



Review

Vacuum-assisted breast biopsy: a critical review

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Abstract

Vacuum-assisted biopsy is an image-guided technique introduced in 1995 that is thought to be superior to 14G automated-needle biopsy for the evaluation of non-palpable breast lesions. However, prospective randomised studies evaluating its accuracy are unavailable. We conducted a critical review of the currently available literature on the accuracy of vacuum-assisted biopsy and compared it with published data on the accuracy of 14G automated-needle biopsy. The diagnostic performance of vacuum-assisted biopsy was evaluated by reviewing all available English-language literature published in Medline between 1995 and November 2001. Four independent reviewers used standard forms to extract the data. Twenty-two published studies were included. *High-risk* and *DCIS underestimate rates*, as well as the *miss-rate* of cancer, were assessed. *High-risk* and *DCIS underestimate rates* for 11G vacuum biopsy were 16% (95% Confidence Interval (CI) 12–20%) and 11% (95% CI 9–12%), respectively, and both were lower than the rates reported for 14G automated-needle biopsy (40% (95% CI 26%;56%) and 15% (95% CI 8%;26%), respectively). Due to incomplete follow-up of the benign lesions, it was impossible to calculate the *miss-rates* and the sensitivity rate. The results of this review indicate that vacuum-assisted biopsy can decrease the *high-risk* and *DCIS underestimate rates*, but it is unclear whether it can also decrease the *miss-rates* of cancer.

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Keywords: Vacuum-assisted biopsy; Non-palpable breast disease; Review**1. Introduction**

Stereotactic 14-gauge (14G) automated-needle biopsy has been shown to be comparably accurate to wire-localised surgical excision for evaluating non-palpable breast lesions [1–3]. This has resulted in a worldwide increase of large-core needle biopsies. Currently, it is estimated that, in the USA, 1 million needle biopsies are performed yearly, of which approximately 300 000 are for non-palpable breast lesions [4]. Although sensitivity rates for 14G automated-needle biopsy are high (97%), some cancers are missed. Another shortcoming is that the severity of the disease is sometimes underestimated, i.e. when findings at surgical excision show a higher degree of pathology than at the previous breast biopsy [5]. The finding of carcinoma after a biopsy diagnosis of atypical ductal hyperplasia (ADH),

or of invasive carcinoma after a biopsy diagnosis of ductal carcinoma *in situ* (DCIS), define *ADH-* and *DCIS-underestimates*, respectively. Not only is it psychologically distressing for patients when breast cancer is underestimated, but it also implies a delay in establishing the definitive diagnosis and, hence, appropriate treatment. Many of these patients will need additional surgical procedures. Finally, 16–18% of scheduled stereotactic large core-needle biopsies are cancelled, partly due to sub-optimal lesion localisation or lesion size [6,7]. In an attempt to overcome some of these negative aspects of large-core needle biopsy, vacuum-assisted breast biopsy was developed at the end of 1995 [8,9].

The vacuum-assisted biopsy device acquires tissue samples by using a single insertion of the probe (11 or 14G) and vacuum suction to retrieve the core specimens. An advantage of this method is that more samples can be obtained in a shorter period of time, and the samples are larger than those obtained with a 14G-needle and automated gun [8,10,11,12]. Furthermore, the

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vacuum probe can be used for taking biopsies from small (<5 mm) mammographical lesions, from superficial lesions and from thin breasts. Disadvantages are the costs associated with the disposable materials of the vacuum suction system, which are 10–20 times higher than for 14G-automated-needle biopsy. In addition, vacuum-assisted biopsy of a malignant lesion may lead to difficulties in estimating the true size of the tumour at excision (when most of the lesion has been sampled at vacuum biopsy), which is an important indicator for adjuvant therapy.

