

Randomized trial on PET/CT imaging requires adequate follow-up

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TO THE EDITOR: With great interest we read the article by Lebech et al. (1) on diagnostic imaging in patients with non-specific symptoms or signs of cancer, and commend the authors for using a randomized controlled design to compare positron emission tomography/computed tomography (PET/CT) with CT imaging. However, the study appears to have examined a self-fulfilling prophecy, because PET/CT was evidently scrutinized less rigorously than CT.

Test accuracy was determined by comparing initial diagnostic test results (from either PET/CT or CT) with the final diagnosis, which was “based on a clinical approach using data obtained from all examinations”. The acceptance of the final diagnosis as the reference standard may have led to bias, because patients received different additional diagnostic tests depending on the group they had been randomized to. On average, patients with suspected cancer after initial PET/CT underwent 1.4 tests, while patients in the CT group underwent 1.6 tests; however, the authors fail to present similar data on those patients in whom cancer was not suspected after initial imaging. Due to an overly optimistic trust in PET/CT, additional diagnostic measures might have been applied less frequently or less stringently in this group. In the worst scenario, a negative scan result was accepted as a true-negative result, without any further testing. A systematic follow-up after discharge would have been meaningful in order to verify that test-negative patients were truly free from disease.

In addition, randomized controlled trials on diagnostic imaging should examine patient-relevant outcomes rather than test accuracy measures, because the latter can also be analyzed in non-randomized cohort studies, where each patient undergoes both imaging procedures. It is a promising finding that in the present trial, test accuracy was higher in the PET/CT group. But this finding is only useful if this advantage was not offset by false-negative results caused by an incomplete diagnostic work-up. It would also have been important to examine whether the patients’ fear of cancer decreased or their quality of life increased through better imaging. Furthermore, side effects caused directly by diagnostic testing or indirectly by inadequate treatment should have been recorded and reported. Finally, the study is not registered in a WHO-certified study registry, even though study registration has been an established research standard for many years (2) – without a pre-specified primary outcome measure, the results have to be regarded as explorative.

In conclusion, we recommend that the authors follow all patients for some months to make sure that the negative results observed were truly negative. Until further information is available, the authors’ statement that “PET/CT is superior to CT” appears to be far too optimistic and requires confirmation by further, more robust trials.

REFERENCES

1. Lebech AM, Gaardsting A, Loft A, et al. Whole body 18F-FDG PET/CT is superior to CT as first line diagnostic imaging in patients referred with serious non-specific symptoms or signs of cancer: a randomized prospective study of 200 patients. *J Nucl Med*. 2017; published online ahead of print.

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