

## Stereotactic Vacuum-assisted Breast Biopsy (VABB) – A patients' Survey

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**Abstract.** *Aim: To analyze how patients experience Stereotactic guided vacuum-assisted breast biopsy (VABB) both physically and mentally. Patients and Methods: Two hundred and eleven consecutive women underwent VABB using one of two different biopsy devices (ATEC<sup>®</sup> and Mammotome<sup>®</sup>). Patients were queried using a questionnaire. Results: One hundred and eighty-nine patients were included. 90% would again prefer VABB over a surgical biopsy. Average grading for the condition during the procedure was 2.5 (very good to good) and 2.1 (very good) for the condition the week following VABB. Minor complications were mentioned in 37%. (>90% pain and hematoma). 97% of the women were satisfied by the cosmetic results. Patients with malignant histology and younger age experienced the procedure significantly worse. A significant higher rate of minor complications was found in younger patients and in the ATEC<sup>®</sup> group. Conclusion: VABB is a physical and mental stressor to the women. Nonetheless, the majority of women indeed prefer the VABB.*

Certain patterns of microcalcifications in mammography are known to be associated with ductal carcinoma *in situ* (DCIS) or invasive breast cancer. In these cases a histological diagnosis is mandatory (1-7). For a long time surgical biopsy represented the reference standard to verify histology with the necessity of hospitalisation and general anesthesia (8). However, since the end of the 20th century stereotactic-guided vacuum assisted breast biopsy (VABB) became an accepted interventional alternative for obtaining tissue samples from areas of suspicious breast microcalcifications. VABB is minimally-invasive, thus gentler to the patient and

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can be done on an out-patient basis with local anesthesia (9-12). It is potentially more cost-effective for the health system by avoiding hospitalisation cost as well as costs for a surgical biopsy including general anesthesia (11, 13).

On the other hand VABB could be a traumatic and mentally-incriminating procedure for the patient (14-16) as it is normally performed in full consciousness. Furthermore, positioning on the biopsy table may be uncomfortable and the biopsy itself despite local anesthesia painful. Long-term pain, hematoma and swelling are frequent minor complications of the procedure (15-19).

To our knowledge there are only a few studies to have investigated to which extent patients' condition is altered by VABB (14, 20). The purpose of the present study was to evaluate how much the patients' condition is affected mentally as well as in a physical respect while undergoing the biopsy procedure itself, as well as after the intervention.

### Patients and Methods

*Patients.* Two hundred and eleven consecutive women underwent VABB for histological clarification of breast microcalcifications that were classified as BI-RADS<sup>®</sup> 4 or 5 according to the Breast Imaging Reporting and Data System (BI-RADS<sup>®</sup>) (21). The questionnaire was sent to all eligible women. All women who did not send back the questionnaire were contacted by phone (n=46).

*Procedure of the VABB.* On the day of their first referral the women were explained in detail by a physician how VABB is performed. On the biopsy day the women were positioned on the biopsy table by the technician in a prone position. In all patients 5-10 ml of local anesthesia (mepivacainhydrochloride 1%, Scandicain, AstraZeneca, Wedel, Germany) were applied by the radiologist for superficial and deeper anesthesia of the skin and breast tissue. The skin was incised with a scalpel no.11 (Feather Disposable Scalpel, Osaka, Japan). The biopsy was performed by a radiologist with the Mammotest<sup>®</sup>Plus/S (Fischer Imaging, Norderstedt, Germany) biopsy table. Two different biopsy devices, the Mammotome<sup>®</sup> system (Mammotome<sup>®</sup> ST 11 gauge (G), Ethicon Endosurgery, Cincinnati, USA) and the ATEC<sup>®</sup> (9-G, Suros, Indianapolis, USA) were used.

Questionnaire
Question 1: How would you classify your condition during the biopsy procedure (Grade 1-5; 1 = excellent, 2 = very good; 3 = good, 4 = fair; 5 = poor)?
Question 2: How would you classify your condition during the week after the biopsy procedure (Grade 1-5; 1 = excellent, 2 = very good; 3 = good, 4 = fair; 5 = poor)?
Question 3: Were there any complications (Yes/ No)?
Additional, concerning Question 3: If yes, please specify.
Question 4: How would you evaluate the cosmetic result after the biopsy procedure (1 = satisfying; 2 = not satisfying)?
Question 5: Retrospectively, would you again prefer the vacuum-assisted biopsy to an open surgical biopsy (Yes/ No)?

