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FULL PAPER

Contrast-enhanced digital breast tomosythesis and breast MRI to monitor response to neoadjuvant chemotherapy: patient tolerance and preference

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Objective: Contrast-enhanced digital breast tomosynthesis (CE-DBT) is a novel imaging technique, combining contrast-enhanced spectral mammography and tomosynthesis. This may offer an alternative imaging technique to breast MRI for monitoring of response to neoadjuvant chemotherapy. This paper addresses patient experience and preference regarding the two techniques.
Methods: Conducted as part of a prospective pilot study; patients were asked to complete questionnaires pertaining to their experience of CE-DBT and MRI following pre-treatment and end-of-treatment imaging. Questionnaires consisted of eight questions answered on a categorical scale, two using a visual analogue scale (VAS), and a question to indicate preference of imaging technique. Statistical analysis was performed with Wilcoxon signed rank test and McNemar test for related samples using SPSS v. 25.
Results: 18 patients were enrolled in the pilot study. Matched CE-DBT and MRI questionnaires were completed after 22 patient episodes. Patient preference was indicated after 31 patient episodes. Overall, on 77% of occasions patients preferred CE-DBT with no difference between pre-treatment and end-of-treatment imaging. Overall experience (p = 0.008), non-breast pain (p = 0.046), anxiety measured using VAS (p = 0.003), and feeling of being put at ease by staff (p = 0.023) was better for CE-DBT. However, more breast pain was experienced during CE-DBT when measured on both VAS (p = 0.011) and categorical scale (p = 0.021).
Conclusion: Our paper suggests that patients prefer CE-DBT to MRI, adding further evidence in favour of contrast-enhanced mammographic techniques.
Advances in knowledge: Contrast mammographic techniques offer an alternative, more accessible imaging technique to breast MRI. Whilst other studies have addressed patient experience of contrast-enhanced spectral mammography, this is the first study to directly explore patient preference for CE-DBT over MRI in the setting of neoadjuvant chemotherapy, finding that overall, patients preferred CE-DBT despite the relatively long breast compression.

BACKGROUND

Breast cancer remains the most common malignancy in females in the European Union, accounting for 13.3% of all cancer diagnoses, and 7.3% of all cancer deaths.[1] With advances in oncological treatment, increasing numbers of females are receiving pre-surgical neoadjuvant chemotherapy (NACT). Initially used to downstage inoperable, locally advanced tumours, NACT is increasingly used to reduce extent for surgery, *e.g.* downgrading from mastectomy to breast conservation surgery.[2]

Imaging monitoring of treatment response is necessary throughout the course of NACT to gauge *in vivo* chemosensitivity and guide surgical planning. Contrast-enhanced MRI is considered the current gold-standard technique both for predicting complete pathological response and residual tumour size.[3–5] Unfortunately, due to pressures on imaging services, it can be difficult to obtain in a timely fashion. It is an expensive and time-consuming technique and for some patients, it is either contraindicated or poorly tolerated.[6–8]

Contrast-enhanced digital breast tomosynthesis (CE-DBT) is a novel technique which allows acquisition of contrast-enhanced spectral mammography (CESM) and digital breast tomosynthesis (DBT) images during the same breast

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compression episode. CESM is a functional imaging technique which demonstrates the vascularity of breast lesions through dual energy subtraction. DBT is a pseudo-3D mammographic technique, which eliminates overlapping breast tissue and improves visibility of malignant structural features. DBT has demonstrated increased cancer detection rates, especially in dense breasts, when compared with full field digital mammography.[9] Published studies have demonstrated that CESM is at least as accurate as MRI for the detection of breast cancer[10,11] and early evidence suggests CESM may be comparable to MRI for monitoring patients treated with NACT.[12,13]

