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Patient Perception, Preference and Participation

### Perception of care and experience of examination in women at risk of breast cancer undergoing intensive surveillance by standard imaging with or without MRI

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for the Magnetic Resonance Imaging study group (STIC IRM 2005)<sup>1</sup>

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#### ABSTRACT

*Objective:* Intensive surveillance in women at breast cancer risk is currently investigated in a French prospective, non-randomized, multicenter study, in which standard imaging – mammography  $\pm$  ultrasound ('Mx') and standard imaging combined with magnetic resonance imaging ('MRI') are compared with regard to perception of care and examination experience.

*Methods:* 1561 women were invited to complete the STAI-State Anxiety Inventory and breast cancer risk perception items at baseline (T0), and MGQ (MammoGraphy Questionnaire) and MRI discomfort items within 2 days after examinations (T1).

*Results:* Baseline compliance was high (>91%). Women from the 'MRI' group were significantly younger and displayed higher education level and risk perception. MRI discomfort related to the duration, immobility, prone position or noise was experienced by more than 20% of women. In multivariate analyses, 'MRI' was associated with more favorable examination psychological experience ( $p \le .001$ ), especially in women younger than 50; baseline STAI-State anxiety was associated with lower MGQ scores ( $p \le .001$ ) and higher MRI discomfort ( $p \le .001$ ).

*Conclusion:* In spite of the discomfort experienced with MRI, perception of care and experience with this surveillance procedure was more positive than with standard imaging.

*Practice implications:* Information and support may assuage some of the adverse effects of an uncomfortable examination technique.

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#### 1. Introduction

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Various prospective multicenter studies have demonstrated the significantly higher sensitivity of magnetic resonance imaging (MRI) compared to standard imaging (mammography, ultrasound) to detect breast cancer [1]. However, in view of its cost and moderate specificity, MRI appears to be especially indicated for the surveillance of young women at very high risk of breast cancer, in whom the disease prevalence is high [2]. The efficacy of MRI in terms of survival has yet to be determined and this examination is known to more frequently lead to further targeted investigations, close follow-ups or diagnostic surgical procedures for conditions that eventually prove to be benign (false-positive) [3].

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Although the medical value of MRI for the surveillance of women at high risk for breast cancer has been studied extensively, the experience and acceptability of intensive breast surveillance from the subject's point of view is largely unknown [1]. However, adherence to this type of surveillance can be affected by the woman negative experience of examinations or dissatisfaction with care [4,5].

The negative effects of breast cancer surveillance may be related to the examinations themselves, such as pain or discomfort. Rijnsburger et al. [6] reported pain and discomfort rates of 30% and 70% for mammography, and 12% and 45% for MRI, respectively, and MRI elicited anxiety in 37% of cases. More than one half of women may experience pain related to mammography [7,8].

In one study, although 5% of high-risk women refused MRI because of claustrophobia, 44% of these women preferred this examination to mammography [9], and Zakaria et al. [1] reported that this examination does not induce any major discomfort and is perceived, particularly by women with a personal history of breast cancer, as beneficial for management of their disease.

Most of the published studies are exploratory [10], performed with non-validated [1,9] or generic questionnaires [6], and do not address the perception of care, especially with regard to the communication skills of healthcare professionals, although this aspect of care may affect adherence to medical recommendations [11].

Thus, it seemed important to evaluate the perception of care and experience of breast cancer imaging, particularly MRI, on a large multicenter sample of women at risk of breast cancer invited to undergo a supplementary MRI examination compared to women undergoing standard breast cancer imaging (mammography  $\pm$  ultrasound).

The primary objective of this study was to compare the perception of care and psychological experience related to the MRI examination compared to mammography, based on assessment of the MRI examination by women undergoing the standard imaging plus MRI and assessment of mammography by women undergoing the standard imaging only. This study was also designed to assess the discomfort specifically experienced by women during MRI.

We formulated the hypothesis of less favorable perception of care and experience in women assessing MRI compared to those assessing mammography, as the MRI examination can be considered to elicit anxiety due to the need to remain immobile, alone, enclosed in the MRI tunnel for a long period of time, the noise associated with the examination and the higher risk of an abnormal result [10].

