Advanced Breast Biopsy Instrumentation (ABBI®) System for non-palpable breast lesions

July 2001

MSAC Application 1037

Assessment report

®**ABBI is a registered trade mark of United States Surgical Corporation, Tyco Healthcare Group.**

© Commonwealth of Australia 2002

ISBN 0 642 30590 7

ISSN (Print) 1443-7120

ISSN (Online) 1443-7139

First printed - February 2002

This work is copyright. Apart from any use as permitted under the C*opyright Act 1968*, no part may be reproduced by any process without written permission from the Commonwealth. Requests and inquiries concerning reproduction and rights should be directed to the Manager, Copyright Services, Information Services, GPO Box 1920, Canberra ACT 2601 or by email to Cwealthcopyright@finance.gov.au.

Electronic copies of the report can be obtained from the Medical Service Advisory Committee's Internet site at http://www.msac.gov.au/.

Hard copies of the report can be obtained from:
The Secretary
Medical Services Advisory Committee
Department of Health and Ageing
Mail Drop 107
GPO Box 9848
Canberra ACT 2601.

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

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

This report was prepared by MSAC with the assistance of Mrs Kim Dalziel, Ms Emily Petherick, Dr Elmer Villanueva and Dr Omar Abdulwadud, Centre for Clinical Effectiveness, Monash Institute of Health Services Research, Monash University, and Dr Bruce Hollingsworth, Health Economics Unit, Monash University.

The report was endorsed by the Commonwealth Minister for Health and Aged Care on 18 September 2001.

Publication approval number: 2992

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

Contents

Tables

Figures

Executive summary

The procedure

Advanced breast biopsy instrumentation (ABBI) is a device for diagnostic biopsy of detected lesions of the breast. The procedure involves utilisation of a stereotactic imaging system.

The procedure, which is conducted by a surgeon and a diagnostic radiologist, involves the removal of a core of breast tissue (5–20 mm in size) using stereotactic localisation and an advanced biopsy device.

The patient is positioned prone on a table and the lesion is targeted using stereotaxis. Then, still under stereotactic guidance, a localisation needle is inserted into the lesion and, when the position is satisfactory, a wire is deployed to secure the lesion.

Medical Services Advisory Committee – role and approach

The Medical 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 Commonwealth Minister for Health and Ageing on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing 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. A team from the Monash Institute of Health Services Research was engaged to conduct a systematic review of the literature on the ABBI System for non-palpable breast lesions. A supporting committee with expertise in this area then evaluated the evidence and provided advice to MSAC.

MSAC's assessment of the ABBI System

Clinical need

Breast cancer is the leading cause of cancer death in women and is the greatest cause of cancer-related mortality in Australian women between the ages of 45 and 64 years. More than 2,600 Australian women die from breast cancer every year, and 10,096 new cases of breast cancer were diagnosed in Australia in 1997.

The ABBI procedure, which is conducted by a surgeon and a diagnostic radiologist, involves the removal of a core of breast tissue (5–20 mm in size) 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.

Safety

Safety data differs widely as ABBI requires specialised surgical techniques and surgeon experience differs between centres. Eleven studies reported the occurrence of haematoma which varied from one to 12.5 per cent. Wound infection varied from 0 to 3 per cent and was reported by six studies. Three studies reported dehiscence or wound problems ranging from 1 to 3 per cent. Bleeding was reported in three studies and ranged from 0.4 to 4.2 per cent. Other reported adverse events included nausea, vomiting, hypertension, bruising, anxiety attack, fainting, pneumothorax, venous thrombosis and cellulitis.

The adverse events associated with ABBI were often as a result of technical or equipment failure. Technical problems varied from 3 per cent to 32 per cent and included episodes such as cautery snare failure (although this has subsequently been addressed by manufacturers), poor precision/calibration, t-wire destabilisation, detachment of blade and computer malfunction.

Effectiveness

No randomised controlled trials comparing ABBI with any other therapeutic or diagnostic procedure or properly designed diagnostic studies have been completed to date. Studies have compared ABBI to core needle biopsy, mammotome and wire localised biopsy. Sensitivity and specificity of ABBI was comparable with core needle biopsy and mammotome in one study. Discordant rebiopsy rates appeared to be lower for ABBI compared with core needle biopsy and mammotome in the same study. Technical success was slightly lower for ABBI compared with core needle biopsy, mammotome and open wire localised biopsy. In another study all margins for ABBI and needle localisation with excisional breast biopsies were positive. Mean blood loss for ABBI was significantly less than for needle localisation with excisional breast biopsy. These comparative studies failed to provide detailed rebiopsy rates.

For the case series studies that reported rebiopsies (occasions when the initial ABBI failed to obtain sufficient material for histopathological diagnosis), the rates varied from 0.05 to 2.9 per cent of all ABBI procedures initially performed. Between 1 and 23 per cent of ABBI procedures were converted to another form of biopsy or aborted before ABBI was completed.

Malignancy of the ABBI biopsy varied from 11 to 44 per cent. Between 57 and 95 per cent of malignant biopsies obtained using the ABBI procedure had positive margins. Mean procedure time varied from 22 to 80 minutes. Five out of 13 studies reported some measure of patient satisfaction or cosmetic results. Patient satisfaction outcomes were generally good and the procedure was generally acceptable to women.

Cost-effectiveness

There is some evidence of cost savings from using ABBI compared with other biopsy procedures. But even if there were cost savings, this may not translate into a better cost-effectiveness ratio. Limited published evidence on the costs and effects of ABBI precludes the provision of specific cost-effectiveness estimates.

Recommendation

MSAC recommended that, on the strength of evidence pertaining to ABBI, public funding should be supported for the diagnostic use of this procedure, as long as fees are such that health system costs do not exceed those of comparators. There is insufficient evidence for the use of ABBI in a therapeutic role for breast cancer.

The use of the ABBI equipment is to be limited to surgeons and radiologists with sufficient training and expertise in the procedure, in order to reproduce in Australian practice the results reported in the literature.

A costing study should be carried out to assist in the setting of the appropriate Medicare rebate.

— The Minister for Health and Aged Care accepted this recommendation on 18 September 2001. —

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of the Advanced Breast Biopsy Instrumentation (ABBI) System, a device used in the management of non-palpable breast lesions. MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Schedule (MBS) in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

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

This report summarises the assessment of current evidence for the ABBI System.

Background

The procedure

The ABBI System is a device for diagnostic biopsy of detected lesions of the breast. The procedure involves utilisation of a stereotactic imaging system.

The procedure, which is conducted by a surgeon and a diagnostic radiologist, involves the removal of a core of breast tissue (5–20 mm in diameter) using stereotactic localisation and an advanced biopsy device. The average length of tissue cores is usually 25 mm or longer.

The patient is positioned prone on a table and the lesion is targeted using stereotaxis. Then, still under stereotactic guidance, a localisation needle is inserted into the lesion, and when the position is satisfactory a wire is deployed to secure the lesion.

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 dressing the wound or cauterisation, as required. 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 usually discharged within one hour of completion and normally require one aftercare follow-up consultation.

Intended purpose

The previous MSAC application (MSAC 1999) looked at the validity of ABBI as a diagnostic tool. In this application the scope has been broadened at the request of the manufacturer to propose that ABBI be utilised primarily as a diagnostic device but with the ability to remove small lesions, entirely and intact, with clear pathological margins as confirmed by an assessment of the excised specimen.

ABBI potentially provides early and accurate diagnosis of breast cancer. It is indicated for biopsy of breast lesions (<15 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.

Due to constraints of the technology, ABBI may not be suitable for a specific subset of patients including:

- patients with mass, asymmetry or clustered microcalcifications that cannot be targeted using digital imaging equipment (Velanovich et al 1999);
- patients unable to lie prone and still for 30 to 60 minutes (Velanovich et al 1999);

- breasts less than 20 mm in thickness (Velanovich et al 1999);
- women on anticoagulants or currently taking aspirin;
- lesions that are too close to chest wall or lesions that are subareolar (behind the nipple) as the blood supply may be compromised (Velanovich et al 1999);
- patients weighing more than 135 kg due to possible instability of the table (ASERNIP-S 2000); and
- women with prosthetic breast implants.

ABBI: May 1999 MSAC report

The previous evaluation was undertaken by MSAC in 1999 (MSAC 1999). At that time, based upon the existing published data, it was established that there was insufficient evidence to conclude that ABBI is better than conventional stereotactic core biopsy or hookwire breast localisation. The evaluators found that there was 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.

Based upon this finding MSAC recommended that additional funding for the ABBI procedure not be warranted at that time, and that ABBI should continue to be funded under the existing MBS items.

Clinical need/burden of disease

Breast cancer is the leading cause of cancer death in women and is the greatest cause of cancer-related mortality in Australian women between the ages of 45 and 64 years. More than 2,600 Australian women die from breast cancer every year, and 10,096 new cases of breast cancer were diagnosed in Australia in 1997 (Australian Institute of Health and Welfare 2000c). In 1998 BreastScreen Australia detected a national average of 15.5 small (95% CI=14.6, 16.4) invasive cancers (≤10mm) per 10,000 women screened in the 50–69 year age group (Australian Institute of Health and Welfare 2000b). Data on the number of benign lesions identified by mammography cannot be readily located.

Breast cancer was one of the 15 leading causes of burden of disease in Australia in 1996. It is the third leading cause of burden of disease in females, accounting for 2.2 per cent of the total disease adjusted life years (DALYs) (Australian Institute of Health and Welfare 2000a). The DALY is a summary measure of population health that combines information on mortality and non-fatal outcomes. It uses time as a common currency and is a measure of the years of healthy life lost due to illness or injury – one DALY is one lost year of healthy life.

Increasingly, women are participating in mammographic screening, which results in earlier detection of non-palpable lesions. The five-year relative survival rate for females diagnosed with breast cancer from 1982 to 1994 was 77 per cent. The rate has increased over time, with those diagnosed in the 1990s showing a better five-year survival rate

(79%) than those diagnosed in the 1980s. Women diagnosed with breast cancer in their 40s had the best relative survival, whereas those aged in their 80s and 90s had the worst survival (Australian Institute of Health and Welfare 2000a).

The Australian distributor, Auto Suture Company, has advised that there are presently five centres with ABBI units in Australia (Wesley Hospital, Queensland; Westmead Hospital, New South Wales; Sydney Adventist Hospital, New South Wales; Royal Women's Hospital, 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 benign and malignant small breast lesions (<10 mm in size) biopsied in Australia annually. Table 1 shows the rate of small diameter (≤10 mm) invasive cancers detected in women screened by age in 1998, in both initial and subsequent screening rounds.

Table 1. Age specific rate of small diameter (<10 mm) invasive cancers detected per 10,000 women screened (Australian Institute of Health and Welfare 2000b)

Age group (years)	40–44	45–49	50–54	55–59	60–64	65–69	70–74	75–79	80–84	85+	All ages: crude rate	Age standardised rate (Aust population) (95% CI)
Number of cancers detected	2.5	6.0	10.8	14.1	18.6	21.7	25.9	32.8	26.8	43.1	13.2	13.2 (12.1, 14.4)

Statistics regarding the Medicare benefits paid on a fee-for-service basis provide an indication of the relative usage of service, as does data provided by BreastScreen Australia. The exclusion from these statistics of services to public patients in hospital and of those paid for by Veterans' Affairs limits the completeness of the figures.

Existing procedure and comparators

Women who are found to have a 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. A difficulty is that lesions are not diagnosed with a single 'gold standard' test, but rather are diagnosed by a variety of tests. The extent of use, and purpose for use of these comparators varies between settings.

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. It should be noted that the comparators discussed below are primarily diagnostic in nature.

Wire localisation biopsy

The main types of localisation biopsy are hookwire or carbon fibre. This procedure is generally performed under general anaesthesia in Australia, although the procedure has been known to be performed under local anaesthesia in other countries. The patient

usually lies in a supine position during the wire placement procedure (although they can be positioned supine, prone or seated depending on method of localisation).

Firstly a patient is imaged to determine the exact location of the lesion targeted for removal. A needle is then inserted through the lesion, and its position is confirmed with another mammograph. A small wire is then inserted through the hollow needle. When in place the needle is withdrawn leaving the wire in place as a surgical guide to the target lesion.

Once the end of the wire has been located internally an incision is made so both the lesion and the wire are easily accessed and removed. If the procedure is successful only one sample will be required for histological analysis. The scar from this procedure is usually between two to five centimetres, depending upon the depth of the lesion and the size of the woman's breast. The patient is usually free to leave hospital the same day.

Vacuum-assisted core biopsy

The two main forms of vacuum-assisted core biopsy (VACB) are also known as minimal invasive breast biopsy (MIBB) and mammotome. Both of these forms of breast biopsy are in rapid evolution and different methods are used according to surgical preference and the availability of stereotactic tables. MSAC evaluation no. 1015, Directional Vacuum-assisted Breast Biopsy, gives a complete report of this method.

Minimal invasive breast biopsy

This procedure is also referred to as directional vacuum-assisted biopsy in other literature (National Breast Cancer Centre 2000). The VACB probe requires a single-step placement into the area of interest, and multiple core biopsies are made around the area where the probe has been commissioned. Each core is evacuated from the probe by a vacuum suction into a drainage system (Wong et al 2000). The patient is positioned either seated or supine whilst the procedure is undertaken. The patient is usually free to leave hospital the same day.

Mammotome

This system works in a manner similar to that described above although the patient lies in a prone position. The mammotome procedure for mammographically detected lesions involves the use of an arm attachment. Biopsies are removed manually from the sample chamber with forceps. The tissue cores may be grouped into separate tissue cassettes as required (eg 1–3 o'clock, 3–6 o'clock) and identified accordingly either by pencil labelling or by different coloured cassettes prior to dispatch for histopathology (Wong et al 2000).

Wounds from both vacuum methods do not require any form of suturing, and scarring, if any, is minimal due to the small incision.

