A Comparison of Spring-loaded and Vacuum-assisted Techniques for Stereotactic Breast Biopsy of Impalpable Microcalcification Lesions: Experience at Chang Gung Memorial Hospital at Linkou

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Background: The aim of this study was to assess the diagnostic performance of stereotactic core needle breast biopsy using spring-loaded or vacuum-assisted techniques for impalpable microcalcification lesions in Taiwanese women.

Methods: We retrospectively reviewed the data of patients who received stereotactic core needle breast biopsy for impalpable mammographic microcalcification lesions from January 1999 to February 2009. The accuracy, false negative rate, ductal carcinoma in situ (DCIS) upgrade rate and rate of concordance with biopsy procedures were determined. We also compared the diagnostic performance between the vacuum-assisted and spring-loaded techniques.

Results: A total of 335 breast stereotactic core needle biopsy procedures (218 by spring-loaded and 117 by vacuum-assisted technique) were enrolled for analysis. The overall accuracy, false negative rate, DCIS upgrade rate and concordance rate with stereotactic core needle biopsy were 88.5%, 17.3%, 23.1% and 83.8% respectively. The vacuum-assisted technique yielded better results than the spring-loaded technique in accuracy (100% vs. 84%), and the false negative (7.1% vs. 21%), DCIS upgrade (0% vs. 37.5%), and concordance rates (95% vs. 79.6%).

Conclusion: Stereotactic core needle biopsy is a feasible technique in diagnosing impalpable microcalcification lesions of the breast in Taiwanese women. The diagnostic performance of the vacuum-assisted technique was better than that of the spring-loaded technique.

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Key words: breast biopsy, stereotactic biopsy, microcalcifications, needle biopsy

Medical audit of the diagnostic performance of imaging techniques is important to provide better management of diseases. Breast biopsy is recommended for lesions classified as Breast Imaging

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Reporting and Data System (BI-RADS) 4, but documentary evidence has shown a wide range of malignant probability from 2% to 95%.[1] Minimal-invasion percutaneous core needle biopsy has been accepted as a cost-effective and reliable alternative to surgical biopsy for tissue sampling of suspicious breast lesions, in both screening and clinical diagnostic contexts.[2-9] Image guidance can facilitate the proper sampling of target lesions. The impact on the clinical management of breast lesions has been established, particularly for diagnosis of impalpable breast cancers.

Stereotactic core needle biopsy is a mammographic guided procedure using computer calculated x, y, and z coordinates. It has become an important diagnostic tool for mammography detectable breast lesions. The most significant value of this technique is to accurately retrieve subtle or small microcalcification lesions for early histological diagnosis of breast cancer in-situ or pre-malignant breast lesions before they can be palpated. In this retrospective report, we audited the 10-year results of stereotactic core needle biopsies on isolated microcalcification breast lesions in our hospital. In the past ten years, we used the spring-loaded core needle for stereotactic biopsy of breast microcalcifications. We started to utilize the recently developed vacuum-assisted technique for stereotactic biopsy in our institution as well in 2007. We thus herein compared our clinical performance with these biopsy techniques (vacuum-assisted vs. spring-loaded core needle techniques) in diagnosing impalpable breast microcalcifications. To the best of our knowledge, no report of stereotactic core needle biopsy has been previously published in Taiwan.

METHODS

We reviewed and analyzed the medical records of stereotactic core needle biopsies of impalpable breast microcalcification lesions performed in our institution, the Department of Diagnostic Radiology at Chang Gung Memorial Hospital at Linkou, from January 1999 to February 2009. Totally, 335 biopsy procedures for isolated impalpable breast microcalcification lesions in 325 patients (ages 32 to 74 years) were performed. From January 1999 to June 2008, 237 biopsies were undertaken using the prone table of a multicare unit (Lorad Stereo Guide, Danbury, CT, U.S.A.). From August 2008 to February 2009, 98 biopsies were carried out using mammography with an add-on biopsy unit (Lorad) with the patient in either a sitting or lateral position. A total of 218 biopsies were sampled by a spring-loaded biopsy gun (Bard Magnum, Covington, CA, U.S.A.) with a 14-gauge tru-cut core needle (Bard Magnum) while 117 biopsies were performed by a vacuum-assisted biopsy device with 9-gauge (10 cases by Atec, Suros surgical systems, Indianapolis, IN, U.S.A.) or 10-gauge (107 biopsies by Bard Vacora, Covington, CA, U.S.A.) needles.