A secondary objective was to investigate factors associated with the perception of care and examination experience in this setting from the women's sociodemographic, clinical and psychological characteristics and the breast imaging center.

#### 2. Methods

This study protocol was approved by the local ethical committee and by the *Commission Nationale Informatique et Libertés* (CNIL: French Information Technology and Privacy Commission). All women recruited provided a written informed consent.

#### 2.1. Study design

This study was a prospective, non-randomized, observational study conducted in 21 centers in France (cancer centers, teaching hospitals or private clinics) experienced in breast MRI techniques. It was designed to compare the health economic and psychological impact of two surveillance modalities, one comprising mammography with or without ultrasound ('Mx'), and the other comprising these same radiological examinations plus MRI ('MRI') [12].

Women attending the imaging services of the participating centers were consecutively invited to participate in the study by a radiologist who explained the objectives and procedures of the psychological assessment. When she gave her written consent to participate, she received, firstly, a questionnaire form to be filled in at home or at the imaging center during the week before the radiological examinations (T0; i.e. in a maximum of 7 days before the imaging examinations), and then a second questionnaire form to be filled in immediately after the considered examination, either mammography or MRI (T1; i.e. within 2 days after the last imaging examination – which could be performed over a period of up to 30 days), and before being informed about the results.

#### 2.2. Study population

Both study subgroups were composed of women aged between 20 and 70, with no clinical signs of breast cancer, no ongoing cancer treatment, no metastasis, no bilateral mastectomy.

Women eligible for 'MRI' included either women with a demonstrated genetic mutation; non-tested women with a first-degree relative with a demonstrated genetic mutation; women with a probability of a genetic mutation of at least 40% (Claus Model [13]); or women with a first-degree relative with a probability of a genetic mutation of at least 80%. Among these women, the lifetime breast cancer risk is  $\approx$ 40–60% and current guidelines recommend annual breast surveillance with MRI, starting at age 30 [2].

Women eligible for 'Mx' included either women with a personal history of pathological breast lesions or breast cancer between age 40 and 50 without any family history of breast or ovarian cancer, or with only one first-degree relative diagnosed with breast cancer between age 50 and 70, or women in whom MRI was contraindicated. Among these women (except those of the last inclusion criteria, i.e.  $\approx 2\%$  of the sample), the lifetime breast cancer risk is  $\approx 15-20\%$  and the yearly risk of breast cancer recurrence is  $\approx 1\%$ ; current guidelines recommend annual breast surveillance by standard imaging starting at breast cancer or pathological breast lesion diagnosis [2].

#### 2.3. Psychological measures

#### 2.3.1. Breast cancer risk perception

Breast cancer risk perception was measured at baseline by three items in a verbal form (low to very high risk perception) or by a quantitative score (absolute risk percentage or relative risk categories) with the possibility of indicating one's ignorance concerning her breast cancer risk. A total score may be computed ranging between 0 (very low perceived risk) and 1 (very high perceived risk).

### 2.3.2. State component of the State-Trait Anxiety Inventory (STAI-State anxiety)

The STAI-State anxiety has well-documented psychometric properties [14,15]. It consists of a generic measure of state (transitory) anxiety and was administered in this study at baseline and within 2 days after the examinations. The global score ranges from 20 to 80 and a score greater than 46 is considered to indicate moderate to very high anxiety [14].

#### 2.3.3. MammoGraphy Questionnaire (MGQ)

The MGQ questionnaire was developed in Norway [16,17]; it evaluates the psychological experience of mammography, perception of interactions with radiology staff, organization of care and the physical surroundings of the mammography setting. The MGQ has been translated into French and adapted to breast cancer surveillance imaging [18]. The MGQ comprises 27 items scored on

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a 5-point Likert agreement scale (from strongly agree to strongly disagree). All responses are coded so that a high score indicates a positive judgment. The questionnaire instructions indicate the type of examination assessed, either mammography or MRI; it was administered within 2 days after the examinations. Exploratory factor analysis was performed on data collected in this study, separately in the two 'MRI' and 'Mx' groups. A clearly interpretable two-factor solution, similar in the two groups, was adopted. One of the factors, explaining 12.5% and 10.5% of score variance in the 'MRI' or 'Mx' group, respectively, assessed the woman's perception of quality of care during the examination (e.g. "I felt free to ask about anything"; "The examiner seemed to be professionally capable") and the other factor, explaining 8.6% and 8.8% of score variance in the 'MRI' or 'Mx' group respectively, assessed the women's examination psychological experience (e.g. "The examination made me uneasy"; "The examination cause discomfort") (Table 1). Each factor comprised 6 items (score from 6 to 30) and presented adequate estimates of internal consistency for each groups (Cronbach's alpha ranging from 0.68 to 0.79).