Emerging evidence of patient experience of CESM suggests an overall preference for CESM in place of MRI. Hobbs et al consider patient tolerance of CESM and MRI in the local pre-operative staging of breast cancer. They include feedback from 49 patients, with a significantly higher overall preference for CESM.[14] Phillips et al review patient preference and experience of CESM, MRI and digital mammography in the context of high risk screening, with 79% of patients indicating they would prefer CESM to MRI.[15] However, we can find no published studies on patient preference concerning contrast-enhanced mammographic techniques in the context of NACT. Furthermore, there appears to be no published evidence on patient experience with CE-DBT, which requires a longer period of compression in each position to allow the additional DBT acquisition. If CE-DBT is to replace MRI for some patients for monitoring response to NACT, it is essential to assess patient acceptability, specifically in this context.

METHODS

This research was conducted as part of the ethically approved prospective imaging study: CONtrast enhanced Digital breast tomosynthesis for monitoring Of Response to neoadjuvant chemotherapy (CONDOR). The aim of this pilot study was to compare the use of breast MRI with CE-DBT for monitoring tumour response to NACT. The results of the comparative accuracy of the two techniques will be published separately. Females aged over 18 years with symptomatic and screen-detected cancers undergoing NACT were eligible for inclusion. Exclusion criteria were contraindication to iodinated contrast, history of previous breast cancer surgery or implants, pregnancy and lactation.

Patients were imaged with both modalities prior to starting chemotherapy, at mid-treatment and at end-of-treatment, prior to surgery. Investigation of patient acceptability and preference was included in the aims of the study, and is the subject of this report. CE-DBT images were acquired using the commercially available Selenia Dimensions system (Hologic, Massachussetts). Imaging was commenced 3 min after intravenous (i.v.) administration of 1.5 mg/kg iodinated contrast agent (Omnipaque 300, GE Healthcare, Buckinghamshire), at rate of 2–3 ml/s. After 3 min, imaging in the CE-DBT unit was commenced. At pre-treatment, bilateral two-view (CC and MLO) CE-DBT was performed with delayed MLO of the index breast(s) acquired 9 min after injection. At mid- and end-of-treatment, only the breast(s) with malignancy were imaged. Breast MRI was performed on a Siemens 3T Prisma Fit scanner (Siemans Healthineers, Erlangen, Germany), using a dynamic contrast-enhanced protocol. The sequences included T1 2D axial high resolution, T2 axial turbo spin echo, diffusion sequences, T1 3D dynamic sequences (two pre-contrast and seven post-contrast) and a delayed T1 axial high resolution sequence, with a total scan time of approximately 40 min.

Participants were asked to complete questionnaires regarding their experience of CE-DBT and MRI, both following pre- and post-treatment imaging. The questions were identical on both questionnaires (Figure 1). There were eight questions with a 4-point categorical response scale. Two questions regarding anxiety and breast pain were assessed using a visual analogue scale (VAS); participants were asked to place a mark on a linear scale from 0 to 100. Finally, at both imaging time points, patients were asked to indicate a preference. To capture preference based on patient experience, rather than expectation of the test accuracy, the preference question was prefaced with 'assuming CE-DBT and MRI provided equivalent diagnostic information'. Several free-text boxes were provided to allow the participants to expand on responses.

Statistical analysis

The Wilcoxon signed-rank test for related samples was used to assess for significant differences between the modalities on those questions using categorical response scales. Due to small sample size, it was not possible to analyse categorical data from the pre- and post-treatment questionnaires separately. Non-parametric VAS data were also analysed using a Wilcoxon signed-rank test as recommended by Heller et al.[16] In addition to the combined data set, subset analysis of pre-treatment breast pain and anxiety VAS data was performed. Binary outcome data were analysed using a McNemar test for related samples. The content of the free-text responses was summarised according to the subject matter and relative frequencies are shown in Table 1. All statistical analysis was performed on SPSS v. 25.0 (IBM, Armonk, NY).

