

High Risk Breast Cancer Screening is a Double Edged Sword: A Qualitative Study of Patient Perspectives on the Ontario High Risk Breast Cancer Screening Program

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Abstract

We explored MRI screening for women at high risk of breast cancer using in-depth interviews. Twenty-one women were included - 71% had experienced ≥ 1 abnormal screen. MRI provided a “psychological safety net” that outweighed the distress of abnormal screens. Women accepted this trade-off as a “two-edged sword” that provided a sense of control. Suggestions for improvement included access to counselling.

Background: MRI-based breast cancer screening for high-risk women has been associated with false positives. This study explored the benefits and drawbacks of MRI-based screening using in-depth patient interviews. **Methods:** This was a qualitative study of interviews with women participating in the High Risk Ontario Breast Screening Program. Women enrolled at two centers who had completed at least one round of screening were invited to participate. Recruitment was suspended when thematic saturation was reached. Semi-structured telephone interviews were conducted and transcribed verbatim. Emergent themes were identified and a coding framework established. **Results:** 21 women (median age 41 years) participated in telephone interviews. Women had been in the program a median of 4 years (IQR 1-5), and 71% had experienced at least one abnormal screen. Eight participants (38%) had undergone biopsies. Six women (29%) were BRCA mutation carriers. MRIs were described as intimidating, uncomfortable, and claustrophobic. Participants were concerned about long-term exposure to gadolinium contrast. Compared to MRI, mammography alone was viewed as painful, less sensitive, and a “useless...waste of time.” MRI provided a “psychological safety net” that outweighed the distress associated with abnormal screens. Many women accepted this trade-off as a “two-edged sword” that was “worth it” and provided a sense of control. Suggestions for improvement included more information regarding the risks of MRI, and access to counselling. **Conclusions:** Women participating in MRI-based screening strongly value reassurance from a highly sensitive screening test. This outweighed the distress of abnormal screens. There are areas for improvement around patient communication and psychosocial support.

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Introduction

Breast cancer screening protocols based on magnetic resonance imaging (MRI) have been increasingly accepted and incorporated as a valuable addition to mammography in several countries.^{1–6} While MRI-based screening was initially reserved for women with BRCA mutations, it has since expanded to include other high-risk non-mutation carrier populations.^{4,5,7(p192)} These populations include women who have an approximate 25% lifetime risk of breast cancer on the basis of strong family history, non-BRCA genetic mutations, or a personal history of chest wall radiation.^{3,4}

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The High-Risk Ontario Breast Screening Program (OBSP) offers annual mammography and MRI screening to women aged 30 to 69 at high risk of developing breast cancer.^{2,4} While MRI is highly sensitive at detecting breast cancer, it is known to lack specificity,^{8,9} with false positive rates as high as 10%.² Screening with MRI and mammography has higher positive predictive values compared to either modality alone, enables earlier cancer detection, and may increase quality-adjusted life years in BRCA mutation carriers.^{10–16} However, there is less evidence for MRI screening as it pertains to long-term outcomes, especially in non-mutation carriers.¹⁷ In a previous analysis of 169 non-mutation carriers at two sites in the High-Risk OBSP, we found 64% experienced at least one abnormal screen over a median 3 years of screening.¹⁸ False positives during breast cancer screening have been found to cause short-term psychological distress, especially in response to invasive procedures such as core-needle biopsy.^{19,20,21(p),22–24} However, much of this research was not conducted in the context of a high-risk screening program, and there is some evidence that women enrolled in these programs may not suffer the same distress after false positives and abnormal screens.^{25–32} Some authors have suggested women entering high-risk screening programs may be buffered from psychological harm because they are more prepared to encounter abnormal screens.²⁹

There is still an incomplete understanding of the psychological impact of MRI-based screening in high-risk women, and direct patient perspectives are needed. For quality improvement, it is also important to understand how women in these programs perceive the drawbacks and benefits of MRI-based screening. The objective of this study was to explore the experiences of women enrolled in the High-Risk OBSP with MRI-based screening using in-depth patient interviews and qualitative methodology.

Materials and Methods

Study design

This was a qualitative study^{33,34} investigating patient perspectives on participating in the High Risk OBSP. The Research Ethics Boards at St. Michael's Hospital (#15-168) and Sunnybrook Health Sciences Center (#397-2016) reviewed and approved this study.

