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FULL PAPER

Effects on short-term quality of life of vacuum-assisted breast biopsy: comparison between digital breast tomosynthesis and digital mammography

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Objective: To compare the effects of digital breast tomosynthesis (DBT)-guided and digital mammography (MMx)-guided vacuum-assisted breast biopsy (VABB) on short-term quality of life (QoL).

Methods: From November 2014 through March 2015, females undergoing VABB in an academic medical centre participated in a survey after biopsy. VABB was performed under DBT (Group 1) or MMx guidance (Group 2). Biopsy experience was assessed with a modified testing morbidities index (TMI). 10 attributes were assessed: six related to the procedures (pain or discomfort before and during testing, fear or anxiety before and during testing, physical and mental function after testing) and four not related to the procedures (familiarity for cancer and clinical history, embarrassment during testing and overall satisfaction). Non-parametric standard statistics were used to compare data of Group 1 and data of Group 2.

Results: A total of 90 females (mean age, 55.8 years; range, 40–87 years) were enrolled: 45 underwent DBT-

VABB and 45 MMx-VABB. The sum of the 6 of 10 items related to the procedures was significantly worse for DBT ($p < 0.02$), but no differences were observed for the single items. The median value for DBT-VABB and MMx-VABB was 95.2 and 90.1, respectively ($p < 0.02$). The 4 of 10 TMI items not related to the procedures did not differ significantly between the two groups. Four females fainted during DBT-VABB and three females during MMx-VABB; all of these patients underwent VABB procedures in sitting position.

Conclusion: Females in the DBT-VABB study group have a decreased short-term QoL compared with the MMx-VABB group. DBT-VABBs were less tolerated than MMx-VABBs.

Advances in knowledge: DBT-VABB was less tolerated than MMx-VABB. Females in the DBT-VABB study group had a decreased short-term QoL compared with the MMx-VABB group. Overall satisfaction was similar for both procedures.

INTRODUCTION

Digital breast tomosynthesis (DBT) is rapidly emerging as a relatively new imaging modality able to detect breast lesions not visible at mammography.^{1,2} With DBT, several reports found that the cancer detection rate is increased, and the false-positive recall rate is decreased compared with those of mammography.^{3–6} Therefore, medical literature is starting to report results regarding biopsies for DBT-detected abnormalities not visible with other breast imaging modalities.^{2,7} It has also been suggested that DBT may replace prone stereotactic vacuum-assisted breast biopsy (VABB) and that DBT-guided biopsy is likely to expand the number of mammographic lesions considered amenable to mammographic VABB.⁸ Consequently, percutaneous core

needle biopsies on DBT-detected lesions are going to increase. Percutaneous core needle biopsies are associated with pain and emotional distress, and there are some differences in the techniques related to VABB performed on DBT or digital mammography (MMx).^{9,10} Mammographic VABB is associated with a mild-to-moderate short-term decline in a patient's quality of life (QoL).⁹ Percutaneous breast biopsies, under ultrasound, core needle or VABB guidance, are linked to pain and emotional distress of the patient especially at the time of biopsy.^{10,11} To the best of our knowledge, there are no data on short-term QoL comparing VABB under DBT guidance or MMx guidance. Therefore, the purpose of our study was to compare the effects of DBT-guided and MMx-guided VABB on short-term QoL.

METHODS AND MATERIALS

All the patients included were enrolled in Institutional Review Board-approved trials and gave their written informed consent to participate.

