Advanced breast biopsy instrumentation

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MSAC application 1001

Final assessment report

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Electronic copies of the report can be obtained from the Medicare Service Advisory Committee's Internet site at:

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Hard copies of the report can be obtained from:

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Enquiries about the content of the report should be directed to the above address.

The Medicare Services Advisory Committee is an independent committee which has been established to provide advice to the Commonwealth Minister for Health and Aged Care on the strength of evidence available on new medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform Government decisions about which new medical services should attract funding under Medicare.

This report was prepared by the Medicare Services Advisory Committee (MSAC). The report was endorsed by the Commonwealth Minister for Health and Aged Care on 11 May 1999.

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MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

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Advanced breast biopsy instrumentation (ABBI) is a device for biopsy of suspicious small lesions of the breast for diagnosis. The procedure involved utilises a stereotactic imaging system and is minimally invasive.

Medicare Services Advisory Committee — role and approach

The Medicare Services Advisory Committee (MSAC) is a key element of a measure taken by the Commonwealth Government to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Minister for Health and Aged Care on the evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of the available evidence is thus the basis of decision making when funding is sought under Medicare. The medical literature on the new technology is searched and the evidence is assessed and classified according to the National Health and Medical Research Council (NHMRC) four-point hierarchy of evidence. A supporting committee with expertise in this area evaluates the evidence and provides advice to MSAC.

Assessment of ABBI

From the literature available on ABBI, the sensitivity and specificity of the procedure from the studies retrieved was unclear, most of the studies being quasi-experimental in design, and providing limited detail on patient selection, blinding and randomisation.

Clinical need

Breast cancer is the second leading cause of cancer deaths in women, and is the highest cause of cancer-related mortality in Australian women between the ages of 45 and 64. More than 2600 women die from breast cancer every year in Australia.

There is a need for women who are found, via mammography, to have suspicious small breast lesions investigated, to determine whether the lesion is invasive, in-situ, or benign.

Safety

The limited safety data available suggests that the procedure is safe, with a low complication rate and the absence of major complications (level IV evidence).

Effectiveness

Currently there is insufficient evidence to conclude that ABBI is superior to the standard diagnostic tests for breast lesions of less than 10 mm, which are core biopsy or hookwire breast localisation needle for open surgical biopsy.

Cost effectiveness

Since there is insufficient evidence to conclude that ABBI is superior to the standard diagnostic tests, no cost-effectiveness analysis has been undertaken.

Recommendation

MSAC noted that the advanced breast biopsy instrumentation (ABBI) is being performed by a small number of surgeons and that it can be claimed under the Medicare Benefits Schedule (MBS). However additional remuneration has been sought.

MSAC also noted that the available evidence indicates that ABBI is equivalent to existing diagnostic tests. However, it is considered that there is insufficient evidence to conclude that ABBI is superior to existing diagnostic tests which are on the MBS.

MSAC therefore recommended that additional funding is not warranted at this time, and that ABBI should continue to be funded under the existing MBS items.

Introduction

The Medicare Services Advisory Committee (MSAC) has assessed advanced breast biopsy instrumentation (ABBI®)†, which is a device for diagnostic breast biopsy. MSAC evaluates new health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, taking into account other issues such as access and equity. MSAC uses an evidence-based approach for its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are shown in Appendix A. MSAC is a multidisciplinary expert body, with members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics and health administration.

This report summarises the assessment of current evidence for advanced breast biopsy instrumentation.

† ABBI® is a registered tradename of the United States Surgical Corporation.

Background

Advanced breast biopsy instrumentation

How it works

ABBI is a device for diagnostic biopsy of suspicious small lesions of the breast. the procedure involved utilises a stereotactic imaging system and is minimally invasive.

The procedure, which is conducted by a surgeon and a diagnostic radiologist, involves the removal of a core of tissue (5 mm–20 mm in size) from the breast using stereotactic localisation and an advanced biopsy device. The equipment involves the use of a prone stereotactic localisation table together with an ABBI device for core biopsy.

Following stereotactic localisation of a small breast lesion, a surgical incision is made in the breast. A rotating, cylindrical blade is inserted through the incision and advanced until the lesion has been included in the core, at which point an integrated diathermy wire detaches the deep end of the core and the core of tissue containing the lesion is withdrawn from the breast. Any bleeding is stopped by the surgeon and the wound is closed. Radiography of the biopsy sample is undertaken to confirm the removal of the target tissue and the sample is submitted to a histopathologist for examination.

ABBI is an outpatient procedure; patients are discharged within one hour of completion and normally require one aftercare follow-up consultation.

