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Comparison of vacuum-assisted excision (VAE) and breast lesion excision system (BLES) in the treatment of intraductal papillomas

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ABSTRACT

Purpose: This study aims to compare the feasibility of VAE and BLES in the treatment of intraductal papillomas.
Material and methods: Patients with a suspected intraductal papilloma who underwent a BLES or a VAE procedure were included in this retrospective study. The BLES procedures were performed between November 2011 and June 2016 and the VAE procedures between May 2018 and September 2020 at the Department of Radiology of Helsinki University Hospital (HUH). The procedures were performed with an intent of complete removal of the lesions.
Results: In total, 72 patients underwent 78 BLES procedures and 95 patients underwent 99 VAE procedures. Altogether 52 (60%) papillomas with or without atypia were completely removed with VAE, whereas 24 (46%) were completely removed with BLES, $p = 0.115$. The median radiological size of the high-risk lesions completely removed with BLES was 6 mm (4–12 mm), whereas with VAE it was 8 mm (3–22 mm), $p = 0.016$. Surgery was omitted in 90 (94.7%) non-malignant breast lesions treated with VAE and in 66 (90.4%) treated with BLES, $p = 0.368$.
Conclusion: Both VAE and BLES were feasible in the treatment of intraductal papillomas. In most non-malignant lesions surgery was avoided, but VAE was feasible in larger lesions than BLES. However, follow-up ultrasound was needed more often after VAE. The histopathologic assessment is more reliable after BLES, as the lesion is removed as a single sample.

1. Introduction

The routine treatment of high-risk or B3 breast lesions, including papillomas has previously been surgical excision to exclude concomitant invasive or in situ cancer. Since vacuum-assisted excision (VAE) was approved by Food and Drug Administration (FDA) in 2002 and the breast lesion excision system (BLES) in 2005, percutaneous image guided excision has become an alternative to surgery. According to previous studies, both VAE and BLES are safe procedures providing a reliable histological diagnosis and should be preferred to surgery in the diagnosis as well as for the removal of small non-malignant breast lesions without atypia [1–6]. However, the routine treatment for atypical ductal hyperplasia (ADH) is surgery [7,8], including papillary lesions with atypia [8].

Percutaneous breast lesion excision under local anaesthesia is a less invasive method compared to surgery [9] and it is also associated with lower costs, when compared with surgery [10,11]. In addition, the patients appreciate this less invasive procedure [1]. However, the size of the lesion, size of the breast and the location of the lesion can be limiting factors for percutaneous breast excisions [2,5,12].

According to our previous study, BLES is a feasible method in management of intraductal papillomas [13]. However, VAE is currently used at our unit due to unavailability of BLES needles. Nevertheless, BLES is currently not commercially available.

The aim of the present study is to compare the feasibility of VAE and BLES in the treatment of intraductal papillomas in consecutive patients.

Abbreviations: VAE, vacuum-assisted excision; BLES, Breast Lesion Excision System; CNB, core needle biopsy; FNAC, fine needle aspiration cytology.

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2. Material and methods

2.1. Patients

The patients with a suspected intraductal papilloma in breast imaging or percutaneous core needle biopsy (CNB) or fine needle aspiration cytology (FNAC) who underwent a BLES procedure or a VAE procedure were included in this retrospective study. The BLES procedures were performed between November 2011 and June 2016 and the VAE procedures between May 2018 and September 2020 at the Department of Radiology of Helsinki University Hospital (HUH). The procedures were performed with an intent of complete removal of the lesions. To ensure total lesion removal, cavity margins were shaved during VAE, when possible. When margin shaving was not possible, a follow-up ultrasound was performed, usually 12 months after VAE. In three cases, all with intraductal papillomas without atypia, the follow-up ultrasound was omitted according to decision of the multidisciplinary team. These three cases were not included in the current study.

The data was gathered retrospectively from electronic patient records and the picture archiving and communications system (PACS). No ethical approval was required due to the retrospective nature of the study. The institutional research permission was granted by HUH Diagnostic Centre.

2.2. VAE and BLES procedures

All the VAE procedures were performed under ultrasound control with HOLOGIC ATEC Sapphire Breast Biopsy System by an experienced breast radiologist. The needle size was 9G or 12G. The goal was to excise the whole lesion into the first sample container. When no visible lesion on ultrasound was left the cavity was rinsed. Then the sample container was changed without removing the biopsy needle and the cavity's margins were shaved into the second sample container. Thereafter, a clip mark was inserted into the biopsy cavity. The 5 mm skin incision was closed with strips. Total procedure time was approximately 45 min.