Study participants and recruitment

Participants were enrolled in the High Risk OBSP (eligibility criteria presented in Supplementary Material 1) at two academic hospitals in Toronto, Ontario. Inclusion criteria for this study included: 1) English-speaking, 2) had undergone at least one round of MRI and mammographic screening in the program, and 3) no history of breast carcinoma prior to enrollment. Between June 2015 and March 2017, 465 individuals enrolled in the High-Risk OBSP at the two sites were sent invitations to complete demographic surveys and obtain consent for chart review.¹⁸ In each case, three monthly requests for questionnaire completion and consent were mailed to potential participants. From the larger cohort of patients who returned surveys and have participated in previous studies by our group,^{18,32} we recruited participants for individual telephone interviews using a maximum variation sampling approach.^{35,36} We aimed to ensure that we sampled the following groups: 1) both study sites, 2) mutation carriers and non-mutation carriers, 3) recent and more long-standing participants, and 4) those who had

undergone further investigation and biopsies due to an abnormal screen. Recruitment was suspended when thematic saturation was reached.³⁵

Data collection

Surveys collected demographic data, socioeconomic status, genetic counselling use, and family histories. Chart review was undertaken by a trained chart abstractor at the two study sites from participant enrollment to December 2017. We defined an abnormal screen as any investigation or procedure that was ordered as a result of an abnormal finding on either screening MRI or mammogram. Screening in the program was performed at accredited sites and met standards set by the Canadian Association of Radiologists.³⁷ They were reported according to the 5th edition of the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS).^{38,39}

Semi-structured telephone interviews were conducted according to a piloted interview guide developed through expert consultation and literature review (Supplementary Material 2). All interviews at one study site were conducted by a member of the research team (ER; N = 11), and the interviews at the second site were performed by a clinical research specialist with extensive experience in qualitative research (N = 10). The interview guide focused on understanding participants' experiences around program enrolment, undergoing screening tests, and specifically thoughts around abnormal screens and biopsies. Interviews were digitally recorded for verbatim transcription.

Data analysis

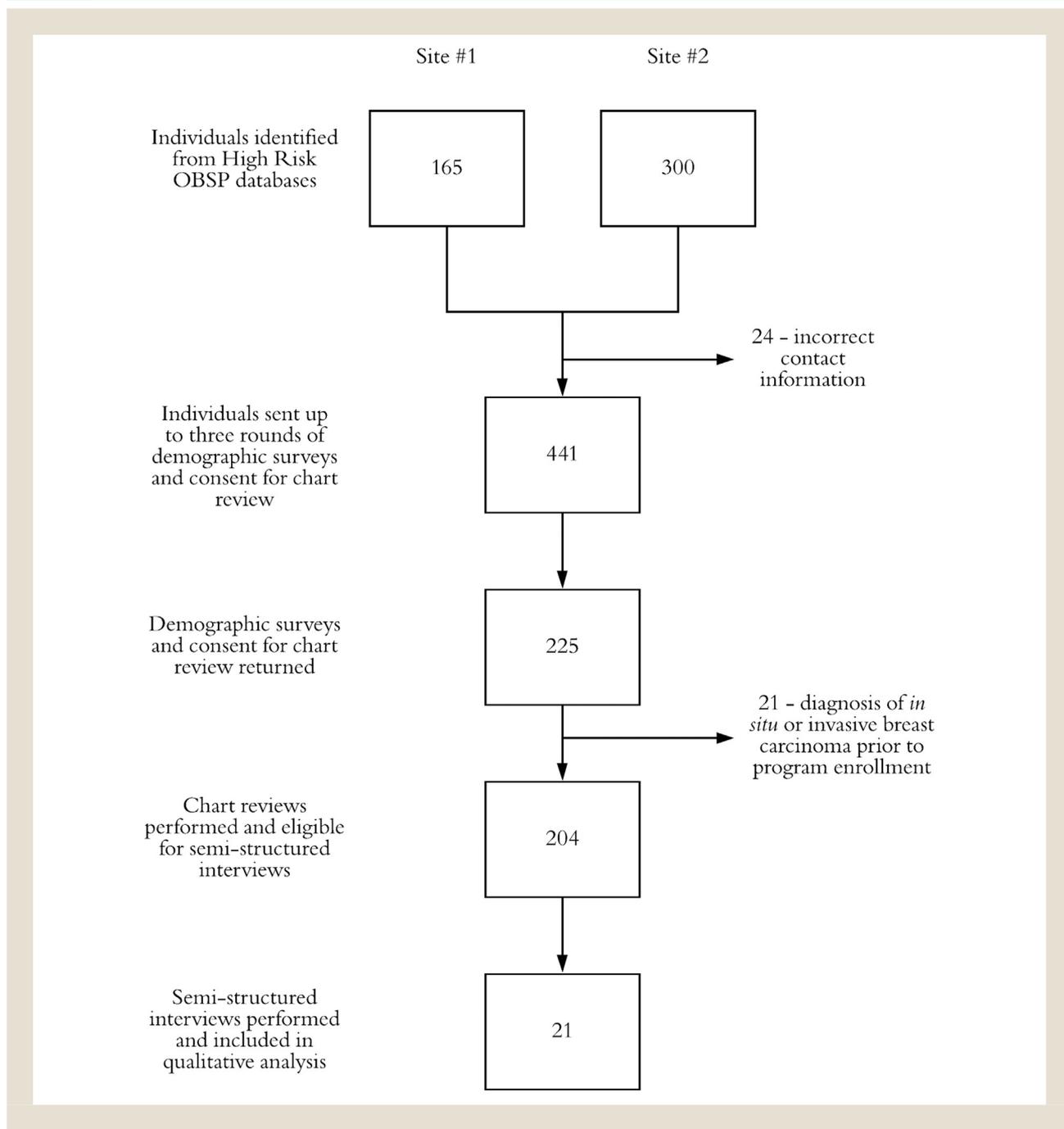
Patient characteristics were tabulated and stratified by mutation status. Continuous variables were presented as medians with interquartile ranges (IQRs). In keeping with qualitative methodology, data analysis occurred in conjunction with data collection in an iterative process.⁴⁰ Textual data from the interview transcripts were analyzed inductively, using the approach of qualitative description.^{33,34} Data were validated through peer debriefing, during which themes and analyses were discussed within the study team, and a coding framework was established based on consensus.^{33,34,41} A primary analyst (ER) coded all the transcripts, with a second analyst (MC) coding a subset independently using NVivo software.⁴² The statistical analysis was prepared using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and R (R Foundation for Statistical Computing, Vienna, Austria).