Vacuum-assisted biopsy is expected to decrease the *miss-rate* and the number of *ADH-* and *DCIS-underestimates*. For 14G-automated-needle biopsy, these rates are 3% (95% Confidence Interval (95% CI): 1–5%), 40% (95% CI 26–56%) and 15% (95% CI 8–26%), respectively, as published in a meta-analysis [13]. Although many studies have reported on these aspects of the vacuum-assisted breast biopsy, well-designed clinical studies comparing vacuum-assisted biopsy with surgical excision are as yet unavailable. We reviewed the literature to assess the diagnostic performance of vacuum-assisted breast biopsy and to evaluate its potential benefits.

2. Patients and methods

2.1. Reference retrieval and inclusion and exclusion criteria

We performed a Medline search of the English-language literature published between 1995 and November 2001. ‘Breast AND biopsy AND vacuum’ or ‘mammotome’ were used as search terms. A cross-reference search completed the exploration.

Publications were included in the review if they met the following list of preset inclusion criteria: (1) all histological diagnoses of vacuum-assisted biopsy specimens were confirmed by either surgical biopsy or adequate follow-up; (2) the absolute number of benign and malignant diagnoses was derivable; (3) the method of guidance was stereotaxis; (4) the size of the used vacuum probe was described. Duplicated publications (where data were collected over the same period at the same centre) were excluded. We retrieved a total of 88 papers when using the above search terms. Most of these studies reported on non-palpable lesions, but this was not always clear, even though the development of image-guided breast biopsy techniques was originally intended for non-palpable lesions. Of the 88 relevant articles, 48 were excluded: 45 because the diagnostic performance of the vacuum-assisted biopsy was not the object of study and three because they were review articles on various biopsy techniques. Of the remaining 40 articles that addressed the diagnostic accuracy of large-core needle biopsy, a further 18 were excluded.

Six of these were excluded because they partly described the same data that was published in another paper, already included in our meta-analysis. Five papers reported on sonographically-guided vacuum-biopsy. Four studies were excluded because the histological diagnoses from core biopsy and surgical excision or follow-up were not given. In three papers, the absolute number of (non-palpable) lesions was not derivable. (A list of the 18 excluded publications and the reasons for their exclusion is available upon request). Thus, we included 22 studies in the meta-analysis [4,14–34].

All four authors independently extracted the data from the studies using a standard extraction form. Study period, number of patients and lesions, method of patient selection, type of lesion (calcifications or density), needle size, results of surgical excision, follow-up data, complications and the number of cancelled procedures were registered. In cases where there were discrepancies, a consensus was reached.

2.2. Analysis of the diagnostic performance

The diagnostic performance of vacuum-assisted biopsy was assessed using the method introduced by Burbank and Parker [5]. For this purpose, the histological outcomes from the vacuum-assisted biopsy procedures were classified according to one of the following four categories: (1) benign breast disease; (2) high-risk lesions; (3) DCIS, and (4) infiltrating breast cancer. Subsequently, the actual disease status was assessed. Lesions that were surgically removed were divided into the same four categories according to the histological diagnosis. Micro-invasive carcinoma was considered as invasive cancer. Lesions with a benign histological vacuum biopsy result were most often not surgically removed and were classified as benign if no progression requiring re-biopsy was observed during adequate follow-up. We intended to include studies if at least 90% of the benign lesions were either surgically removed, or mammographically followed for at least 2 years. If this was not the case, numbers of benign lesions and numbers missing were described, but without trying to combine them. If no information about follow-up was available, the studies were excluded.

To assess the diagnostic performance, we computed estimates of (1) inconclusive lesions (2) *high-risk underestimate rate* (3) *DCIS underestimate rate* and (4) *miss-rate* in each study. Homogeneity of the estimates among the individual study results was tested using the Chi-square test [35]. If the study results were homogeneous, a combined estimate was computed. Combined estimates were also computed according to (1) the size of the probe used, i.e. 11G or 14G vacuum probe; and (2) lesions consisting of calcifications only.

The proportion of inconclusive biopsy results was assessed; these are defined as lesions for which re-biopsy is indicated, because a pathohistological diagnosis concordant with mammographical findings was not drawn from the vacuum-biopsy.

