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THE ROLE OF BREAST MRI IN ASSESSING THE PRE-THERAPY LOCOREGIONAL SPREAD OF BREAST CANCER

SUMMARY OF THE TECHNOLOGICAL EVALUATION REPORT

March 2010

Department of Assessment of Medical and Surgical Procedures

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LIST OF ABBRÉVIATIONS

A: Accuracy;

CI: Confidence interval;

D: Frequency of detection;

EIC: Extensive intraductal components;

FP: False positive;

ILC: Invasive lobular carcinoma;

IDC: Invasive ductal carcinoma;

ISDC: In-situ ductal carcinoma;

NPV: Negative predictive value;

PPV: Positive predictive value;

Se: Sensitivity;

Spe: Specificity;

TP: True positive.

GLOSSARY

Multicentricity and multifocality	In histological terms, a multifocal tumour is defined by the discovery of multiple tumoral foci, either invasive or in-situ, separated by healthy tissue. The lesion is described as multifocal if all the foci are within 5 cm of each other, and multicentric if they are further apart. In clinical terms, the term 'multifocal' is used when the lesions are within the same quadrant of the breast or centred around the primary tumour, and 'multicentric' when the lesions are in separate quadrants. This is the definition that will be used in this report.

Parameter for the diagnostic performance of a diagnostic test:

	Sick	Healthy
Positive test	a (true positives)	b (false positives)
Negative test	c (false positives)	d (true negatives)

Sensitivity (Se)

The sensitivity of a diagnostic test or examination is its ability to produce a positive result when the disease (or condition) is present, Se = a / (a+c).

Specificity (Spe)

The specificity of a diagnostic test or examination is its ability to produce a negative result when the disease (or condition) is not present, Spe = d / (b+d).

Predictive values

These express how the results of a diagnostic examination will predict the presence or absence of a disease.

Positive predictive value (PPV)

This expresses the probability that the subject does have the disease under investigation, PPV = a / (a+b).

Negative predictive value (NPV)

This expresses the degree of certainty, the guarantee in terms of probability that the subject does not have the disease under investigation, NPV = d / (c+d)

Accuracy (A)

This is calculated by dividing the correct results (true positives + true negatives) by the total number of tests performed, A = (a+d) / (a+b+c+d).

SUMMARY

I. INTRODUCTION

Magnetic resonance imaging (MRI) is a technique which can be used at any stage of breast cancer management. It can be used to screen high-risk women, to investigate a clinical abnormality (palpable lesion which may be a tumour, uniporous seeping from the nipple, inflamed breast), without mammography and/or ultrasound backup data, to confirm and/or locate a lesion of an indeterminate nature detected on standard imaging, to determine the locoregional spread of breast cancer, to guide biopsy, assess the response to treatment, explore a relapse or check the integrity of a breast prosthesis. However, the risk/benefit ratio of this procedure is not always correctly estimated depending on the clinical situation.

This report will only consider the role of breast MRI in assessing the pre-therapy locoregional spread of breast cancer. It will assess the diagnostic performance of breast MRI compared to conventional imaging (mammography and/or ultrasound) in this indication. The purpose of assessing the locoregional spread of breast cancer is to ascertain the size of the tumour, investigate multifocality and multicentricity in the homolateral breast, any disease in the contralateral breast, and any lymph node involvement (axilla, internal mammary chain). All these factors can affect therapeutic decisions and have an impact on the risk of local or remote recurrence and/or patients' life expectancy. The findings of the assessment of locoregional spread are therefore important in deciding on the best therapeutic strategy to propose (conservative surgery with or without oncoplasty, versus mastectomy, axillary exploration using either the sentinel lymph node technique or axillary curettage).

The question of the role of breast MRI in assessing the locoregional spread of breast cancer is very important from the individual's point of view, in view of the consequences for patients' health, but it also has a social impact. This is because almost 50,000 women a year may require assessment of locoregional spread of breast cancer.