From 10 November 2014 through 20 March 2015, females undergoing VABB in our academic medical centre were asked to participate in this survey. On the day of biopsy, patients who agreed to participate received the survey materials before the procedure. To avoid selection biases, we asked every consecutive female undergoing VABB to participate in the survey until two groups of 45 patients were formed. Of 93 females, 90 females were enrolled because 3 females refused to participate. 45 females underwent DBT-guided VABB (Group 1; Selenia® Dimensions® digital mammography system with Affirm™ Breast Biopsy Guidance System; Hologic, Bedford, MA), whereas 45 females underwent MMx-guided procedure (Group 2; Lorad MultiCare Platinum prone breast biopsy table; Hologic). Biopsies were performed by two experienced radiologists (MC and ST) with 15 and 7 years' experience, respectively in VABB, DBT and MMx; biopsies were performed in a random order (one-to-one ratio) by the two different radiologists to avoid biases related to the different operators. Needle size was not different between DBT-VABB or MMx-VABB. Survey material was given to patients on the day of biopsy. The days after the procedure, before receiving the results of the biopsy, females went through a telephone interview in order to collect the survey data. The phone calls were always performed by the same medical doctor (LG) different from the two radiologists who performed the biopsies to avoid biases related to the examiner. In addition, the interviewer did not know which procedure the females had received to avoid an interviewer bias.

Biopsy experience was described with the testing morbidities index (TMI), a validated instrument for assessing short-term QoL related to diagnostic testing and slightly modified for the purpose of the study.¹² A total of 10 attributes were assessed: (a) pain or discomfort before the test, (b) pain or discomfort during the test, (c) fear or anxiety before the test, (d) fear or anxiety during the test, (e) physical function after testing, (f) mental function after testing, (g) embarrassment during the test, (h) familiarity for cancer, (i) clinical history of breast biopsy or surgery and (l) overall satisfaction. The first six attributes (a–f) were strictly related to the procedures, whereas the latter (g–l) were not. We arbitrarily decided to consider attribute g as not necessarily related to the procedure, although this item could also be considered related to the procedure. The patients used a 5-point scale assessment for the first 4 attributes (a–d) and to describe the level of embarrassment during the test (g), where 1 = none, 2 = mild, 3 = moderate, 4 = severe and 5 = extreme.¹²

Regarding physical and mental function after testing (e and f), the following scale was used: 1 = no problems, 2 = mild problems, 3 = moderate problems, 4 = severe problems and 5 = extreme problems. Familiarity for cancer (h) and clinical history of breast biopsy or surgery (i) were assessed as follows: 0 = none and 1 = yes.¹²

The survey also included questions about the patient's satisfaction, such as "the staff showed concern for my worries" and "the doctor

explained what to expect during the biopsy". According to these issues, patients assessed their overall satisfaction (l) by the means of the following 4-point scale: 1 = strongly agree, 2 = somewhat agree, 3 = somewhat disagree and 4 = strongly disagree.

In order to compare the effects of these two VABB modalities on short-term QoL, we considered the six attributes related to the procedure (a–f); therefore, the global score ranged from 6 (no adverse effects, all best scores) to 30 (worst possible experience).

TMI scores were obtained before giving biopsy results to patients to avoid biases related to the result of the procedure. Standard statistics to compare categorical variables were used to compare data of Group 1 and data of Group 2: Mann–Whitney *U* test was used assuming a *p*-value < 0.05 as significant. In a generalized linear model univariate analysis (regression) the TMI score was tested to assess whether age was a significant independent predictor of the score. Multivariate analysis was performed with SPSS® software (IBM Corp., New York, NY; formerly SPSS Inc., Chicago, IL) after adjustments for personal or family history of cancer, previous biopsy, pathology results of biopsy and age of patients. Data are presented after adjustment. McNemar test was used to compare TMI scores of females diagnosed with breast cancer after VABB and females with no diagnosis of cancer after VABB.

RESULTS

Of the 90 females included, 45 underwent DBT-guided VABB and 45 underwent MMx-guided VABB. The mean patient age was 55.8 years (range, 40–87 years). Table 1 shows patient characteristics. The final pathological diagnosis was malignant disease in 29 of the 90 patients (15 on DBT and 14 on MMx). Of these patients, 16 had ductal carcinoma *in situ*, 2 had lobular carcinoma *in situ*, 7 had invasive ductal carcinoma and finally 4 had invasive lobular carcinoma.