#### 2.3.4. MRI-specific discomfort items

Six MRI-specific questions adapted from Anderson et al. [19] concerning the discomfort related to the duration of the examination, immobility and the need to remain lying prone in the tunnel, the loud noise or panic feelings, were elaborated and administered within 2 days after this examination. Exploratory factor analysis was performed on the data collected in this study, resulting in a factor composed of 5 items with adequate internal consistency (Cronbach's alpha = 0.73). The percentage of missing data per item was less than 1.4%. A global score ranging from 0 to 20 was calculated for subjects responding to at least 3 of the 5 items based on the mean score for the items to which they responded.

#### 2.4. Statistical analysis

In this comparative, non-randomized study, differences in the composition of the two subgroups were controlled statistically before comparing responses to the psychological questionnaires. Hierarchical multiple regression analysis was used to perform this control [20]; control variables were introduced into a first block and the surveillance modality variable into a second block. When the second regression significantly improved the explanatory power of the regression, it was concluded with relative confidence that the examination (mammography versus MRI) introduces differences, taking into account all other variables. For exploratory purposes, all interactions between the surveillance modality and other variables were tested. The effect of the surveillance center was then evaluated in each surveillance modality for the 14 centers ('MRI' group) and 11 centers ('MRI' group) that could be considered due to the number of women included by each center.

Statistical analyses were performed with SPSS software version 16.0.

#### 3. Results

From November 2006 to June 2008, 1,561 women were recruited: 900 in the 'MRI' group and 661 in the 'Mx' group. Fig. 1 describes the number of evaluations performed according to the assessment times defined in the protocol and which were therefore eligible for analysis in each group. At T1, 329 women in the MRI group and 37 in the Mx group were excluded from eligible women because their assessment times did not comply with one or more of the following criteria: (1) for assessment at T0, lapse of time between T0 and T1 less than 7 days; for assessment at T1; (2) questionnaires completed within 2 days of last imaging examination and lapse of time between imaging examinations not superior to 30 days; (3) questionnaires completed after the examination to

Table 1

MammoGraphy Questionnaire (MGQ) items factor loadings for the two-factor solution obtained using principal axis factoring with varimax rotation.

MGQ items <sup>a</sup>	MRI		Mx	
	F1	F2	F1	F2
1. I was surprised I had to undress.	0.11	0.05	0.16	0.00
2. The examiner was to rough with me.	0.19	0.14	0.09	0.30
3. I felt free to ask about anything.	0.65	0.03	0.54	0.07
4. The examination made me feel embarrassed.	0.14	0.48	0.08	0.40
5. The examiner seemed to be professionally capable.	0.57	0.06	0.46	0.07
6. The examination made me uneasy.	-0.08	0.45	-0.04	0.45
7. The staff told me all I wanted to know.	0.70	0.19	0.62	0.08
8. The examination situation made me feel awkward.	0.03	0.66	0.09	0.38
9. The staff used words that were easy to understand.	0.73	0.07	0.62	0.00
10. I was worried in case my body could be injured.	0.11	0.20	0.16	0.30
11. The staff did not explain what was to be done with me.	0.19	0.04	0.16	0.19
12. I found this examination painful.	0.18	0.40	-0.09	0.67
13. I was able to undress undisturbed.	0.37	0.03	0.32	0.00
14. I had to wait too long before getting an appointment.	0.15	0.04	0.11	0.21
15. The staff «pushed» me quickly through.	0.08	0.15	0.10	0.17
16. The examination room was unpleasant.	0.33	0.21	0.12	0.08
17. I was treated worse than I expected.	0.40	0.11	0.15	0.18
18. The waiting room was pleasant.	0.24	0.20	0.31	0.18
19. I sat too long before being examined.	0.21	0.02	0.29	0.20
22. This examination caused me discomfort.	-0.01	0.57	0.03	0.68
23. I will not dread another examination.	0.12	0.58	0.12	0.46
24. The staff did anything to ensure my comfort.	0.54	0.30	0.64	0.23
25. I found nothing to complain about.	0.46	0.34	0.61	0.26
26. I would advice others not to have the examination.	0.25	-0.03	0.03	0.11
27. Certain things should have been done otherwise.	0.29	0.22	0.33	0.17
% Explained variance	12.5%	8.6%	10.5%	8.8%