For VAE, the maximum radiological lesion size was 15 mm. The minimal radial distance between the lesion and the nipple was 10 mm and the minimum distance from the lesion to the skin was 3 mm, but there was no limit for minimum breast thickness at the site of the lesion. When the lesion was too close to the skin, muscle or nipple, margin shaving was not performed. In these cases, a follow-up ultrasound was done. The VAE excisions were considered complete when the shaved margins were clear of intraductal papilloma or when the follow-up ultrasound was free of residual tumour.

The BLES procedure was performed as described in our earlier study [13]. One BLES procedure was done under stereotactic control and the others under ultrasound guidance. For BLES, the maximum lesion size was 10 mm. For the wire basket to open safely the minimum thickness of the breast at the site of the lesion was 14 mm and the minimal radial distance from the lesion to the nipple was 6 mm. The minimum distance from the lesion to the skin and the distance between the lesion and pectoral muscle was 3 mm.

Even though the maximum size was 15 mm for VAE, and 10 mm for BLES also larger lesions were included if the shape of the lesion was suitable for total removal and the size of the breast was large enough.

Contraindications for VAE were pregnancy and breast feeding. In addition to those, cardiac pacemaker was a contraindication for BLES. Anticoagulants were recommended to be stopped one week prior to both the BLES and VAE procedures.

The histopathologic assessment of the specimens was performed as described in our previous study [13].

In all cases, further treatment or follow-up after VAE and BLES was decided at the multidisciplinary team meeting. When the completeness of lesion excision was uncertain, surgery or a follow-up ultrasound was performed. A follow-up ultrasound was also performed in all VAE patients with an intraductal papilloma and atypia**.** The follow-up ultrasound was done usually at 12 months, but in seven patients at 3–6 months.

In patients with atypical lesions, further follow-up at public health care or in biannual screening programme was recommended.

2.3. Statistical methods

Statistical analysis was performed with SPSS (Statistical Package for the Social Sciences) version 27.0. Mann-Whitney *U* test was used for comparison of continuous variables and Fisher's exact test for comparison of non-continuous variables. A p-value < 0.05 was considered to represent statistical significance.

3. Results

In total, 72 patients underwent 78 BLES procedures and 95 patients underwent 99 VAE procedures during the study period. Five patients underwent a VAE as the radiological findings were suspicious of intraductal papilloma even though the previous needle biopsy was negative. Two cases, one with BLES and one with VAE, underwent the procedures without previous needle biopsy due to suspicion of an intraductal papilloma. All the other lesions had a previous needle biopsy concordant with an intraductal papilloma. Table 1.

The median age of the BLES patients were 60 (25–84) years and the VAE patients 60 (21–84) years, respectively ($p = 0.542$). The median radiological tumour size was 7 mm (range 3–16) for BLES and 8 mm (3–22) for VAE ($p = 0.003$). The pre-VAE and pre-BLES characteristics of the lesions are summarized in Table 1.

Three BLES procedures failed. In one procedure the basket was empty. In the second case the breast was not large enough and the procedure was interrupted. In the third case, visibility was lost due to haemorrhage and the wire basked did not catch the target. All these patients underwent surgical excision of the lesion. In one additional case, the radiofrequency cautery did not work, but another basket was used successfully.

A complication occurred in two (2.6%) patients following the BLES procedure. One haematoma after a BLES procedure turned into an abscess and was treated with oral antibiotics. In addition, one thermal injury of the skin was treated under local anaesthesia after a BLES procedure. Following VAE, there were no complications requiring treatment.

In 23 (23.2%) VAE cases, margin shaving was not possible. In nine cases the lesion was too close to the skin, pectoral muscle, nipple, or a breast implant. In two cases the reason was the small size of the breast. In two cases visibility was lost after the injection of local anaesthetic or due to haematoma. In the remaining ten cases the reason was not documented.

In the final histopathology, altogether 41 (52.6%) lesions were intraductal papillomas without atypia after BLES and 73 (73.7%) after VAE, $p = 0.007$. Eleven (14.1%) lesions were intraductal papillomas with atypia after BLES and thirteen (13.1%) after VAE, $p = 0.829$. Altogether 52 out of the 86 (60%) papillomas with or without atypia were completely removed with VAE, whereas 24 out of 52 (46%) were completely excised with BLES, $p = 0.115$. The BLES procedures that failed were included in incomplete removals. The median radiological size of the high-risk lesions completely removed with BLES was 6 mm (4–12 mm), whereas with VAE it was 8 mm (3–22 mm), $p = 0.016$. The high-risk lesions partially

Table 1
Lesion characteristics before VAE and BLES.