High-risk lesions are benign lesions known to have a high risk of simultaneous carcinoma in the ipsilateral breast and include ADH, atypical lobular hyperplasia, lobular carcinoma *in situ*, radial scar, papillary lesions or a possible phyllodes tumour. These high-risk lesions at biopsy are always an indication for surgical excision [36–40]. The *high-risk underestimate rate* was defined as the percentage of high-risk lesions on vacuum-assisted biopsy that was upgraded to DCIS or invasive cancer in the surgical specimen [5]. Lesions that were not surgically excised and without follow-up of at least 2 years were not used in the analyses.

The *DCIS underestimate rate* was defined as the percentage of DCIS lesions on vacuum-assisted biopsy upgraded to invasive cancer at the subsequent excision [5].

The *miss-rate* was defined as the proportion of all carcinomas with a benign diagnoses on vacuum-assisted biopsy. Conventionally, sensitivity is defined as one minus the false-negative rate. The false-negative rate is defined as the proportion of negative diagnoses (here, benign diagnoses on vacuum-assisted biopsy) among all true positive diagnoses (here, carcinomas) based on the gold standard (surgery or adequate follow-up). Thus, sensitivity equals one minus the *miss-rate*.

Statistics were performed using the Statistical Package for Social Sciences 9.0 (SPSS Inc. Chicago, IL). For studies with >20 lesions, large-approximation 95% CI were calculated for all of the estimates. For studies that included ≤20 patients, exact 95% CI (binomial distribution) were used.

3. Results

Twenty-two studies were included in the present review, of which seven reported on inconclusive lesions [18,21–23,29,33,34]. 17 contributed data to the combined *high-risk underestimate rate* [14–24,28,30–34]. 15 contributed to the combined *DCIS underestimate rate* [4,19–28,31–34] and, finally, seven studies reported on the follow-up of benign lesions [20–23,29,32,33]. Four out of the 22 studies reported on all of these endpoints [21–23,33].

Characteristics of all the studies are presented in Table 1. Three studies mentioned complications that occurred as a result of the vacuum-assisted biopsy [20,21,30], including bleeding or haematoma ($n=4$), vasovagal reaction ($n=1$), infection ($n=1$), seizure ($n=1$) and nausea ($n=1$). One study reported that no complications occurred [32]. Two studies reported that two and three planned procedures were cancelled, respectively [24,33].

3.1. Inconclusive results

Seven studies reported on the number of inconclusive diagnoses, e.g. lesions for which re-biopsy was indicated, because a clear pathohistological diagnosis could not be drawn from the vacuum-biopsy [18,21–23,29,33,34]. The proportion of these lesions varied from 0.5% (1/216) to 9.0% (32/354), (median, 1.2%), and in 3 of 28 cases that were followed by surgical excision, a malignancy was found (11%).

3.2. High-risk underestimate rate

Fifteen studies contributed data to compute the *high-risk underestimate rate* for stereotactic 11G vacuum-assisted breast biopsy [14–24,28,32–34]. Testing of homogeneity of the *high-risk underestimate rates* for each individual study was non-significant ($\chi^2=13.7$; 14 degrees of freedom (df); $P>0.25$). A total of 416 high-risk lesions were detected in these 15 studies. For 57 lesions, the definitive diagnosis was missing: they were not removed by surgery, or disease-free follow-up over 2 years was not reported. Therefore, these lesions were excluded from the analysis. Of the remaining 359 high-risk lesions, 57 were proven to be malignant (*high-risk underestimate rate* = $57/(416-57)=15.9\%$ (95%CI 12.1–19.7%)) (Table 2).

Three studies reported on the 14G vacuum probe [28]. Homogeneity testing showed these studies did not differ significantly ($\chi^2=4.3$; df=2; $P>0.1$), and the combined *high-risk underestimate rate* was $24/(117-14)=23.3\%$ (95%CI 19.1–31.5%) [30,31]. The difference between the 11G and 14G vacuum biopsy results was not statistically significant ($P>0.05$).