Though breast MRI is a more sensitive procedure than mammography, its role in assessing the pre-therapy locoregional spread of breast cancer remains contentious. The French Radiology Society (SFR) and the French Mastology and Breast Imaging Society (SOFMIS) have asked the HAS to investigate this question.

II. BACKGROUND

II.1 Breast cancer

II.1.1 Natural course

There are various histological forms of breast cancer. The vast majority of breast cancers are adenocarcinomas (95%), which are divided into ductal and lobular forms. Eight out of ten are ductal carcinomas. If the cancer cells remain confined to the parenchyma of the original site and do not infiltrate beyond the basal layer, the carcinoma is described as in-situ. Otherwise it is described as infiltrating (or invasive). Infiltrating carcinomas can spread via the lymphatic system (lymphatic metastasis) or via the blood vessels (remote metastasis). The lymph nodes most often attacked by breast cancer cells are the axillary lymph nodes. Breast cancer

can also metastise into the bones, lungs, pleura and liver. A clinical examination of these sites must also be performed. In total, 8 to 12% of breast cancers which are treated in France at present have already metastasised at the time of diagnosis.

II.1.2 Epidemiological data

In France, breast cancer is the second most common of all cancers, accounting for 36.7% of all new cases of cancer in women. The standardised incidence is 101.5 in every 100,000 individuals, with an estimated 49,814 new cases in 2005. The incidence of breast cancer rose by 2.4% a year on average between 1980 and 2005. Mortality rose very little over the same period thanks to early diagnosis, screening, and progress in treatment. However, although the overall rate of relative survival five years after diagnosis is 85% at present, with 11,201 deaths a year and a standardised mortality rate of 17.7 per 100,000 individuals, breast cancer is still the principal cause of death from cancer in women (18.9%).

II.2 Current strategy for the diagnosis and treatment of breast cancer

II.2.1 Circumstances under which the condition is discovered

Breast cancer can be discovered by chance by the patient herself (discovery of a lump, seeping, etc.), by her GP or gynaecologist during a routine check-up, or by a radiologist during a screening test.

II.2.2 Initial diagnostic assessment of breast cancer

The initial diagnosis of breast cancer is established on the basis of a clinical assessment, imaging (mammography and/or ultrasound) and anatomopathological tests. Mammography allows any abnormality in the breasts to be detected. However, it does not ascertain definitely whether or not cancer is present. Mammography is fairly sensitive, but it is not specific and can only allow the practitioner to conclude that the patient may have or probably has breast cancer. Breast MRI, involving injection of a contrast agent, is rarely indicated in the initial diagnostic assessment of breast cancer, except in particular difficult diagnostic situations (N.B.: this report does not deal with that indication for breast MRI in the initial diagnostic assessment of breast cancer). A histological diagnosis of cancer can only be established by examination of a biopsy sample (percutaneous micro- or macro-biopsies).

II.2.3 Assessment of spread

Once breast cancer has been diagnosed, decisions on treatment depend on the results of an assessment of the locoregional spread and metastasis.
The assessment of locoregional spread can be conducted on the basis of the initial mammograms or new mammograms carried out with additional views focused on the lesion. Ultrasound is another option.

II.2.4 Treatment

Breast cancer treatment is often based on a strategy involving multiple forms of treatment: surgery, chemotherapy, targeted treatments, radiotherapy and hormone therapy. This strategy is decided on according to the initial stage of the tumour, the patient's age and general condition, the assessment of the spread of the disease and tumour histo-prognostic factors (size, grade, histological type,

mitotic or proliferation index, multifocality and/or multicentricity, whether the contralateral breast is affected, spread to the lymph nodes, metastatic spread, hormone receptors and Her2 status). The decision as to which mix of treatments to offer is taken by a multidisciplinary team involving several specialists (anatomopathologist, surgeon, medical gynaecologist, radiologist, radiotherapist, medical oncologist).

