± 0·75	0·61	0·86	160 (66·05)	62 (25·62)	11 (4·55)	9 (3·72)	5 (2·06)
2	1·20 ± 0·46	0·55	0·87	202 (82·06)	38 (15·45)	6 (2·24)	0 (0·0)	1 (0·41)
3	1·19 ± 0·56	0·54	0·87	212 (86·85)	21 (8·61)	7 (2·87)	4 (1·64)	3 (1·23)
4	1·33 ± 0·62	0·78	0·86	178 (73·49)	50 (20·66)	11 (4·55)	3 (1·24)	5 (2·06)
5	1·37 ± 0·74	0·69	0·86	185 (75·16)	37 (15·04)	17 (6·91)	7 (2·85)	1 (0·41)
6	1·17 ± 0·52	0·68	0·86	217 (88·91)	15 (6·15)	10 (4·10)	2 (0·82)	3 (1·23)
7	2·10 ± 1·10	0·61	0·86	90 (36·83)	85 (34·84)	23 (8·43)	46 (18·85)	3 (1·23)
8	1·89 ± 1·10	0·60	0·86	122 49·94)	67 (27·46)	15 (6·15)	40 (16·39)	3 (1·23)
9	1·64 ± 0·96	0·44	0·87	151 (61·58)	53 (21·63)	20 (8·16)	21 (8·57)	2 (0·82)
10	1·93 ± 1·09	0·60	0·86	118 (47·92)	66 (26·83)	24 (9·76)	38 (15·45)	1 (0·41)
11	1·42 ± 0·74	0·74	0·86	173 (70·85)	45 (18·44)	21 (8·61)	5 (2·05)	3 (1·23)
12	1·65 ± 0·86	0·59	0·86	138 (56·50)	63 (25·82)	34 (13·93)	9 (3·69)	3 (1·23)
13	1·33 ± 0·69	0·65	0·86	191 (78·24)	30 (12·30)	19 (7·79)	4 (1·64)	3 (1·23)
14	1·22 ± 0·67	0·50	0·87	215 (87·37)	17 (7·91)	4 (1·63)	10 (4·07)	1 (0·41)
15	1·3 ± 0·88	0·48	0·87	141 (58·20)	63 (26·03)	25 (10·31)	13 (5·37)	5 (2·06)
16	1·25 ± 0·75	0·03	0·88	217 (88·20)	11 (4·47)	4 (1·63)	14 (5·69)	1 (0·41)
17	1·69 ± 0·93	−0·11	0·89	138 (55·63)	59 (24·28)	30 (12·35)	16 (6·58)	4 (1·65)
18	1·18 ± 0·60	0·22	0·87	220 (89·04)	17 (6·88)	2 (0·81)	8 (3·24)	0 (0·00)

solution. However, item 16-18 demonstrated communality values <0·2 and/or factor loadings <0·4. For this reason, the factor analysis was recalculated after exclusion of these items. Also this analysis resulted in a two-factor model, supported by the parallel analysis. This model explained 59·5% of the total variance and no item demonstrated multiple loadings in the rotated factor solution. The first factor consisted of 12 items about anxiety symptoms, with factor loadings between 0·48 and 0·86. The second factor consisted of three items abouy relaxation symptoms, with factor loadings between 0·74-0·91 (Table 3). The excluded items considered reliance on staff; 'I had confidence in the staff' (item 16), 'It felt safe having the alarm' (item 17) and 'I was certain that they took me out of the scanner if needed' (item 18). The correlations between MRI-AQ (15 item) and the two factors were as follows; MRI-AQ & factor I (anxiety symptoms) $r_s = 0{\cdot}86$ ($P < 0{\cdot}001$) and MRI-AQ & factor II (relaxation symptoms)) $r_s = 0{\cdot}86$ ($P < 0{\cdot}001$).

Internal consistency

Internal consistency for the total scale (MRI-AQ) was good ($\alpha = 0{\cdot}90$) and for Symptoms of anxiety ($\alpha = 0{\cdot}90$) and Symptoms of relaxation ($\alpha = 0{\cdot}89$).

Criterion-related validity

As hypothesized, MRI-AQ, Anxiety and Relaxation correlated stronger with anxiety (HAD-A) than with depression (HAD-D). None of the MRI-AQ factors correlated with depression (HAD-D). The strongest correlations were found between MRI-AQ and patient worry (Table 4).

