Improving Pediatric Breast Ultrasound Reporting and Recommendations: A Quality Improvement Initiative

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*The Association for Medical Imaging Management (AHRA)
Pediatric Breast Imaging

• Breast masses are uncommon in the pediatric population
  – Frequently cause considerable concern for the patient and their parents

• Ultrasound (US) is the preferred imaging modality
  – Lack of ionizing radiation
  – Adequate tissue characterization
  – Easy availability

• Mammography is not advised in children
  – Low incidence of malignancy
  – Risk of radiation to the immature glandular tissues
  – Poor lesion conspicuity in dense fibroglandular breasts
Pediatric Breast Ultrasound

- At CHLA, pediatric breast ultrasound is reviewed by pediatric radiologists

- Recommendations are generally based on individual experience and practice
  - No formal guidelines, consensus or recommendations for management of imaging findings on pediatric breast ultrasound

- Inconsistent recommendations can confuse clinicians
  - May lead to additional, unnecessary imaging, procedures, and/or surgery
Current Practices

- Breast Imaging-Reporting and Data System (BI-RADS) is a widely used risk assessment and quality assurance tool
  - Mammography, ultrasound or MRI
  - Developed for adult women

What are the current recommendations for pediatric breast ultrasound?
Goals

• To find or establish literature based guidelines for recommendations based on common pediatric breast US findings
  – Can BI-RADS be used in the pediatric population?

• To consistently offer standardized recommendations for common pediatric breast US findings
  – What are the current recommendations for the pediatric population?

• To stop routinely encouraging further imaging
  – Recommend complementary imaging modalities only when clearly indicated for further characterization
Quality Improvement: Plan-Do-Study-Act Model

**PLAN**
- Literature Search
- Retrospective Chart Review

**DO**
- Standards Development Implementation

**STUDY**
- Retrospective Chart Review

**ACT**
- Solicit Feedback
- Revise Standards
Quality Improvement: Plan

PLAN

DO

ACT

STUDY

Literature Search
To build evidence for our initiative, we performed a search of the current scientific literature to establish best practices.

Specifically, we searched the literature for:
- Appropriateness of applying BI-RADS to the pediatric population
- Current recommendations for ultrasound findings specific to the pediatric population

Pubmed database was queried with the following search terms on 7/21/15:
- Pediatric, breast ultrasound, BI-RADS
BI-RADs in Pediatric Breast Ultrasound

Original Article

Breast Imaging-Reporting and Data System (BI-RADS) classification in 51 excised palpable pediatric breast masses☆,☆☆

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Koning, et al

- Retrospective review of all surgically excised breast masses* at a single tertiary care pediatric hospital (UCSD) between July 2010 and November 2013

- Patients** with preoperative breast ultrasound and a BI-RADS-US classification were selected.
  - Clinical notes, laboratory data, and surgical pathology reviewed via EMR

- Surgical pathology reports were used for correlation of BI-RADS classification

* Patients operated on for gynecomastia or breast abscess were excluded
**Postmenarchal females age 15-19
Study Population

- 119 palpable masses
- 81 masses imaged preoperatively
- 59 ultrasound reports available
- 51 masses assigned BI-RADS classification
- Surgical pathology available for all 51 masses
BI-RADS US Classification

Table 2
BI-RADS US categories in 51 masses with surgical pathology.

<table>
<thead>
<tr>
<th>BI-RADS US category</th>
<th>Number of masses ($n = 51$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BI-RADS 0</td>
<td>2 fibroadenoma</td>
</tr>
<tr>
<td>BI-RADS 2</td>
<td>5 fibroadenoma, 1 myxoid fibroadenoma, 1 juvenile fibroadenoma</td>
</tr>
<tr>
<td>BI-RADS 3</td>
<td>15 fibroadenoma, 1 fibroadenoma with PASH\textsuperscript{a}, 1 PASH\textsuperscript{a}</td>
</tr>
<tr>
<td>BI-RADS 4</td>
<td>21 fibroadenoma, 3 tubular adenoma, 1 fibrocystic change</td>
</tr>
</tbody>
</table>

\textsuperscript{a} PASH—pseudoangiomatous stromal hyperplasia.

No masses were assigned BI-RADS category 5 or 6.
Pathologic Classification of Excised Masses

Table 3
Surgical pathology in 119 palpable pediatric breast masses.

<table>
<thead>
<tr>
<th>Surgical pathology</th>
<th>Number of masses—n (% of 119)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional fibroadenoma</td>
<td>84 (70.6%)</td>
</tr>
<tr>
<td>Juvenile fibroadenoma</td>
<td>7 (5.9%)</td>
</tr>
<tr>
<td>Tubular adenoma</td>
<td>5 (4.2%)</td>
</tr>
<tr>
<td>Fibroadenoma with PASH(^a)</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Other(^b)</td>
<td>20 (16.8%)</td>
</tr>
<tr>
<td>Total</td>
<td>119 (100%)</td>
</tr>
</tbody>
</table>

\(^a\) Pseudoangiomatous stromal hyperplasia.