II.3 Current conditions under which this procedure is paid for by statutory health insurance

Breast MRI screening is paid for by statutory health insurance in France. It can come into one of two categories in the CCAM system, which defines medical procedures: QEQN001 (remnography [MRI] of the breast, without intravenous injection of contrast agent) and QEQJ001 (remnography [MRI] of the breast, with intravenous injection of contrast agent). It is paid for by statutory health insurance irrespective of indication.

III. ASSESSMENT METHOD

III.1 Literature search

The literature search was conducted for the period from 01/1999 to 09/2009, and a later update covered the period up till 31/10/09.

The following sources were investigated:

- for international literature: the Medline database;
- for literature in French: the Banque de Données en Santé Publique [Public Health Database];
- the Cochrane Library ;
- websites publishing recommendations and technological or economic assessment reports;
- websites of learned societies with an interest in this area.

This research was backed up by a review of the literature by experts and examination of the references mentioned in the documents analysed.

III.2 Selection of documents identified

Taking all sources together, 1,332 references were identified. 929 of these were eliminated after a first phase of selection by title and summary, 423 were preselected and 103 eventually accepted.

Three hundred and twenty articles were ruled out:

- 84 did not match the scope of this report (search for primary breast cancer, screening of women at very high risk of breast cancer, remnographic guidance for biopsy, assessment of response to neo-adjuvant treatments, search for local recurrence after conservative treatment, checking the integrity of a breast implant);
- 28 were commentaries or editorials;
- 41 were written to explain the issues involved in breast cancer management;
- 68 were reviews of the literature which we excluded for various reasons: some referred to papers published before 1999, some dealt with breast MRI indications in general, and some dealt with MRI performance in

assessing the locoregional spread of breast cancer. In the latter case, we considered the reports analysed by these reviews in our report;
- 1 was a meta-analysis which did not fall within our remit (45% of the studies were conducted prior to 1999);
- 4 were already included in meta-analyses and did not provide any additional information;
- 72 were recommendations not specific to breast MRI;
- 22 studies used MRI equipment operating at below 1.5 tesla. Most teams currently work with magnetic fields of 1.5 tesla.

III.3 Working group

A working group was set up with representatives of the following disciplines: radiology, medical oncology, medical gynaecology, plastic surgery, gynaecological surgery, radiotherapy and anatomopathology.
The working group met and discussed the analysis of the literature and indications for breast MRI in assessing the spread of breast cancer.

IV. RESULTS OF THE ASSESSMENT

IV.1 Diagnostic performance of breast MRI in assessing morphological parameters of breast cancer

All the studies analysed in this chapter were carried out on populations of women diagnosed with breast cancer, or who were thought highly likely to have breast cancer following a clinical assessment and mammogram, and who underwent a breast MRI to assess the locoregional spread of their cancer. The benchmark for all these studies was histological assessment.

The results are expressed in terms of sensitivity (Se), specificity (Spe), accuracy (A), positive predictive value (PPV), negative predictive value (NPV), tests (MRI compared to mammography and/or ultrasound) or correlation coefficients (to assess tumour size).
The performance of MRI scans and other tests, both in assessing the presence of lesions and the morphological parameters of the tumour, depend on a certain number of factors, the most important of which are the histological tumour type, its grade, and breast density. These factors were taken into account when analysing the results.

IV.1.1 Assessment of the presence of lesions

IV.1.1.1 General data

Fifteen diagnostic studies conducted on a total of 3,248 patients were analysed. In the studies analysed, the Se, Spe, PPV, NPV and accuracy (A) values achieved by breast MRI were greater than those obtained by mammography and ultrasound in assessing the presence of cancerous lesions in women diagnosed with breast cancer.

IV.1.1.2 Influence of histological type

Twenty-five studies examined the diagnostic performance of breast MRI according to histological cancer type.