Known-group validity

As hypothesized, patients who examined the heart scored significantly higher values on the MRI-AQ, Anxiety and Relaxation compared with those who underwent MRI of the spine (Table 5).

Stability (test-retest)

The items in MRI-AQ demonstrated acceptable test-retest reliability. One-hundred and eleven participants completed MRI-AQ a second time the day after the examination. In the test-retest, the weighted kappa coefficients showed fair to good agreement ($K_w = 0{\cdot}42$-$0{\cdot}79$). (Table 6). Stability for the total scale of MRI-AQ and the two factors between day one and two is described in Table 7. The intraclass correlations varied between 0·49–0·94 and the Lin concordance correlations varied between 0·48 and 0·94.

Discussion

To our knowledge, there is no instrument evaluating patient anxiety during MRI examinations. Therefore, the knowledge from this study bridges a gap in the existing literature. It enables evaluation of anxiety in a group of patients

Table 3 Basis for the two-factor solution with eigenvalue >1·0 of the Magnetic Resonance Imaging –Anxiety Questionnaire. Factor loadings for each item. Communality calculated on unrotated factor analyses.

Item		Anxiety symptoms	Relaxation symptoms	Communality values
Factor I/Anxiety symptoms				
1	I felt that I controlled the situation	**0·55**	0·34	0·42
2	I had palpitations	**0·60**	0·21	0·40
3	I found it hard to breathe	**0·63**	0·18	0·43
4	I was afraid	**0·86**	0·27	0·81
5	I wanted to come out	**0·74**	0·25	0·61
6	I panicked	**0·75**	0·24	0·62
9	I worried in advance	**0·48**	0·18	0·26
11	I had to force myself to manage the situation	**0·78**	0·29	0·69
12	Self -control was required when going through the examination	**0·71**	0·15	0·52
13	I needed support and encouragement	**0·75**	0·18	0·59
14	I wished to have someone with me	**0·56**	0·15	0·33
15	I needed more detailed information	**0·54**	0·16	0·31
Factor II/Relaxation symptoms				
7	I felt relaxed	0·21	**0·84**	0·76
8	I felt safe	0·16	**0·91**	0·85
10	I felt calm	0·24	**0·74**	0·60
	Eigenvalues after rotation	7·19	1·74	
	Explained variance after rotation, %	47·95	11·58	**59·53**[a]

[a]Total variance explained, ≥50 is regarded as acceptable (Pett *et al.* 2003).

whose expressions of anxiety while being in an MRI scanner have not been addressed by specific questionnaires previously. In our study, this newly designed instrument shows overall good psychometric properties.

Patient anxiety during MRI examinations has been evaluated with instruments measuring general anxiety in more common terms, for example, STAI-S (Kilborn & Labbé 1990, Katz *et al.* 1994, Thorpe *et al.* 2008, Tazegul *et al.* 2015). Using an instrument recognized from previous studies confers interpretative strength. Still, we propose the need of a very specific instrument for the MRI scanner examination. To ensure content validity, items were constructed from the result of interviews with 19 patients telling their experience from MRI examinations (Tornqvist *et al.* 2006b).

MRI-AQ showed high response frequency and missing items were few and randomly distributed throughout the instrument, which may indicate that no item was more difficult to answer than any of the others. Even if MRI examinations are anxiety- ridden for a substantial group of patients, there is a larger group that either copes or thinks the situation is unproblematic. With this larger group answering 'not at all', the instrument has a floor effect. During instrument development this effect is unwanted (Streiner & Norman 2008, Fayers & Machin 2009), but in this inhomogeneous group, floor effects are unavoidable.

The factor analysis demonstrated that MRI-AQ is a multidimensional scale consisting of two factors. The results corresponded partly with the findings from the interview study (Tornqvist *et al.* 2006b) as the two extracted factors in the present study can be related to two of the three subthemes identified by Tornqvist *et al.* (2006b). 'Anxiety symptoms' relates to the sub-theme, 'threat to self-control' and 'relaxation symptoms' to 'effort to handle the situation'. The third sub-theme 'need for support' related to the factor 'reliance on staff' which was, after factor analysis, excluded due to too low communalities and factor loadings. The finally MRI-AQ scale consisting of 15 items and two factors has good measurement properties and explained variance. The MRI-AQ has the potential to provide a useful and relevant measure to assess anxiety during MRI, both used clinically and in research. The MRI-AQ scale includes subjective experiences attributable to the MRI procedure.

