# Considerations on the application of EUSOMA criteria for preoperative MRI

I read with interest the report by Bernardi et al., EUSOMA criteria for performing pre-operative MRI staging in candidates for breast conserving surgery: Hype or helpful?,[1] recently published in *The Breast*.

EUSOMA recommendations[2] represented the consensus reached in 2009 by a panel of 23 experts on indications for breast MRI. Differently from settings such as high-risk screening, carcinoma unknown primary syndrome, neoadjuvant chemotherapy, and breast implants evaluation, preoperative MRI (preop-MRI) is a controversial issue, although conclusive patient outcome evidence is currently not available also for the other aforementioned indications. In fact, preop-MRI, due to its higher sensitivity than that of conventional imaging (mammography/ultrasonography [US]), implies a risk of overdiagnosis/overtreatment of cancers which could be cured by radiation and/or systemic therapy. This possibility, if not counteracted by favorable impact on patient outcome, works against breast conserving surgery (BCS). Thus, the controversy is justified.

The EUSOMA panel reached an agreement[2] on ten recommendations for preop-MRI. Only the first four, "considering special available information for particular subgroups", regarded "acceptable indications to preop-MRI with potential advantages", i.e. patients newly diagnosed with a breast cancer (BC) in case of: 1. Invasive lobular cancer (ILC) histopathology; 2. High-risk status; 3. Age $<60$ with mammography/US discrepancy in size $>1$ cm; 4. Selection to partial breast irradiation. The remaining recommendations were: 5. Women newly diagnosed with a BC should always be informed of the potential risks and benefits of preop-MRI if this is under consideration; 6. Results of preop-MRI should be interpreted taking into account clinical breast examination as well as mammography and US; 7. MRI findings with impact on treatment should be verified by percutaneous biopsy whenever possible; 8. Lesions visible on MRI alone require MR-guidance for needle biopsy with pathological assessment and/or presurgical localization; 9. Treatment delay due to preop-MRI and workup should not be $>1$ month; 10. Changes in therapy resulting from preop-MRI should be decided by a multidisciplinary team. Placing the preop-MRI controversy in the real world, points 4–10 should be considered at least relevant as points 1–3.

Bernardi et al.[1] applied points 1–3 on 200 candidates to BCS, using the number of mastectomies retrospectively recommended due to MRI as an end-point for measuring preop-MRI advantage. This recommendation was based on tumor-to-breast volume assessed by breast radiologists, not on a team decision, as per point 10 of the EUSOMA recommendations. They obtained a mastectomy rate of: 7/39 (18%) for ILC cases versus 28/161 (17%) for other pathologic subtypes ($p = 0.87$); 5/34 (15%) for high-risk versus 30/166 (18%) for non-high-risk patients ($p = 0.82$); 9/28 (32%) for mammography/US discrepancy $>1$ cm versus 26/172 (15%) for cases without that discrepancy ($p = 0.05$); 19/88 (27%) for cases with $\geq 1$ criterion versus 16/112 (14%) for cases without any criterion ($p = 0.24$). They conclude that "these findings suggest that EUSOMA criteria for selection for preop-MRI may be inefficient as they do not appear to differentiate those at risk of having more extensive disease and likely to receive a mastectomy recommendation, with the exception of mammography/US tumor size discrepancy".[1]

These 200 subjects were a consecutive series of newly diagnosed BC patients selected for preop-MRI, not of newly diagnosed BC patients having routine MRI. This was acknowledged by the authors. However, this difference between two types of consecutiveness has consequences on measured test outcomes.[3] In other words, the authors did not compare patients with one criterion with all the remaining patients without that criterion but with those without that criterion in a population selected to preop-MRI. This 'selection' is suggested by the high proportion of patients at high-risk (17%), with ILC (20%), or with $\geq 1$ of the criteria (44%).[1]

Interestingly, in this relatively small series mammography/US discrepancy $>1$ cm is confirmed as a criterion for recommending preop-MRI, without any age restriction based on previous evidence.[4] Moreover, if we compare patients with $\geq 1$ criterion with those without any criterion, mastectomy likelihood appears higher for the former (22%) than for the latter group (14%). Notably, 8% of additional mastectomies due to preop-MRI is a clinically relevant difference, also reported in two meta-analyses.[5,6] The sample size of the study[1] was probably too small to get a statistical significance.