RESULTS

Of the 31 patients eligible for the study, 10 declined. Reasons given were feeling overwhelmed (5)concerns regarding cannulation and/or contrast (2),extra travel (1)unknown (2) Three patients could not be recruited due to hospital logistics, leaving 18 patients who participated in the study. Average age of patients was 52.7 years (range 32–72 years). Average time between CE-DBT and MRI was 9.56 days (range 0–31 days) and 3.64 days (range 0–13 days) for pre- and post-treatment imaging respectively. On 11 (34%) occasions CE-DBT was performed first; the studies were performed on the same day on 7 (22%) occasions and MRI was performed first on 14 (44%) occasions. One patient withdrew at mid-treatment due to difficult intravenous access. Post-treatment MRI was omitted in two patients, as per standard care, as they only received four cycles of chemotherapy. Post-treatment CE-DBT was omitted for one patient who developed metastatic disease over the course of treatment. Therefore, 18 patients had pre-treatment CE-DBT and MRI and 14 had both CE-DBT and MRI post-treatment.

At pre-treatment, 17 (94%) and 14 (78%) patients completed questionnaires for CE-DBT and MRI respectively, with 13 (72%)

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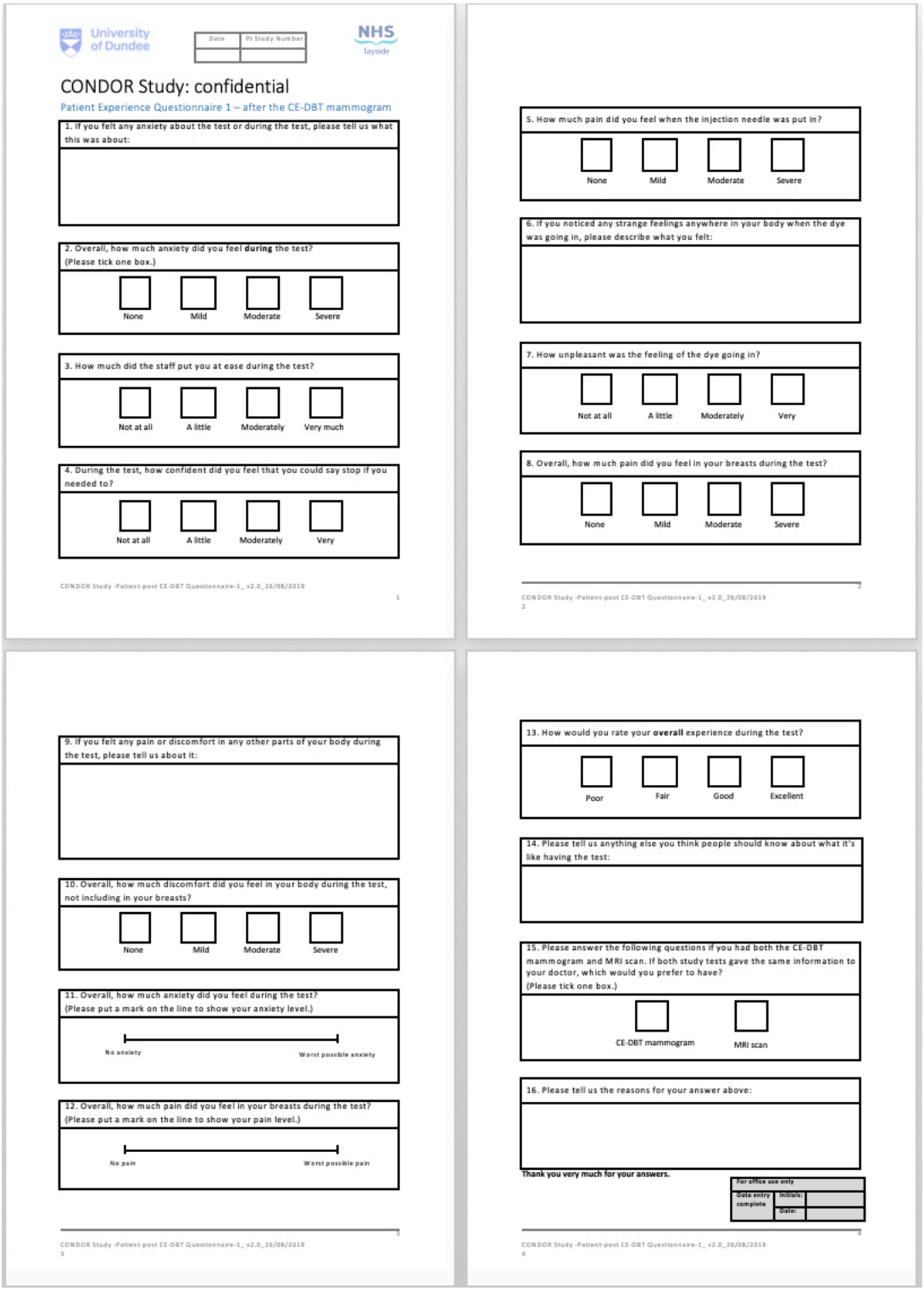
Figure 1. Patient questionnaire.



