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REVIEW ARTICLE

Differentiating vacuum-assisted breast biopsy from core needle biopsy: Is it necessary?

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ABSTRACT

Needle biopsy has replaced excisional biopsy as a definitive diagnostic technique for breast tumours, although excisional biopsy is still used for complete tumour removal for therapeutic and/or diagnostic purposes. Many vacuum-assisted breast biopsy (VAB) systems have been made available by several manufacturers since the release of the Mammotome (MMT) by Johnson & Johnson in 1995. Several recent discussions have been conducted to identify whether core needle biopsy (CNB) or VAB, is more appropriate. However, currently available VAB systems differ from the conventional system (*i.e.* articulate arm type 11-gauge (G) MMT), and the characteristics of both CNB and VAB have been improved. In CNB, a 14-G needle is frequently used to obtain a larger sample. By contrast, VAB is considered easier to perform because it uses a thinner needle and a lighter, non-tethered system. When differentiating CNB from VAB, the type of VAB should also be defined. In this review, we discuss the characteristics of ultrasonography-guided VAB and CNB with a focus on practical issues such as the number of samples and volume of tissue obtained during ultrasonography-guided needle biopsy.

INTRODUCTION

Although advancements in imaging technology now allow for the detection of tiny breast lesions, the definitive diagnosis of such subtle lesions requires a pathological examination. Currently, three image-guided biopsy techniques are available: stereo-guided, ultrasonography-guided and MRI-guided biopsy. The stereo-guided technique is indicated for breast lesions with calcifications, whereas the MRI-guided technique is appropriate for lesions only detectable by MRI. Both techniques mainly target ductal proliferating lesions. By contrast, the ultrasonography-guided biopsy technique is indicated for a wide spectrum of lesions.

Needle biopsy has recently replaced excisional biopsy as the standard diagnostic modality for breast lesions. Currently, the two main needle biopsy methods are core needle biopsy (CNB) and vacuum-assisted biopsy (VAB). The Mammotome® (MMT) VAB system was released by Johnson & Johnson in 1995 and became available in Japan in 1998. Since then, several manufacturers have released other VAB systems. As a result, many discussions have focused on whether CNB or VAB should be used, as well

as the indications for each biopsy system.^{1–5} Although CNB is less invasive, it yields smaller specimens.^{1–4,6,7} VAB uses a suction system, which allows a larger tissue sample to be obtained from a single insertion. Additionally, VAB systems differ in terms of characteristics such as needle thickness and form, sample collection and the requirement for a separate insertion for each sample.^{1–5,8,9}

To date, the characteristics of both CNB and VAB have been improved. A larger needle is now used for CNB, while both a non-tethered design and thin needle are available for VAB. These advances have led to the need for discussions regarding the number of samples or amount of tissue that should be obtained during ultrasonography-guided needle biopsy. Additionally, although image-guided percutaneous breast interventional procedures have become the standard method in clinical practice, guiding principles for their practice have only been established in Germany. Specifically, the indications, technical requirements and follow-up intervals for VAB, as well as other aspects, were described in the Interdisciplinary Consensus Recommendations for the use of Vacuum-Assisted Breast Biopsy under

Sonographic Guidance, which was first published in Germany in 2005 and updated in 2012.¹⁰

In Japan, a questionnaire survey regarding image-guided fine-needle aspiration (FNA) or needle biopsy was administered to 402 Japanese Breast Cancer Society councillors in 2016, and the results were published in 2017.¹¹ The survey included 18 questions that aimed to assess the number of biopsy cases per year, use of image-guided biopsy methods, initial approach for breast lesions (FNA, CNB or VAB), secondary approach after unsuccessful FNA results and the most predominantly used method (CNB vs VAB). Of the respondents, 27% reported patient complications such as pneumothorax or bleeding requiring surgical treatment. However, that study involved only a questionnaire survey and was not intended to provide a consensus or guideline for use in Japan. Rather, the survey attributed the findings of adverse events to the unavailability of standardised image-guided techniques. Regarding the annual frequency of CNB and VAB, 76% of the respondents more frequently performed CNB, whereas 19% more frequently performed VAB; of the latter, VAB was preferred because it allowed the collection of a larger tissue sample. The remainder of respondents reported performing CNB and VAB at equal frequencies.