Females undergoing DBT-VABB gave higher scores to each of the 6 of 10 attributes related to the procedure, thus emphasizing a worst biopsy experience in terms of pain or discomfort before and during the test, fear or anxiety before and during the test and regarding physical and mental function after testing. In particular, global score (the sum) of these attributes was significantly worst for DBT at Mann–Whitney *U* test for independent samples, with a *p*-value < 0.02. The median value for DBT-VABB and MMx-VABB was 95.2 and 90.1, respectively (*p* < 0.02). Figure 1 shows the total scores of the six attributes related to the two different procedures. Table 2 shows the median values and interquartile range for the six attributes related to the two different procedures.

Scores of the 4 of 10 TMI items not related to the procedures did not differ significantly between the two groups, as shown in Table 3. Indeed, more than half of the patients, both in Group 1 and Group 2, had no personal or family history of breast cancer and had not previously undergone breast biopsy. Also, the level of embarrassment during testing and the overall satisfaction was similar for both the procedures. 21 of 90 patients underwent biopsy procedure in the sitting position, 15 from Group 1 and 6 from Group 2. Among these patients, a vasovagal reaction occurred

Table 1. Patients characteristics of the females who underwent the survey

Patient characteristics	Number of patients (<i>n</i> = 90)	DBT-VABB (<i>n</i> = 45)	MMx-VABB (<i>n</i> = 45)	<i>p</i> -value
Age (years)				
≤50	32	16	16	NS
51–59	25	12	13	NS
≥60	33	16	17	NS
Personal or family history of breast cancer				
No	57	28	29	NS
Yes	33	17	16	NS
Previous biopsy				
No	65	30	35	NS
Yes	25	12	13	NS

DBT, digital breast tomosynthesis; MMx, digital mammography; NS, not significant; VABB, vacuum-assisted breast biopsy.

in seven females, in four females during DBT-VABB and in three females during MMx-VABB.

Three females of the DBT-VABB group had already undergone MMx-VABB procedure in the past. This group of patients reported that the DBT-guided biopsy was completed within shorter time interval than the MMx-VABB.

In a generalized linear model univariate analysis (regression), patient age (examined as continuous predictors) was a significant

independent predictor of TMI score ($p = 0.001$). TMI scores were lowest in the youngest age group, with short-term QoL decreasing with the decrease in patient age. McNemar test did not find significant differences in TMI scores of females diagnosed with breast cancer after VABB and females with no diagnosis of cancer after VABB.

DISCUSSION

In our study, we assessed the effect of DBT-VABB and MMx-VABB on female's short-term QoL using a TMI. When participants were

Figure 1. Total scores of the six attributes that were considered related to the two different procedures: pain before: pain or discomfort before the test, pain during: pain or discomfort during the test, anxiety before: fear or anxiety before the test, anxiety during: fear or anxiety during the test, physical function after: physical function after testing, and mental function after: mental function after testing. DBT, digital breast tomosynthesis; MMx, digital mammography.

Table 2. Median values and interquartile range for the six items that were considered related to the procedure in 45 patients per group

Attributes	Median		Interquartile range		<i>p</i> -value
	DBT	MMx	DBT	MMx	
Pain before the test	3	3	2–4	2–3	0.70
Anxiety before the test	3	3	2–3	2–4	0.35
Pain during the test	3	3	3–4	3–4	0.76
Anxiety during the test	3	3	2–4	2–3	0.36
Physical function after the test	3	3	2–4	2–3	0.34
Mental function after the test	3	3	2–4	2–3	0.25

DBT, digital breast tomosynthesis; MMx, digital mammography.

Using non-parametric tests (Mann-Whitney *U* test), the sum of these six items was statistically significant ($p = 0.02$).