Figure 1. Questionnaire design.

After the biopsy radiographs of all specimens were taken to confirm that microcalcifications were included. A clip marker was inserted to mark the biopsy site in all women with no radiographically visible residual microcalcifications in control images during VABB. After the procedure patients were instructed to apply local pressure to the biopsied breast for at least 60 min and accompanied back to the waiting room. Local pressure to the breast was re-assured by a bandage circumferential to the chest.

In all patients a post-interventional digital mammography in craniocaudal (CC) and mediolateral (ML) view (Novation®, Siemens, Erlangen, Germany) was performed to document the biopsy result more than 60 min after the VABB.

*Patient questionnaire and evaluation.* At least 4 weeks after the VABB the patients were asked to answer a questionnaire regarding their subjective rating of the VABB. The questionnaire was designed with a combination of ordinal scaled (grading scale from 1 – excellent to 5 – poor), dichotomic and optional open questions (Figure 1).

The questionnaire was sent by mail in an anonymous setting. If the written questionnaire was not answered within 2 weeks it was tried to reach the patients by phone and asked if they were willing to answer the questionnaire orally. All phone calls were performed by the same physician (AE), who was not known to the patients. Informed consent for the investigators to use patient data was obtained from all patients. The study was performed in concordance with the local ethic committee. Statistical analysis was calculated using the Microsoft Excel 2003 and SPSS 15.0 (Chicago, IL, US) using Pearson’s Chi-Square-test. A *p*-value <0.05 was considered to be statistically significant.

For statistical testing the study group was subdivided in three pairs of subgroups – for the two different biopsy devices (Mammotome®, ATEC®), an older/younger age group (divided by the median age of the woman which was 61 years) and with respect to the final histological result (benign/malignant).

## Results

*Study group.* The time range between biopsy and interrogation was 1 to 44 months (median 24 months). One hundred and sixty-nine written questionnaires were filled-out and sent back by the patients. Another 24 patients could be reached by phone and were willing to answer the questionnaire orally. In 22 cases neither the written questionnaire nor an orally answered questionnaire were available. Thus, 189 patients could be included in the study evaluation. In two cases question 5 was not answered on the written questionnaire, oral answers could not be inserted as these two patients were unavailable by phone.

The median age of the women was 61 years (range=32-87 years). The younger group (younger than 61 years per definition) included 96/189 (51 %) patients, the older group 93/189 (49 %) patients. In 150 cases the ATEC® system with a diameter of 9-G, in 39 cases the Mammotome® system with a diameter of 11-G was used. An overview of the distribution regarding age, biopsy devices and histology is shown in Table I.

Post-interventional mammograms were available in 179/189 (95%) cases (Mammotome® 34/39, 87%; ATEC® 145/150, 97%). In the other cases the images were given to the patients and therefore not available for this analysis.

*Imaging and histological findings.* VABB was performed in 155/189 (82 %) women by one of two radiologist with more than seven years of experience in breast imaging and breast intervention. In 34/189 (18 %) women VABB was performed by three different less experienced radiologists and residents under supervision of a consultant.

Table I. *Participants' age distribution, histology and biopsy device.*

Biopsy device	No. biopsies	Patient age median in years (range)	Benign n (%)	Malignant n (%)	Lesion size (mm)
Mammotome®	39	62 (45-83)	30 (77%)	9 (23%)	8.7±7.2
ATEC®	150	61 (32-87)	105 (70%)	45% (30%)	8.2±5.4
Σ	189	61 (32-87)	135 (71%)	54 (29%)	8.3±5.8

Table II. *Questionnaire results.*

Results of the patient questionnaire (Q1 – Q4: n=189; Q5: n=187)

	Excellent	Very good	Good	Fair	Poor
Q1 – condition during biopsy?	27 (14%)	79 (42%)	55 (29%)	16 (9%)	12 (6%)
Q2 – condition in the week after?	39 (20%)	104 (55%)	30 (16%)	11 (6%)	5 (3%)
	yes		no		
Q3 – complications?	69 (37%)	120 (63%)			
Q4 – cosmetic result satisfying?	184 (97%)	5 (3%)			
Q5 – again choose VABB?	169 (90%)	18 (10%)			

Q: Question.