		VAE[a] (n = 99)		BLES[b] (n = 78)		p
		N	%	N	%	
Radiological finding	Circumscribed mass	62	62.6%	56	71.8%	0.057
	Cystic and solid mass	21	21.2%	10	12.8%	
	Irregular mass	16	16.2%	8	10.3%	
	Microcalcifications	0	0%1	3	3.8%	
	Architectual distorsion	0	0%	1	1.3%	
Bi-RADS	3	14	14.1%	11	14.1%	1.00
	4	84	84.8%	66	84.6%	
	5	1	1%	1	1.3%	
Pre-VAE/BLES biopsy method	CNB[c]	98	99%	71	91%	0.007
	FNAC[d]	0	0%	6	7.7%	
	None[e]	1	1%	1	1.3%	
Pre-VAE/BLES biopsy	Intraductal papilloma	88	89.8%	69	89.6%	0.759
	Intraductal papilloma with atypia	5	5.1%	7	1.3%	
	Intraductal papilloma with suspicion of in situ carcinoma	0	0%	1	1.3%	
	Atypical ductal hyperplasia	1	1%	0	0%	
	Fibroadenoma	1	1%	0	0%	
	Fibrosis	1	1%	0	0%	
	Fibrocystic disease	1	1%	0	0%	
	Necrosis	1	1%	0	0%	
Radiological tumour size (mm)		median 8 (3–22)		median 7 (3–16)		0.003

[a] Vacuum-assisted excision.
[b] Breast Lesion Excision System.
[c] Core needle biopsy.
[d] Fine needle aspiration cytology.
[e] Radiologically suspicious intraductal papilloma or another lesion in the same breast diagnosed as intraductal papilloma on previous CNB.

removed with BLES had a median size of 9 mm (4–16 mm) and with VAE 9 mm (4–22 mm), p = 0.467. Table 2.

In 18 (23.1%) lesions excised with BLES and in nine (9.1%) excised with VAE neither high-risk nor malignant lesions were found, p = 0.012. The histopathological diagnosis of these lesions were fibrocystic disease in eight cases, fibroadenoma in five, fibrosis in five, adenomyoepithelioma in two, adenosis in three, necrosis in one, reactive changes in one, epithelial hyperplasia without atypia in one and granulation tissue in one. It is possible that a small intraductal papilloma was excised at the prior CNB procedure in cases of necrosis, reactive changes or granulation tissue.

A follow-up ultrasound was performed in 46 (46.5%) cases after VAE and 17 (21.8%) cases after BLES, p < 0.001. The median size of the lesions removed by VAE with a follow-up ultrasound in our unit was 7 mm (3–22 mm), whereas the lesions with no follow-up ultrasound or surgery had a median size of 9 mm (4–18 mm), p = 0.332. The median size of the lesions excised by BLES with a follow-up ultrasound in our unit was 7 mm (3–11 mm), whereas the lesions with no follow-up ultrasound or surgery had a median size of 7 mm (4–14 mm), p = 0.560. At the follow-up ultrasound, residual intraductal papilloma was found in three VAE cases. In two cases, the margins were not shaved and in the third case there was papilloma in the shaved margins. Two patients with residual diseases underwent surgery and the third underwent a new VAE. Tables 3 and 4.

Surgery was omitted in 90 (94.7%) non-malignant breast lesions treated with VAE and in 66 (90.4%) treated with BLES, p = 0.368.

Three (3.5%) high-risk lesions were excised surgically after an incomplete removal by VAE, and four (7.7%) after BLES (p = 0.425). In two of the three VAE lesions, surgery revealed intraductal papilloma with atypia and in the third case reactive changes. In two of the four BLES cases surgery revealed intraductal papilloma. In the other two, no intraductal papilloma was found. In total, residual high-risk lesions were found either in the follow-up ultrasound or in surgery in

Table 2
Histopathological findings and outcome after VAE and BLES.

	VAE[a] (n = 99)	BLES[b] (n = 78)	P
Intraductal papilloma with or without atypia	86 (86.9%)	52 (66.7%)	0.002
Total excision	52 (60%)	24 (46%)	0.115
Partial excision	34 (40%)	28 (54%)	
Intraductal papilloma without atypia	73 (73.7%)	41 (52.6%)	0.007
Total excision	47 (64.4%)	18 (43.9%)	0.048
Partial excision	26 (35.6%)	23 (56.1%)	
Intraductal papilloma with atypia	13 (13.1%)	11 (14.1%)	0.829
Total excision	5 (38.5%)	6 (54.5%)	0.682
Partial excision	8 (61.5%)	5 (45.5%)	
Invasive or in situ carcinoma	4 (4%)	5 (6.4%)	0.507
Total excision	0 (0%)	0 (0%)	
Partial excision	4 (100%)	5 (100%)	
Procedure failed	0 (0%)	3 (3.8%)	0.084
Other miscellaneous benign lesions	9 (9.1%)	18 (23.1%)	0.012
Surgery omitted in non-malignant lesions	90/95 (94.7%)	66/73 (90.4%)	0.368

[a] Vacuum-assisted excision.
[b] Breast Lesion Excision System.