Results

Participant characteristics

From a larger study cohort of 204 women enrolled in the High Risk OBSP, 21 agreed to participate in the semi-structured interviews (Figure 1). Participant characteristics are presented in Table 1. Median age was 41 years (IQR 35–48). The majority of participants were white (71%), completed college or University education (57%), and reported household income of over \$75,000 CAN per year (67%). Most participants had a single-first degree relative with a history of breast cancer (71%), and the median IBIS lifetime risk of breast cancer was 28.1% (IQR 27.8–31.0%; range 25.0–39.4%). Women had been in the program a median

Figure 1 Creation of a cohort of women in the High Risk Screening Program at two sites in Toronto, Ontario. A subset of the final cohort was invited for semi-structured interviews and included in the qualitative analysis.



of 4 years (IQR 1-5), during which they underwent a median of 3 MRIs (IQR 2-5). Most women had experienced at least one abnormal screen (71%), and 2 participants (9.5%) had experienced three abnormal screens. Eight participants (38%) had undergone biopsies.

Among the 21 participants, six (29%) were BRCA mutation carriers and the remaining 15 were high-risk non-mutation carriers. Characteristics between these groups are summarized in Table 2. Median number of MRIs in BRCA carriers and non-mutation carriers

were 5 and 3, respectively. Rates of abnormal screens were 33% and 87% in mutation carriers and non-mutation carriers, respectively. Table 3

Program enrollment

Family Physicians generated most referrals to the High Risk OBSP based on a family history of breast cancer. Some participants were first connected with a geneticist who then referred eligible participants to the program. One participant was referred by

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Table 1 Characteristics of women who participated in the semi-structured interviews.

Characteristic	N = 21 ¹
Age	41 (35, 48)
Mutation status	
BRCA-1	2 (9.5%)
BRCA-2	4 (19%)
No mutation	15 (71%)
Race	
Asian	2 (9.5%)
Black	1 (4.8%)
Hispanic	1 (4.8%)
Other	2 (9.5%)
White	15 (71%)
Married	16 (76%)
Children	15 (71%)
Highest education attained	
College/University	12 (57%)
Graduate school	4 (19%)
High school	1 (4.8%)
Some college/University	4 (19%)
Employment status	14 (67%)
Household income (CAD)	
\$0-\$40,000	2 (9.5%)
\$40,000-\$75,000	4 (19%)
>\$75,000	14 (67%)
Missing	1 (4.8%)
Number of first degree relatives with breast cancer	
0	3 (14%)
1	15 (71%)
2	3 (14%)
IBIS lifetime risk score	28.1 (27.8, 31.0)
Missing	6
Years in the program	4.00 (1.00, 5.00)
MRIs	3.00 (2.00, 5.00)
Abnormal screens	
0	6 (29%)
1	10 (48%)
2	3 (14%)
3	2 (9.5%)
Biopsies	
0	13 (62%)
1	6 (29%)
2	2 (9.5%)

¹Median (IQR); n (%)

IBIS - International Breast Cancer Intervention Study

her Radiation Oncologist due to history of chest wall radiation. Two others were referred by an Obstetrician and a Pediatrician for a breast lump found during fertility treatment and mastitis, respectively. For non-mutation carriers, participation was perceived to be “*the next step*” (Participant 10), capable of catching “*cancer sooner...so that [it] can be dealt with earlier*” (Participant 9), and “*an extra level of care and monitoring, just given the family history.*” (Participant 2)

For mutation carriers, involvement in the program extended naturally from a positive genetic result.

High Risk Screening – Participant Feedback

Participants noted many drawbacks to high risk screening, both physical and psychological. Despite this, dual modality screening with a mammogram and MRI was held as the “gold standard” with anything less being inferior/placing women at increased risk of a

Table 2 Patient characteristics for mutation carriers and high risk non-mutation carriers.