Intended purpose

ABBI potentially provides early and accurate diagnosis of breast cancer. It is indicated for biopsy of small breast lesions (usually <10 mm in size) that have been detected by mammography. The lesion concerned may be an invasive carcinoma, an in situ carcinoma or, in some cases, a benign lesion. ABBI is not proposed for the definitive extirpation (complete destruction) of a breast carcinoma.

Clinical need/burden of disease

Breast cancer is the second leading cause of cancer deaths in women and accounts for the greatest cause of cancer-related mortality in Australian women between the ages of 45 and 64 years. More than 2600 Australian women die from breast cancer every year, with 9846 new cases of breast cancer diagnosed in Australia in 1996.[1]

Increasingly, women are participating in mammographic screening, which results in earlier detection of nonpalpable lesions. The National Alliance of Breast Cancer Organizations (NABCO) in New York states that there is more than a 97% five-year survival rate after treatment for early stage breast cancer.[2]

BreastScreen Australia detected 14.2 cancers per 10,000 women screened in 1997. Small invasive cancers were detected in 952 women, of which 36% were small-diameter cancers (<10 mm in size), which is the size that could be biopsied using ABBI.[1]

The Australian distributor, Auto Suture Company, has advised that there are presently four centres with ABBI units in Australia (Wesley Hospital, Queensland; Westmead Hospital,

New South Wales; Austpath Breast Centre, New South Wales; and Queen Elizabeth Hospital, South Australia). At this stage, the potential usage for these units is unclear due to the lack of available data on the total number of small breast lesions (<10 mm in size) biopsied in Australia annually.

Statistics regarding the Medicare benefits paid on a fee-for-service basis provide an indication of the relative usage of service. The exclusion of services to public patients in hospital, those undertaken by BreastScreen Australia and those paid for by Veterans' Affairs, however, limits the information.

Existing procedure

Women who are found to have a suspicious small breast lesion following mammography will be referred for further diagnostic tests. These may include additional mammography, ultrasound and needle core biopsy or hookwire breast localisation needle for open surgical biopsy.

Comparator

Potentially ABBI could replace core biopsy or hookwire breast localisation needle for open surgical biopsy for breast lesions of less than 10 mm. These are therefore appropriate comparators.

Marketing status of the device

ABBI has been approved by the United States Food and Drug Administration (FDA) under Section 510(k), for biopsy use only. The instrumentation is listed on the Australian Register of Therapeutic Goods. Before listing, sponsors are required to submit information such as labelling, product literature and, for certain categories, evidence of quality systems compliance, compliance with standards and test certificates to the Therapeutic Goods Administration (TGA) for assessment.

Current reimbursement arrangement

Procedures involving ABBI can currently be claimed under the Medicare Benefits Schedule using the item numbers 30363, or 30345G/30346S with radiology item numbers 59312 (two breasts) or 59314 (one breast; see Table 1 for definitions of item numbers).

Table 1 Breast biopsy Medicare Benefits Schedule services rendered 1997–98

Item no	Item description	Number of services
30345G[a]	Breast, excision of cyst, fibroadenoma or other local lesion or segmental resection for any other reason, where frozen section biopsy is performed or where specimen radiography is used	52
30346S[b]	Breast, excision of cyst, fibroadenoma or other local lesion or segmental resection for any other reason, where frozen section biopsy is performed or where specimen radiography is used	6716
30360	Fine needle breast biopsy, imaging guided — but not including imaging	22,160
30361	Breast, preoperative localisation of lesion of, by hookwire or similar device, using interventional techniques — but not including imaging	3774
30363	Breast, core biopsy of solid tumour or tissue of, using mechanical biopsy device, for histological examination	2986
59312	Radiographic examination of both breasts, in conjunction with a surgical procedure on each breast, using interventional techniques — examination and report	85
59314	Radiographic examination of one breast, in conjunction with a surgical procedure using interventional techniques — examination and report	1246
59318	Radiographic examination of excised breast tissue to confirm satisfactory excision of one or more lesions in one breast or both following preoperative localisation in conjunction with a service under item 30361 — examination and report	1046

[a] General practioners; [b] Specialists

Approach to assessment

MSAC reviewed the literature available on ABBI and convened a supporting committee to evaluate the evidence of the procedure and provide expert advice.