Fourteen of these, carried out on a total of 2,833 patients, examined the performance of MRI for in-situ breast cancer (the most common form of ductal cancer).
The six studies which assessed the performance of MRI and of mammography found that the Se, PPV, NPV and A values achieved by breast MRI were higher than those achieved by mammography and ultrasound, but no firm conclusions could be drawn in respect of Spe (only one study).
Eighteen studies carried out on a total of 3,810 patients (some women took part in more than one study) and a meta-analysis of eight studies examined the performance of MRI in cases of invasive cancer. In the eight studies which assessed the performance of MRI and mammography, the Se values achieved by MRI were higher than those achieved by mammography and ultrasound, irrespective of histological type. The Spe values were identical or inferior (five studies).

IV.1.1.3 Influence of tumour size

Only two studies, carried out on 255 patients in total, investigated the diagnostic performance of MRI according to tumour size.
Analysis of these two studies shows that it is difficult to draw any conclusions as to the influence of tumour size on the sensitivity of breast MRI. However, MRI sensitivity does not seem to be affected by tumour size, in contrast to mammography sensitivity, which according to one study increases with tumour size. The same study found that MRI Se remains greater than mammography Se irrespective of tumour size.

IV.1.1.4 Influence of tumour grade in in-situ ductal carcinomas (ISDC)

Three studies carried out on a total of 439 patients investigated the Se of breast MRI according to the tumour grade of in-situ ductal carcinomas.
The Se of breast MRI is greater for high tumour grades than for low tumour grades. It is still higher than that of mammograms irrespective of tumour grade (according to one study).

IV.1.1.5 Influence of breast density

Three studies carried out on a total of 300 patients analysed MRI performance in dense breast tissue.
Two studies found that the Se values of breast MRI are higher than those of mammograms and ultrasound in dense breast tissue for any type of cancer.

IV.1.2 Assessment of tumour size

IV.1.2.1 General data

Ten studies carried out on a total of 1,297 patients examined the performance of MRI in assessing tumour size.
Two of the studies analysed found that the estimated tumour size shown by MRI was more accurate than the estimated tumour size shown by mammography when the findings were compared to actual tumour size as shown by the histological sample.
One study found that MRI overestimated tumour size more than mammography.

IV.1.2.2 Influence of histological type

Twelve studies carried out on a total of 939 patients assessed MRI performance in assessing tumour size for different sub-groups of carcinomas. In the studies analysed, the estimated tumour size shown by MRI was more accurate than the estimated tumour size shown by mammography when the findings were compared to actual tumour size as shown by the histological sample. This was true both of in-situ cancers and invasive cancers. Under-estimation of tumour size was less common.

IV.1.2.3 Influence of tumour size

Only one study, carried out on 77 patients, analysed the performance of MRI in estimating tumour size according to the size of the tumour. The study analysed found that MRI underestimated tumour size more frequently when it was used to examine small tumours, and overestimated tumour size more frequently when it was used to assess large tumours.

IV.1.2.4 Influence of tumour grade

Two studies conducted on 138 patients reported correlations between tumour size (ISDCs) as estimated by MRI and tumour size as calculated on the basis of the histological sample for various grades of tumours. Only one study investigated the relative performance of mammography and breast MRI.

For all tumour grades, the estimated tumour size shown by MRI was more accurate than the estimated tumour size shown by mammography when the findings were compared to actual tumour size as shown by the histological sample. Tumour size (ISDCs) was less often overestimated or underestimated.

It is also not possible to state whether correlation is better with higher-grade tumours or with lower-grade tumours. The two studies are contradictory. However, one of the studies found that the size of low-grade ISDC tumours was overestimated and underestimated more often than was the case for high-grade ISDC tumours.

IV.1.2.5 Influence of breast density

Two studies carried out on 139 patients analysed the ability of MRI to estimate tumour size in dense breast tissue (BI-RADS category 4).
In dense breast tissue, the estimated tumour size shown by MRI was more accurate than the estimated tumour size shown by mammography when the findings were compared to actual tumour size as shown by the histological sample.
Tumour size underestimation was less common; no conclusions can be drawn as to the frequency of overestimation.

IV.1.3 Assessment of multifocality and multicentricity

This section deals with the general performance of MRI in detecting multifocality and multicentricity (clinical definition), rather than the ability of MRI to detect additional lesions which may be multicentric or multifocal.