Preop-MRI in high-risk women is a particular issue. Given the increasing acceptance of MRI for high-risk screening, the majority of these cancers will be MRI detected (and staged) at once (interval cancers 5–10%),[7] partially overcoming the discussion on this preop-MRI indication.

Preop-MRI for ILC is a relevant issue. The rationale for mastectomy rate as an end-point for validating preop-MRI criteria stems from a preconception: "apart from patient outcome, additional mastectomies are the only relevant effect of preop-MRI". This is not true: 1. Preop-MRI determines a wider local excision in about 3–5% of patients[5,6] (partly acknowledged by the authors); 2. Preop-MRI may even reduce mastectomy rate. Mann et al.,[8] although using a retrospective design, reported a reduction in reoperation rate in patients with ILC who underwent MRI (9%) versus those who did not (27%) and a decreased mastectomy rate (48% versus 59%, respectively), showing that preop-MRI can downsize the surgical treatment. Thus, mastectomy indication is not a good way for validating preop-MRI indication for ILC.

Preop-MRI is a complex issue.[9,10] In this context, Bernardi et al.[1] brought new information, confirming mammography/US size discrepancy $>1$ cm as preop-MRI indication, without any age restriction. These new data provide evidence to support consensus-recommended criteria. High-quality research is needed to further clarify role and effect of preop-MRI.

## Ethical approval

Not required.

## Funding sources

None to be declared.

## Conflict of interest statement

None to be declared.

## References

1. Bernardi D, Ciatto S, Pellegrini M, Valentini M, Houssami N. EUSOMA criteria for performing pre-operative MRI staging in candidates for breast conserving surgery: Hype or helpful? *Breast* 2012;**21**:406–8.
2. Sardanelli F, Boetes C, Borisch B, et al. Magnetic resonance imaging of the breast: recommendations from the EUSOMA working group. *Eur J Cancer* 2010;**46**:1296–316.

3. Houssami N, Ciatto S. Design-related bias in estimates of accuracy when comparing imaging tests: examples from breast imaging research. *Eur Radiol* 2010;**20**:2061–6.
4. Deurloo EE, Klein Zeggelink WF, Teertstra HJ, et al. Contrast-enhanced MRI in breast cancer patients eligible for breast-conserving therapy: complementary value for subgroups of patients. *Eur Radiol* 2006;**16**:692–701.
5. Houssami N, Ciatto S, Macaskill P, et al. Accuracy and surgical impact of magnetic resonance imaging in breast cancer staging: systematic review and meta-analysis in detection of multifocal and multicentric cancer. *J Clin Oncol* 2008;**26**:3248–58.
6. Plana MN, Carreira C, Muriel A, et al. Magnetic resonance imaging in the preoperative assessment of patients with primary breast cancer: systematic review of diagnostic accuracy and meta-analysis. *Eur Radiol* 2012;**22**:26–38.
7. Sardanelli F, Podo F, Santoro F, et al. Multicenter surveillance of women at high genetic breast cancer risk using mammography, ultrasonography, and contrast-enhanced magnetic resonance imaging (the HIBCRIT-1 study): final results. *Invest Radiol* 2011;**46**:94–105.
8. Mann RM, Loo CE, Wobbes T, et al. The impact of preoperative breast MRI on the re-excision rate in invasive lobular carcinoma of the breast. *Breast Cancer Res Treat* 2010;**119**:415–22.
9. Sardanelli F. Overview of the role of pre-operative breast MRI in the absence of evidence on patient outcomes. *Breast* 2010;**19**:3–6.
10. Sardanelli F. Additional findings at preoperative MRI: a simple golden rule for a complex problem? *Breast Cancer Res Treat* 2010;**124**:717–21.

Francesco Sardanelli*
*Department of Biomedical Sciences for Health, University of Milan School of Medicine, Radiology Unit, IRCCS Policlinico San Donato, Piazza E. Malan 2, 20097 San Donato Milanese, Milan, Italy*

* Tel.: +39 0252774468.
*E-mail addresses:* f.sardanelli@grupposandonato.it, francesco.sardanelli@unimi.it

http://dx.doi.org/10.1016/j.breast.2013.02.016