INFORMATION BRIEF (RAPID REVIEW)

SPIRAL BREAST CT (SBCT) SCAN

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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Rapid Review
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TITLE: nu:view – SPIRAL BREAST CT SCAN (SBCT)

PURPOSE

To provide brief information on the efficacy/effectiveness, safety and cost-effectiveness of spiral breast CT (SBCT) scan. The [redacted] was developed by German company [redacted].[1] The review was requested by the Director of Medical Development Division, Ministry of Health (MOH) due to proposal submitted by the company to introduce the SBCT for breast cancer in MOH.

BACKGROUND

The [redacted] - (SBCT) scan is a dedicated breast CT scanner with a spiral acquisition mode and a direct converting photon-counting detector. The scanner rotated on a helical path with a pitch of one, a rotation time of two second and with 2,000 projections per rotation. The scanner is fixed with a tube voltage of 60kV and a manual adjustable current-time-product (CTP). According to the manufacturer, an imaging with a CTP between 25 and 32mAs enabled glandular doses below 6.5mGy with high signal-to-noise ratios.[2]

During examination, patient will be in prone position where the breast is placed through an opening of a patient table and is hanged freely through the opening. Then the imaging was performed without compression of the breast. The examinations are performed before and two minutes after contrast media injection, the contrast media is infused with an automated injector through a cubital vein cannulation at a weight-dependent dose.[2]

EVIDENCE SUMMARY

There were four studies on [redacted] SBCT included in this information brief report. The included studies were conducted within 2019 to 2024. No study retrieved comparing between the [redacted] SBCT with other breast cancer screening device.

EFFICACY/ EFFECTIVENESS

A study by Weber J. et. al. assessed the density values of breast lesions and breast tissue using non-contrast spiral breast CT (nc-SBCT) imaging. The study involved 40 women who were not preferred to go mammography examination from April 2023 to October 2023. All the 40 patients underwent [redacted] nc-SBCT scan and the images were independently analysed by two readers with different level of experience in breast imaging; Reader 1 (3-months experience) and Reader 2 (> 5-years' experience). The two readers conducted the analysis,

placing regions of interest (ROI) in index lesions and in the glandular tissues. They were informed about the position of the target lesion but not about the histology. The ROI diameter, mean density (in HU unit) and standard deviation values were annotated for each measure. With the SBCT scan, the 40 women were detected with 12 malignant lesions (ML), 10 fibroadenomas (FA), 15 cysts. Meanwhile, nine women with extremely dense glandular breast tissue showed no findings on either the SBCT or ultrasound. Table 1 simplified the analysis between two readers for mean ROI diameter, and median density values. For both readers, densities were significantly different for ML versus EDB ($p < 0.001$) and cysts ($p < 0.001$) and for FA versus EDB ($p \leq 0.003$). The AUC was 0.925 (95 % CI 0.858–0.993) for R1 and 0.942 (0.884–1.00) for R2 when comparing ML versus others and 0.792 (0.596–0.987) and 0.833(0.659–1) when comparing ML versus FA. The intra-class correlation coefficient (ICC) showed an almost perfect inter-reader (0.978) and intra-reader agreement (>0.879 for both readers). Based on this analysis, it showed that nc-SBCT malignant lesions had higher density values compared to normal tissue and measurement of density values were reproducible between different readers.[4]

Table 1:

	Malignant Lesions		Fibroadenomas		Cysts		Extremely dense breast	
	Reader 1	Reader 2	Reader 1	Reader 2	Reader 1	Reader 2	Reader 1	Reader 2
Mean ROI diameter	7.4 ± 2.6mm	8.2 ± 3.5 mm	6.2 ± 2.0mm	7.0 ± 2.8 mm	7.3 ± 2.5mm	10.0 ± 4.5 mm	28.7 (24.2–33.0) HU	33.3 (31.7–36.8) HU
Median density values	60.2 (53.3–67.3) HU	62.5 (55.67–76.3) HU	46.3 (41.9–59.5) HU	44.5 (40.5–59.8) HU	35.3 (24.3–46.0) HU	39.7 (26.7–52.0) HU	-	-