Review of literature

The medical literature was searched to identify relevant studies and reviews for the period between January 1982 and May 1998. Searches were conducted via Medline, Healthstar, EMBASE, Austrom, Austhealth, Cochrane, Biosis, Cancerlit, IAC Health & Wellness, Pascal and Elsevier Biobase. The search terms used included 'advanced breast biopsy', 'advanced breast biopsy instrumentation', 'advanced breast biopsy', 'advanced breast biopsy instrumentation', 'ABBI', and 'stereotactic excisional breast biopsy'. From this search, nine articles were identified. Additional information was sought on the Internet, from international technology assessment agencies, from references quoted in retrieved articles and from the distributor for ABBI.

Articles selected included those examining breast biopsy using the ABBI device. Articles excluded were those providing a description of the ABBI device or procedure and those not using the ABBI device.

After applying the inclusion and exclusion criteria described above, five papers, two poster abstracts and unpublished data from the United States FDA were selected, providing information on five clinical studies.

The evidence presented in the retrieved studies was assessed and classified according to the NHMRC revised hierarchy of evidence shown in Table 2. Most of the studies were quasi-experimental in design and provided limited detail on patient selection, blinding and randomisation.. The sensitivity and specificity of the studies was therefore unclear.

The design and quality of the studies are shown in Table 3.

Table 2 Designation of levels of evidence

I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with control group.
III-3	Evidence obtained from comparative studies with historical control, two and more single arm studies or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test.

Source: NHMRC[3]

Expert advice

A supporting committee, including members with expertise in relation to breast surgery and breast lesion diagnosis, was convened to assess the evidence on the procedure. In selecting members for supporting committees, MSAC's practice is to approach appropriate medical colleges, associations or specialist societies for nominees. Membership of the supporting committee is shown in Appendix B.

Table 3 Evidence summary

Level	Author	Study design	Comments	Outcomes
Level III-2	D'Angelo et al 1997[4]	Comparative study, needle localisation with open surgical biopsy *n*=46, (23 ABBI)	Women with mammograms displaying microcalcifications or suspicious non-palpable noncystic nodular densities	Biopsies obtained with ABBI were smaller than needle- ocalised open biopsies in: diameter (P<0.03); volume (P<0.01) and weight (P<0.03) Blood loss (mL): ABBI 14 ± 9.7, needle-localised open biopsy 20 ± 9.8 Size of biopsy (g): ABBI 7.4 ± 2.63, needle-localised open biopsy 11.6 ± 7.21 Malignancy in margins: ABBI 5/23, needle-localised open biopsy 5/23 Patient acceptance: ABBI = high; needle-localised open biopsy = high
Level IV	Ferzli and Hurwitz 1997[5]	Case series *n* = 34		6/34 patients excluded[a]; 27/28 specimens successfully removed with a mean time of 30 minutes
	Ferzli et al, 1997[6]	Case series *n* =58	Apparent continuation of Ferzli & Hurwitz (1997)	9/58 patients excluded[a]; 47/49 specimens successfully removed with a mean time of 28 minutes; 14/47 required further excision to complete biopsy; 7/47 malignant lesions
	Kelley et al 1998[7]	Case series from 8 centres *n* = 654	Unpublished	654/656 specimens were successfully removed; 3/654 required a second biopsy; 124/654 malignant lesions
	Koretz et al 1997[8]	Case series *n* = 33	Abstract	33/33 specimens were successfully removed with a mean procedure time of 42 mins; 5/14 malignant lesions were completely removed with clear surgical margins; mean volume of tissue removed was 26 cm^3 vs 6.5 cm^3 for a similarly matched series of needle-localisation biopsies
	Silich and Williams, 1997[9]	Case series *n* = 180	Abstract	19/130 procedures converted to open procedure; average length of procedure 28 minutes; 14/116 malignant lesions, 9/14 with positive margins, 5/14 with negative margins.
	Wetzig et al 1998[10]	Case series *n* = 12	Abstract	12/12 procedures were completed successfully; 3/12 malignant lesions.

[a]The ABBI procedure is not suitable for patients with thin ptotic breasts which compress to less than 30 mm thickness, where the lesion is close to the chest wall or high in the axillary tail, patients who weigh more than 140 kg or those who cannot lie still for 20–30 minutes because of back problems, chronic obstructive pulmonary disease, asthma or psychiatric conditions.[6, 10]

Results of assessment

Is it safe?

Procedures using both ABBI and the comparators are associated with low rates of adverse events (Table 4). However, the safety data for ABBI are limited and are mainly derived from data submitted by the manufacturing company to the United States FDA. These data include the only direct comparison of ABBI with open biopsy procedures but details of the study methodology of this multicentre comparison are not included.