Currently, seven types of VAB systems and CNB are available. Additionally, several needle sizes are currently used for VAB in clinical practice, including 11-gauge (G) and 8 G for MMT EX® (Devicor, Inc., Cincinnati, OH); 10 G and 8 G for MMT revolve® (Devicor, Inc.); 13 G for MMT Elite® (Devicor, Inc.); 10 G and 7 G for EnCor® (BARD, GmbH, Karlsruhe, Germany); 10 G for VACORA® (BARD, GmbH); 12 G and 9 G for ATEC® (Hologic Inc., Bedford, MA) and 12 G for Celero® (Hologic Inc.). For CNB, although several needle sizes are available, this parameter is perceived to have little difference on outcomes. Therefore, the 14 G needle is considered the standard for CNB.

Herein, we review the characteristics of ultrasonography-guided VAB and CNB. As these techniques are not hugely different in terms of the collected tissue quantity and procedural invasiveness, it is more reasonable and practical to compare and discuss them in terms of the number of samples and amount of tissue that should be obtained. As several VAB systems have been recently released with characteristics more similar to those of CNB than of conventional VAB, we also discuss the features of the various available VAB systems, particularly in terms of concepts and features.

DISCUSSION

Needle biopsy has replaced excisional biopsy as a definitive diagnostic technique for breast tumours. In particular, VAB has been used for more than 20 years, and many VAB systems with varying needle sizes, vacuum systems, tethered or non-tethered designs and sample collection methods have been released. Here, we reviewed the VAB and CNB systems currently available in clinical practice. We searched the PubMed database for articles regarding these biopsy techniques, using the keywords “breast biopsy” × “vacuum-assisted breast biopsy” × “core needle biopsy” × “ultrasonography-guided”. The selections were filtered

Table 1. Comparison of the sample weights and complete removal rates achieved with five vacuum-assisted biopsy systems and seven needle gauges

Biopsy system	Gauge	Weight (g) of sample from turkey phantom	Complete removal rate
Mammotome EX*	11	0.084 ± 0.032	>20 mm; 68%; ≤20 mm; 87%
	8	0.192 ± 0.027	67–97.2%
Mammotome revolve*	8	0.334 ± 0.046	No data
VACORA*	10	0.142 ± 0.006	90.2–91.9%
EnCor*	10	0.221 ± 0.039	No data
	7	0.363 ± 0.053	97.8%
ATEC*	9	0.121 ± 0.014	No data

for the English language, full-text availability and publication within the last 10 years. We excluded articles only on MRI- and stereo-guided biopsy and case reports.

Amount of the sample

Previous studies have noted that the 11 G MMT probe obtains approximately 100 mg of tissue per sample collection procedure, whereas the 14 G core probe acquires approximately 15 mg per sample.^{12,13} In one study that applied five VAB systems to a turkey breast phantom, EnCor 7 G obtained the largest tissue amount per single specimen, followed by the MMT revolve 8 G EnCor 10 G, MMT 8 G, VACORA 10 G, ATEC 9 G and MMT 11 G (Table 1).¹⁴ Notably, the MMT revolve obtained a larger sample relative to the MMT EX and Elite systems.

Several reports have also discussed the use of VAB for the complete removal of breast lesions. In a gel-simulation model-based study, MMT 11 G and 8 G were used to remove benign breast lesions measuring 10–12 mm and up to 20 mm in diameter, respectively.¹⁵ Although the EnCor 7 G and MMT 8 G yielded significantly higher complete benign tumour removal rates relative to the VACORA, 10 G, the two former techniques did not differ considerably in terms of performance.⁵ These findings suggest that a thick needle can be used to obtain a large specimen. However, other factors should be considered, including the needle structure, suction power and suction duration.