Another three studies reported on lesions consisting of calcifications only [15,21,23]. Twelve malignancies were diagnosed in 83 patients with surgery or adequate follow-up ($116-33=83$). The combined *high-risk underestimate rate* was $12/83=14.5\%$ (95% CI 7.7–23.9%) (Table 3).

3.3. DCIS underestimate rate

Thirteen studies reported on the *DCIS underestimate rates* with a 11G vacuum probe [19]. Homogeneity testing of the individual study results did not show any significant differences ($\chi^2=16.6$; df=12; $P>0.1$). A total of 1157 DCIS lesions were diagnosed in these 13 studies [20–28, 32–34]. 52% of these lesions were detected in one multi-institutional study (describing the results of 16 centres) [27]. One hundred and twenty-two lesions showed invasive cancer at surgery: the combined *DCIS underestimate rate* was $122/(1157-4)=10.6\%$ (95% CI 8.8–12.4%) (Table 4).

Four studies reported on DCIS lesions at 14G vacuum biopsy [4,27,28,31]. However, the test for homogeneity was significant ($\chi^2=14.9$; df=3; $P<0.01$), and the calculated combined estimate ($52/409=12.7\%$ (95% CI 9.5–15.9%)) should be regarded with caution.

Two studies reported on *DCIS underestimate rates* at 11G stereotactic vacuum biopsy for lesions appearing as calcifications only [21,23] and they were 5% (1/21) and 8% (1/12), respectively (Table 5).

3.4. Miss-rate

The finding of benign lesions at 11G stereotactic vacuum-biopsy with at least some follow-up was

described in seven studies [20–23,29,32,33]. However, follow-up of these lesions was inadequate according to our preset inclusion criteria (surgery or follow-up for 90% of patients for at least 2 years) (Table 6). In one study [22], 12 of 491 patients with benign lesions had adequate follow-up: 2 underwent excision which showed a malignancy, and 10 had unchanged, unsuspected mammograms 2 years after vacuum-assisted biopsy. In two other studies [21,23], 1/61 and 4/120 benign lesions diagnosed at 11G vacuum biopsy lesions had been

Table 1
Characteristics of the studies included in the meta-analysis

[Ref.]	First author, year of publication ^a	Probe used	Consecutive patients	Age (years) mean (Range)	% Calcifications	Palp	% DCIS and invasive cancer	Data on lesions used for analysis:						
								Complications	Inconclusive	HR u/e	DCIS u/e	Benign		
[14]	Brem, 1999	11G	Only HR	58.1 (35–74)	90	?	25	?			X			
[15]	Adrales, 2000	11G	Only HR	53.8 (36–82)	100	?	15	?			X			
[16]	Philpotts, 2000	11G	Non-cons	?	56	?	?	?			X			
[17]	Manganini, 2001	11G	Only HR	?	91	Np?	?	?			X			
[18]	Philpotts, 1999	11G	Non-cons	?	53	Np?	?	?	X		X			
[19]	Burak, 2000	11G	Non-cons	?	65	Np?	20	?			X	X		
[20]	Beck, 2000	11G	Non-cons	?	?	Np?	18	2/594			X	X	X	
[21]	Lieberman, 1998	11G	Only mc	M55 (31–85)	100	Np?	29	3/112	X		X	X	X	
[22]	Lai, 2001	11G	Consecutive	54.7 (22–89)	?	?	22	?	X		X	X	X	
[23]	Cangiarella, 2001	11G	Non-cons	53.5 (34–79)	100	Np	9	?	X		X	X	X	
[24]	Lattanzio, 2001	11G	Consecutive?	54 (33–75)	76	Np?	35	3/115 cancelled			X	X		
[25]	Won, 1999	11G	Only DCIS	?	95	Np?	100 ^b	?				X		
[26]	Brem, 2001	11G	Non-cons	58 (35–78)	75	Np	100 ^b	?				X		
[27]	Jackman, 2001	11G	Only DCIS	57.0 (32–88)	91	Np	100 ^b	?				X		
[28]	Darling, 2000	14G 11G	Consecutive	54 (24–89)	98	?	?	?			X	X		
[29]	Jackman, 1999	14G 11G	Non-cons ^b	52 (29–89)	68	Np	Benign only	?	X					X
[4]	Lieberman, 2001	14G 14G	Non-cons	53 (26–84)	100	Np	88	?				X		
[30]	Jackman, 1997	14G	Only HR	58 (38–92)	84	Np	?	3 (0,14%)			X			
[31]	Soo, 1999	14G	Non-mc only	?	0	Np	25	?			X	X		
[32]	Zannis, 1998	11 + 14G	Consecutive	57.7 (25–90)	83	Np	22	0			X	X	X	
[33]	Ohsumi, 2001	11 + 14G	Consecutive?	51.6 (30–77)	91	Np	35	2/90 cancelled	X		X	X	X	
[34]	Joshi, 2001	11 + 14G	Consecutive	55.7 (30–84)	58	Np?	15	?	X		X	X		