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CONDOR Study: confidential

Patient Experience Questionnaire 1 – after the CE-DBT mammogram

1. If you felt any anxiety about the test or during the test, please tell us what this was about:

2. Overall, how much anxiety did you feel **during** the test? (Please tick one box.)
None | Mild | Moderate | Severe

3. How much did the staff put you at ease during the test?
Not at all | A little | Moderately | Very much

4. During the test, how confident did you feel that you could say stop if you needed to?
Not at all | A little | Moderately | Very

CONDOR Study -Patient-post CE-DBT Questionnaire-1_ v2.0_26/08/2019
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5. How much pain did you feel when the injection needle was put in?
None | Mild | Moderate | Severe

6. If you noticed any strange feelings anywhere in your body when the dye was going in, please describe what you felt:

7. How unpleasant was the feeling of the dye going in?
Not at all | A little | Moderately | Very

8. Overall, how much pain did you feel in your breasts during the test?
None | Mild | Moderate | Severe

CONDOR Study -Patient-post CE-DBT Questionnaire-1_ v2.0_26/08/2019
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9. If you felt any pain or discomfort in any other parts of your body during the test, please tell us about it:

10. Overall, how much discomfort did you feel in your body during the test, not including in your breasts?
None | Mild | Moderate | Severe

11. Overall, how much anxiety did you feel during the test? (Please put a mark on the line to show your anxiety level.)
No anxiety — Worst possible anxiety

12. Overall, how much pain did you feel in your breasts during the test? (Please put a mark on the line to show your pain level.)
No pain — Worst possible pain

CONDOR Study -Patient-post CE-DBT Questionnaire-1_ v2.0_26/08/2019
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13. How would you rate your **overall** experience during the test?
Poor | Fair | Good | Excellent

14. Please tell us anything else you think people should know about what it's like having the test:

15. Please answer the following questions if you had both the CE-DBT mammogram and MRI scan. If both study tests gave the same information to your doctor, which would you prefer to have? (Please tick one box.)
CE-DBT mammogram | MRI scan

16. Please tell us the reasons for your answer above:

Thank you very much for your answers.

For office use only
Data entry complete | Initials: | Date:

CONDOR Study -Patient-post CE-DBT Questionnaire-1_ v2.0_26/08/2019
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patients completing both. Post-treatment, 15 (94%) completed questionnaires following CE-DBT and 10 (67%) completed questionnaires following MRI, with 9 (64%) completing both. Thus, there were a total of 22 participant episodes completed by 16 patients, where all questionnaires were completed. As disproportionately more patients returned questionnaires following MRI, only matched questionnaires were used for further comparative statistical analysis. The content of free-text responses was reviewed for all completed questionnaires (CE-DBT $n = 32$, MRI $n = 24$). Free-texts were grouped according to content of the responses. For example, in response to the question regarding anxiety, responses classified as 'general anxiety'

