

The 4th Edition of BI-RADS: Updated 2009

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Lecture Objectives

To provide guidance for using BI-RADS:

- **Proper use of assessment categories**
- **Assessment / management concordance**
- **Integrated BI-RADS assessments**

BI-RADS

Breast

Imaging

Reporting

And

Data

System

BI-RADS — Objectives

Standardize mammographic reporting

Reduce confusion in interpretation

Facilitate outcome monitoring

BI-RADS — Components

Lexicon of descriptive terms & definitions

Standardized reporting language

Medical audit and outcome monitoring

BI-RADS Assessment and Management

| Category | Terms | Recommendation |
|----------|---------------------------------|--------------------------|
| 0 | Incomplete | Additional imaging |
| 1 | Negative | Routine screening |
| 2 | Benign | Routine screening |
| 3 | Probably benign | Short-interval follow-up |
| 4 | Suspicious | Tissue diagnosis |
| 5 | Highly suggestive of malignancy | Appropriate action |
| 6 | Known biopsy-proved malignancy | Appropriate action |

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The FDA requires use of a BI-RADS assessment category in every mammography report, but there is no such requirement for use of a BI-RADS management recommendation. This has fostered discordances between assessment and management.

BI-RADS Assessment and Management

Use of standard BI-RADS assessment categories should lead the radiologist to concordant recommendations for subsequent management.

BI-RADS Assessment Category 0

| Category | Terms | Recommendation |
|----------|-------------------|-----------------------------------|
| 0 | Incomplete | Additional imaging work-up |
| 1 | Negative | Routine screening |
| 2 | Benign | Routine screening |

Category 0: use when additional imaging is required to make a final assessment (primarily for screening exams)

BI-RADS Assessment Category 0

| Category | Terms | Recommendation |
|----------|------------|----------------------------|
| 0 | Incomplete | Additional imaging work-up |
| 1 | Negative | Routine screening |
| 2 | Benign | Routine screening |

Category 0: also use when prior mammograms are not available for comparison (“awaiting prior films”), but re-assessment must be made within 30 days, preferably sooner. Note that this approach increases medicolegal exposure.

BI-RADS Final Assessment Category 1

| Category | Terms | Recommendation |
|----------|------------|----------------------------|
| 0 | Incomplete | Additional imaging work-up |
| 1 | Negative | Routine screening |
| 2 | Benign | Routine screening |

Category 1: use when mammography report describes no specific benign findings (standard “normal” report)

BI-RADS Final Assessment Category 2

| Category | Terms | Recommendation |
|----------|------------|----------------------------|
| 0 | Incomplete | Additional imaging work-up |
| 1 | Negative | Routine screening |
| 2 | Benign | Routine screening |

Category 2: use only when mammography report describes specific benign imaging findings

BI-RADS Assessment – Palpable Mass

Clinical scenario: palpable mass but no imaging findings at either diagnostic mammography or ultrasound. What should be the BI-RADS assessment (negative, suspicious, incomplete)?

BI-RADS Assessment – Palpable Mass

| Category | Terms | Recommendation |
|----------|------------|----------------------------|
| 0 | Incomplete | Additional imaging work-up |
| 1 | Negative | Routine screening |
| 4 | Suspicious | Tissue diagnosis |

Assessment in imaging report should reflect imaging findings, not management based on clinical breast examination

BI-RADS Assessment – Palpable Mass

Likelihood of cancer is only 0.1% - 4% for symptomatic patients if mammography and ultrasound are both negative.