Non-cons, non-consecutive patients; M, median; Np, non-palpable; np?, probably non-palpable; p, palpable; mc, microcalcifications; HR u/e, high-risk underestimates; X, contributed data to combined estimate; G, gauge; DCIS, ductal carcinoma *in situ*; Palp, palpable?

^a All, but four, studies were conducted in the United States; one study was conducted in Germany [20], one in Canada [22], one in Italy [24], and one in Japan [33].

excised, but no malignancies were found. Due to incomplete follow-up of benign lesions in all studies, we were unable to calculate the *miss-rate* and thus the sensitivity rate.

4. Discussion

The present review shows that stereotactic 11G vacuum-assisted breast biopsy results in a *high-risk underestimate rate* and a *DCIS underestimate rate* of 16 and 11%, respectively. When we compare these rates to published data on stereotactic 14G biopsy with an automated gun, we find a significant decrease in the *high-risk underestimate rate* (40%; difference = 24%;

$P < 0.05$) and a non-significant decrease in the *DCIS underestimate rate* (15%; difference = 4%; $P > 0.05$) [13].

Most of the studies provided limited data on patient selection. In many of the studies, it was not clear whether the patients enrolled were those with non-palpable breast lesions, or if consecutive patients were included. The prevalence of carcinoma varied largely between the studies (Table 1), which may indeed indicate patient selection for the vacuum procedure. Given the large number of studies with missing data for various characteristics (as presented in Table 1), we were unable to take into account the effect of these covariates. For example, for the DCIS underestimate rate, which is a predictive value, the prevalence of DCIS among all cancers influences this rate and is thus an important

Table 2
High-risk underestimate rates (HR u/e) for stereotactic vacuum-assisted breast biopsy

[Ref.]	High-risk at biopsy <i>n</i>	Inadequate FU/no excision <i>n</i>	Used for analysis <i>n</i>	Malignant at excision <i>n</i>	HR u/e (%)	95% CI
11G probe						
[14]	20	4	16	4	25.0	(5.7–43.7)
[15]	90	28	62	9	14.5	(5.8–23.3)
[16]	26	0	26	6	23.1	(6.9–39.3)
[17]	44	11	33	4	12.1	(0.3–28.2)
[18]	21	4	17	4	23.5	(3.4–43.7)
[19]	46	0	46	6	13.0	(3.3–22.8)
[20]	13	0	13	0	0	(0–24.7)
[21]	12	1	11	1	9.1	(0.2–38.5)
[22]	12	0	12	2	16.7	(2.1–48.4)
[23]	14	4	10	2	20.0	(1.8–42.8)
[24]	10	5	5	1	20.0	(0.3–44.5)
[28]	86	0	86	16	18.6	(10.4–26.8)
[32]	4	0	4	0	0	(0–60.2)
[33]	3	0	3	2	66.7	(13.3–100)
[34]	15	0	15	0	0	(0–21.8)
Total	416	57	359	57	15.9	(12.1–19.7)
14G probe						
[28]	28	0	28	11	39.3	(30.1–57.4)
[30]	88	14	74	13	17.6	(13.2–26.3)
[31]	1	0	1	0	0.0	(0–97.5)
Total	117	14	103	24	23.3	(19.1–31.5)

