



Decreasing Benign Breast Ultrasound Biopsies: Prospective Use of AI Decision Support

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DISCLOSURES

Victoria L Mango:

Koios Medical Inc (Financial compensation as radiologist reader)
Bayer Healthcare (Consultant)

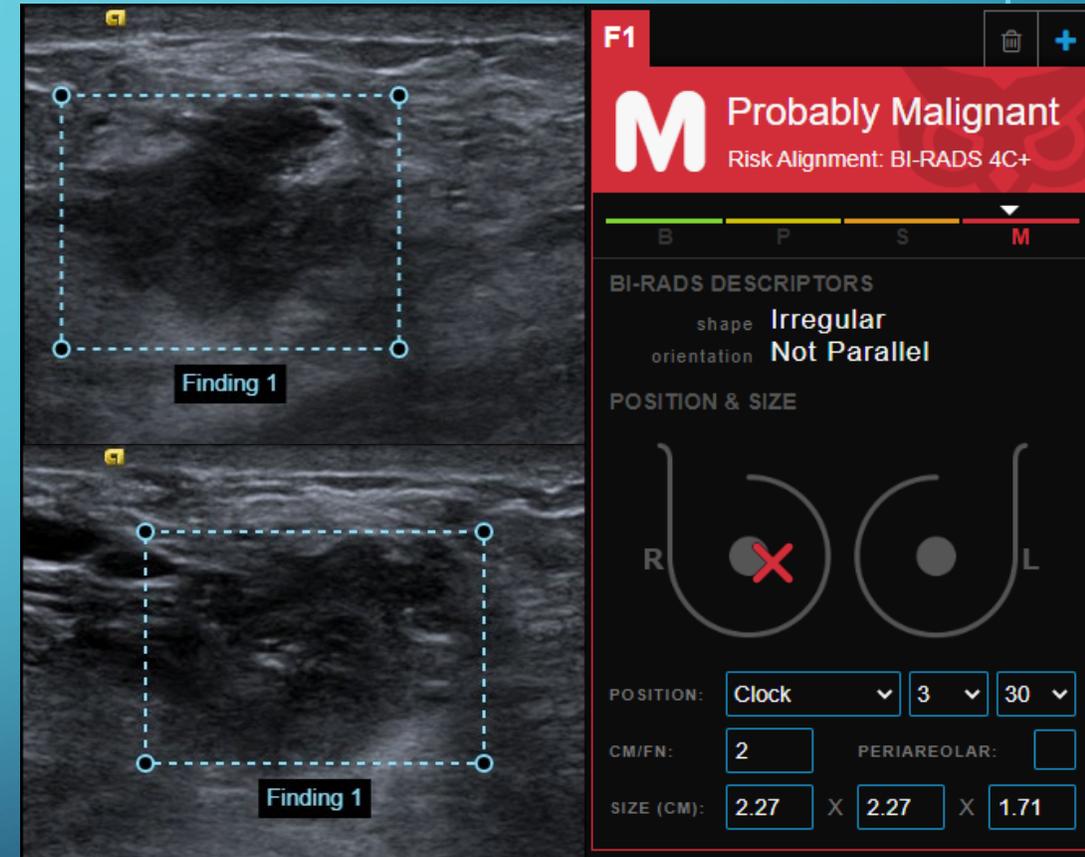
Lev Barinov:

Employee of Koios Medical, Inc

Nothing to Disclose: Kristen Coffey and Richard Ha

BACKGROUND

- AI decision support (DS) for breast ultrasound
 - Koios DS for Breast
- Uses machine learning/AI to generate probability of malignancy for a user-selected region of interest
- Probability of malignancy mapped to four categories (benign, probably benign, suspicious, probably malignant) which are then aligned with BI-RADS categories



PURPOSE

To examine the affect of prospective AI decision support (Koios DS for Breast) use on breast ultrasound biopsy performance metrics.

METHODS

- QI/QA analysis: Non-identifiable, HIPAA compliant data
- Evaluation of breast ultrasound biopsy performance metrics:
Large private practice radiology group for a 12-month period before and for 12 months following a 6 month adaptation period of AI technology

PROSPECTIVE USE OF AI DECISION SUPPORT

- Radiologists utilized AI technology in real-time
 - At their discretion, part of their routine clinical practice
- DS use verified via audit and quality logs from Koios Medical
- Impact on physician performance assessed by comparing retrospectively obtained metrics of physician performance before Koios DS was in use to prospective metrics after Koios DS was implemented, following a 6-month acclimatization period

RESULTS

- 12 radiologists (10 breast fellowship trained)
 - AI utilization rate on diagnostic breast ultrasound studies: 57.9%
 - 1 radiologist left the practice and 4 joined in assessed intervals

