

A Single-Centre Audit of ACR BI-RADS 3 Assessment Category Utilization

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ACR BI-RADS® Category 3

- American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS)
- Category 3 *Probably Benign*
- Likelihood of malignancy $\leq 2\%$
- For diagnostic breast examinations (not screening)
- Management
 - Short-interval (6-month) follow-up until 2-year stability is documented
- Goal
 - To reduce biopsy rates while retaining a high sensitivity for early breast cancer detection

Audit Purpose and Targets

➤ Purpose

- To evaluate 24-month outcomes of mammographic and ultrasound findings assessed as BI-RADS 3 at our breast assessment centre

➤ Setting

- St. Joseph's Healthcare in Hamilton, Ontario

➤ Targets

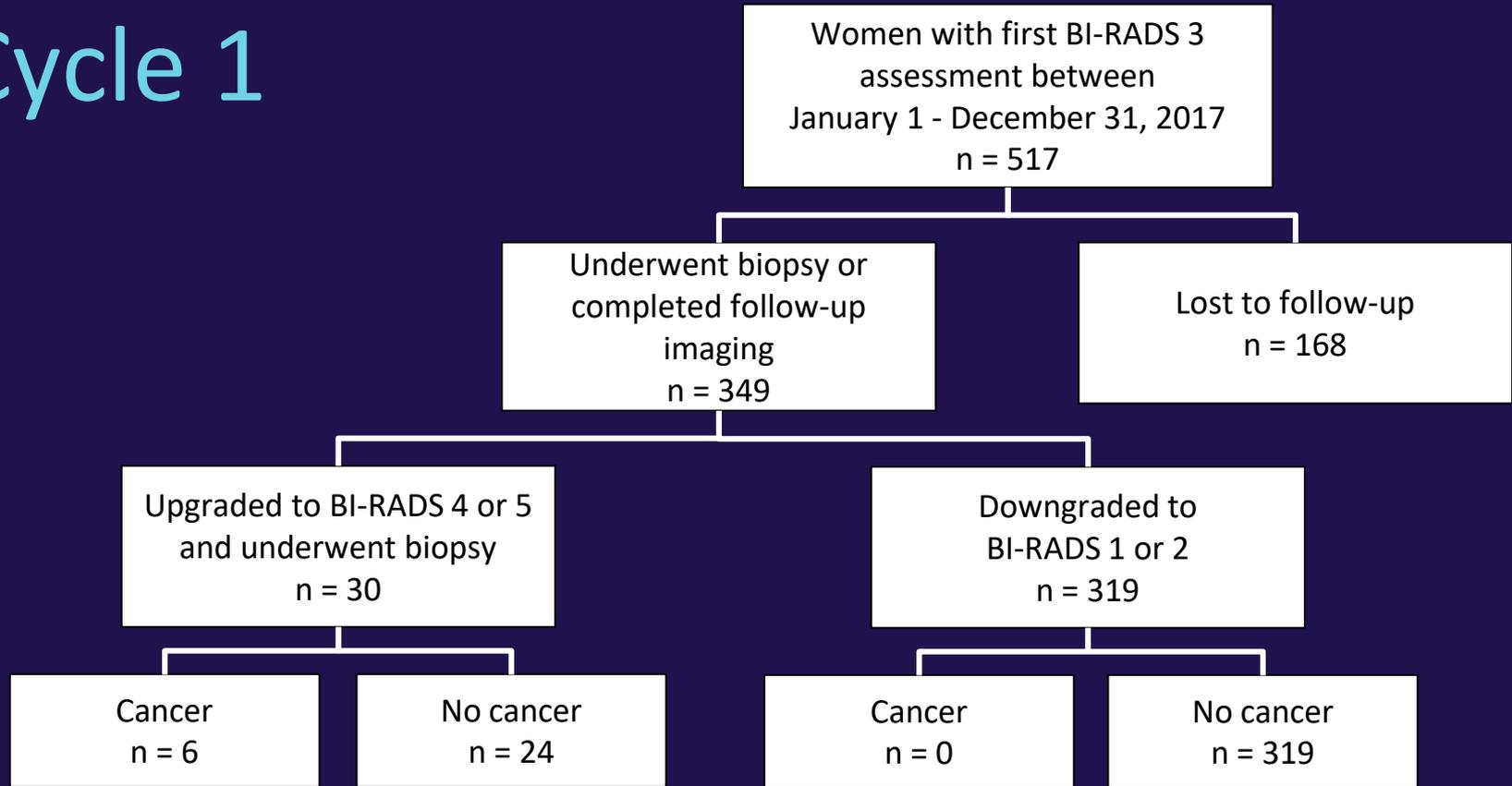
- **Cancer yield <2 %**
 - <2% of findings initially classified as BI-RADS 3 with malignant pathology on biopsy
- **Sensitivity 100%**
 - 0 cancers initially classified as BI-RADS 3 downgraded to BI-RADS Category 1 *Negative* or Category 2 *Benign*

Methods

- Inclusion criteria
 - Average-risk females of all ages
 - Mammographic and/or ultrasound finding initially assessed as BI-RADS 3 at our institution between January 1-December 31, 2017
 - Any breast imaging indication
 - ± Breast implants