In 51/189 (27%) cases biopsy revealed a malignant result, including 42 ductal carcinomas *in situ* (DCIS) and 9 invasive ductal breast cancers. The remaining 138/189 (73%) lesions included benign histologies like fibrocystic disease in 84 women. The other benign histologies revealed fibroadenomas in 27 cases, necrotic fat and scar tissue in 14 cases and sclerosing adenosis in 6 cases.

In 2/189 (1.1%) cases the VABB tissue samples were not representative as samples did not contain a representative amount of microcalcifications. In one of the two cases it was due to patient movement during the procedure. In these cases an open biopsy was performed with the histological result of scar tissue in one case and fibrocystic changes in the other case.

Histology revealed atypical ductal hyperplasia (ADH) in 5 women and papilloma in one woman. These histologies were classified as B3 lesions (uncertain malignant potential) (22). Final pathology after surgical biopsies revealed high-grade DCIS in one and low-grade DCIS in 2 patients, atypical ductal hyperplasia in one patient and a benign papilloma in one patient.

In the statistical evaluation the 3 patients with a finally malignant histological result were evaluated in the patient group with malignant histology.

*Results of the questionnaire.* Table II gives the results of the interrogation. Average grade for question 1 (How would you classify your condition during biopsy procedure [Grade 1-5;

1 - excellent; 5 - poor?]) was 2.5, for question 2 (How would you classify your condition during the week after the biopsy procedure? [Grade 1-5; 1 - excellent, 5 - poor]) 2.1. 69/189 (37%) reported of minor complications (Question 3: Were there any complications?). The add-on posed question (If yes, please specify.), revealed hematoma (51/69, 74%), severe pain (23/69, 33%), both combined (7/69, 10%) or palpable scar tissue (3/69, 4%). This results in a difference from 69 women reporting minor complications to 84 women writing down a specification. These 15 women obviously did not regard their hematoma or pain as a complication.

No complications required hospitalisation or further treatment. To our knowledge there was no case of an infection of the biopsy site.

184/189 (97%) were satisfied with the cosmetic post-biopsy result. 169/187 (90%) patients would again prefer VABB to open surgical biopsy in a comparable clinical situation. This result includes 44/54 (81.5%) patients who were diagnosed with a malignant disease. Two patients did not answer this question.

Hematomas could be visualised in 74 (41%) of the 179/189 (95%) available post-interventional mammograms with a mean size of 21±12 mm (range=6-80 mm). Sub-divided for the both devices this means 62/145 (43%) hematomas on post-interventional mammograms in patients biopsied with ATEC® system and 12/34 (35%) hematomas in the Mammotome® cases. In contrast to the mammographical result only 58/189

(31%) patients mentioned a post-interventional hematoma as a complication. These subjectively noticeable hematomas matched with the hematomas seen by mammography in 22/74 (30%) cases (3/12; 25% in the Mammotome<sup>®</sup> group; 19/62; 31 % in ATEC<sup>®</sup> group).

An example for a post-interventional mammographically-visible hematoma is given in Figure 2. This patient did not report hematoma as a complication after VABB in the questionnaire. Some patients used the possibility to add a free comment. Three times the complaint occurred about the lack of time of the medical staff. Five times the negative stressor of the whole exhausting situation, (process of biopsy, wound compression and mammography) was mentioned. One patient complaint about the lack of privacy, sitting in the waiting area with other women and applying local pressure on the biopsied breast was described as exhausting leading to a subsequent wish for more privacy.

**Statistical results. Biopsy devices.** Comparing the two biopsy devices no significant difference was found between the two devices regarding the patient condition while undergoing/after the biopsy (question 1,  $p=0.25$ ; question 2,  $p=0.2$ ). In question 3 the ATEC<sup>®</sup> system was significantly more frequently associated with complications (ATEC<sup>®</sup>: 62/150; Mammotome<sup>®</sup>: 7/39,  $p=0.005$ ). The two different devices did not show significant differences regarding biopsy accuracy.

