Vacuum Assisted Excision (VAE): A single-step approach to the diagnosis and percutaneous treatment of Early Breast Cancer (THE VAE BReast 01 TRIAL)

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Introduction

Vacuum-assisted excision (VAE) of breast lesions is a technique used for diagnostic and therapeutic purposes and is performed on an outpatient basis, with local anesthesia and image guidance. Currently, VAE is used in the management of benign lesions and lesions of uncertain malignant potential (B3 lesions). More recently, there has been interest in VAE for the percutaneous treatment of small breast cancers, the aim of which was to reduce morbidity and aggressive surgical treatment. Due to how conventional VAE is performed, histopathological assessment of the resection margins is not possible. Obtaining free margins after a breast cancer resection is a primary objective in the surgical treatment of this disease. If VAE could ensure free margins and the absence of residual tumor in the surgical excision, it would represent a safe method for a minimally invasive treatment, providing an effective percutaneous treatment of small early breast cancers.

Methods and Materials

The prospective VAE-BREAST 01 study explores the role of VAE associated with cavity margin sample shaving (CMSH) as a one-step approach in the diagnosis and complete excision of small breast tumors, ensuring the absence of residual disease in surgical pathology. Women with lesions smaller than 1.5 cm, ACR BI-RADS™ (American College of Radiology Breast Imaging Reporting and Data System) category 4 or 5, and identified by screening or clinical alteration are included. Multifocal, multicentric breast cancers and breast cancers associated with diffuse and extensive calcifications are excluded. The sensitivity, specificity, accuracy, positive predictive value, negative predictive value, and the false-negative and false-positive rates of VAE+CMSH for the complete excision of breast cancers will be calculated. The collected data also will include patients' demographics, image characteristics of the lesions, information regarding the VAE+CMSH and surgical procedure, biopsy and surgical pathology, and data on side effects, patient acceptance, cosmetic results, and patients' experiences during VAE.

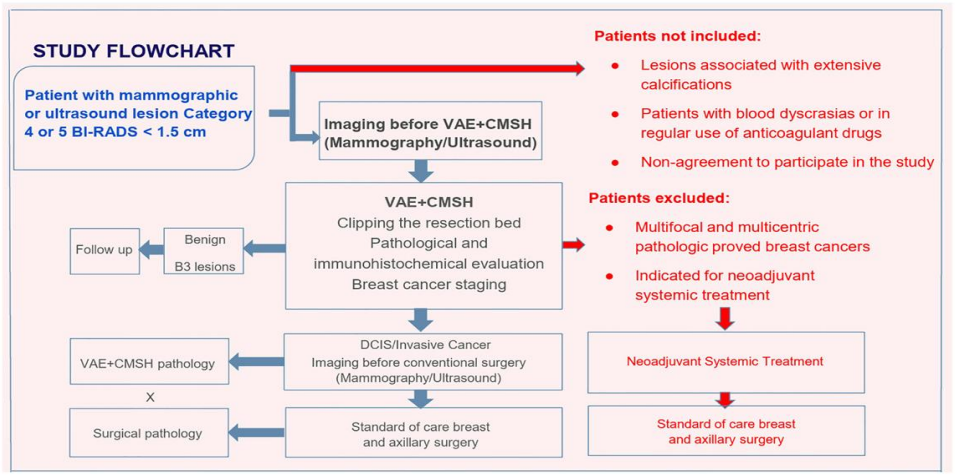


FIGURE 1
Study flowchart. *VAE*, vacuum-assisted excision; *CMSH*, cavity margin sample shaving; *B3 lesions*, lesions of uncertain malignant potential in core needle biopsy; *DCIS*, ductal carcinoma *in situ*.

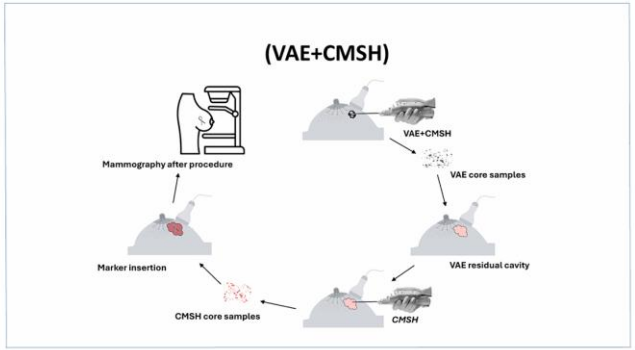


FIGURE 2
Standard protocol of vacuum-assisted excision (VAE) and cavity margin sample shaving (CMSH).

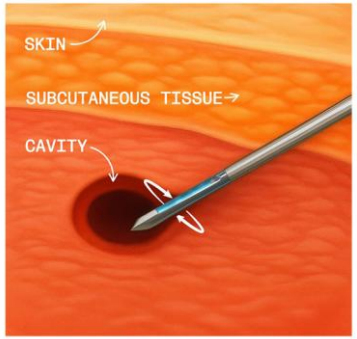


FIGURE 3
Cavity margin sample shaving (CMSH).

Conclusions

This trial design will provide an opportunity to standardize VAE associated with the CMSH procedure, as well as will evaluate its efficacy in achieving complete excision with clear margins in small breast cancers and other breast lesions ≤1.5 cm. The results of this trial will be crucial for advancing the de-escalation of breast cancer treatment.

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