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Table 1. Summarised free-text responses from all completed questionnaire

Question	Free-text response (grouped)	True for CE-DBT (n = 32)	True for MRI (n = 24)
If you felt any anxiety about the test or during the test, please tell us what this was about:			
	General anxiety	3 (9%)	5 (21%)
	Breast pain / discomfort / compression	3 (9%)	0
	Cannulation / contrast	4 (13%)	0
	Being enclosed	0	3 (13%)
	Noise	0	1 (4%)
	Controlling breathing / Keeping still	0	2 (8%)
	Non-breast pain	0	1 (4%)
If you noticed any strange feelings anywhere in your body when the dye was going in, please describe what you felt:			
	Heat / flushing	23 (71%)	2 (8%)
	Cold sensation	0	6 (25%)
	Numbness	2 (6%)	0
	Need to urinate	12 (0.38)	3 (0.13)
	Strange taste	7 (0.22)	2 (0.08)
If you felt any pain or discomfort in any other parts of the body during the test, please tell us about it:			
	Leg (sciatic)	1 (3%)	1 (4%)
	Shoulders / upper limbs	0	7 (29%)
	Face / forehead	0	3 (13%)
Please tell us anything else you think people should know about what it's like having the test:			
	Noise	0	5 (20%)
	Headache / off balance	0	2 (8%)
	Wish to reassure other females / share positive experience	14 (44%)	5 (21%)
	Leaflet / more information	0	2 (8%)
	Non-breast pain	0	1 (4%)
	Sensation associated with contrast	5 (6%)	0
	Breast pain / discomfort	1 (3%)	0
Please tell us the reason for your answer above: [preference of technique]			
	Quicker technique	13 (41%)	0
	More comfortable	11 (34%)	4 (17%)
	More confidence in technique	1 (3%)	3 (13%)
	Less intimidating / more in control	3 (9%)	0
	Feeling unwell after MRI	2 (6%)	0

CE-DBT, contrast-enhanced digital breast tomosynthesis.

included "A little anxious. Mainly because it is the first time I have been in the breast screening clinic" [CE-DBT] and "I felt apprehensive beforehand" [MRI]. The free text responses to the question "*Please tell us anything else you think people should know about what it's like having the test*" were very varied. For example, many participants noted positive comments to reassure future patients regarding the imaging studies. These comments were classified as 'wish to reassure other females / share positive experience' and included comments such as "There is nothing to worry about" [CE-DBT] and 'It gets easier after the first one" [MRI]. The categorised responses are shown in Table 1.

Outcome data for questions answered with 4-point categorical response format is shown in Table 2; statistically significant results are given in bold.

Answers measured using VAS are displayed in Table 3.

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Table 2. Patient experience from matched questionnaire, categorical data

	Rating	CE-DBT	MRI	*p*
Overall how much anxiety did you feel during the test?				
	None	14	9	
	Mild	6	10	
	Moderate	2	2	
	Severe	0	1	0.052
How much pain did you feel when the needle was put in?				
	None	11	10	
	Mild	11	12	
	Moderate	0	0	
	Severe	0	0	0.655
Overall, how much pain did you feel in your breasts during the test?				
	None	12	20	
	Mild	7	1	
	Moderate	1	1	
	Severe	1	0	**0.021**
Overall, how much discomfort did you feel in your body during the test, not including in your breasts?				
	None	16	11	
	Mild	5	8	
	Moderate	1	2	
	Severe	0	1	**0.046**
How much did the staff put you at ease during the test?				
	Very much	21	15	
	Moderately	1	5	
	A little	0	2	
	Not at all	0	0	**0.023**
During the test, how confident did you feel that you could say stop if you needed to?				
	Very much	22	19	
	Moderately	0	1	
	A little	0	1	
	Not at all	0	1	0.109
How unpleasant was the feeling of the dye going in?				
	Not at all	15	18	
	A little	6	3	
	Moderately	1	1	0.257
	Very much	0	0	
How would you rate your overall experience?				
	Excellent	14	8	
	Good	8	7	
	Fair	0	7	
	Poor	0	0	**0.008**

CE-DBT, contrast-enhanced digital breast tomosynthesis.

