National Institute for Health and Clinical Excellence

741 –Image guided radiofrequency excision biopsy of breast lesions

Consultation Comments table

IPAC date: 15th May 2009

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 2 Patient Interest Organisation (Charity Sector)	**1.1**	1.1 Breakthrough Breast Cancer agrees that due to the lack evidence on image-guided RF excision biopsy of breast lesions, the procedure should be restricted to use with special arrangements for clinical governance, consent and audit or research.	Thank you for your comment.
2	Consultee 2 Patient Interest Organisation (Charity Sector)	**1.2**	1.2 Breakthrough Breast Cancer welcomes the measures put in place for clinicians wishing to undertake image-guided RF excision biopsy of breast lesions. Â We support and encourage the requirement to ensure that patients and carers are well informed about the procedure and its current limitations. Â It is crucial for patients to be able to make informed decisions that reflect their individual needs and personal choice. Â In addition, the recommendation to audit and review clinical outcomes in patients who have undergone this procedure is essential. Â It is important to gain evidence on this technique for future assessments of image-guided RF excision biopsy. Â	Thank you for your comment. The use of 'Understanding NICE guidance' is recommended, but healthcare professionals may wish to produce patient information that is tailored to local circumstances or patients with particular needs.
3	Consultee 2 Patient Interest Organisation (Charity Sector)	**1.3**	1.3 The call for further research to develop the evidence base will be important if this procedure is found to be beneficial for use more widely in the future. Â However, it may also be necessary to focus the aim of the research at the safety and efficacy of this technique.	Thank you for your comment. Section 1.3 reflects what the Committee would wish to know in order to reduce uncertainty about the procedure as it was scoped in this case.

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4	Consultee 4 Private Sector professional Bupa employee	**1**	Bupa agrees that this should not be performed routinely. The Royal College of Pathologists is advancing thinking on the evaluation of lab tests, and the principles they are promoting are applicable to all tests. There are four key questions: does the biomarker being measured link to the disease of interest? Does the test measure the biomarker? What are the tests sensitivity, specificity, and positive & negative predictive values in the relevant patient population? Does the test improve the eventual health outcome when incorporated into a care pathway? Answers to these questions are shaky or non-existent for this test: there is a case to be made that it should be research only.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
5	Consultee 4 Private Sector professional Bupa employee	**2.1**	2.1.2. If you are mentioning ductal ca in situ and fibroadenomas, why are you not also mentioning lobular ca in situ?	Thank you for your comment. The Committee considered this comment but decided not to change the guidance. Lobular carcinoma in situ is not an indication for this technique and was not reported in the literature.
6	Consultee 1 Professional and Specialist Advisor	**2.2**	2.2.1 could read " deliver an intact specimen for histological examination WITH A COMPLETE MARGIN" this essentially confirms that the lesion is completely excised and leaves no doubt as to whether any residual lesion could alter the final diagnosis	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
7	Consultee 1 Professional and Specialist Advisor	**2.3**	additional paper not considered is Killebrew LK, Oneson RH. Breast J. 2006 Jul-Aug 12(4):302-8	Thank you for your comment. The paper identified is not an intervention with a radiofrequency technique, and as such does not fall within the scope for this guidance.
8	Consultee 2 Patient Interest Organisation (Charity Sector)	**2.3**	As other biopsy options are available the relative efficacy of image-guided RF excision biopsy of breast lesions needs to be directly compared with the standard comparators.	Thank you for your comment. It is not in the remit of the IP programme to compare the efficacy and safety of interventions against comparator interventions.
9	Consultee 4 Private Sector professional Bupa employee	**2.3**	Why no mention of lobular ca in situ? Am I misunderstanding something?	See response to comment no. 5.
10	Consultee 1 Professional and Specialist Advisor	**2.4**	additional paper not considered is Killebrew LK, Oneson RH. Breast J. 2006 Jul-Aug 12(4):302-8	Thank you for your comment. The paper identified is not an intervention with a radiofrequency technique, and as such does not fall within the scope for this guidance.