Core needle biopsies

With a core needle biopsy the woman is positioned either seated, lateral or lying prone. The procedure utilises local anaesthetic and hospitalisation is not required. After carefully disinfecting the skin, the physician uses a special fenestrated compression paddle to compress and immobilise the breast and the lesion is accessible through a window (Heywang-Kobrunner et al 1997).

The conventional stereotactic core biopsy device comprises a spring-loaded handle, together with a disposable 14-gauge core biopsy needle. The tissue cores obtained are approximately 1 mm in diameter (Wong et al 2000). Usually three to four cores are obtained to guarantee sufficient tissue. In the case of microcalcifications, more cores may be necessary (Figure 1). Core biopsies can also be obtained using ultrasound guidance. A simple adhesive bandage is sufficient to cover the site of wound following the procedure.

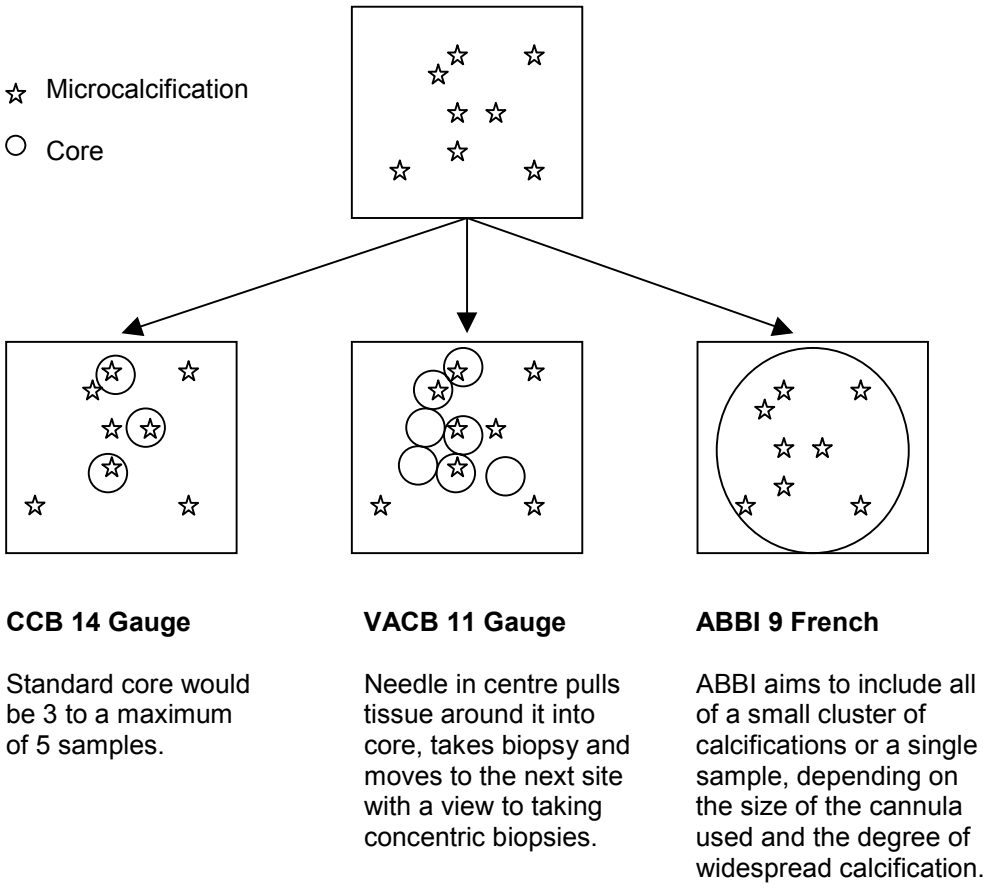

Figure 1. Schematic representation of breast biopsy techniques (adapted from Wong et al 2000)

This diagram demonstrates the manner in which the same focus of mammographic microcalcifications is sampled by conventional core biopsy (CCB), VACB and ABBI. CCB removes some of the microcalcifications, while others are left behind. VACB removes some of the area by multiple sampling. ABBI attempts to remove a large portion or the whole area as a single intact core of tissue.

Marketing status of the device

ABBI has been approved by the United States Food and Drug Administration under Section 510(k), to be used when stereotactically localised large-diameter breast biopsies, identified by the placement of a needle localisation wire, are desired for diagnostic sampling of a mammographic abnormality where malignant disease is suspected (ie usually Breast Imaging Reporting and Data System class four or five). The ABBI device is intended to provide breast tissue for histological examination with partial or complete removal of the imaged abnormality.

The instrumentation is listed on the Australian Register of Therapeutic Goods number AUST L54966. Before listing, sponsors are required to submit to the Therapeutic Goods Administration for assessment information such as labelling, product literature and, for certain categories, evidence of quality systems compliance, standards compliance and test certificates.

Current reimbursement arrangement

Breast biopsy services currently covered under the MBS and the number of services rendered for each in 1998–2000 are listed in Table 2. Procedures involving ABBI can currently be claimed under MBS using item numbers 30361 and 30363 with radiology item numbers 59312 (two breasts) or 59314 (one breast). Claims could also be made under item numbers 30345G and 30346S until May 2000, when they were deleted after consideration by the Medicare Benefits Consultative Committee. See Table 2 for definitions of item numbers.

Table 2. Breast biopsy MBS services rendered 1998–2000

Item no	Item description	Number of services			
		1997	1998	1999	2000
30339	Breast, benign lesion up to and including 50 mm in diameter, including simple cyst, fibroadenoma or fibrocystic disease, open surgical biopsy or excision of, with or without frozen section histology				2237
30343	Breast, abnormality detected by mammography or ultrasound where guidewire or other localisation procedure is performed, excision biopsy of				1468
30344	Breast, malignant tumour, open surgical biopsy of, with or without frozen section histology				228
30345G*	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	40	56	33	13‡
30346S†	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	7006	6819	6105	2486‡
30347	Breast, malignant tumour, complete local excision of, with or without frozen section histology				2286
30358	Breast, biopsy of solid tumour or tissue of, using a vacuum-assisted breast biopsy device under imaging guidance, for histological examination, where imaging has demonstrated:(a) microcalcification of lesion; or (b) impalpable lesion less than 1 cm in diameter – including pre-operative localisation of lesion where performed, not being a service to which item 30363 applies				30
30360	Fine needle aspiration of an impalpable breast lesion detected by mammography or ultrasound, imaging guided – but not including imaging	19062	26032	27816	27175
30361	Breast, preoperative localisation of lesion of, by hookwire or similar device, using interventional techniques – but not including imaging	3679	4082	4009	4254
30363	Breast, core biopsy of solid tumour or tissue of, using mechanical biopsy device, for histological examination	2843	3467	4279	5327
59312	Radiographic examination of both breasts, in conjunction with a surgical procedure on each breast, using interventional techniques – examination and report	3	165	164	116
59314	Radiographic examination of one breast, in conjunction with a surgical procedure using interventional techniques – examination and report	217	2340	2634	2723
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	142	2139	2691	3253

* General practitioners.
† Specialists.
‡ January–May 2000 only.

Approach to assessment

Review of literature

This review builds and expands on previously reported work (MSAC 1999). The assessment applies techniques derived from the National Health and Medical Research Council (NHMRC 2000), the Cochrane Collaboration (Clarke et al 1999), the Quality of Reporting of Meta-analysis (QOROM) group (Moher et al 1999) and Centre for Reviews and Dissemination (Kahn et al 2001).

The evaluation sought to answer the following questions:

1. In subjects with non-palpable, mammographically detected lesions, what are the safety characteristics of the ABBI System compared with stereotactic hook wire localisation biopsy, core breast biopsy, directional vacuum assisted biopsy (mammotome), open surgical breast biopsy or other methods?

2. In subjects with non-palpable, mammographically detected lesions, what are the diagnostic characteristics of the ABBI System compared with other methods? What information exists to better situate the ABBI System against currently available alternatives?

3. Subject to considerations of safety and effectiveness, what are the cost-effectiveness characteristics of the ABBI System compared with other methods?

Literature search

The biomedical literature was searched to identify relevant studies and reviews for the period between 1966 and March 2001. Table 3 lists the electronic databases used in the search.

Table 3. Electronic databases (including edition) used in the review

Database	Period covered
Best Evidence (Ovid)	1991 to January/February 2001
Biological Abstracts (Ovid)	1980 to December 2000
CINAHL (Ovid)	1982 to February 2001
Cochrane Library including: the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effectiveness, the Cochrane Controlled Trials Register, Health Technology Assessment Database, and the NHS Economic Evaluation Database	Issue 1, 2001
Current Contents (Ovid)	Week 26 1993 to Week 14 2001
Embase (Ovid)	1980 to Week 10 2001
HealthSTAR	1975 to March 2001
Medline (Ovid)	1966 to December 2000
National Guidelines Clearinghouse	March 2001

A sensitive search strategy was applied in order to widen the selection of potentially relevant articles, with the expectation of an increase in the number of potentially

irrelevant articles identified by the strategy (Haynes et al 1994a, Haynes et al 1994b). A search strategy was parsimoniously derived from numerous pilot searches of the electronic literature and refined iteratively. The final strategy is shown in Table 4 and incorporates the search strategy of the previous report (MSAC 1999).

Table 4. Refined search strategy and its implementation in selected electronic databases*

Strategy	Database
ABBI.mp OR ((biops$.mp AND breast$.mp) AND (three-dimension$.mp OR automat$.mp OR advance$.mp OR instrument$.mp))	Ovid databases
ABBI* OR ((biops* AND breast*) AND (three-dimension* OR automat* OR advance* OR instrument*))	Cochrane Library

* Electronic databases apply different characters as "wildcard" symbols. These symbols refer to characters or groups of characters that appear in the terminus of a word fragment. For the Ovid databases, the wildcard character is the dollar sign ("$"); the Cochrane Library uses the asterisk ("*"). In this case, "biops$" expands to "biopsy", "biopsies", etc.

Electronic searching included the Internet sites of health technology assessment groups (listed in Appendix D), professional medical organisations, medical centres and health service providers, and relevant national and international government agencies. Data provided by the manufacturer of the device was included where relevant, but confirmation of the information was sought from independent sources.

Textbooks and book chapters were assessed, as were conference proceedings and collections of abstracts. Reference lists of publications were scanned and relevant citations retrieved.

Entry criteria

Collected citations were filtered through a multi-level review involving a team with skills in clinical medicine, public health, health informatics, basic science, clinical epidemiology, and biostatistics. Articles were excluded if they met the following criteria:

- pre-clinical studies involving in vitro experiments, animals, isolated human organs or cadavers;
- studies that did not focus on the use of the ABBI System in the management of non-palpable breast lesions;
- studies enrolling less than 10 subjects;
- case reports, non-systematic reviews, and opinions published as editorials or letters to the editor;
- articles that included data published in later studies; and
- level IV evidence (case series) available only in abstract form.

The evaluation was restricted to studies published subsequent to the release of MSAC Application 1001 (MSAC 1999). No restrictions were placed on publication types or population characteristics.

Review profile

The search identified 298 studies. Of these, 179 (60.07%) were excluded on the basis of the criteria previously defined. The remaining 119 articles were retrieved for more detailed evaluation. These included articles that did not provide enough preliminary information to make a decision about inclusion or exclusion (ie for reasons such as unclear or missing abstracts and uninformative titles). Detailed evaluation of articles necessitated assessment of the full text. A final decision about entry was made by consensus between two independent reviewers.

Of the 119 citations requiring full text assessment, 103 (86.55%) were excluded for the following reasons: 77 were narrative reviews, 21 were expert opinions, three studies contained data that had been published previously, and two were available only in abstract form. These 103 excluded studies are listed in Appendix E. The remaining 16 studies provide the basis of this review.

Study flow is described in Figure 2.

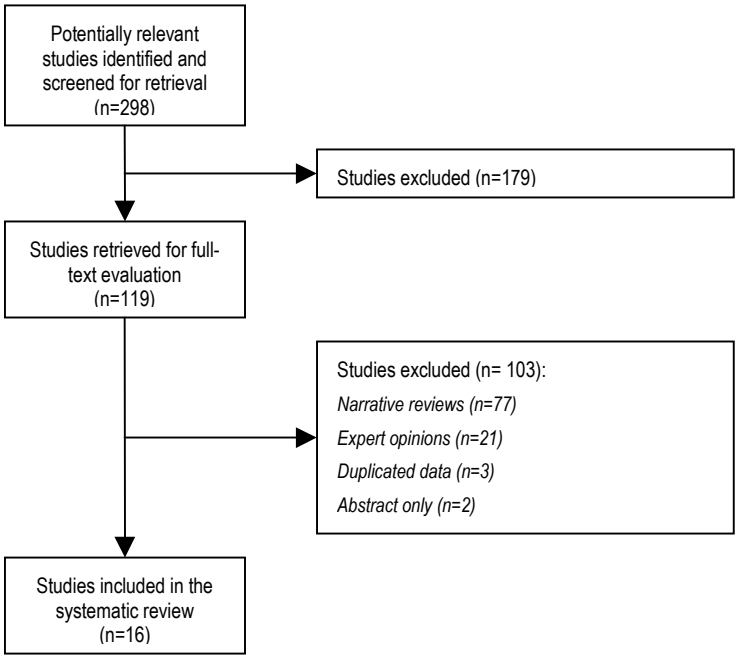

Figure 2. Flow diagram summarising the results of the literature search and the application of entry criteria

Data extraction

The review extracted data from the included articles using a standardised instrument created for this assessment. In some cases, quantitative information was poorly presented. In these instances, every effort was made to apply statistical techniques to derive estimates of effect size or variability if enough information was available. Otherwise, a statement indicating the paucity of primary information was made.

Two independent reviewers examined each article. Discrepancies in evaluation were discussed and resolved through consensus.

Dimensions of evidence

The NHMRC recommends that evidence assessment move toward an evaluation of specific 'dimensions'. These dimensions (Table 5) consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input to determine.