However, it is important for all patients to have a good interaction with the staff, particularly for those who are anxious (Youssefzadeh *et al.* 1997, Tornqvist *et al.* 2006b, Tazegul *et al.* 2015). The three items that express reliance on staff can be of great value, even if they are not included in the instrument. It is particularly important to evaluate the quality of nursing care in connection with interventions.

The internal consistency was good for both MRI-AQ and the two- factors, symptoms of Anxiety and Relaxation

The MRI-AQ showed higher correlation with instruments trying to predict fear of MRI (MRI-FSS) and measuring anxiety (STAI-S and HAD anxiety) compared with instruments measuring depression (HAD depression), but the correlation was weak. Patients who are anxious in everyday life are probably also inclined to be anxious during MRI examinations. However, there are also patients who very rarely or never experience anxiety in their regular life, but who may have feelings of losing control and anxiety when

Table 4 Correlation between MRI-AQ; (total score of MRI-AQ, the factors Anxiety symptoms and Relaxation symptoms) and MRI-FSS, STAI-S, HAD-A, HAD-D, patient experience and patient worry.

Scale/factors	MRI-FSS	STAI-S	HAD-A	HAD-D	Patient Experience	Patient Worry
MRI-AQ	0·37**	0·46**	0·32**	0·17*	0·56**	0·72**
Anxiety symptoms	0·42**	0·41**	0·32**	0·15*	0·57**	0·75**
Relaxation symptoms	0·35**	0·37**	0·28**	0·14*	0·43**	0·58**

*$P < 0.05$; **$P < 0.001$. Spearman's (r_s) correlation.
Total score MRI-AQ, Magnetic Resonance Imaging-Anxiety Questionnaire; MRI-FSS, Magnetic Resonance Imaging Fear Survey Schedule; STAI-S, Spielberg State Anxiety Index-State; HAD-A, Hospital Anxiety and Depression Scale – Anxiety; HAD-D, Hospital Anxiety and Depression Scale – Depression. Patient experience and patient worry = 10-point scale.

Table 5 Mean score for Magnetic Resonance Imaging –Anxiety Questionnaire (MRI-AQ) and the two factors in the heart and spine examination groups.

	Heart (n = 54) mean ± SD	Spine (n = 193) mean ± SD	P value*
MRI-AQ	29·65 ± 7·98	25·59 ± 7·73	<0·001
Anxiety symptoms	19·38 ± 6·64	15·77 ± 5·59	<0·001
Relaxation symptoms	5·49 ± 1·82	4·74 ± 1·85	0·003

*Significance for score differences was evaluated with t-test.

positioned in the MRI scanner. Although the instruments (STAI-S, HAD anxiety and MRI-AQ) are supposed to measure the same construct, anxiety, this new instrument focuses on anxiety in the very specific situation of being in a MRI scanner, while the others measure general anxiety in a broader sense (STAI-S, HAD- anxiety), or predict fear of MRI (MRI-FSS). The highest correlation was found between MRI-AQ and patient ratings of their worry, which seems relevant as both relate to feelings during the examination. Altogether, these findings indicate that the scales measure different aspects of anxiety and that MRI-AQ is justified for use in this context as it is more specific for this situation than the other questionnaires.

Evaluation of known-group validity, an aspect of construct validity, supported that by using MRI-AQ it was possible to discriminate between patient groups examining the spine or the heart. As hypothesized, the patients in the heart group scored significantly higher levels of anxiety compared with the patients in the spine group. This difference could be explained by the time needed for a full examination of the heart and the need for patient cooperation. While an MRI examination of the spine is short and no cooperation from the patient is needed (more than lying still in the tunnel), MRI of the heart is much more time consuming and the patient has to cooperate by holding their breath 40-50 times during the examination. In addition, a coil is positioned over their chest and the need to remain still is even higher than in MRI of the spine. Having a heart condition is also more life-threatening and thereby more anxiety-ridden for the patients. The differences in anxiety and discomfort between the two groups were supported both by the number of patients, albeit few, needing intravenous sedation (Diazepam 5 mg/ml) during the MRI investigation and of the patient ratings of the experience and worry. Of the 193 patients who examined the spine, 6 (3%) needed sedation compared with 6 (11%) patients of the 54 who examined the heart. There was a significant difference between the patient ratings of experience with higher scores for heart patients. Katznelson *et al.* stated that patients who had undergone coronary artery bypass graft surgery more frequently interrupted the MRI examination (14%) (Katznelson *et al.* 2008) than those who had not (1·2-5·0%) (Kilborn & Labbé 1990, Meléndez & McCrank 1993). HAD depression, HAD anxiety and STAI-S did not indicate any difference between the two study groups. MRI-AQ showed no difference in the level of anxiety between ages or between genders.