Table 3
Ultrasound follow-up and surgery after VAE and BLES.

	VAE[a] (n = 99)	BLES[b] (n = 78)	p
Follow-up ultrasound at our unit	46 (46.5%)	17 (21.8%)	<0.001
Indication for ultrasound follow-up			
No margin shaving	23 (50%)	–	
Partially excised intraductal papilloma without atypia. Decision of the multidisciplinary meeting	11 (23.9%)	11 (64.7%)	
Partially excised intraductal papilloma with atypia	5 (10.9%)	0 (0%)	
Completely excised intraductal papilloma without atypia. Decision of the multidisciplinary meeting	2 (4.3%)	1 (5.9%)	
Completely excised intraductal papilloma with atypia.	2 (4.3%)	0 (0%)	
Benign lesion. Decision of the multidisciplinary meeting	3 (6.5%)	5 (29.4%)	
Surgery in all lesions	8 (8.1%)	12 (15.4%)	0.154
Surgery in non-malignant lesions	5/95 (5.3%)	7/73 (9.6%)	0.368
Reason of surgery			
In situ or invasive carcinoma	3 (37.5%)	5 (41.7%)	
Partial excision of intraductal papilloma with atypia	3 (37.5%)	1 (8.3%)	
Partial excision of intraductal papilloma without atypia	0 (0%)	3 (25%)	
Procedure failed	0 (0%)	3 (25%)	
Residual at follow-up ultrasound	2 (25%)	0 (0%)	

[a] Vacuum-assisted excision.
[b] Breast Lesion Excision System.

Table 4
Residual high-risk disease in non-malignant lesions.

	VAE[a] (n = 94)	BLES[b] (n = 73)	p
Residual	5 (5.3%)	2 (2.7%)	0.470
Discovery method			
Ultrasound	3 (60%)	0 (0%)	
Surgery	2 (40%)	2 (100%)	
Treatment of residual			
VAE[a]	1 (20%)	0 (0%)	
Surgery	4 (80%)	2 (100%)	

[a] Vacuum-assisted excision.
[b] Breast Lesion Excision System.

five (5.1%) high-risk lesions after VAE and in three (3.8%) after BLES (p = 1.000). Neither in situ nor invasive carcinoma was detected in the follow-up ultrasound or in surgery. Tables 3 and 4

3.1. Malignant lesions

Altogether five (6.4%) lesions excised with BLES and four (4%) lesions excised with VAE were in situ or invasive cancer, p = 0.507. One patient with invasive carcinoma diagnosed with VAE did not undergo further surgery, due to the patient frailty. All the other patients with malignant lesions underwent surgery. In two cases excised with BLES the subsequent surgery revealed intraductal papilloma with atypia but neither in situ nor invasive carcinoma. In all the other cases residual in situ or invasive carcinoma was found.

4. Discussion

4.1. BLES and VAE in the treatment of intraductal papillomas

According to our knowledge, this is the first study comparing VAE and BLES in the treatment of intraductal papillomas. Both VAE and BLES were feasible in the treatment of almost all lesions, but the lesions treated with VAE were somewhat larger than the lesions treated with BLES.

In general, VAE seems more feasible than BLES. BLES requires larger breast dimensions for the wire basket to open safely. Therefore, BLES is not an option in patients with very small breasts. Also, the lesion shape and size must fit in to the basket to achieve complete excision. Furthermore, the needle location can be adjusted during the VAE procedure, whereas the BLES basket cannot be relocated once opened. With VAE it is possible to remove more tissue than with a single BLES basket and the lesions shape is not a limiting factor. Therefore, larger lesions and lesions of more various shapes are possible to excise with VAE. On the other hand, a follow-up ultrasound was needed more often after VAE when compared to BLES. The size of the lesions did not affect whether a follow-up ultrasound was performed or not in our study. The reason for most of the follow-up ultrasounds after VAE was that margin shaving was not possible. After BLES the most common reason for follow-up ultrasound was incomplete removal.

