Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Inform discussions on new topics received by HTW.
2. Determine the quantity and type of evidence available on a topic.
3. Assess the topic against HTW selection criteria.

Topic:	Automated Breast Ultrasound (ABUS)
Topic exploration report number	TER002
Referrer:	Dr Jyoti Bansal
Topic exploration undertaken by:	Health Technology Wales

Aim of Search

Health Technology Wales researchers searched for evidence on the use of automated breast ultrasound for the assessment of symptomatic patients referred to a breast clinic for investigation. Aspects of interest included comparisons with other tests as well as both clinical and cost-effectiveness.

Summary of Findings

One potentially relevant systematic review of automated breast ultrasound was identified, along with a number of primary studies. No existing technology assessments or economic evaluations were identified.

Technology assessments
No relevant technology assessments were identified.

Clinical effectiveness
One systematic review estimated the diagnostic accuracy of automated breast ultrasound, but did not compare this to any other diagnostic options. The search identified ten studies comparing the performance of ABUS to hand-held ultrasound, mammography, or both, in terms of various outcomes (diagnostic accuracy, inter-rater reliability, image quality, detection rates of tumours/other lesions).

Cost effectiveness
No evidence was identified that reported any economic outcomes about the use of automated breast ultrasound.

Conclusions

Evidence exists about the clinical effectiveness of automated breast ultrasound for assessing breast lesions. However, it is not clear whether evidence is available for all outcomes of interest, or whether the evidence is relevant to the setting of interest. No evidence was identified about the cost effectiveness of automated breast ultrasound compared to other options, and no systematic review comparing ABUS to currently used tests was identified.

Areas of Uncertainty

The areas of uncertainty identified include:

- Where the most relevant evidence is found – studies of women referred to a breast clinic for assessment or women undergoing routine screening.
- Whether this test is particularly advantageous for special populations (such as women with dense breasts or low risk)
- Which tests/diagnostic techniques are currently used in this setting and so would be most relevant as the comparator.
- Which outcomes are the most relevant to measure the effectiveness of ABUS
- Which factors are the most relevant in terms of estimating cost/resource use.
- The manufacturers that make this device.
- Which devices are available in the UK.

Feasibility of Technology Assessment

There is potential for ABUS to provide benefits in terms of time and resource savings through simpler and more efficient testing as well as quicker results availability, but there is insufficient evidence available to assess its clinical or cost-effectiveness in comparison to existing treatment options.

Quality of care is potentially improved by offering testing to more patients.

As the initial search identified very limited secondary evidence (one systematic review) and no economic evaluations it is unlikely that there is sufficient evidence upon which to base a technology assessment.

HTW's Assessment Group concluded not to progress this topic further.

Brief literature search results

Resource	Results
UK guidelines and guidance	
SIGN	We did not identify any relevant evidence on ABUS from this source.
NICE	We did not identify any relevant evidence on ABUS from this source.
Secondary literature and economic evaluations	
CRD Database	We did not identify any relevant evidence on ABUS from this source.
Cochrane library	We did not identify any relevant evidence on ABUS from this source.
epistemonikos.org	We identified one HTA by Health Quality Ontario identified, but this assessed any type of ultrasound (automated or hand-held) and only when used as an adjunct to mammography.
evidence.nhs.uk	Royal College of Pathologists. Guidelines for non-operative diagnostic procedures and reporting in breast cancer screening. June 2016. (we checked these guidelines for relevance, but they do not mention ABUS).
Primary studies	
Medline	1. Choi EJ, Choi H, Park EH, Song JS, Youk JH. Evaluation of an automated breast volume scanner according to the fifth edition of BI-RADS for breast ultrasound compared with hand-held ultrasound. Eur J Radiol. 2018 Feb;99:138-145. doi: 10.1016/j.ejrad.2018.01.002. Epub 2018 Jan 4. PMID: 29362145. 2. Zhan J, Diao XH, Pang Y, Wang Y, Chen L, Chen Y. Is there an extraclinical value of automated breast volume scanner compared with hand-held ultrasound?: A pilot study. Medicine (Baltimore). 2017 Sep;96(37):e7765. doi: 10.1097/MD.0000000000007765. PubMed PMID: 28906361; PubMed Central PMCID: PMC5604630. 3. Barr RG, DeVita R, Destounis S, Manzoni F, De Silvestri A, Tinelli C. Agreement Between an Automated Volume Breast Scanner and Handheld Ultrasound for Diagnostic Breast Examinations. J Ultrasound Med. 2017 Oct;36(10):2087-2092. doi: 10.1002/jum.14248. Epub 2017 Jun 1. PubMed PMID: 28569407. 4. Schmachtenberg C, Fischer T, Hamm B, Bick U. Diagnostic Performance of Automated Breast Volume Scanning (ABVS) Compared to Handheld Ultrasonography With Breast MRI as the Gold Standard. Acad Radiol. 2017 Aug;24(8):954-961. doi: 10.1016/j.acra.2017.01.021. Epub 2017 Mar 20. PubMed PMID: 28336007. 5. Vourtsis A, Kachulis A. The performance of 3D ABUS versus HHUS in the visualisation and BI-RADS characterisation of breast lesions in a large cohort of 1,886 women. Eur Radiol. 2018 Feb;28(2):592-601. doi: 10.1007/s00330-017-5011-9. Epub 2017 Aug 21. PubMed PMID: 28828640. 6. Xiao YM, Chen ZH, Zhou QC, Wang Z. The efficacy of automated breast volume scanning over conventional ultrasonography among patients with breast lesions. Int J Gynaecol Obstet. 2015 Dec;131(3):293-6. doi: 10.1016/j.ijgo.2015.05.036. Epub 2015 Aug 28. PubMed PMID: 26493011. 7. An YY, Kim SH, Kang BJ. The image quality and lesion characterization of breast using automated whole-breast ultrasound: A comparison with handheld ultrasound. Eur J Radiol. 2015 Jul;84(7):1232-5. doi: 10.1016/j.ejrad.2015.04.007. Epub 2015 Apr 20. PubMed PMID: 25975896. 8. Meng Z, Chen C, Zhu Y, Zhang S, Wei C, Hu B, Yu L, Hu B, Shen E. Diagnostic performance of the automated breast volume scanner: a systematic review of inter-rater reliability/agreement and meta-

