Report of preliminary experience of the prone table stereotactic breast core biopsy at the King Fahad National Guard Hospital

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Abstract

A report of 18 months experience of using the prone table stereotactic breast biopsy equipment (Lorad Multicare Platinum Hologic Company) is made to share our experience including successes and failures.

Out of 5,462 breast examinations involving diagnostic and screening population, 85 patients with American BI-RADS (Breast Imaging and Reading Data System) 3 to 5 micro-calcifications or non-palpable masses provided the material for the study. Six to 10 cores were obtained and confirmed for the presence of micro-calcification and subsequently sent for hispathology.

Seven out of the 85 patients were cancelled due to various reasons. Out of the 78 that were successfully biopsied, 17 patients were positive for malignancy. The overall positive rate was 22% and 100% for all BI-RADS 5 cases and these are within the international standard. No significant complications.

In conclusion, the prone table stereotactic biopsy equipment is easily used with the training of the mammographic staff on the purchased machine. The procedure has resulted in the reduction of the invasive localization surgical biopsy. However, in unsuccessful cases, localization surgical biopsy remains imperative for BI-RADS 4 and 5 cases. Seemingly a significant number of mammographic examinations would be needed in the institution to merit the presence of the stereotactic core biopsy equipment.

Introduction

With the constant media information about breast cancer and the benefits of breast screening, healthcare institutions and private healthcare deliverers are confronted with all forms of breast imaging equipment to undertake a comprehensive screening and diagnostic programme. Often, there are no guidelines or pre-requisite to purchase such equipment. The marketing companies readily provide documented successful information of these equipments in developed countries where specialized radiologist and radiographers in breast imaging are available and quality control regime and self auditing of staff are encourage to improve performance.

The usefulness of performance and results of stereotactic core biopsy of breast micro-calcification and non-palpable lesions that are not well seen in ultrasound is well documented in the literature from developed countries [1-6].

However, there is little if any reports from developing countries where specialized radiologist and technologist in breast imaging are very limited. This communication intends to share our first 18 months experience of using the prone table stereotactic biopsy equipment [Lorad Multicare Platinum Hologic Company] with the automated gun biopsy [Vacora Vacuum Assisted Biopsy] System.

Pre-requisite for purchasing the equipment, initiation process to the use of the machine and general experience will be discussed. It is hoped that others from the region will learn from our shortcomings and success.

Subjects and Methods

A retrospective study of 5462 patients, who had breast examinations over the period of 18 months (June 2008 to December 2009) at the King Fahad National Guard Hospital, eighty-five (85) patients provided the materials for this study. These patients had American BI-RADS (Breast Imaging and Reading Data System) [6] lesions of BI-RADS 3 [N=51], BI-RADS 4 [N=22], BI-RADS 5 [N=12]. They were micro-calcifications only [N=73]. Micro-calcification and mass [N=8], mass [N=4].

Pre-biopsy preparation included full explanation to the patients about the biopsy procedure and obtaining signed consent. Patients were asked about anticoagulant therapy or other medical problems. They were advised to empty their bladder before the examination. Keeping still throughout the examination was also emphasized. The equipment used is the prone table stereotactic core biopsy machine [Lorad Multicare Platinum Hologic Company]. Biopsy specimens

were obtained with the Vacora Vacuum Assisted Biopsy system. The 10-gauge needle was used for most of the patients after an initial discovery that the 14-gauge produced crushed specimens. The biopsy process basically involved standardization of the machine, accurate positioning of the lesion with good compression and obtaining the stereotactic pair of images to confirm accurate location of the lesion. Between 6 to 8 cores where usually obtained and x-ray of the specimen to confirm the presence of micro-calcification was usually done. [Figs.I and II] Post Biopsy markers were also used in some cases. Compression of the trajectory was between 5-10 minutes. Post-biopsy information sheet was also given to the patient.