Test-retest for items showed satisfactory stability between answers given on the examination day and the day after. The highest Kappa value was found for the item 'I was afraid' and the highest agreement for 'I found it hard to breathe'. Both are found in the factor 'Anxiety symptoms'. One reason could be that anxiety is a strong feeling and something that is remembered for a long time. Eight of the 15 items in the final MRI-AQ had a kappa value exceeding 0·60 which is considered as a good agreement (Altman 1991). In the comparison between day one and day two, there was no significant difference in the result.

Limitations

One limitation in this study was the low response rate. There could be several reasons for this. The invitation to

Table 6 Test-retest reliability for Magnetic Resonance Imaging–Anxiety Questionnaire (MRI-AQ) between the day of the examination and the day after.

		Weighted Kappa K_w	(K_w/95% Cl)	r_s	Percentage agreement (%)
MRI-AQ					
1	I felt that I controlled the situation	0·53	0·35-0·70	0·55	75
2	I had palpitation	0·66	0·49-0·89	0·70	90
3	I found it hard to breath	0·67	0·47-0·89	0·73	93
4	I was afraid	0·79	0·68-0·89	0·85	89
5	I wanted to come out	0·75	0·62-0·89	0·84	89
6	I panicked	0·61	0·38-0·84	0·66	91
7	I felt relaxed	0·42	0·29-0·57	0·47	62
8	I felt safe	0·46	0·32-0·61	0·55	67
9	I worried in advance	0·72	0·59-0·85	0·75	83
10	I felt calm	0·46	0·31-0·61	0·46	68
11	I had to force myself to manage the situation	0·69	0·56-0·82	0·77	84
12	Self-control was required when going through the examination	0·58	0·45-0·72	0·66	72
13	I needed support and encouragement	0·70	0·55-0·86	0·69	86
14	I wished to have someone with me	0·56	0·34-0·78	0·56	86
15	I needed more detailed information	0·59	0·47-0·71	0·69	69

The value; K_w renders a grade as follows: <0·2, poor agreement; 0·21-0·40, fair agreement; 0·41-0·60, moderate agreement; 0·61-0·80, good agreement; and 0·81-1·00, very good agreement (Altman 1991).
K_w/Cl(95%), Spearman's rank correlation(r_s); and percentage agreement.
Cl, confidence interval.

Table 7 Intraclass correlation (ICC) and Lin's concordance correlation coefficient (CCC) for the total scale of Magnetic Resonance Imaging–Anxiety Questionnaire (MRI-AQ) and the two factors, between day one and day two.

	Day 1	Day 2	ICC		CCC	
	Mean ± SD		r	95% CI	rho c	95% CI
MRI-AQ	1·49 ± 0·51	1·43 ± 0·52	0·90	0·85-0·93	0·90	0·85-0·93
Anxiety symptoms	1·37 ± 0·48	1·36 ± 0·49	0·94	0·91-0·96	0·94	0·92-0·96
Relaxation symptoms	1·98 ± 1·0	1·72 ± 0·83	0·49	0·32-0·62	0·48	0·34-0·62

Cl, confidence interval.

participate was sent together with the time schedule for the examination and could have disappeared among other, in that situation, more important information, such as time schedule and necessary information about the examination and contraindications. Even if the response rate is low, a validation study is just only validated on the group of participants who responded the items. Validation is also an ongoing process and the result can change over time (Nunnally & Bernstein 1994). Recommendations about the sample size necessary for a factor analysis vary. A higher number of participants reduces variance (Guadagnoli & Velicer 1988) and the factor loadings become better estimates of population loading (MacCallum *et al.* 1999). Recommendations for sample size can be calculated as a ratio between the number of participants and items. Pett *et al.* (2003) recommended 10–15 per item. There are also different recommendations about the sample size needed, with a minimum of 100 up to 1000, which is considered as excellent (MacCallum *et al.* 1999). In the present stud, with primarily 18 items answered by 216-246 participants, the ratios varied between 12-13·7 respondents per item.