Table 5. Evidence dimensions (NHMRC 2000)

Type of evidence	Definition
Strength of the evidence	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design.*
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The *p*-value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

* See Table 6.

The strength of the evidence is composed of three sub-domains. Previous assessments concentrated only on the first of these, the level of the evidence (NHMRC 1999). Table 6 lists the designations recommended by the NHMRC.

Table 6. Designations of levels of evidence*

Level of evidence	Study design
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 pseudorandomised controlled trials (alternate allocation or some other method).
III–2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
III–3	Evidence obtained from comparative studies with historical control, two or 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/post-test.

* Modified from (NHMRC 1999).

The assessment of quality, another important sub-domain, was based on characteristics known to reflect important aspects of study design (Schulz et al 1995, Jadad et al 1996). Table 7 summarises these characteristics and the ordinal scale used in the assessment.

Table 7. Study design characteristics used to assess methodologic quality

Randomisation	
Adequate	Method of allocation is random, such as computer-generated number sequences and tables of random numbers.
Unclear	Trials in which the authors failed to describe the method of randomisation with enough detail to determine its validity.
Inadequate	Method of allocation is non-random, such as alternation methods or the use of case numbers.
Concealment of allocation	
Adequate	Adequate measures to conceal allocations such as central randomisation; serially numbered, opaque, sealed envelopes; or other descriptions that contain convincing elements of concealment.
Unclear	Unclearly concealed trials in which the author failed to describe the method of concealment with enough detail to determine its validity.
Inadequate	Method of allocation is not concealed.
Masking	Masking strategy applied (single, double, etc).
Participant inclusion	Intention to treat analysis was performed.
Losses to follow-up	Losses specified.

Expert advice

A supporting committee with expertise in breast surgery, general surgery, public health, and consumer issues was established to evaluate the evidence and provide advice to MSAC from a clinical perspective. In selecting members for supporting committees, MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations and consumer bodies for nominees. Membership of the supporting committee is provided at Appendix B.

Results of assessment

Is it safe?

Comparative Studies

These studies mainly reported on adverse events experienced with the ABBI procedure and do not provide detailed comparisons with the other procedures. Two studies (Yang et al 2000, Velanovich et al 1999) do not report any safety outcomes for their comparative procedures. The study by D'Angelo et al (1997) reported no complications out of 23 procedures for needle localisation breast biopsy (Table 8). Yang et al (2000) report that two out of 100 ABBI patients experienced a bleeding complication (Table 8). The study by Velanovich et al (1999) compared ABBI with core needle biopsy and reported that all ABBI rebiopsies in the first 30 cases were the result of technical failure. In the third comparative study (D'Angelo et al 1997) no complications or infections were noted for the 23 procedures.

Table 8. Distribution of adverse events for patients undergoing ABBI as reported in comparative studies

Study	Outcomes	Number of ABBI procedures	Number of cases (%)
Yang et al 2000	Bleeding Incomplete excision	100	2 (2.0) 5 (5.0)
Velanovich et al 1999	Technical failure resulting in rebiopsy	104	All rebiopsies in first 30 cases*
D'Angelo et al 1997	Complications Infections	23	0 (0) 0 (0)

* Number not stated.

Case Series

Adverse events

The adverse events associated with ABBI and reported by the appraised studies included haematoma, ecchymosis, bleeding, wound infection, and others. The incidence of haematoma ranged from 1 per cent (LaRaja et al 1999) to 12.5 per cent (Rebner et al 1999) –Table 9. Bleeding was reported by only three studies and ranged from 0.4 per cent (Sheth et al 1999) to 4.2 per cent (Rebner et al 1999). The incidence of wound infection was variable and ranged from nil (Damascelli et al 1998, LaRaja et al 1999, Leibman et al 1999, Portincasa et al 2000) to 3 per cent (Rebner et al 1999, Perelman et al 2000) – Table 9. The study by Bloomston et al (1999) reported that ecchymosis was not uncommon after the ABBI procedure but did not provide data. LaRaja et al (1999) stated that bleeding varied with each patient but was controlled in every instance with cautery.

Matthews et al (1999) reported that there were no intraoperative complications in the 110 biopsies performed and Sheth et al (1999) reported no cases of intolerance to the ABBI procedure in 230 biopsies.

Table 9. Distribution of adverse events for patients undergoing ABBI as reported in case series studies

Study	Number of		Outcomes	Number of cases (%)
	patients	biopsies		
Atallah et al 2000	65	67	Haematoma	8 (12.3)
Perelman et al 2000	34	34	Haematoma	2 (6.0)
			Wound infection	1 (3.0)
			Dehiscence	1 (3.0)
			Nausea/ vomiting/ hypotension	4 (12.0)
			Bruising	1 (3.0)
			Anxiety attack	1 (3.0)
Portincasa et al 2000	165	165	Haematoma	0
			Wound infection	0
			Seromas	0
Bloomston et al 1999	100	99	Haematoma	2 (2.0)
Ferzli et al 1999	135	132	Haematoma	2 (1.3)
			Dehiscence	1 (0.9)
			Fainting	1 (0.9)
LaRaja et al 1999	127	127	Haematoma	1 (0.8)
			Wound infection	0
			Seromas	0
Leibman et al 1999	53	54	Haematoma	3 (5.7)
			Wound infection	0
Matthews et al 1999	107	110	Haematoma	2 (1.9)
			Wound infection	1 (0.9)
Rebner et al 1999	89	90	Haematoma	9 (12.5)
			Bleeding	3 (4.2)
			Wound problems	2 (2.8)
			Pneumothorax	1 (1.4)
			Venous thrombosis	1 (1.4)
Sheth et al 1999	223	230	Bleeding	1 (0.4)
Damascelli et al 1998	75	77	Haematoma	3 (4.0)
			Wound infection	0
Kelley et al 1998	?	654	Haematoma	11 (1.7)
			Cellulitis	1 (0.2)

The adverse events listed in Table 9 are of low incidence and likely to be of little health significance. Notably, the definition of adverse events varied across the included studies, and consistent parameters were not used to evaluate adverse events associated with the ABBI procedure. This made the evaluation of adverse events across the studies difficult to quantify and collate. A clear definition of adverse events and parameters is needed in the future to assess the impact of ABBI.

Technical problems

The adverse events associated with ABBI were often as a result of technical or equipment failure. Technical problems varied from 3 per cent (Damascelli et al 1998) to 32 per cent (Perelman et al 2000) and included episodes such as computer malfunction, poor precision, the cutting blade detaching, and t-wire destabilisation. Likewise, the occurrence of mechanical malfunctions or equipment failure ranged from 2 per cent (Leibman et al 1999) to 23.5 per cent (Ferzli et al 1999) – Table 10. For the Bloomston et al (1999) study, equipment malfunction was a mechanical failure resulting directly from malfunction of the ABBI device.

Table 10. Technical problems arising for patients undergoing ABBI

Author(s)	Number of		Outcomes	Number of cases (%)
	patients	biopsies		
Perelman et al 2000	34	34	Cautery snare failure	3 (9.0)
			Poor precision/calibration	5 (15.0)
			T-wire destabilisation	2 (6.0)
			Computer malfunction	1 (3.0)
			Lesion displacement	1 (3.0)
			Other minor difficulties	1 (3.0)
Bloomston et al 1999	100	99	Equipment malfunction	3 (3.0)
			Conversion to open biopsy due to mechanical failure	1 (1.0)
Ferzli et al 1999	135	132	Cautery snare failure	12 (9.1)
			Poor calibration	2 (1.5)
			Needle moved nodule changing coordinates	7 (5.3)
			Deployment of the T-bar moved the neoplasm	4 (3.0)
			T-bar and specimen dislodged as blade withdrawn	6 (4.5)
Leibman et al 1999	53	54	T-bar fracture	3 (5.7)
Damascelli et al 1998	75	77	Detachment of blade	1 (1.3)
			Failure of imaging computer during procedure	1 (1.3)

Five out of the 12 case studies reported technical problems. Adverse events were reported for all studies although the numbers of adverse events were generally low. The percentages indicate that technical problems may have been more common than adverse events. There were two centres that experienced particularly high numbers of technical problems, and technical problems often led to adverse events (Perelman et al 2000, Ferzli et al 1999). The results of these studies highlight the need for careful calibration of imaging equipment. The manufacturer acknowledges that early production cannulae were more problematic with deployment of the snare. Manufacturing processes were changed over 2–3 years ago to improve the mechanism, and the manufacturers maintain that frequency of the snare failure has been reduced.

A significant issue likely to affect the outcome of adverse events and technical problems is related to the staff performing the ABBI procedure. The observed variations in the type of adverse events across the studies may be attributed to the difference in the training, experience and qualification of the staff performing the ABBI procedure. Hence, the quality and experience of those undertaking the procedure must be taken into consideration. The adverse events related to technical or mechanical factors may also

reflect the rapid and evolving technological advances being made in regards to the ABBI equipment.

Clinical practice guidelines

The Australian Safety and Efficacy Register of New Interventional Procedures – Surgery (ASERNIP–S) has developed guidelines for ABBI (Walsh et al 2000). The guidelines are based on a review of the literature. A breast surgeon drafted the guidelines and a review group was formed to critique them. The guidelines have been disseminated through the Royal Australasian College of Surgeons.

The guidelines include recommendations on lesion selection, patient selection, technical factors, credentials, pathological specimens and financial considerations.

Recommendations include:

- ABBI biopsy is appropriate only for impalpable breast lesions, lesions clearly visible on a diagnostic mammogram and diagnosis of malignant lesions.
- Proven malignant lesions should not routinely undergo ABBI biopsy.
- The patient should not be anti-coagulated, must weigh less than 130 kg and must be able to lie immobile in the prone position.
- The lesion should not be too close to the chest wall, the compressed breast should not be too small to allow ABBI biopsy, and mammographic lesions behind the nipple should be approached with caution.
- ABBI biopsy is a day patient procedure; orally administered premedication appears to facilitate the procedure; post biopsy mammography and specimen radiology should be routinely performed.
- The ABBI room must meet appropriate radiological and surgical standards.
- The ABBI system should be operated by practitioners specifically trained and accredited in its use and a patient database should be established at all ABBI centres.
- The ABBI technique requires both radiological and surgical skills; the procedure should be subject to surgical audit; and ABBI biopsies should be viewed by a multidisciplinary team.
- The ABBI biopsy specimen should always be submitted for histopathological examination, and a copy of the specimen X-ray should be sent with the ABBI specimen.
- Frozen sections are not routinely recommended for ABBI specimens; the localisation and fixation T-bar should remain in the specimen; and orientation sutures should be placed in the specimen.

Limitations of the guidelines include a potentially narrow search strategy, unclear methods of formulating recommendations, and recommendations that are based on low-level evidence that is prone to bias. A review of the guidelines is expected in 2001.

Is it effective?

Comparative studies

Descriptive characteristics

The literature search uncovered a total of 16 studies that provided evidence about the effectiveness of ABBI and that were published since the previous MSAC report (MSAC 1999). The ideal study design for assessing the clinical effectiveness of a therapeutic procedure is a randomised controlled trial. The ideal study design for assessing diagnostic accuracy is the independent blind comparison of an appropriate spectrum of consecutive patients, all of whom have undergone both the diagnostic test and the reference standard. No randomised controlled trials or properly designed diagnostic studies have been completed to date. Three of the included studies are comparative studies (Table 11). One comparative study compared ABBI with core needle biopsy; another compared ABBI and needle localisation under general anaesthesia; and the other compared ABBI with core needle biopsy and wire localised biopsy. The most recent publication for each relevant study was included.

Table 11. Descriptive characteristics of comparative studies

Study	Location	Dates of enrolment	Intervention group*	Comparison groups*	Population characteristics		
					Total number of patients	Age (years)†	Length of follow-up
Yang et al 2000	Korea	Dec 1996 to Aug 1998	ABBI (100)	Core needle biopsy (59)	159	?‡	In hospital
Velanovich et al 1999	USA	Jan 1997 to Mar 1998	ABBI (104)	Core needle biopsy (245) Mammotome (107) Wire-localised biopsy (520)	976	?	6 months
D'Angelo et al 1997	USA	Mar 1996 to Jun 1996	ABBI (23)	Needle localisation with excisional breast biopsies (23)	46	Interven-tion=62 (13) Compari-son=68 (11)	?

*The number in brackets refers to the number of procedures that were performed.
†The standard deviations for age are given in brackets.
‡Data not reported or unknown.

Three reports of comparative studies were found (D'Angelo et al 1997, Velanovich et al 1999, Yang et al 2000) – Table 11. All three comparative studies had concurrent control groups. Two studies were conducted in the USA and the other in Korea. Patients were recruited in the late 1990s (Table 11).

The study by Velanovich et al (1999) reports that both the mammotome and ABBI were new procedures at their institution at the commencement of their study. In this study most patients were followed up at six months with mammograms; some had clinical

examination only; and some were simply referred back to their primary care physicians. For the D'Angelo et al (1997) study the comparator-needle localisation with excisional breast biopsies was performed in the operating room under general anaesthesia. Some patients chose in this study (D'Angelo et al 1997) not to have the newer ABBI procedures, and those women already in need of an operation for another cause were allocated to the comparison group.

The exclusion criteria varied between studies. The study by Yang et al (2000) excluded patients with highly suspicious malignancies and palpable breast lesions. Another study (Velanovich et al 1999) excluded patients who underwent ultrasound-guided biopsies, and cystic lesions were excluded from biopsy in the D'Angelo et al (1997) study.

Quality

None of the studies were randomised. All three studies were comparative studies with concurrent controls. The allocation of patients to ABBI or core needle biopsy in the Yang et al (2000) study was performed according to clinical criteria (ABBI for microcalcifications not more than 2 cm). Another study (Velanovich et al 1999) did not provide details of the methods used to allocate patients to ABBI, core needle biopsy, mammotome or wire-localised biopsy but allocation appears to also be based on clinical selection criteria. The study by D'Angelo et al (1997) allocated patients to ABBI or needle localisation biopsies based on patient preferences and clinical convenience (women already scheduled for general anaesthesia had the needle localisation biopsies). Inadequate randomisation and concealment of allocation are significant potentials for bias as they have been related to a 30 per cent overestimation in the measures of effect (Schulz et al 1995).