<sup>a</sup> Items 20 which asks to report on waiting time (factual rather than subjective information) and item 21 which assesses the perception of examination cost (>21% missing data for item not relevant in France) were not included in the exploratory factor analysis. The 'Perception of Care Quality' subscale is composed of items 3, 5, 7, 9, 24, 25; the 'Examination Psychological Experience' subscale comprises items 4, 6, 8, 12, 22, 23.

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Fig. 1. Flow chart describing the number of questionnaires available for statistical analysis.

be evaluated either MRI or Mx; (4) questionnaires completed before the communication of imaging results; and (5) and before start of further investigations.

The sociodemographic and clinical characteristics of all eligible women, all *per protocol* subjects at T0 and all *per protocol* subjects at T1 were mostly not significantly different or differences were of small magnitude, ranging from 1 to 4% (Table 2).

#### 3.1. Characteristics of the study subgroups

'MRI' and 'Mx' subgroups were significantly different in terms of age, level of education, breast cancer risk perception and, as expected, personal history of breast cancer (p < .001) (Table 2). A higher percentage of women in the 'Mx' group were not aware of their breast cancer risk compared to the 'MRI' group (37.1% versus

19.0%). Only a small percentage of women were referred to the 'Mx' group because of claustrophobia (1.4%).

#### 3.2. Perception of quality of care and psychological experience

The mean scores on the MGQ Perception of care quality scale were very high in both surveillance modalities (27.3 and 27.1), while mean scores for the MGQ Psychological experience scale were slightly poorer (24.6 and 23.4) (Table 2).

In multivariate analysis, the regression model (Table 3) including the 'surveillance modality' variable significantly improved the explanation of variance of the MGQ Psychological experience scores ( $F_{change}(1, 880) = 16.8, p < .001; R^2$  change = .015) but not that of the MGQ Perception of care quality scores ( $F_{change}(1, 878) = .31$ , not significant) (Table 3). The 'Mx'

Table 2

Demographic, clinical, breast cancer risk perception, state anxiety, perception of care, and examination psychological experience in women at risk of breast cancer according to surveillance modality.

	MRI + mammography		Standard mammography			
	Eligible ( <i>N</i> = 900)	Baseline respondents (N=818)	Respondents at T1 (N=365)	Eligible (N=661)	Baseline respondents (N=641)	Respondents at T1 ( <i>N</i> =604)
Age category (years) (%)*						
<50	58.5	58.4	59.1	34.5	34.9	34.3
50-59	26.7	27.1	26.9	49.7	49.5	49.7
≥60	14.8	14.6	14	15.9	15.6	16.1
Education level (%) <sup>*</sup>						
Elementary	11.6	11.1	9.9	15.0	14.9	15.1
Secondary	40.5	40.1	37.6	47.5	47.5	47.7
Tertiary	47.9	48.8	52.5	37.5	37.7	37.3

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#### Table 2 (Continued)