There were some reports of incomplete amputation of the core tissue, requiring either conversion to open biopsy or scissor dissection.[6] However, the applicant, Dr C Furnival (personal correspondence) has reported that more recently this design problem appears to have been corrected by the manufacturers.

Table 4 Adverse events

		ABBI		Needle core biopsy	
Author	**Outcomes**	***r/n*[a]**	**%**	***r/n*[a]**	**%**
United States FDA data[11]	Bleeding	2/313	0.64	1/72	1.39
	Infection	3/313	1.92	0/72	0
	Haematoma	6/313	1.92	4/72	5.56
	Other	5/313	1.6	3/72	4.17
Ferzli et al 1997[6]	Pain (postprocedure — not graded)	18/30	60	–	–
	Minimal discomfort	12/30	40	–	–
	Electrocautery	8/47	17	–	–
	Conversion to open biopsy	14/47	30	–	–
	Computer malfunction	2/47	4	–	–
	Preferred biopsy	2/8	25	5/8	63
Kelley et al 1998[7]	Cellulitis	1/654	0.2	–	–
	Haematoma/ecchymoses	11/654	1.7	–	–
	Unsatisfactory cosmetically	1/654	0.2	–	–
Koretz et al 1997[8]	Haematoma	3/33	9	–	–

– = not reported

[a] *r* = number reported; *n* = total number

Is it effective?

In selected patients, the procedure involving ABBI is a minimally invasive, yet effective, excisional breast biopsy technique (level of evidence III-2) (see Table 3). In a nonrandomised trial, D'Angelo et al compared 23 women who had breast biopsies using ABBI with 23 women who concomitantly had conventional excisional breast biopsies.[4] Ten women were found to have invasive carcinoma (five for each technique), as indicated by the breast biopsies. All these specimens were found to have malignancy at the biopsy margins, indicating that the core did not isolate the entire lesion.

Ferzli and Hurwitz conducted a case-series study of 34 women.[5] Six cases were not suitable for the procedure due to either lack of visualisation or thinness of the breast on compression. Of the remaining 28 patients, 27 had a completed biopsy, with further excision in three patients due to inadequate margins (level of evidence IV). Pathology identified three cases of carcinoma.

A further study, reported the successful removal of 47 out of 58 lesions; however, in 14 of the 47 cases mechanical problems were experienced with the ABBI device and the biopsy had to be converted to an open procedure (level of evidence IV).[6]

Kelley et al evaluated data on the use of ABBI for the first 654 cases from eight institutions.[7] Specimens were successfully removed in 99.7% of cases, with a second diagnosis being required in 0.4% of cases (level of evidence IV). The positive predictive value (PPV) of the ABBI biopsy with mammography was 19% for malignancy; however, it should be noted that the PPV for this procedure is not a measure of utility, but a measure of patient selection.

Koretz et al removed specimens from 33 patients using the ABBI device.[8] Pathology tests showed 14 carcinomas, of which five were completely removed with clear surgical margins. The mean volume of tissue removed by ABBI was 26 cubic cm, compared to 65 cubic cm for a similarly matched series of needle localisation biopsies (level of evidence IV).

Silich and Williams considered 180 women for the ABBI procedure.[9] ABBI was used for 130 biopsies, but 14% were completed by conversion to the open procedure. Pathology tests showed 11% carcinomas, 7% with positive margins and 7% with negative margins (level of evidence IV).

Wetzig et al reported their initial experience with the use of ABBI for 12 women in Australia.[10] Of these, nine were for benign lesions and three were for malignant lesions. All lesions were successfully removed with minimal bleeding and no sign of complications. The size of the lesion ranged from 2 mm to 18 mm.

Very little has been written regarding the cosmetic aspects of the procedure; however, D'Angelo et al reported that no complications were noted and that cosmetic outcomes were excellent in the view of both patient and surgeon.[4] Kelley et al reported good cosmetic results in 653 cases (99.8%) and unsatisfactory results in one patient.[7]

However, Ferzli et al found that the biopsy incision could not be placed around the nipple of the breast (circumareolarly).[6] Furthermore, the cannula cut (and removed) tissue from the dermis to a point 15 mm beyond the lesion, whereas in open biopsy the tissue between the skin and the lesion can often be dissected rather than removed.

What are the economic considerations?

The literature review identified three United States studies that compared the cost of stereotactic core needle biopsy with open surgical biopsy, image-guided large core needle biopsy, surveillance mammography, wire localisation followed by open excision and ultrasound-guided large core needle biopsy.[12–14] However, none of these studies specifically stated whether the technology compared was ABBI.