Breast J 2000; 6:247-251

Radiology 2001; 219:186-191

AJR 2003; 180:935-940

Radiology 2002; 222:856-859

Radiology 2002; 223:581-582

Sample “Tailored” Disclaimer

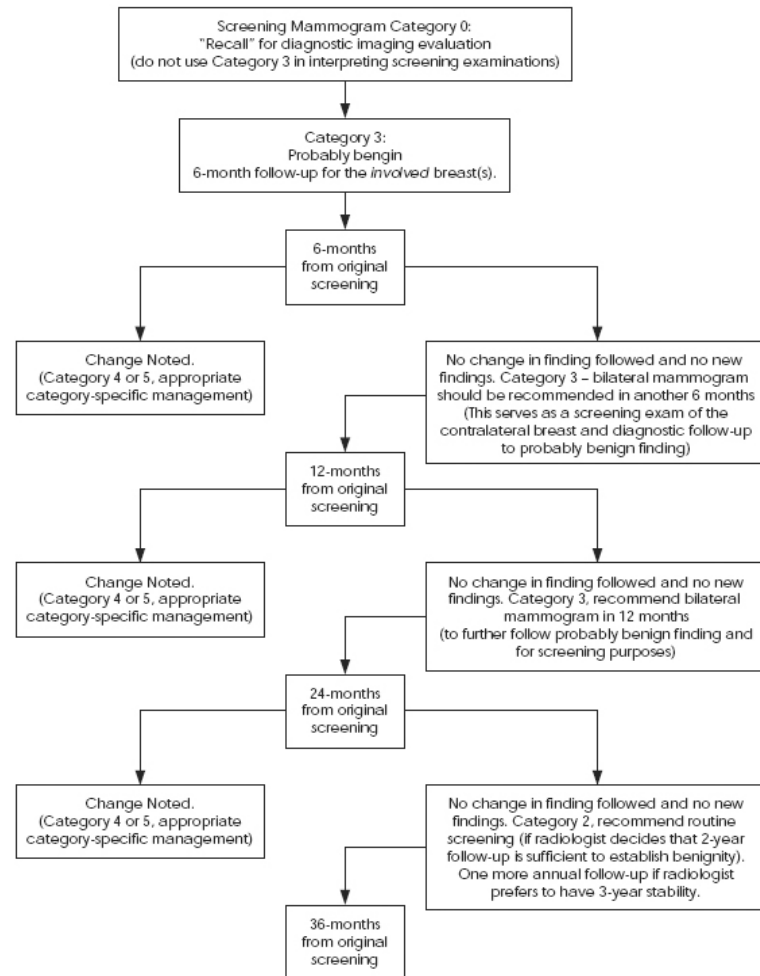
There is no mammographic or sonographic correlate to the reported symptom of _____ in the _____ breast. Management of this symptom should be based on findings at clinical breast examination.

BI-RADS Final Assessment Category 3

| Category | Terms | Recommendation |
|----------|---------------------------------|--------------------------|
| 3 | Probably benign | Short-interval follow-up |
| 4 | Suspicious | Tissue diagnosis |
| 5 | Highly suggestive of malignancy | Appropriate action |

Category 3: $\leq 2\%$ likelihood of malignancy; use only after full diagnostic imaging evaluation. Solitary group of punctate calcifications, noncalcified circumscribed solid mass, focal asymmetry. Almost never used if previous examinations are available for comparison.

Figure 1. Category 3 Algorithm



Periodic Surveillance Protocol (2 Years)

| Exam | Assessment | Follow-up Interval |
|------------|--------------|--------------------|
| Diagnostic | Prob. benign | 6 months |
| SIFU | Prob. benign | 6 months |
| Annual | Prob. benign | 1 year |
| Annual | Benign | Routine screening |

Periodic Surveillance Protocol (3 Years)

| Exam | Assessment | Follow-up Interval |
|------------|--------------|--------------------|
| Diagnostic | Prob. benign | 6 months |
| SIFU | Prob. benign | 6 months |
| Annual | Prob. benign | 1 year |
| Annual | Prob. benign | 1 year |
| Annual | Benign | Routine screening |

BI-RADS Assessment – Probably Benign

Clinical scenario: probably benign finding at imaging but patient requests biopsy rather than follow-up. What should be the BI-RADS assessment (probably benign, suspicious)?

