PharmacoEconomics - Open
https://doi.org/10.1007/s41669-026-00663-w

ORIGINAL RESEARCH ARTICLE

Budget Impact Analysis of Vacuum-Assisted Excision Versus Surgical Excision for the Assessment of Breast Lesions of Uncertain Malignant Potential in Italy

Carla Rognoni[1] · Ludovico Cavallaro[1] · Gaia Grassi[1] · Francesca Caumo[2,3] · Catherine Depretto[4] · Secondo Folli[4] · Salvatore Minelli[5] · Modestino Pezzella[6] · Nicola Rocco[7] · Valeria Romeo[7] · Anna Russo[6] · Gianfranco Scaperrotta[4] · Rosanna Tarricone[1,8]

Received: 29 November 2025 / Accepted: 22 May 2026

Abstract

Background/Objective B3 breast lesions, of uncertain malignant potential, pose diagnostic challenges owing to their intermediate malignancy risk. While surgical excision (SE) is traditionally used for definitive diagnosis, vacuum-assisted excision (VAE) offers a less invasive alternative. As diagnostic practices evolve, this study assesses the financial impact of adopting VAE for B3 lesion management from the hospital perspective within the Italian healthcare system.

Materials and Methods A budget impact analysis (BIA) was conducted from the hospital perspective over a 5-year time horizon. Clinical complication rates for SE and VAE were derived through a systematic literature review and meta-analysis. A micro-costing approach was used to estimate direct medical costs on the basis of detailed resource utilization data collected via structured questionnaires administered across five Italian hospitals. One-way sensitivity analyses and scenario analyses were conducted to test the robustness of the results.

Results VAE was associated with significantly lower costs than SE, mainly owing to reduced hospitalization, operating room use, and personnel time. The average per-patient cost was €820 for VAE versus €1663 for SE, yielding savings of €843. Over 5 years, with VAE adoption rising from 20% to 80%, cumulative hospital savings were estimated to be between €11.1 million and €13.7 million. These findings were further confirmed by multiple budget impact scenario analyses, which consistently demonstrated a favorable economic profile for VAE across all tested assumptions.

Conclusions In our analysis, VAE represented a cost-saving, minimally invasive alternative to SE for the management of B3 breast lesions from the hospital perspective in Italy. Its adoption can enhance hospital efficiency and support more sustainable resource allocation within the Italian healthcare system.

1 Introduction

Breast cancer remains the most frequently diagnosed malignancy among women worldwide, with an estimated 2.3 million new cases and approximately 670,000 deaths reported globally in 2022 [1]. The incidence is steadily increasing, particularly among women over 50 years, with a peak occurrence in peri and post-menopausal individuals [2]. However, recognizing malignancies in younger women is crucial, as they may sometimes be misdiagnosed as benign conditions, such as fibroadenomas, which are common in women aged 20–30 years [3]. These tumors often display aggressive biological behavior and are frequently linked to hereditary predisposition.

Key Points for Decision Makers

A 5-year budget impact analysis conducted from the hospital perspective in Italy showed that vacuum-assisted excision (VAE) is likely to be a cost-saving alternative to surgical excision (SE) for the management of B3 breast lesions in selected clinical cases within breast units, with per-patient savings of approximately €843.

Increasing the adoption of VAE from 20% to 80% was projected to generate cumulative hospital savings of €11.1–13.7 million over 5 years, improving resource allocation within the Italian healthcare system.

Sensitivity and scenario analyses confirmed that the economic advantage of VAE over SE remained robust across a wide range of assumptions, supporting its relevance for decision-making under uncertainty.

Extended author information available on the last page of the article

Published online: 09 June 2026

In Italy, breast cancer is also the most commonly diagnosed malignancy among women after skin cancer, representing around 30% of all female malignancies. Approximately 800,000 women in Italy are living with a breast cancer diagnosis, accounting for 44% of all female cancer survivors. In 2016, it was the leading cause of cancer-related death among Italian women, with over 12,000 deaths, though mortality has been steadily declining, especially in women under 50 years [4]. The 5-year and 10-year survival rates are 87% and 80%, respectively, reflecting improvements in early detection and treatment [4].

The economic impact of breast cancer on social systems is considerable. Direct costs include diagnostics, surgical interventions, chemotherapy, and radiotherapy, while indirect costs, such as lost productivity and caregiving responsibilities, exacerbate financial strain. Although advances in early detection and treatment have improved survival rates, the economic and social burden remains a major challenge worldwide. In Italy, annual hospitalizations exceed 75,000 cases, costing the healthcare system around €300 million, with an estimated total societal burden of €257 million per year [5].

A strategic focus on early diagnosis and appropriate technology use can reduce mortality while managing the economic burden, aligning with a sustainable and equitable approach to breast cancer care.

Advances in molecular and genetic profiling have further refined tumor classification, facilitating more precise diagnosis and treatment strategies. Mammography remains the primary screening tool for breast cancer. A negative result allows patients to continue regular screening, whereas a positive finding necessitates further evaluation. Histopathological evaluation is essential for confirming malignancy and follows the following standardized categorization [6]: B1—normal or inadequate sample, B2—benign lesion, B3—lesion of uncertain malignant potential, B4—suspicious for malignancy, and B5—malignant neoplastic lesion.

With the increased ability of diagnostic imaging in identifying small breast lesions, also thanks to the even wider availability of contrast-enhanced examinations (i.e., magnetic resonance imaging [MRI] and contrast enhanced mammography [CEM]) and the possibility to perform MRI and CEM-guided biopsy, the occurrence of B3 histological findings has become more frequent in the clinical practice [7].

B3 lesions include atypical ductal hyperplasia, radial scars, papilloma, and some benign phyllodes tumors. These lesions carry an intermediate malignancy risk, requiring vigilant monitoring or biopsy for a definitive diagnosis. Comprehensive breast cancer diagnosis combines imaging techniques with histopathological analysis of biopsied tissue. Biopsy techniques include fine needle aspiration cytology, core needle biopsy, and vacuum-assisted breast biopsy (VABB). The latter, with a sensitivity of 98% and specificity of 99% [8], is particularly suited for investigating small or scattered microcalcifications. When VABB is performed with the intent of lesion excision, it is referred to as vacuum-assisted excision (VAE), which is frequently employed for managing B3 lesions.

For B3 lesions, where malignancy risk is uncertain, VAE offers a minimally invasive alternative to traditional surgical excision (SE) with comparable effectiveness [9–12]. VAE allows precise lesion removal with minimal tissue damage, reducing the need for more extensive surgery. European guidance [11, 13] generally reserves SE for B3 lesions with higher upgrade risk or uncertain percutaneous clearance and any discordant or large lesions not amenable to complete VAE. By contrast, VAE is typically appropriate for papilloma without atypia, radial scar without atypia, and flat epithelial atypia when imaging–pathology is concordant and complete removal is feasible. The UK screening program similarly frames VAE as second-line for most B3s rather than open biopsy [14]. However, in cases where malignancy is suspected, conventional SE remains the preferred approach to ensure clear margins and comprehensive histological assessment [15].

The aim of this study is to develop an evaluation framework to estimate the potential financial impact of introducing VAE as an alternative to SE for the management of specific breast lesions. The analysis focuses on the hospital perspective in the Italian healthcare context, aiming to inform resource allocation decisions and support the adoption of minimally invasive technologies. Financial evaluations, particularly when conducted early, can provide valuable insights into the cost implications and potential advantages of innovative technologies, even before their widespread implementation. VAE, a less invasive technique compared with SE, is associated with potential clinical and organizational benefits, such as shorter procedure time, reduced need for operating room, and quicker patient recovery. However, its adoption also depends on financial sustainability within hospital budgets.

This study aims to quantify the financial impact of VAE compared with SE in terms of direct medical costs, by assessing comprehensive clinical scenarios and care pathways. The analysis intends to support hospitals and decision-makers in evaluating whether the integration of VAE into clinical practice can lead to more efficient use of healthcare resources without compromising clinical outcomes.

2 Materials and Methods

A budget impact analysis (BIA) was carried out by developing a research protocol designed to gather data on hospital resource utilization among patients undergoing lesion

excision using the two treatment approaches: VAE and SE. To estimate the financial implications of introducing VAE, a BIA model was constructed assessing its effect on healthcare expenditures from the hospital perspective over a 5-year period in the Italian context. The analysis has been conducted in alignment with the ISPOR BIA Good Practice II principles [16] and reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) (see Supplementary Materials, CHEERS 2022 checklist) [17, 18]. The model development followed the steps described below. A conceptual diagram illustrating the BIA model development and analyses is reported in Fig. 1.

2.1 Clinical Data Collection

A systematic literature review was conducted on Pubmed scientific database to determine the incidence of complications associated with SE and VAE in the context of B3 breast lesions, using the following search query:

("breast") AND ("B3" OR "lesion*" OR "uncertain*") AND ("surgical excision" OR "vacuum-assisted excision*" OR "vacuum assisted excision*" OR "VAE") AND ("complication*" OR "adverse event*")

Eligible studies included randomized clinical trials and clinical observational (prospective or retrospective) studies reporting complication rates after VAE or SE for B3 breast lesions. Reviews, case reports, conference abstracts without full data, and nonclinical studies were excluded. The studies included in the meta-analyses were appraised to evaluate their methodological quality and identify potential biases in design, conduct, and analysis. The selection process was carried out in three stages: (1) title screening, (2) abstract review, and (3) full-text analysis.