It should be noted that overseas economic analyses may have limited relevance to the situation in Australia, due to major differences in patterns of health resource utilisation and unit costs.

As with many new techniques there is a 'learning curve' that affects costs and outcomes. The proposed fee provided by the applicant for the procedure using ABBI is based on the 1997 Medicare Benefits Schedule and totals approximately $1200, including a fee of $500 for the surgeon, a fee for the radiologist and the cost of disposable items. The cost of converting to an open biopsy procedure, if necessary, is not included. The 1 November 1998 Medicare Benefits Schedule fee for item number 30345G/30346S is $198.25 when undertaken by a general practitioner and $247.10 when undertaken by a specialist. The fee for item 30363 was $104.55. The fee for radiolographic examination item numbers 59312 (two breasts) and 59314 (one breast) are $83.65 and $50.45, respectively (see Table 1 for definitions of item numbers).

Conclusions

Safety

The evidence available shows that the ABBI procedure is safe with a low complication rate and absence of major complications.

Effectiveness

The data examined in this report provide insufficient evidence to conclude that ABBI is better than conventional stereotactic core biopsy or hookwire breast localisation needle with open biopsy.

There is a need to determine a specific range of conditions for which ABBI would be applicable in the spectrum of investigations available for both benign and malignant breast disease in preference to the widespread and standard practice, particularly as it relates to conventional stereotactic core biopsy or hookwire breast localisation needle with open biopsy.

Cost-effectiveness

Cost-effectiveness analysis was not undertaken.

Recommendation

MSAC noted that the advanced breast biopsy instrumentation (ABBI) is being performed by a small number of surgeons and that it can be claimed under the Medicare Benefits Schedule (MBS). However additional remuneration has been sought.

MSAC also noted that the available evidence indicates that ABBI is equivalent to existing diagnostic tests. However, it is considered that there is insufficient evidence to conclude that ABBI is superior to existing diagnostic tests which are on the MBS.

MSAC therefore recommended that additional funding is not warranted at this time, and that ABBI should continue to be funded under the existing MBS items.

? The Minister for Health and Aged Care accepted this recommendation on 11 May 1999 ?

Appendix A MSAC terms of reference and membership

The terms of reference of the Medicare Services Advisory Committee are to advise the Commonwealth Minister for Health and Aged Care on:

- the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness; and
- references related either to new and/or existing medical technologies and procedures.

The membership of the Medicare Services Advisory Committee comprises a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning:

Member	**Expertise**
Professor David Weedon (Chair)	pathology
Ms Hilda Bastian	consumer health issues
Dr Ross Blair	vascular surgery (New Zealand)
Mr Stephen Blamey	general surgery
Dr Paul Hemming	general practice
Dr Terri Jackson	health economics
Professor Brendon Kearney	health administration and planning
Dr Richard King	gastroenterology
Dr Michael Kitchener	nuclear medicine
Professor Peter Phelan	paediatrics
Dr David Robinson	plastic surgery
Ms Penny Rogers	Assistant Secretary of the Diagnostics and Technology Branch of the Commonwealth Department of Health and Aged Care
Associate Professor John Simes	clinical epidemiology and clinical trials
Dr Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council (from 1/1/99)
Dr Doris Zonta	population health, representing the Australian Health Ministers' Advisory Council (until 31/12/98)

Appendix B Supporting committee

Supporting committee for MSAC application 1001 Advanced breast biopsy instrumentation

Dr David Robinson (Chair) MBBS, FRACS, FRCS President of the Senior Medical Staff Association, Princess Alexandra Hospital, Brisbane	member of MSAC
Dr Maxwell Coleman MBBS, FRACS, FRCS Surgeon to Central and East Sydney BreastScreen; Visiting Medical Officer, St Vincent's Hospital, Sydney	co-opted member
Mr John Collins MBBS, FRACS, FACS Head of the Breast Unit, Royal Women's Hospital, Melbourne; Chairman of the Breast Study Committee of the Anti-Cancer Council of Victoria	nominated by the Royal Australasian College of Surgeons
Dr Richard West MBBS, FRACS, FRCS Surgeon to Central and East Sydney BreastScreen; Visiting Medical Officer, Royal Prince Alfred Hospital and Rachel Forster Hospital, Sydney	co-opted member

Abbreviations

ABBI	Advanced breast biopsy instrumentation
FDA	Food and Drug Administration (United States)
MSAC	Medicare Services Advisory Committee
NABCO	National Alliance of Breast Cancer Organizations (United States)
NHMRC	National Health and Medical Research Council
PPV	positive predictive value
TGA	Therapeutic Goods Administration

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