BI-RADS Assessment – Probably Benign

| Category | Terms | Recommendation |
|----------|-----------------|--------------------------|
| 3 | Probably benign | Short-interval follow-up |
| 4 | Suspicious | Tissue diagnosis |

Assessment in imaging report should reflect imaging findings, not management based on patient's preference

BI-RADS Final Assessment Category 4

| Category | Terms | Recommendation |
|----------|---------------------------------|--------------------------|
| 3 | Probably benign | Short-interval follow-up |
| 4 | Suspicious | Tissue diagnosis |
| 5 | Highly suggestive of malignancy | Appropriate action |

Category 4: Includes all findings that are between Categories 3 (probably benign) and 5 (classic cancer): > 2% to < 95% risk. Most recommendations for tissue diagnosis are Category 4, ranging from aspiration of complicated cysts to surgical excision of very suspicious masses and calcifications.

BI-RADS Final Assessment Category 4

Category 4A **Low suspicion**
(complicated cyst, solitary dilated duct,
noncalcified fibroadenoma, etc)

Category 4B **Intermediate suspicion**
(round partially ill-defined mass,
amorphous calcifications, etc)

Category 4C **Moderate suspicion**
(irregular and indistinct mass,
fine-linear calcifications, etc)

**Subdivision of Category 4 is optional in BI-RADS, and
not covered by FDA regulations**

BI-RADS Final Assessment Category 4

- Category 4A** **Low suspicion**
(complicated cyst, solitary dilated duct, noncalcified fibroadenoma, etc)
- Category 4B** **Intermediate suspicion**
(round partially indistinct mass, amorphous calcifications, etc)
- Category 4C** **Moderate suspicion**
(irregular and indistinct mass, fine-linear calcifications, etc)

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BI-RADS Assessment – Work-up Before Bx

Clinical scenario: suspicious finding at standard imaging but you want more imaging to decide how to do the biopsy.

Should be the BI-RADS assessment be suspicious or incomplete?

BI-RADS Assessment – Suspicious

| Category | Terms | Recommendation |
|----------|------------|----------------------------|
| 0 | Incomplete | Additional imaging work-up |
| 4 | Suspicious | Tissue diagnosis |

Assessment in imaging report should reflect imaging findings, not management based on how biopsy may be done

BI-RADS Final Assessment Category 5

| Category | Terms | Recommendation |
|----------|---------------------------------|--------------------------|
| 3 | Probably benign | Short-interval follow-up |
| 4 | Suspicious | Tissue diagnosis |
| 5 | Highly suggestive of malignancy | Appropriate action |

Category 5: $\geq 95\%$ probability of cancer (i.e., classic cancer). For cases where surgical treatment could *theoretically* be planned without preliminary biopsy (one-step surgical procedure: excise, do frozen section and if cancer, do lumpectomy & node sampling).

BI-RADS Final Assessment Category 6

- Findings already confirmed malignant by biopsy
- Imaging is performed prior to surgical excision
- Imaging evaluates response to neoadjuvant chemotherapy
- Category 4 or 5 lesions supersede Category 6 lesions
- Should not be confused with post-lumpectomy imaging, where typical post-surgical changes should be assigned a Category 2 (benign) assessment
- Category 6 cases should be excluded from medical audits

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BI-RADS Overall Assessment (Mammo/US)

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Findings from each examination in one report with a single final assessment based on the most important findings from both. Each examination should be described in a separate paragraph.

BI-RADS Overall Assessment (Mammo/US)

| Category | Terms | Recommendation |
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Generally the assessment for the more abnormal examination prevails, unless the findings for the other examination are characteristically benign (e.g., fat-density mass, simple cyst).

BI-RADS Breast Imaging Descriptors

Use of standard BI-RADS terminology to describe breast imaging findings can lead the radiologist to a concordant assessment of these findings and hence to concordant recommendations for subsequent management.

Conclusion

This makes breast imaging reports readily understandable by health care providers, increasing the likelihood that imaging recommendations are acted upon both appropriately and in a timely fashion.

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