IV.1.3.1 General data

Five studies carried out on a total of 1,242 patients have addressed this issue. The two studies analysed appear to show that MRI is more effective than

conventional imaging techniques in detecting multifocality and multicentricity. MRI seems to be better at detecting multifocal lesions than multicentric lesions.

IV.1.3.2 Influence of histological type

Four studies carried out on a total of 542 patients investigated the performance of MRI in assessing multifocality and multicentricity in various sub-types of cancer. Too few studies on multifocality or multicentricity according to cancer sub-group have been carried out to allow any conclusions to be drawn as to the relative performance of MRI in ISDCs and invasive cancers.

IV.1.3.3 Influence of breast density

Two studies carried out on 51 patients assessed MRI performance in diagnosing multifocality and multicentricity in dense breast tissue.
The Se, PPV and NPV of MRI appear to be better than those of mammography in assessing multifocality in dense breast tissue, while the Spe appears to be equivalent (one study).

IV.1.4 Assessment of the presence of additional lesions

This part assesses the ability of MRI to detect additional lesions which are not picked up by mammography or clinical examination.

IV.1.4.1 General data

A total of four studies carried out on 1,106 patients, and a meta-analysis of 19 studies conducted on 2,610 patients, assessed the ability of MRI to detect new lesions.

MRI detects additional lesions not found by mammography (or ultrasound) in approximately one in five patients.

The three studies which investigated MRI found it to be 100% sensitive.
A recent meta-analysis indicates a PPV of 66% and a true positive/false positive ratio of 1.91, i.e. 30% of the results produced by the procedure are false positives.

IV.1.4.2 Influence of histological type

Two studies carried out on a total of 418 patients, and a meta-analysis of five studies conducted on 146 patients with ILC, assessed the ability of MRI to detect new lesions in various sub-groups of cancers. It is difficult to draw any conclusions from the studies analysed as to the influence of histological tumour type on the performance of MRI in terms of detection of additional lesions which are not identified by mammography (two contradictory studies).
A meta-analysis indicates a frequency of detection in cases of ILC of 32%.

IV.1.5 Assessment of bilaterality

IV.1.5.1 General data

Eight studies conducted on a total of 2,742 patients and a meta-analysis of 18 studies carried out on 3,147 patients assessed the performance of MRI in diagnosing lesions in the contralateral breast. The studies analysed indicate that

MRI appears to have good Se and Spe in assessment of bilaterality, but two studies and the meta-analysis report a PPV of below 50%. MRI has higher Se than mammography (two studies).

A meta-analysis reports a frequency of detection of additional lesions in the contralateral breast of 9.3%; the positive predictive value of 48% brings the rate of detection of "true" new cancers down to 4%.

IV.1.5.2 Influence of histological type

Four studies carried out on 1,100 patients assessed the performance of MRI in diagnosing contralateral lesions according to the cancer sub-group of the index lesion. It seems difficult to draw any conclusions as to the performance of MRI in assessing bilaterality for various cancer sub-types.
Invasive cancers seem to be detected more frequently than in-situ cancers.

IV.1.6 Assessment of axillary lymph nodes

Four studies carried out on 176 patients assessed the performance of MRI in diagnosing lymph node metastasis. The small number of studies and the wide variability in MRI performance in these studies mean that it seems difficult to draw any conclusions as to the performance of MRI in assessing lymph nodes.

IV.2 The prognostic impact of breast MRI used to assess the spread of breast cancer

Two studies have analysed the prognostic impact of breast MRI in assessing the spread of breast cancer. One investigated local recurrence (346 patients) while the other looked into patient survival (756 patients). Local recurrence was more frequent in patients who had not undergone MRI, while survival rates were the same irrespective of whether or not patients had undergone MRI. The methodological quality of these studies was questionable.