	MRI + mammography		Standard mammography			
	Eligible (N=900)	Baseline respondents (N=818)	Respondents at T1 (N=365)	Eligible (N=661)	Baseline respondents (N=641)	Respondents at T1 (N=604)
Work status (%)						
Employed	66.3	66.5	70.0	67.8	68.0	68.3
Retired	16.2	16.1	15.2	17.5	17.2	17.2
Unemployed	17.5	17.4	14.9	14.6	14.8	14.8
Living with a partner (%)	79.6	79.2	78.7	75.0	75.2	75.9
Inclusion criteria for MRI (%) <sup>a</sup>						
Demonstrated mutation	73.8	73.8	78.1	-	-	-
Demonstrated mutation in 1st d° relative	0.6	0.5	0.5	-	-	-
Probability of mutation > 40%	5.8	5.6	5.6	-	-	-
Probability of mutation in 1st d° relative > 80%	0.4	0.5	0.5	-	-	-
Family history of breast or ovarian cancer	14.4	14.4	14.4	-	-	-
A combination of above criteria	5.0	5.1	5.1	-	-	-
Inclusion criteria for Mx (%) <sup>a,b</sup>						
Personal breast cancer history	-	-	-	69.1	69.6	70.5
Pathological breast lesions	-	-	-	28.7	28.5	28.0
Contra-indication for MRI	-	-	-	0.8	0.5	0.5
Claustrophobia	-	-	-	1.4	1.4	1.0
Mutation status (%) <sup>b</sup>						
Positive result	74.4	73.8	78.1	-	-	-
True negative	10.6	10.8	9.0	-	-	-
Uninformative result	15.0	15.4	12.9	-	-	-
Personal breast cancer history (%) <sup>*,b</sup>	51.6	51.2	47.4	69.1	69.6	70.5
Previous breast MRI (%) <sup>b</sup>	35.3	35.4	39.1	-	-	-
Risk perception (%)*						
Breast cancer risk perceived as very high	-	14.9	15.0	-	3.4	3.3
Don't know	-	19.0	16.7	-	37.1	37.2
Specific measure [0–1] Mean (S.D.)*	-	0.54 (0.17)	0.54 (0.17)	-	0.39 (0.17)	0.39 (0.18)
Baseline STAI-State		. ,			. ,	
Mean (S.D.)	-	40.5 (13.3)	41.1 (13.6)	-	41.6 (14.0)	41.7 (14.0)
MammoGraphy Questionnaire Mean (S.D.)						
Perception of care [6–30]	_	_	27.3 (3.7)	_	_	27.1 (3.6)
Psychological experience [6-30]*	-	-	24.6 (4.5)	-	_	23.4 (4.8)

<sup>a</sup> MRI = standard imaging + MRI; Mx = standard mammography.

<sup>b</sup> Significant difference between baseline respondents and respondents at T1 ( $p \le .05$ ).

\* Significant difference between baseline respondents according to surveillance modality (p < .001).

group had significantly lower MGQ Psychological experience scores ( $\beta$  = -.147) than the 'MRI' group (p < .001).

The MGQ Perception of care quality and Psychological experience scores were lower in women with higher anxiety scores at T0 ( $\beta$  = -.131 and  $\beta$  = -.392); MGQ Psychological experience scores

#### Table 3

Hierarchical multiple regression analysis showing predictors of MammoGraphy Questionnaire perception of care and psychological experience scale scores at T1<sup>a</sup> (overall sample; N=969).

Variable	MGQ-Perception of care β	MGQ-Psychological experience β
Elementary Secondary Age Employed Retired Living with partner Breast cancer history Risk perception STAI-State at TO Surveillance modality (standard)	.058 .023 006 .073 .078 .003 026 013 131	.038 .065 <sup>*</sup> .116 <sup>**</sup> .075 .033 .027 095 <sup>**</sup> 008 392 <sup>***</sup> 147 <sup>***</sup>
Model 1 (control variables) Model 2 (+ surveillance modality) $R^2$	$F(9, 879) = 2.78^{**}$ $R^2 = .028$ $F_{change}(1, 878) = .31$ $R^2$ change < .001 .028	$F(9, 881) = 24.84^{***}$ $R^2 = .202$ $F_{change}(1, 880) = 16.8^{***}$ $R^2$ change = .015 .217

<sup>a</sup> T1 = between 0 and 2 days after surveillance.

<sup>∗</sup> p≤.05.

*p* ≤ .01.

<sup>••••</sup> *p* ≤ .001.

were also lower in women with a history of breast cancer ( $\beta = -.095$ ), in younger women ( $\beta = .116$ ) and in women with tertiary education compared to those with secondary education ( $\beta = .065$ ). Breast cancer risk perception had no effect on the two MGQ scale scores.