**Sub-groups according to age.** Significant different findings were made in question 1 and 3. Older women evaluated the procedure as less consciousness-affecting (question 1) than younger ( $p=0.02$ ). The younger group announces a higher frequency ( $p=0.02$ ) of complications (question 3).

**Sub-groups according to histological result.** Patients diagnosed with a malignant lesion rated the VABB statistically significantly worse in the questions 1, 2 and 4 ( $p=0.011$ ;  $p=0.035$ ;  $p=0.024$ ) than those with a benign histology.

Table III presents quantitative analyses of the sub-group results.

## Discussion

VABB is an established method for diagnostic work-up of suspicious microcalcifications of the breast (3, 5, 7, 9, 10, 20). In several studies the high accuracy and specificity of VABB in the assessment of breast lesions has been proven (8, 10, 23). This goes in concordance with our study achieving representative tissue samples in 99%.

Most studies on VABB report only on major complication rates and not on the patients' acceptance and subjective impression of the VABB. Liberman reported in a series of 800 lesions with 11-G vacuum assisted biopsy that 2.1% of the women required more than the normal post-procedural

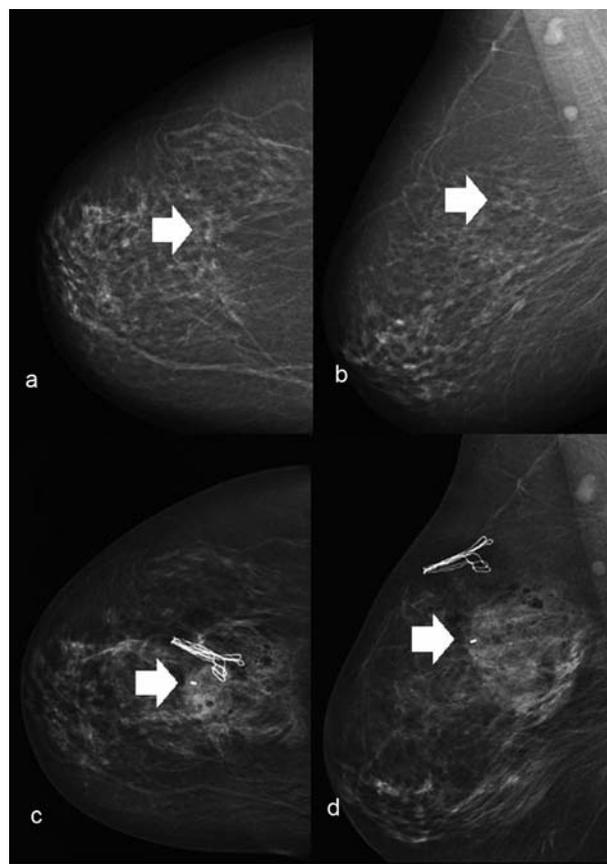


Figure 2. Example of a post-interventional hematoma on mammography. Despite the radiographically-visible hematoma the patient did not mention a clinically-visible hematoma as a complication. a and b show the craniocaudal (cc) and mediolateral (ml) view of the pre-interventional mammography, the location of the micro-calcifications are marked by an arrow. c and d show the craniocaudal (cc) and mediolateral (ml) view of the post-interventional mammography with diffuse intraparenchymal bleeding. The clip-marker is visualized at the location of the removed microcalcifications (arrow).

aftercare (24). This was mainly due to prolonged bleeding, delayed hematoma and vasovagal reactions. Kettritz *et al.* (10) reported about 2,874 women who underwent VABB with the 11-G Mammotome<sup>®</sup>. In this multi-center study 10 women had to be admitted to the hospital due to hematomas, persistent bleeding or vasovagal episodes. In our study no major complications were reported and none of our patients required hospitalization.

Minimally-invasive procedures are usually performed in full consciousness of the patient. So it is not only important that the medical procedure is performed adequately regarding its technical aspects, but also the quality of life of the patient during and after such procedures is an essential issue.