Characteristic	Non-mutation carrier, N = 15 ¹	Mutation carrier, N = 6 ¹
Age	40 (34, 48)	51 (41, 59)
Race		
Asian	2 (13%)	0 (0%)
Black	1 (6.7%)	0 (0%)
Hispanic	1 (6.7%)	0 (0%)
Other	1 (6.7%)	1 (17%)
White	10 (67%)	5 (83%)
Married	11 (73%)	5 (83%)
Children	9 (60%)	6 (100%)
Highest education attained		
College/University	9 (60%)	3 (50%)
Graduate school	3 (20%)	1 (17%)
High school	0 (0%)	1 (17%)
Some college/University	3 (20%)	1 (17%)
Employment status	11 (73%)	3 (50%)
Household income (CAD)		
\$0-\$40,000	1 (6.7%)	1 (17%)
\$40,000-\$75,000	3 (20%)	1 (17%)
> \$75,000	10 (67%)	4 (67%)
Missing	1 (6.7%)	0 (0%)
Number of first degree relatives with breast cancer		
0	1 (6.7%)	2 (33%)
1	11 (73%)	4 (67%)
2	3 (20%)	0 (0%)
Years in the program	3.00 (1.00, 4.00)	5.00 (5.00, 5.00)
MRIs	2.00 (1.50, 4.00)	5.00 (4.25, 5.00)
Abnormal screens		
0	2 (13%)	4 (67%)
1+	13 (87%)	2 (33%)
Biopsies		
0	8 (53%)	5 (83%)
1+	7 (47%)	1 (17%)

¹Median (IQR); n (%)

IBIS - International Breast Cancer Intervention Study

missed diagnosis. Participant 10 elaborated that MRI is her “*frame of reference and if that’s the most I could do, anything less than that would ... make me feel uncomfortable*”.

Physical drawbacks

Phrases used by participants to describe their MRI experiences included: intimidating, scarier than expected, uncomfortable, claustrophobic, and awkward. Participants partly attributed these feelings to poor preparation for the MRI process itself. Women were not prepared for the application of Vitamin E or cod liver oil to the nipples, prone positioning, requirements to remain still, the narrow MRI tunnel and machine noises, and the need for intravenous (IV) contrast. Maintaining a prone position was prohibitive to sleeping, coughing or alleviating pain. Some participants expressed concern about repeated exposure to MRI noise and its long-term impact on hearing. Another drawback of MRI was the length of time in which participants were unclothed, which some felt was “*embar-*

assing” (Participant 18). However, some longstanding participants of the program noted that imaging duration had reduced over time.

“It was unexpected. Um, I didn’t know I’d be face down to tell you the truth. They’d tape these capsules to your breasts. Sorry, but what on earth is that?...I found my neck started to hurt during the test. And that was, it was awful. And, I didn’t want to press the button to have them wheel me out and start all over again. ...I started getting, uh, a little rash and a bit of tightness in my chest...that did concern me too because I didn’t know the Gadolinium until I went online and I wanted to find out about allergic reactions. And, I started reading all this stuff about how it can be toxic...So, then I felt like a guinea pig” (Participant 16)

Mammography was described as feeling “*like a pancake*”, “*pulling on [one’s] breast*”, and “*being pinched*” as recounted by Participants 20, 6, and 9, respectively. In reference to MRI, some partic-

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Table 3 Selected quotes from relevant emergent themes. Quotes are identified by their participant number.