4.2. Margin evaluation

The lesion margins can be evaluated from BLES specimen, as the lesion is removed as a single specimen. The VAE specimen consist of pieces and the margins cannot be assessed. Our VAE protocol included shaving the cavity margins as a separate specimen to determine whether the lesions have been totally excised. This method is not completely reliable, however. Inter-operator variability especially under ultrasound guidance is possible and the method cannot be fully standardized. The amount of VAE fragments and volume of the removed tissue depends on the size of the lesion as well as the radiologist's assessment. However, HOLOGIC ATEC Sapphire Breast Biopsy System allows rinsing the biopsy cavity with saline which prevents air sucking into the cavity, so the visibility remains good throughout the procedure.

Margin shaving has not been used in previous studies, but the total lesion removal has been mainly confirmed by ultrasound follow-up. Small papilloma fragments in the shaved margins not visible on ultrasound but detected in the histopathological assessment might be the reason why our VAE removal rate for intraductal papillomas without atypia (64.4%) was lower than in previous studies (84.9%–93.6%) [14–18]. Another reason could be the needle size used in the procedure but more importantly the amount of tissue removed. The breast size is a limiting factor for the tissue amount that can be removed. Neither the size of the breast nor the amount of removed tissue at the procedure has been recorded in the previous studies or in the present study.

Probably most of the papillomas even with positive shaving margins were totally removed at the VAE procedure because of the margin shaving. Only one residual among the lesions with positive shaving margins was detected.

In our study, almost all of the procedures were performed under ultrasound guidance. In most of the previous studies stereotactic guidance has been used rather than ultrasound. In two previous studies both stereotactic and ultrasound guidance was used in the removal of breast lesions with BLES, and these studies have comparable results to ours with BLES [19,20].

4.3. Complications and risks

Both methods are considered safe for the patients and the reported complication rates vary from 0.8 to 7.5% [21], which is in close agreement with the present study. Even though we did not have any haematomas requiring further treatment following VAE, the bleeding risk is believed to be higher with VAE than BLES, because VAE does not coagulate the surrounding breast tissue. This should be taken into consideration in patients with an increased risk of bleeding.

Previous studies report device-related complications comparable to ours using BLES, of which empty basket is the most common [22]. Thermal artifact is another device-related problem with BLES but it is unlikely to affect the histopathological analysis [22]. These device-related complications do not occur in VAE procedures.

4.4. Papillary lesions with atypia

The upgrade rate for B3 lesions with atypia is about 30% and may be even higher (36%) for papillary lesions with atypia [8,23]. Of the B3 lesions upgraded to malignancy in Sharma et al. [23] study 15.1% were low-grade ductal carcinoma in situ and 18.7% were high-grade ductal carcinoma in situ, 8.81% were grade 1 invasive cancer and 10.97% were 2 or 3 invasive cancers. It was previously assumed that these upgraded B3 lesions represent almost always either low-grade ductal carcinoma in situ or grade 1 invasive cancer. However, according to a recent study, about 60% of the B3 lesions upgraded to malignancy were grade 2–3 invasive cancers or grade 2–3 ductal in situ cancers [23]. In addition, it can be impossible for the pathologist to distinguish between ADH and ductal carcinoma in situ from a fragmented sample, as the area might not be measurable [24]. Unlike VAE, the histopathologic assessment of lesions excised with BLES is reliable, as the lesions is removed as a single sample.

4.5. Limitations of the study

Recurrent intraductal papillomas after percutaneous image guided excisions are rare but can occur even more than two years after the procedure [25]. We did not have a systematic follow-up of the patients. Only patients with atypical lesions were followed-up and even them mainly in primary health care. We do not have the data of these follow-ups nor whether the patients went to the recommended follow-up. Another limitation is the retrospective study setting.

5. Conclusion

Both VAE and BLES were feasible in the treatment of intraductal papillomas. In most non-malignant lesions surgery was avoided, but VAE was feasible in larger lesions than BLES. On the other hand, follow-up ultrasound was needed more often after VAE. In addition, the histopathologic assessment is more reliable after BLES, as the lesion is removed as a single sample.

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Declaration of competing interest

The authors declare that they had no conflict of interest.

Ethical approval

No ethical approval was required due to the retrospective nature of the study.

CRediT authorship contribution statement

Michaela Björnström: Investigation, Data curation, Formal analysis, Writing – original draft, Visualization. **Laura Niinikoski:** Investigation, Writing – review & editing. **Tuomo J. Meretoja:** Writing – review & editing. **Marjut H.K. Leidenius:** Writing – review & editing. **Katja Hukkinen:** Conceptualization, Methodology, Writing – review & editing, Supervision, Project administration.

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