Results

The procedure duration was between 25 to 60 minutes. It was very well tolerated by all our patients. One patient who denied any anticoagulant therapy had unusual bleeding during the procedure. This however, settled with post-biopsy compression of 10 minutes without any hematoma. Otherwise, there were no complications.

Table I shows the overall performance. Seven cases were cancelled due to various reasons. Two cases had crushed specimens with inconclusive histology.

Table II shows the pathological results in relation to the B1-RADS classification of lesions biopsied. Out of the 85 cases, 78 were successfully biopsied

Out of 76 patients with complete pathological report, 17 cases had malignancy.

On the overall performance, the cancer detection rate was 22 % and 100 % in the B1-RADS 5 lesions. These are with the International Predictive Value [13].

Table 1: Overall Performance

Total number intended for Biopsy	=	85
Total number of cancellation	=	7 [BI-RADS 3= 5 BI-RADS 4= 2]
Total number Biopsied	=	78
Total number with Complete Report	=	76
Total number with Crushed Specimen	=	2

Table 2

Classification B1 RADS	No. of Lesions	Malignant	Benign	% + Malignancy
Indeterminate Probably Benign BI-RADS 3	46	_	32	0 %
Probably Malignant BI-RADS 4 (Higher or Lower Category)	20	5	atypia	25 %
Malignant BI-RADS 5	12	12	-	100 %

Reasons for Cancellation

A total of 7 cases (5 BI-RADS 3, 2 BI-RADS 4) were cancelled. Technical problems with a faulty Vacora biopsy system was the cause in 3 cases. We however, had to replace the faulty Vacora biopsy system. In 2 cases lesions were too faint to be seen despite adequate compression. These were located in dense large breast. In 1 case, the lesion was too close to the chest wall and in the other, the breast was too thin and that caused a negative stroke margin.

Out of the 2 BI-RADS 4 lesions cancelled, one was malignant on localization biopsy while the other was benign. Of the 5 BI-RADS 3 lesions, three are being followed-up while two were benign at localization biopsy. Two BI-RADS 4 specimens were considered crushed and inadequate for accurate histological assessment. These were performed with a 14-gauge needle with the Vacora biopsy system. Excision biopsy was performed for these cases and they were positive for malignancy.

We have since then stopped using a 14-gauge and prefer the 10-gauge needle, which produces more satisfactory tissue.

Discussion

Within a period of 18 months, we successfully biopsied 78 cases who required breast biopsy for micro-calcifications and non-palpable lesions with the prone table stereotactic equipment. The overall positive rate is 22%, and 100% for the **BI-RADS** 5 lesions, which is within the international range [7], as shown in table one. In cases with micro-calcifications, specimen radiography confirmed the presence of micro- calcifications before it was sent for histological evaluation [Fig. I and II). The histologic reports also confirmed the presence of calcification in the cores sent for analysis. The procedure with the prone table was very well tolerated by all our patients. The entire performance took 25 minutes to 1 hour. Apart from one patient, who denied anticoagulant medication who had unusual bleeding during the procedure, we had no significant complication. The biopsy was successfully accomplished quickly within 25 minutes and post biopsy compression of 10 minutes stopped the bleeding without any palpable hematoma.

An obvious benefit was the reduction of cases for localization surgical biopsy to half the numbers as compared with an equivalent period of 18 months previous to when we started stereotactic biopsy.

Compared with the open surgical biopsy, the procedure is about 1/3 the cost [8-9] with variation in different countries. Also, unlike surgical biopsy, stereotactic needle biopsy does not distort the breast tissue to cause difficulty with reading future mammograms [8, 10].

We had 7 cases of cancellation. The factors being technical failure with the Vacora biopsy system (N=3), inability to visualize the lesion for biopsy in large dense breast despite accurate compression (N=2). In one case, the lesion was too close to the chest wall while in the last case, the breast was too flat and there was negative stroke margin.