IV.3 The therapeutic impact of breast MRI used to assess the spread of breast cancer

IV.3.1 General data

Ten diagnostic studies carried out on 1,271 patients and one meta-analysis of 13 articles have investigated how often MRI leads to planned surgery being changed.
The information provided by the MRI led to a change in patient management in 9 to 40% of cases, resulting in a change from the initially proposed surgery.

IV.3.2 Influence of histological type

Eight studies carried out on 1,160 patients and a meta-analysis of six studies have investigated changes to surgical treatment as a result of MRI in various sub-types of cancer.
The studies analysed appear to show higher frequencies for invasive cancers, but several comparative studies found no difference in how often surgical treatment was changed following MRI according to cancer sub-type.
Frequency of changes in treatment does exist, but is not affected by cancer type.

IV.4 Consequences for patient treatment of breast MRI used to assess the spread of breast cancer

This chapter investigates whether or not changes to surgical treatment as a result of breast MRI used to assess the locoregional spread of breast cancer are justified.

IV.4.1 General data

Eleven diagnostic studies carried out on a total of 1,222 patients assessed MRI in terms of the consequences for patient treatment. The studies analysed show that the rates of justified change in surgical treatment vary from 6 to 30% of cases, and rates of unjustified change in surgical treatment vary from 0 to 22%.

IV.4.2 Influence of histological type

Six studies carried out on 798 patients have assessed the consequences for patient treatment of MRI for various cancer sub-types. Histological tumour type does not appear to affect whether or not changes in surgical treatment as a result of MRI are justified.

V. CONCLUSION FROM THE ANALYSIS OF THE LITERATURE

The Se and NPV of breast MRI used to assess the locoregional spread of breast cancer are often better than those of mammography (negative result strongly correlated with absence of cancer):

- in terms of the ability of the procedure to assess the presence of lesions and estimate tumour size. Tumour size assessed by MRI is often better correlated with the size of the histological sample than tumour size assessed by mammography. It is difficult to draw any conclusions as to the effect of histological tumour type and tumour grade because of the small number of studies available;
- in terms of detection of multifocality and/or multicentricity. However, caution is essential when comparing the performance of breast MRI to that of mammography, as very few comparative studies have been carried out;
- in terms of additional lesions detected. MRI detects lesions which did not show up in mammography in one in five patients;
- and in terms of assessment of bilaterality.

However, MRI has low PPV in the following cases:

- in the detection of additional lesions (positive predictive value equal to 66% in a meta-analysis of 19 articles);
- in the assessment of bilaterality (the positive predictive value reported in two studies and a meta-analysis of 18 articles is below 50%).

The ability of breast MRI to detect additional lesions and to identify lesions in the controlateral breast leads to changes in the surgical management of patients in 9 to 42% of cases depending on the study.

However, these changes are not always justified because of the low PPV of MRI in detecting additional lesions which are not picked up by mammography and in assessing bilaterality. These changes are justified in 6 to 30% of cases and not justified in 0 to 22% of cases.

Finally, no conclusions can yet be drawn as to the long-term effects of breast MRI in assessing the locoregional spread of breast cancer, local recurrence, or patient survival. There are only two studies, which reach contrary conclusions, and one of these studies has been criticised for inclusion bias.

VI. ADDENDUM

The initial findings of the multi-centre randomised prospective COMICE study, conducted by the UK National Health Service (1), were published after the analysis of the literature, the experts' discussions and the cut-off point for a bibliographical search update.

This study is the only multi-centre, randomised controlled study available to date. These methodological characteristics justify its inclusion in this addendum.

The main aim of this study was to ascertain whether performing a breast MRI in addition to clinical, radiological and histological assessment of breast cancer resulted in more accurate tumour location and in a reduction in reintervention rates in women scheduled to undergo tumour removal.

The main conclusion of the report is as follows:

Although conducting a breast MRI on women diagnosed with breast cancer (confirmed by histology) and who have been offered conservative surgery does allow the tumour to be more accurately located, it does not as a consequence reduce reintervention rates.

