MRI-guided vacuum-assisted breast biopsy in Switzerland: Comparison to the stereotactic and sonographically guided technique.

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Purpose

The purpose of the study was to analyse the development of MRI-guided vacuum-assisted biopsies (VAB) and to compare the procedure with stereotactic and sonographic VAB in Switzerland on the basis of data available the database hosted by the MIBB-group from the years 2009-2011. The study will also examine whether the MRI-guided procedure results in differences in the technical success rate, the complication rates and the accuracy of histological results when compared to the stereotactic and sonographic procedures.

Methods and Materials

The working group "Image-guided Minimally Invasive Breast Biopsies" (MIBB) of the Swiss Society of Senology (SGS) records all minimally invasive breast biopsies (VAB) performed in Switzerland for the purposes of documentation and quality assurance on behalf of the Federal Office of Public Health [BundesamtesfürGesundheit (BAG)] within the scope of legal specifications. The MIBB working group has also developed quality guidelines which define minimal standards for the execution of a vacuum biopsy for the physician and the institute.

Stereotactic and sonographic VAB have been recorded since 2008. MRI-guided biopsies have been recorded only since 2009. As any subsequent surgery must also be recorded in addition to the histopathological result of the VAB, the completion of a case may be delayed by up to 3 months. The period between 2009 and 2011 was selected as the study period. A total of 9113 records of vacuum-guided breast biopsies including the specification of the biopsy method were entered in the database during the study period between 2009 and 2011.

For data collection purposes, ADJUMED-Services AG (Zurich, Switzerland) provided an online questionnaire (one per intervention) to be completed by the institutions. This database forms the basis of the present study.

The data used were available in anonymised form so that the identities of patients, surgeons and institutions could not be ascertained.

As part of the information provided to patients before a vacuum biopsy, a standardised information protocol informs the patients that the collected data "... are made available
to specialists and authorities (...) in anonymised form for evaluation within the scope of quality assurance..." and that these data would only be published in anonymised form after the declaration of their consent[1], whereby the respective surgeon/institution is responsible for informing the patient.

The responsible ethics committee confirmed that the evaluation and publication of data within the scope of this study is permissible.

For further evaluation, all mammographically guided biopsies, which were performed using either a stereotaxis table with the patient supine (n = 5340) or an "upright" device with the patient seated (n = 564), were included in the "stereotactic vacuum biopsy" method. A distinction between these two procedural variations was maintained only for the analysis of complications and the chronological development of the biopsy methods.

We refer to the literature with regard to the technical implementation of image-guided VAB [2,3]

Images 1 and 2 display examples of MRI-guided vacuum biopsies performed at the institute of the lead author. In both patients, the second-look ultrasound was negative. Histology resulted in one invasive carcinoma each.

Categorical variables were compared between groups using the chi-square test. P-values less than 0.05 are considered statistically significant. IBM SPSS Statistics version 20 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses. When single methods were compared with each other, a Bonferroni correction was used to address the problem of multiple comparisons. Because two methods (stereotactic biopsy und sonographic biopsy) respectively were compared with MRI-guided biopsy, p < 0.025 was considered significant for these comparisons. In the analysis of complication rates, three methods (VAB using a stereotaxis table, an "upright" device and ultrasound) were compared with the MRI-guided method. Consequently, p < 0.017 is considered significant in these comparisons. Sensitivity, specificity, negative (NPV) and positive (PPV) predictive values were presented as percentages with 95% Wilson confidence intervals. Microsoft Excel 2010 (Microsoft Corporation, Redmond, Washington, USA) was used for additional analyses and figures.

Images for this section:
Fig. 1: (a-h) 77-year old female patient with diffuse hardening of the right breast (a-d) Mammography in 2 projections on both sides with slight volume asymmetry on the left side as well as densification of the interstitial structures on the right when compared side by side. Therefore decision on MRI(e-f) T1 and post-contrast subtraction: incidental findings displayed as T1 hypointense star-shaped lesion at 11 o’ clock and during 1st subtraction early contrast medium image (g) T1: Biopsy (h) Histology: Infiltrate of an invasive, lobular, predominantly pleomorphic breast carcinoma.
Fig. 2: (a-f) 68-year old female patient with positive family history (mother) (a-b) Densification in upper outer quadrant without sonographic correlation (not shown) (c-e) T1 and post-contrast subtractions: T1 star-shaped hypointense densification with early contrast medium image (f) Biopsy, histologic proof of extensive infiltration of an invasive lobular mamma carcinoma
Results