All the failed BI-RADS 4 cases (2 cancellation and 2 crushed specimen) and 2 of the BI-RADS 3 (5 cancellations) had localization biopsy and 3 of the BI-RADS 4 cases were positive for malignancy. Three cases with BI-RADS 3 lesions are

being followed-up. The findings within the cancelled cases are in accordance with the report of Verkooijen et al (11, 12) who pointed out the risk factors for cancellation of stereotactic core biopsy. Apart from the technical problems with the vacora biopsy system, the other reasons are well known cases of failure at stereotactic core biopsy (11, 12, 13). We have replaced the faulty Vacora system with a new one. However, we hope to acquire one of the directional vacuum-assisted biopsy system (e.g. Encur, Suros, etc.), which are preferable for small lesions and lesions that are superficial or in thin breast [9]. These also have the advantage of obtaining several cores with single needle insertion.

The two cases where the specimens were reported as crushed and unsuitable for accurate pathological report. The 14-gauge needle biopsy with the Vacora System was used. We have since then adapted the 10-gauge large bore needle and have had no problem with specimen quality.

Part of our success is attributed to the fact that all members of the team i.e. mammographers and technologists were trained on ground simultaneously with our machine by the application specialist from abroad.

Our limitations include the number reported, which is rather small but it only represents the first 18 months experience. Also, due to the short duration involved, false negative cases are not yet available. However, we are still following up the negative cases particularly with BI-RADS 4 category and the cancellations.

For establishment intending to purchase the equipment, it is prudent to consider the potential number of patients requiring breast examination annually. This includes both diagnostic and screening population. Considering our experience of total number (85 out of 5462) requiring the use of stereotactic biopsy, a setting with less than 2000 patients per annum may have a hypothetical number of about 3 patients requiring stereotactic core biopsy in a month. This number is hardly adequate to maintain staff competence and may not be considered cost effective. This is because most masses can be identified by ultrasound and can therefore, be biopsied by ultrasound-guided procedure, which is simpler, faster and less expensive.

A budget plan to purchase the stereotactic machine should include other accomplishment such as needles, localization marker, a directional vacuum-assisted biopsy machine, and equipment for specimen radiography even though some are sold by different companies. This would avoid delay in the use of the machine. Prolonged delay in the use of the machine due to lack of the accessories can result in ultimate abandonment. It is also important to note, that some of the equipment demands the use of consumables produced only by the same company.

There is obvious advantage for the training of radiologists and technologists at the same time and on the purchased machine by the application specialist. This is contrary to handpicking some staff to go abroad to train on the use of the machine, while others would have to depend on the knowledge of the privileged ones.

In conclusion, we have successfully used the stereotactic prone table breast biopsy system. It is well tolerated by patients and has significantly reduced localizations surgical biopsy. Our positive predictive rate for malignancy is compatible with the International Standards. We have discussed our suggestion involving purchasing the equipment and accessories, the process of staff orientation and consideration of the patient population that may be involved.

Acknowledgement

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Figures

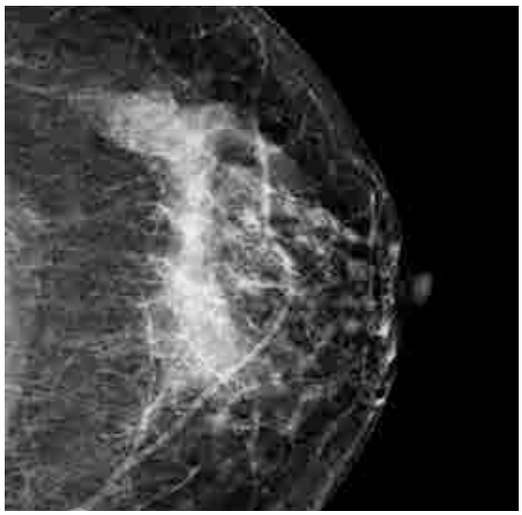

Fig. 1a: (Benign Biopsy) A cluster of pleomorphic microcalcification is shown centrally in the breast arrow.