All patients signed consents for the procedure. After localizing the target microcalcifications within the biopsy window, two mammographic projections at + 15 and –15 degrees were chosen for the target coordinates. The biopsy needle was then automatically brought to the entry point on the planar of x and y coordinates. The needle then penetrated in front of the target according to the depth of the z coordinate following local anesthesia and a small excision (Fig. 1). The biopsy procedures for the two techniques differed. The spring-loaded core needle needed to be fired at least 4 times for every individual sampling. Additional firing was necessary until microcalcifications were demonstrated on a specimen mammogram, but there were no more than 12 firings in our series. For vacuum-assisted core needle biopsy, a coaxial needle was used as guiding canal for multiple biopsies over the target area to avoid repeated needle penetration. Six retrievals were routinely carried out with the multidirectional biopsy notch in different clock allocations. Additional retrieval depended on the sufficiency of excised microcalcifications on specimen mammography.

The pathologic classifications were categorized as benign, suspicious and malignant for concordance correlation with biopsy and surgical pathology in our series. Malignant lesions included invasive carcinoma and ductal carcinoma in situ (DCIS). We considered atypical ductal hyperplasia, atypical lobular hyperplasia, and lobular carcinoma in situ to be suspicious lesions. Lesions that were not categorized as histologically malignant or suspicious were classified as benign. Pathologic results of the core specimens and surgical specimens were reviewed to assess the accuracy, false negative rate, DCIS upgrade rate and concordance rate. We also compared the diagnostic performance of the vacuum-

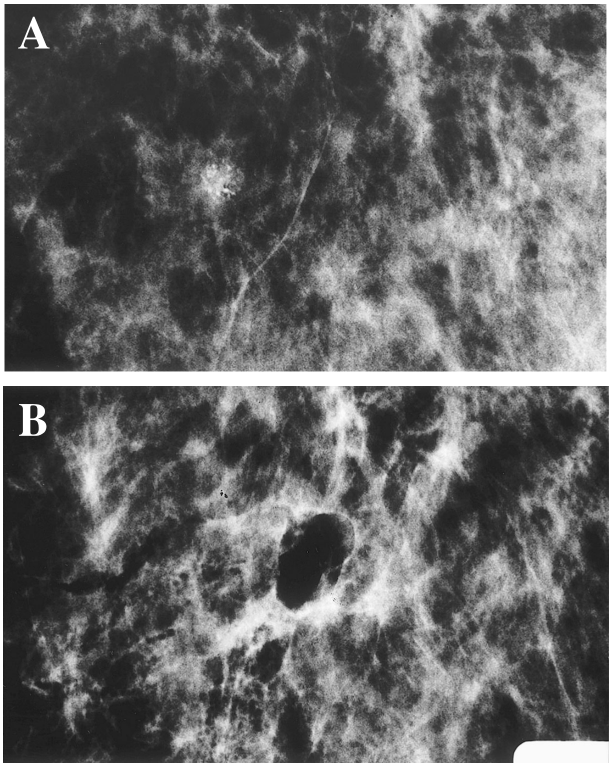

Fig. 1 A 57 year-old woman with clustered pleomorphic microcalcifications in the upper outer quadrant of the right breast. (A) A pre-procedure image reveals clustered pleomorphic microcalcifications in the center of the image. (B) The post-biopsy image reveals complete removal of the microcalcifications.

assisted technique with the spring-loaded technique. The definitions of parameters were in accordance with the standard specified National Health Service Breast Screening Programme (NHSBSP) Publication Number 50.[10] The accuracy was defined as the number of malignant or suspicious lesions diagnosed by needle biopsy (that had subsequent surgical histology) expressed as a percentage of the total number of surgically proven malignant cases. The false negative rate was the number of false negative results expressed as a percentage of total cancer. The DCIS upgrade rate was the number of DCIS upgrades to invasive cancer at subsequent surgical histology expressed as a percentage of needle- diagnosed DCIS with subsequent surgical proof. The concordance rate was the number of biopsies with the same surgically proven histological classification as a percentage of the total surgically proven lesions. The accuracy, and false negative, upgrade to DCIS and concordance rates were all presented together with their respective 95% confidence intervals (CI).

RESULTS

Microcalcifications were successfully retrieved in 175 (80.3%) of 218 spring-loaded core needle biopsies and in 117 (100%) of 117 vacuum-assisted core needle biopsies.

