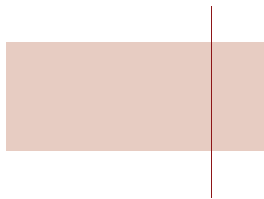


# Vacuum-assisted Breast Biopsy

Summary

AGENCE D'ÉVALUATION DES TECHNOLOGIES  
ET DES MODES D'INTERVENTION EN SANTÉ





# Vacuum-assisted Breast Biopsy

Summary

Technical note prepared for AETMIS by

**Wilber Deck**

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The mission of the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) is to contribute to improving the Québec health-care system and to participate in the implementation of the Québec government's scientific policy. To accomplish this, the Agency advises and supports the Minister of Health and Social Services as well as the decision-makers in the health-care system, in matters concerning the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including assistive devices for disabled persons, as well as the modes of providing and organizing services. The assessments take into account many factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic implications.

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# FOREWORD



## Vacuum-assisted breast biopsy

Vacuum-assisted breast biopsy is a technique designed to take a breast-tissue sample at the site of a non-palpable mammographic abnormality in order to verify whether or not it is cancerous, and if so, to guide further clinical therapy.

There is a clinical consensus that core needle biopsy under ultrasound or stereotactic guidance is a less invasive and less costly procedure than open surgical biopsy and that it accurately diagnoses the majority of breast abnormalities. A variant of this technique, vacuum-assisted breast biopsy (VAB), is already being used in at least 14 centres in Québec and accounted for roughly 3,000 of the 13,000 core needle biopsies performed in 2004. It has therefore become important to know if the clinical benefits of the VAB technique warrant expanding its use and covering its high costs.

This is the context in which the Agence de la santé et des services sociaux de Montréal asked the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to examine the quality of the scientific evidence underpinning the VAB and the advisability of offering this procedure to patients requiring a breast biopsy after detection of a non-palpable mammographic abnormality. This technical note assesses the scientific evidence on the diagnostic performance of the VAB in relation to that of conventional core needle biopsy (CNB). It also examines the economic aspects and the quality-assurance measures required to guarantee that core needle biopsies yield maximum benefits while avoiding errors and complications.

The analysis was limited by the lack of comparative studies, given that all the studies report on the experience of health-care teams with either one or the other technique. Nevertheless, the available data suggest that vacuum-assisted biopsy offers a slight diagnostic advantage, with a 3.1% rate of undetected cancers for conventional (non-vacuum-assisted) biopsies compared with 1.6% for vacuum-assisted biopsies. The vigilance of a multidisciplinary team of experts who can detect any discordance between mammographic and biopsy findings should allow for the identification of most of these missed cases. The limited clinical benefits that can be attributed to the VAB do not justify its major additional costs.

In conclusion, vacuum-assisted breast biopsy should not replace conventional core needle biopsy for all biopsies of non-palpable breast abnormalities. Nevertheless, it would be important for an expert committee to identify the clinical indications that may justify the use and higher cost of the VAB. All core needle biopsies of non-palpable lesions should be performed only in centres that have achieved a high level of expertise in diagnosing breast abnormalities and that have multidisciplinary teams collaborating closely to assess the cases and to review their diagnostic performance in the use of these core needle biopsy techniques.

In submitting this technical note, AETMIS hopes to contribute to the optimal use of breast biopsy techniques in favour of women with non-palpable breast abnormalities.

Dr. Luc Deschênes  
President and Chief Executive Officer



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## DISCLOSURE OF CONFLICTS OF INTEREST

Dr. Deck also works for the Direction de santé publique Gaspésie–Îles-de-la-Madeleine, where he co-ordinates the breast-screening activities that are part of the Québec breast-cancer screening program (*Programme québécois de dépistage du cancer du sein*, PQDCS). He also holds shares in Johnson & Johnson.

# SUMMARY

## Assessment request: is it advisable to switch to vacuum-assisted biopsies?

Vacuum-assisted breast biopsy is a technique designed to take a breast tissue sample at the site of a non-palpable mammographic abnormality in order to verify whether or not it is cancerous, and if so, to guide further clinical therapy.

There is a clinical consensus that core needle biopsy under ultrasound or stereotactic guidance is a less invasive and less costly procedure than open surgical biopsy and that it accurately diagnoses the majority of breast lesions. A variant of this technique, vacuum-assisted breast biopsy (VAB), is already being used in at least 14 centres in Québec and accounted for roughly 3,000 of the 13,000 core needle biopsies performed in 2004. It has therefore become important to know if the clinical benefits of this new technique warrant expanding its use and covering its high costs.

This is the context in which the Agence de la santé et des services sociaux de Montréal asked the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to examine the quality of the scientific evidence underpinning the VAB and the advisability of offering this procedure to patients requiring a breast biopsy after detection of a non-palpable mammographic abnormality. This technical note also examines the economic aspects and the quality-assurance measures required to guarantee that core needle biopsies yield maximum benefits while avoiding errors and complications.

