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LETTER – BREAST ONCOLOGY

Response to: "Intact Excision of Breast Lesions Using BLES™: Is There a Clinical Indication Yet?"

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TO THE EDITORS:

In response to our article[1], in her editorial[2] Yao states that a second procedure was needed to achieve clear margins in 27% of patients: "Of 124 cancer patients, 55% had clear margins after undergoing a biopsy with the BLES device, 27% underwent another procedure with the BLES device to establish negative margins". She repeats this error when summarizing the results in cancer patients: "In the current study, 55% of cancerous lesions (DCIS and invasive carcinoma) had complete excision, with one procedure using the BLES device, and 45% of patients had to undergo another procedure, either with the BLES device or surgical excision".

In our article, we clearly state that patients having excision of small cancers had one procedure: "Patients with DCIS or invasive cancers (recent diagnostic biopsy with core or Intact device) had an MI excision procedure that included a second Intact capture to provide a shaved margin. All such patients were registered". Therefore, the percentage of patients recently diagnosed with small cancers who had clear margins with the Intact excision procedure (excision and shaved margin) was 82%, which compares favorably with traditional open lumpectomy.

Second, Yao states "This study reports an upgrade rate of 2.4% for HRLs". This is incorrect if it refers to upgrades following biopsy with the Intact device. There were no upgrades after diagnostic Intact biopsy. While there was an upgrade rate of 2.4% with Intact excision following non-excisional, diagnostic biopsy with other devices, none occurred after Intact diagnostic or excision biopsy. While, this is clear from the Consort diagram, a clarifying sentence was omitted from the manuscript in the editing process.

Third, Yao states that, in spite of findings in very large US series demonstrating low complication rates compared with traditional open lumpectomy (including the present study), another report found a high complication rate of 20%: "… a more recent study reported that approximately 20% of patients had complications ranging from hematoma, delayed wound healing, skin burn, and infection. Of note, 60% of these complications occurred days to months after the biopsy was performed, therefore this procedure is not without risk. This study underscores the need for longer-term follow-up of these patients to determine the true rate of complications associated with the BLES device".

This quoted study represents an early experience in a European setting. The authors reporting the series concluded the device was safe compared with other biopsy devices as complications were grade 1/5 in 27 patients and grade 2/5 in one patient. In summary, all studies reporting complications with the device have demonstrated low complication rates. No studies have reported high complication rates or a need for further study of complications.

Finally, Yao states a 2 mm margin for DCIS is standard care based on the recent Society of Surgical Oncology–American Society for Radiation Oncology–American Society of Clinical Oncology consensus guideline. In context, the guideline states that "Use of a 2-mm margin as the standard for an adequate margin in DCIS treated with whole-breast irradiation is associated with lower rates of IBTR and has the potential to decrease re-excision rates, improve cosmetic outcomes, and decrease health care costs. Clinical judgment should be used in determining the need for further surgery in patients with negative margins narrower than 2 mm".

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The primary intent of the guideline statement was to decrease re-excisions in practices requiring larger margins for DCIS. The statement recognizes that use of a 2 mm margin has no survival benefit and reiterates the 'ink on tumor' standard for re-excision: "Negative margins narrower than 2 mm alone are not an indication for mastectomy, and factors known to affect rates of IBTR should be considered in determining the need for re-excision".

We feel these errors, left uncorrected, fundamentally negate the value of the article and unjustifiably compromise the potential positive impact for women who otherwise will be advised to have more traditional, more extensive procedures.

REFERENCES

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2. Yao K. Intact excision of breast lesions using BLES^{TM}: Is there a clinical indication yet? *Ann Surg Oncol*. 2019;26(4):933–5.