Sample collection also depends on the hardness of the target lesion. VAB can obtain larger samples from a soft lesion than a hard lesion; accordingly, thin samples will be obtained from hard tissues. Although the suction time could potentially be increased to overcome this issue, no previous study has evaluated the effects of suction power during biopsy. The suction power cannot be compared among VAB systems because of variability in the units of suction power, according to operating manuals or white papers.

Regarding the sample amount, a 2008 German guideline on the early detection of breast cancer recommended the collection

Table 2. Repeat biopsy rates and false-negative rates associated with seven core needle biopsy devices and 10 needle gauges

Biopsy system	Needle gauge	Repeat biopsy rate	False-negative rate
Mammotome EX	11	8.2–9.8%	0.6–1.0%
	8	7.8%	No data
Mammotome elite	13	11.2%	No data
VACORA	10	10.8%	No data
EnCor	10	12.5%	No data
	7	5.7%	No data
ATEC	12	5.7%	No data
	9	6.2%	No data
Celero	12	11.2%	No data
Spring-loaded CNB	14	10.9%	1.6–3.0%

CNB, core needle biopsy.

of four or more specimens via ultrasound-guided CNB using needles thicker than 14 G, but made no recommendations regarding VAB.¹⁶ The 2012 update of the Interdisciplinary Consensus Recommendations for the use of Vacuum-Assisted Breast Biopsy under Sonographic Guidance recommended the collection of more than 10 specimens using an 11 G needle or more than 6 specimens using an 8 G needle.¹⁰

Reliability of the pathological diagnosis via needle biopsy

The amount of required tissue depends on the needle size and target lesion. A large needle would be expected to yield a larger sample size, thus reducing the number of samples required to collect a certain amount of tissue. Additionally, more tissue is needed for the definitive diagnosis of some lesions, such as a non-mass lesion suspected to be ductal carcinoma *in situ* or an irregular distorted lesion that differentiates into sclerosing adenosis, as well as a radial scar from invasive ductal carcinoma.^{10,17–21} In addition to sample size, the lesion consistency is also a factor, as samples that are not crushed or fragmented are preferable, particularly for the previously described lesion types.

Two indicators of the reliability of a pathological diagnosis via needle biopsy have been identified: the repeat biopsy rate and false-negative rate (Table 2). The repeat biopsy rate is the rate at which a repeat needle biopsy or surgical biopsy is performed after a benign diagnosis. A false-negative rate indicates the frequency of cases in which benign findings were obtained from the first biopsy and malignant results were obtained from a repeat biopsy which was performed because of discordance between the histological and imaging findings. The rates of repeat biopsy for all 7 available biopsy systems and 15 needle sizes were reviewed in The American Society of Breast Surgeons' Mastery of Breast Surgery Registry.²² Notably, the Finesse® 14 G had the highest repeat biopsy rate, followed by the Finesse 10 G, EnCor 10 G, Celero 12 G, MMT Elite 13 G, EnCor 12 G, Bard® CNB 14 G, VACORA 10 G, VACORA 14 G, MMT 11 G, MMT 8 G, EnCor 360 9 G, ATEC 9 G, ATEC 12 G and EnCor 7 G. Notably, small-gauge needles were associated with

a high repeat biopsy rate, whereas large-gauge needles and tethered devices yielded significantly lower repeat biopsy rate.^{22–24} All tethered instruments outperformed the CNB 14 G. This result might be attributable to suction power, although this point remains to be confirmed. In a comparison of four VAB systems, Cerelo 12 G had a higher rate of repeat biopsy when compared to MMT Elite 13 G.

Among non-tethered instruments, Finesse, Celero, MMT Elite and VACORA were not superior to CNB in terms of the cost per cancer diagnosis.²² Although non-tethered VAB is more simple and convenient, it cannot obtain adequately large tissue samples and thus is not superior to CNB. Several studies have reported false-negative rates of 1.1–3.3%^{2,6,7,23–28} and 0.6–3.5%^{8,9,17,29,30} for CNB and VAB, respectively. However, MMT® was the only VAB system studied in those reports.