FU, follow-up; 95% CI, 95% Confidence Interval; *n*, number. In study [28], the number of patients without surgery or adequate follow-up is not specifically reported. Studies [32–34]: both 14G and 11G probes were used, and biopsies per probe cannot be determined separately. Study [15]: 3 patients had a simultaneous breast carcinoma ipsilaterally. They are not used in the analyses. Study [31]: only lesions NOT consisting of calcifications were included.

Table 3
High-risk underestimates after 11G vacuum-assisted breast biopsy for lesions consisting of microcalcifications only

[Ref.]	High-risk at biopsy <i>n</i>	Inadequate FU/no excision <i>n</i>	Used for analysis <i>n</i>	Malignant at excision <i>n</i>	HR u/e (%)	95% CI
[15]	90	28 ^a	62	9	14.5	(5.7–23.3)
[21]	12	1	11	1	9.1	(0.2–38.5)
[23]	14	4	10	2	20.0	(1.8–42.8)
Total	116	33	83	12	14.5	(7.7–23.9)

^a Study [15]: 3 patients had a simultaneous breast carcinoma ipsilaterally. They are not included in the analyses.

determinant of the underestimate rate. However, the proportion of patients with DCIS among all patients with carcinoma could only be derived for a small number of the studies. However, we believe that among the populations described in the included studies, this proportion will not vary considerably, given that mainly

non-palpable lesions and comparable age groups were included.

An important conclusion of the present study is that the *miss-rate* could not be determined due to incomplete or non-reported follow-up of the benign lesions that were not surgically removed (also referred to as a ver-

Table 4
DCIS underestimate rates for stereotactic vacuum-assisted breast biopsy

Reference	DCIS at biopsy <i>n</i>	Inadequate FU/no excision <i>n</i>	Used for analysis <i>n</i>	Invasive CA at excision <i>n</i>	DCIS u/e (%)	95% CI
11G probe						
[19]	89	0	89	10	11.2	(4.7–17.8)
[20]	74	0	74	0	0	(0–48.6)
[21]	21	0	21	1	4.8	(0.1–23.8)
[22]	48	0	48	6	12.5	(3.1–21.9)
[23]	13	1	12	1	8.3	(0.2–36.0)
[24]	18	0	18	4	22.2	(6.4–47.6)
[25]	20	0	20	3	15.0	(3.2–37.9)
[26]	39	1	38	4	10.5	(0.8–20.3)
[27]	605	0	605	69	11.4	(8.9–13.9)
[28]	175	0	175	18	10.3	(5.8–14.8)
[32]	9	0	9	0	0	(0–33.6)
[33]	24	2	22	5	22.7	(5.2–40.2)
[34]	22	0	22	1	4.5	(0.1–22.8)
Total	1157	4	1153	122	10.6	(8.8–12.4)
14G probe						
[4]	12	0	12	6	50.0	(21.7–78.9)
[27]	348	0	348	38	10.9	(7.6–14.2)
[28]	47	0	47	8	17.0	(6.3–27.8)
[31]	2	0	2	0	0	(0–84.2)
Total	409	0	409	52	12.7	(9.5–15.9)

CA, cancer. In study [28] the number of patients without surgery or adequate follow-up is not specifically reported. Studies [32–34]: both 14G and 11G probe used, but biopsies per probe cannot be determined separately. Study [31]: only lesions NOT consisting of calcifications were included.