- Exclusion criteria
 - High-risk females
 - Males
 - Initial BI-RADS 3 assessment before January 1, 2017 or on an outside examination referred to our centre for consultation

Cycle 1



Cycle 1 Results

- n = 517 women (Median age 52 [13-89] years)
- 349 women (68%) were biopsied or completed follow-up imaging up to 36 months
 - Loss to follow-up 32%
- Cancer Yield = $6/349 * 100\% = 1.7\%$
 - Target $\leq 2\%$ ✓
- Sensitivity = $TP/(TP+FN) = 6/(6+0) * 100\% = 100\%$
 - Target 100% ✓

36-Month Follow-Up

Interval since initial BI-RADS 3 assessment	No. of women in surveillance	No. of women with examination recorded		No. of women with biopsies		No. of cancers	Positive biopsy rate (%)	Cancer yield per time period (%)	No. of women with imaging downgraded to BI-RADS 1 or 2		No. of women lost to follow-up	
			%		%					%		%
0-90 days	517	27	5.2	8	29.6	0	0.0	0.0	7	25.9	86	16.6
6 months (91-270 d)	424	352	83.0	10	2.8	3	30.0	0.9	82	23.3	35	8.3
12 months (271-460 d)	304	256	84.2	10	3.9	3	30.0	1.2	58	22.7	32	10.5
18 months (461-640 d)	211	78	37.0	1	1.3	0	0.0	0.0	20	25.6	14	6.6
24 months (641-820 d)	177	147	83.1	1	0.7	0	0.0	0.0	124	84.4	0	0.0
30 months (821-1000 d)	53	23	43.4	0	0.0	0	na	0.0	19	82.6	0	0.0
36 months (1001-1180 d)	34	11	32.4	0	0.0	0	na	0.0	9	81.8	1	2.9
>36 months	24											
Overall	349*	894**	na	30	8.6	6	20.0	1.7	319	91.4	168	32.5

* Underwent biopsy or completed follow-up imaging up to 36 months.

** Total number of examinations recorded for 517 women in surveillance.

Predictors of Loss to Follow-up

- *Age was not a significant predictor of loss to follow-up ($p = 0.835$)*
- *Women with **prior breast imaging** were 49% less likely to be lost to follow-up than those without ($p = 0.003$)*
- *Women with imaging for **diagnostic evaluation of a breast symptom** were 84% more likely to be lost to follow-up than those recalled for additional evaluation of a screening mammogram ($p = 0.014$)*

Next Steps - Cycle 2

Implemented strategies to improve follow-up (April 2021)

- Automatic scheduling of follow-up studies for BI-RADS 3 assessments at the time of the baseline study
- Patient handout explaining the *Probably Benign* (BI-RADS 3) assessment category

Re-audit after 24 months (April 2023)

References

D'Orsi CJ, Sickles EA, Mendelson EB, Morris EA et al. **ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System.** Reston, VA, American College of Radiology; 2013.

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New
BI-RADS 3
Handout



St. Joseph's
Healthcare Hamilton

Dear Patient,

You recently had a breast examination (Mammogram and/or Ultrasound) at St. Joseph's Healthcare Hamilton, which showed a finding assessed as **Probably Benign** by the reporting radiologist. This finding is assigned to Category 3 of the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS®), which is a validated reporting system for breast examinations used by radiologists across North America. The likelihood that this finding represents cancer is **extremely low (less than 2%)**.

The recommended management of this finding is a **short-term follow-up examination (Mammogram and/or Ultrasound)**. Typically, follow-up examinations occur at 6-month or 12-month intervals until 2 years of stability have been documented. Follow-up examinations may consist of a Mammogram and/or Ultrasound examination of one or both breasts depending on the findings. If the finding has not significantly changed after 2 years of follow-up, or if it resolves or decreases in size on the follow-up examinations, the likelihood that it represents a cancer is **essentially 0%** and no additional follow-up of this finding is required. At this point, you will be advised to resume routine breast cancer screening.

If the finding increases in size or demonstrates other potentially concerning changes on a follow-up examination, the radiologist may recommend a biopsy, as the likelihood that it represents a cancer has **increased slightly (to greater than 2%)**. Importantly, studies have shown that the extent to which the cancer has spread is not significantly increased in patients with findings initially classified as Probably Benign as long as the patient completes the recommended follow-up examination(s).

The alternative to short-term follow-up of Probably Benign findings is biopsy. However, biopsy is not recommended for most patients with these findings as the likelihood of cancer is low relative to the risks of biopsy. However, a patient may choose to proceed with a biopsy of a Probably Benign lesion at any time during the follow-up period after discussion with the radiologist about the benefits and risks of biopsy.

Your follow-up examination is booked for: _____

We look forward to seeing you then.

If you have any questions or concerns about your breast examination, please contact your family physician or referring physician. They should have received a complete copy of the radiology report including management recommendations within 7 days of the date of your examination. If they are unable to answer your questions to your satisfaction, one of our radiologists can address them with you at your next follow-up examination.