PROJECTED HEALTHCARE ECONOMIC BENEFIT ASSOCIATED WITH OPTO-ACOUSTIC IMAGING: POTENTIAL FOR REDUCING BREAST BIOPSIES

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BACKGROUND

Cancers do not grow beyond 2 mm without developing new vessels, or neovascularity1. This results in increased blood flow to cancerous tissue. Cancers are generally more metabolically active and deoxygenate hemoglobin more than benign entities or normal tissue. Optical energy from a laser is absorbed by oxygenated and deoxygenated hemoglobin and is emitted as a sound wave2-4.

REAL-TIME HEMOGLOBIN MAP

METHODS

In the 100 subject blinded reader study, women were referred for diagnostic breast ultrasound due to a palpable mass or a suspicious mammographic finding. Patients with BI-RADS 3, 4a, 4b, and 4c lesions at conventional diagnostic ultrasound (CDU) were eligible for the study.

RESULTS

In the pilot study, using OA, seven independent readers were able to downgrade biopsy-proven benign masses coded by the site investigator as follows:

- BI-RADS 4a to 3 in 23% of cases
- BI-RADS 4a to 3 in 37% of cases
- BI-RADS 4b to 2 in 16% of cases
- BI-RADS 3 to 2 in 33% of cases

Downgrades to BI-RADS 3 may decrease the number of negative biopsies and downgrades to BI-RADS 2 may decrease negative biopsies as well as short interval follow-up exams.

In the 100 subject blinded reader pilot study demonstrated the potential of OA to downgrade benign masses and potentially spare negative biopsies.

BASIS FOR OPTO-ACOUSTIC (OA) IMAGING

Cancers do not grow beyond 2-mm without developing new vessels, or neovascularity. This results in increased blood flow to cancerous tissue. Cancers are generally more metabolically active and deoxygenate hemoglobin more than benign entities or normal tissue. Optical energy from a laser is absorbed by oxygenated and deoxygenated hemoglobin and is emitted as a sound wave.

REFERENCES

5. Centers for Medicare & Medicaid Services

CONCLUSION

Imagio appears to prospectively help identify benign masses that do not require biopsy, and in some cases, also reduce the need for short interval follow-up. This is being validated in a larger pivotal trial. Downgrading benign-appearing masses to BI-RADS 3 or 2 without missing cancers potentially offers significant cost saving implications for both patients and the healthcare system, as well as helps spare women from the anxiety associated with breast biopsies.

POTENTIAL AREAS OF COST SAVINGS

Sparing a biopsy for a benign mass avoids a $1,000-$1,500 cost (including histopathology), and sparing subsequent follow-up visits avoids a $200-$500 cost (excluding other diagnostic imaging studies).1,4

Potential Downgrades

- BI-RADS 4b to 3
- BI-RADS 4a to 3
- BI-RADS 4a to 2
- BI-RADS 3 to 2

*Cost savings based on Medicare only.4,6

POTENTIAL AREAS OF COST SAVINGS

Biopsy

Biopsy

Biopsy and/or follow-up

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