

May 2020

Triage Breast Patients during the Pandemic

AI Decision Support on Ultrasound Images to Reclassify and Prioritize BI-RADS 3 Cases

Artificial intelligence decision support helps accurately prioritize cases and reduce unnecessary biopsies and mitigate virus transmission risk in response to the backlog of deferred follow-up breast examinations caused by the Covid-19 pandemic. A recent study of over 700 patients showed:

- **Over 70% of patients were reclassified for risk**
- **Significant potential reduction of benign biopsies and recommended follow-up**
- **Additional cancers found in highest risk patients**
- **Staff exposure reduced by deferring appointments for low-risk patients**

“Our AI decision-support software once again delivered exciting patient outcomes and results to our radiologist partners, delivering on our promise of elevating care especially in this challenging Covid-19 environment.”

— Chad McClennan, CEO, Koios Medical

Situation

The Covid-19 pandemic caused a dramatic reduction in elective procedures and examinations. Canceled breast examination appointments in March, April and May 2020 will create in a significant backlog and a corresponding delay in important treatment by weeks or months. Worse, capacity is reduced by more frequent disinfecting of examination rooms. Rescheduled appointments increase exposure of front-line staff, sonographers and radiologists to patients infected with Covid-19.

Until effective vaccines or treatments for Covid-19 are widely available, patients are likely to continue to want to avoid medical facilities, particularly if earlier examinations found lesions to be low risk.

During this disruption, the accuracy of diagnosis becomes even more important, so that vital care is delivered promptly while unnecessary visits are avoided.

Department leaders must address the large and growing backlog and prioritize patients in a manner that balances the risk of cancer to patients and the risk of Covid-19 to both patients and healthcare providers.

Objective

To determine the degree to which lesions judged by radiologists as BI-RADS 3 can be accurately and appropriately reclassified by risk utilizing AI software (Koios DS Breast), resulting in reprioritization in patient scheduling, and to determine the net effect on the demand for follow-up examinations and treatment.

Materials and Methods

- IRB-approved retrospective review of ultrasound images of 206 breast lesions reported as BI-RADS 3 or 4: 199 (96.6%) benign + 7 (3.4%) malignant based on pathology or minimum of 6-month stable follow-up
- AI system (Koios DS Breast) evaluated images and categorized as Benign, Probably Benign, Suspicious and Probably Malignant; these risk categories align with BI-RADS categories 2, 3, 4AB and 4C, respectively
- System outputs evaluated against ground truth

Results and Additional Investigation

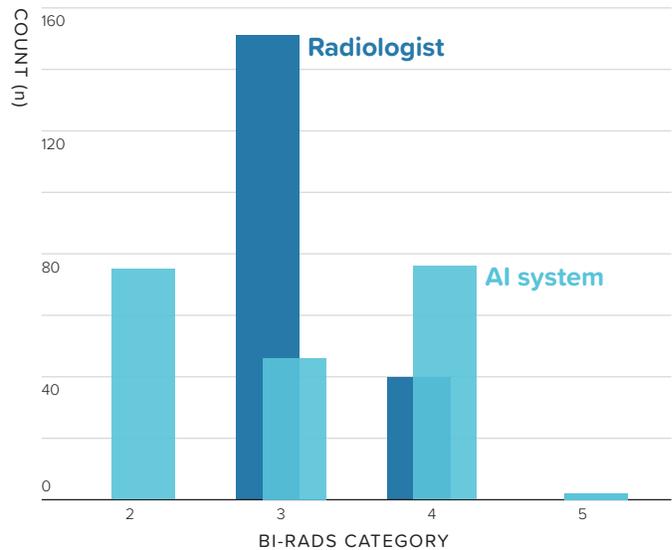
- BI-RADS 3 downgrades to BI-RADS 2: **41.1%**
- BI-RADS 3 upgrades to BI-RADS 4: **26.8%**
- BI-RADS 3 no change: **32.0%**

The upgrade rate of 26.8% raised the question of what, if any, impact the upgrades to BI-RADS 4 would have on the overall benign biopsy rate. To answer this, 500 BI-RADS 4/5 lesions were included in a subsequent analysis in order to see if downgrades of these cases would offset upgrades from BI-RADS 3. We observed the following results.

- Benign biopsy reduction: **23.4%**, $p < .001$ (radiologist count: 333; system count: 255)
- Benign follow reduction: **6.3%**, $p = .004$ (radiologist count: 128; system count: 120)
- Benign no follow increase of **330.8%**, $p < .001$ (radiologist count: 26; system count: 112)
- Sensitivity (BI-RADS 4 and malignant): radiologists **100%**, system **97%**, $p = 0.057$

The BI-RADS 2 increase is inflated since the population of BI-RADS 2 lesions included in this assessment stems only from incidental screening findings, but there is still a very clear increase in the utilization of this category.

Over time, the sensitivity of radiologists in practice will never reach 100% as was the case in the BR4+ study cohort; based on prior studies¹, there will likely be a net improvement in sensitivity similar to the net reduction in benign biopsy and benign follow-up.



CONCLUSION

Using an AI system (Koios DS Breast) to analyze and classify breast ultrasound exams scheduled for follow-up (BI-RADS 3) will enable effective re-prioritization of patients based on more accurate likelihood of malignancy.

This study suggests that Koios DS Breast can downgrade a large percentage of cases to BI-RADS 2, while simultaneously improving sensitivity from upgraded cases.

Deferring patient appointments and reducing the anticipated surge mitigates the risk of exposure and virus transmission to front-line staff, sonographers and radiologists.

1. Mango, Victoria L., et al. "Should We Ignore, Follow, or Biopsy? Impact of Artificial Intelligence Decision Support on Breast Ultrasound Lesion Assessment." American Journal of Roentgenology (2019): 1-8.