

Health

February 20, 2009

Dear Colleague:

Attached is the recently approved *Clinical Access Guidelines for Breast MRI in Nova Scotia*. At this time, breast MRI is only recommended in specific clinical indications (outlined in the guideline). In addition to this hard copy, the guidelines will be posted to the Nova Scotia Breast Screening Program website at www.breastscreening.ns.ca.

Breast MRI is relatively new technology with limited objective research. Much of the literature has compared the benefits of breast MRI to that of analogue mammography and not digital. As a result, a small committee, led by the Department of Health and chaired by Brenda Payne, former Executive Director, Acute and Tertiary Care Branch, was formed to review the literature, conduct a cross jurisdiction review, develop guidelines and estimate the demand for this specific breast imaging tool.

The guidelines were collaboratively developed by representatives of the Nova Scotia Breast Screening Program (NSBSP) and Department of Health (DoH), and subsequently reviewed by the Cancer Care Nova Scotia Breast Cancer Site Team and the team at Maritime Medical Genetics Service at the IWK. Following the consultation, the guidelines were approved by the Department of Health committee in May 2008.

Target Wait Times have also been developed for Breast MRI and these are:

- Level I (Urgent) 1 week to booking
- Level II (Elective for cancer) 2 weeks
- Level III (elective) associated with breast cancer screens and booked every 1-2 years

Any questions related to these guidelines should be directed to the Nova Scotia Breast Screening Program at (902) 473-3960.

Yours sincerely,

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Approval Date: December 1, 2008



Clinical Access Guidelines for Breast MRI in Nova Scotia

PREAMBLE

The purpose of this guideline is to help radiologists, oncologists, surgeons and General Practitioners understand the role of MRI in breast cancer and to utilize the resource effectively in the appropriate clinical settings by outlining the indications for use in Nova Scotia.

This guideline applies to women in Nova Scotia where breast MRI will:

- enhance treatment planning, problem solving or diagnostic evaluation of the breasts
- or
- serve as an additional screening modality for those women who are at high lifetime risk for breast cancer development (i.e > 25% lifetime risk of breast cancer).

At the current time, breast MRI is not recommended as a screening tool in the general population of asymptomatic women.

MRI is an adjunctive test that should complement mammography and other radiologic modalities (i.e ultrasonography) and is only recommended for specific clinical situations outlined below.

Breast MRI is a referral-based service, and patients cannot self-refer.

Patients should undergo standard mammography and/or other breast imaging prior to breast MRI; these studies and reports should be available to the radiologist reporting the MRI study.

The request for MRI of the breast should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

The ability to perform image-directed biopsy of lesions seen on MRI is an essential adjunct to breast MRI.

Documentation that satisfies medical necessity includes:

- 1) signs and symptoms and/or
- 2) relevant history (including known diagnoses)
- 3) additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

Possible contraindications to breast MRI may include, but are not limited to, patient size, the presence of cardiac pacemakers, ferromagnetic intracranial aneurysm clips, certain neurostimulators, certain cochlear implants, and certain other ferromagnetic implants, devices, foreign bodies, or electronic devices.

The decision to scan during pregnancy should be made on an individual basis. There is no known adverse effect of MRI on the fetus. The safety of gadolinium contrast has not been established for pregnant or nursing mothers. However, it is known that gadolinium-based MR contrast media crosses the human placenta and into the fetus when given in clinical dose ranges. Current data indicates that very little gadolinium is secreted in breast milk, with no known toxic effects on the infant.

CURRENT INDICATIONS

1. High risk screening

Where a greater than 25 % lifetime risk of breast cancer, based on utilization of standard risk models (e.g. Gail model) exists; this would include patients with known or suspected breast cancer susceptibility gene mutations, such as BRCA 1 or 2 mutations. This screening should ideally be done in the context of a formal genetic counseling service.

2. Treatment planning of histologically proven breast cancer (invasive or DCIS)

Where, in the opinion of the referring surgeon, oncologist and/or radiologist, there is (1) a significant risk of locally extensive, multi-focal, multi-centric and/or contralateral disease (particularly for invasive lobular cancer or extensive DCIS) and (2) the results of MRI would potentially alter management decisions

3. Evaluation of residual disease post-lumpectomy

Where, in a patient who has not had a pre-operative MRI and has “close” or “positive” margins post-lumpectomy and, in the opinion of the referring surgeon, oncologist and/or radiologist, there is benefit to assess the extent of local disease and detect unsuspected multi-focal or multi-centric disease.

4. Assessment axillary metastases in patients with an unknown primary

Where, in the absence of clinical, mammographic or ultrasound evidence of a primary breast cancer, there is benefit to detect or exclude an occult breast primary.

5. Assessment of disease extent and/or response in the setting of neoadjuvant (pre-operative) systemic therapy

Where, in the opinion of the referring surgeon, oncologist and/or radiologist, the results of either a pre-treatment (baseline) MRI and/or MRI evaluation of disease response would be useful in guiding management.

6. Assessment of Questioned Recurrent Breast Cancer (Versus scar)

Where MRI might be of value (following complete clinical and mammographic evaluation) in breast cancer patients post-breast conserving Rx and/or breast reconstruction. Breast MRI is NOT recommended for post-mastectomy screening or surveillance.

7. Problem Solving

Where MRI might be useful to further assess the rare instance of suspicious, but still indeterminate breast findings following complete clinical and mammographic/ultrasonic assessment.

8. Silicone Breast Implant Augmentation

Where MRI may be useful for evaluation of implant integrity.

ORDERING BREAST MRI

Breast MRI is to be approved by a Breast Imaging Radiologist who in turn is responsible for reporting the MRI and/or reviewing the MRI with the attending clinician, in conjunction with all other breast imaging modalities. All breast MRI studies will be booked and reported through the NSBSP database.

TIMELINES

LEVEL 1 (Urgent) 1 week to booking

LEVEL II (Elective for Cancer) 2 weeks to booking

LEVEL III (Elective) associated with breast cancer screens and booked every 1-2 years

REFERENCES

Breast MRI – diagnosis and intervention

Edited by Morris and Liberman

Springer 2005

Setting Up a Breast Magnetic Resonance Imaging Program

Elizabeth A. Morris MD

Chapter 3 pp 15-22

Breast MRI – diagnosis and intervention

Edited by Morris and Liberman

Springer 2005

Magnetic Resonance Imaging as a Clinical Tool

David Dershaw MD

Chapter 16 pp 256 – 265

ACR - Practice Guideline for the Performance of Magnetic Resonance Imaging (MRI) of the Breast.

Amended 2006 (Res. 35) Effective 10/01/04

Breast Cancer Risk Calculator on the National Cancer Institute's website at

<http://www.cancer.gov.brisktool/>.

GUIDELINE DEVELOPMENT

This guideline was developed by

- Representatives of the Nova Scotia Breast Screening Program (NSBSP)
- Radiologists
 - Dr. Judy Caines, Capital Health
 - Dr. Gerry Schaller, Capital Health
 - Dr. Sian Iles, Cape Breton District Health Authority
 - Dr. Eric Woods, South West Nova District Health Authority
- The Nova Scotia Department of Health
 - David Elliott, Epidemiologist
 - Brenda Payne, former Executive Director, Acute and Tertiary Care (Chair)
- Dr. Geoff Porter, Clinical Head of the Capital Health Cancer Care Program.

The Cancer Care Nova Scotia Breast Cancer Site team and the Maritime Medical Genetics Service provided input into the draft guideline.

APPROVAL

Approved:

Date:

Review Date: December 2013

Questions about this guideline should be directed to the Nova Scotia Breast Screening Program (902) 473-3960.