Theme	Participant	Quote
Becoming involved in the program	Participant 1	"My mom did just recently...had genetic testing done. I didn't qualify, but she qualified, so, we had genetic testing done on her, and they said she was fine. . . .based on what's going on with our family history, It's a good idea to get you checked out. You know? Just in case, because it doesn't hurt to do it, so better to be safe than sorry, right?"
	Participant 10	"Based on the information that I knew about my family that I wasn't a candidate for that, so that was a bit of a relief but then staying in the High Risk program was kind of the next step to, for me to just stay on top of it."
	Participant 11	"I would go at like 27 or whatever age I was and get and basically get attitude from the technicians there, wondering what I am doing there being so young. It's like when I go to the breast cancer clinic it's, there's no like second guessing like I am there to get, to get screened because of the family history."
Experience of MRI, mammography, and ultrasound	Participant 3	"Well, I'm going to avoid having radiation by just having an MRI instead of a mammogram.' But they're like, 'No, you actually do both.' So, I was like, 'Oh, okay... I'm, like, worried because I'm starting much earlier than the average person, if that's something that might actually lead to cancer."
	Participant 15	"It wasn't scary. It wasn't overwhelming, it was just I guess the unknown. That you just didn't know what it was going to be like..."
	Participant 17	"[the MRI] was a little nervy. Like, 'Wow, I signed up for this.'... You know, like it goes on for maybe 40 minutes. And, the sound is loudish and you're in this machine. And, you know, face down with your, you know, you can't really see anything. It's, uh, so it was 'wow.' Like, I remember just thinking 'oh, when is this going to be over.'... it's one of those things that once you do it once, you know, the second time it's not so bad."
	Participant 20	"They locked it into this thing that makes you feel like a pancake and it's really embarrassing especially after children. But, that's okay. You got, you know, you got to just sort of let it all go. And so, I felt that was a little bit uncomfortable."
Double-Edged Sword – the experience of abnormal screens	Participant 2	"If false positives are part of being part of the program, like, to me, that's a very... minor thing to deal with, in comparison to not being monitored or not knowing what's going on in my body. So yeah, I view them as a minor inconvenience. I don't really think about them... I view it as part of a process, so it doesn't really bother me that much... it's been explained to me that, you know, younger breasts are denser, and so there are more false positives. So no, it never caused me a lot of stress, in the sense that like, I thought I was sick. I never really did. I looked at it more as an information gathering exercise"
	Participant 10	"it just makes me feel like I am doing the most in this sense that I can do medically to, to make sure that I am on top of this... it feels like even though it's probably very overly thorough as a tool though it gives me that kind of peace of mind"
	Participant 11	"But the cancer thing, you can't avoid that one. So, then I would think, you know, whatever of the worst evil that I need to take, then go that route. So out of all the screenings that I have to do, I would say this is probably the one that I would have to still continue on."
	Participant 17	"that's the thing with the MRIs. I guess they detect a lot of things. Um, so, you know, and when somethings been detected, you'll have, you kind of have no choice but to follow it through... That's all part of the program I guess. You know, like that comes with it."
	Participant 18	"Like, I said there is the anxiety of the call backs for sure. But, it outweighs - the knowing; it outweighs it. It's knowing one way or the other. It's a peace of mind for me. It holds an awful lot of value."
	Participant 21	"It was really stressful... I mean it's better to know and get it done than not to let something grow and not know what it is... you can't have your cake and eat it too... I have a daughter now and I don't know if she has the BRCA gene but, she would definitely be part of a high-risk screening program when she gets older. So I think, you know, everything that I've had to go through was necessary."
Benefits	Participant 2	"Just the knowledge that I'm taking the steps that I need to take to care of myself. So, if something happens down the road, you know what? Well, I did everything that I could... I have family that lives in the United States, and I understand that MRI tests are very expensive. So, I just feel really fortunate that I'm able to have these tests for free. I don't see any downsides... I'm receiving a very high level of care...I feel like my appointments were all kept. Instructions were clear. Timing usually was good. Got me in as quickly as possible, sometimes Saturday morning, which I thought it was quite flexible."
	Participant 7	"Reassuring... heaven forbid if I was to feel something, I would have a place to phone. That, I think, is more comforting than...the psychological safety net... So, this feels more like I've got one house, and the house has got it all. So heaven forbid if I, I feel like it's all centred."
	Participant 16	"Someone is with you. It's like you have human contact. You're not alone...They're very polite. They're very reassuring. Very kind and thoughtful... And, very gentle"

(continued on next page)

Table 3 (continued)

Theme	Participant	Quote
	Participant 19	<i>"it's very efficient when I go in, I don't have to wait a long time. Um, the people who do the MRI's are good at explaining what's going on, making sure I'm comfortable, making sure they're telling me what's going on... the doctors that, um, do the high-risk program are quite friendly and wonderful; and answer questions you know, they're very relaxed and matter of fact. But, very personable... And, I feel like I get good information and that I'm treated well and personally."</i>
	Participant 20	<i>"regular assessments are really, really beneficial. Because I, they let you have peace of mind for a period of time. And then, you get rechecked. And, you get peace of mind again... you also feel, um, healthier, happier, more informed and, um, and more relieved that you don't have that concern. That you don't have to worry because you know you will be, um, that there's follow up... I think the benefits so out weight, and are quite frankly priceless to the participant."</i>
Drawbacks	Participant 10	<i>"sometimes you have to fill out that form and it asks you a couple of questions about the various kind of qualifying characteristics... sometimes I don't know what that stuff necessarily means... I am little worried if I do have pain, what do I do, should I call the doctor, is this normal... those qualifying questions are not necessarily explained, there's not that much context, I don't really know if it's a yes or no sometimes"</i>
	Participant 15	<i>"The only thing is, they give you crazy hours now to come... So, that was a bit of an annoyance because sometimes my appointments were late at night."</i>
	Participant 18	<i>"It was a real hassle to try and figure out when because I'm not regular. And then, line it up with hospital when they actually have appointments available."</i>
Suggestions for improvement	Participant 1	<i>"So like, ideally, it would have been nice, to just do the mammogram, and then just wait for the results and then just go home and that'll be it, instead of having to come back."</i>
	Participant 15	<i>"[Receiving callback test results] absolutely has to be fast... to be waiting any length of time would be awful."</i>
	Participant 16	<i>"... it's not really honest and they could have told you that this dye is possibly could cause side effects long term or something like that. I just maybe more information like about dye given to people. My concern is that people go in there and they don't know they have something wrong with their kidney. You know, and then, um, what happens then? You know?"</i>
	Participant 18	<i>"So, you just kind of waited to see if something showed up in the mail. And that to me, is harder than having someone just give you a quick phone call saying 'all clear.' Because you don't know how long you have to wait for. Or, how slow the mail is going to be."</i>
	Participant 20	<i>"I don't know of any sort of support system for people living with cancer or people dealing with cancer. And, when I saw the toll it took on my friend. Uh, after the fact and, and it took a toll even on her marriage. And took a toll on like relationships all over the place because she fell apart after all the stress and had no place to turn... Who helps them deal when their partner or friend has been diagnosed? Who helps them, you know, get past their fear and, um, know that there's comfort?"</i>
How would you feel if you were no longer involved in the program	Participant 5	<i>"Lost, I would probably my first step would probably talk to Dr _____ to find out what I should do and in some ways maybe I would take it as a great thing that he or whoever is doing it doesn't see me as high risk enough to be in it"</i>
	Participant 5	<i>"I don't remember not being in the program... but yeah, at the same time I don't like identify as a high risk cancer person so I would... adapt. There would be a lost feeling like that initial it might last for 7 days but then I would get over it"</i>
	Participant 6	<i>"I think that there's already a lot of strain on the medical system, and I personally wouldn't want to be taking away, like, doctors' time or treatments or anything from someone who is at much higher risk... maybe go on a case by case basis, and you know, discontinue the extra screening for people who it really seems like they're not at that high risk."</i>
	Participant 9	<i>"I think I would still ask for screening from my family doctor even if it's not from the program."</i>
	Participant 16	<i>"I'm of two minds about that. I'm kind of relieved to not go and do that machine and you know, the psychological impact. And then, the physical as well with the dye. So a bit relieved."</i>
	Participant 20	<i>"I think when you ask that question, like I just get a lump in my throat because I just think it is a part of my, of my mental well-being to be tested and to know, and to get an answer; a definitive you know, 'you're fine.' That makes a big difference in my life. And then, how comfortable I am in my skin."</i>