## Analysis: how to measure diagnostic performance?

The analysis of the diagnostic performance of core needle biopsies is limited by the lack of comparative studies, given that all the studies report on the experience of health-care teams using either one or the other technique in isolation. Moreover, the indicators most commonly used to measure the underdiagnosis of *in situ* or invasive cancers are calculated with the denominator being the total number of biopsies with that finding, which yields a good indicator for guiding clinical follow-up but not for evaluating if the technique is capable of accurately detecting cancer. We therefore recalculated the appropriate performance indicators using data published after 1999 in studies with at least 100 biopsy results. We also estimated the fixed and variable costs of core needle biopsy in Québec. Finally, we examined the quality assurance measures required to guarantee that core needle biopsies yield maximum benefits while avoiding errors and complications.

## Results: difficult comparison, similar outcomes

The available data suggest that vacuum-assisted breast biopsy yields slightly fewer **missed cancers**, with a 3.1% rate for conventional core needle biopsy and 1.6% for vacuum-assisted biopsy. The literature indicates that about 70% of these errors could be corrected through the vigilance of a multidisciplinary team of experts who can detect discordance between mammographic and biopsy findings.

There are two types of underdiagnosis of breast lesions: underdiagnosis of cancer *in situ* (i.e., the biopsy reveals only a high-risk lesion, usually atypical hyperplasia), and underdiagnosis of invasive cancer (i.e., the biopsy indicates only a high-risk lesion or cancer *in situ*). In the reviewed studies, the VAB was more successful in avoiding an **underdiagnosis of cancer *in situ***, with a rate of 4.0% compared with 10.7% for the CNB. For the **underdiagnosis of invasive cancer**, the reverse is true: the VAB is associated with an underdiagnosis rate of 17.7%, while the CNB underdiagnoses only 11.6% of these breast

lesions. In both cases, the clinical follow-up is not greatly affected because, according to current standards of practice, any high-risk or *in situ* lesion is surgically excised by partial mastectomy.

Diagnostic performance indicators		
INDICATORS	14-G CNB	11-G VAB
Missed cancers (benign according to biopsy)	3.1%	1.6%
<i>Early misses (70%)</i>	2.2%	1.1%
<i>Delayed misses (30%)</i>	0.9%	0.5%
Underdiagnosis of cancer <i>in situ</i>	10.7%	4.0%
Underdiagnosis of invasive cancer	11.6%	17.7%

14-g CNB: core needle biopsy with a 14-gauge needle; 11-g VAB: vacuum-assisted breast biopsy with an 11-gauge probe.

Unfortunately, the limited benefits offered by the VAB are also associated with much higher costs. Although both examinations require similar personnel and time, the cost of disposable supplies (needles/probes, guides, suction equipment) adds from \$400 to \$700 per procedure. The cost of the stereotactic and biopsy devices are similar for both techniques, but their return on investment is strongly a function of the number of procedures performed, especially in Québec where most centres operate at low volume.

## Conclusions: high cost for low gains, importance of quality

Given the lack of high-quality studies offering a direct comparison of conventional and vacuum-assisted core needle biopsies, the conclusions proposed here should be interpreted with caution.

- 1) Vacuum-assisted breast biopsy (VAB) should not replace conventional core needle biopsy (CNB) for all biopsies of non-palpable breast abnormalities. Vacuum-assisted breast biopsy is more of an evolutionary than a revolutionary practice. The diagnostic performance of the VAB is comparable to that of the CNB, and the case series published in the literature suggest that the limited clinical gains that can be attributed to the VAB do not justify its major additional costs.
- 2) In spite of this general observation, some clinical indications may justify the use of vacuum-assisted breast biopsy. In such cases, the VAB may offer the advantage of avoiding open surgery. However, it is not very logical to believe that this would reduce the bottlenecks in surgical departments. It would be important to identify the clinical indications for which the use and higher cost of the VAB may be justified. In Québec, the mandate to develop a protocol defining these indications should be entrusted to an expert committee working in collaboration with the mammography committee of the Association des radiologistes du Québec and with the Collège des médecins du Québec.
- 3) Whether vacuum-assisted or not, core needle biopsy offers a safe alternative to surgical biopsy, provided that high levels of expertise are achieved. In particular, detection of the discordance between benign histological findings and suspicious mammographic findings should help correct the diagnosis for most missed cancer cases, but doing so requires expertise and multidisciplinary collaboration. All core needle biopsies of non-palpable breast abnormalities should therefore be performed only in centres that have achieved a high level of expertise in diagnosing breast abnormalities and that have multidisciplinary teams collaborating closely to assess the cases. These teams should have a formal procedure for evaluating the diagnostic performance of core needle biopsy techniques by

measuring statistical parameters such as their positive predictive value in order to avoid an excessive number of invasive diagnostic examinations. These teams should also undertake to reserve the VAB for clinical indications for which it offers clear advantages over conventional biopsy techniques.

Referring patients to specialized clinics would entail the need to re-evaluate the relevance of continuing to have such a large number of centres providing core needle biopsies in Québec. It would also offer the advantage of curtailing costs arising from the unnecessary duplication of technical infrastructures, while reserving the more costly techniques to women who would most benefit from them.

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