analysis of diagnostic accuracy for differentiating benign and malignant breast lesions. Eur Radiol. 2015 Dec;25(12):3638-47. doi: 10.1007/s00330-015-3759-3. Epub 2015 Apr 28. Review. PMID: 25916389.
9. Kuzmiak CM, Ko EY, Tuttle LA, Steed D, Zeng D, Yoon SC. Whole Breast Ultrasound: Comparison of the Visibility of Suspicious Lesions with Automated Breast Volumetric Scanning Versus Hand-Held Breast Ultrasound. Acad Radiol. 2015 Jul;22(7):870-9. doi: 10.1016/j.acra.2015.03.006. Epub 2015 Apr 11. PubMed PMID: 25872862.
10. Jeh SK, Kim SH, Choi JJ, Jung SS, Choe BJ, Park S, Park MS. Comparison of automated breast ultrasonography to handheld ultrasonography in detecting and diagnosing breast lesions. Acta Radiol. 2016 Feb;57(2):162-9. doi: 10.1177/0284185115574872. Epub 2015 Mar 11. PMID: 25766727.
11. Choi WJ, Cha JH, Kim HH, Shin HJ, Kim H, Chae EY, Hong MJ. Comparison of automated breast volume scanning and hand- held ultrasound in the detection of breast cancer: an analysis of 5,566 patient evaluations. Asian Pac J Cancer Prev. 2014;15(21):9101-5. PMID: 25422185.
12. Brem RF, Tabár L, Duffy SW, Inciardi MF, Guingrich JA, Hashimoto BE, Lander MR, Lapidus RL, Peterson MK, Rapelyea JA, Roux S, Schilling KJ, Shah BA, Torrente J, Wynn RT, Miller DP. Assessing improvement in detection of breast cancer with three-dimensional automated breast US in women with dense breast tissue: the SomoInsight Study. Radiology. 2015 Mar;274(3):663-73. doi: 10.1148/radiol.14132832. Epub 2014 Oct 17. PMID: 25329763.
13. Golatta M, Baggs C, Schweitzer-Martin M, Domschke C, Schott S, Harcos A, Scharf A, Junkermann H, Rauch G, Rom J, Sohn C, Heil J. Evaluation of an automated breast 3D-ultrasound system by comparing it with hand-held ultrasound (HHUS) and mammography. Arch Gynecol Obstet. 2015 Apr;291(4):889-95. doi: 10.1007/s00404-014-3509-9. Epub 2014 Oct 14. PubMed PMID: 25311201.
14. Chen L, Chen Y, Diao XH, Fang L, Pang Y, Cheng AQ, Li WP, Wang Y. Comparative study of automated breast 3-D ultrasound and handheld B-mode ultrasound for differentiation of benign and malignant breast masses. Ultrasound Med Biol. 2013 Oct;39(10):1735-42. doi: 10.1016/j.ultrasmedbio.2013.04.003. Epub 2013 Jul 9. PubMed PMID: 23849390.
15. Golatta M, Franz D, Harcos A, Junkermann H, Rauch G, Scharf A, Schuetz F, Sohn C, Heil J. Interobserver reliability of automated breast volume scanner (ABVS) interpretation and agreement of ABVS findings with hand held breast ultrasound (HHUS), mammography and pathology results. Eur J Radiol. 2013 Aug;82(8):e332-6. doi: 10.1016/j.ejrad.2013.03.005. Epub 2013 Mar 27. PMID: 23540947.
16. Kim SH, Kang BJ, Choi BG, Choi JJ, Lee JH, Song BJ, Choe BJ, Park S, Kim H. Radiologists' performance for detecting lesions and the interobserver variability of automated whole breast ultrasound. Korean J Radiol. 2013 Mar-Apr;14(2):154-63. doi: 10.3348/kjr.2013.14.2.154. Epub 2013 Feb 22. PMID: 23482698; PubMed Central PMCID: PMC3590325.

Other	
Evidence identified by topic proposer	1. Giger ML, Inciardi MF, Edwards A et al. Automated Breast US in breast cancer screening in women of dense breasts: Reader study of mammograpgy negative and mammography positive cancers. Am J Radiol,June 2016;206(6):1341-1350 2. Wilczek B, Wilkzek HE, Rasouliyan M et al. Adding 3D automated breast US to mammography screening in women with heterogeneously dense and extremely dense breasts: report from a hospital based, single centre, high volume screening programme. Eur J Radiol June 2016; 5:1554-1563 3. Bream RF, Tabar L, Duffy SW et al. Assessing improvement in detection of breast cancer with 3D automated breast US in women with dense breast tissue: The Somolnsight Study. Radiol.March 2105;274(3):663-673 4. Vourtsis A, Kachulis A. Eur Radiol 2017. The performance of 3D ABUS versus HHU in the visualisation and BIRADS characterisation of breast lesions in a large cohort of 1886 women. Doi10.1007/s00330-017-5011-9 5. Bujang MA, Adnan TH. J Clin Diagn Res 2016;10(10):YE01-YE06 Requirement for minimum sample size for sensitivity and specificity Analysis.

Date of search:	13 April 2018
Concepts used:	automated breast ultrasound/ultrasonography; ABUS