ipants felt that mammography was more painful (Participants 4, and 10), less effective (Participant 4), less thorough (Participant 9), and a "useless...waste of time" (Participant 21). Some participants

were concerned about the long-term risk of malignancy associated with routine radiation exposure from frequent mammography, and viewed MRI alone as a safer option.

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Psychological drawbacks

Abnormal screens and the resulting investigations/biopsies were found to be highly distressing. Over seventy percent of participants experienced at least one abnormal screen. Abnormal screens and the resulting workup were characterized as cumbersome, stressful, and panic-inducing. Although informed of the higher rate of false positives associated with MRI, Participant 17 felt that she *“had no choice but to follow through on [the subsequent investigations]”* and found the process *“wearing.”* Some participants questioned whether to continue with the program.

Other drawbacks

The High Risk OBSP was reported to have a number of other drawbacks. While many participants valued flexibility in scheduling, some found attending late night MRI appointments inconvenient. Many participants also reported lengthy commutes, lack of available parking, and the opportunity cost of missing work themselves or having a partner miss work to drive them.

A common difficulty faced by participants was timing screening tests with their menstrual cycle when the breast is less dense and less likely to result in false positive results. Women with irregular cycles felt this was logistically impractical.

Perceived benefits

Overall, participants felt that MRI-based screening provided peace of mind that outweighed the stress of false positives (Participants 5, 10, 12, and 18). They felt that false negative results or forgoing screening entirely would cause delayed detection and treatment of breast cancer, with worse outcomes. Relative to these consequences, some saw abnormal screens as *“not a big deal at all”*, a *“minor convenience”* and *“worth it”* (Participants 18, 2, and 3). Participant 6 was even *“grateful”* for the abnormal screen result, because to her, this showed that the program *“wanted to check, double check, and sometimes triple check”*.

Participant 21 summarized the balance between frequent abnormal screens and the anxiety of further investigation as *“you can't have your cake and eat it too. You have to do what you gotta do”*. This sentiment was similarly described as a *“two-edged sword”* (Participant 7), *“part of the process”* (Participant 2), and *“side effects [that] go with the territory”* (Participant 7).

“I guess maybe briefly questioned whether it was worth having, you know, the extra worry. Except in the end like, rationally it makes sense. I would rather there a few false-positives and there not be any false-negatives...that's just the price you pay... Yeah, I think it's a necessary evil of a screening program.” (Participant 19)

Participants discussed their perspectives on this balance, and their reasons for continuing screening. Participant 17 *“keeps in mind that [the program] is...for a good cause”*. Some viewed the process as evidence that they were doing everything they could to manage their breast cancer risk, and felt empowered to take an active approach to screen. Participant 20 believed participating in the program was *“doing yourself justice and a favour”*.

“It's worth it, to find out and hopefully, prevent worse things happening...I have small children, I want to be around for them if I can. And, it would be, yeah, I totally feel it would be negligent to not

take advantage of the screening whether it causes me extra stress or not” (Participant 3)

Many women expressed sentiments similar to Participant 3, who considered MRI the *“best test...for early detection [of cancer].”* Participants perceived mammograms alone as having inferior detection that could possibly result in late diagnosis.