Starting from an initial pool of 164 articles, 4 duplicates were removed. Subsequently, a title-based screening excluded 98 irrelevant articles. The remaining abstracts were then reviewed, resulting in the exclusion of an additional 14 articles. Finally, the full texts of the remaining studies were assessed in detail, and 33 more articles were excluded owing to insufficient or nonpertinent data. As a result, 15 studies were ultimately included in the meta-analysis [10, 19–32]. A visual summary of this selection process is presented in the PRISMA flow diagram [33] (Fig. 2).

From the final pool of selected studies, relevant complication frequencies were extracted and categorized for both SE and VAE (study characteristics and detailed outcome data are presented in Supplementary Table 1 for SE and in Supplementary Table 2 for VAE):

- Incomplete excision: failure to completely remove the targeted lesion, which may require additional procedures;
- Hematoma: a localized collection of blood under the skin, often causing swelling and bruising;
- Infection: bacterial contamination at the procedure site, potentially leading to redness, swelling, fever, or discharge;
- Pain: discomfort at the biopsy or excision site;
- Vasovagal reaction (VAE only): a sudden drop in heart rate and blood pressure, possibly causing fainting or dizziness during or after the procedure;
- Bleeding (VAE only): excessive or prolonged bleeding from the excision site, which may require intervention.

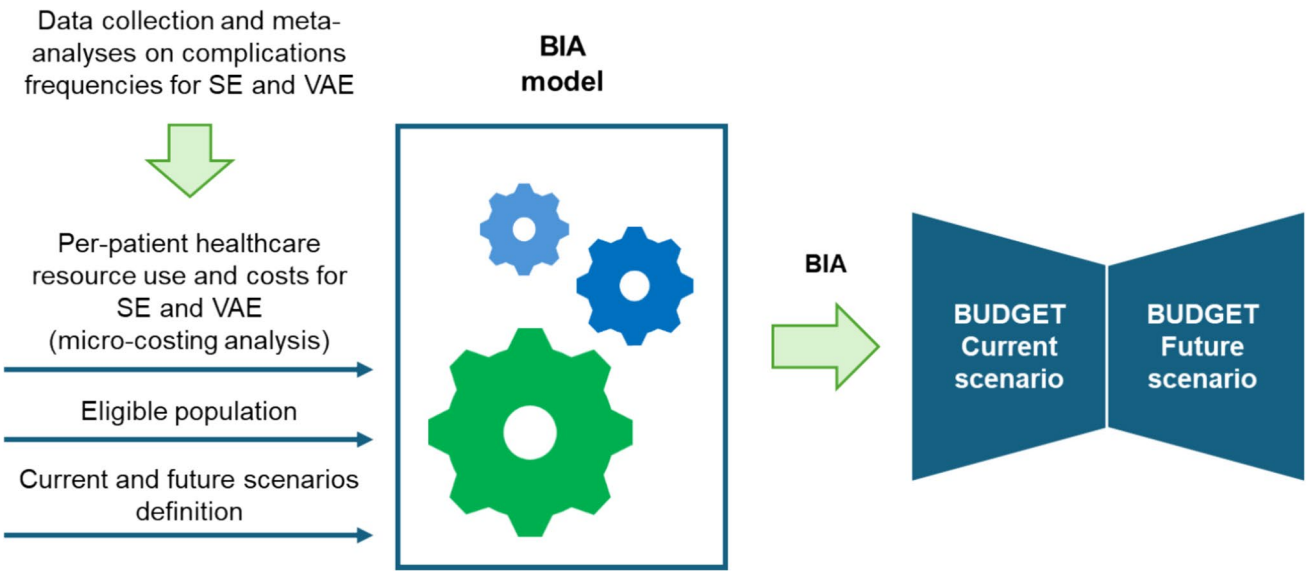

Fig. 1 Conceptual diagram illustrating the budget impact analysis (BIA) model development and analyses. *SE* surgical excision, *VAE* vacuum-assisted excision

As only one comparative study was identified and it was nonrandomized [30], pooled estimates were derived independently for each intervention group rather than through direct comparative meta-analysis. On the basis of the data extracted from the selected clinical studies, separate meta-analyses were therefore conducted on an absolute scale (percent of patients) to estimate the incidence of complications for SE and VAE. The analysis was conducted in STATA using the *metaprop* command. Table 1 presents the meta-analyses results, while forest plots are reported in the Supplementary Materials (Meta-analyses results are presented as Forest plots).

Differences in complication rates between VAE and SE were reported using 95% confidence intervals (CIs). These intervals were presented to reflect parameter uncertainty and to define plausible ranges for sensitivity analyses. Accordingly, complication rates were incorporated into the budget impact model as input parameters with their corresponding uncertainty bounds.

VAE showed lower incomplete excision rates (3.08%) compared with SE (11.22%). However, the surgical excision estimate comes from only two studies in which a high proportion of lesions (47–77%) were > 2 cm, so this comparison should be interpreted with caution. VAE is associated with higher incidence of hematoma (7.04%) and postoperative pain (16.01%), potentially owing to procedural technique and use of local rather than general anesthesia. In addition, most studies did not grade pain severity; where reported, pain was generally mild and not considered a serious complication. Infection rates are comparable for both techniques, with VAE showing a slight advantage. VAE also carries a small risk of vasovagal reactions (0.79%) and bleeding (2.43%), with variability across studies. Overall, VAE achieved better lesion clearance but was associated with higher rates of minor complications, underscoring the

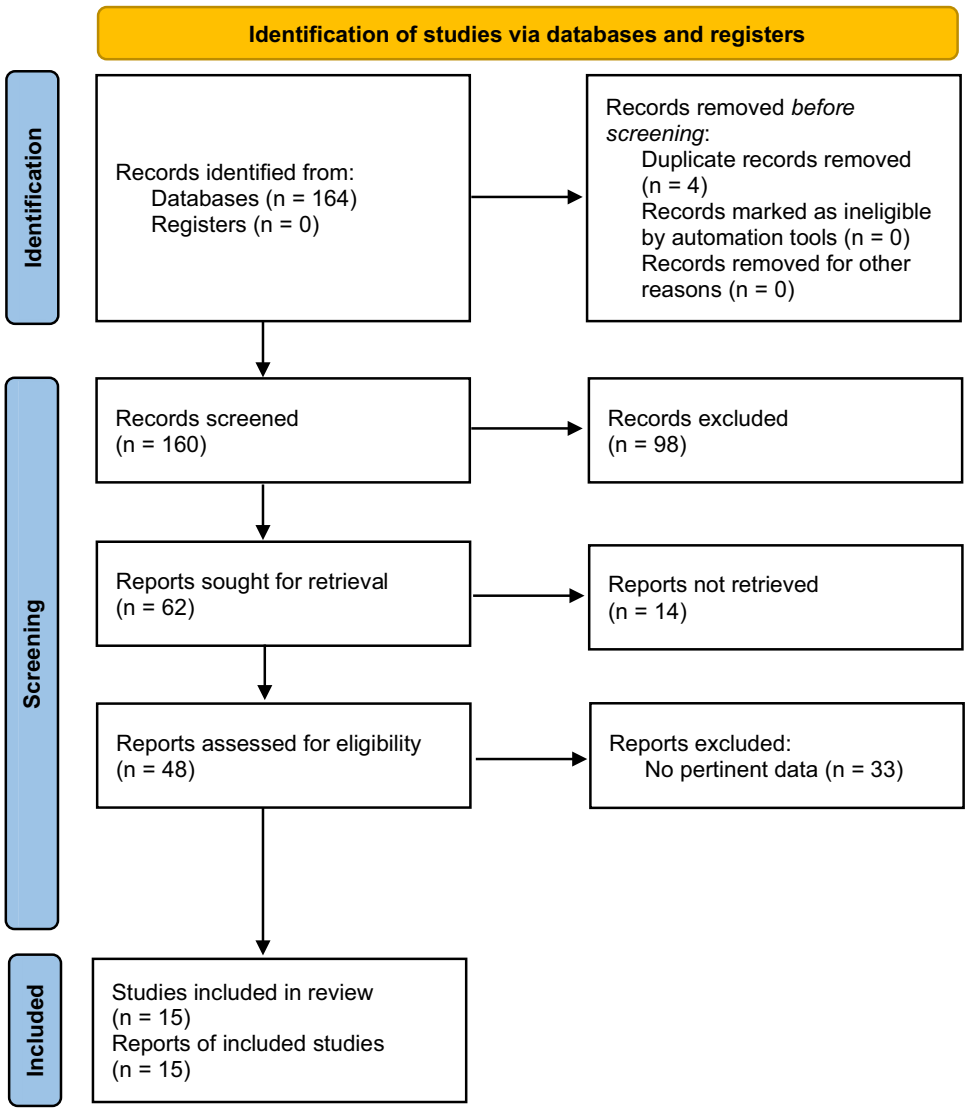

Fig. 2 PRISMA 2020 flow diagram illustrating the study selection process for the systematic review and meta-analysis

importance of careful patient selection and post-procedural monitoring. Notably, rates of bleeding, hematoma, pain, and incomplete excision demonstrated substantial variability across studies (see Supplementary Materials, Meta-analyses results, Forest plots), likely reflecting differences in lesion characteristics, operator experience, and outcome reporting standards.