Table 5
DCIS underestimates (DCIS u/e) after 11G vacuum-assisted biopsy for lesions consisting of microcalcifications only

[Ref.]	DCIS at biopsy	Inadequate FU/no excision	Used for analysis	Invasive CA at excision	DCIS u/e (%)	95 CI
[21]	21	0	21	1	4.8	(0.1–23.8)
[23]	13	1	12	1	8.3	(0.2–36.0)
Total	34	1	33	2	6.1	(0.7–20.2)

N/A, not available.

Table 6
Follow-up of benign lesions diagnosed with 11G stereotactic vacuum-assisted breast biopsy

[Ref.]	Total benign lesions at biopsy	Inadequate or missing FU	Adequate FU	Cancer	Remarks on follow-up (FU):
[20]	476	476	0	N/A	Not reported for 11G vacuum biopsy separately
[21]	61	60	1	0	1 excision, rest not reported
[22]	491	479	12	2	2 excisions; 6 months FU for 254; 12 months for 43 patients
[23]	120	116	4	0	4 excisions; 6–36 months for 76 patients
[29]	146	146	0	N/A	6 months for 146 patients
[32]	56	56	0	N/A	Unsuspectious mammograms at 6 months for 33 patients
[33]	56	55	1	1	1 excision: invasive CA; FU not reported for 11G separately
Total	1406	1388	18	3	

N/A, not available.

ification problem: benign lesions are not surgically removed). The *miss-rate* for 14G automated biopsy is 3%, and it is not clear from the available data in this study that this rate is lower when using vacuum biopsy [3,13].

To estimate the benefit of vacuum biopsy over 14G automated-needle biopsy, we calculated the number of preventable underestimated diagnoses in a representative, non-selective population of patients with non-palpable breast lesions. We used the underestimate rates computed in the present study as data for the vacuum probe method, and as data for 14G automated-needle biopsy, we used those figures reported in a previous meta-analysis [13]. Furthermore, we used data from a recent multicentre trial in The Netherlands, which included women who were referred for a biopsy of a suspicious non-palpable breast lesion [3], to estimate the number of preventable underestimated diagnoses. In this population of 858 women, a total of 20 high-risk lesions and 158 DCIS lesions were diagnosed by surgery. 14G automated-needle biopsy would have yielded 33 high-risk lesions (underestimate rate 40.0%, 20 high-risk and 13 malignant at surgery) and 187 DCIS lesions (underestimate rate 15.5%, 158 DCIS and 29 invasive carcinomas at surgery). Vacuum biopsy would yield 24 high-risk and 176 DCIS lesions instead. Consequently, if vacuum biopsy was used for these women, 9 out of 858 (1.0%) women would be spared a *high-risk underestimate* diagnosis and 11 out of 858 (1.3%) would be spared a *DCIS underestimate* diagnosis. Hence, the total decrease in underestimated diagnoses would have been 20/858 (2.3%) when using the vacuum biopsy method instead of an automated-needle biopsy in this well-defined population.

Selective use of vacuum biopsy for lesions for which 14G automated biopsy is less accurate, such as lesions consisting of calcifications only [41], would be another option that could be further explored. In the present study, we also looked at lesions consisting of calcifications only, and although the number of lesions was very low, the combined *high-risk underestimate rates* (14.5%) and *DCIS underestimate rates* (6.1%) were comparable to rates found in studies describing all lesions. However, for logistic and financial reasons, it is not always possible to use both techniques in one institution. We agree with Jackman and colleagues [27] that there is probably not one universally cost-effective breast biopsy method that is best for all lesions. The diagnostic accuracy of image-guided breast biopsy techniques is already very high, and perhaps this could be best increased by focusing on multidisciplinary discussions on the outcomes of the biopsies and by constant monitoring of the quality, and not by further improving the technical performance of the biopsy devices.

In conclusion, the results of the present review indicate that vacuum-assisted biopsy, in comparison to 14G

automated-needle biopsy, can decrease *high-risk underestimate rates* and *DCIS underestimate rates*, but it is unclear whether it can decrease the *miss-rates* of cancer. Therefore, at this time, it is impossible to assess whether the benefits outweigh the additional costs of the procedure.

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