Sixty-six cancers (19.7%) were diagnosed by 335 stereotactic core needle biopsies, 18 cancers (15.4%) by 117 vacuum-assisted core needle biopsies and 48 cancers (22%) by 218 spring-loaded core needle biopsies (Fig. 2). Sixteen of 25 suspicious lesions were diagnosed with vacuum-assisted and 9 by spring-loaded techniques. The other 244 lesions were diagnosed as benign lesions, 83 lesions with vacuum-assisted and 161 lesions with spring-loaded techniques.

Overall, 74 patients received subsequent operations, including 43 lesions diagnosed as malignant, 10 as suspicious, and 21 as benign by stereotactic core biopsy. Among these, 52 breast cancers were diagnosed, consisting of 29 (55.8%) invasive ductal cancers (IDC) and 23 (44.2%) DCIS. Among the spring-loaded core needle biopsy cases, 13 (34.2%) DCIS and 25 (65.8%) invasive cancers were finally diagnosed; in vacuum-assisted core needle biopsy cases, 10 (71.4%) DCIS and 4 (28.6%) invasive cancers were finally diagnosed. Missed cancer was defined as a needle- biopsy diagnosed benign lesion which was discovered to be malignant at subsequent surgical histology. Six breast cancers were missed by spring-loaded core needle biopsy. Among these missed cancers, the diagnoses of cancer were made either by vacuum-assisted core needle biopsy or surgery (3 cases in each).

Follow-up of the patients with needle diagnosed benign or suspicious lesions without subsequent excision biopsy was performed either by sonography or mammography. The follow-up period for the 94 patients with spring-loaded needle -diagnosed benign lesions was 50.2 ± 38.3 (mean ± SD) months (range 3 to 127 months). Two of these 94 cases were discovered to be DCIS and IDC by surgical pathology 2 and 3 years after the needle biopsy, respectively. For those 2 spring-loaded needle diagnosed suspicious lesions, no breast cancer was discovered during