None of the studies made mention of masking patients or investigators. There is evidence that lack of masking leads to performance bias which has been associated with up to 17 per cent overestimation of effect (Schulz et al 1995). It is unclear whether patients were analysed in the groups to which they were originally allocated. None of the studies mentioned whether the results were conducted using the 'intention-to-treat' principle.

Two studies (Yang et al 2000, D'Angelo et al 1997) had no loss to follow-up, and the other study (Velanovich et al 1999) failed to provide details of loss to follow-up. It is important that the two groups do not vary in their loss to follow-up. All of the studies had a short length of follow-up, limiting the application of results to the clinical setting.

None of the studies reported sample size/power calculations. It is possible that the studies did not have sufficient sample sizes to detect differences between groups. Although the studies were comparative in design the main results were often reported only for the ABBI group. There was only one outcome related to safety (complications) in one study (D'Angelo et al 1997) that was reported for ABBI and a comparator. One study (Velanovich et al 1999) presented the results graphically and failed to report actual figures.

Case series studies

Descriptive characteristics

Twelve of the 16 included studies are case series studies (Table 12). This design is highly prone to bias and is classified as level IV evidence according to the NHMRC levels of evidence (NHMRC 2000). Sample sizes ranged from 34 to 654 procedures (Table 12). The two largest studies were both from the USA (Kelley et al 1998, Sheth et al 1999). In studies that reported age, participants had a mean age between 47 and 62 years. The duration of follow-up varied between studies, with four studies assessing patients only while they remained in hospital (Leibman et al 1999, Sheth et al 1999, Perelman et al 2000, Smathers 2000). The longest period of follow-up was two years in the French study by Atallah et al (2000) – Table 12.

One of the studies (Kelley et al 1998) was a multi-centre study involving eight separate institutions. One of the included studies also reported results independently and has been excluded to avoid assigning double weight to its findings. Another study was reported in three articles at three separate stages. Only the most recent paper has been included (Ferzli et al 1999). One study was written in French (Atallah et al 2000); all the other papers were English publications.

Table 12. Descriptive characteristics of case series studies

Study	Location	Dates of enrolment	Number of ABBI procedures	Age (years)*	Length of follow-up
Atallah et al 2000	France	?	67	?†	2 Years
Perelman et al 2000	Canada	Sep 1997 to May 1998	34	?	In hospital
Smathers 2000	USA	Apr 1997 to Aug 1998	101	?	In hospital
Portincasa et al 2000	Italy	?	170	51 (34–81)	I week
Bloomston et al 1999	USA	Apr 1996 to May 1997	100	62 (34–87)	Mean of 7 months
Ferzli et al 1999	USA	Apr 1996 to Apr 1997	132	52 (32–76)	1 week
LaRaja et al 1999	USA	Jul 1996 to Feb 1998	127	?	24–48 hours
Leibman et al 1999	USA	Feb 1997 to Dec 1997	54	53 (32–85)	In hospital
Matthews et al 1999	USA	Feb 1997 to Jan 1998	110	61 (31–83)	6 months
Rebner et al 1999	USA	May 1997 to Mar 1998	90	?	11 months
Sheth et al 1999	USA	Apr 1997 to Jun 1998	230	47 (30–88)	In hospital
Damascelli et al 1998	Italy	Jun 1997 to Jan 1998	77	?	1 week
Kelley et al 1998	USA	?	654	?	?

* The range for age is shown in brackets.
† Data not reported or unknown.

Quality

Case series study designs are highly prone to bias. A major flaw is the failure to compare the procedure with another procedure. There has been no attempt to assess the quality of these studies.

Comparative studies

Results

Table 13. Summary of overall clinical results of comparative studies

Study	Total number of patients	Outcomes	Number of procedures (%)				
			ABBI	Core needle biopsy	Mammotome	Open wire localised biopsy	Needle localisation with excisional breast biopsies
Yang et al 2000	159	Malignant Benign Additional biopsy Residual cancer Incomplete excision of lesion Incomplete removal of calcification	9 (10.0) 91 (90.0) ?* ? 5 (5.0) 3 (3.0)	13 (22.0) 46 (78.0) 7 (18.9) 4 (57.1) ? ?			
Velanovich et al 1999	976	Positive margins (malignant lesions) Discordant/rebiopsy rate Technically successful (enable diagnosis) Sensitivity Specificity Residual cancer rate	(63.6) (5–10)‡ (92.5)‡ (90–100)‡ (90–100)‡ (71.4)	? (25–30)‡ (94.3) (80–90)‡ (90–100)‡ ?	? (20–25)‡ (96.4) (80–90)‡ (90–100)‡ ?	(50.9) ? (98.7) ? ? (70.4)	
D'Angelo et al 1997	46	Malignant Benign Positive margins Mean procedure time (minutes) Mean blood loss (cc) Mean solitary nodular density (mm) Residual abnormalities (after ABBI) Residual cancer (on resection)	5 (21.7) 18 (78.3) 5 (100) 18 (9–38)‡ 14 (9.7)† 9 (3.9)† 2 (8.7) 3 (60.0)				5 (21.7) ? 5 (100) ? 20 (9.8)† 12.8 (7.3)† ? 2 (40)

* Data not reported or unknown.
† Number shown in brackets is a standard deviation.
‡ Number shown in brackets is a range.

In the Yang et al (2000) study malignancy was diagnosed by ABBI in nine patients. Six of these nine patients were diagnosed with ductal carcinoma in situ (DCIS) and three with invasive ductal carcinoma (IDC). Ninety patients were diagnosed by ABBI with benign disease (58 with fibrocystic disease, 30 with fibroadenoma and two with atypical hyperplasia). In the same study 13 patients were diagnosed with malignancy using the stereotactic core biopsy technique (11 with DCIS and two with IDC) and 46 with benign disease (38 with fibrocystic disease and 8 with fibroadenoma). In the D'Angelo et al (1997) study five malignancies were diagnosed by ABBI (three invasive lobular carcinomas and two invasive ductal carcinomas). The Velanovich et al (1999) study reports the types of malignancies only in graphical format. When the stereotactic core biopsy technique was used, 1–10 per cent of lesions were atypical ductal hyperplasia (ADH); for mammotome 10–20 per cent of lesions were ADH, for ABBI 0–10 per cent of lesions were ADH; and for wire localisation biopsy 0–10 per cent of lesions were ADH. No other figures of malignancy are presented in the Velanovich et al (1999) study.

The size of ABBI cannulae varied between studies, with D'Angelo et al (1997) using a 20-mm cannula, Velanovich et al (1999) a 10–20-mm cannula and Yang et al (2000) a 5–20-mm cannula.

The study by D'Angelo et al (1997) reports that patient acceptance of the ABBI procedure was high: out of 23 cases, subjective comfort was rated excellent in 21, good in two and poor in none. Pain was mostly due to lying prone on the ABBI table or the injection of local anaesthetic. Cosmetic results were 'excellent' to both patient and surgeon, with no breast dimpling or hollow spots seen. In comparison, patient acceptance of needle localisation breast biopsy was high, and the cosmetic appearance of the breast was acceptable to all women. The other two comparative studies (Yang et al 2000, Velanovich et al 1999) failed to report patient satisfaction or cosmetic results.

The comparative studies have provided very little data on the primary outcome of rebiopsy rates.

Case series studies

Results

Rebiopsy rates refer to subsequent rebiopsies that were required after the completion of an ABBI procedure. In these cases the initial ABBI failed to obtain sufficient material for histopathological diagnosis. Six of the 13 studies reported that rebiopsies were required (Table 14). For the studies that reported rebiopsies the rates varied from 0.05 to 2.9 per cent of all ABBI procedures initially performed.

Table 14. Number of rebiopsies required following completed ABBI procedures

Study	Total number of patients	Type of rebiopsy	Number of rebiopsies resulting (%)
Perelman et al 2000	34	Needle-guided excisional biopsy	1 (2.9)
Smathers 2000	101	Open surgical biopsy	2 (2.0)
Bloomston et al 1999	100	Needle localisation and excisional biopsy	1 (1.0)
Leibman et al 1999	54	Needle localisation	1 (1.9)
Sheth et al 1999	224	Biopsies	?*
Kelley et al 1998	654	Diagnostic procedure	3 (0.05)

* Data not reported or unknown.

Table 15 shows the number of ABBI procedures that were completed from the case series studies. It must be noted that some of the studies that report 100 per cent completed procedures only included results for the procedures that were successfully completed. These figures relate to procedures that were commenced as ABBI procedures and were completed as ABBI procedures. These figures do not reflect patients who were excluded prior to the commencement of the procedure because they did not meet inclusion criteria or the lesion could not be localised.

Table 15. Summary of number of completed ABBI procedures in case series studies

Study	Total number of patients	Total number of ABBI procedures completed (%)
Atallah et al 2000	67	6 (84)
Perelman et al 2000	34	34 (100)
Smathers 2000	101	99 (98)
Portincasa et al 2000	165	165 (100)
Bloomston et al 1999	100	99 (99)
Ferzli et al 1999	132	101 (77)*
LaRaja et al 1999	127	127 (100)
Leibman et al 1999	54	54 (100)
Matthews et al 1999	110	110 (100)
Rebner et al 1999	90	72 (80)
Sheth et al 1999	224	224 (100)
Damascelli et al 1998	77	75 (97)
Kelley et al 1998	654	654 (100)

* The high percentage of incomplete procedures in the Ferzli (1999) study was largely due to technical problems.

Table 16 reports a summary of conversions to other methods or procedures when the ABBI procedure was initially commenced. This table does not include subsequent procedures that were performed after the completion of the ABBI procedure. Procedural failure most commonly resulted in conversion to an open biopsy which was reported for four studies (Atallah et al 2000, Bloomston et al 1999, Ferzli et al 1999, Rebner et al 1999). The conversions listed in Table 16 occurred for various reasons including problems with imaging, technical problems or patient condition.

Table 16. Summary of ABBI procedures that were converted to open biopsy or aborted

Study	Total number of procedures	Description	Number of occurrences (%)
Atallah et al 2000	67	Conversion to open biopsy	11 (16.4)
Bloomston et al 1999	100	Conversion to open biopsy	1 (1.0)
		Further freehand dissection	2 (2.0)
Ferzli et al 1999	132	Conversion to open biopsy	31 (23.5)*
Leibman et al 1999	54	ABBI rebiopsy using larger cannula	1 (1.9)
Rebner et al 1999	90	Aborted procedure, conversion to core biopsy or failure to remove lesion	18 (20.0)
Damascelli et al 1998	77	Further freehand dissection	1 (1.3)
		Conversion to conventional excisional biopsy	1 (1.3)

* The high percentage of incomplete procedures in the Ferzli (1999) study was largely due to technical problems.

Few studies used the 5-mm ABBI cannula. The most frequently used cannulae in these studies were the 15-mm and 20-mm sizes.

Table 17. Summary of ABBI cannula sizes used in case series studies

Author	Total number of procedures	5-mm cannula (%)	10-mm cannula (%)	15-mm cannula (%)	20-mm cannula (%)
Atallah et al 2000	67	0	0	18 (24)	49 (73)
Perelman et al 2000	34	0	1 (3)	2 (6)	31 (91)
Smathers 2000	101	0	6 (6)	66 (65)	29 (29)
Portincasa et al 2000	165	1 (1)	1 (1)	16 (10)	147 (89)
Bloomston et al 1999	100				
Ferzli et al 1999	132	1 (1)	39 (30)	66 (50)	26 (20)
LaRaja et al 1999	127				
Leibman et al 1999	54				
Matthews et al 1999	110	5 (5)		0	
Rebner et al 1999	90	0	0		
Sheth et al 1999	224				
Damascelli et al 1998	77	0	0	13 (17)	64 (83)
Kelley et al 1998	654	0	174 (27)	259 (40)	327 (50)

Table 18. Summary of overall results of case series studies

Study	Number of procedures	Outcomes	Number of patients (%)
Atallah et al 2000	67	Malignant	12 (18)
		Benign	55 (82)
		Positive margins	9 (75)
		Mean procedure time (minutes)	60
		Specificity (%)	100
		Sensitivity (%)	100
		Type of lesions – microcalcifications	42 (63)
Perelman et al 2000	34	Malignant	7 (21)
		Positive margins	4 (57)
		Mean procedure time (minutes)	47 (11)*
		Mean specimen size (mL)	17.7 (14.2)*
Smathers 2000	101	Malignant	27 (27)
		Benign	74 (73)
		Positive margins	23 (85)
		Mean length of specimen (SD) cm	5.51 (2.18)*
		Mean width of specimen (SD) cm	1.65 (0.46)*
		Mean area of specimen (mL)	11.1
		Mean area surrounding specimen (cm^2)	10.1
		Mean area of lesion (cm^2)	1.05
Portincasa et al 2000	165	Malignant	64 (39)
		Benign	101 (61)
		Mean procedure time (minutes)	25 (15–45) †
		Mean Lidocaine use (mL)	15 (5–30) †
		Type of lesion – microcalcifications	89 (54)
		– nodules	41 (25)
		– nodules with microcalcifications	18 (11)
		– distortions	17 (10)
Bloomston et al 1999	100	Malignant	18 (18)
		Benign	81 (82)
		Positive margins	16 (89)
		Mean procedure time (minutes)	20 (8)*
		Mean incision length (cm)	2.7 (1.6)*
		Type of lesion – solid nodular density	60 (61)
		– microcalcifications	27 (27)
		– both	12 (12)
Ferzli et al 1999	127	Malignant	21 (17)
		Benign	106 (83)
		Positive margins	20 (95)
		Mean procedure time (minutes)	62.5 (21–130) †
		Mean specimen volume (mL)	15.1

Table 18 (cont.). Summary of overall results of case series studies

Study	Number of procedures	Outcomes	Number of patients (%)
LaRaja et al 1999	54	Malignant	7/53 (13)
		Benign	44 (81)
		Positive margin	6 (86)
		Mean length of specimen (cm)	4.85
		– obtained at biopsies for indeterminate microcalcifications (cm)	4.90
		– obtained at biopsies for breast mass (cm)	4.90
		– for fibroadenomas (cm)	5.40
		– for breast carcinoma (cm)	4.80
Matthews et al 1999	110	Malignant	29 (26)
		Benign	81 (74)
Rebner et al 1999	90	Malignant	11 (12)
		Benign	61 (68)
		Positive margins	7 (64)
		Mean maximum diameter (mm)	7.6 (4–9) †
		– internal calcifications (mm)	8 (4–10) †
		– clustered calcifications (mm)	<10 (3–15) †
		– asymmetric density (mm)	8
		– area of architectural distortion	15
		Type of lesions – masses	30 (33)
		– calcifications	53 (59)
		– masses and calcifications	3 (3)
		– asymmetric density	3 (3)
		– architectural distortion	1 (1)
Sheth et al 1999	224	Malignant	36 (17)
		Positive margins	23 (72)
		Mean procedure time (minutes)	65 (20–135) †
		Mean volume of specimen (mL)	12.2
Damascelli et al 1998	77	Malignant	34 (44)
		Benign	43 (56)
		Positive margins	24 (71)
		Mean procedure time (minutes)	80
Kelley et al 1998	654	Mean size of scar from 10mm cannula (mm)	14.4
		– 15mm cannula (mm)	18.6
		– 20-mm cannula (mm)	21.7

* The number in brackets is a standard deviation.
† The number in brackets is a range.