All exploratory interaction analyses performed on the MGQ scales only demonstrated an interaction between age and surveillance modalities: women younger than 50 tended to have higher scores for quality of care for MRI compared to mammography examination, while the reverse effect was observed in women older than 50 ( $\beta$  = .110); and women younger than 50 had lower scores for the psychological comfort for mammography compared to 'MRI' examination, but this difference was not observed for women 50 years or older ( $\beta$  = .100) (Fig. 2).

In the 'Mx' group, the MGQ perception of care score was significantly lower in one of the 14 centers (with a sufficient sample size to allow analysis) ( $\beta = -.130$ ) versus the reference center (Table 4).

In the 'MRI' group, MGQ perception of care scores were significantly lower in two of the 11 centers (with a sufficient sample size to allow analysis) ( $\beta$  = -.158 and  $\beta$  = -.196) versus the reference center (Table 5).

Previous MRI experience or genetic mutation status had no effect on the perception of care quality and psychological experience in this group (data not shown).

#### 3.3. MRI discomfort

Pearson's *r* correlation coefficients between MGQ perception of care quality or psychological experience scales and MRI discomfort scores were -.138 (*p* = .009) and -.537 (*p* < .001), respectively.

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#### MGQ Perception of care



Model (no interaction); $F(10,878) = 2.53$ , $p = .005$ , $R^2 = .028$	
Model 2 (+group * age interaction); F change(1,877) = 5.96, $p = .015$ , $R^2$ change=.007	
$P_{2} = 0.025$	Î

MGQ Examination psychological experience



<sup>1</sup>T1= between 0-2 days after surveillance; <sup>2</sup> Means computed on values predicted by regression analysis

**Fig. 2.** MammoGraphy Questionnaire perception of care and psychological experience scores according to age by surveillance modality at  $T1^{1,2}$  (overall sample; N = 969).

#### Table 4

Hierarchical multiple regression analysis showing predictors of MammoGraphy Questionnaire perception of care and psychological experience scores at  $T1^{a,b}$  (Mx sample; N = 604).

	MGQ-Perception of care	MGQ-Psychological experience
Variable	β	β
Elementary	.108 <sup>*</sup>	.067
Secondary	.045	.093*
Age	.064	.142**
Employed	.112	.093
Retired	.054	.055
Living with	.027	.039
Breast cancer history	031	108
Risk perception	043	069
STAI-State at TO	126**	358***
Center A	028	081
Center B	072	075
Center C	.125	025
Center D	.006	.044
Center E	.086	.040
Center F	022	042
Center G	004	$100^{*}$
Center H	.003	035
Center I	014	012
Center J	.053	.050
Center K	024	001
Center L	.008	012
Center M	058	.023
Center N	130 <sup>*</sup>	019

Table 4 (Continued)

	MGQ-Perception of care	MGQ-Psychological experience
Variable	β	β
Model 1 (control variables) Model 2 (+ center) $R^2$	$F(9, 509) = 3.04^{**}$ $R^{2} = .051$ (adjusted $R^{2} = .034$ ) $F_{change}(14, 495) = 2.09^{*}$ $R^{2} = change = .053$ $R^{2} = .104$ (adjusted $R^{2} = .062$ )	$F(9, 510) = 15.91^{***}$ $R^{2} = .219$ $(R^{2} \text{ adjusted} = .205)$ $F_{change}(14, 496) = 1.46$ $R^{2} change = .031$ $R^{2} = .250$ $(adjusted R^{2} = .215)$

<sup>a</sup> T1 = between 0 and 2 days after surveillance.

<sup>b</sup> Only 15 centers provided sufficient data to be included in the analysis.

*p* ≤ .05.

 $p \le .01.$ 

 $p \le .001.$ 

Significant MRI discomfort related to duration, immobility, prone position, noise or panic feelings was experienced by 35%, 38%, 21%, 65%, 6% of women, respectively (Table 6).

In multivariate analysis, the regression model significantly explained the variance of MRI-specific discomfort items total score (F(13.327) = 3.35, p < .001;  $R^2 = .118$ ), but only level of anxiety at T0 was predictive of discomfort perception with the MRI examination ( $\beta = .287$ ) (Table 7).

Previous MRI experience, genetic mutation status and center (not shown) had no effect on this outcome.

#### Table 5

Hierarchical multiple regression analysis showing predictors of MammoGraphy Questionnaire perception of care and psychological experience scale scores at T1<sup>a,b</sup> (MRI sample; N=365).