Considering the observational nature of the included studies, the risk of bias was assessed using the ROBINS-I tool [34], which evaluates bias in nonrandomized studies across seven domains: confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of the reported result. The results of this assessment are presented in Supplementary Table 3. The overall quality of the evidence was judged mainly as moderate across the included observational studies. The main sources of bias were related to structural confounding inherent to their design. Specifically, the nonrandomized comparative study [30] allocated treatment on the basis of patient preference, introducing potential baseline imbalances and selection bias. Similarly, other two studies were susceptible to confounding related to temporal changes in practice patterns, operator experience, and lesion characteristics [29, 35].

2.2 Healthcare Resource Utilization and Micro-Costing Analysis

To collect real-world data on hospital resource utilization, a structured questionnaire was developed and administered to clinicians specialized in radiology and breast surgery. To enhance the national representativeness of the BIA, the finalized questionnaire was subsequently distributed to five hospitals selected for their geographic and organizational diversity across Italy: *Istituto Nazionale dei Tumori* (Milan, Lombardy—North), *IRCCS Ospedale Sacro Cuore Don Calabria* (Verona, Veneto—North-East), *Istituto Oncologico Veneto* (Padua, Veneto—North-East), *Federico II University Hospital* (Naples, Campania—South), and *AORN Antonio Cardarelli* (Naples, Campania—South). These institutions were chosen as representative centers (performing 60–70 VAE procedures per year) to capture regional differences in clinical practice and hospital resource use, thereby improving the general applicability of results to the Italian healthcare context.

Table 1 Summary of meta-analyses comparing the incidence of complications between vacuum-assisted excision (VAE) and surgical excision (SE) for B3 breast lesions

Outcome	% Patients VAE (95% CI)	% Patients SE (95% CI)
Incomplete excision	3.08% (1.08–5.80%)	11.22% (6.17–17.41%)
Hematoma	7.04% (3.38–10.99%)	0.18% (0.00–2.32%)
Infection	0.00% (0.00–0.21%)	1.28% (0.00–4.42%)
Pain	16.01% (5.86–29.39%)	1.06% (0.03–5.79%)
Vasovagal reaction	0.79% (0.43–1.33%)	–
Bleeding	2.43% (0.25–6.05%)	–

VAE vacuum-assisted excision, *SE* surgical excision, *95% CI* 95% confidence interval

The questionnaire was designed following a micro-costing approach, which involves the detailed identification and quantification of all individual components of healthcare resource consumption. This method allows for a more precise estimation of costs by capturing granular data, rather than relying on aggregate or average figures. The development of the questionnaire was conducted under the clinical supervision of several physicians, to ensure the accuracy and relevance of the items from a clinical perspective.

The questionnaire was introduced with an explanatory note, clarifying the scope and purpose of the research and the intended use of the collected data. Clinicians were asked to report on the standard care pathway for a typical patient diagnosed with a B3 breast lesion, based on their personal clinical experience. Specifically, the questionnaire collected data on four key domains: healthcare personnel, visits, materials, and pharmaceuticals. In particular, the types and number of clinical visits, diagnostic exams, and healthcare personnel involved, including the time spent by each healthcare professional category (specialist physician, nurse, radiology technician). In addition, respondents were asked to specify the materials used, the proportion of patients receiving each material, the quantities used, and the associated unit costs. The same level of detail was requested for pharmaceuticals, including the active ingredient, percentage of patients treated, dosage, and costs. For each category, the average, minimum, and maximum values were calculated to reflect variability in practice. All information was collected not only for the main procedures, VAE and SE, but also for the management of their respective complications, according to the list obtained by the literature search. For VAE, participants were asked to report the proportion of cases in which SE is subsequently performed after an incomplete excision.

The questionnaire was completed by at least one senior clinician from each institution, with multidisciplinary input provided where appropriate.

All collected data were systematically translated into monetary values to enable per-patient cost comparison and integration into the BIA model, where per-patient costs for SE and VAE served as input parameters. Specifically, the time dedicated by hospital personnel (recorded in minutes for medical specialists, nurses, and radiology technologists) was monetized using salary benchmarks published by the Italian Ministry of Economy and Finance (MEF) [36]. These salary values were adjusted for inflation to 2025 levels using

a specific ISTAT deflator coefficient, allowing the calculation of an estimated cost per minute for each professional category.

2.3 Budget Impact Analysis (BIA)

The key features of the BIA are reported below in accordance with the ISPOR Budget Impact Analysis Good Practice II principles [16].

2.3.1 Features of the Healthcare System

The Italian National Health Service (NHS) is a publicly funded, universal healthcare system that provides comprehensive coverage to all citizens and legal residents, largely free at the point of care. The NHS is financed mainly through general taxation and organized on a regional basis, meaning that Italy's 20 regions are responsible for planning and delivering healthcare services within national guidelines set by the central government. Services include primary care, hospital care, specialist visits, emergency services, and preventive care. While most essential services are covered, patients may pay modest co-payments for certain outpatient visits, diagnostic tests, and medications, with exemptions for vulnerable groups.

2.3.2 Perspective

The analysis considered the hospital perspective within the Italian NHS, therefore the budget holder is the hospital provider responsible for procedural, personnel, and hospitalization costs.

2.3.3 Use and Cost of Current and New Interventions

2.3.3.1 Eligible Population To estimate the total number of B3 lesions, the publication "*I numeri del cancro in Italia 2023*" by AIOM (Associazione Italiana di Oncologia Medica) was consulted [37]. This report indicates an incidence of about 55,900 new breast cancer diagnoses and 15,500 deaths in 2023. Specifically, according to a study conducted in the Veneto region [38], B3 lesions account for 10.5% of all biopsies performed. This would imply an estimated 5870 B3 lesions per year. This figure is conservative, considering the possibility that a single patient may present with multiple lesions, as suggested by literature data. The model considered the value of 5870 as baseline annual population to conduct the analysis.

2.3.3.2 Current Interventions In the BIA, the current scenario assumes 100% utilization of SE, reflecting the fact that VAE has thus far been limited to a small number of centers across the country.

2.3.3.3 Uptake of New Intervention and Market Effects For the future 1- to 5-year projections, VAE increasing adoption rates of 20%, 40%, 60%, 70%, and 80% of the total procedures were considered. These adoption rates were derived from a consensus among nine clinicians–three breast surgeons and six breast radiologists–from the participating breast centers. They were further informed by comparisons with international experience and reflected the expected uptake of VAE in Italian centers performing breast excisions, taking into account its clinical indications [11, 13]. The progressive increase in VAE adoption reflects realistic organizational and clinical implementation constraints, including the availability of dedicated equipment, adequately trained personnel, and structured breast units capable of integrating radiology, pathology, and follow-up pathways. Adoption is also influenced by learning curve effects, procedural capacity (e.g., dedicated slots), and the need to apply VAE selectively on the basis of imaging-pathology concordance and the feasibility of complete percutaneous lesion removal. Importantly, the assumed uptake trajectory represents a policy-driven implementation scenario designed to explore the potential budgetary consequences of gradual diffusion under structured adoption strategies, rather than a prediction or market forecast of actual future uptake.

2.3.3.4 Cost of the Current or New Intervention Mix The cost of the current and future intervention mix was estimated by multiplying the unit cost borne by the budget holder (hospital) for each intervention by the proportion of the eligible population receiving that intervention and by the total size of the eligible population. Unit costs for VAE and SE were derived using a micro-costing approach that captured all relevant resource components, including the index procedure and the management of procedure-related complications.

2.3.4 Time Horizon

A 5-year time horizon was selected in line with ISPOR BIA Good Practice guidance [16], which recommends a short- to medium-term perspective consistent with budget planning cycles. This timeframe enables the assessment of the financial impact of gradual adoption while remaining relevant for hospital-level resource allocation and investment decisions.

2.3.5 Time Dependencies and Discounting

The model enabled a comparison between the current scenario and projected future scenarios to evaluate the financial impact of increased adoption of VAE on the hospital budget. Costs were reported undiscounted, in accordance with ISPOR BIA guidance [16], as the analysis aimed to estimate the expected annual financial impact within hospital

budget cycles rather than to conduct a long-term economic valuation.

2.3.6 Choice of Computing Framework

The budget impact model was developed in Microsoft Excel. All tables and figures were generated directly from the budget impact model.

2.3.7 Uncertainty and Scenario Analysis

To examine the robustness of the model's outcomes and to identify which parameters most significantly influence the cost differential between VAE and SE, a one-way sensitivity analysis was performed. This approach is particularly relevant since, although VAE is already approved, its limited adoption means that uncertainty around some variables remains higher than it would be in a more mature stage of technology use.

To explore uncertainty related to adoption dynamics, alternative uptake scenarios were modeled, thereby reducing reliance on a single expert-based trajectory and enhancing the representation of decision uncertainty. In the first scenario, a slower linear diffusion from 20% to 40% over the 5-year horizon was assumed. In the second scenario, uptake was assumed to plateau at 60% (20% in year 1, 40% in year 2, and 60% from years 3–5).