The number of biopsies performed varied from 34 to 654 (Table 18). All studies were published between 1998 and 2000. Most studies reported the proportion of lesions that were malignant or benign. Malignancy varied from 11 to 44 per cent of all lesions present in the ABBI biopsies (Table 18). The time to complete the ABBI procedure varied from an average in each study of 20–80 minutes (Table 18). The time taken to complete the procedure, however, depends on whether investigators included the time necessary for

localisation of the lesion, haemostasis, suturing and dressing, in addition to time to excise the lesion. All of the studies reported high percentages of positive margins for the malignant specimens (57–95%) – Table 18. The percentage of positive margins depends on the objective of the procedure, whether it was intended to be diagnostic or therapeutic, and the size of the cannula, although this is not specifically stated.

Table 19. Evidence summary – malignancy and type of lesions

Study	Number of procedures	Benign lesions (%)	Malignant lesions					
			DCIS*	ILC*	IDC*	L*	U*	Total (%)
Atallah et al 2000	67	55 (82)	3				9	12 (18)
Perelman et al 2000	34	27 (79)	6		1			7 (21)
Smathers 2000	101	74 (73)					27	27 (27)
Portincasa et al 2000	165	101 (61)					64	64 (39)
Bloomston et al 1999	100	81 (82)†	4	5	9			18 (18)
Ferzli et al 1999	132	118 (89)					14	14 (11)
LaRaja et al 1999	127	106 (83)					21	21 (17)
Leibman et al 1999	54	44 (81)‡	5		2			7 (13)
Matthews et al 1999	110	81 (74)§	7	2	19		1	29 (26)
Rebner et al 1999	90	61 (68)	7		4			11 (12)
Sheth et al 1999	224		12	4	20			36 (17)
Damascelli et al 1998	77	43 (56)	11	5	17		1	34 (44)
Kelley et al 1998	654		45		78	1		124 (19)

* Abbreviations: DCIS=ductal carcinoma in situ, ILC=infiltrating/invasive lobular carcinoma, IDC=invasive/infiltrating ductal carcinoma, L=lymphoma, U=unclassified.

† The 81 benign lesions include 5 fibrosis, 4 ductal epithelial hyperplasia, 4 adipose tissue, 2 papilloma, and 1 adenoma and 1 chronic inflammatory changes.

‡ The 44 benign lesions included 4 reactive lymph node, 15 fibroadenoma and 15 cystic breast disease.

§ The 81 benign lesions consisted of 3 tubular adenoma, 6 fat necrosis, 1 fatty tissue, 3 intraductal papillomatosis, 7 sclerosing adenosis, 1 lymph node, 2 radial scar, 1 chronic mastitis.

Malignancy of the ABBI biopsy varied from 11 to 44 per cent (Table 19). Conversely, the proportion of benign specimens varied from 56 to 89 per cent (Table 19). One study failed to report the proportion of benign specimens obtained (Kelley et al 1998). Some studies reported in detail the rates of different types of malignant and benign lesions (Table 19).

Subsequent procedures

The number of subsequent procedures performed was reported in most papers. Detailed information can be found in Appendix G.

Patient satisfaction and cosmetic results

Five studies report some measure of patient satisfaction or cosmetic result. The study by Damascelli et al (1998) did not measure cosmetic results but reported that they were 'good' for patients who did not undergo further surgical procedures. Rebner et al (1999) reported that 3 out of 72 patients experienced scarring (the extent of the scarring was not qualified in the paper). The study by LaRaja et al (1999) followed up patients by telephone 24–48 hours after the procedure to ask patients about their satisfaction with the procedure. Authors report 'excellent' patient satisfaction, although no data is provided. Kelley et al (1998) report that the cosmetic result was considered satisfactory in all but one case (99.8%). It is unclear whether the result was satisfactory to clinicians or

patients. The patient satisfaction outcomes were all positive, although it must be noted that often only the patients who had 'successful procedures' were measured.

Perelman et al (2000) reported that 2 patients out of 34 (6.0%) experienced local pain and a further two experienced positioning discomfort during the ABBI procedure. The Kelley et al (1998) study reports that information was available on postoperative analgesics in 488 patients out of 654. They report that 12 patients (2.4%) used a prescribed pain medication. Once again it is unclear whether these figures were obtained from clinicians or patients. The study by Atallah et al (2000) reports that the procedure was well accepted by women.

None of the studies evaluated the effect on the women of being positioned uncomfortably for significant periods of time. The studies that assessed cosmetic result did not follow women for more than 48 hours. None of the studies reported pain experienced by the women other than to report the surrogate measure of analgesic use. There was no mention in the papers of the procedure leading to back or neck pain due to the positioning, and there was no evaluation of psychological effects to the women undergoing the procedure.

Missed lesions

Four of the papers report the number of missed lesions according to follow-up procedures (Smathers 2000, Damascelli et al 1998, Bloomston et al 1999, Sheth et al 1999). Smathers (2000) reported that two lesions had been missed out of 100 biopsies, and rebiopsies were performed using the open method. Bloomston et al (1999) reported that, by the seven-month follow-up, one out of 55 lesions had been missed. There was one case out of 224 that was an incorrect diagnosis of ductal carcinoma in situ and was later found to be invasive.

There was no mention of results to follow-up of benign lesions for nine of the studies (Atallah et al 2000, Smathers 2000, Portincasa et al 2000, Ferzli et al 1999, LaRaja et al 1999, Leibman et al 1999, Matthews et al 1999, Rebner et al 1999, Kelley et al 1998).

Previous health technology assessments

The Agencia de Evaluación de Techologías Sanitarias (AETS 1999) has produced a health technology assessment on mammography screening for breast cancer. The assessment includes a description of techniques used to diagnose abnormal mammographic findings (core needle biopsy, fine needle aspiration, surgical biopsy, mammotome, vacuum assisted biopsy and ABBI). The assessment is based on consensus opinion and literature searches.

The assessment concludes that the available studies do not contribute sufficient information regarding the effectiveness of the ABBI technique and that the diagnostic accuracy of ABBI has not been established. The AETS report also states that there are methodological problems related to the study design of current research that limits validity.
ABBI was not the main focus of the AETS report and was not directly compared with other procedures.

Ongoing studies

Three studies were found in searching the following clinical trials databases:

- National Research Register
- Current Controlled Trials
- ClinicalTrials.gov.

All three studies were listed on the National Research Register, which is based in the UK. All studies are as yet unpublished. Details of these studies are outlined in Appendix F.

What are the economic considerations?

General framework

The framework for the economic evaluation of any medical technology considered by MSAC is the comparison of the costs and benefits of that technology compared with the current alternative treatment for patients. Cost-effectiveness analysis involves the calculation of an incremental cost-effectiveness ratio $(C_I-C_C)/(O_I-O_C)$ where C_I is the total cost of resources used associated with the intervention, C_C is the total cost of resources used by the comparator, O_I is the output associated with the intervention, and O_C is the outcome associated with the comparator.

Where there are two comparators, a weighted average of cost and outcome can be calculated where the weights are the proportion of patients who are likely to receive each of the comparator treatments.

We have undertaken a literature review of the published economic evidence.

Economic evaluation

None of the published economic evaluations quoting costs of ABBI is a cost-effectiveness study. Most are cost-consequences studies, where effectiveness and costs are considered separately, not related to each other in the form of, for example, a cost per life year gained.

Liberman et al (1999, 2000) note that the ABBI system has the advantage of potentially being able to remove a small lesion in its entirety as a single specimen, but also note numerous disadvantages. These include a high frequency of lesions not suitable for ABBI biopsy, large volume of tissue removal (compared with conventional core biopsy), high complication rate, and a high frequency of tumour at the margins when cancer is present. Any complications may result in higher costs.

Liberman et al (1999, 2000) also report that ABBI has higher costs for disposables associated with percutaneous breast biopsy tissue acquisition devices, costing US$560, compared with US$215 for directional vacuum-assisted biopsy with an 11-gauge probe (US$135 with a 14-gauge probe), and US$14–24 for 14-gauge automated core needle. Complete removal of mammographic target is also reported as possible with 14-gauge

stereotactic directional vacuum-assisted biopsy, but complete removal by whatever method does not ensure complete excision of the histologic process. Further research is needed to establish which lesions, if any, it is advantageous to remove.

Damascelli et al (1998) report a cost of US$1,555, although no breakdown is given.

Bloomston et al (1999), in a study of 100 consecutive women undergoing ABBI (99 successful), report an average procedural cost (based on charges to patients) of US$3,406.

In a comparative study of ABBI (n=23) and open excisional breast biopsy (n=23) with needle localisation, D'Angelo et al (1997) quote costs of US$1,500 and US$2,500 respectively, although no explanation or breakdown is given.

LaRaja et al (1999) quote a cost saving of US$1,000 over standard excisional biopsy with preoperative needle localisation in a study of 139 patients, where 12 patients were unable to complete the procedure – no explanation or breakdown is given.

Matthews et al (1999) in a retrospective review of 110 procedures (109 successful) quote patient charges of US$2,378 for ABBI and US$3,028 for open excisional needle localised biopsy.

Leibman et al (1999) quote costs from Ferzli et al (1997) and conclude from a retrospective review of 53 patients that ABBI has no advantages over core needle biopsy for either malignant or benign lesions.

Ferzli et al (1997) quote the cost of ABBI at US$1,200, compared with US$2,700 for an open biopsy. ABBI is stated to be more expensive than core biopsy (no data provided), but most of the saving is due to not needing an operating room. However, Ferzli et al (1999) state that because of the potential for technical problems with ABBI, it must be undertaken in a room with facilities approaching those of an operating room, as conversion to open procedure may be required. This means costs are greater than for a large core biopsy, although no figures are quoted.

Velanovich et al (1999), in answer to a question recorded in the discussion section of their paper, quote a cost difference of US$1,800 between ABBI and wire localised biopsies.

To summarise, the literature suggests costs for ABBI ranging from US$1,200–3,406, giving a mean of US$1,658. This would translate to Australian costs of A$2,316–6,574, with a mean of A$3,200[1].

Cost/patient

The submission suggests Australian costs of $1,726 for ABBI, and costs of $2,179 for a comparator – needle-localised wide local excision biopsy.

[1] Exchange rate of US$1 to A$1.93.

Key areas of economic uncertainty

- The evidence on costs of ABBI in the literature is mainly from the USA. This may not be applicable in the Australian setting and the relative health care costs may differ.
- In the submission, the breakdown of the costs of the comparator service, needle-localised wide local excision biopsy, is not transparent.
- There are a number of comparators which may be appropriate.
- The published evidence that is presented is not based on randomised controlled trials and, where comparator costs are quoted, it is not transparent how they were calculated.
- There is no evidence on the cost effectiveness of the procedure.
- There may be manpower issues concerning the training of clinicians in any new procedure. This may affect the number of adverse events, the failure rate, and the effectiveness of the procedure.
- Any safety issues, increased complications, or the need to switch to another procedure may lead to increased costs.

Likely number of patients per year

The submission suggests 5,660 procedures.

Financial cost

Based on the suggested number of procedures and costs of ABBI presented in the submission, the total costs would be $12.3 million. Incremental cost savings, again using data from the submission, would be $2.56 million if the comparator were needle-localised wide local excision biopsy.

Summary

- The evidence on the costs of the procedure varies; there is some evidence of cost savings from using ABBI compared with other biopsy procedures.

- Even if there were cost savings, this may not translate into a better cost-effectiveness ratio. For example, if costs were lower for a certain procedure but the procedure was less effective than a comparator (for example in terms of life years gained), the cost per life year gained may be higher than for a comparative procedure, which may cost more but is more effective.

- Limited published evidence on the costs and effects of ABBI precludes the provision of specific cost-effectiveness estimates.

Conclusions

Safety

Safety data differs widely as ABBI requires specialised surgical techniques and surgeon experience differs between centres. Eleven studies reported the occurrence of haematoma which varied from 1 to 12.5 per cent. Wound infection varied from 0 to 3 per cent and was reported by six studies. Three studies reported dehiscence or wound problems ranging from 1 to 3 per cent. Bleeding was reported in three studies and ranged from 0.4 to 4.2 per cent. Other reported adverse events included nausea, vomiting, hypertension, bruising, anxiety attack, fainting, pneumothorax, venous thrombosis and cellulitis.