In a prospective study Denton *et al.* compared pain and discomfort in 200 women undergoing image-guided

Table III. Quantitative analysis by subgroups.

	Subgroups					
	By device		By age		By histological result	
	MT	ATEC®	Young (<61 years)	Old (>61 years)	Benign	Malignant
n	39	150	96	93	135	54 (52 in Q5)
Q1 grade 1-5 (%)	8/20/8/2/1 (21/51/21/5/2)	19/59/47/14/11 (13/39/31/9/8)	7/39/33/8/9 (7/41/34/8/10)	20/40/22/8/3 (22/43/24/9/2)	24/62/34/8/7 (18/46/25/6/5)	3/17/21/8/5 (6/31/39/15/9)
Q2 grade 1-5 (%)	11/23/5/0/0 (28/59/13/0/0)	28/81/25/11/5 (19/54/17/7/3)	15/50/21/6/4 (16/52/22/6/4)	24/54/9/5/1 (26/58/10/5/1)	34/74/17/8/2 (25/55/13/6/1)	5/30/13/3/3 (9/55/24/6/6)
Q3 y/n (%)	7/32 (18/82)	62/88 (41/59)	43/53 (45/55)	26/67 (28/72)	46/89 (34/66)	23/31 (43/57)
Q4 y/n (%)	1/38 (3/97)	4/146 (3/97)	1/95 (1/99)	4/89 (4/96)	1/134 (1/99)	4/50 (7/93)
Q5 y/n (%)	36/3 (92/8)	132/15 (88/12)	83/10 (86/14)	85/8 (91/9)	124/10 (92/8)	44/8 (85/15)

Q=Question, y=yes, n=no, MT=Mammotome®.

interventions. 69 women had an ultrasound-guided 14-G guided biopsy, 54 a stereotactically-guided 14-G biopsy and 38 a fine needle aspiration of a cyst (25). They found no significant pain experience between core needle biopsy and fine needle aspiration but pain differed significantly dependent on the physician.

In our study there was no difference in the patient answers regarding the performing physician. However, as a consequence of this study our Institution modified the training and practice guidelines for interventional breast biopsy procedures.

In a follow-up study of the Denton study, Satchithananda *et al.* reviewed pain and discomfort of women during image-guided breast procedures in the same institution (26). This time they found no significant difference in pain scores between the radiologists or with the number of cores taken, but there was a highly significant difference in pain scores with procedure type and needle size. The biopsies were undertaken with a needle size of 21-G for fine-needle aspiration (FNA), 14-G for the core biopsy, and 11-G for the vacuum-assisted core biopsy. All patients received local anesthetics except for the women with FNA. In the study it is not reported how many women in the FNA group didn't receive local anesthesia but the level of pain was significantly higher in the FNA group while there was no significant difference in pain level in the other two groups. The authors concluded that this result was due to the lack of local anesthesia and they consequently changed again their procedure.

Verkooijen *et al.* in a prospective study compared the quality of life of 30 women with non-palpable breast lesions who underwent primarily stereotactic large-core needle biopsy with 27 women who had open breast biopsy as initial

diagnostic procedure (27). With their questionnaire they could demonstrate that patients in the needle biopsy-group had higher quality of life scores on physical functioning, physical performance, pain and social performance after the diagnostic intervention.

Hemmer *et al.* in a prospective study evaluated 150 women regarding the perception of pain and discomfort during stereotactic large-core needle breast biopsies with a 14-G biopsy gun (28). They found no correlation between pain and the underlying discomfort nor the performing physician. Pain was significantly increased in women with dense breast tissue ( $p=0.0001$ ) and the depth of the biopsy ( $p=0.0028$ ). Deeper breast lesions were felt to be more painful at biopsy.

Domeyer *et al.* questioned 102 patients undergoing VABB with 11-G and having benign lesions regarding health-related quality of life before the biopsy, in short-term (4 days after VABB) and long-term (18 months after VABB) follow-up (29). They found that VABB affects the women prior to its performance at a psychological level, immediately after its performance at a functioning-physical level and has long-term effects associated with pain.