Considering the conservative estimate of the annual number of cases treated (5870), we conducted an additional scenario analysis incorporating the maximum observed mean number of lesions per patient reported in the studies included in our meta-analysis. Specifically, the value of 2.39 derived from Yao et al. [32] was used to represent a scenario reflecting centers managing a higher burden of multifocal lesions. In this scenario, both possibilities were considered: management of multiple lesions within the same intervention session and management through separate intervention sessions. In the former case, to reflect a minimum resource-use scenario, it was assumed that additional lesions were removed during the same procedural session, using the same healthcare personnel and materials.

An additional aspect explored concerned the uncertainty surrounding the incomplete excision rate for SE, which appeared counterintuitively higher than that observed for VAE in the meta-analyses. To address this structural uncertainty, two dedicated scenario analyses were conducted by varying the SE incomplete excision parameter. Specifically, a lower-bound scenario assuming a SE incomplete excision rate of 0% and a parity scenario assuming equal incomplete excision rates for SE and VAE were evaluated.

While VAE is typically performed in an outpatient setting under local anesthesia within a radiology-based setup, SE requires a surgical environment with sterility standards, operating room availability, and a dedicated surgical–anesthesia team. The duration of post-SE hospitalization may vary across centers (day surgery versus overnight stay); however, the need for operating-theatre resources remains a structural driver of the organizational differences between the two care pathways. Recognizing that some centers may perform SE entirely in a day-surgery setting, an additional scenario analysis was conducted assuming SE without overnight hospitalization to address this organizational variability.

Finally, scenario analyses combining adoption rates and key cost drivers have been performed to strengthen decision relevance. Specifically, the following adoption trajectories were tested: (1) slower uptake (linear diffusion from 20% to 40% over the 5-year horizon), (2) a plateau at an intermediate level (20% in year 1, 40% in year 2, and 60% from years 3 to 5) and (3) the base-case trajectory (20% in year 1, 40% in year 2, 60% in year 3, 70% in year 4, and 80% in year 5). These uptake scenarios were combined with the minimum and maximum values of the two primary cost drivers identified in the deterministic sensitivity analysis. These combined scenarios allowed to assess the robustness of cumulative savings under plausible real-world conditions where both diffusion speed and procedural costs may vary simultaneously.

2.3.8 Validation

Face validity was assessed through review of the model structure, assumptions, time horizon, and cost components by the clinicians involved in the study. Technical validation was performed by systematically verifying all formulas and conducting internal consistency checks within the Excel-based cost calculator.

3 Results

3.1 Micro-Costing Analysis

The results of the micro-costing analysis, reporting per-patient costs for the index procedures, are presented in Table 2. An in-depth analysis depicting the average cost per component reveals that expenses for consumables, the needle in particular, constitute the most substantial share of the overall procedural costs for VAE (57.3%), while the most impactful shares for SE are the hospitalization (31.1%), the specialist medical services (27.3%) and the use of the operating room (19.8%). For SE, the key driver of material-related costs is the sterilization kit required for the operating theatre.

The overall cost advantage of VAE is mainly attributable to structural and organizational efficiencies, such as

the absence of hospital stay, the use of outpatient facilities rather than surgical theatres, and shorter time requirements for high-cost personnel, including breast radiologists and surgeons.

Another essential dimension of the analysis concerns the cost associated with the management of procedure-related complications (Table 3).

From a clinical perspective, the complications associated with VAE are generally mild and manageable in an outpatient setting, although the average costs are higher than those of SE owing to a greater frequency of minor events such as pain or vasovagal reactions. Infection represents the most expensive complication to manage, followed by vasovagal reaction and bleeding, although these rarely require hospitalization or invasive procedures. The cost differences observed among centers mainly reflect organizational variability, such as the optional use of follow-up ultrasound, rather than differences in clinical severity. Overall, VAE confirms a good safety and tolerability profile, with complications of minimal clinical relevance and limited economic impact.

Table 4 presents the overall comparison between per-patient costs for the two procedures, considering also the management of complications. In this case the management cost for the single complication has been weighted according to its frequency. Complication-related costs included: (1) healthcare personnel time; (2) pharmacological treatment of post-procedural events (e.g., antibiotics for infection or analgesics for pain control); (3) hospitalization costs, limited to the exceptionally rare cases requiring inpatient observation or extended care; and (4) costs associated with incomplete procedures, capturing re-intervention or repeat excision when the lesion was not fully removed during the initial procedure. In the case of incomplete VAE, questionnaire responses indicated that surgical excision (SE) is subsequently performed in 97.5% of cases.

Results are also presented according to cost components categorized as variable (directly proportional to procedure volume), semi-variable (activity-dependent but organizationally modifiable, such as operating room use and hospitalization), and fixed (capital and implementation costs, not included in the base-case model).

Given the low frequency of certain complications, a few management-related cost components are negligible (e.g., drugs, hospitalizations for the management of complications). Infection was the most expensive complication to manage after VAE, followed by vasovagal reaction and bleeding. The overall baseline analysis shows a lower total

Table 3 Results of the micro-costing analysis for the management of complications

Complications costs		Average	Minimum	Maximum
VAE	Infection	€124.42	€51.82	€269.72
	Bleeding	€91.21	€41.18	€220.29
	Hematoma	€48.04	€32.06	€76.99
	Pain	€24.42	€15.82	€48.78
	Vasovagal Reaction	€116.04	€85.72	€152.46
SE	Infection	€49.57	€20.67	€92.80
	Hematoma	€27.69	€20.81	€39.05
	Pain	€5.28	€3.62	€6.16

Average, minimum, and maximum costs associated with the management of VAE- and SE-related complications (costs refer to the management of a single event)

VAE vacuum-assisted excision, *SE* surgical excision

Table 2 Results of the micro-costing analysis (per-patient costs) for the main procedure

Procedure costs	Minimum VAE (% of total)	Average VAE (% of total)	Maximum VAE (% of total)	Minimum SE (% of total)	Average SE (% of total)	Maximum SE (% of total)
Specialist medical services	€76.76 (17.5%)	€118.98 (15.6%)	€189.12 (16.4%)	€400.49 (35.2%)	€407.44 (27.3%)	€439.43 (24.1%)
Nursing services	€3.01 (0.7%)	€17.40 (2.3%)	€62.42 (5.4%)	€31.38 (2.8%)	€36.58 (2.4%)	€40.63 (2.2%)
Radiologic technologist services	€7.23 (1.6%)	€14.49 (1.9%)	€32.77 (2.8%)	€4.52 (0.4%)	€4.52 (0.3%)	€4.52 (0.2%)
Pharmaceutical ingredients	€1.43 (0.3%)	€5.77 (0.8%)	€11.10 (1.0%)	€1.59 (0.1%)	€7.80 (0.5%)	€11.71 (0.6%)
Consumables	€286.89 (65.3%)	€438.35 (57.3%)	€560.76 (48.6%)	€76.45 (6.7%)	€128.92 (8.6%)	€140.76 (7.7%)
Personnel for the procedure	€45.05 (10.3%)	€72.72 (9.5%)	€121.61 (10.5%)	€99.01 (8.7%)	€147.78 (9.9%)	€183.59 (10.1%)
Ambulatory/operating room	€18.65 (4.2%)	€96.83 (12.7%)	€175.00 (15.2%)	€92.93 (8.2%)	€296.46 (19.8%)	€500.00 (27.5%)
Hospitalization	€0.00 (0.00%)	€0.00 (0.00%)	€0.00 (0.00%)	€430.33 (37.9%)	€465.17 (31.1%)	€500.00 (27.5%)
TOTAL	€439.02 (100%)	€764.54 (100%)	€1152.77 (100%)	€1136.69 (100%)	€1494.67 (100%)	€1820.63 (100%)

Breakdown of average, minimum, and maximum cost components for vacuum-assisted excision (VAE) and Surgical Excision (SE)

VAE vacuum-assisted excision, *SE* surgical excision

cost for the VAE (€820) compared with SE (€1663), with total savings of €843.

The economic difference between VAE and SE was primarily driven by variable costs for VAE (88%), whereas for SE this cost component accounted for only 54% of total costs.

Scenario analyses, reflecting inter-center variability in healthcare costs, confirmed the robustness of the model, with total savings ranging from €700 to €865 per patient across lower and upper bound assumptions.

3.2 Budget Impact Analysis (BIA)

The BIA evaluating the implementation of VAE with adoption rates ranging from 20% to 80% over a 5-year period shows that, from the hospital's perspective, cost savings can be progressively achieved. In the first year, estimated savings amount to €989,278, followed by €1,978,557 in the second year, €2,967,835 in the third, €3,462,475 in the fourth, and €3,957,114 in the fifth year. As detailed in Fig. 3, the cumulative savings over the 5-year horizon amount to a total of €13,355,259, corresponding to a saving of €455.07 per patient (with VAE utilization rates from 20% to 80%).

The main contributors to savings are the absence of hospitalization costs and reduced operating room and personnel resource use.

The BIA conducted using both minimum and maximum baseline values showed total savings of €11,092,745 and €13,714,200, respectively, corresponding to a saving per patient of €377.98 and €467.30.