- Total 6087 diagnostic breast ultrasound exams following the implementation of AI
 - 2060 in 6-months immediately following AI installation
 - 4027 in 7-18 months following AI installation that were tracked for comparison to the 12 months preceding AI installation

RESULTS

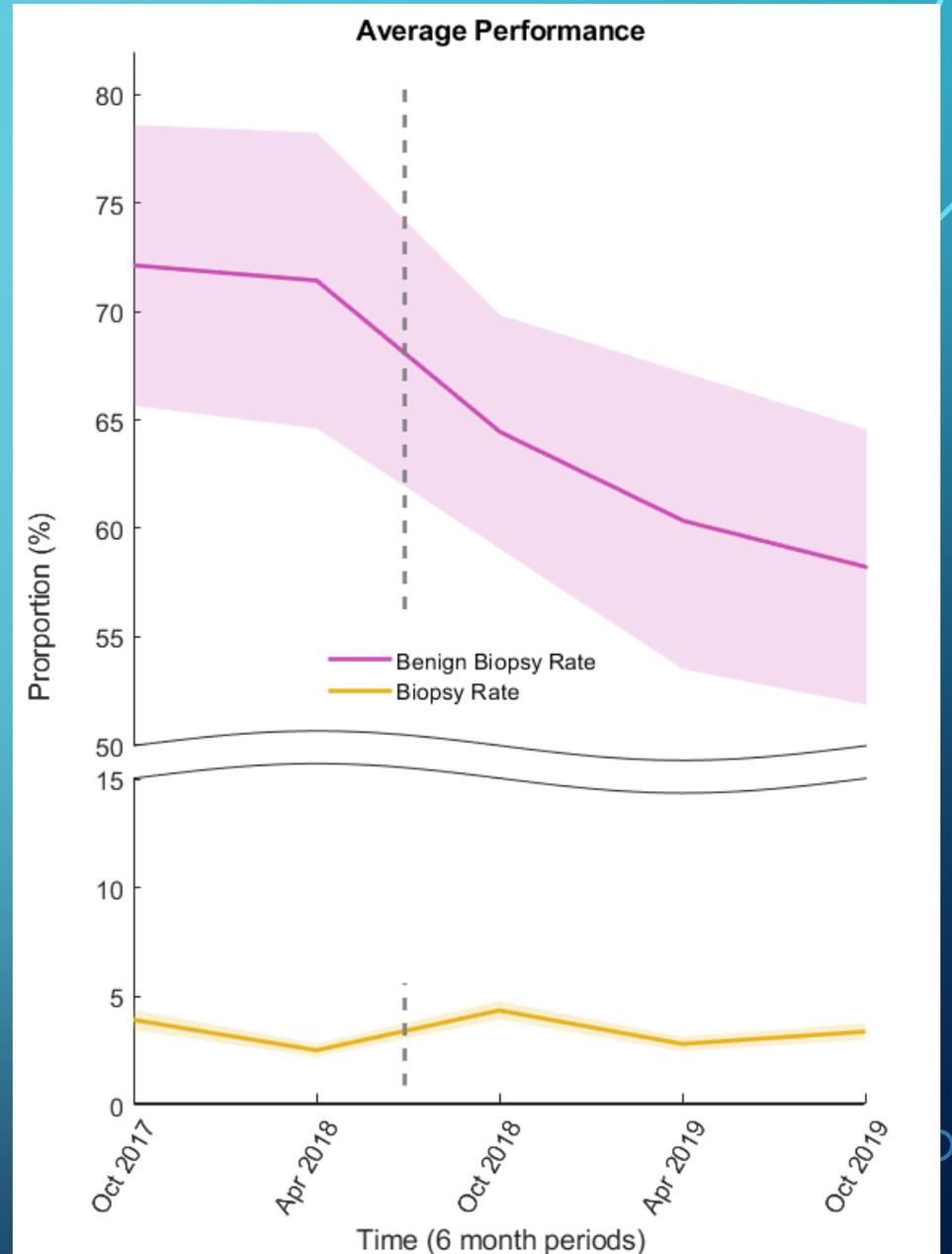
When comparing 12 months prior to AI implementation to the tracked 12-month period after:

- Benign biopsy rate decreased

71.79% to 59.2% ($p = .04$)

- Overall biopsy rate unchanged

117/3761 (3.1%) to 125/4027
(3.1%) ($p = 0.98$)



Graph illustrating changes in biopsy rate (yellow line) and benign biopsy rate (solid pink line with shaded pink 95% CI); Gray vertical dashed line = mid-point of 6-month AI decision support adaptation period