“The fact that MRI catches things on a really, really tiny level. Or...what's it called, mammograms, you can only really catch the cancer if it's become something like a tumor or something worse. An MRI caught my Mom's precancerous cells, so I feel like that's a great place to have the diagnosis.” (Participant 12)

The yearly negative screens from the High Risk OBSP provided participants with *“peace of mind”*, *“relief”*, and *“reassurance.”* Participant 7 called it a *“psychological safety net”*. Screening in general was perceived to be *“lifesaving”* and *“frankly priceless”* by Participants 13 and 20, respectively.

“Benefits for myself is the reassurance for every time I go and I get the 'all clear' means ...we're good for another year. I'm all set. I don't have to worry about it anymore.” (Participant 18)

If participants were no longer able to continue in the High Risk OBSP, some stated they would feel concerned and afraid. Having had experience with MRI screening, a negative result from mammography screening no longer felt sufficient to reassure participants. Some stated they would attempt to arrange MRI screening outside of the High Risk OBSP or offer to pay for continued eligibility.

“I don't know what I would do. That would be terrible. We would look for another program. I would feel like the, um, the medical system is failing me.” (Participant 21)

Others framed potential loss of eligibility in a more positive light. Participant 16 would feel *“relieved”* of the MRI imaging experience, the psychological impact of false positive results, and the toxicity of contrast dye. Some said they would try and interpret this as reassurance that their risk of breast cancer is not as high as previously thought.

“But if it was, I guess, the medical establishment saying 'Listen, your risk is low enough that you really are covered by your one year mammogram, without these others. You really are covered.' you would feel, you would deal with it” (Participant 7)

Perceptions of MRI efficacy

Participants perceived MRI to be *“more sensitive”* (Participant 9), *“more effective”* (Participant 4), the *“best”* test (Participants 12 and 17) the *“gold standard”* (Participant 2), and capable of detecting cancer early (Participants 2, 15, 12, 17, 18 and 21). Compared to MRI, mammography was felt to have inferior sensitivity at detecting early cancer (Participants 1, 4, 9, 17 and 21) and introduce uncertainty that then required elucidation using MRI (Participant 2). Participants believed that MRI's superior sensitivity meant it detected cancer earlier and therefore ensured a more favourable prognosis.

“Hopefully, I’ll never get breast cancer, but if I do, hopefully, it’ll be at such an early stage, because I will have... MRI. Like, it seems like that’s the gold standard...” They seem very sure, whereas the mammogram is always kind of, ‘Oh, there’s a shadow [or] density - ’ and these kind of nebulous terms. ‘You know, we’re not sure.’ So yeah, I do feel like the MRI seems to be a better screening tool... MRI took away the uncertainty that the other ones introduced.” (Participant 2)

Suggestions for program quality improvement

In general, participants felt a lack of information and support when proceeding with MRI screening. Several women would prefer the opportunity to ask more questions about the MRI process, including the risk of allergy from contrast dye, the impact on kidney function, and safety around noise exposure. Some did not feel they had been fully informed of the risks associated with MRI.

The availability of psychosocial support was further identified as an area of deficiency. Participants suggested having counsellor appointments available to teach coping strategies and for support when they are found to have an abnormal screen. It was also suggested that these services be extended to family members and support persons.

“Expanding the program...if you need it to be a counsellor or somebody to kind of debrief...I think make such a huge impact on people’s psychological wellbeing...So, anything that would kind of you know, skills of breathing, meditation, yoga...to just kind of clear your head...here’s a, a little piece of paper that or a little hand out that these are the things that maybe you already do in your life or maybe that we know are, are proven stress reducers if that’s how you are feeling” (Participant 4)

Discussion

This qualitative study of individuals undergoing high risk breast cancer screening as part of the OBSP demonstrated that the majority of patients perceived abnormal screens and false positives to be an acceptable drawback of the MRI-based breast cancer screening program; wherein the benefits exceeded the drawbacks. Benefits of the program included the annual reassurance patients could expect, access to a sensitive and scarce imaging modality, and the quality of service provided by program staff. Drawbacks included the distress caused by imaging experience and abnormal screens, the inconvenience and opportunity cost of attending appointments, and the lack of education and support when faced with abnormal screens. Suggested areas for improvement include information about the use of contrast dye, guidance around MRI safety, results turnaround time, and access to counselling while waiting for results or after receipt of abnormal screens. If participants were to lose program eligibility, some participants would pursue MRI screening outside of the program, as mammography-based screening no longer feels sufficient to them.