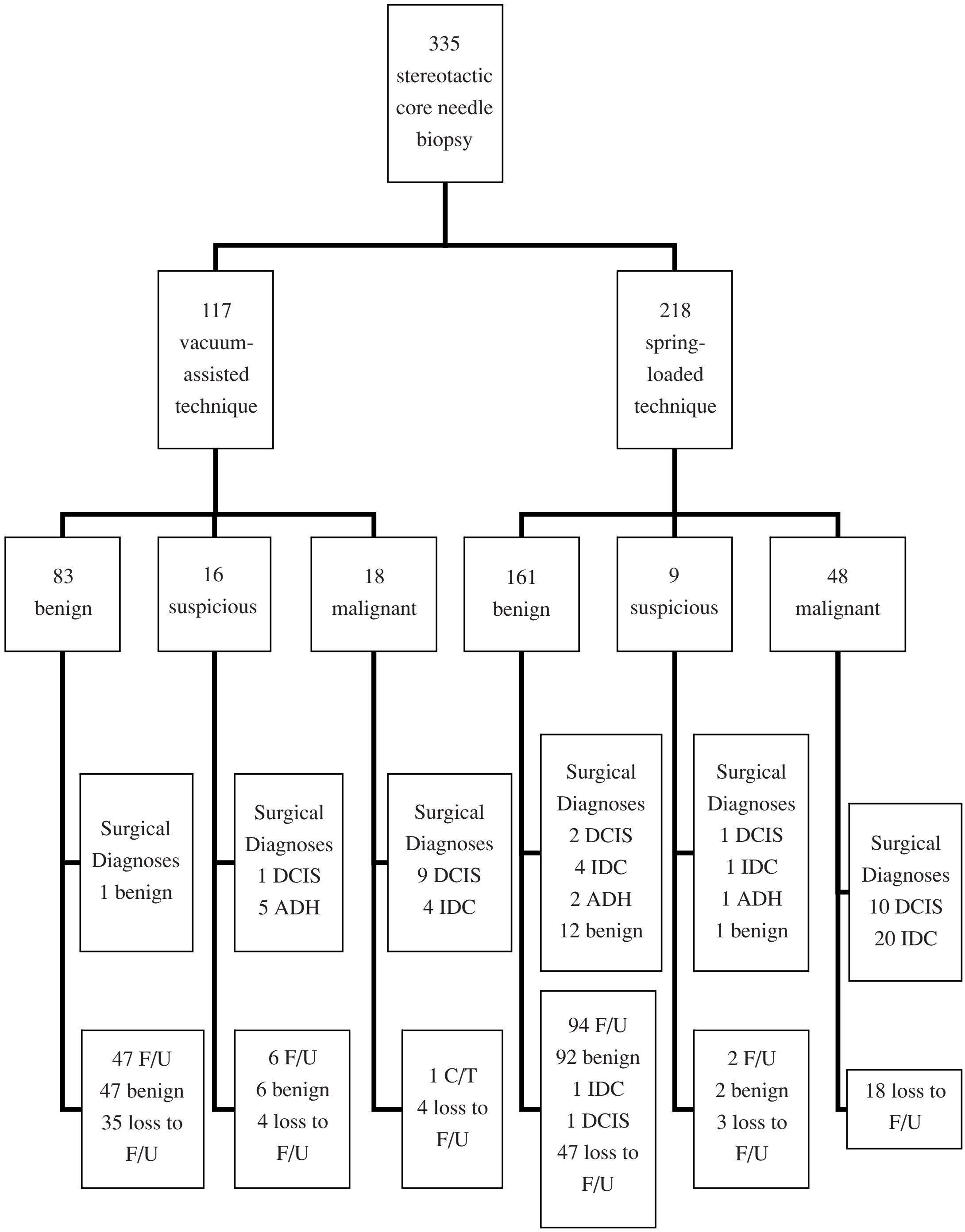

Fig. 2 Flow chart of patients and lesions. Abbreviations used: DCIS: ductal carcinoma in situ; IDC: invasive ductal carcinoma; ADH: atypical ductal hyperplasia; C/T: chemotherapy; F/U: follow-up.

the 15 and 64 months follow-ups, individually. Otherwise, the follow-up period for the 47 patients with vacuum-assisted needle diagnosed benign lesions and the 6 with suspicious lesions were 12.6 ± 5.2 (range 4 to 25) and 15.2 ± 5.3 (range 11 to 23) months, respectively. No malignant breast lesion was found in the follow-up period.

The upgrade rate from ADH to cancer was 30%, and for DCIS to IDC was 23.1%, for an overall upgrade rate of 25%. Of the 6 ADH cases diagnosed by vacuum-assisted core needle biopsy, only 1 (16.7%) was finally upgraded to DCIS at subsequent surgery. None of 10 surgical DCIS vacuum-assisted biopsy cases was found to be underestimated from IDC. On the other hand, the spring-loaded core needle biopsy yielded 4 ADH cases in which 2 (50%) were upgraded to cancers at subsequent surgery. Otherwise, 6 of 16 (37.5%) spring-loaded needle diagnosed DCIS cases were upgraded to IDC.

The overall accuracy, false negative rate, DCIS upgrade rate, and concordance rate for stereotactic core needle biopsy were 88.5%, 17.3%, 23.1% and 83.8%, respectively (Table 1). For the spring-loaded technique, these results were 84% (CI, 68.8% to 94.0%), 21% (CI, 9.6% to 37.3%), 37.5% (CI, 15.2% to 64.6%) and 79.6% (CI, 66.5% to 89.4%), respectively. The vacuum-assisted technique, yielded better results of 100% (CI, 76.8% to 100.0%), 7.1% (CI, 0.2% to 33.9%), 0% (CI, 0% to 30.9%) and 95% (CI, 75.1% to 99.9%) respectively.

Table 1. Diagnostic Perfomance of Two Stereotactic Core Needle Breast Biopsy Techniques

	Spring-loaded core needle	Vacuum-assisted core needle
Accuracy	32/38 (84%)	14/14 (100%)
False negative rate	8/38 (21%)	1/14 (7.1%)
DCIS upgrade rate	6/16 (37.5%)	0/10 (0%)
Concordance rate	43/54 (79.6%)	19/20(95%)

Accuracy: number of malignant or suspicious lesions on needle biopsy/total number of surgical proved cancers; False negative rate: number of cancers not diagnosed by needle biopsy/total surgical proved cancers; DCIS upgrade rate: number of DCIS subsequently discovered to be IDC with subsequent surgical histology/number of needle- diagnosed DCIS proved with surgical histology; Concordance rate: number of biopsies with same histological classification as the surgically proven classification /total number of biopsies with surgery.

Ecchymosis, hematoma and pain sensation were unavoidable complications associated with the biopsy procedure. However, there were no major complications such as uncontrollable bleeding, severe post-procedural inflammation, abscess formation or skin retraction in our series.