surveyed about their biopsy experiences, their median TMI score was assessed with six items related to the procedures (pain or discomfort before and during testing, fear or anxiety before and during testing, physical and mental function after testing) and four items not related to the procedures (familiarity for cancer and clinical history, embarrassment during testing and overall satisfaction) as suggested by literature.⁹ The total TMI score of the six items related to the procedures was 812 for DBT and 768 for MMx, resulting in a score that was significantly worse for DBT, whereas the four TMI items not related to the procedures did not differ significantly between DBT-VABB and MMx-VABB. These data support the hypothesis that the patient-reported experience during VABB procedure performed under DBT guidance was worse than that performed under MMx guidance. It was not feasible to randomize the patients because we preferred to biopsy the lesion using MMx-VABB or DBT-VABB owing to the better visibility of the lesion, but to avoid selection biases, we asked every consecutive female undergoing VABB to participate in the survey until two groups of 45 patients were complete. A potential bias could be that some lesions were better visualized on DBT than on MMx so that a DBT-VABB had to be chosen. However, this bias is normal in clinical practice. Also, the interviewer did not know which procedure the females had received to avoid an interviewer bias. In our sample, several patients had a biopsy performed in the sitting position (21 of 90 patients); in this group of patients, there were seven vasovagal reactions, whereas no vasovagal reactions were noted when biopsy was performed in the supine position. We

performed DBT-VABB using equipment made by only one vendor that did not allow the biopsy in the supine position but only on a lateral decubitus or in a sitting position. Therefore, according to our experience, alternative patient positions should always be preferred to the sitting position, when possible.

Considering the data that we obtained as a whole, this survey held in our academic medical centre emphasized that DBT-VABB is less tolerated than MMx-VABB. DBT biopsy experience was described as unpleasant, if compared with MMx, in terms of pain or discomfort before and during the test, fear or anxiety before and during the test and regarding physical and mental function after testing. According to previous literature⁹ on breast biopsy, univariate analyses demonstrated that age was a significant predictor of short-term QoL related to breast biopsy. Considering that VABB is a known physical and mental stressor to females, the impact on QoL of different VABB procedures is important from both patient and physician perspective.¹³ In our study, females in the DBT-VABB group had a decreased short-term QoL. The shorter time of performance of DBT-VABB could make these kinds of biopsies more easily tolerable. This observation, to be confirmed in larger series, was suggested by the three enrolled females who underwent both DBT and MMx procedures. Different from a previous study that found that patients with malignant histology had a significantly worse procedure experience, in this study, we did not find significant differences in TMI scores of females diagnosed with breast cancer

Table 3. Median values and interquartile range for the four items that were considered not related to the procedure in 45 patients per group

Attributes	Median		Interquartile range		<i>p</i> -value
	DBT	MMx	DBT	MMx	
Embarrassment during the test	3	3	2–4	2–3	0.65
Familiarity for cancer	3	3	2–3	2–4	0.55
Clinical history of breast biopsy or surgery	3	3	3–4	2–3	0.46
Overall satisfaction	3	3	2–4	2–4	0.76

DBT, digital breast tomosynthesis; MMx, digital mammography.

Using non-parametric tests (Mann-Whitney *U* test), the sum of these items was not statistically significant ($p = 0.02$).

after VABB and females with no diagnosis of cancer after VABB.¹³ These data suggest that final diagnosis of breast cancer did not influence the results of the study. Furthermore, worse short-term QoL results of DBT could also be related to the learning curve for this new biopsy approach, although this hypothesis is unlikely owing to the operators have a long experience in breast biopsies with different techniques. Another possibility is that the position of the patients appears less tolerable for DBT-VABB owing to technical reasons. We believe that DBT-VABB should be implemented by manufacturers to increase patients' short-term QoL after biopsy. A limitation of our study is that it represents the experience of a single academic institution and that the sample size is relatively small. In addition, at the present time, we are not aware of any reference on what is considered to be a minimal clinically important difference or the smallest change in an outcome that a patient

would identify as important. We hope that further research will fill this gap. Also, this is a non-randomized trial, with potential interviewer bias and selection bias as mentioned in the Methods section. Therefore, based on our data, we cannot strictly affirm that DBT-VABB is worse than MMx-VABB; indeed, the overall satisfaction was similar for both procedures. We noted that four females fainted during DBT-VABB in a sitting position (and three during MMx-VABB), so we can suggest using the supine position for both biopsies. Only with the sum of the six items strictly considered related to the procedure did DBT-VABB result in being less tolerable than MMx-VABB.

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