Vacuum biopsy developments in Switzerland between 2009 and 2011

Between the years 2009 and 2011, a total of 9113 vacuum-assisted breast biopsies with specification of the biopsy method were performed in Switzerland and entered in the database. Of these, 557 (6%) were performed on an MRI-guided basis, 5391 (59%) on a stereotactic basis (at a dedicated stereotaxis table), 569 (6%) on a stereotactic "upright" device and 2596 (28%) on a sonographically guided basis.

MRI-guided biopsies displayed a growth rate of 97% over the entire period with a growth of 49% between 2009 and 2010 and 32% between 2010 and 2011. The development of all vacuum biopsies, including those performed with the use of a stereotaxis table, "upright" device and ultrasound are displayed in Figure 3.

Family and carcinoma history

A positive family history was deemed present when the patient's mother, sister or daughter (1st degree of kinship) exhibited a positive history of breast carcinoma. The lifetime risk was not taken into consideration. For MRI-guided VAB the family history was positive in 144/548 (26%). The comparison to the stereotactic and sonographic VAB is shown in Figure 4.

A history of carcinoma was given in 227/548 (41%) of MRI-guided biopsies. The comparison to stereotactic and sonographic VAB is shown in Figure 5.

Complications

Complications were divided into medical (haemorrhages without or with open revision and infection) and non-medical (technical complications, missed lesions, lesion inaccessibility) complications. Non specific complications were indicated in 52/9037 cases and terminated intervention was indicated in 19/9037 cases without stating medical or technical grounds. These 71/9037 cases were therefore not included in the evaluation of the complication rate. The various vacuum biopsy methods were distributed among these 71 cases as follows: 4/548 were MRI-guided, 32/5340 were performed with a
stereotaxis table, 20/564 with the use of a stereotactic "upright" device and 15/2585 were sonographically guided.

The distribution of the complication rate and the comparison between MRI an the other VAB modalities is shown in figure 6. We highlight, that there was not one single case with the need for open revision by MRI-guided VAB.

The histology of the vacuum assisted biopsy

The histological result of the vacuum assisted biopsy was specified as "other" in 175/9037 (2%) (21 MRI-guided, 82 stereotactically and 72 sonographically guided), so that a distinction between malignant, "high risk" or benign histology was impossible. These data were therefore not included in the analysis of the malignancy rate. Thus, vacuum biopsy histologies were available for 527/548 of the MRI-guided cases, for 5822/5904 of the stereotactic and for 2513/2585 of the sonographic cases.

For the entire study population, vacuum assisted biopsy revealed malignant lesions in 1853/8862 (21%) cases, benign lesions in 5524/8862 (62%) cases and high-risk lesions 1485/8862 (17%). For the entire study population, MRI-guided vacuum biopsy revealed malignancies in 137/527 (26%) cases, benign lesions in 283/527 (54%) cases and high-risk lesions in 107/527 (20%) cases. Stereotactic VAB revealed a malignancy rate of 24% (1408/5822). Stereotactic VAB revealed benign lesions in 3407/5822 (59%) cases and high-risk lesions in 1007/5822 (17%) cases. Sonographic VAB verified malignant lesions in 308/2513 (12%) cases, benign lesions in 1834/2513 (73%) cases and high-risk lesions in 371/2513 (15%) cases.

Histology of a subsequent surgical excision

Of the 8862 findings clarified via vacuum assisted biopsy with known histological results, a total of 2434 (27%) lesions were further clarified via subsequent surgery, whereby a histological result of the surgery was likewise available. No histological result for the surgery was available in 131 cases, so that these were not included in the analysis. Ninety percent (1660/1853) of the malignant lesions, 5% (255/5524) of the benign lesions and 35% (519/1485) of the high-risk or B3 lesions were surgically excised.