DISCUSSION

Percutaneous core needle biopsy of the breast is a feasible method for histopathologic diagnosis of detectable breast lesions. In an analysis of 4035 biopsies, the diagnostic accuracy of image-guided percutaneous core needle biopsy, with either sonographic or stereotactic guidance, for screening-detected or clinically-detected breast lesions was reported to be 90.8% for masses, 91.9% for isolated microcalcifications and 62.2% for parenchymal distortion.[11] Sonography- guided core needle biopsy is often recommended when the lesion is sonographically detectable. However, the stereotactic mammographic guided core needle biopsy has been accepted as an optimal method for impalpable isolated microcalcification lesions.

Isolated breast microcalcifications mostly occur secondary to benign processes; however potentially malignant or malignant lesions are possible as well. Such microcalcifications can be objectively seen on mammograms, but are possibly undetectable or poorly visualized on sonograms depending on the existing background.[12] For example, microcalcifications are more obviously noted within hypoechoic masses. Beneficially, mammography can clearly demonstrate the morphology and distribution of microcalcifications. Using the descriptions of microcalcifications from the BI-RADS 4th edition lexicon, the cancer probability according to morphologic descriptors was assessed at 7% for coarse heterogenous, 11% for punctate, 20%-26% for amorphous, 25%-41% for fine pleomorphic, and > 80% for linear/branching lesions, and for distribution descriptors, 36% for cluster, 46% for regional, 68% for linear, and 78% for segmental lesions.[13] Diffuse, symmetrical microcalcifications in the bilateral breasts are usually considered benign processes, however the incidences of the above microcalcification distributions should still alert clinicians to coexisting suspicious microcalcifications. On the other hand, for diffuse microcalcifications in the unilateral breast, the clinician needs to refer to the morphology of microcalcifications.[13] Retrieval of suspicious microcalcifications is necessary for histopathologic diagnosis. Isolated microcalcifications probably represent landmarks of comedo necrosis of intraductal cancers on microscopy. That is why the outcome of a biopsy will be influenced by whether the core specimens contain microcalcifications or not. A final diagnosis of cancer is more likely in core specimens with calcifications (84% vs. 71%) and it is more likely that a diagnosis of cancer will be missed in core specimens without microcalcifications (11% vs. 1%).[14]

Stereotactic core needle biopsy is now considered a first-line procedure in diagnosing isolated suspicious microcalcifications to avoid unnecessary surgery. European guidelines for interventional procedures on the breast advise repeated biopsy or preoperative wire localization when the diagnosis of core needle biopsy is discordant with the imaging appearance.[15] The breasts of Taiwanese and Asian women are commonly smaller, more tender and denser than those of Western women (less than 3 cm in compressed thickness) which often limits the firing of pring-loaded core needles. In our experience, this is the most common reason for canceling a spring-loaded procedure. However, the vacuum-assisted core needle biopsy could solve this problem by adjusting the length of the protruding biopsy needle from 2 cm to 1 cm or by pushing the biopsy needle through the target for a suction biopsy without firing. Using vacuum-assisted core needle biopsy, the minimal compressed breast thickness in our series was 1.7 cm.

Radiographs of obtained specimens are essential to check if the calcification has been retrieved from the targeted microcalcification lesions, which affects the biopsy outcome. The presence of retrieved calcifications has a small but reliable association between the biopsy method and the number of specimens obtained ($r = 0.33$, $p < .001$).[16] Less tissue or more blood is obtained with acquisition of more than 5 specimens by spring-loaded core needle biopsy over the same area.[17] However, the design of vacuum-assisted core needle biopsy makes it easy for the operators to obtain 6 to 12 specimens over the same area. More and larger specimens can easily be obtained by vacuum-assisted than spring-loaded core needle biopsy. However, microcalcifications are sometimes not retrieved (calcification not visualized on specimen radiograph). This occurs more often with spring-loaded (14% of 1236 cases by 14-gauge needle) than vacuum-assisted core needle biopsy (1% of 4781 cases by 11-gauge needle and 3% of 492 cases by 14-gauge needle).[16] Similarly, the failure rate of microcalcification retrieval improved from 20% with the spring-loaded technique to 0% with the vacuum-assisted technique in our series.