\(^b\) Other masses—supernumerary nipple (n = 3), myxoid fibroadenoma (n = 2), fibrocystic change (n = 2), benign cyst (n = 2), ductal ectasia (n = 2), hamartoma (n = 2), fibroadenoma with necrosis (n = 2), PASH (n = 1), galactocele (n = 1), fibrosis (n = 1), chronic lymphocytic mastitis (n = 1), and vascular malformation (n = 1).

All masses were found to be benign on pathology.
Conclusions

• BI-RADS was developed to assess risk of malignancy in adult patients and to communicate the risk of malignancy
  – It has been increasingly applied to US performed on pediatric patients and adolescents

• Authors noted that management of a BI-RADS 4 classification is significantly different from a BI-RADS 3 classification
  – Likely resulting in biopsy of masses that could have been managed with observation

• Concluded that BI-RADS classification overstates the risk of malignancy in the pediatric and adolescent population
Current recommendations for ultrasound findings specific to the pediatric population from Pediatric Radiology and European Journal of Radiology
Table 2 Summary of appropriate differential diagnoses and clinical recommendations for diagnosis of pediatric breast masses

<table>
<thead>
<tr>
<th>Clinical situation</th>
<th>Differential diagnosis</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate or young child</td>
<td>Physiological response to maternal hormones, Gynecomastia</td>
<td>Do not biopsy, clinical follow-up is sufficient</td>
</tr>
<tr>
<td>Simple cystic mass</td>
<td>Must demonstrate the following features: unilocular, well-circumscribed, anechoic, posterior acoustic enhancement</td>
<td>If vascular, likely hemangioma</td>
</tr>
<tr>
<td>Duct ectasia</td>
<td>If any internal debris or vascularity is present, refer to complex cystic mass</td>
<td>Most commonly no treatment or follow-up is necessary.</td>
</tr>
<tr>
<td>Complex cystic mass</td>
<td>Abscess, Hematoma/fat necrosis, Galactocele</td>
<td>Aspiration could be pursued for significant pain or to confirm liquid contents if sonography is confused by internal debris/complexity</td>
</tr>
<tr>
<td>Adolescent with breast mass &lt;5 cm, benign US features</td>
<td>Most likely fibroadenoma, Less likely PASH, phyllodes tumor</td>
<td>Observe and culture nipple discharge. Likely to resolve spontaneously</td>
</tr>
<tr>
<td>Adolescent with breast mass &gt;5 cm, benign US features</td>
<td>Giant fibroadenoma, Phyllodes tumor</td>
<td>Aspiration, consider follow-up US</td>
</tr>
<tr>
<td>Breast mass with irregular shape, angular margins, shadowing or in setting of personal cancer</td>
<td>Malignancy, Abscess, PASH, Galactocele, Fat necrosis</td>
<td>US follow-up</td>
</tr>
<tr>
<td>Any solid or complex cystic mass in setting of prior/known cancer or prior radiation therapy to breast tissue</td>
<td>Metastasis is the primary concern</td>
<td>If stable for 2 years, clinical follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If growing or painful → core biopsy and referral to breast surgeon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surgical consultation for anticipated surgical excision.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lesions of this size cannot be distinguished by needle tissue sampling</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tissue sampling or surgical excision</td>
</tr>
</tbody>
</table>

*PASH* pseudoangiomatosus stromal hyperplasia
Gao, et al

Fig. 27. How to approach breast lesions in children and adolescents – a diagnostic and management algorithm.
Quality Improvement Project: Plan

PLAN
- Literature Search
- Retrospective Chart Review

DO

ACT

STUDY
Pathologic Correlation

- We reviewed all breast ultrasounds performed at CHLA from 2013-2015
- Nine breast masses with pre-operative ultrasound imaging were surgically excised from 2013-2015

<table>
<thead>
<tr>
<th>Pathology</th>
<th>No. of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Juvenile fibroadenoma</td>
<td>6</td>
</tr>
<tr>
<td>Phyllodes</td>
<td>1</td>
</tr>
<tr>
<td>Tubular adenoma</td>
<td>1</td>
</tr>
<tr>
<td>Gynecomastia</td>
<td>1</td>
</tr>
</tbody>
</table>

Benign pathology was consistent with that published in the literature (Koning, et al)
Quality Improvement: Do

PLAN
- Literature Search
- Retrospective Chart Review

DO
- Standards Development

ACT

STUDY
Development of Standards

• Recommendations from the literature were synthesized into a chart
  – Organized by age and common ultrasound findings

• Recommendations underwent interdisciplinary review, with subsequent revision to reflect expert feedback
  – Board certified radiologist with subspecialty training in Women’s Imaging
  – Board certified surgeon with subspecialty training in Pediatric Surgery
Literature based, standardized recommendations were developed for common ultrasound imaging findings at CHLA