Variable $\beta$ $\beta$	
Elementary –.026 .033	
Secondary .070 .044	
Age –.079 .113	
Employed –.010 .040	
Retired .013 –.069	
Living with partner061 .042	
Breast cancer history069068	
Risk perception .000 .074	
STAI-State at T0099431***	
Center A –.021 .036	
Center B015057	
Center C032080	
Center D158***054	
Center E196***077	
Center F .029013	
Center G030036	
Center H .019 .058	
Center I –.019 –.032	
Center J –.095 –.036	
Center K –.050 –.096	
Model 1 $F(9, 331) = 1.15$ $F(9, 332) = 9.70^{***}$	
(control $R^2 = .030$ $R^2 = .208$	
variables) (adjusted $R^2 = .004$ ) (adjusted $R^2 = .187$ )	)
Model 2 (+ center) $F_{change}$ $F_{change}$	
$(11, 320) = 2.04^{*}$ $(11, 321) = .96$	
$R^2$ change = .064 $R^2$ change = .026	
$R^2$ $R^2 = .094$ $R^2 = .234$	
(adjusted $R^2 = .037$ ) (adjusted $R^2 = .186$ )	)

<sup>a</sup> T1 = between 0 and 2 days after surveillance.

<sup>b</sup> Only 12 centers provided sufficient data to be included in the analysis.

° *p* ≤ .05.

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 $p \le .01.$ 

 $p \le .001.$ 

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#### Table 6

Responses to MRI-specific items (percentages, N = 365).<sup>a</sup>

Sedative agent before MRI (yes)	10.3
Time spent in the tunnel	
Short	2.8
Normal	61.9
Long/very long	35.3
Immobile	
Easy	28.3
Unconcerned	34.2
Difficult/very difficult	37.5
Lying in the tunnel	
Easy	43.3
Unconcerned	36.1
Difficult/very difficult	20.6
Noise of the machine	
Low	2.8
Normal	32.6
High/very high	64.6
Panic feelings during MRI	
Never or rarely	72.1
Sometimes	21.8
Often/almost always	6.1

<sup>a</sup> Item missing data range from 0.8 to 1.4%.

#### Table 7

Hierarchical multiple regression analysis showing predictors of MRI-specific item total score at T1<sup>a</sup> (MRI sample; *N* = 365).

Variable	β
Elementary	.001
Secondary	.058
Age	041
Employed	.107
Retired	.051
Living with partner	.025
Breast cancer history	.062
Risk perception	.030
STAI-State at TO	.287***
Previous breast MRI	.009
Previous MRI	.000
Negative genetic test	061
Unknown genetic test	032
Model	$F(13, 327) = 3.35^{***}$ $R^2 = .118$

 $p \le 0.001.$ 

#### 4. Discussion and conclusion

#### 4.1. Discussion

This multicenter observational study evaluated the perception of quality of care and examination psychological experience related to MRI compared to mammography in women at risk of breast cancer.

In contrast with the initial hypothesis, these two surveillance modalities were not associated with different levels of perceived quality of care. However, women reported a relatively higher level of psychological discomfort in the mammography setting compared to MRI: mammography was associated with feelings of malaise, anxiety and more marked apprehension than MRI.

In this study, analysis of perception of care data emphasizes the fairly reassuring nature of MRI. This result is in line with that of a recent study [1] reporting the absence of any marked discomfort with this examination that was generally perceived as being beneficial for subsequent management.

A more favorable perception and experience with MRI was essentially observed in women younger than 50, while older women reported more positive opinions for mammography. Layperson representations of a recent medical technology in terms of efficacy or security may differ by age. Besides, since MRI is a recent technique, younger women may be more informed about this examination and it is possible that this information focus on the benefits of MRI, so as for mammography in a recent study [21].

Although perception of care and examination experience scores were high regardless of the surveillance modality, three centers presented significantly lower score levels compared to the reference center: two centers in relation to MRI and one center in relation to mammography. In practice, this finding may provide feedback indicating the need to improve quality of care in these centers. Three of the six items of the MGQ perception of quality of care scale concern the quality of communication (staff listened to questions, staff provided clear information), indicating aspects of care that may need to be improved; communication between clinicians and patients has been found to be a predominant component of experience with mammography in the general population [11,22].