The one-way sensitivity analyses are reported in the tornado diagram in Fig. 4. The tornado diagram presents the impact of varying each parameter individually between its lower (low) and upper (high) bounds while holding all other inputs constant. The analysis reveals that the most critical determinants are the costs of consumables and healthcare personnel associated with VAE, which show the widest range of variation and thus the highest influence on the economic comparison. The hospitalization costs and the rate of incomplete excision for SE also substantially affect the model.

Conversely, variables related to professional time for the management of complications and drug costs show a relatively limited impact, suggesting that procedural efficiency and material consumption are the main levers of economic difference.

VAE consumables were identified as the primary cost driver. While the base case assumed a cost of €438.35, a sensitivity analysis was conducted by substituting this value with its lower (€286.89) and upper (€560.76) estimates, keeping all other parameters constant. The results showed that the total cost difference between VAE and SE ranged from − €994 in the low-cost scenario to − €720 in the high-cost scenario. The BIA using the minimum cost for VAE consumables demonstrated a per-patient saving of €536.92. When applying the maximum cost estimate, the per-patient saving was reduced to €388.92.

3.2.1 Scenario Analyses

The scenario assuming slower linear uptake for VAE from 20% to 40% over the 5-year horizon resulted in total savings of €7,419,589, corresponding to approximately €253 per patient. The plateau scenario at 60% uptake generated total savings of €11,871,342, equivalent to about €405 per patient.

Table 4 Overall per-patient cost comparison between vacuum-assisted excision (VAE) and surgical excision (SE)

Healthcare resources	Cost classification	Cost of healthcare resources		Difference
		VAE (% of total)	SE (% of total)	
Initial procedure—healthcare personnel	Variable (time-based)	€223.59 (27%)	€596.32 (36%)	− €372.74
Initial procedure—drugs	Variable	€5.77 (1%)	€7.80 (0%)	− €2.02
Initial procedure—consumables	Variable	€438.35 (53%)	€128.92 (8%)	€309.43
Initial procedure—operating room	Semi-variable	€96.83 (12%)	€296.46 (18%)	− €199.64
Initial procedure—hospitalization	Semi-variable	€0.00 (0%)	€465.17 (28%)	− €465.17
Management of complications—healthcare personnel	Variable (frequency-based)	€9.29 (1%)	€0.67 (0%)	€8.62
Management of complications—drugs	Variable (frequency-based)	€1.14 (0%)	€0.06 (0%)	€1.08
Management of complications—hospitalization	Variable (frequency-based)	€0.00 (0%)	€0.01 (0%)	− €0.01
Management of incomplete procedure	Variable (frequency-based)	€45.50 (6%)	€167.79 (10%)	− €122.28
TOTAL		€**820**	€**1663**	**− €843**

Comprehensive comparison of healthcare resource costs for VAE and SE, including the initial procedure and the management of complications (baseline analysis)

VAE vacuum-assisted excision, *SE* surgical excision

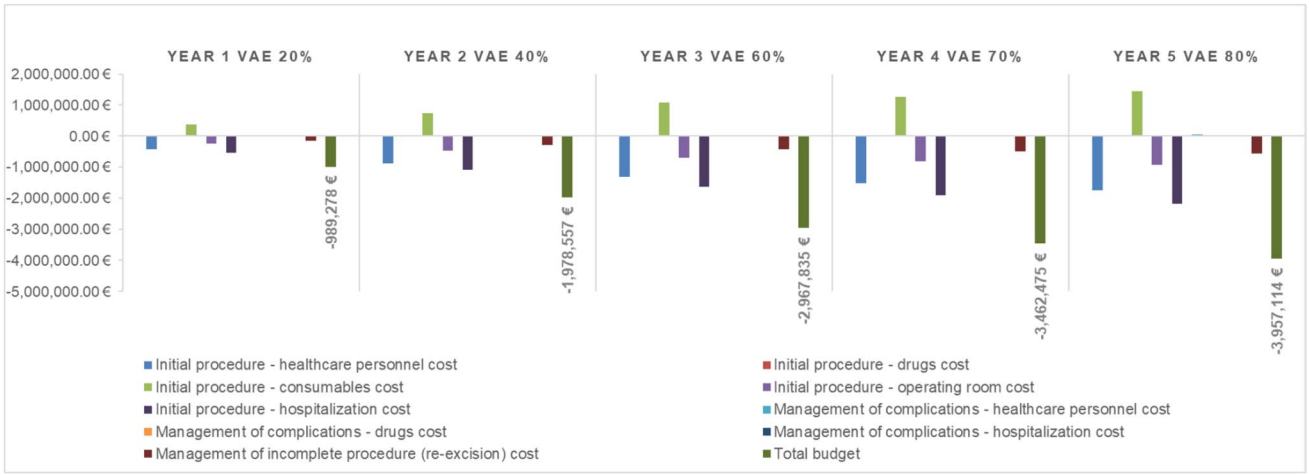

Fig. 3 Budget impact analysis of increasing adoption of vacuum-assisted excision (VAE) over a 5-year period (negative values indicate savings associated with increased use of VAE relative to surgical excision [SE], while positive values reflect higher costs)

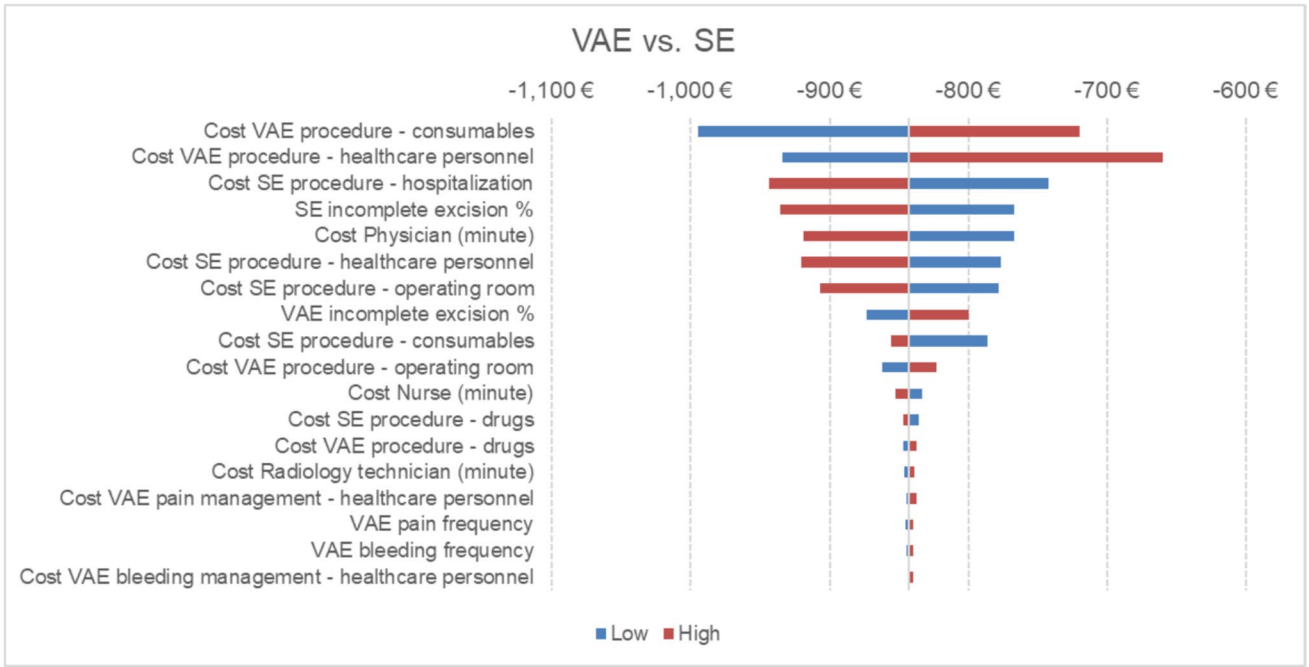

Fig. 4 One-way sensitivity analyses (tornado diagram) of per-patient cost differences between vacuum-assisted excision (VAE) and surgical excision (SE) (baseline result – €843)

The scenario incorporating the maximum observed mean number of lesions per patient reported in the meta-analysis (2.39), assuming management within the same intervention session, did not alter total costs or per-patient savings compared with the base-case scenario. By contrast, the scenario assuming management in separate dedicated sessions resulted in increased total savings of €31,919,070, corresponding to per-patient savings of €1088.

The scenario assuming an SE incomplete excision rate of 0% resulted in a per-patient cost of €1495, compared with €1663 in the base case, thereby reducing total savings to €10,696,260 (approximately €364 per patient). The parity scenario, assuming incomplete excision rates for SE equal to those of VAE (3.08%), reduced total savings to €11,426,182 (about €389 per patient).

If SE is performed in a day-surgery setting and hospitalization costs are avoided for both the index procedure and any potential re-excision, the per-patient cost decreases to €1146, resulting in total 5-year savings of €5,377,749, corresponding to approximately €183 per patient.

From the deterministic sensitivity analysis emerged that the two primary cost drivers were the costs for consumables and for the healthcare personnel for the VAE procedure.

Under the scenario combining slower linear diffusion from 20% to 40% over the 5-year horizon with minimum VAE consumable and healthcare personnel costs, total savings amounted to €9,560,609 (approximately €326 per patient). When maximum values for VAE consumables and personnel costs were applied under the same diffusion assumption, total savings decreased to €4,734,609 (about €161 per patient).

