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Title [Diagnostic accuracy and clinical utility of PET/CT amyloid in mild cognitive impairment]

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Aim

The main objectives of this report are to evaluate the effectiveness and safety of amyloid cerebral PET in the diagnosis of cognitive impairment, Alzheimer's disease or other dementias, as well as its impact on the diagnostic and therapeutic management of these patients.

Conclusions and results

According to the literature reviewed, there is great variability in the diagnostic accuracy and clinical usefulness of amyloid PET.

Three systematic Cochrane reviews that evaluated the effectiveness of each of the amyloid radiopharmaceuticals (florbetaben, florbetapir and flutemetamol) in the diagnosis of the progression of MCI to AD or other dementias, and two systematic reviews with meta-analysis that evaluated the diagnostic validity of the three radiopharmaceuticals in the detection of AD were included. By updating one of the meta-analyses, 12 primary studies, 8 diagnostic test studies and 4 on the influence of amyloid PET on the clinical management of patients with dementia were identified. In addition, by carrying out complementary searches, we located two cost-effectiveness studies, 4 qualitative studies on the perspectives of patients, relatives/caregivers or clinicians and 4 consensus papers on ethical issues. The percentage of false positives and false negatives was highly variable (11-34.3% and 8-58% respectively). Two studies in which flutemetamol and florbetapir were used did not report any cases of false positives or negatives. The sensitivity (S) and specificity (E) of amyloid PET in the progression from MCI to AD or other dementias was around 50-100% and 50-88% respectively, while poor results were described for the progression from MCI to other non-AD dementias (S=0% and E=38-40%) (florbetapir only). As regards the diagnostic validity of amyloid PET in AD, highly variable results were also described (S=60-100% and E=52-100%). The percentage of patients who experienced modification in diagnosis and medical/therapeutic management after performing amyloid PET was very variable (11-92%), with differences between the group of patients who obtained a positive or negative PET result. The economic and organisational impact of amyloid PET does not seem to be relevant; it is a cost-effective technique and its implementation in clinical practice should not imply a high impact. The literature states that most patients wish to know the outcome of PET in order to plan their future. From an ethical point of view, adequate informed consent should be given prior to testing, and the communication of results should be ruled out by the bioethical principles of autonomy, no maleficence and benefit.

Recommendations

Following the recommendations described in the main expert consensus, this technique should be used in a small group of patients with clinically confirmed MCI with the aim of increasing diagnostic certainty or modifying the clinical management of the patient. In addition, special attention should be paid to the indication process of the test to be performed by appropriate informed consent, as well as the communication of PET results.

Methods

Specific search strategies were designed to identify studies that assess the safety and/or effectiveness of amyloid PET in the diagnosis of MCI, AD or other dementias, its economic and organizational impact, patient acceptability and satisfaction, and ethical, social and legal aspects derived from its use. These strategies were performed in March 2018 in the main medical literature databases. A qualitative synthesis of the evidence was performed using the GRADE system, for which 12 outcomes were selected, classified by clinicians as important or critical, except for two, which were considered of low importance and therefore eliminated from the analysis (complications derived from the use of radiopharmaceuticals and mortality). In order to evaluate the risk of bias of the studies, specific tools were used according to the type of study. The quality of evidence was evaluated using the GRADE system for quantitative studies and the GRADE-CERQual version was used for qualitative studies. Both the extraction of data from the studies and the synthesis and evaluation of the evidence were carried out by two researchers independently and blindly.

Further research/reviews required

It will be necessary to perform new clinical research aimed to assess the diagnostic utility and cost-effectiveness of amyloid PET in comparison to other imaging or cerebrospinal fluid biomarkers in Alzheimer’s disease.

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