The adverse events associated with ABBI were often as a result of technical or equipment failure. Technical problems varied from 3 per cent to 32 per cent and included episodes such as cautery snare failure (although this has subsequently been addressed by manufacturers), poor precision/calibration, t-wire destabilisation, detachment of blade and computer malfunction.

Effectiveness

No randomized controlled trials or properly designed diagnostic studies comparing ABBI with any other therapeutic or diagnostic procedure have been completed to date. Studies have compared ABBI with core needle biopsy, and wire localised biopsy. Sensitivity and specificity of ABBI were comparable with core needle biopsy in one study. Discordant rebiopsy rates appeared to be lower for ABBI compared with core needle biopsy in the same study. Technical success was slightly lower for ABBI compared with core needle biopsy, and open wire localised biopsy. In another study all margins for ABBI and needle localisation with excisional breast biopsies were positive. Mean blood loss for ABBI was significantly less than for needle localisation with excisional breast biopsy. These comparative studies failed to provide detailed rebiopsy rates.

For the case series studies that reported rebiopsies (occasions when the initial ABBI failed to obtain sufficient material for histopathological diagnosis) the rates varied from 0.05 to 2.9 per cent of all ABBI procedures initially performed. Between 1 and 23 per cent of ABBI procedures were converted to another form of biopsy or aborted before ABBI was completed.

Malignancy of the ABBI biopsy varied from 11 to 44 per cent. Between 57 and 95 per cent of malignant biopsies obtained using the ABBI procedure had positive margins. Mean procedure time varied from 22 to 80 minutes. Five studies reported some measure of patient satisfaction with cosmetic results. Patient satisfaction outcomes were generally good and the procedure was generally acceptable to women.

Cost-effectiveness

There is some evidence of cost savings from using ABBI compared with other biopsy procedures. But even if there were cost savings, this might not translate into a better cost-effectiveness ratio. Limited published evidence on the costs and effects of ABBI precludes the provision of specific cost-effectiveness estimates.

Recommendation

MSAC recommended that, on the strength of evidence pertaining to Advanced Breast Biopsy Instrumentation (ABBI), public funding should be supported for the diagnostic use of this procedure, as long as fees are such that health system costs do not exceed those of comparators. There is insufficient evidence for the use of ABBI in a therapeutic role for breast cancer.

The use of the ABBI equipment is to be limited to surgeons and radiologists with sufficient training and expertise in the procedure, in order to reproduce in Australian practice the results reported in the literature.

A costing study should be carried out to assist in the setting of the appropriate Medicare rebate.

—The Minister for Health and Aged Care accepted this recommendation on 18 September 2001.—

Appendix A MSAC terms of reference and membership

MSAC's terms of reference are to:

- advise the Commonwealth Minister for Health and Ageing 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;
- advise the Commonwealth Minister for Health and Ageing on 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;
- advise the Commonwealth Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC), and report its findings to AHMAC.

The membership of MSAC 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
Mr Alan Keith	Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Ageing
Associate Professor Richard King	internal medicine
Dr Michael Kitchener	nuclear medicine
Professor Peter Phelan	paediatrics
Dr David Robinson	plastic surgery
Professor John Simes	clinical epidemiology and clinical trials
Associate Professor Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council

Appendix B Supporting committee

Supporting committee for MSAC application 1037 Advanced Breast Biopsy Instrumentation (ABBI) System for Non-palpable Breast Lesions

Dr David Robinson (Chair) MB BS, FRACS, FRCS President of the Senior Medical Staff Association, Princess Alexandra Hospital, Brisbane	member of MSAC
Dr Maxwell Coleman MB BS, FRACS, FRCS Surgeon to Central and East Sydney BreastScreen, Visiting Medical Officer, St Vincent's Hospital, Sydney	co-opted member
Mr John Collins MB BS, FRACS, FACS Specialist Breast and General Surgeon Head of the Breast Unit, Royal Women's and Royal Melbourne Hospitals Chairman of the Breast Study Committee of the Anti-cancer Council of Victoria;	nominated by the Royal Australasian College of Surgeons
Dr John Primrose MB, BS(Hons), FRANZCR Senior Medical Adviser, Health Access and Financing Division, Commonwealth Department of Health and Ageing	medical adviser to MSAC
Associate Professor Dr Richard West A.M. MB BS, FRACS, FRCS Surgeon to Central and East Sydney BreastScreen, Head of Department of Breast Surgery, Royal Prince Alfred Hospital, Sydney	co-opted member
Dr Neil Wetzig MB BS, FRACS, FRCS Breast and Endocrine Surgeon Visiting Surgeon to Brisbane South Breast Screening and Assessment Service & Wesley Breast Clinic	co-opted Member
Ms Robyn Wicks RN RM Counsellor BreastScreen Western, Consumer Representative Breast Cancer Action Group, NSW	nominated by the Consumers' Health Forum

Appendix C Studies included in the review

Comparative studies

D'Angelo P.C., Galliano D.E. and Rosemurgy A.S. 1997, 'Stereotactic excisional breast biopsies utilizing the advanced breast biopsy instrumentation system', *American Journal of Surgery,* 174**:** 297–302.

Velanovich V., Lewis F.R. Jr, Nathanson S.D. et al 1999, 'Comparison of mammographically guided breast biopsy techniques', *Annals of Surgery,* 229**:** 625–630 (discussion 630–3).

Yang J.H., Lee S.D. and Nam S.J. 2000, 'Diagnostic utility of ABBI™ (Advanced Breast Biopsy Instrumentation) for non-palpable breast lesions in Korea', *Breast Journal,* 6**:** 257–62.

Case series studies

Atallah N., Karam R., Younane T. et al 2000, 'Stereotactic excisional biopsy (ABBI technique) on dedicated digital prone tables. Advantages. Disadvantages. Indications. About 67 cases', *Journal Medical Libanais,* 48: 70–6.

Bloomston M., D'Angelo P., Galliano D. et al 1999, 'One hundred consecutive advanced breast biopsy instrumentation procedures: complications, costs, and outcome' (see comments), *Annals of Surgical Oncology,* 6: 195–9.

Damascelli B., Frigerio L.F., Lanocita R. et al 1998, 'Stereotactic excisional breast biopsy performed by interventional radiologists using the advanced breast biopsy instrumentation system' (see comments), *British Journal of Radiology,* 71: 1003–11.

Ferzli G.S., Puza T., Vanvorst-Bilotti S. et al 1999, 'Breast biopsies with ABBI™: Experience with 183 attempted biopsies', *Breast Journal*, 5: 26–8.

Kelley W.E. Jr, Bailey R., Bertelsen C. et al 1998, 'Stereotactic automated surgical biopsy using the ABBI biopsy device: A multicenter study', *Breast Journal,* 4: 302–6.

LaRaja R.D., Saber A.A. and Sickles A. 1999, 'Early experience in the use of the Advanced Breast Biopsy Instrumentation: a report of one hundred and twenty-seven patients', *Surgery*, 125: 380–4.

Leibman A.J., Frager D. and Choi P. 1999, 'Experience with breast biopsies using the Advanced Breast Biopsy Instrumentation System', *AJR American Journal of Roentgenology*, 172: 1409–12.

Matthews B.D. and Williams G.B. 1999, 'Initial experience with the advanced breast biopsy instrumentation system', *American Journal of Surgery*, 177: 97–101.

Perelman V.S., Colapinto N.D., Lee S. et al 2000, 'Experience with the advanced breast biopsy instrumentation system', *Canadian Journal of Surgery*, 43: 437–41.

Portincasa G., Lucci E., Navarra G.G. et al 2000, 'Initial experience with breast biopsy utilizing the Advanced Breast Biopsy Instrumentation (ABBI)', *Journal of Surgical Oncology*, 74: 201–3.

Rebner M., Chesbrough R. and Gregory N. 1999, 'Initial experience with the advanced breast biopsy instrumentation device' (see comments), *AJR American Journal of Roentgenology*, 173: 221–6.

Sheth D., Wesen C.A., Schroder D. et al 1999, 'The advanced breast biopsy instrumentation (ABBI) experience at a community hospital', *American Surgeon* 65: 726–9 (discussion 729–30).

Smathers R.L. 2000, 'Advanced breast biopsy instrumentation device: percentages of lesion and surrounding tissue removed', *AJR American Journal of Roentgenology*, 175: 801–3.

Appendix D List of health technology agencies

- Agencia de Evaluación de Tecnologías Sanitarias (AETS)
- Agencia de Evaluación de Tecnologías Sanitarias de Andalucia (AETSA)
- Alberta Heritage Foundation for Medical Research (AHFMR)
- Agency for Healthcare Research and Quality (AHRQ)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP–S)
- L'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES)
- L'Agence Nationale pour le Développement de l'Evaluation Medicale (ANDEM)
- British Columbia Office of Health Technology Assessment (BCOHTA)
- Catalan Agency for Health Technology Assessment
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA)
- Center for Medical Technology Assessment (CMT)
- College voor Zorgverzekeringen (CVZ)
- Conseil d'évaluation des technologies de la santé du Québec (CETS)
- German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information (DAHTA@DIMDI)
- Danish Institute for Health Technology Assessment
- Danish Institute for Health Services Research (DSI)
- ECRI
- EUROSCAN
- Finnish Office for Health Care Technology Assessment (FinOHTA)
- Health Council of the Netherlands (GR)
- Minnesota Health Technology Advisory Committee (HTAC)
- Instituto Naciónal de Higiene Epidemiologia y Microbiologia (INHEM)
- Institute of Technology Assessment of the Austrian Academy of Science (ITA)

- International Network of Agencies for Health Technology Assessment (INAHTA)
- International Society of Technology Assessment in Health Care (ISTAHC)
- Medical Technology Assessment Group (M-TAG)
- Medical Technology & Practice Patterns Institute (MTPPI)
- National Coordinating Centre for Health Technology Assessment (NCCHTA)
- National Horizon Scanning Center (NHSC)
- National Institute for Clinical Excellence (NICE)
- New Zealand Health Technology Assessment (NZHTA)
- Netherlands Organization for Scientific Research (NWO)
- Basque Office for Health Technology Assessment (OSTEBA)
- Swedish Council on Technology Assessment in Health Care (SBU)
- The Norwegian Centre for Health Technology Assessment (SMM)
- Swiss Science Council/Technology Assessment (SWISS/TA)
- Unidad De Tecnologías De Salud (ETESA)
- TNO Prevention and Health (TNO)
- Veterans' Affairs Technology Assessment Program (VATAP)
- WHO Health Technology Assessment Programme (Collaborating Centres)

Appendix E List of excluded studies

Narrative reviews

Amman M., Haid A., Breitfellner G. 2000, ['Advanced breast biopsy instrumentation (ABBI). Histopathologic evaluation of a new investigation method'], *Pathologe*, 21: 234–9.

Anonymous 1996a, 'Special stereotactic breast biopsy issue', *American Surgeon*, 62: 89–165.

Anonymous 1996b, 'Stereotactic breast biopsy moving to forefront', *Advanced Technology in Surgical Care*, 14: 40–2.

Anonymous 1998, 'New advances in breast biopsy', *Point of View*, 36: 14–20.

Atallah N., Karam R., Younane T., Aftimos G. 2000, 'Stereotactic excisional biopsy (ABBI technique) on dedicated digital prone tables. Advantages. Disadvantages. Indications. About 67 cases.' *Journal Medical Libanais*, 48: 70–6.

Azavedo E. and Svane G. 1990, 'Preoperative diagnostic and prognostic information on nonpalpable breast tumors', *Recent Results in Cancer Research*, 119: 114–5.

Boshaw D.L. 1997, 'New instrumentation allows for removal of non-palpable breast lesions', *AORN Journal*, 66: 296–8.

Buchels H.K. 1997, ['Surgical therapy of primary breast carcinoma – options and perspectives'], *Langenbecks Archiv für Chirurgie*, Supplement – Kongressband 114: 1207–11.

Burns R.P. 1997, 'Image-guided breast biopsy', *American Journal of Surgery*, 173: 9–11 (discussion 2–3).

Bussieres E., Dilhuydy M.H., Barreau B. et al 2000, 'Surgical biopsies with the ABBI device: Diagnosis, treatment?', *Sein*, 10: 124–9.

Chalas E. and Valea F. 1994, 'The gynecologist and surgical procedures for breast disease', *Clinical Obstetrics & Gynecology*, 37: 948–53.

Cole C.F. 1998, 'Issues in breast imaging', *Lippincott's Primary Care Practice*, 2: 141–8.

Dall P., Hanstein B. and Mosny D.S. 2000, 'Excision of suspicious, non-palpable, intramammary lesions by automated, stereotactic breast-biopsy techniques ', *Gynakologe*, 33: 309–13.

Damascelli B., Frigerio L.F., Patelli G. et al 1998, ['Diagnosis of non-palpable lesions of the breast with stereotactic excisional biopsy with cannula. Advanced Breast Biopsy Instrumentation (ABBI) with fine diameter of 20 mm]', *Radiologia Medica*, 95: 437–44.

de Paredes E.S., Langer T.G. and Cousins J. 1998, 'Interventional breast procedures', *Current Problems in Diagnostic Radiology*, 27: 133–84.

Dershaw D.D. 2000, 'Equipment, technique, quality assurance, and accreditation for imaging-guided breast biopsy procedures', *Radiologic Clinics of North America*, 38: 773–89, ix.

Dilhuydy M.H., Henriques C., Barreau B. et al 1999, 'Advanced breast biopsy instrumentation and minimally invasive breast biopsy', *Sein*, 9: 118–25.

Endo T. 1996, 'Nippon Geka Gakkai Zasshi' ['Recent improvement of mammographic diagnosis'], *Journal of Japan Surgical Society*, 97: 333–7.

Foster R.S. Jr & Wood W.C. 1998, 'Alternative strategies in the management of primary breast cancer', *Archives of Surgery*, 133: 1182–6.

