
Use of Saline Lavage to Reduce Hematoma Rate During Vacuum-Assisted Breast Biopsy: A Multi-Disciplinary Approach

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Introduction

Over the years, minimally invasive breast biopsy has become the gold standard method for diagnosing breast abnormalities. Minimally invasive procedures like vacuum-assisted breast biopsy (VABB) decrease costs, reduce the risk of complications and lead to fewer potentially adverse cosmetic results compared to open surgical biopsy.

While the goal of a minimally invasive biopsy procedure – in addition to providing an accurate assessment of the lesion – is to minimize trauma to the breast and the patient, there are still complications that can occur. Aside from post-procedural pain and infection, the most significant concern associated with VABB procedures is hematoma formation. With any VABB device, bleeding is a known complication, regardless of physician skill-level or device type. However, continued and excessive bleeding often leads to the occurrence of a hematoma, which can negatively impact both patients and physicians during and after the procedure. The incidence of mammographically evident hematoma as a result of VABB has been shown to reach as much as 45 percent¹.

The formation of a hematoma during the procedure can obstruct visualization of the lesion, preventing physicians from obtaining adequate samples for pathological assessment. If a post-procedural hematoma does not reabsorb, it can also cause distortion on subsequent follow-up mammograms, making it difficult for physicians to accurately assess the patient's condition. For patients, hematomas can be painful and distressing. When a hematoma persists, creating a palpable lump, it often contributes to increased anxiety and mental stress for patients who believe their abnormality is growing. Hematomas can also lead to an increased risk of infection or, in rare cases, chronic seroma.

If surgical intervention is required based on the biopsy results, the presence of a hematoma may delay subsequent treatment. Depending on the size of the hematoma, physicians may choose to wait until the hematoma is resolved prior to proceeding with definitive breast cancer surgery. On average, a hematoma can take between 2-8 weeks to reabsorb, which causes a significant delay in treatment.

The purpose of this study is to examine the use of a VABB device that combines constant aspiration with saline lavage capabilities and whether such features decrease the rate of hematoma formation.

ATEC® Breast Biopsy & Excision System

With the ATEC breast biopsy and excision system, physicians have many choices for ultrasound-guided breast biopsy, from partial to complete removal of tissue of interest, to sampling of breast tissue for diagnostic review. ATEC under ultrasound-guidance is FDA-cleared for removal of benign breast tissue for diagnostic sampling.

The fully-closed system produces samples every 4.5 seconds and enables continuous delivery of anesthetic to the biopsy site without interrupting the procedure. It is the only vacuum-assisted breast biopsy device that delivers saline lavage directly to the biopsy cavity. The combination of saline lavage and constant aspiration facilitates high-quality tissue samples with every cycle.

Materials & Methods

Over a five-month period (June-October 2010), ultrasound-guided, vacuum-assisted breast biopsy procedures were performed with the ATEC 9-gauge needle on a total of 110 patients at Breast Care Specialists (Columbus, OH) and Magee Women's Hospital of Cranberry (Cranberry Township, PA). If bleeding occurred during the procedure, physicians lavaged and aspirated the cavity until active bleeding stopped. Follow-up ultrasounds were performed on all patients within 7-14 days of the biopsy to assess hematoma formation.

The following data was recorded for each patient: size/type of lesion, hematoma formation during procedure, size of hematoma (if applicable), length of time for lavage, duration of compression held at the biopsy site, follow-up time period, and follow-up ultrasound findings.

“As a physician, it’s important to recognize that you will frequently encounter bleeding during VABB, but when a hematoma develops it can be painful and distressing for the woman. If we can minimize trauma to the breast and prevent hematoma formation, we will improve the biopsy experience for patients.”

-Dr. Han

Results

Physicians acquired an average of 6.8 core samples. Length of lavage ranged from 0 to 180 seconds, while the duration of compression at the incision site spanned 5 to 11+ minutes. Bleeding during the procedure was noted in 50 (45.5 percent) of the 110 patients studied and all were subjected to saline lavage (Figure 1). Most bleeding that occurred was minor but in 5 patients was significant enough that longer lavage was required to control and evacuate the hematoma. Follow-up ultrasound findings indicated the presence of hematoma in 28 patients (25.5 percent) (Figure 2). Of those 28 patients, 9 had undergone vacuum-assisted excisions, in which the entire lesion was removed using the ATEC under ultrasound-guidance. The average number of cores in these patients was 8.0. The hematomas ranged in size from 0.9 cm to 6 cm with an average size of 2 cm. The physicians noted that none of the patients requiring subsequent intervention experienced a delay in treatment as a result of hematoma formation.

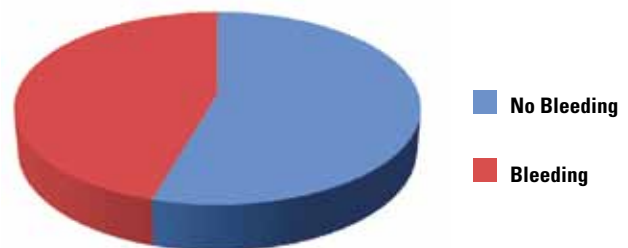


Figure 1. Bleeding During Procedure.

