Cost analysis of managing B3 breast lesions by vacuum excision at Leeds Breast Unit using a decision model

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ABSTRACT

Objective  To develop an economic model to evaluate the cost of using vacuum-assisted excision (VAE) for managing B3 breast lesions.

Design  A decision tree of managing B3 breast lesions was developed to compare the costs of VAE with diagnostic excision (DE) from the perspective of the healthcare provider. Two different diagnostic pathways were compared which describe alternative approaches to the management of B3 lesions using inputs derived from a mix of primary and secondary data.

Setting  Based on a study conducted at Leeds Breast Unit, UK.

Participants  398 patients enter the model having undergone initial core needle biopsy, or vacuum-assisted biopsy, and diagnosed with B3 breast lesion.

Main outcome measures  The economic impact, in terms of cost, of various scenarios using analysis of extremes and probabilistic sensitivity analysis.

Results  VAE reduced the cost per patient by £1510.75. Analysis of extremes showed that managing B3 lesions using VAE was cost saving except the case where a combination of the highest cost associated with VAE and the lowest cost for DE were used. Probabilistic sensitivity analysis showed that using VAE for managing B3 lesions has a probability of 0.9 of being cost saving compared with using DE.

Conclusion  This analysis shows the potential cost saving of using VAE as an alternative for managing B3 breast lesions compared with DE. Further research in this area and the effect of the VAE on patients’ quality of life is warranted.

INTRODUCTION

In the UK, B3 lesions are histologically defined as lesions of uncertain malignant potential. This is a heterogeneous category of different pathological diagnosis that may be associated with malignancy to varying degrees,1 and online supplemental appendix table 1 outlines the different types of B3 lesions.

The management of these lesions has traditionally been by surgical diagnostic excision (DE). However, in 2018 the National Health Service Breast Screening Programme (NHSSP) published guidelines on how to manage these lesions using vacuum-assisted excision (VAE) rather than DE, where possible, to minimise over treatment.2 VAE is usually performed with a 7 or 8 gauge needle, where the biopsy needle is placed either just underneath or within the lesion being sampled. The biopsy needle applies vacuum drawing the tissue into the biopsy aperture and then a rotating cutting device cuts the tissue. The sample is then transported into the collection chamber within the needle biopsy device. The biopsy needle stays in the breast until the sampling/excision is completed.

Studies have shown that VAE is a safe alternative to DE in managing B3 lesions2,3 and the procedural aspects of conducting VAE indicate that it might be a cost saving alternative to DE. VAE is performed in either an ultrasound room or a stereo room. It only requires local anaesthesia, a minimum of two operators, and is performed within 60 minutes. DE in comparison is a surgical diagnostic biopsy where a surgical theatre is needed: full theatre staff; general anaesthetic and recovery area for the patient.

This article presents a cost analysis using an economic decision model that evaluates the use of VAE versus traditional DE in the management of B3 lesions. The analysis uses...
Figure 1  Decision tree showing the pathways of managing B3 lesions. DE, diagnostic excision; MFU, mammographic follow-up; RS, routine screening; TS, therapeutic surgery; VAB, vacuum-assisted biopsy; VAE, vacuum-assisted excision.

a study conducted at Leeds Breast Unit, and it adopts the perspective of the healthcare provider in a secondary care NHS setting. Given the limited data available on the topic, we explore analysis of extremes and parameter uncertainty to provide insights into the cost implications of using VAE.

METHODS
Model description
A decision tree (figure 1) was constructed, using Microsoft 365 Excel software Version 2111, to derive expected costs of alternative procedures. The decision tree is relatively simple, yet we believe it to be adequate for the stated decision problem and reflects the clinical pathway as described in Shaaban and Sharma. The NHS secondary healthcare perspective was adopted, since the major audience for this study are local health authorities, NHS trusts and government agencies. Discounting of costs is unnecessary, as all the medical events associated with each pathway occur within a single year.

Patients enter the model having undergone initial needle core biopsy (NCB) or vacuum-assisted biopsy (VAB) and diagnosed with B3 breast lesion. Two different diagnostic pathways were compared which describe alternative approaches to the management of B3 lesions. The two arms considered in this analysis are defined as follow: 1. Pathway A: using VAE for the management of B3 lesions—patients diagnosed with B3 lesions on NCB or VAB are offered a VAE. If the patient is not upgraded by VAE, and based on the sample pathological findings, they are either discharged back to routine screening or offered 5 years mammographic follow-up (MFU). Patients who are upgraded to malignant diagnosis following VAE will progress to therapeutic surgery (TS). Cases that are not upgraded to malignancy by VAE will undergo a DE, if there are ongoing pathological or radiological concerns. Patients diagnosed with B3 lesions, who are not suitable for VAE, will be offered a DE. However, these patients will follow different pathways according to the pathological finding of epithelial atypia on initial NCB/VAB. If the initial diagnosis is without atypia, and not upgraded by DE, the patient will be discharged to routine screening. If they are upgraded to malignant diagnosis, the patient will progress to TS. Patients diagnosed with atypia on an NCB or VAB, and not upgraded by DE, will be discharged to 5 years MFU. If the patients are upgraded to malignant diagnosis, they will progress to TS.

