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Title Usefulness of contrast-enhanced mammography in breast cancer diagnosis strategy

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Aim

HAS has assessed contrast-enhanced mammography (CEM) in the breast cancer diagnosis strategy to issue an opinion on listing the procedure in the joint classification of medical procedures. The aim of the assessment was to i) compare the diagnostic performances of contrast-enhanced mammography to breast MRI in certain indications, ii) to evaluate safety in relation to exposure to ionising radiation and to reactions secondary to iodinated contrast agent injection, iii) to evaluate the impact of CEM on the therapeutic strategy and iv) to assess organisational impacts of CEM.

Conclusions and results

The data available could only be used to assess three indications out of the five selected during the scoping phase, which are: 1/ situations of problem solving after inconclusive conventional imaging results , 2/ locoregional staging for the detection of additional lesions and/or for assessing tumour size, 3/ assessment of the response to neoadjuvant chemotherapy (NAC)

Concerning the diagnostic performance of CEM compared to breast MRI,

Analysis of the data from the literature showed, for tumour size assessment, concordance between the measurements taken on CEM images with those taken on breast MRI images and on a surgical specimen, in locoregional staging, before NAC or during assessment of the response to NAC.

Conversely, analysis of the data from the literature could not be used to determine

- whether CEM exhibited similar diagnostic performance to breast MRI in the detection of additional lesions as part of locoregional staging, as the results of the trials could not be correlated ;
- the diagnostic performance of CEM in situations of problem solving after inconclusive conventional imagining procedures as no data was found in the literature further to the systematic document search.

The experts consider that CEM can be used in the following indications:

- problem solving, to confirm the presence of a suspect lesion or to rule out the presence of a lesion, with necessary follow-up, however;
- when contrast imaging is required:
  - locoregional staging (tumour size and detection of additional lesions);
  - assessment of the response to neoadjuvant chemotherapy;
- tumour assessment before neoadjuvant chemotherapy, however the experts nevertheless specified that breast MRI is currently the gold standard examination in this indication.

Concerning the safety aspects, analysis of the data from the literature, the expert opinion and the position of the IRSN made it possible to conclude that the dose level is acceptable in the relevant indications, especially taking account of the patient's age and/or radiosensitivity and that the risk of serious adverse reactions to iodinated contrast agents is very rare; precautions being necessary before, during and after administration (medical questionnaire etc.).

The IRSN and the experts also stated that, depending on the manufacturer, devices may present variability in terms of the dose delivered and diagnostic performance.

Concerning the organisational aspects, the assessment showed that contrast-enhanced mammography had certain advantages in terms of organisation compared to breast MRI, especially shorter waiting time for CEM, shorter examination time, and better acceptability by patients (more comfortable, examination producing less anxiety compared to MRI etc.). For the professionals, the examination appears to be easier to read and interpret and there is a perfect match between the anomalies detected on the mammography images and those of contrast-enhanced mammography, which makes it easier for surgeons to read images from the same incidence.

Recommendations

With regard to all of the above, contrast-enhanced mammography could be useful in patients:

- **with contraindications to MRI, in**
  - situations of problem solving;
  - locoregional staging;
  - tumour assessment before and after neoadjuvant chemotherapy;
- **with no contraindications to MRI**, in locoregional staging or before/after neoadjuvant chemotherapy, to assess tumour size, especially for the perfect match with mammography images.

Methods

The assessment method consisted of:

- a critical analysis of the literature identified after a systemic document search;
- consultation of experts from areas concerned by the subject; these experts were brought together in a working group (by video conference) in order to collect their substantiated opinion on the data from the literature and their practices;
- collection of the Institut de Radioprotection et de Sureté Nucléaire (IRSN)'s stance on aspects relating to exposure to ionising radiation;
- consultation of professional bodies and patients' associations concerned by the subject, questioned as stakeholders in order to collect their collective points of view on a draft version of the report containing the data analysis, the experts' opinion and conclusions that could be drawn from them;
- the compilation of all of these elements in a technological assessment report.

Conclusions have been reviewed by the Commission recommendations, relevance, paths and indicators (CRPPI), the one of HAS specialized appraisal committees, and finally approved by the HAS College.

Further research/reviews required

HAS also considers that it is fitting to set up a quality control protocol for contrast-enhanced mammography to help optimise doses and to ensure installation performance is maintained.
In prospect, HAS recommends collecting supplementary data.
In effect, even if the currently available diagnostic performance data suggest similar efficacy to that of breast MRI in the previously selected indications, the fact remains that the demonstrated diagnostic efficacy of CEM has yet to be confirmed by more robust performance tests, likely to be included in a meta-analysis.
It should also be noted that the impact of contrast-enhanced mammography on therapeutic management (number of biopsies, relevance of the decision to operate, repeat surgery rate etc.) for all indications could not be assessed, especially due to the lack of hindsight as to the technique and the variability of practices among centres.
HAS therefore recommends conducting clinical research studies to confirm the diagnostic performance data, to demonstrate the clinical relevance of CEM and to specify the role of contrast-enhanced mammography in the diagnostic strategy. HAS also recommends setting up a national register for collecting data on the decision to use CEM in the therapeutic strategy in France.

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