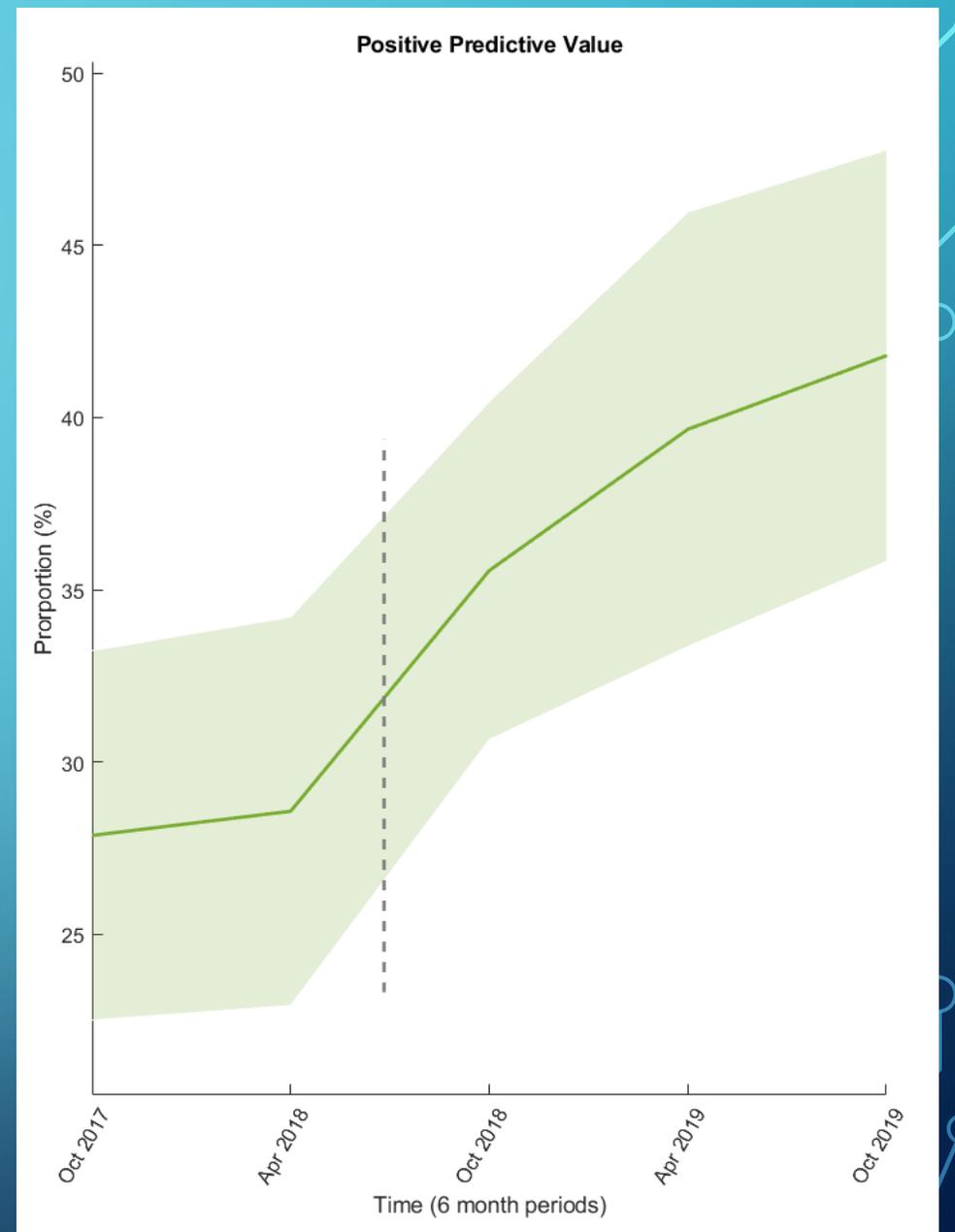
RESULTS

When comparing 12 months prior to AI implementation to the tracked 12-month period after:

- PPV₃ increased

28.2% to 40.8%

(p = .04)



Graph illustrating changes in positive predictive value (PPV₃) (solid green line with shaded green 95% CI) over time. Gray vertical dashed line = mid-point of 6-month AI decision support adaptation period

CONCLUSIONS AND LIMITATIONS

- Prospective use of AI decision support in breast ultrasound interpretation by radiologists in our quality assessment correlates with improved diagnostic performance with decreased benign biopsy rates and increased PPV_3 , while maintaining a consistent biopsy rate.
- A direct causal relationship cannot be inferred and warrants further investigation with a control group study design.