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Table 3. Patient experience from matched questionnaires, questions answered using VAS

	CE-DBT (mean ± SD)	MRI (mean ± SD)	*p*
Anxiety (full data set)	6.45 ± 8.06	16.91 ± 20.77	**0.003**
Anxiety (pre-treatment only)	9.08 ± 9.31	22.92 ± 23.78	**0.015**
Breast pain (full dataset)	11.14 ± 18.60	3.86 ± 9.92	**0.011**
Breast pain (pre-treatment only)	14.23 ± 22.90	5.92 ± 12.54	**0.155**

CE-DBT, contrast-enhanced digital breast tomosynthesis; VAS, visual analogue scale.

Significant differences in favour of CE-DBT were seen for non-breast pain ($p = 0.046$), being put at ease by staff ($p = 0.023$) and overall experience ($p = 0.008$). Anxiety was lower for CE-DBT when measured using VAS ($p = 0.003$) and this remained significant for subset analysis of the pre-treatment data; there was no statistically significant difference when measured with the categorical scale. Breast pain was significantly higher with CE-DBT when measured with both the categorical scale ($p = 0.021$) and whole data set VAS ($p = 0.011$). While breast pain was higher for CE-DBT on subset analysis, this was not statistically significant. No statistically significant difference was seen between CE-DBT and MRI in patients' confidence that they could stop the test if needed.

Patient preference was recorded after 31 episodes, 16 following initial imaging, 15 following final imaging. One patient who selected both CE-DBT and MRI after final imaging this episode was excluded from further analysis. 11 patients recorded a preference at initial and final imaging. Results are displayed in Table 4.

Overall, on 77% of occasions patients preferred CE-DBT. Of the 11 patients who responded at both time points, there was no significant change in in the proportion preferring CE-DBT; 10 (91%) and 8 (82%) at initial and final imaging respectively, $p = 0.25$.

DISCUSSION

To our knowledge, this is the first study to assess patient experience of CE-DBT; furthermore, it is the first study to assess patient preference for any form of contrast-enhanced mammographic technique when used for assessing response to NACT.

It is beyond the scope of this paper to assess the relative accuracy of CE-DBT and MRI. This is the primary aim of the pilot study, and therefore patients were aware that the accuracy of CE-DBT for assessing response to NACT is currently unknown when they consented to join the study. This study has demonstrated that, assuming the test provided equivalent diagnostic information, the majority of patients preferred CE-DBT. This did not vary between pre- and post-treatment, suggesting that previous experience of the techniques did not influence attitude.

Table 4. Patient preference

Time point	Preference	
	CE-DBT (%)	MRI (%)
Pre-treatment	13 (81%)	3 (19%)
Post-treatment	10 (71%)	4 (29%)
Total	23 (77%)	7 (23%)

CE-DBT, contrast-enhanced digital breast tomosynthesis.

Overall experience was also significantly more positive for CE-DBT, with 64% reporting it as excellent, as opposed to only 36% reporting an excellent MRI experience. These findings are supported by previous studies that report a patient preference for CESM over MRI both in the setting of local staging and high risk screening. Similar to previous studies, the most common reasons for preference of CE-DBT or CESM were faster time and greater comfort.[14,15] Unlike the study by Hobbs et al, noise level was not cited as a reason for preference in our cohort, although five patients mentioned MRI-associated noise in the free-text boxes.