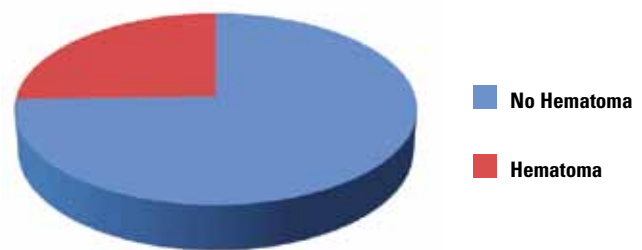


Figure 2. Post Biopsy Hematoma Formation.

“When comparing the ATEC to other biopsy devices, I noticed the saline lavage led to a decrease in the overall length of active bleeding during the procedure, which can contribute to a reduction in the hematoma rate.”

-Dr. Gizienski

Discussion

Based on the study, physicians noted a marked reduction in the post-biopsy hematoma rate using the ATEC compared to previous anecdotal experience with other VABB devices. When hematoma formation did occur, physicians observed a decrease in the overall size of the hematomas compared to prior experience with other biopsy devices.

In comparison to published literature, which shows an incidence of hematoma associated with VABB of up to 45¹ percent, the physicians noted a reduced rate of hematoma formation of 25% as well as a reduction in the average size of hematoma. The reduced hematoma rate can be attributed to the use of saline lavage with the ATEC system. With any VABB device, the aspiration enables physicians to evacuate blood from the biopsy cavity as it forms. However, physicians observed the addition of saline lavage led to a decrease in the overall amount of continued bleeding. When hemorrhaging occurred, physicians were able to direct the aperture of the biopsy device to the site of the bleeding and utilize the saline lavage and aspiration. This produces a tamponade effect, exerting force on the vessel to stop the bleeding (Figures 3 and 4).

Based on previous experience, physicians have noticed a positive correlation between the amount of bleeding and the probability of developing a hematoma. With the ability to not only evacuate blood from the cavity but also stop the bleeding sooner, the use of saline lavage and aspiration contributed to less overall hematoma formation, or when hematomas did form, to a decrease in overall size. In addition, the combination of saline lavage and aspiration evacuates blood and helps collapse the biopsy cavity, further reducing the opportunity for a hematoma to form.

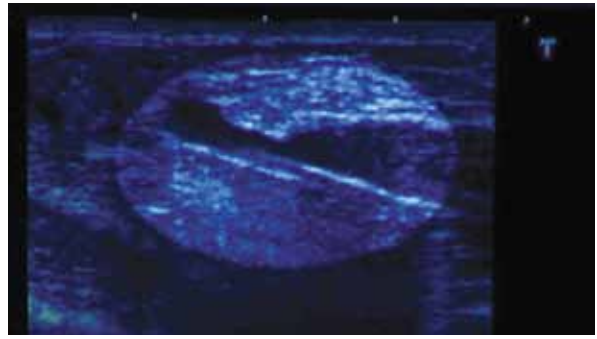


Figure 3. Active Bleeding During an Ultrasound-guided Breast Biopsy with ATEC

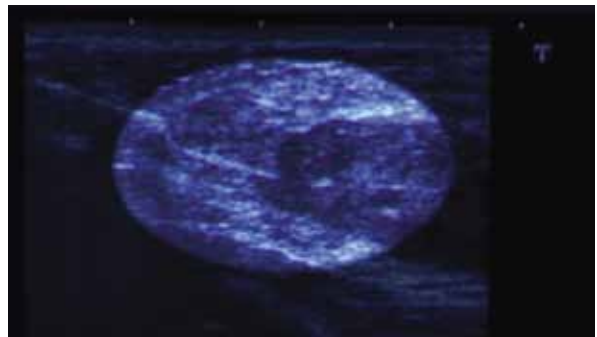


Figure 4. Biopsy Cavity Following Saline Lavage.

Conclusion

The use of saline lavage during vacuum-assisted breast biopsies reduces the post-biopsy hematoma rate. When a hematoma develops, it can be painful and often results in a palpable mass, which leads to significant emotional stress for the patient. In addition, the presence of a hematoma may require physicians to postpone subsequent treatment until the hematoma is resolved. Minimizing the hematoma rate will improve the patient experience during and after minimally invasive biopsy procedures. Most importantly, if a hematoma does not develop, there is no delay in subsequent treatment if surgical intervention is required.

“Based on experience and the data collected, the hematoma formation appears to be significantly less, which can be attributed to the use of saline lavage with the ATEC device.”

-Dr. Han

Dr. Han is a board-certified surgeon specializing in the prevention and treatment of benign and malignant breast diseases. Her practice, Breast Care Specialists, Inc., is dedicated exclusively to the treatment of breast-related problems and breast health issues. Dr. Han received her medical degree from Indiana University and completed her surgical residency at The Ohio State University. She is currently an attending surgeon and Medical Advisor for Breast Services at Mount Carmel St. Ann's Hospital in Westerville, Ohio. Dr Han is actively involved in clinical trials sponsored by the American College of Surgeons Oncology Group, the National Cancer Institute and the Columbus Community Oncology Program. Dr. Han is a consultant to Hologic, Inc.

Dr. Gizienski is the Director of Breast Imaging and Clinical Assistant Professor of Radiology at the University of Pittsburgh Medical Center Passavant and UPMC Passavant Cranberry. She received her medical degree from Pennsylvania State University and completed her residency, as well as a fellowship in mammography, at the University of Virginia. She has published scientific papers on digital mammography, breast ultrasound and sentinel node biopsy in breast cancer staging. Dr. Gizienski was an individual contributor to this paper.

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