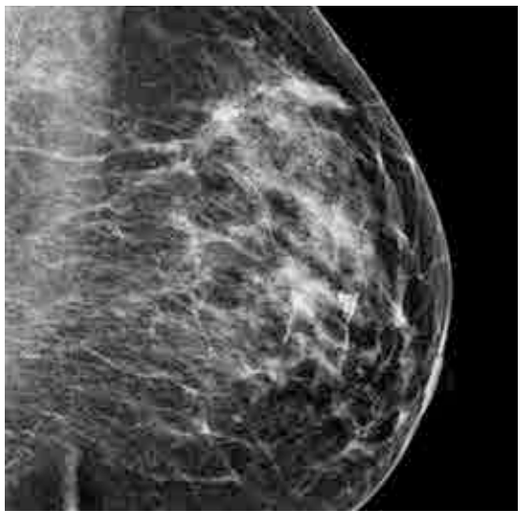

Fig. 2a: (Malignant Biopsy) Pleomorphic microcalcification in the retro areola region.

Fig. 1b: Specimen tray showing the microcalcification in the central chamber and at 12 o'lock.

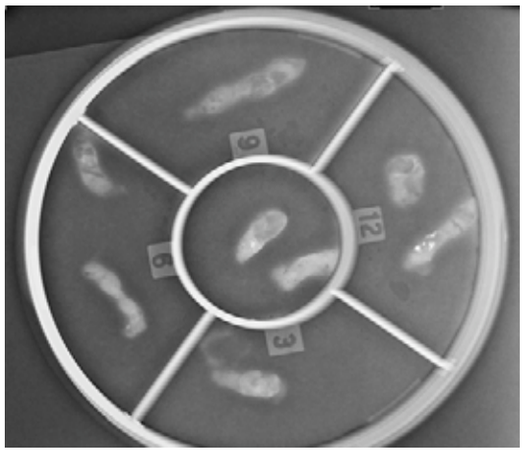

Fig. 2b: Specimen tray showing microcalfication in several cores.

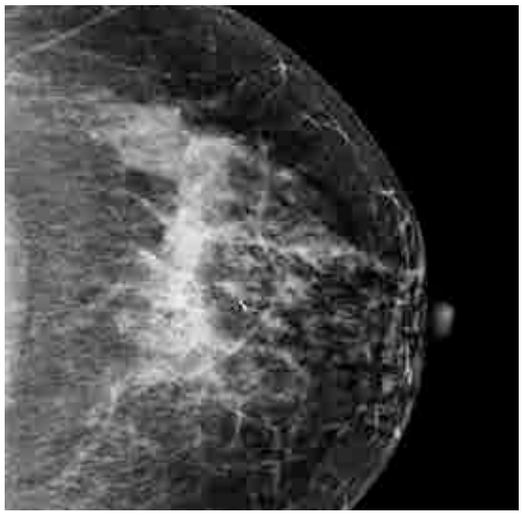

Fig. 1c: Post biopsy view shows a clip in the area biopsied with total removal of the microcalcification.

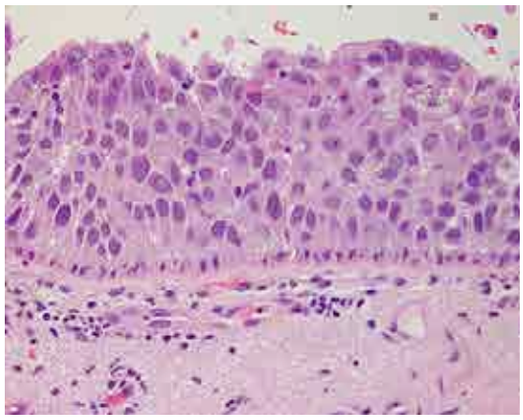

Fig. 2c: Pathological Specimen Showing Features of DCIS.