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11	Consultee 1 Professional and Specialist Advisor	**2.4**	Failure to deliver an accurate sample is surely a reported adverse event rather than a theoretical. It currently appears in both lists. haemorrhage and haematoma are continuum of the same process and should be put as reported events. Also i am surprised that temporary pain has not been reported also.	Section 2.4.3 is the opinion of the Specialist Advisers. Failure to deliver an adequate sample will be removed from the list of theoretical adverse events.
12	Consultee 2 Patient Interest Organisation (Charity Sector)	**2.4**	Breakthrough Breast Cancer regularly consults with members of our Clinical Experts Reference Group for their comments on a range of breast cancer issues. It was reported to Breakthrough by one breast surgeon that “Image-guided core biopsy using radiofrequency to seal the vessels is recognised. Â There should be no risk of false positives and it is safe.” Â This may be positive in using it more commonly to develop the evidence base. Emphasis on a high patient quality of life is important. Â This is supported in this procedure by the extremely low pain score reported by patients, as well as no significant adverse effects seen in patients at the 4-6 month follow-up (1). Â It is key that patients have a range of treatment options available to them, particularly minimally invasive procedures which are safe and effective. This procedure may be beneficial in treating elderly or other patients for whom a surgical procedure under general anaesthetic is contraindicated, as image-guided RF excision biopsy of breast lesions can be conducted using local anaesthetic. (1): Fine, R. E. & Staren, E. D. (2006) Percutaneous radiofrequency assisted excision of fibroadenomas. Am J Surg 192:545-7.	Thank you for your comment. Pain outcomes from the referenced study are reported in 2.4.1.
13	Consultee 3 NHS Professional	**2.4.3**	I think the most likely complication of any needle biopsy technique would be a haematoma and although I might be splitting hairs, it would perhaps be worth considering substituting ‘bleeding/haematoma’ for ‘bleeding’ in the dataset and collection tool.	Thank you for your comment. Section 2.4.3 is the opinion of the Specialist Advisers. The audit tool will be changed to separate bleeding and haematoma outcomes.

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14	Consultee 3 NHS Professsional	**General**	- Perhaps the most interesting thing about this technique is its possible potential as a therapeutic tool for completely excising breast lesions as opposed to simply sampling the lesion in the breast to establish a diagnosis which is the main limitation of current biopsy techniques which apart from mammotome (VAC) excision are always followed by surgical excision as the actual treatment. The use of radiofrequency excision would not be particularly contentious in the management of benign lesions but there have been some suggestions that radiofrequency excision or ablation could be used as a treatment for breast cancer, the main limitation being the ability to establish whether or not the cancer has been completely removed. Failure to achieve a clear margin of healthy tissue around the tumour is not surprisingly one of the main factors predicting local recurrence following breast conserving surgery. The only way of determining this following radiofrequency would be In a study where following the removal of a breast cancer by radiofrequency excision, the resulting cavity was then excised for histological examination to establish whether or not there was any residual disease. I appreciate that this is essentially moving into the realms of research and may not be appropriate for your audit tool but if any group was using radiofrequency excision to remove breast lesions especially if they proved to be cancerous, it would clearly be very important to record the findings from any subsequent surgical excision, including a note of whether or not the lesion had been completely removed by the initial radiofrequency excision.	Thank you for your comment. Section 1.3 of the guidance specifies that further research should be in the form of “diagnostic studies aimed at quantifying the risk of false-negative results associated with the procedure”. The use of RF technique as a therapeutic tool falls outside the remit for this guidance as defined in the scope, which defined the intervention to be ‘radiofrequency breast lesion excision’ The consultee may wish to notify the IP programme of this as a potential new procedure.
15	Consultee 3	**General**	- The diagnostic ‘accuracy’ of the biopsy depends mainly on the experience and expertise of the radiologist/radiographer with whichever form of image guidance they are using and as long as this allows them to insert the device into the correct part of the breast, it probably doesn’t matter which device they have used to take the biopsy. While it would be useful to collect these data, they may not reflect the usefulness or otherwise of the biopsy device. One possible consideration may be the quality of the biopsy obtained – I am not sure how much tissue damage is done by radiofrequency probes but it may be worth thinking about how to record whether or not the pathologists encountered any problems in interpreting the biopsy findings?	Thank you for your comment. The evidence presented to the Committee clearly showed that specimens obtained using this technique can be diagnosed. Operator experience as a variable and biopsy quality as an outcome would be interesting factors for any future research to consider.

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