Vacuum-assisted Breast Biopsy: More Cores, More Hematomas?

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Abstract. Background: Vacuum-assisted breast biopsy (VABB) is used for the diagnosis of non-palpable breast lesions. Hematoma has been recognized as the main complication of the procedure. Its main disadvantage is the underestimation rate. Generally speaking, approximately up to 24 cores are excised in most published series. It has been suggested that excision of more cores per lesion can reduce the underestimation rate. The present study aims to evaluate hematoma formation with regard to the number of cores excised. Patients and Methods: A total of 660 women underwent VABB; 232 women were allocated to the standard protocol (24-36 cores excised, 2-3 offsets) and 428 women were allocated to the extended protocol (96 cores excised, 8 offsets). Cases were derived from a double blind study, as well as from the periods before (standard protocol) and after (mainly extended protocol) the study. In all cases, the occurrence of organized hematomas within the subsequent 20 days was followed up by ultrasound. Results: In the standard protocol, the frequency of clinically significant and subsequently organized hematomas was 3.5%. However, in the extended protocol the respective hematoma percentage was 7.5%. Clinically significant and subsequently organized hematomas were significantly more frequent in the extended chi-squared=4.29, protocol (Pearson's p=0.038). Conclusion: Despite the superiority of the extended protocol in terms of underestimation, the approximately two-fold increase in hematoma occurrence prompts the need for careful patient selection prior to its performance.

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Vacuum-assisted breast biopsy (VABB) is a promising method for the diagnosis of non-palpable breast lesions, with ever-growing use in common clinical practice. The main disadvantage of the method is the underestimation of atypical ductal hyperplasia, lobular neoplasia and ductal carcinoma *in situ*.

Up to 24 cores are excised in most published series on VABB. Despite controversial reports (1), it has been suggested that excision of more cores per lesion can reduce the underestimation rate (2). Indeed, an 'extended protocol' comprising 96 cores has demonstrated promising results in regard to underestimation (3).

Hematoma has been recognized as the main complication of this procedure in various settings; the incidence of mammographically evident hematoma has been shown to reach as much as 45% (4-8). Although the majority of hematomas seem not to necessitate further intervention, the clinical significance of the existing studies remains somehow obscure due to the variability in the criteria adopted (5-8). Given that VABB is performed in the outpatient setting and women are discharged from the hospital within one hour after biopsy, knowledge about the progression of hematoma is an important issue. To our knowledge however, there are no studies focusing specifically on hematoma formation and progression. The present study aims to evaluate hematoma formation with regard to the number of cores excised.

Patients and Methods

The material of this study consisted of 660 women with a median age of 52 (range 31-76) years, on whom VABB was performed for non-palpable mammographic lesions (BI-RADS 4).

VABB was performed on a digital prone table (Mammotest, Fischer Imaging, Denver, CO, USA) using 11-gauge Mammotome vacuum probes, under local anesthesia. A total of 232 women were allocated to the standard protocol (24-36 cores excised, 2-3 offsets) and 428 women were allocated to the extended protocol (96 cores excised, 8 offsets). Cases were derived from a double blind study

(3), as well as from the periods before (standard protocol) and after (mainly extended protocol) the study. After VABB, mammograms were obtained from the women's breasts. In all cases, the occurrence of organized hematomas within the subsequent 20 days was followed up by Ultrasound.

The incidence of clinically significant and subsequently organized hematomas was monitored in both protocols. The binomial 95% confidence intervals were calculated. Pearson's chi-square was performed for the evaluation of the discrepancy in hematoma incidence between the two protocols. Statistical analysis was performed with STATA 8.0 statistical software (Stata Corporation, College Station, TX, USA).

Permission has been obtained from the local Institutional Review Board for publication of the findings summarized in this study.

Results

In the standard protocol, the frequency of clinically significant and subsequently organized hematomas was 3.5% (8/232, 95% CI: 1.5%-6.7%). However, in the extended protocol, the respective hematoma percentage was 7.5% (32/428, 95% CI: 5.2%-10.4%). Clinically significant and subsequently organized hematomas were more frequent in patients who underwent the extended protocol (Pearson's chi-square=4.29, p=0.038).

Discussion

Despite the superiority of the extended protocol in terms of underestimation, the approximately two-fold increase in hematoma occurrence prompts the need for careful patient selection prior to its performance. Although previous results had not documented a significant difference, the larger sample size of the present study permitted the documentation of this noteworthy drawback (3).

This finding is in line with our observation that the extended protocol, with more cores and greater tissue volume excised, is associated with increased frequency of scars (9). However, as mentioned above, the majority of hematomas do not need surgical intervention (5-8). However, after the adoption of extended protocols with the higher possibility of hematoma formation and the potential of organization, pressure on the affected breast by an elastic adhesive bandage may be useful for a longer than usual interval. A closer follow-up may also be needed to assess whether drainage should be performed. Additionally, a Fogarty catheter to limit hemorrhage has also been proposed in the literature (10-11).

Furthermore, since hematoma is a rather underinvestigated issue in the context of VABB, additional associated factors may be implicated. Importantly, as experience accumulates, it is tempting to anticipate a list of clinical and radiological/morphological indications, the presence of which will point to the necessity for an extended protocol in place of a standard one.

Although minimization of underestimation is desirable, the decision relating to the most suitable protocol should not neglect hematoma formation. Indeed, underestimation and hematoma formation represent two constituents of a fine balance.

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Competing interest

The authors declare that they have no competing interests.

Authors' contributions

FZ: conceived the idea, participated in the design of the study and assisted in the writing of the manuscript; AG: assisted in the writing of the manuscript, participated in the design of the study and reviewed critically the manuscript; PL: performed vacuum-assisted breast biopsy and open surgery and assisted in the writing of the manuscript; DC: performed vacuum-assisted breast biopsy and open surgery; IF: performed vacuum-assisted breast biopsy and open surgery; GB: assisted in the writing of the manuscript and performed vacuum-assisted breast biopsy; GG: performed vacuumassisted breast biopsy and the radiological evaluation of the lesions; NM: performed vacuum-assisted breast biopsy and open surgery; PS: performed vacuum-assisted breast biopsy and open surgery; GZ: participated in the design of the study, performed vacuum-assisted breast biopsy and open surgery, evaluated critically the manuscript and gave the final approval for the manuscript to be published; TS: conceived the idea, participated in the design of the study, performed the statistical analysis, assisted in the writing of the manuscript and evaluated critically the manuscript

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