Wetzl M. et. al. conducted a study to intra-individually compare patient comfort of SBCT versus digital mammography (DM). The final analysis involved 79 patients who were answering questionnaire on 'Overall patient comfort' and sub-criteria pain and body position separately for DM and SBCT. The assessment also involved two independent breast radiologisst for visibility of fibroglandular tissue in SBCT. The analysis was rated with 10-point Likert Scale and subgroup analysis of menopausal status and body mass index (BMI) was also conducted. At the end of the studies, patients reported significant lower pain during SBCT (4.73 ± 0.57) compared to DM (4.09 ± 0.90; $p < 0.01$). However, pain reduction by SBCT was most pronounced in pre-menopausal (SBCT versus DM: 4.79 ± 0.50 versus 3.89 ± 0.99) compared to post-menopausal patients (4.71 ± 0.77 versus 4.20 ± 0.89. Overall patient comfort in pre-menopausal patients tended to be higher in SBCT compared to DM ($p = 0.08$). Meanwhile, for radiologist assessment, they rated the SBCT procedure generally as positive (average: 4.62 ± 0.56). Coverage of fibroglandular tissue in SBCT was generally high (9.82 ± 0.43) and interrater agreement was good ($\kappa = 0.77$).[2]

Another study by Burger N. et. al. aimed to assess the first clinical experience using SBCT with a single photon-counting detector ([redacted] SBCT). The study was conducted retrospectively that involved 300 consecutive women who refused to have mammography. Most of the patients

(84.7%) prefer SBCT over mammography because of a lack of breast compression. The images from the SBCT were analyse by two experienced radiologists separately (Reader 1 and Reader 2). One hundred two (102) possible lesions were detected through SBCT images including four cases of breast cancer (1.3% of all patients) by both readers. An additional ultrasound was performed in 226 patients (102 due to detected lesions and 124 due to dense breast tissue). From the analysis, nine lesions were visible either in SBCT and in ultrasound and were rated with Breast Imaging and Reporting and Data System (BI-RADS) 4 or higher. Those nine lesions underwent biopsy and histological analysis (5 invasive ductal cancers, 2 invasive lobular cancers and 2 sclerosing adenosis). Meanwhile, three of the malignant lesions were only visible in ultrasound. In terms of architectural distortions, two out of 591 SBCT images were detected. For micro-calcifications, both readers found the micro-calcifications in 175 SBCT images and 10 SBCT disagreeing results.[5]

Berger N. et. al. reported in an early publication on first clinical in vivo application of a new SBCT equipped with photon-counting detector ([redacted]-SBCT). The study involved 12 women who were referred for breast cancer screening and underwent bilateral SBCT. Out of the 12 women, five women had a previous mammography. Additional sonography was performed in case of dense breast tissue or any breast CT finding. Soft tissue and high resolution images were reconstructed. Two independent radiologist performed separately the readout for subjective image quality and for imaging findings detection. All women were asked to report about positioning comfort and overall comfort during data acquisition. The major pectoral muscle was included in 15 breast CT scans (62.5%); glandular component was partially missing in 2 (8.3%) of the 24 scanned breasts. A thin “ring artefact” was present in all scans but had no influence on image interpretations; no other artefacts were present. Subjective image quality assessment showed excellent agreement between the 2 readers ($\kappa = 1$). Three masses were depicted in SBCT and were confirmed as simple cysts in sonography. Additional 5 simple cysts and 2 solid benign lesions were identified only in sonography. A total of 12 calcifications were depicted with a median size of 1.1 mm (interquartile range, 0.7–1.7 mm) on HR and 1.4 mm (interquartile range, 1.1–1.8 mm) on soft tissue images.[6]

SAFETY/ORGANISATIONAL

The [redacted] – spiral breast CT obtained CE certification since 2018. No other safety issue or adverse events related to [redacted] was retrieved.

Wetzl M. et. al. reported that from the technician comments, patients with age-related hyperkyphosis of the thoracic spine, lower back pain or very skinny body composition and patient with recent surgeries had difficulties with the SBCT.[2] In addition to that, during in vivo study by Berger N. et. al. out of 12 patients, 2 women (16.7%) reported that mild discomfort due to the position of the rib cage resting on the table at the margin of the gantry.[6]

For organisational issue, one study by Berger N. et. al. reported in their study that SBCT had to be restarted three times during the examinations of the 300 women. A system shutdown was performed twice at the end of the day for service and one event of software system crashed due to technical issues after one breast acquisition and no additional examination was possible on the same day.[5]

COST-EFFECTIVENESS (If any)

No economic evaluation studies on [redacted] – spiral breast CT were retrieved from scientific databases. The price range was RM6.5 million to RM 7.5 million.

CONCLUSION

The [redacted] spiral breast CT scan is proposed as an alternative device for breast cancer screening especially among women who are not comfortable with compression during mammography. Based on the review, there was limited evidence on the accuracy of [redacted] spiral breast CT scan especially in detecting early stage of breast cancer. However, the available evidence showed the [redacted] spiral breast scan able to provide clear image with good agreement among radiologists and less pain. Few issues on patient comforts especially in those with certain morbidities and technical issues need to be considered. The cost-effectiveness of the technology should also be taken into consideration.

REFERENCES

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