One limitation of this study is that some final outcomes were not obtained for the following reasons: (1) Some patients with needle-diagnosed cancers did not have subsequent surgery becasuse they sought a second opinion at other hospitals; (2) Some patients with needle-diagnosed ADH refused subsequent surgery; (3) Some patients with needle-diagnosed benign lesions were lost to follow up; and (4) There was a lack of histological support for cases of needle-diagnosed benign disease. A vast of majority of patients who did not undertake subsequent operations at our hospital remain unclassified, although many of them were followed up for more than 2 years. In our analysis, we ought to presume those cases will not have cancer.

Basically, core needle tissue is also a kind of histological diagnosis. The diagnostic value is theoretically equivalent to excision biopsy. Also, complete excision of subtle or small breast cancers is possible with the multiple and larger excisions in vacuum assisted core needle biopsy. Complete excision of breast tumors and cancer has been reported using sonographically-guided or stereotactic-guided vacuum-assisted core needles.[18,19] In the Liberman et al. series, 20% of isolated microcalcification lesions were microscopically proved to be completely removed.[18] In our series, 2 of our 10 needle-diagnosed DCIS (20%) were microscopically revealed to be free of residual cancer. Only atypical ductal hyperplasia was observed at the edge of the biopsy sites. Therefore, the sensitivity, specificity, false positive or false negative might be interrupted.

False negatives must be avoided or minimized as much as possible. The false negative rate using vacuum-assisted core needle biopsy averaged 7.6%. A larger biopsy needle can also lower the false negative rate from 22.2% (with a 14 gauge biopsy needle) to 3.3% (with a 11 gauge biopsy needle).[20] The upgrade rate of ADH was reported to be 21.1% in one study, but there were no difference in the frequency of ADH or upgrade rates between needle sizes.[21]

The accuracy, false negative rate, DCIS upgrade rate, and concordance rate of overall stereotactic core needle biopsy in our series were 88.5%, 17.3%, 23.1% and 83.8% respectively. There are two possible reasons for the high false negative rate. The first is insufficient tissue sampling, as 8 of the 9 false negative cases were performed with spring-loaded core needle biopsy. However, the results improved with the use of area sampling by vacuum-assisted core needle biopsy instead of point sampling by spring-loaded core needle biopsy. The second reason is the inexperience of both the radiologist and pathologist at the beginning of the study. Six of the 9 false negative cases occurred within the first 5 years of the study, and the other 3 cases occurred after 5 years experience.

Conclusively, stereotactic core needle biopsy is feasible to provide the histopathologic diagnosis for the management of impalpable suspicious microcalcifications in Taiwanese women. Based on the data we analyzed, using the vacuum-assisted technique could immediately improve the accuracy, false negative rate, DCIS upgrade rate, and concordance rate from 84% to 100%, 21% to 7.1%, 37.5% to 0% and 79.6% to 95%, repectively compared with the spring-loaded technique.

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乳房立體定位切片檢查針對不可觸知的乳房微鈣化病灶：使用自動彈簧切片針與眞空輔助切片針的比較——林口長庚醫院的經驗

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背 景： 評估針對臺灣婦女不可觸知的乳房微鈣化病灶，使用自動彈簧切片針與眞空輔助切片針進行乳房立體定位切片的診斷性能。

方 法： 我們回顧本院針對不可觸知的乳房微鈣化病灶進行立體定位切片檢查的經驗與資料，期間自民國八十八年一月至民國九十八年二月。分別計算出乳房立體定位切片對微鈣化病灶的診斷正確度、假陰性率、原位性乳癌提升率與診斷符合率。同時比較使用自動彈簧切片針與眞空輔助切片針的診斷性能。

結 果： 我們總共收集並分析了 335 例乳房立體定位切片檢查 (218 例使用自動彈簧切片針與 117 例使用眞空輔助切片針)。全體的診斷正確度、假陰性率、原位性乳癌提升率與診斷符合率分別爲 88.5%、17.3%、23.1% 及 83.8%。使用眞空輔助切片針比自動彈簧切片針有較好的診斷性能，診斷正確度分別爲 100% 與 84%，假陰性率爲 7.1% 與 21%，原位性乳癌提升率爲 0% 與 37.5%，診斷符合率爲 95% 與 79.6%。

結 論： 立體定位切片針對臺灣婦女不可觸知的乳房微鈣化病灶是一項可實行的診斷工具；且使用眞空輔助切片針比自動彈簧切片針有較好的診斷性能。
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關鍵詞： 乳房切片，立體定位切片，微鈣化，粗針切片

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