<table>
<thead>
<tr>
<th>Age</th>
<th>History/Physical Exam</th>
<th>Imaging</th>
<th>DDx</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate</td>
<td>Nipple Discharge</td>
<td>Not necessary</td>
<td>Response to maternal hormones</td>
<td>Clinical follow-up</td>
</tr>
<tr>
<td>Neonate-Infant</td>
<td>Subareolar nodules</td>
<td>Not necessary</td>
<td>Gynecomastia</td>
<td>Clinical follow-up</td>
</tr>
<tr>
<td>Pre-pubertal</td>
<td>Asymmetric breast tissue</td>
<td>Normal breast tissue, duct ectasia,</td>
<td>Asymmetric breast buds</td>
<td>Clinical follow-up with optional initial ultrasound</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cystic change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pubertal-Post</td>
<td>Palpable lump</td>
<td>Simple cyst or normal breast tissue</td>
<td>Simple cyst or breast tissue</td>
<td>Initial ultrasound, but no further imaging</td>
</tr>
<tr>
<td>pubertal</td>
<td></td>
<td></td>
<td></td>
<td>required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Complex cyst or cystic mass</td>
<td>Hematoma, galactocele, abscess</td>
<td>Imaging follow-up to resolution +/- drainage for abcess</td>
</tr>
<tr>
<td>Pubertal-Post</td>
<td>Breast discharge with</td>
<td>Duct Ectasia</td>
<td>Physiologic, debris, papilloma or papillomatosis</td>
<td>Culture fluid and clinical follow-up</td>
</tr>
<tr>
<td>pubertal</td>
<td>benign features⁴</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pubertal-Post</td>
<td>Breast discharge with</td>
<td>Intraductal mass or mass with</td>
<td>Clot, debris, ductal carcinoma in situ (DCIS), papilloma, intracystic papillary carcinoma</td>
<td>Tissue sample or refer for surgical consultation (excision)</td>
</tr>
<tr>
<td>pubertal</td>
<td>suspicious features⁵</td>
<td>intraductal extension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pubertal-Post</td>
<td>Subareolar nodules (Male)</td>
<td>Normal breast tissue</td>
<td>Gynecomastia</td>
<td>Clinical follow-up</td>
</tr>
<tr>
<td>pubertal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹Benign features: Lack of malignant findings, circumscribed margins, parallel orientation, ellipsoid, thin echogenic pseudocapsule
²Stable: No increase in size or change in symptoms. If increase in size or painful, do core needle biopsy or refer to surgery
³Suspicious features: Irregular shape, angular margins, non-parallel orientation, posterior shadowing, associated calcifications, wide transition zone, increased malignancy risk
⁴Benign features: Bilateral, multiple ducts, spontaneous or stimulated, milky, green, yellow
⁵Suspicious features: Unilateral, unifocal, bloody, clear, spontaneous

Society for Pediatric Radiology
May 2017
Quality Improvement: Do

PLAN
- Literature Search
- Retrospective Chart Review

DO
- Standards Development
- Implementation

ACT

STUDY
Standards Implementation

• Standardized recommendations were implemented January 11, 2015
  – Literature review results and standardized recommendations were presented to the radiology staff at a department-wide journal club
  – Feedback on the recommendations was solicited

• The standardized recommendations were electronically disseminated to the radiology staff for future reference

• Periodic feedback from the radiology staff was solicited at 3 month intervals
Quality Improvement Project

PLAN
- Literature Search
- Retrospective Chart Review

DO
- Standards Development
- Implementation

ACT

STUDY
- Retrospective Chart Review
Breast Ultrasound Recommendations: Pre-intervention

• Retrospective analysis of the recommendations provided on the 76 diagnostic breast ultrasounds performed from 2013-2015
  – 9 examinations were discarded, as the standard recommendations were not applicable to the ultrasound findings

• Standard recommendations were compared to the recommendations provided on the remaining 67 pre-intervention ultrasounds
  – 35 (52%) of the examinations were found to have recommendations consistent with developed standard recommendations
Breast Ultrasound Recommendations: Post-Intervention

- 91 ultrasounds performed from 1/11/2016-1/11/2017
  - 9 examinations were discarded, because the standardized recommendations were not applicable to the ultrasound findings
    - 7 of the 9 discarded examinations were for male patients

- Standard recommendations was applied to the remaining 82 post-intervention ultrasounds
  - 66 examinations (80%) had recommendations consistent with the standard recommendations
Following intervention, the number of recommendations consistent with the literature-based standard recommendations increased from 52% to 80%
Quality Improvement Project

PLAN
- Literature Search
- Retrospective Chart Review

DO
- Standards Development and Implementation

ACT
- Solicit Feedback
- Revise Standards

STUDY
- Retrospective Chart Review
Future Directions

- Encourage consistent use of the standardized recommendations
- Solicit multidisciplinary practice feedback
- Further refine recommendations in response to practice feedback
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References