As in other published studies [9,23], claustrophobia preventing MRI was a rare phenomenon in this study, reported in only 1.4% of cases. However, a relatively high percentage of women reported discomfort related to MRI, mostly concerning noise (65%), immobility (38%) and the duration of the examination (37%).

Of the various study subject-related factors, only initial anxiety systematically affected the perception of quality of care, psychological experience of the examination and discomfort related to MRI. This finding supports, in this context of breast cancer surveillance, the hypothesis that evaluation of perceptions of care is highly dependent on the support and reassurance provided by staff, as the woman is generally faced with uncertainty related to the medical setting and dependence on healthcare professionals [24]. State anxiety and not trait anxiety (more lasting personality trait) was evaluated in this study; an effect of negative affect which may have altered women's responses in terms of their perception of quality of care therefore cannot be excluded.

Few factors other than initial anxiety were found to be correlated with the women opinions. As a correlation between perception of care quality and adhesion to medical guidelines has been established [25,26], this result highlights the major role of distress in adhesion to breast cancer surveillance [27], emphasizing the need to take this factor into account to ensure optimal health behavior.

The level of breast cancer risk perception had no impact on perceived quality of care, psychological experience or discomfort related to MRI; these judgments therefore did not appear to be affected by the expectation of detecting an abnormality.

In contrast, the fact that a personal history of cancer was associated with poorer outcomes in terms of perception of psychological experience related to MRI or mammography may reflect apprehension related to the fear of relapse, a common concern in breast cancer survivors [28]. The psychological experience related to radiological examinations is also affected by age and level of education, indicating more anxious anticipation in younger women with tertiary education.

Unlike a recent study [29], a previous experience of MRI did not affect women's examination psychological experience, but most women in the present study were only starting this MRI intensive surveillance program.

A number of limitations must be emphasized for this study, including the specific characteristics of the study population, especially in terms of a higher level of education compared to the general population; the missing data due to failure to comply with the timing of the assessments as defined in the protocol; and the absence of randomization between the two surveillance modalities compared.

Missing data was observed in particular for the MRI group, in which the logistics of administration of the questionnaire was more complicated since it required passage of the questionnaires sometimes at 2 different times according to whether MRI was performed before or after standard imaging. These exclusion rates

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are high; nevertheless, the slight differences between all eligible women and *per protocol* women in terms of descriptive variables supports the validity of the results obtained. However, our sample is composed of women recruited in urban centers participating in cancer research and characterized by a higher education level than the general population; hence this study results may not be generalized to all French women at breast cancer risk.

The statistical method used was meant to control for baseline difference; however as this is not a randomized study, it is possible that other variables not considered in this study explain difference between these groups.

In order to ensure optimal return of questionnaires with a minimum of missing data, the number of questionnaires administered to women was kept to a minimum. However, a better understanding of the determinants of perception of care and examination experience in this setting could have been obtained by studying various other explanatory variables that have been shown to be relevant in the cancer genetic testing setting: care aspects, such as the medical follow-up procedure [30], the content (e.g. follow-up recommendations communicated) and the mode of patient/healthcare professional communication (e.g. proposal of an individual visit; communication based on the shared medical decision-making model) [31] and subjects' characteristics, such as their beliefs/knowledge [21] and their expectations in relation to care [32], their coping mode or their perception of social support [32,33] or the presence of a history of psychopathology [34].

#### 4.2. Conclusions

Perception of quality of care and examination experience in the setting of surveillance in women at risk of breast cancer did not differ between MRI and mammography. However, MRI was associated with a more favorable perception of examination psychological experience than mammography. Women's opinion identified participating centers in which care improvement should be considered. The major systematic effect of initial anxiety on women's reports about examinations emphasizes the important role played by healthcare professionals in support and communication in this surveillance setting of women at risk of breast cancer.

#### 4.3. Practice implications

In spite of the physical and psychological discomfort inherent to the MRI examination, more positive perception of care and experience is evidenced with this examination. These results underline the importance of adequate care in terms of information and support to assuage some of the adverse effects of an uncomfortable examination technique.

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