2. Pathway B: using DE for the management of B3 lesions—all patients in this arm will be offered DE after an initial diagnosis on NCB or VAB. The pathways differ according to the pathological finding of epithelial atypia on initial diagnosis. Patients with atypia, who are not upgraded by DE, will be discharged to routine screening. If the patients are upgraded to malignant diagnosis after a DE, they will progress to TS. Patients with atypia, who are not upgraded by DE, will be discharged to 5 years MFU. If the patients are upgraded to malignant diagnosis after a DE, they will progress to TS.

Patient and public involvement
No patient involved.

Model assumptions and parameterisation
The parametrisation of this model was undertaken making use of a mix of secondary and primary data sources. The parameters used in this model can be broadly categorised into transition probabilities and cost values.

Probabilities
Parameters describing the probability of events related to the natural history of the management of B3 lesions are given in table 1. These have been estimated using proportion of patients in each pathway as has been reported in the study by Strachan et al.

Assumptions
1. The decision tree is an accurate simplification of the clinical situation.
2. Probability of having epithelial atypia is the same in pathways A and B.
3. Probability of having epithelial atypia and receiving a DE is the same in pathways A and B.
4. Probability of having epithelial atypia and receiving a DE and TS is the same in pathways A and B.
5. Probability of not having epithelial atypia and receiving DE is the same in pathways A and B.
6. Probability of not having epithelial atypia and receiving DE and TS is the same in pathways A and B.
7. Binomial probabilities have beta distribution.
mapped and costing system (PLICS) to obtain these costs and includes variable costs such as radiology, pathology, pharmacy facilities. The expenditure of these resources is calculated using the actual costs incurred by the organisation.5 The costs that we have used in this analysis are in UK pounds sterling for the year 2019/2020. Based on Shaaban and Sharma,3 we retrospectively selected a small pragmatic sample of 16 patients. These patients were chosen as they represent the different pathways of managing B3 lesions at Leeds’ teaching hospital, and we extracted the associated costs for each patient’s clinical pathway. We have used Leeds Teaching Hospital patient-level information and costing system (PLICS) to obtain these costs and mapped them to the healthcare resources associated with managing B3 lesions for this sample. PLICS provides a detailed account of all resources used by an individual patient within NHS trusts from referral to discharge. This includes variable costs such as radiology, pathology, pharmacy costs, and fixed costs accounting for staffing and facilities. The expenditure of these resources is calculated using the actual costs incurred by the organisation.5 The resource use costs used in this study are given in table 2.

We have used the decision tree to estimate the cost associated with each pathway. The expected cost is calculated by multiplying the probability of each event happening by the mean cost associated with that specific event. We then sum all the individual branch costs leading to the final outcome.

Sensitivity analysis

We have examined a number of important uncertainties in the analysis using scenario analysis, maximum and minimum cost variations and probabilistic sensitivity analysis (PSA). We implemented PSA by combining the statistical distributions for each of the input parameters with Monte Carlo simulation; drawing parameter values at random 1000 times, to produce probability distributions for each of the outputs of the model. This provides a quantification of the credible range for the expected costs.5

RESULTS

Taking all parameters at baseline, the expected total cost per patient for B3 lesions management using VAB was £2381.66 and £3892.41 for using DE. The deterministic analysis associated VAE with a cost reduction of £1510.75. To explore the uncertainty in cost estimates, we have run an analysis of extremes using the highest and lowest possible costs of each medical event instead of using the mean values. The analysis shows that managing B3 lesions using VAE was cost saving except the case where a combination of the highest cost associated with VAE and the lowest cost for DE were used. Online supplemental appendix table 2 presents all the results of the analysis of extremes. We also constructed a tornado diagram presenting the result of univariate sensitivity analyses on a single graph. The cost of DE and VAE varied between the lowest and highest values, and the scenario where all patients assumed to be either with atypia or without atypia was also analysed. The tornado diagram is stacked in order of decreasing width, indicating that variations in variables near the top (expected DE cost) have the greatest effect on incremental cost (figure 2).

We have calculated every tenth percentile of the aggregate costs distribution for each arm of the decision tree after running a PSA using a gamma distribution for cost (figure 3). The chart is a line graph with the percentile along the x-axis and the aggregate cost along the y-axis. It shows that using VAE for managing B3 lesions has a probability of 0.9 of being a cost saving alternative to using DE. Repeating the analysis using lognormal distribution for cost confirms our findings (figure 4).

