Benefit of PET in patients with head and neck tumors cannot be assessed

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The benefit and harm of positron emission tomography (PET) in patients with head and neck tumours, applied alone or in combination with computed tomography (CT), cannot currently be reliably assessed. This is the result of a final report published by the German Institute for Quality and Efficiency in Health Care (IQWiG). The Institute was commissioned by the Federal Joint Committee (G-BA) to assess the advantages and disadvantages of this diagnostic method. However, as the authors of the report explain, suitable studies for this purpose are lacking.

Tobacco and alcohol are important risk factors

Various types of cancer are summarized under the term "head and neck tumours". Among others, these are malignant tumours of the oral cavity (lips, tongue etc.), the pharynx, the larynx, the nose and paranasal sinuses, as well as the outer neck. In Germany about 20,000 people per year develop a malignant head and neck tumour. Men are affected about three times more often than women. In German men, cancer of the oral cavity and pharynx is the seventh most common type of cancer. The consumption of tobacco and alcohol are important risk factors. Prospects of cure vary, depending on the localization of the cancer. For example, the 5-year survival rate in patients with lip tumours is over 90%, whereas in those with pharyngeal tumours the rate is only 30-40%.

PET makes increased metabolic activity visible

By using PET, doctors hope to improve the diagnosis of tumours and the determination of exact tumour expansion. Treatment (e.g. of metastases) could then be targeted more accurately than after the application of other diagnostic techniques. Conventional imaging methods such as computed tomography (CT) show the structure and location of healthy and abnormal tissue. Beyond this, PET can measure metabolic activity in the tissue. The PET image indicates areas of increased metabolic activity in the body by means of a weak radioactive substance. However, such changes can have many other causes; for example, metabolic activity is also increased if tissue is inflamed.

With so-called integrated devices (PET/CT) the patient undergoes a CT and PET in one investigation in which he or she is transported through a tube that includes both systems (two detector ring systems). The images produced are fused together in a computer.

Only consequences tangible for the patient are classified as a benefit

As, from a medical point of view, an additional test is only meaningful if it leads to an improvement in treatment, IQWiG primarily assessed whether the potentially greater diagnostic accuracy of PET or PET/CT also has an impact on the success of treatment for a head and neck tumour. In this context, events that had tangible consequences for patients were classified as having a benefit. For example, a benefit exists if mortality rates are lower, patients experience fewer recurrences or have a higher quality of life, or PET better supports decision-making on the choice of correct treatment than do other diagnostic techniques.

In the benefit assessment IQWiG considered studies with or without random allocation of study participants to treatment groups (randomization). However, they identified only one study directly

investigating the benefit of PET. This study included a small number of participants and, due to methodological deficits, was susceptible to bias.

Benefit neither proven nor refuted

In a direct comparison, this study investigated a diagnostic-therapeutic strategy with and without PET. However, for the primary outcome of this study (2-year recurrence-free survival) no difference between groups could be demonstrated. However, the number of participants (102) and recurrences experienced (6 with PET and 4 without PET) was very small. On the basis of these study results, a patient-relevant benefit of PET can neither be proven nor refuted.

No proven advantages of PET for diagnostic accuracy

The second research question of the report was whether by means of PET or PET/CT it can be determined more reliably than with conventional diagnostic techniques what stage the tumour has reached ("staging"), whether it responds to treatment and can ultimately be treated successfully, as well as whether the disease (in the case of justified suspicion) has actually reappeared ("recurrence"). It was also investigated whether by means of PET or PET/CT the tumour search is improved in patients with an unknown primary tumour. These are patients with head and neck metastases, the origin of which is unknown.

These questions are summarized under the term "diagnostic accuracy", which is the ability of a test to distinguish correctly between sick and healthy patients. However, studies that only investigate diagnostic accuracy do not allow conclusions about the benefit for patients. This is because greater diagnostic accuracy does not automatically lead to the choice of a more targeted therapy or to an increase in quality of life or a decrease in mortality rates.

A larger number of studies were available on this topic; however, their informative value was shown to be greatly limited. This is due to the fact that, on the one hand, the number of participants per study was low and, on the other, the studies were planned or conducted in such way that bias could not be excluded or was even probable.

Overall, in the comparison of PET with CT, no technology was superior to another. PET identifies new tumours relatively accurately, but also is often the cause of false alarms. However, here too the results were ultimately of insufficient informative value.

Researchers call for further studies

In view of this unsatisfying evidence base, overall the authors of the report see a substantial need for improvement in the planning, conduct and reporting of diagnostic studies. They also call for additional studies. This is because PET may have advantages, especially in the diagnosis of recurrences and unknown primary tumours.

However, this would urgently demand further investigation, primarily requiring studies that directly compare PET/CT with the current diagnostic standard (e.g. CT or MRT). Even if PET/CT showed higher diagnostic accuracy here, it would still need to be proved that patients have a tangible benefit from the more reliable diagnosis, for example by surviving longer or having a better quality of life. Such proof can in principle only be provided by means of randomized controlled trials.

Provided by Institute for Quality and Efficiency in Health Care

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