One of the questionnaires (MRI-FSS) used for calculations of criterion validity has not been validated in Swedish but Cronbach's alpha, in this study, indicates a high internal consistency. The result should, however, be judged with caution.

Anxiety is probably stronger before and during the examination than afterwards. After the examination patients are

relieved and the earlier feelings of anxiety are something they want to forget. Answering a questionnaire during an MRI examination is not possible due to the strong magnetic field, the narrow environment and the necessity of lying still. This is a limitation to all studies of the experience of MRI examinations and in that way findings are comparable.

Conclusion

The 15 items of MRI-AQ showed satisfactory psychometric properties and shall be used as a two-factor model until there are more evidence about the factor structure indicating untether result. The instrument demonstrated good validity and reliability and has hence the potential to become a valuable addition to anxiety assessment. The MRI-AQ bridges a gap in knowledge and is a simple and useful tool for measuring patient anxiety during MRI examinations, during interventions, or when new procedures are introduced.

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Conflict of interest

The authors have no conflicts of interest.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]:

- substantial contributions to conception and design, acquisition of data or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

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Appendix 1
Magnetic Resonance Imaging- Anxiety Questionnaire (MRI-AQ)

INSTRUCTIONS: Below are some statements that can be used to describe your feelings. Read each statement and circle the number 1 to 4 that best describes your feelings during the MRI examination. Do not reflect too much on any statement, but respond in the way you think best corresponds to your feelings during the examination.

		Not at all	Somewhat	Moderately	Very much so
1*	I felt that I controlled the situation	1	2	3	4
2	I had palpitation	1	2	3	4
3	I found it hard to breath	1	2	3	4
4	I was afraid	1	2	3	4
5	I wanted to come out	1	2	3	4
6	I panicked	1	2	3	4
7*	I felt relaxed	1	2	3	4
8*	I felt safe	1	2	3	4
9	I worried in advance	1	2	3	4
10*	I felt calm	1	2	3	4
11	I had to force myself to manage the situation	1	2	3	4
12	Self-control was required when going through the examination	1	2	3	4
13	I needed support and encouragement	1	2	3	4
14	I wished to have someone with me	1	2	3	4
15	I needed more detailed information	1	2	3	4

Items marked * are to be inverted before calculation. Higher score will then indicate higher level of anxiety.

Appendix 2
Magnetic Resonance Imaging- Anxiety Questionnaire (MRI-AQ)

INSTRUKTION: Nedan följer några påståenden som man kan använda för att beskriva hur man känner sig. Läs varje påstående och ringa in den av siffrorna 1 till 4 som bäst svarar mot hur du kände dig under magnetkameraundersökningen. Fundera inte för mycket på något påstående utan svara såsom Du tycker bäst passade in hur du kände Dig vid undersökningen.

		Inte alls	Ganska lite	Ganska mycket	Mycket
1*	Jag kände att jag behärskade situationen	1	2	3	4
2	Jag fick hjärtklappning	1	2	3	4
3	Jag hade svårt att andas	1	2	3	4
4	Jag kände rädsla	1	2	3	4
5	Jag ville komma ut	1	2	3	4
6	Jag fick panik	1	2	3	4
7*	Jag kände mig avslappand	1	2	3	4
8*	Jag kände mig säker	1	2	3	4
9	Jag oroade mig i förväg	1	2	3	4
10*	Jag kände mig lugn	1	2	3	4
11	Jag fick ansträngа/ bemöda mig för att klara av situationen	1	2	3	4
12	Det krävdes självkontroll för att kunna genomföra undersökningen	1	2	3	4
13	Jag behövde stöd och uppmuntran	1	2	3	4
14	Jag hade velat ha någon med mig	1	2	3	4
15	Jag hade behov av information	1	2	3	4

Frågor markerade * inverteras före kalkylering. Då kommer höga värden alltid att indikera högre ångset.

[Correction added on 11 April 2016, after first online publication: the Swedish versions of the statements have been corrected]

