Pilot study of the links between presbyacusis and lexical disorders in patients with Alzheimer's disease or related disease (LOOP)

1. Justification / context

In France, Alzheimer's disease accounts for 70 to 80% of the causes of neurocognitive disorders, i.e. 600,000 to 800,000 patients. It is a neurodegenerative pathology that causes evolutionary cognitive dysfunction, mainly affecting memory functions. The inability to name familiar objects (lack of the word) is one of the most commonly noted symptoms at an early stage of the disease.
Presbyacusis, or age-related hearing loss, is the most common sensory deficit in the elderly which is manifested socially by a progressive discomfort of verbal communication. Presbyacusis remains underdiagnosed and undertreated: 2/3 of the patients are not using hearing aid.
In recent years, a link between neurocognitive disorders and hearing loss has been shown by investigating general cognition. In this study, we are investigating lexical disorders.

2. Objectives

2.1. Main objective

To determine the relationship between word loss and presbycusis suspected or proven in patients with Alzheimer's disease or related disorders.

2.2. Secondary objective

Study variables associated with word loss in patients with Alzheimer's disease or related disorders.

3. Outcome measures

3.1. Primary outcome measure

The lack of word score (BIMM questionnaire) according to the score at the hearing questionnaire.

3.2. Secondary outcome measure

Age, gender, socio-cultural level, accommodation, laterality, main diagnosis, hearing aid, speech language therapy according to lack of word score.

4. Outline of the research

Monocentric study on a series of cases.

5. Eligibility criteria

5.1. Inclusion criteria

- > 65 years old
- French mother tongue
- Good vision with or without correction
- Alzheimer's or related disease (15 <Mini-Mental State Examination<25)
- Affiliate or beneficiary of a social security
- Informed consent

5.2. Exclusion criteria

- Cognitive disorders related to another pathology (cerebrovascular accident, head trauma, epilepsy ...)
- Protected patient (under guardianship) or person deprived of liberty by judicial or administrative decision

6. Feasibility and recruitment procedures

Recruitment will take place in the various departments of the Centre de Soins pour Personnes Agées (CSPA): geriatric day hospital, long-term care units, follow-up care and rehabilitation units.

7. Research procedures

7.1. Consent

During the inclusion visit, the doctor, neuropsychologist or speech-language pathologist informs the participant and answers all questions about the objective, the nature of the constraints, and the expected benefits of the research. It also specifies the participant's rights in a research project and checks the eligibility criteria. The patient gives his or her consent orally or in writing, which is documented in the medical file.

7.2. Conducting the visit

Study participants will benefit from an additional speech therapy consultation of approximately one hour. During this visit, they will pass the lack of word questionnaire (BIMM noun and verb naming tests) and complete the hearing questionnaire.

7.3. Rules for stopping a person from participating in the research

At any time, if desired, the patient may withdraw from the study. He will continue to receive the best possible medical care.
Discontinuations from research will be patients for whom evaluations have not been completed. These patients will not be replaced.

8. Study size

Expected new entries are of 10 patients per month at the Centre de Soins pour Personnes Agées. The recruitment potential is 50 patients over the duration of the study.
Taking into account possible refusals to participate, patient availability and service organization, we plan to enroll 45 patients.

9. Duration

- Duration of the inclusion period: 5 months
- Participation duration of each participant: 1 hour
- Total duration of the research: 5 months

10. Statistical aspects

The parameters collected will be presented in tables with descriptive statistics for the entire study population and sub-populations (patients with hearing impairment and patients without hearing impairment).

The correlation study between the overall score obtained at the lack of word questionnaire and the score obtained at the hearing questionnaire will be presented in a scatter plot and the Pearson correlation coefficient will be calculated.

The study of the relationship between factors and word deficiency in patients with Alzheimer's disease or related disorders will be carried out by bivariate analysis and then by logistic regression.

11. Monitoring of the research

11.1. Access to data

Acceptance of participation in the protocol implies that carers will make available the documents and individual data strictly necessary for the monitoring, quality control and audit of the research, to persons having access to these documents in accordance with the laws and regulations in force.

11.2. Source data

All information contained in original documents, or in authenticated copies of these documents, relating to clinical examinations, observations or other activities conducted as part of a research study and necessary for the reconstitution and evaluation of the research. The documents in which the source data are saved are called the source documents.
The data that will be entered directly into the case report form and that will not have any source data as a result are all the scores and reaction times obtained in the lack of word and hearing questionnaires.

11.3. Data confidentiality

In accordance with the legislative provisions in force, persons having direct access to source data will take all the necessary precautions to ensure the confidentiality of information relating to investigational medicinal products, research, participants, especially as regards their identity and the results obtained. These people, like the investigators, are subject to professional secrecy.

During or at the end of the research, the data collected on the participants and sent to the sponsor by the investigators (or any other specialised contributor) will made anonymous. The data must never explicitly mention the names of the persons concerned or their addresses.

12. Expected benefits

If this study does show a link between presbycusis and lexical disorders in patients with Alzheimer's disease or related disorders, a new study will be required in a larger, multicentre population to confirm the results.

Prevention and management of patients with Alzheimer's disease or related disorders could be improved. Indeed, systematic screening for hearing disorders could be considered as soon as Alzheimer's or related diseases are suspected. In addition, in these patients, speech and language therapy management may evolve to include two areas: management of language and memory disorders, and management of hearing disorders.