The results of our retrospective study suggest that VABB is well-accepted by the patients. In comparison to the results of a previous study of Huber *et al.* (20) our patients rated their condition undergoing VABB more negative. In this study 98% of patients rated the stereotactic guided VABB grade 1 or 2 (in our study 56%). Additionally, 98% in the study of Huber *et al.* rated their condition grade 1 or 2 in the week after the procedure – compared to 75% in our study. However, compared to the study of Huber *et al.* our design was essentially different as we interrogated the patients

retrospectively 1 to 44 months after the procedure – in the announced previous study the questionnaire was handed out on biopsy day. Another difference is the labelling of grades, in our study from 1 – excellent, 2 – very good, 3 good to Huber *et al.* with 1 – excellent, 2 – good, 3 – varying.

Nearly 40% of our patients claim the incidence of minor procedure-associated complications like hematomas, pain and swelling affecting their well-being particularly while the biopsy is taken. Hematomas were complained in 58/189 (31%) cases. Mammographically-visualised hematomas were reported in 74 cases. Patient information and objective findings did not correlate very well with concordant findings in only 22 cases. Patients describing a post-interventional hematoma didn't give information in the questionnaire about its size. Hence a correlation between the mammographic findings and the patient data is not possible. Zagouri *et al.* (18) described a hematoma incidence of 7.5%, using ultrasound to detect hematoma which might lead to exclusion of superficial subcutaneous and diffuse hematomas.

Patients diagnosed with malignant disease at VABB judged the biopsy procedure (question 1), the complication rate (question 3) and the cosmetic result (question 4) more negative than the group with benign findings. This might be influenced in this retrospective view by the upcoming procedures that patients underwent, as oncological treatment and open surgery had to be performed. One should also consider that the judgement of the cosmetic result might be misunderstood and influenced by the following surgery or radiation therapy.

A TEC<sup>®</sup> is judged significantly more negative with respect to the incidence of minor complications in our study. An obvious difference in both systems is the needle diameter, measuring 9G in the A TEC<sup>®</sup> and 11G in the Mammotome<sup>®</sup> system suggesting a higher traumatic potency in the A TEC<sup>®</sup> system. A comparison of the A TEC<sup>®</sup> (9 and 12G) and Mammotome<sup>®</sup> (8 and 11G) system was made by Hahn *et al.* under sonographic guidance and with different needle diameters (30). They found no medical complications with either of the systems but they didn't specify the term complication and the focus of their study was not the patient's condition.

Schaefer *et al.* compared the Mammotome<sup>®</sup> and the A TEC<sup>®</sup> -system with different needle diameters regarding bleeding, hematoma and scar-formation in 178 cases of stereotactically VABBs with benign histology (31). They found more interventional bleedings and post-interventional hematomas with the larger needle-sizes significantly for Mammotome<sup>®</sup> (11-G *versus* 8-G) and not significant for A TEC<sup>®</sup> (12-G *versus* 9-G). The comparison of the

11-G-Mammotome<sup>®</sup>-system revealed significantly less bleedings/hematomas compared to the A TEC<sup>®</sup>-12-G-system while there were no significant differences for the large-systems. No significant correlation was found between scar formation, VABB system or needle size and no correlation

between risk of scar-formation after bleeding or hematoma with the examined VABB-systems or needle size.

Salem *et al.* compared two different VABB devices (Vacora<sup>®</sup> and Mammotome<sup>®</sup>) regarding pain and complications in 1114 consecutive patients (32). They found a higher immediate and late complications rate with the Mammotome<sup>®</sup> and more often acute severe pain with the Vacora<sup>®</sup>. Patient age and the experience of the persons performing the biopsy were the major factors influencing pain.

There are certain limitations to our study: The retrospective design with the varying time range from 1-44 months between intervention and patient interview. However, a significant correlation between time to interview and evaluation of the procedure could not be found. Some patients used the question sheet to add free comments. Several times the complaints about the lack of time of the medical staff and the short face-to-face situation were assigned to be mental stressors to the patient. These points of criticism could not be statistically evaluated but improved our inner-institutional workflow.

In conclusion VABB is an accurate biopsy method of breast microcalcifications with a high patient acceptance and an acceptable rate of minor complications. Nevertheless, peri-procedural patient care in a physical and psychological respect might leave room for optimization.

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