However, it should be added that these initial findings do not at this stage provide any new information regarding the impact of performing breast MRI on long-term survival for patients with histologically proven breast cancer. The only survival results presented are for one-year survival, which does not appear significant given the natural course of the disease.

The results of this study are taken into account in the conclusion of the report.

VII. POSITION OF THE WORKING GROUP

The working group points out that the use of breast MRI to assess locoregional spread is decided on after taking account of various factors and in the context of overall management; the MRI findings add to information already available from clinical examination, mammography and ultrasound. The use of breast MRI in assessing the spread of breast cancer should be reserved for clearly defined clinical situations.

The diagnostic performance of breast MRI is better than that of mammography in terms of sensitivity and negative predictive value in assessing locoregional spread of breast cancer.
The use of MRI in pre-therapy diagnosis leads to an increase in the number of total mastectomies.

The working group also stresses the lack of reliable data which could help assess the benefit in terms of recurrence and survival following the use of breast MRI to assess the pre-therapy locoregional spread of breast cancer. Randomised prospective studies would be very helpful. The findings of a

controlled randomised study (COMICE study), currently being carried out in the UK, could clarify the situation.

Consequently, as regards the homolateral breast:

The option of total mastectomy rather than treatment with conservative surgery and irradiation of the entire breast must not be considered unless there is histological evidence of multifocality or multicentricity.

A breast MRI may be indicated to assess the locoregional spread of breast cancer in the following cases in particular:

- Where a lack of agreement between clinical features, mammography and ultrasound could lead to a change in therapeutic management;
- Where difficult treatment choices have to be made (oncoplastic surgery, neoadjuvant treatments);
- In women under 40 years of age;
- In women with a high familial risk of breast cancer.

The studies available show that MRI has a positive predictive value of 25 to 40% in the assessment of bilaterality and so is capable of detecting 3 to 4% of cancers in the controlateral breast which are not detected by conventional imaging; this represents a third of in-situ tumours. However, the cumulative risk of expected controlateral cancer is only approximately 0.5% a year. This low risk is partly due to systemic treatment of the homolateral cancer. This data is not sufficient to either confirm or undermine the usefulness of performing a breast MRI to examine the controlateral breast.

VIII. CONCLUSION OF THE EVALUATION

The bibliographical data analysed in this report shows that breast MRI outperforms mammography in terms of sensitivity and negative predictive value in the context of assessment of the pre-therapy locoregional spread.

Breast MRI can therefore offer additional information to that gained by clinical examination, mammography and ultrasound, and this additional information can influence therapeutic decisions.

It seems to be widely accepted that the use of breast MRI in the assessment of locoregional spread leads to a not inconsiderable change in the therapeutic management of patients (increase in the number of mastectomies). However, it does not as a result reduce reintervention rates, and the data currently available is insufficient to allow any conclusions to be drawn as to its impact in terms of recurrence and patient survival.

The sensitivity of breast MRI in detecting additional lesions, which is greater than that of mammography, is qualified by the existence of false positives in proportions that vary according to the populations studied. These false positives mean that caution is needed when considering any change in therapeutic management on the basis of breast MRI results.

Consequently, the critical analysis of the literature and the position of the working group lead us to conclude that the considered and non-systematic use of breast MRI in assessing locoregional spread of breast cancer should be reserved for clearly identified clinical situations, in particular:

In the homolateral breast:

- Where a lack of agreement between clinical features, mammography and ultrasound could lead to a change in therapeutic management;
- Where difficult treatment choices have to be made (oncoplastic surgery, conservative treatment or mastectomy, neoadjuvant treatment);
- In women under 40 years of age;
- In women with a high familial risk of breast cancer.

No data is available about the controlateral breast which would allow us to confirm or deny the value of performing breast MRI to examine the controlateral breast.

Furthermore, it should be pointed out that diffusion and perfusion MRI techniques, and the long-term findings of the randomised controlled study carried out by the UK National Health Service into the impact of MRI on recurrence and survival, could alter the conclusions of this report.