In the scenario combining a plateau uptake at 60% over the 5-year horizon with minimum VAE consumable and personnel costs, total savings reached €15,296,975 (about €521 per patient). When maximum VAE consumable and personnel costs were assumed under the same uptake pattern, total savings decreased to €7,575,375 (about €258 per patient).

Finally, under the base-case uptake trajectory combined with minimum VAE consumable and personnel costs, total savings amounted to €17,209,097 (approximately €586 per patient). When maximum values for these cost drivers were applied, total savings decreased to €8,522,297 (about €290 per patient).

4 Discussion

This study evaluated the financial sustainability of VAE versus SE for managing B3 breast lesions in the Italian healthcare system. A distinctive strength of this work is its integrated methodology, combining evidence from the literature with real-world data to provide a comprehensive and context-sensitive assessment. On the literature side, the analysis integrates a systematic review and meta-analysis with a budget impact analysis (BIA) using a micro-costing approach. On the real-world side, it incorporates structured surveys from five Italian hospitals, enabling a bottom-up reconstruction of costs across multiple resource categories. This dual strategy ensures both scientific rigor and practical relevance, making the findings directly applicable to hospital decision-making.

From a clinical point of view, VAE maintains the same diagnostic accuracy as surgery while offering a more favorable safety and tolerability profile. Complications are generally mild, manageable in an outpatient setting, and only exceptionally require hospitalization. Even more relevant is the lower incidence of incomplete excision, which reduces the need for reinterventions, strengthens diagnostic reliability, and shortens the overall diagnostic–therapeutic pathway.

From an economic perspective, the evaluation showed that VAE is financially more sustainable than SE, regardless of the scenario analyzed. The savings were primarily driven by reduced infrastructure use: VAE is typically performed in outpatient settings or day surgery units, thereby avoiding the high costs associated with operating rooms and inpatient hospitalization. Moreover, the procedural time is shorter, translating into lower personnel costs, particularly for surgeons and anesthesiologists. While SE shows marginal advantages in the management of specific complications (e.g., hematoma, lack of vasovagal reactions), these are statistically and financially negligible in the broader cost framework.

In public healthcare systems, where the introduction of new procedures often requires both clinical validation and financial justification, the availability of concrete, locally relevant economic data becomes essential. Hospitals are under increasing pressure to allocate limited resources efficiently, and this study provides the structured, scenario-based evidence to support a transition toward informed, value-based procurement decisions. For hospital administrators, these findings offer a strong strategic rationale for transitioning to a minimally invasive, cost-saving solution that maintains high standards of patient outcomes.

From an organizational perspective, shifting from SE to VAE may require adjustments in resource allocation and care pathways. In some centers, breast procedures are distributed across different departments, which can affect budget attribution and operational efficiency. Clear definition of responsibilities and integration within existing breast units may facilitate effective and sustainable implementation.

In health systems facing increasing constraints in technical and human resources, the nonsurgical management of B3 lesions constitutes an effective allocation strategy that preserves theatre time for cases with clear oncologic urgency. Concentrating surgical capacity on malignant disease aligns with value-based care objectives by maximizing health gains per unit of constrained capacity and enhancing equity of access for patients who most require operative treatment.

The results of the present study are in line with the ones presented in the literature. Yaziji et al. conducted a cost analysis comparing VAE and SE for B3 breast lesions in the UK. Using real-world data, VAE was found to reduce per-patient costs by £1510.75 and was cost-saving in 90% of modeled scenarios [39]. A retrospective cohort study among patients with benign breast masses or high-risk lesions demonstrated that ultrasound-guided VAE incurs significantly lower procedural costs (about US$1350) compared with open surgery (US$3100), without compromising care [40]. A single-center retrospective cohort study in the Netherlands found that implementing VAE for benign and high-risk

breast lesions led to a mean cost reduction of €1004 per patient. While cosmetic outcomes were statistically similar, VAE maintained comparable diagnostic effectiveness while offering cost advantages [10]. A review article emphasized that VAE is increasingly adopted as a less invasive option to open SE, particularly for benign and B3 (high-risk) lesions, as recommended in European clinical guidelines [11]. A systematic review and meta-analysis of benign phyllodes tumors compared ultrasound guided-VAE with traditional SE and found no significant difference in local recurrence rates. This suggests that VAE can be a safe, minimally invasive therapeutic option [41].

While the results of this study are both promising and well-substantiated, certain limitations must be acknowledged to provide a transparent and balanced interpretation of the findings.

The cost data used in the economic model were collected from five healthcare centers, which may raise concerns about generalizability owing to the limited sample size. In particular, the participating hospitals reported a 1-day hospitalization for SE, a practice that may differ across other clinical centers depending on institutional protocols, available resources, and patient characteristics. Such variability should be considered when interpreting the organizational and economic implications of our findings. Nonetheless, the centers were strategically selected to ensure geographic diversity, representing hospitals from northern, northeastern, and southern Italy. This selection captures a wide spectrum of organizational structures and clinical practices, thereby enhancing the representativeness of the results at the national level.

Second, although the survey-based micro-costing methodology allowed for a detailed and granular breakdown of costs, including personnel time, material usage, and complication management, some data points were incomplete, particularly concerning drug costs and facility-specific resource allocation. To address this limitation, we implemented a cross-checking strategy, comparing the reported data with publicly available procurement contracts and regional hospital purchase records. This validation process revealed no substantial discrepancies, supporting the reliability of the cost estimates. Moreover, minimum and maximum values were used to model cost variability, and sensitivity analyses were conducted to assess the stability of the results under different cost conditions. These methodological precautions significantly reduced the risk of over-reliance on potentially biased or incomplete data.

Another limitation lies in the availability of cost-relevant clinical outcome data in the literature. The meta-analysis included only two studies reporting outcomes on SE [30, 35], which constrains the robustness of the comparative clinical evidence, especially regarding the high rate of incomplete excision, derived from only two studies [30, 35], and the lower rate of pain, for which data were available from a single study [35]. Moreover, the comparison between techniques is based on estimates derived from noncomparative observational series, in which outcome definitions are not always fully harmonized (e.g., radiological versus histological assessment). For this reason, the incomplete excision rate reported for SE may appear counterintuitive. This finding likely reflects differences in case-mix (with larger or more complex lesions preferentially referred to surgery), heterogeneity in the criteria used to define completeness, and variation in procedural intent (diagnostic excision versus wider surgical removal). Accordingly, this parameter should be interpreted cautiously within the broader clinical context. Nevertheless, scenario analyses testing alternative assumptions for the SE incomplete excision rate consistently confirmed the cost-saving profile of VAE. Future research with larger, high-quality comparative studies is needed to strengthen the evidence base and provide more reliable estimates of clinical outcomes, which would in turn enhance the robustness of economic evaluations in this field.

Furthermore, the model was based on the number of patients rather than the number of lesions, acknowledging that some patients may present with multiple lesions. This approach likely underestimated the total number of procedures. However, adopting this conservative assumption strengthens the credibility of the per-patient savings estimate, which remains robust regardless of lesion count, given the patient-centric costing structure of the model.

An additional limitation concerns the exclusion of implementation and start-up costs associated with scaling up VAE adoption. The BIA was intentionally designed to estimate recurrent procedural and complication-related costs from the hospital perspective and therefore did not incorporate one-off investments such as acquisition of vacuum-assisted systems (where not already available), staff training, reorganization of clinical pathways, or potential short-term productivity losses during the transition phase. These implementation costs are highly context-specific and vary substantially across institutions depending on baseline infrastructure, breast unit organization, and existing expertise. Consequently, in centers requiring substantial initial investment, early-year net savings may be lower than those estimated in the base-case model. However, given that many medium- and high-volume breast centers already utilize vacuum-assisted biopsy platforms, incremental capital requirements may be limited in a considerable proportion of settings. Over a multi-year horizon, recurrent cost differences are expected to mitigate the impact of initial expenditures, although this dynamic was not explicitly modeled and should be considered when interpreting short-term budget projections.

While the patient perspective was not deeply analyzed in this study, existing literature suggests that patients may prefer VAE over SE [20, 27, 42]. This is largely owing to aesthetic benefits (smaller and less visible scarring), reduced invasiveness (no general anesthesia required), no need for

hospitalization, and limited perceived pain. Although these aspects were not monetized in the economic model, they represent a significant added value in a patient-centered care framework to further reinforce the appeal of VAE from both a clinical and organizational standpoint.

Despite the limitations, the present study demonstrated that VAE reduces hospital burden, improves procedural efficiency, and aligns with evolving trends in minimally invasive care and the shift of activities from hospital-based to outpatient settings [43–46]. These findings were further supported by scenario and sensitivity analyses showing that, although the magnitude of savings varied depending on adoption dynamics, organizational assumptions, and key cost drivers, the direction of the budget impact consistently favored VAE across all tested conditions with savings ranging from €161 to €1088 per patient.