The operationquote dependent on the histological result of the VAB by the different VAB-procedures and also the upgrade rate from a benign or high risk VAB-result to a malignoma by surgical excision is show in Figure 7.
Fig. 3: Development VAB 2009-2011; a) all procedures: 2009-2010 increase 12%, 2010-2011 decrease 10 %; b) MRI-guided VAB: 2009-2010 increase 49%, 2010-2011 increase 32%; c) Stereotactic-guided (by table) VAB: 2009-2010 increase 18%, 2010-2011 decrease 6%; d) Stereotactic-guided (by "upright") VAB: 2009-2010 increase 5%, 2010-2011 decrease 3%; e) Sonographic-guided VAB: 2009-2010 increase 0.4%, 2010-2011 decrease 31%
**Fig. 4:** Family History * No significant difference to MRI (p=0.23) ** Significantly lower than MRI (p< 0.001)
Fig. 5: Carcinoma history * Significantly lower than MRI (p < 0.001)

Fig. 6: Complication rate: * Total complication rate: No significant difference to MRI (p=0.08) ** Total complication rate: No significant difference to MRI (p=0.02) *** Total complication rate: Significantly lower than MRI (p < 0.001)
Fig. 7: VAB results in correlation to subsequent open biopsy
Conclusion

The study showed that the total number of image-guided vacuum biopsies in Switzerland remained mostly constant throughout the study period with an overall growth rate of 2%, whereby the number of MRI-guided VAB rose significantly by 97%. The growth rate for the procedure using a stereotaxis table was 14%. The growth rates for the procedures using an "upright" device and sonography declined by 1% and 31% respectively.

The total complication rate for MRI-guided VAB (8%) showed no significant difference from the rates for the procedure using a stereotaxis table (6%) (p=0.08) and the procedure using an "upright" device (5%) (p=0.02). The total complication rate for the MRI-guided procedure is significantly higher (p<0.001) compared to the sonographic procedure (4%). The majority of the complications for MRI-guided VAB consisted of haemorrhages not requiring intervention (7%). Non-medical complications occurred 1% of the cases. The total complication rate of MRI-guided VAB lies within the range of complication rates published in the literature (2-14%) [4-8,12].

With regard to a positive family history, there is no significant difference between the MRI-guided procedure and the stereotactic procedure (p=0.23). The significantly higher difference (p<0.001) with regard to a positive family history in MRI-guided VAB compared to sonographic VAB can be explained by the fact that no distinction was made between a therapeutic and diagnostic approach to vacuum biopsy and that sonographic VAB is also performed as a treatment for confirmed benign lesions. This results in a different composition of the patient population for these two methods. The lack of a significant difference in family history between the MRI-guided and stereotactic procedure shows that MRI has as yet not been established in Switzerland as a screening method for high-risk patients as recommended in some of the literature [9].

The significantly larger difference in the positive personal carcinoma history for a breast carcinoma in MRI-guided procedures when compared to the stereotactic (p<0.001) or the sonographic (p<0.001) procedures can be explained by the indication of the diagnostic MRI, as this examination is indicated, among others, as a screening method to assess additional ipsilateral carcinomas and contralateral extension in newly diagnosed breast carcinomas, to determine the spread of the disease and for post-examination purposes and the resulting "selection bias" [9].

The malignancy rate after MRI-guided VAB was 26%; there was no significant difference (p=0.35) compared to that of stereotactic VAB (24%). The malignancy rate of sonographically guided VAB was 12% and was therefore significantly (p<0.001) lower compared with the MRI-guided procedure. This is due to the lack of distinction
between diagnostic and therapeutic sonographic vacuum biopsy as mentioned above. The malignancy rate of MRI-guided VAB corresponds with the malignancy rates of 22-33% from the literature [6,7,10-13].

A limiting factor of this study is that the data was recorded by the individual MIBB centres in Switzerland, making errors in data input conceivable. This was particularly conspicuous in the histological results, as conflicting information was found. Due to the anonymised data situation, elimination of errors by viewing the original findings is not possible. On the other hand, the large number of participating centres resulted in the availability of a very large volume of data on which this study was based, which provides an advantage over other studies with partly significantly smaller case numbers.

In summary MRI-guided VAB is a safe and specific procedure has the largest growth rate in Switzerland and is the method of choice for ambiguous breast findings which can only be defined by the use of MRI.

References


**Personal Information**