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Benefits, evidence, cost and harms all missing from recap of genetic test for breast cancer patients

REVIEWED BY



RATING



CATEGORIES

Breast cancer, University news release

TAGS

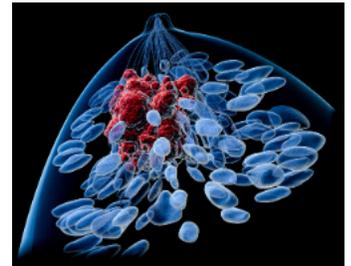
bisphosphonates, genetic testing, University of Sheffield



Genetic test could help fight secondary breast cancer

OUR REVIEW SUMMARY

The news release gives a strong impression that a new genetic test could help women “fight” secondary breast cancers, specifically bone metastases. The genetic test would direct treatment to include (or not include) a specific class of drugs called bisphosphonates. Although the published [study](#) reports results from an international clinical trial, there was no mention of cost or context of the results seen by researchers. The release did mention that the results found in the UK needed to be confirmed in a second trial before any specific recommendation is made to incorporate testing for this new genetic marker.



WHY THIS MATTERS

Prematurely announcing a new genetic marker to be used in determining treatment courses for breast cancer patients is confusing for patients.

CRITERIA

[Does the news release adequately discuss the costs of the intervention?](#)

✘ Not Satisfactory

There was no mention of the cost of the proposed genetic testing for MAF amplification (MAF is a gene expressed in certain cancers and used as a biomarker for bone metastasis) nor any mention of the cost of treatment with a bisphosphonate. Treatment with a bisphosphonate is often recommended for 5 years so this cost should be included.

As is the case with many new genetic tests when they become available, there’s a lag between when a test is approved and when insurance will actually cover the cost.

[Does the news release adequately quantify the benefits of the treatment/test/product/procedure?](#)

✘ Not Satisfactory

The news release did not provide numerical context for the specific benefits of having the MAF amplification genetic testing nor of taking a bisphosphonate drug. All readers, but especially those diagnosed with breast cancer, deserve to know specific benefits of testing and treatment. General statements such as "...could benefit thousands of breast cancer patients..." and "...can help prevent the disease from spreading to the bone" do not inform decisions.

The published study used invasive disease-free survival as the outcome. "Disease-free survival" is a surrogate or proxy for overall survival – which is the outcome that patients care about most. To learn more see our toolkit page on the use of [surrogate markers](#) in clinical trials.

Finally, readers should have been provided some context as to what extent the researchers found positive outcomes.

[Does the news release adequately explain/quantify the harms of the intervention?](#)

✗ Not Satisfactory

The release does not mention any of the possible side effects of taking a bisphosphonate. For some women, those side effects are significant and thus they should be included.

Additionally, we're wondering how the genetic test is performed since there was no description offered. Is it a blood test or is it more invasive, complex and risky, requiring acquisition of tumor tissue?

[Does the news release seem to grasp the quality of the evidence?](#)

✗ Not Satisfactory

While readers are told the study was part of a phase 3 clinical trial that involved 3,360 women with stage II or III breast cancer, the news release does not explain that this part of the study included only 865 of the women in the broader trial. No specific information was provided about other characteristics of the patients who may have benefited from taking bisphosphonates beyond the quote from a study leader, Professor Robert Coleman, who noted that "It only seems to be effective in some patients, particularly older women..." The release should have pointed out that the treatment seems most effective in postmenopausal women.

In addition, the study results were mixed when taking into account menopausal status.

[Does the news release commit disease-mongering?](#)

✓ Satisfactory

There was no disease mongering and as the study co-author, Professor Roger Gomis, observed the current study could help clinicians "...avoid unnecessary treatment of patients who would not benefit or could be harmed by the treatment."

[Does the news release identify funding sources & disclose conflicts of interest?](#)

✗ Not Satisfactory

The release didn't note any funding sources. The published study stated that the study was funded by Novartis, which makes the bisphosphonate drug Zometa, and by Inbiomotion which developed the MAFTest that tests for amplification of the MAF gene. (The release does mention that the test was developed by Inbiomotion.)

Clearly, both companies would benefit from positive study results and positive news coverage and thus must be mentioned in the news release as funders of the study in the interest of transparency.

[Does the news release compare the new approach with existing alternatives?](#)

✗ Not Satisfactory

The release doesn't name any alternatives for preventing metastasis in women with breast cancer. It would have been helpful to note in the news release that the drug was given in addition to "standard adjuvant systemic therapy," according to the journal article, which presumably would include chemotherapy and hormone therapy.

[Does the news release establish the availability of the treatment/test/product/procedure?](#)

✓ Satisfactory

The release states that "The results need to be confirmed in a second trial, currently underway in the United States, before the test is likely to receive approval for wider use in patients." A direct statement that the test is not yet available anywhere would have been more helpful to readers but the quote does let readers know that the test is part of another trial and has not yet been approved.

[Does the news release establish the true novelty of the approach?](#)

✓ Satisfactory

The news release claims novelty with the statement that this is "...a potential new genetic test." It would be more clear to readers if they were told whether there are existing tests for MAF amplification or whether this is the first test available to determine MAF amplification. It's not completely clear to us that the test is novel or a new application of an already available tool, but we'll give the benefit of the doubt here and rate it Satisfactory.

[Does the news release include unjustifiable, sensational language, including in the quotes of researchers?](#)

✓ Satisfactory

There is no unjustifiable language.

Total Score: 4 of 10 Satisfactory