By combining evidence from the literature with real-world field data, the analysis provided a comprehensive and decision-oriented foundation for the wider implementation of VAE. Conducting this analysis within the Italian setting also created a timely opportunity to generate evidence in line with the recent European Health Technology Assessment (HTA) Regulation [47, 48] and the Italian HTA Program for Medical Devices [49, 50]. Moreover, the presence of several highly specialized, high-volume breast centers with consolidated expertise in both VAE and SE may strengthen Italy's capacity to contribute robust evidence to inform health technology assessments and support decision-making at both the national and European levels.

Although the financial analysis favored VAE from a hospital budget perspective, clinical preference should also be considered. Evidence indicated comparable diagnostic reliability in appropriately selected B3 lesions, with VAE offering the advantages of minimally invasive management. However, SE may remain preferable for larger lesions, imaging-pathology discordance, or higher suspected upgrade risk, where wider excision is clinically indicated. In this context, the choice between VAE and SE is not purely economic but depends on patient selection, lesion characteristics, and multidisciplinary clinical judgment. Within this framework, VAE emerged as a cost-saving and clinically appropriate option for selected patients, supporting its integration into breast care pathways while preserving surgery for cases in which it remains indicated.

5 Conclusions

Our analysis showed that, from the hospital perspective in Italy, vacuum-assisted excision represents a clinically appropriate and economically advantageous alternative to surgical excision for selected B3 breast lesions. Its adoption was associated with substantial cost savings, primarily driven by reduced reliance on operating-room resources and hospitalization. When implemented within clearly defined eligibility criteria and structured clinical governance frameworks, vacuum-assisted excision can support more efficient resource allocation while maintaining patient safety. Further prospective comparative studies are warranted to strengthen the evidence base and refine its integration into breast care pathways.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s41669-026-00663-w.

Funding This study was conducted with the support of Becton Dickinson Italia SpA. No interferences occurred in carrying out the research project and in writing the manuscript for which the authors are the sole responsibility.

Declarations

Author Contributions Carla Rognoni contributed to the study conception and design and performed data collection and analysis. Ludovico Cavallaro and Gaia Grassi contributed to data collection and analysis. Francesca Caumo, Catherine Depretto, Secondo Folli, Salvatore Minelli, Modestino Pezzella, Nicola Rocco, Valeria Romeo, Anna Russo, and Gianfranco Scaperrotta provided clinical expertise and critically revised the manuscript. Rosanna Tarricone provided scientific supervision. Carla Rognoni drafted the manuscript, and all authors reviewed, edited, and approved the final version.

Data Availability The data supporting the findings of this study are available from the corresponding author upon reasonable request. However, access may be subject to restrictions, as center-specific hospital cost details cannot be disclosed.

Code Availability The budget impact model was developed in Microsoft Excel. The model structure and calculations are available from the corresponding author upon reasonable request.

Conflict of Interest The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

Consent to Participate Not applicable.

Consent for Publication Not applicable.

References

1. Breast cancer [Internet]. [cited 2025 Aug 21]. https://www.who.int/news-room/fact-sheets/detail/breast-cancer. Accessed 21 Aug 2025.
2. Breast cancer facts [Internet]. Breast Cancer Now. [cited 2026 Apr 21]. https://breastcancernow.org/about-us/our-impact/breast-cancer-facts-and-statistics. Accessed 21 Apr 2026.
3. Radkiewicz J, Dobruch-Sobczak K. Fibroadenoma of the breast—diagnostic misleads. Eur J Obstet Gynecol Reprod Biol. 2024;293:100–1. https://doi.org/10.1016/j.ejogrb.2023.08.282.
4. Nardin S, Mora E, Varughese FM, D'Avanzo F, Vachanaram AR, Rossi V, et al. Breast cancer survivorship, quality of life, and late toxicities. Front Oncol [Internet]. Frontiers; 2020;10:864. https://doi.org/10.3389/fonc.2020.00864.
5. Mennini FS, Trabucco Aurilio M, Gazzillo S, Nardone C, Sciattella P, Marcellusi A, et al. An analysis of the social and economic costs of breast cancer in Italy. Int J Environ Res Public Health. 2021;18:9005. https://doi.org/10.3390/ijerph18179005.
6. Ellis IO, Humphreys S, Michell M, Pinder SE, Wells CA, Zakhour HD. Best practice No 179. Guidelines for breast needle core biopsy handling and reporting in breast screening assessment. J Clin Pathol. 2004;57:897–902. https://doi.org/10.1136/jcp.2003.010983.
7. Hoffmann O, Stamatis GA, Bittner A-K, Arnold G, Schnabel R, Krüger K, et al. B3-lesions of the breast and cancer risk—an analysis of mammography screening patients. Mol Clin Oncol. 2016;4:705–8. https://doi.org/10.3892/mco.2016.790.
8. Lu W, Tu L, Xie D, Yao F, Lin L, Li Y, et al. A systematic review and meta-analysis: value of ultrasound-guided vacuum-assisted biopsy in the diagnosis and treatment of breast lesions. Gland Surg. 2021;10:3020–9. https://doi.org/10.21037/gs-21-611.
9. Yoo H-S, Kang W-S, Pyo J-S, Yoon J. Efficacy and safety of vacuum-assisted excision for benign breast mass lesion: a meta-analysis. Medicina (Mex). 2021;57:1260. https://doi.org/10.3390/medicina57111260.
10. van de Voort EM, Struik GM, van Streun SP, Verhoef C, Uyl-de Groot CA, Klem TM. Hospital costs and cosmetic outcome of benign and high-risk breast lesions managed by vacuum-assisted excision versus surgical excision. Br J Radiol. 2022;95:20220117. https://doi.org/10.1259/bjr.20220117.
11. Rubio IT, Wyld L, Marotti L, Athanasiou A, Regitnig P, Catanuto G, et al. European guidelines for the diagnosis, treatment and follow-up of breast lesions with uncertain malignant potential (B3 lesions) developed jointly by EUSOMA, EUSOBI, ESP (BWG) and ESSO. Eur J Surg Oncol. 2024;50:107292. https://doi.org/10.1016/j.ejso.2023.107292.
12. Björnström M, Niinikoski L, Meretoja TJ, Leidenius MHK, Hukkinen K. Comparison of vacuum-assisted excision (VAE) and breast lesion excision system (BLES) in the treatment of intraductal papillomas. Eur J Surg Oncol. 2022;48:67–72. https://doi.org/10.1016/j.ejso.2021.10.020.
13. Elfgen C, Leo C, Kubik-Huch RA, Muenst S, Schmidt N, Quinn C, et al. Third International Consensus Conference on lesions of uncertain malignant potential in the breast (B3 lesions). Virchows Arch. 2023;483:5–20. https://doi.org/10.1007/s00428-023-03566-x.
14. Breast screening: how to record vacuum-assisted excisions [Internet]. GOV.UK. [cited 2025 Oct 6]. https://www.gov.uk/government/publications/breast-screening-how-to-record-vacuum-assisted-excisions/breast-screening-how-to-record-vacuum-assisted-excisions. Accessed 6 Oct 2025.
15. Giannotti E, James JJ, Chen Y, Sun R, Karuppiah A, Yemm J, et al. Effectiveness of percutaneous vacuum-assisted excision (VAE) of breast lesions of uncertain malignant potential (B3 lesions) as an alternative to open surgical biopsy. Eur Radiol. 2021;31:9540–7. https://doi.org/10.1007/s00330-021-08060-z.
16. Sullivan SD, Mauskopf JA, Augustovski F, Jaime Caro J, Lee KM, Minchin M, et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 budget impact analysis good practice II task force. Value Health J Int Soc Pharmacoecon Outcomes Res. 2014;17:5–14. https://doi.org/10.1016/j.jval.2013.08.2291.
17. Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, et al. Consolidated health economic evaluation reporting standards (CHEERS)—explanation and elaboration: a report of the ISPOR health economic evaluation publication guidelines good reporting practices task force. Value Health J Int Soc Pharmacoecon Outcomes Res. 2013;16:231–50. https://doi.org/10.1016/j.jval.2013.02.002.
18. Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, et al. Consolidated health economic evaluation reporting standards (CHEERS) 2022 explanation and elaboration: a report of the ISPOR CHEERS II good practices task force. Value Health J Int Soc Pharmacoecon Outcomes Res. 2022;25:10–31. https://doi.org/10.1016/j.jval.2021.10.008.
19. Bicchierai G, Pugliese F, Amato F, De Benedetto D, Boeri C, Vanzi E, et al. Percutaneous vacuum-assisted excision (VAE) of breast lesions of uncertain malignant potential (B3 lesions): a preliminary single-centre Italian experience. Radiol Med (Torino). 2023;128:528–36. https://doi.org/10.1007/s11547-023-01626-5.
20. Carriero S, Depretto C, Cozzi A, Della Pepa G, D'Ascoli E, Irmici G, et al. Efficacy and safety of vacuum-assisted excision (VAE) of fibroadenomas: experience in a tertiary centre. Radiol Med (Torino). 2023;128:1199–205. https://doi.org/10.1007/s11547-023-01684-9.
21. Chau C, Fung E, Wong C, Kwok K, Leung A, Wong L, et al. Ultrasound-guided vacuum-assisted excision of papillary breast lesions as an alternative to surgical excision: 7-year experience. Hong Kong J Radiol. 2020;23:253–60. https://doi.org/10.12809/hkjr2017066.
22. Maxwell AJ. Ultrasound-guided vacuum-assisted excision of breast papillomas: review of 6-years experience. Clin Radiol. 2009;64:801–6. https://doi.org/10.1016/j.crad.2009.04.007.
23. Panzironi G, Moffa G, Galati F, Pediconi F. Ultrasound-guided 8-Gauge vacuum-assisted excision for selected B3 breast lesions: a preliminary experience. Radiol Med (Torino). 2022;127:57–64. https://doi.org/10.1007/s11547-021-01429-6.
24. Rupa R, Kushvaha S. Vacuum-assisted excision, scarless solution for fibroadenoma breast-a single-center experience. Indian J Radiol Imaging. 2021;31:844–9. https://doi.org/10.1055/s-0041-1735651.
25. Shang QJ, Li N, Zhang MK, He Y, Liu G, Wang ZL. Ultrasound-guided vacuum-assisted excisional biopsy to treat benign phyllodes tumors. Breast Edinb Scotl. 2020;49:242–5. https://doi.org/10.1016/j.breast.2019.12.008.
26. Soliman AH. Ultrasound-guided vacuum-assisted excision biopsy in breast fibroadenomas: an Egyptian center experience. Egypt J Radiol Nucl Med. 2022;53:213. https://doi.org/10.1186/s43055-022-00874-1.
27. van de Voort EMF, Klem TMAL, Struik GM, Birnie E, Sinke RHJA, Ghandi A. Patient reported cosmetic outcome after vacuum assisted excision of benign breast lesions: a cross-sectional study. Br J Radiol. 2020;93:20190994. https://doi.org/10.1259/bjr.20190994.
28. Wang B, Jiang Y, Zhang M-K, Li S-Y, Niu R-L, Liu G, et al. Efficacy and safety of percutaneous ultrasound-guided vacuum-assisted excision for the treatment of clinical benign breast lesions larger than 3 cm: a retrospective cohort study. Ann Transl Med. 2022;10:1345. https://doi.org/10.21037/atm-22-5829.
29. Wang ZL, Liu G, Huang Y, Wan WB, Li JL. Percutaneous excisional biopsy of clinically benign breast lesions with vacuum-assisted system: comparison of three devices. Eur J Radiol. 2012;81:725–30. https://doi.org/10.1016/j.ejrad.2011.01.059.
30. Wang WJ, Wang Q, Cai QP, Zhang JQ. Ultrasonographically guided vacuum-assisted excision for multiple breast masses:

non-randomized comparison with conventional open excision. J Surg Oncol. 2009;100:675–80. https://doi.org/10.1002/jso.21394.
31. Watson JF, Radic R, Frost R, Paton S, Kessell MA, Dessauvagie BF, et al. Vacuum-assisted excision biopsy for definitive diagnosis of breast lesions of uncertain malignant potential (B3 lesions) on core biopsy—a single centre Western Australian experience. J Med Imaging Radiat Oncol. 2023;67:365–76. https://doi.org/10.1111/1754-9485.13502.
32. Yao F, Li J, Wan Y, Zhong Y, Wei W, Tu Y, et al. Sonographically guided vacuum-assisted breast biopsy for complete excision of presumed benign breast lesions. J Ultrasound Med. 2012;31:1951–7. https://doi.org/10.7863/jum.2012.31.12.1951.
33. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ Clin Res Ed. 2021;372:n71. https://doi.org/10.1136/bmj.n71.
34. ROBINS-I | Cochrane Bias [Internet]. [cited 2025 Nov 7]. https://methods.cochrane.org/bias/risk-bias-non-randomized-studies-interventions. Accessed 7 Nov 2025.
35. van de Voort EM, Struik GM, Birnie E, Sinke RH, Verver D, van Streun SP, et al. Implementation of vacuum-assisted excision as a management option for benign and high-risk breast lesions. Br J Radiol. 2023;96:20220776. https://doi.org/10.1259/bjr.20220776.
36. Ministero dell'Economia e delle Finanze [Internet]. MEF. [cited 2022 Nov 30]. https://www.mef.gov.it/. Accessed 30 Nov 2022.
37. I numeri del cancro in Italia [Internet]. AIOM. [cited 2025 Mar 22]. https://www.aiom.it/i-numeri-del-cancro-in-italia/. Accessed 22 Mar 2025.
38. Convegno Nazionale GISMa 2016: Sessione Poster [Internet]. GISMA. [cited 2025 Aug 21]. https://www.gisma.it/atti_dei_convegni/convegno-nazionale-gisma-2016-sessione-poster/. Accessed 21 Aug 2025.
39. Yaziji N, Sharma N, Selfridge J, Sagoo GS. Cost analysis of managing B3 breast lesions by vacuum excision at Leeds Breast Unit using a decision model. BMJ Open. 2021;11:e054525. https://doi.org/10.1136/bmjopen-2021-054525.
40. Whitworth P, Hogan A, Ferko N, Son D, Wang F, Xiong Y, et al. Reduced hospital costs for ultrasound-guided vacuum-assisted excision compared with open surgery in patients with benign breast masses and high-risk lesions. J Breast Imaging. 2020;2:452–61. https://doi.org/10.1093/jbi/wbaa055.
41. Gil MLBV, Coelho BA, Couto HL, Silva HMS, Pessoa EC, Sharma N, et al. Vacuum-assisted excision: a safe minimally invasive option for benign phyllodes tumor diagnosis and treatment—a systematic review and meta-analysis. Front Oncol. 2024. https://doi.org/10.3389/fonc.2024.1394116.
42. Thurley P, Evans A, Hamilton L, James J, Wilson R. Patient satisfaction and efficacy of vacuum-assisted excision biopsy of fibroadenomas. Clin Radiol. 2009;64:381–5. https://doi.org/10.1016/j.crad.2008.09.013.
43. Italy: health system summary 2024 | European Observatory on Health Systems and Policies [Internet]. OBS. [cited 2025 Oct 5]. https://eurohealthobservatory.who.int/publications/i/italy-health-system-summary-2024. Accessed 5 Oct 2025.
44. Cartabellotta A, Gili R, Beltramello C. Modelli organizzativi alternativi al ricovero ospedaliero per i pazienti con malattie acute. Evidence. 2017. https://doi.org/10.4470/E1000175.
45. Tran L, Theissen A, Raucoules-Aimé M. Gestione del paziente in chirurgia ambulatoriale. EMC Anest-Rianim. 2018;23:1–19. https://doi.org/10.1016/S1283-0771(17)87834-8.
46. Ministero della Salute - I dati 2023 su attività, servizi e strutture del Servizio Sanitario Nazionale [Internet]. [cited 2025 Oct 5]. https://www.salute.gov.it/new/it/news-e-media/notizie/i-dati-2023-su-attivita-servizi-e-strutture-del-servizio-sanitario-nazionale/?utm_source=chatgpt.com. Accessed 5 Oct 2025.
47. Regulation on Health Technology Assessment - European Commission [Internet]. 2024 [cited 2024 Aug 6]. https://health.ec.europa.eu/health-technology-assessment/regulation-health-technology-assessment_en. Accessed 6 Aug 2024.
48. Tarricone R, Banks H, Ciani O, Brouwer W, Drummond MF, Leidl R, et al. An accelerated access pathway for innovative high-risk medical devices under the new European Union medical devices and health technology assessment regulations? Analysis and recommendations. Expert Rev Med Devices. 2023;20:259–71. https://doi.org/10.1080/17434440.2023.2192868.
49. Salute M della. Il Programma nazionale di HTA dei dispositivi medici [Internet]. [cited 2024 Sep 27]. https://www.salute.gov.it/portale/dispositiviMedici/dettaglioContenutiDispositiviMedici.jsp?lingua=italiano&id=5201&area=dispositivi-medici&menu=tecnologie. Accessed 27 Sep 2024.
50. Tarricone R, Amatucci F, Armeni P, Banks H, Borsoi L, Callea G, et al. Establishing a national HTA program for medical devices in Italy: overhauling a fragmented system to ensure value and equal access to new medical technologies. Health Policy. 2021;125:602–8. https://doi.org/10.1016/j.healthpol.2021.03.003.

Authors and Affiliations

Carla Rognoni[1] · Ludovico Cavallaro[1] · Gaia Grassi[1] · Francesca Caumo[2,3] · Catherine Depretto[4] · Secondo Folli[4] · Salvatore Minelli[5] · Modestino Pezzella[6] · Nicola Rocco[7] · Valeria Romeo[7] · Anna Russo[6] · Gianfranco Scaperrotta[4] · Rosanna Tarricone[1,8]

✉ Carla Rognoni
carla.rognoni@unibocconi.it

[1] Centre for Research on Health and Social Care Management (CERGAS), SDA Bocconi School of Management, Bocconi University, Via Sarfatti 10, 20136 Milan, Italy

[2] IOV-Istituto Oncologico Veneto-IRCCS, Padua, Italy

[3] Breast Unit, Pederzoli Hospital, Peschiera del Garda, Verona, Italy

[4] Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy

[5] AORN Antonio Cardarelli, Naples, Italy

[6] IRCCS Sacro Cuore Don Calabria, Negrar di Valpolicella, Verona, Italy

[7] Department of Advanced Biomedical Sciences, University of Naples "Federico II", Naples, Italy

[8] Department of Social and Political Sciences, Bocconi University, Milan, Italy