The literature surrounding the potential benefits and drawbacks of MRI-based screening is complex. A study of BRCA 1/2 mutation carriers diagnosed with breast cancer showed that MRI screening detected smaller tumours and reduced treatment morbidity, such as the need for sentinel lymph node biopsy and chemotherapy, but did

not significantly improve survival.¹⁶ The ability of MRI screening to detect cancer earlier has been proven in both mutation and high-risk nonmutation carriers, however longer follow-up is necessary to assess for long-term benefit.¹⁰⁻¹²

Our earlier work with High Risk OBSP participants also showed that while MRI-based screening did cause acute distress, it did not impair coping, daily functioning or result in more psychological distress after abnormal screens or biopsies.³² Others have shown that MRI-based breast cancer screening was perceived by patients to deliver superior care than mammography alone,^{43,44} a sentiment that many participants in this study alluded to when asked how they would feel if they were no longer part of the High-Risk OBSP. False positive results, which are more prevalent in MRI-based screening, remain a source of anxiety, distress, and cancer worry.^{31,45} This may lead to avoidance of future screening,³¹ a phenomenon is also seen with false positive results from mammography screening.²⁰ A proposed solution to mitigate the inevitable distress associated with cancer screening is to incorporate a counselling service into the OBSP. Counsellors would teach coping strategies, create a safe space for debriefing, and provide emotional support to help participants navigate the waiting period or an abnormal screen. Our study is an in-depth exploration of high-risk OBSP participants’ acceptability of false positive results and overall experience in the program. An overwhelming majority of participants felt that the distress associated with abnormal screens was an acceptable drawback relative to the benefits of early cancer detection and reassurance of cancer-free status. Participants accepted that the program is a double-edged sword.

Strengths of this study include the in-depth insights gleaned from using a qualitative interview-based approach. This is an important extension of previous survey-based reports in the literature. We included both BRCA carriers, and non-mutation carriers. The latter population is understudied in previous reports, despite currently representing the majority of participants in the High-Risk OBSP.³⁷ Saturation of interview themes was attained, which affirms that the study was adequately powered.

There are several limitations to this study. Our results may not be generalizable to a broader population of women in MRI-based screening programs – participants in the High-Risk OBSP who had particularly negative or positive experiences may have been more likely to participate. However, experiences were internally consistent and were similar to the reported literature.^{25,26,32,45-47} While all non-mutation carriers underwent genetic counselling, not all had genetic testing performed due to low-pretest probability or patient preference. Therefore we cannot be certain that some patients in the nonmutation carrier group did not in fact have underlying BRCA mutations. We did not observe strong differences between these two groups in the interviews and do not anticipate this would change the results of the study. While telephone interviews were chosen for reasons of feasibility and patient convenience, there are some concerns regarding reduced ability to perceive nonverbal information and to develop rapport compared to in-person interviews.^{46,47} Finally, despite pre-interview assurance that all data will be anonymized, participants may still withhold or hesitate to express the extent of their dissatisfaction with the program. We used a standardized telephone interview guide, and the interview-

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ers were external to the High-Risk OBSP in order to minimize bias.

This qualitative study of MRI-based screening among high-risk predominantly non-mutation carriers showed that while both mammography and MRI have their drawbacks, participants were ultimately in favour of MRI. The detection of malignancy that MRI was perceived to provide and resulting assurance was felt to be worth the transient distress of abnormal screens and inconvenience of the program. While participants accepted the double-edged nature of the OBSP, the program could be further optimized by informing participants about MRI risks, including long-term exposure to contrast and machine noise, as well as improving access to psychosocial supports through recruitment of counsellors to its multidisciplinary team.

Clinical Practice Points

• What is already known about this subject?

Intensive screening for women at high risk for breast cancer included yearly contrast-enhanced breast MRI and mammography. Literature has shown this strategy results in tumours that are smaller at diagnosis and women are less likely to be node-negative. However, MRI-based screening results in false-positives and patient perspectives on the benefits and drawbacks are urgently needed.

• What are the new findings?

Twenty-one women participated in in-depth telephone interviews, which were transcribed and analyzed using qualitative methodology. These women had a median age of 41 years, had undergone MRI-based screening for a median of 4 years, and most (71%) had experienced at least one abnormal screening result. MRIs were described as intimidating, uncomfortable, and claustrophobic. Participants were concerned about long-term exposure gadolinium contrast. Compared to MRI, mammography alone was viewed as painful, less sensitive, and a “useless...waste of time.” MRI provided a “psychological safety net” that outweighed the distress associated with abnormal screens. Many women accepted this trade-off as a “two-edged sword” that was “worth it” and provided a sense of control. Suggestions for improvement included more information regarding the risks of MRI, and access to counselling.

• How might clinical practice be impacted in the foreseeable future?

MRI-based screening programs should improve access to counselling service for patients, and we identified gaps in terms of informed consent around MRI. In particular, women had concerns around long-term exposure to MRI noise and gadolinium contrast.

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Ethics approval

The Research Ethics Boards at St. Michael's Hospital (#15-168) and Sunnybrook Health Sciences Center (#397-2016) reviewed and approved this study.

Competing interests

None to declare.

Availability of data and material

: Due to the nature of this research, participants of this study did not explicitly agree for their data to be shared publicly, so supporting data are not available.

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Supplementary materials

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