Table 1 Transition parameters

| Parameter                                                   | Value |
|-------------------------------------------------------------|-------|
| Probability of having epithelial atypia                     | 0.575 |
| Probability of having epithelial atypia and DE              | 0.135 |
| Probability of having epithelial atypia, DE and TS          | 0.387 |
| Probability of having epithelial atypia, VAE and TS         | 0.202 |
| Probability of having epithelial atypia, VAEM and DE        | 0.111 |
| Probability of having epithelial atypia, VAE and MFU        | 0.561 |
| Probability of having epithelial atypia, VAE and RS         | 0.126 |
| Probability of without epithelial atypia and DE             | 0.272 |
| Probability of without epithelial atypia, DE and TS         | 0.087 |
| Probability of without epithelial atypia, VAE and TS        | 0.024 |
| Probability of without epithelial atypia, VAEM and DE       | 0.089 |
| Probability of without epithelial atypia, VAEM and MFU      | 0.285 |
| Probability of without epithelial atypia, VAEM and RS       | 0.602 |

DE, diagnostic excision; MFU, 5 years mammographic follow-up; RS, routine scanning; TS, therapeutic surgery; VAE, vacuum-assisted excision.

Table 2 Summary costs used in the economic analysis

| Item                                       | Mean cost | Max cost | Min cost |
|--------------------------------------------|-----------|----------|----------|
| Needle core biopsy/vacuum-assisted biopsy  | £900.48   | £1802.49 | £645.18  |
| Diagnostic excision                        | £3124.72  | £5795.23 | £1008.42 |
| Therapeutic surgery                        | £2956.64  | –        | –        |
| Vacuum excision                            | £1338.76  | £1386.45 | £1100.29 |
DISCUSSION
Management of B3 lesions has traditionally been diagnostic surgical excision. The upgrade rate for malignancy is very much dependent on the type of B3 Lesions. B3 lesions with atypia are more likely to be upgraded to malignancy than B3 lesions with no atypia.7

Following the Marmot review, there has been much focus on over diagnosis and over treatment. Traditionally all B3 lesions were managed with DE and this was felt to represent over treatment. The advent of VAE has allowed this to be a viable alternative to surgery and indeed guidelines were published in 2018 supporting the use of VAE as an alternative to DE.8

In this modelling study, we examined the cost of using VAE for the management of B3 lesions when compared with using DE. VAE is considered cost saving given the current evidence. This is the first known attempt to examine the cost associated with introducing VAE in the management of B3 lesions. Cost analysis using a decision tree has been conducted using data collected from Leeds Breast Unit and the study published by Strachan et al.4

The results indicate that VAE is the cost saving option for managing B3 breast lesions. Deterministic and extreme cases analyses indicate that VAE in general is associated with a cost saving of between £171.69 and £3635.51. However, in the case where the highest cost of carrying out VAE is combined with the lowest cost of conducting DE, the analysis showed that DE is the cost saving option. To characterise the uncertainty associated with the estimate, a probability distribution has been assigned to each parameter used in the model. Values were drawn from these distributions and the outputs of the model for each draw were recorded. By repeating the process of draws a thousand times, probability distributions for the costs were compared. PSA revealed that using VAE for managing B3 lesions is likely to be the cost saving option 90% of the time.

As this is an early model, sensitivity analyses are essential to identify the impact of key parameters on the conclusions drawn from the model. We believe that the findings of this early-stage cost analysis are essential for healthcare providers at local level, and furthermore could inform future validation studies given the change in guidance. Nonetheless, a number of limitations are acknowledged. Although real-world cost data were used for the analysis, estimation of cost relied on a small number of data points that were selected pragmatically. The uncertainty of these values was acknowledged and analysed in the sensitivity analysis. Our analysis is based on a single centre, and although we would expect similar findings from other UK-based centres, a multicentre prospective data collection combined with evidence synthesis from the available literature would enhance the accuracy of estimating the overall benefits to the NHS and furthermore could include patient Health Related Quality of Life (HRQoL) to allow estimation of cost effectiveness. Finally, the cost of routine screening and MFUs were not observed and analysed in this study. Incorporating these costs in the analysis will better inform decision makers about the long-term effect of using VAE for managing B3 lesions in the context of the UK NHS BSP.
CONCLUSION

VAE offers a cost saving alternative for managing B3 breast lesions. The results of this study highlight the usefulness of an early cost analysis. In addition to focused additional work, it will inform and streamline the evidence generation pathway for this alternative approach to managing indeterminate breast lesions given that the guidelines have only recently changed. Further research that addresses the impact of VAE on patient’s quality of life is warranted.

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