

Benefit of PET or PET/CT in recurrent bowel cancer is not proven

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For patients in whom a recurrence of bowel cancer is suspected, the study data currently available allow no robust conclusions as to the advantages and disadvantages of using positron emission tomography (PET), alone or in combination with computed tomography (CT). This is because no studies have directly compared the benefits of these imaging techniques in recurrent colorectal carcinoma (bowel cancer) with conventional diagnostic techniques. Although PET or PET/CT show a higher diagnostic accuracy, i.e. in certain cases recurrences can be detected more reliably, it is still unclear how this actually affects patient-relevant outcomes such as quality of life. This is the conclusion of the final report of the German Institute for Quality and Efficiency in Health Care (IQWiG) published on 24th October 2012.

More reliable diagnosis ought to improve treatment

[Bowel cancer](#) is the second most common [malignant tumour](#) in both men and women. Every year, more than 65,000 people are diagnosed with the disease in Germany and more than 25,000 die from it annually. About 80% of the recurrences occur in the first two years after surgery for bowel cancer. After 5 years, virtually no more recurrences are found. These can arise at the original site - the bowel - or as secondary tumours ("metastases"), for example in the liver. Follow-up after surgery should therefore last for 5 years.

Many experts hope that when a recurrence is suspected, an examination

using PET or PET/CT alone or in combination with other methods is better able to distinguish between benign and malignant tumours (recurrence diagnostics) and, if applicable, to classify the stage of the latter correctly, i.e. to determine how advanced the cancer is (recurrence staging). This information should enable patients to be given better [treatment recommendations](#).

Benefits for patients crucial

IQWiG therefore searched the international literature for studies which had examined the consequences of a diagnostic intervention using PET or PET/CT on health aspects of direct relevance to patients. For example, the results of the diagnostic investigation - and appropriately tailored treatment - could contribute to better chances of survival for patients, spare them unnecessary operations or further diagnostic interventions, or improve their quality of life.

As requested by the contracting agency, the Federal Joint Committee (G-BA), this report was to focus on those patients in whom a recurrence had already been detected or in whom there was at least a justified suspicion thereof.

The only benefit study proved to be unsuitable

In its final assessment IQWiG was unable to include any studies that had investigated benefits of relevance to patients. For the preliminary report, i.e. the preliminary results, IQWiG had evaluated one study. This addressed the question as to whether, in patients in whom potentially operable [liver](#) metastases were suspected, unnecessary laparotomies (surgical opening of the abdomen) could be avoided if a PET investigation took place following a diagnostic intervention using contrast-medium-enhanced CT.

As IQWiG has since discovered after requesting information from authors, this study was, however, unsuitable for deriving any conclusions regarding benefit. This was because - in contrast to the original plan - the decision to operate or not was not allowed to be made in dependence upon the PET results. The independent advisory committee had advised against this procedure on ethical grounds. But information on this important change in the conduct of the study was provided neither in the publication of the study results nor by entry in a clinical trials registry.

In certain cases, PET/CT can detect recurrences more reliably

For the preliminary report, IQWiG had already made an additional search for studies in which the diagnostic accuracy and prognostic power of PET or PET/CT had been compared with other [diagnostic techniques](#). This referred to the question as to how often a PET investigation provides a correct result. On the one hand, true malignant tumours should be overlooked as rarely as possible, while on the other, false suspicions should not be aroused.

The results of a total of 5 evidence syntheses and 13 individual studies regarding this question could be evaluated. The conclusion on recurrence detection was as follows: PET and PET/CT appear capable of detecting or excluding recurrences more reliably than a conventional diagnostic intervention consisting solely or predominantly of CT. This applies particularly to local recurrences and distant [metastases](#). It is not possible to state with certainty whether PET and PET/CT differ in terms of their [diagnostic accuracy](#).

Further study results needed

Important questions in relation to PET technology remain unanswered.

For example, it has not yet been examined whether the higher accuracy of PET or PET/CT has a positive effect on mortality, the burden of disease or [quality of life](#).

As long as this deficiency remains, a patient-relevant benefit of PET or of PET/CT as a supplementation to a suspicion-driven diagnostic investigation with conventional methods is not proven. For instance, it is particularly doubtful whether a [recurrence](#) detected by using PET or PET/CT can actually be better treated and thereby produce a perceptible advantage for patients. Experts are therefore eagerly awaiting the results of a Canadian study with more than 400 patients, which is to be published shortly.

Missing information can lead to false conclusions

Stefan Lange, the Deputy Director of IQWiG, commented on the new information gained by IQWiG during the assessment procedure of the study on laparotomies: "The fact that the only benefit study on PET turned out to be unsuitable is extremely regrettable. The rupture of the logical link between diagnosis and treatment devalued the study results." As Lange explained, a basic principle of medicine is that a diagnostic intervention is only of benefit if it enables patients to receive more tailored treatment. The fact that the study authors (Ruers et al., 2009 / Nijmegen University, The Netherlands) had also failed to inform about a fundamental change in their procedure was unacceptable. As Lange stated, because of this there is a danger that researchers, doctors and patients will draw the wrong conclusions.

Procedure of report production

IQWiG published the preliminary results in the form of the preliminary report in September 2011 and interested parties were invited to submit

comments. At the end of the commenting procedure, which included an oral scientific debate including parties who had submitted comments, the preliminary report was revised and sent as a final report to the contracting agency, the Federal Joint Committee (G-BA), in August 2012. The written comments were published in a separate document at the same time as the final report. The report was produced in collaboration with external experts.

Provided by Institute for Quality and Efficiency in Health Care

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