Consistent with a previous study,[14] anxiety was significantly higher in the MRI group when measured using a VAS ($p = 0.003$), and descriptively higher when measured using the categorical rating scale ($p = 0.052$). Specific anxiety related to MRI concerned the enclosed space, lying still for a prolonged period and the noise. Anxieties relating to cannulation and/or contrast administration were only recorded in the free text in relation to CE-DBT, not MRI. However, unlike the findings of Hobbs et al, no significant difference was demonstrated between modalities either in pain on cannulation or unpleasant sensations associated with contrast injection.[14] Sensations described varied between the two techniques, iodinated CE-DBT contrast more commonly associated with heat or flushing, the sensation of passing urine and odd taste, and gadolinium more commonly associated with a cold sensation.

Conversely, significantly more positive responses for CE-DBT were also seen in relation to being put at ease by staff. We suggest that the close proximity of staff during CE-DBT, enabling them to reassure patients, reduced the anxiety patients experienced.

It is accepted that breast pain relating to mammographic compression is a widely reported patient concern, and has been shown to be associated with non-re-attendance for mammographic screening.[17] Consistent with Hobbs et al, it is therefore perhaps not surprising that significantly more females experienced breast pain associated with CE-DBT than MRI (categorical $p = 0.021$, VAS $p = 0.011$).[14] However, it is reassuring that despite the increased compression time necessary to allow DBT acquisition in addition to CESM, compared to standard mammography, overall patient preference and experience remains in favour of CE-DBT. Unlike in previous studies, patients were also asked to

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report on pain in the rest of the body experienced during both techniques; significantly more females experienced non-breast pain with MRI (p = 0.046). Pain was predominantly related to upper limb and pressure on the face / forehead experienced during MRI. This finding has not been previously reported and may offset the increased breast pain experienced with mammographic techniques.

The main limitation of the study is the small sample size of 18 patients. Because of this small sample size, it was necessary to pool responses for pre-treatment and end-of-treatment for statistical analysis of categorical data. Subset analysis of pre-treatment VAS data was performed. The majority of patients (10), were only included at one time point. However, the responses of six patients were included at both time points. As with most prospective trials, there is the possibility of selection bias, as patients opted into joining the study. Therefore, it is possible that the study cohort felt more positive towards new imaging techniques than the general population. Whilst these factors could potentially bias results, our findings are consistent with previous slightly larger studies.

Ideally, the order in which patients were imaged would have been randomised, but this was not possible logistically as the studies were booked according to availability and timing of chemotherapy cycles. Despite this the order in which patients had the two imaging techniques was fairly balanced, with MRI performed first on 44% occasions and CE-DBT on 34% occasions.

This study compared patient experience of CE-DBT to that of a 3 T MRI scanner, as opposed to a 1.5 T MRI scanner. It is possible that the negative experience of some patients associated with MRI may have been compounded by the higher field strength and the narrower bore of the magnet. However, whilst studies have demonstrated that patients experience symptoms such as vertigo/dizziness, headache and spinal pain more frequently with 3 T MRI,[18] in addition to comfort the primary reason for CE-DBT, preference was cited as the shorter study time. This factor would remain true irrespective of magnetic field strength. Therefore, whilst it is possible that the preference of CE-DBT was magnified by the higher field strength it is unlikely that it would alter overall preference.

It is also worth noting that the MRI protocol routinely used in this study is quite lengthy, as evaluation of imaging response to NACT is a research focus of the unit. A faster protocol might have increased patient acceptability.

Establishing patient acceptability is essential prior to any policy change. This pilot study has demonstrated promising results regarding patient experience of contrast mammographic techniques in the context of NACT. A large multicentre study is required to confirm these findings. Assessment of additional factors that may confound patient experience could be included, such as a body mass index, history of claustrophobia, degree of mammographic compression. Overall recruitment rate would likely be improved in centres routinely using CE-DBT at diagnosis as this would reduce the time pressure for patients to decide. Online or text-message based questionnaire versions may improve response rate.

CONCLUSION

Our results demonstrate an overall patient preference for CE-DBT over MRI, when used to monitor response to NACT. This finding supports the use of contrast-mammographic techniques as a potential alternative to breast MRI for an ever-increasing number of indications, assuming clinical effectiveness.

FUNDING

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