Methods for obtaining tissue samples

Characteristically, the large needle size used in VAB allows for the collection of larger samples, compared to CNB. However, VAB systems exhibit minor differences in terms of sample collection. In a conventional MMT biopsy, tissues must be removed during every sampling, despite a single insertion, and this process can be laborious. However, the gross appearance makes it easy to confirm whether the target tissue has been obtained. By contrast, the MMT revolve, MMT Elite, EnCor and ATEC systems automatically acquire samples in a tissue collection basket, and the number of sampling attempts is not identical to the number of acquired tissue samples. However, these systems require higher number of tissue cores, according to the 2012 German Interdisciplinary Consensus Recommendations,¹⁰ because of the risk of blank shooting. Although the VACORA and Celero systems are limited by the need for removal each time a sample is collected, this may be advantageous in terms of confirming tissue acquisition and reducing the repeat biopsy rate.³¹

This review article has a few limitations of note. First, it was compiled as a standard rather than systematic review. Therefore, the literature search may have been biased with respect to database limitations and access to adequate papers. Second, the recent release of several VAB systems has led to changes in the technical approaches of ultrasonography-guided needle biopsy. Accordingly, the methodology should be updated.

Complications

Some disadvantages of needle biopsy have been identified, including bleeding, infection, pain, cost, mental stress and misdiagnosis (Table 3). In addition, large needles are associated with a high risk of bleeding, particularly for VAB relative to CNB.³² However, Povoski et al reported a higher risk of post-procedural bleeding with VAB 8 G than with CNB 14 G for benign tumours, although no difference was noted between these techniques for malignant lesions.² Regarding benign lesions, Hahn et al reported no significant differences in post-procedural bleeding between MMT 11 G and MMT 8 G,³³ while Wang found that the EnCor 7 G and MMT 8 G conferred a higher risk of hematoma during excision, compared to VACORA 10 G.⁵ However, Wang found no difference in hematoma risk between EnCor and MMT.⁵ Another

Table 3. Comparison of the frequencies of bleeding and pain associated with four biopsy devices and five needle sizes

Biopsy system	Gauge	Bleeding	Pain
Mammotome EX	11	76%	No data
	8	2.2–75%	5.8%
VACORA	10	5.2%	4.8%
EnCor	7	14.6%	5.2%
Spring-loaded CNB	14	2.8%	No data

CNB, core needle biopsy.

study used a visual analogue scale to assess the level of discomfort experienced by patients after CNB and VAB.³⁴ The results demonstrated that VAB 11 G was associated with a lower level of patient discomfort relative to the CNB 14 G, which the authors attributed to the method of tissue collection.

Regarding costs, in Japan, ultrasonography-guided CNB costs US\$233 (including the pathological diagnosis fee), while ultrasonography-guided VAB costs US\$706 (including the pathological diagnosis fee). As medical insurance covers 70% of these costs, the remaining 30% billed to the patient is equivalent to \$78 for CNB and US\$235 for VAB. Lee reported that in the USA, the cost of ultrasonography-guided MMT biopsy is approximately

US\$879.³⁵ Further, Grady et al reported a procedural cost of US\$731 for VAB under ultrasound guidance as stipulated in the American Society of Breast Surgeons' Mastery of Breast Surgery Registry.²² Pistolesse et al compared the costs of MMT and VACORA and reported that the initial costs of these two devices differed significantly; additionally, MMT required expensive maintenance.³⁶ However, in an evaluation of the mean cost per diagnosis, Grady reported that VAB was more cost-effective than CNB.²²

CONCLUSIONS

It is difficult to define smaller lesions using imaging findings alone. Therefore, pathological diagnosis is essential. Since the initial release 20 years ago, the concept of the original VAB system configuration has been diversified, leading to more convenient and less invasive options. Additionally, current CNB protocols use a 14 G needle, rather than the thinner needles used previously. Although recent reports have discussed the appropriateness of VAB and CNB, instruments are no longer significantly different. Accordingly, it would be better to categorise ultrasonography-guided biopsy techniques according to the use of tethered or non-tethered devices, rather than CNB or VAB. Additionally, it would be more reasonable to compare techniques according to the number of sampled cores and the weight of the sample necessary for a definitive diagnosis.

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