Greenberg M.L., Camaris C., Psarianos T. et al 1997, 'Is there a role for fine-needle aspiration in radial scar/complex sclerosing lesions of the breast?', *Diagnostic Cytopathology*, 16: 537–42.

Heywang-Kobrunner S.H., Smolny T., Schaumloffel U. et al 1998, ['New methods for minimal invasive assessment of uncertain mammography and MRI tomography findings'], *Zentralblatt für Chirurgie*, 123: 66–9.

Fisher J. 1996, 'Minimally invasive instrument streamlines breast biopsy procedure', *Today's Surgical Nurse*, 18: 8–11.

Kamm B.L. 1999, 'Breast procedures and imaging techniques', *Radiologic Technology*, 71: 58–72.

Kimme-Smith C. and Solberg T. 1994, 'Acceptance testing prone stereotactic breast biopsy units', *Medical Physics*, 21: 1197–201.

Kochli O.R. 2000, ['Developments in minimally invasive breast surgery – overview and our own experience: new diagnostic and therapeutic challenges in breast cancer'], *Gynakologisch-Geburtshilfliche Rundschau*, 40: 3–12.

Liberman L. 1999, 'Advanced Breast Biopsy Instrumentation (ABBI): analysis of published experience' (comment), *AJR American Journal of Roentgenology*, 172: 1413–16.

Liberman L. 2000a, 'Centennial dissertation. Percutaneous imaging-guided core breast biopsy: state of the art at the millennium', *AJR American Journal of Roentgenology*, 174: 1191–9.

Liberman L. 2000b, 'Clinical management issues in percutaneous core breast biopsy', *Radiologic Clinics of North America*, 38: 791–807.

Lifrange E. and Colin C. 2000, ['Supraconservative breast surgery'], *Journal de Gynecologie, Obstétrique et Biologie de la Réproduction*, 29: 285–7.

MacGrogan G., Henriques C., De Mascarel I. et al 1998, ['Large core of non-palpable breast lesions'], *Archives d'Anatomie et de Cytologie Pathologiques*, 46: 241–6.

March D.E., Raslavicus A., Coughlin B.F. et al 1997, 'Use of breast core biopsy in the United States: results of a national survey', *AJR American Journal of Roentgenology*, 169: 697–701.

Marti W.R., Zuber M., Oertli D. et al 2000, ['The Advanced Breast Biopsy Instrumentation (ABBI) for evaluation of mammographically suspicious, non-palpable findings of the breast: a reliable diagnosis with minor therapeutic potential'], *Swiss Surgery*, 6: 111–15.

Mautner B.D., Schmidt K.V. and Brennan M.B. 2000, 'New diagnostic techniques and treatments for early breast cancer', *Seminars in Oncology Nursing*, 16: 185–96.

Morrow M. 1995, 'When can stereotactic biopsy in diagnosing breast cancer replace excisional biopsy? – A clinical perspective' (see comments), *Breast Cancer Research & Treatment*, 36: 1–9.

Mumtaz H., Harms S.E. 1999, 'Biopsy and Intervention Working Group report', *Journal of Magnetic Resonance Imaging*, 10: 1010–15.

Newman J. 1996, 'Role of stereotactic biopsy in diagnosing breast cancer' (corrected – published erratum appears in *Radiologic Technology* 1997 Mar–Apr, 68(4): 285), *Radiologic Technology*, 68: 131–52.

Oertli D., Zuber M., Muller D. et al 1998a, ['The Advanced Breast Biopsy Instrumentation (ABBI), a system for stereotactic excision of mammographically suspect non-palpable findings in the breast'], *Schweizerische Medizinische Wochenschrift – Journal Suisse de Médecine*, 128: 811–16.

Oertli D., Zuber M., Muller D. et al 1998b, ['Initial experiences with the Advanced Breast Biopsy Instrumentation (ABBI), a system for stereotactic excision of non-palpable breast lesions'], *Langenbecks Archiv für Chirurgie* – Supplement: Kongressband, 115: 379–83.

Page D.L. and Simpson J.F. 1996, 'Pathology of preinvasive and excellent-prognosis breast cancer', *Current Opinion in Oncology*, 8: 462–7.

Parker S.H., Dennis M.A. and Stavros A.T. 1995a, 'Critical pathways in percutaneous breast intervention', *Radiographics*, 15: 946–50.

Parker S.H., Stavros A.T. and Dennis M.A. 1995b, 'Needle biopsy techniques', *Radiologic Clinics of North America*, 33: 1171–86.

Parker S.H. and Burbank F. 1996, 'A practical approach to minimally invasive breast biopsy', *Radiology*, 200: 11–20.

Parker S.H. 1998, 'The Advanced Breast Biopsy Instrumentation: another Trojan horse?' (see comments), *AJR American Journal of Roentgenology*, 171: 51–3.

Parker S. 2000, 'Stereotactic core biopsy: a return of the nattering nabobs of negativism' (editorial, comment), *Academic Radiology*, 7: 225–7.

Pastore G., Marano P., Romani M. et al 1999, ['Critical review of 215 cases of non-palpable mammary lesions'], *Radiologia Medica*, 97:344–8.

Peart O. 1992, 'Stereostatic localization pinpoints breast lesions', *Radiologic Technology*, 63: 234–9.

Poilpot S., Sebastien C., Buffet M. et al 2000, ['Stereotactic excisional non-palpable breast lesions using the advanced breast biopsy instrumentation'], *Journal de Gynecologie, Obstétrique et Biologie de la Réproduction*, 29: 142–7.

Robidoux A. 1992, 'Recent trends in the management of breast cancer. 2.Occult breast lesions: when and how to perform a biopsy for mammographic abnormalities', *Canadian Journal of Surgery*, 35: 366–70.

Roe S.M., Mathews J.A., Burns R.P. et al 1997, 'Stereotactic and ultrasound core needle breast biopsy performed by surgeons', *American Journal of Surgery*, 174: 699–703 (discussion, 4).

Roehrig H., Yu T. and Krupinski E. 1995, 'Image quality control for digital mammographic systems: initial experience and outlook', *Journal of Digital Imaging*, 8: 52–66.

Rothenberg L.N. 1993, 'Mammography instrumentation: recent developments', *Medical Progress through Technology*, 19: 1–6.

Rozhkova N.I. 1995, ['Advances in the diagnosis of breast diseases'], *Vestnik Rentgenologii i Radiologii*, 49–50.

Russin L.D. 2000, 'New directions in breast biopsy: review of current minimally invasive methods and presentation of a new coaxial technique', *Seminars in Ultrasound CT & MRI*, 21: 395–403.

Sanders L.M., Kalisher L. and Trikha S. 2000, 'Needle localization using a stereotactic table: a reassessment', *AJR American Journal of Roentgenology,* 174: 1689–90.

Schilling R.B., Cox J.D. and Sharma S.R. 1997, 'Advanced digital mammography', *Journal of Digital Imaging*, 10: 133–5.

Schillings A., Mazy S. and Mazy G. 1995, ['Breast biopsy technique'], *Journal Belge de Radiologie*, 78: 29–33.

Schmidt R.A. 1994, 'Stereotactic breast biopsy', *Ca: a Cancer Journal for Clinicians*, 44: 172–91.

Schwartz G.F. and Feig S.A. 1994, 'Management of clinically occult (non-palpable) breast lesions', *Obstetrics & Gynecology Clinics of North America*, 21: 621–37.

Schwartzberg B., Goates J.J. and Kelley W.E. 2000, 'Minimal Access Breast Surgery', *Surgical Clinics of North America*, 80: 1383–98.

Sheth D., Wesen C.A., Schroder D. et al 1999, 'The advanced breast biopsy instrumentation (ABBI®) experience at a community hospital', *American Surgeon*, 65: 726–9 (discussion, 9–30).

Silverstein M.J. and Silberman H. 1999, 'The breast biopsy paradigm shifts once again' (editorial, comment), *Annals of Surgical Oncology,* 6: 323–4.

Simpson J.F. and Page D.L. 1995, 'Pathology of preinvasive and excellent-prognosis breast cancer', *Current Opinion in Oncology*, 7: 501–5.

Simpson J.F. and Page D.L. 1997, 'Pathology of preinvasive and excellent-prognosis breast cancer', *Current Opinion in Oncology*, 9: 512–19.

Soo M.S., Walsh R. and Patton J. 1998, 'Prone table stereotactic breast biopsy: facilitating biopsy of posterior lesions using the arm-through-the-hole technique', *AJR American Journal of Roentgenology,* 171: 615–17.

Tausch C., Konstantiniuk P., Haid A. et al 2000, 'Early experience with the Advanced Breast Biopsy Instrumentation (ABBI®) System – A report of a multicentre study', *Acta Chirurgica Austriaca*, 32: 99–104.

Teh W.L., Evans A.J. and Wilson A.R. 1998, 'Definitive non-surgical breast diagnosis: the role of the radiologist' (editorial), *Clinical Radiology*, 53: 81–4.

Trevathan-Ramirez D. 1998, 'Innovations in breast disease diagnosis', *Radiologic Technology*, 70: 197–203.

van Gestel R. 1998, ['Presurgical diagnostic stereotaxic biopsy is a good predictor of breast cancer in patients with suspicious deviations on mammograms' (letter, comment), *Nederlands Tijdschrift voor Geneeskunde*, 142: 1472–3.

Vega A., Nava E., Ortega E. et al 1995, ['Radiology of non-palpable breast lesions'], *Revista de Medicina de la Universidad de Navarra*, 39: 11–17.

Watson D.K. 1996, 'Keeping pace with the evolving management of non-palpable breast lesions' (editorial, comment), *Journal of the American Osteopathic Association*, 96: 397.

Winzer K.J., Filimonow S., Guski H. et al 1998, ['The ABBI system as a possibility for evaluating non-palpable lesions]', *Zentralblatt für Chirurgie*, 123: 57–62.

Winzer K.J., Filimonow S., Frohberg H.D. et al 1999, ['Three-dimensional breast biopsy and surgery'], *Chirurg*, 70: 384–93.

Wolf G. and Helbich T. 1998, ['Results of stereotactic guidance of breast excisional biopsy versus stereotactic core biopsy in occult breast lesions'], *Wiener Medizinische Wochenschrift*, 148: 316–20.

Wong A.Y., Salisbury E. and Bilous M. 2000, 'Recent developments in stereotactic breast biopsy methodologies: an update for the surgical pathologist', *Advances in Anatomic Pathology*, 7: 26–35.

Zannis V.J. and Aliano K.M. 1998, 'The evolving practice pattern of the breast surgeon with disappearance of open biopsy for non-palpable lesions', *American Journal of Surgery*, 176: 525–8.

Zuiani C., Bazzocchi M., Dalpiaz G. et al 1995, ['Automatic devices for histologic biopsy of the breast: Comparison of 2 systems'], *Radiologia Medica*, 89: 846–8.

Expert opinion

Anonymous 1993, 'New breast biopsy improves outcomes, patient satisfaction', *Same Day Surgery*, 17: 95–7.

Anonymous 1996, 'ABBI system: a new approach to breast biopsy', *Minimally Invasive Surgical Nursing*, 10: 36–7.

Denton E.R., Michell M.J., Wilson A.R. et al 1999, 'Stereotactic excisional breast biopsy performed by interventional radiologists using the ABBI system' (letter, comment), *British Journal of Radiology*, 72: 828–9.

Guenin M. 1999, 'Wherefore ABBI? Advanced Breast Biopsy Instrumentation' (letter, comment), *AJR American Journal of Roentgenology*, 173: 1410–11.

Guenin M. 2000, 'The low false-negative rate for stereotactic breast biopsy' (letter; comment), *Radiology*, 216: 609–10.

Head J.F. and Elliott R.L. 1996, 'Comment on "When can stereotactic core biopsy replace excisional biopsy?"' (letter, comment), *Breast Cancer Research & Treatment*, 39: 349–51.

Jackson G.L. 1994, 'Re: Doctors debate different breast biopsy techniques' (letter, comment), *Journal of the National Cancer Institute*, 86: 238–9.

Kelley W.E. Jr, Schwartzberg B.S. and Uddo J.F. 1997, 'Advanced breast biopsy instrumentation' (letter, comment), *Journal of the American College of Surgeons*, 185: 604–5.

Klimberg V.S. 1999, 'Advanced breast biopsy instrumentation: not ready for prime time' (editorial, comment), *Annals of Surgical Oncology*, 6: 137–8.

Kuni C. 2000, 'Advanced breast biopsy instrumentation results' (letter, comment), *AJR American Journal of Roentgenology*, 174: 570.

Needham G., Deans H.E., Gilbert F.J. et al 1993, 'Stereotactic localization mammography' (letter, comment), *Clinical Radiology*, 47: 70–1.

Norton L.W. 1997, 'A stereotactic stand-off' (editorial), *American Journal of Surgery*, 173: 151–2.

Poisson R. and Dufresne M.P. 1989, ['An evaluation of breast stereotaxis'], *Union Médicale du Canada*, 118: 100–2.

Reitherman R.W. 1993, 'Non-surgical biopsy: providing a choice', *Radiologic Technology,* 65: 121–2.

Rush J.C. 1994, 'Stereotactic breast biopsy' (letter), *Ca: a Cancer Journal for Clinicians*, 44: 319–20.

Russin L.D. 1999, 'Trojan horses and stereotactic breast biopsy' (letter, comment), *AJR American Journal of Roentgenology*, 172: 834–5.

Tilanus-Linthorst M.M., Obdeijn A.I., Kuenen-Boumeester V. et al 1998, ['Preoperative diagnostic stereotaxic biopsy: a good predictor of breast cancer in patients with mammographic findings indicating a possible malignancy'] (letter), *Nederlands Tijdschrift voor Geneeskunde*, 142: 1167–8.

Tremper A. 1997, 'Two-minute clinic. Stereotactic breast biopsy', *PMA*, 30: 16–17.

van Gestel R. 1998, ['Presurgical diagnostic stereotaxic biopsy is a good predictor of breast cancer in patients with suspicious deviations on mammograms'] (letter, comment), *Nederlands Tijdschrift voor Geneeskunde*, 142: 1472–3.

Winchester D.P. 1998, 'Stereotactic breast biopsy: who should perform it?' (editorial), *Journal of Surgical Oncology*, 67: 213–15.

Zuurbier R.A. 1996, 'Adequacy of stereotaxic breast biopsies' (letter, comment), *Surgery*, 119: 120–1.

Duplicated study data

Ferzli G.S. and Hurwitz J.B. 1997, 'Initial experience with breast biopsy utilizing the advanced breast biopsy instrumentation (ABBI)', *Surgical Endoscopy*, 11: 393–6.

Ferzli G.S., Hurwitz J.B., Puza T. et al 1997, 'Advanced breast biopsy instrumentation: A critique', *Journal of the American College of Surgeons,* 185: 145–51.

Schwartzberg B.S., Goates J.J., Keeler S.A. et al 2000, 'Use of advanced breast biopsy instrumentation while performing stereotactic breast biopsies: review of 150 consecutive biopsies', *Journal of the American College of Surgeons*, 191: 9–15.

Abstract only data

Dookeran K.A., Poller W.R., Turkas D.J. et al 1998, 'Prospective Evaluation of the Advanced Breast Biopsy (ABBI) System as a Method for Stereotactic Breast Biopsy of Mammographic Non-palpable Abnormalities', *Radiology*, 209(P): 524.

Wetzig N., Furnival C. and Hirst C. 1998, 'Initial Australian experience with the ABBI', *Australian and New Zealand Journal of Surgery*, 68: A36.

Appendix F Ongoing primary studies

1. Comparison of three biopsy procedures, Dr S. Reaney, South Manchester University Hospitals NHS Trust

Principal research question

Can ABBI and MIBB procedures be more effective in diagnosis of breast disease than present practice?

Methodology description

Randomised controlled trial.

Sample group description

50 patients with breast abnormalities.

Outcome measure description

Accuracy of ABBI and MIBI biopsy procedures.

2. Breast biopsy and ABBI way: Patient's perspectives and experiences of undergoing breast biopsy using the ABBI system, Elaine Woodman, Castle Hill Hospital, East Yorkshire, UK

Principal research question

By exploring patients' feelings with regard to their need for a breast biopsy, its execution, and post operatively, can nursing care and support be improved?

Methodology description

Semi-structured interview will be conducted with each participant, at their convenience after the biopsy – interview to be taped then typed to form an accurate record of interview; data to be analysed to establish emerging themes regarding views and experience.

Sample group description

Women who have been referred to Day Surgery Unit for stereotactic localisation and excision of breast biopsy using the ABBI system.

Outcome measure description

Patient satisfaction with service.

3. Prospective evaluation of a new minimally invasive system for breast biopsy: the ABBI system, Mr. Michael Kerin, Castle Hill Hospital, East Yorkshire, UK

Principal research question

Is the ABBI system an appropriate and cost-effective primary diagnostic modality for impalpable screen detected mammographic abnormalities?

Methodology description

Prospective controlled.

Outcome measure description

Biopsy quality, cost.

Appendix G Subsequent procedures

Table G1. Subsequent procedures following completed ABBI

Study*	Number of patients	Lumpectomy	Mastectomy	Axillary node dissection	Total further treatment (%)
Atallah et al 2000	67				12 (18)
Perelman et al 2000	34				4 (12)
Bloomston et al 1999	100	12	5		17 (17)
Ferzli et al 1999	132				20 (15)
Leibman et al 1999	53	4	2	5	12 (23)
Matthews et al 1999	107	14	5	18	23 (21)
Rebner et al 1999	89	5	2	4	11 (15)
Sheth et al 1999	224				
Damascelli et al 1998	75				32 (43)

* No data on type of subsequent procedures available from the following studies: Kelley et al 1998, LaRaja et al 1999, Sheth et al 1999, Atallah et al 2000, Perelman et al 2000, Portincasa et al 2000, Smathers 2000.

Nine of the 13 studies reported post-operative outcomes (Table G1). Two of the most recently published studies failed to report post-operative outcomes (Portincasa et al 2000, Smathers 2000). The proportion of patients requiring any additional procedure ranged from 12 to 43 per cent of all patients receiving the ABBI procedure (Table G1). The proportion of subsequent lumpectomies varied from 7 to 13 per cent. Subsequent mastectomies varied from 3 to 5 per cent of all ABBI patients. Three studies reported the numbers of patients requiring further axillary node dissection, with the proportions being 4, 6 and 9 per cent (Table G1). The study by Sheth et al (1999) failed to report actual data on subsequent procedures but did report that there were procedures performed on the patients after they had received ABBI.

Abbreviations

ABBI	advanced breast biopsy instrumentation
ADH	atypic ductal hyperplasia
AETS	Agencia de Evaluación de Tecnologías Sanitarias
AHMAC	Australian Health Ministers' Advisory Council
ASERNIP–S	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical
CCB	conventional core biopsy
CI	confidence interval
DALY	disease-adjusted life years
DCIS	ductal carcinoma in situ
IDC	invasive/infiltrating ductal carcinoma
ILC	invasive/infiltrating lobular carcinoma
L	lymphoma
MBS	Medical Benefits Schedule
MIBB	minimally invasive breast biopsy
MSAC	Medical Services Advisory Committee
n	number
NHMRC	National Health and Medical Research Council
QOROM	Quality of Reporting of Meta-analyses
SD	standard deviation
U	unclassified
VACB	vacuum-assisted core biopsy
WHO	World Health Organisation

References

Agencia de Evaluación de Tecnologías Sanitarias 1999, 'Diagnostico de lesiones mammarias detectadas en cribado poblacional de cancer de mama mediante mamografia', *ABBI: Nuevo instrumento de biopsia histologica por puncion*, Madrid, p. 52.

Atallah N., Karam R., Younane T. et al 2000, 'Stereotactic excisional biopsy (ABBI technique) on dedicated digital prone tables. Advantages. Disadvantages. Indications. About 67 cases', *Journal Medical Libanais*, 48: 70–6.

Australian Institute of Health and Welfare 2000a, *Australia's Health 2000: The seventh biennnial health report of the Australian Institute of Health and Welfare,* Australian Institute of Health and Welfare, Canberra.

Australian Institute of Health and Welfare 2000b, *BreastScreen Australia Achievement Report,* Australian Institute of Health and Welfare, Canberra.

Australian Institute of Health and Welfare 2000c, *Cancer in Australia 1997 – Incidence and mortality data for 1997 and selected data for 1998 and 1999*, Australian Institute of Health and Welfare, Canberra.

Bloomston M., D'Angelo P., Galliano D. et al 1999, 'One hundred consecutive advanced breast biopsy instrumentation procedures: complications, costs, and outcome' (see comments), *Annals of Surgical Oncology,* 6: 195–9.

Clarke M. and Oxman A. (eds) 2000, *Cochrane Reviewers' Handbook 4.1* (updated June 2000)*,* The Cochrane Collaboration, Oxford, England.

Cole C.F. 1998, 'Issues in breast imaging', *Lippincott's Primary Care Practice*, 2: 141–8.

Damascelli B., Frigerio L.F., Lanocita R. et al 1998, 'Stereotactic excisional breast biopsy performed by interventional radiologists using the advanced breast biopsy instrumentation system' (see comments), *British Journal of Radiology*, 71: 1003–11.

D'Angelo P.C, Galliano D.E. and Rosemurgy A.S. 1997, 'Stereotactic excisional breast biopsies utilizing the advanced breast biopsy instrumentation system', *American Journal of Surgery,* 174: 297–302.

Ferzli G.S., Puza T., Vanvorst-Bilotti S. et al 1999, 'Breast biopsies with ABBI™: Experience with 183 attempted biopsies', *Breast Journal*, 5: 26–8.

Ferzli G.S. and Hurwitz J. 1997, 'Initial experience with breast biopsy utilising the advanced breast biopsy instrumentation (ABBI)', *Surgical Endoscopy*, 11: 393–6.

Harris J.R. 1996, *Diseases of the breast,* Lippincott-Raven, Philadelphia.

Haynes R.B., Walker C.J., McKibbon K.A. et al 1994a, 'Performances of 27 MEDLINE systems tested by searches with clinical questions', *Journal of the American Medical Informatics Association,* 1: 285–95.

Haynes R.B., Wilczynski N., McKibbon K.A. et al 1994b, 'Developing optimal search strategies for detecting clinically sound studies in MEDLINE', *Journal of the American Medical Informatics Association*, 1: 447–58.

Heywang-Kobrunner S.H., Schreer I. and Dershaw D.D. 1997, *Diagnostic Breast Imaging – Mammography, Sonography, Magnetic Resonance Imaging, and Interventional Procedures,* Thieme Medical Publishers, New York.

Jadad A.R., Moore R.A., Carroll D. et al 1996, 'Assessing the quality of reports of randomized clinical trials: is blinding necessary?', *Controlled Clinical Trials*, 17: 1–12.

Kahn K., ter Riet G., Glanville J. et al (eds) 2001, *Undertaking systematic reviews of research on effectiveness,* NHS Centre for Reviews and Dissemination, University of York, York, England.

Kamm B.L. 1999, 'Breast procedures and imaging techniques', *Radiologic Technology*, 71: 58–72.

Kelley W.E. Jr, Bailey R., Bertelsen C. et al 1998, 'Stereotactic automated surgical biopsy using the ABBI biopsy device: A multicenter study', *Breast Journal*, 4: 302–6.

LaRaja R.D., Saber A.A. and Sickles A. 1999, 'Early experience in the use of the Advanced Breast Biopsy Instrumentation: a report of one hundred and twenty-seven patients', *Surgery*, 125: 380–4.

Leibman A.J., Frager D. and Choi P. 1999, 'Experience with breast biopsies using the Advanced Breast Biopsy Instrumentation system, *AJR American Journal of Roentgenology,* 172: 1409–12.

Liberman L. 2000, 'Clinical management issues in percutaneous core breast biopsy', *Breast Imaging*, 38: 791–807.

Matthews B.D. and Williams G.B. 1999, 'Initial experience with the advanced breast biopsy instrumentation system', *American Journal of Surgery*, 177: 97–101.

Mautner B.D., Schmidt K.V. and Brennan M.B. 2000, 'New diagnostic techniques and treatments for early breast cancer', *Seminars in Oncology Nursing,* 16: 185–96.

Medicare Services Advisory Committee 1999, *Advanced breast biopsy instrumentation. Application 1001*, Department of Health and Aged Care, Canberra.

Moher D., Cook D.J., Eastwood S. et al 1999, 'Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of Reporting of Meta-analyses', *Lancet,* 354: 1896–1900.

National Breast Cancer Centre 2000, *New technologies in breast cancer diagnosis: Information update,* online: http://www.nbcc.org.au/pages/info/resource/nbccpubs/nt_update/sept2000/lcb.htm (accessed on 23-04-2001).

National Health and Medical Research Centre 1999, *A guide to the development, implementation and evaluation of clinical practice guidelines,* National Health and Medical Research Council, Canberra.

National Health and Medical Research Centre 2000, *How to use the evidence: assessment and application of scientific evidence,* National Health and Medical Research Council, Canberra.

Perelman V.S., Colapinto N.D., Lee S. et al 2000, 'Experience with the advanced breast biopsy instrumentation system', *Canadian Journal of Surgery*, 43: 437–41.

Portincasa G., Lucci E., Navarra G.G. et al 2000, 'Initial experience with breast biopsy utilizing the Advanced Breast Biopsy Instrumentation (ABBI)', *Journal of Surgical Oncology*, 74: 201–3.

Rebner M., Chesbrough R. and Gregory N. 1999, 'Initial experience with the advanced breast biopsy instrumentation device' (see comments), *AJR American Journal of Roentgenology*, 173: 221–6.

Schulz K.F., Chalmers I., Hayes R.J. et al 1995, 'Empirical evidence of bias: Dimensions of methodological quality associated with estimates of treatment effects in controlled trials', *JAMA,* 273: 408–12.

Schwartzberg B.S., Goates J.J., Keeler S.A. et al 2000, 'Use of advanced breast biopsy instrumentation while performing stereotactic breast biopsies: review of 150 consecutive biopsies', *Journal of the American College of Surgeons,* 191: 9–15.

Sheth D., Wesen C.A., Schroder D. et al 1999, 'The advanced breast biopsy instrumentation (ABBI) experience at a community hospital', *American Surgeon* 65: 726–9 (discussion, 729–30).

Silen W., Earle Matory W.J. and Love S.M. 1996, *Atlas of Techniques in Breast Surgery,* Lippincott-Raven, Philadelphia.

Smathers R.L. 2000, 'Advanced breast biopsy instrumentation device: percentages of lesion and surrounding tissue removed', *AJR American Journal of Roentgenology,* 175: 801–3.

Velanovich V., Lewis F.R. Jr, Nathanson S.D. et al 1999, 'Comparison of mammographically guided breast biopsy techniques', *Annals of Surgery,* 229: 625–30 (discussion, 630–3).

Walsh D., Merlin T., Humenuik V. et al 2000, 'Clinical practice guidelines for the Advanced Breast Biopsy Instrument (ABBI), *Australian Safety and Efficacy Register of New Interventional Procedures – Surgical CPG Report No. 1,* Adelaide, South Australia.

Wong A.Y., Salisbury E. and Bilous M. 2000, 'Recent developments in stereotactic breast biopsy methodologies: an update for the surgical pathologist', *Advances in Anatomic Pathology*, 7: 26–35.

Yang J.H., Lee S.D. and Nam S.J. 2000, 'Diagnostic utility of ABBI™ (Advanced Breast Biopsy Instrumentation) for non-palpable breast lesions in Korea', *Breast Journal,* 6: 257–62.