DEPARTMENT OF DEFENSE
HEARING CENTER OF EXCELLENCE

PIHL ANIMAL MODEL NEWSLETTER

2014/NUMBER 1

http://hearing.health.mil/EducationAdvocacy/Newsletters.aspx

A NEW RESOURCE FOR WORK IN NOISE-INDUCED HEARING LOSS

One of the new developments in research on noise-induced hearing loss (NIHL) are regular conference calls among investigators organized by the Hearing Center of Excellence at the Department of Defense. This newsletter is distilled from regular "chats" of a subgroup focused on animal NIHL models. The purpose of this periodic newsletter is to provide updated highlights emphasizing recent publications, funding opportunities and clinical trials. Pharmacotherapy studies in animals, as well as particularly noteworthy basic NIHL studies in animal models, will be reviewed every three months.

Among publications appearing between October 2013 and December 2013, two focused on possible protection against NIHL through reduction of oxidative stress. Claussen et al. (2013) applied five intraperitoneal doses of D-methionine to chinchillas at 200 mg/kg/dose beginning up to three days prior to noise exposure. Although no significant protection was observed for acute threshold shifts (measured one day post-exposure), permanent threshold shifts (PTS; 21 days post-exposure) were reduced. Significant protection of outer hair cells (OHCs) was also observed. Choi et al. (2013) applied a combination of oral 4-hydroxy alpha-phenyl-tert-butylnitrone and N-acetyl-L-cysteine in

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chinchillas four hours after noise exposure, and twice daily for the next two days. Permanent changes in ABR thresholds, distortion products, and hair cell loss were all remediated in a dose-dependent manner. Oral administration is the most-common clinical route of drug delivery; thus, this study utilized a more clinically relevant paradigm. Another study (Wen et al., 2013) tested the protective effects of intravenous dexmedetomidine against NIHL in guinea pigs. Dexemdetomide is an a2 adrenoreceptor agonist. Simultaneous monitoring of cochlear and systemic blood flow along with hearing function showed protection that coincided with preservation of cochlear blood flow. The range of effective doses was limited by potentially problematic systemic reduction of blood pressure.

In addition to these pre-clinical studies, one additional paper (Hickox and Liberman, 2013) is noteworthy for its implications regarding the locus of noise injury that may give rise to tinnitus and/or hyperacusis. Using modest ('sub-clinical') noise in combination with acoustic startle responses in mice, the authors show that changes in the magnitude of ABR wave I are a better predictor of startle behavior suggestive of tinnitus/hyperacusis than are changes in ABR threshold. Although tinnitus/hyperacusis clearly reflect central auditory events, these findings potentially place their initial causal events in the cochlea, and specifically in the kind of synaptopathy that has recently been emphasized by Kujawa and Liberman (2006, 2009).

Jianxin Bao, Ph.D. & Kevin Ohlemiller, Ph.D. - Washington University in St. Louis

RESEARCH HIGHLIGHTS

D-methionine pre-loading reduces both noise-induced permanent threshold shift and outer hair cell loss in the chinchilla.
Int J Audiol. 2013 Dec;52(12):801-7. doi: 10.3109/14992027.2013.840933. Epub 2013 Oct 31.
PubMed PMID: 24175619.

Claussen AD, Fox DJ, Yu XC, Meech RP, Verhulst SJ, Hargrove TL, Campbell KC.
Department of Surgery, Southern Illinois University School of Medicine, Springfield, USA.

OBJECTIVE: This study tested multiple dosing epochs of pre-loaded D-methionine (D-met) for otoprotection from noise-induced hearing loss (NIHL).
DESIGN: Auditory brainstem response (ABR) thresholds were measured at baseline, 1 day, and 21 days following a 6-hour 105 dB sound pressure level (SPL) octave band nosie (OBN) exposure. Outer hair cell (OHC) counts were measured after day 21 sacrifice.
STUDY SAMPLE: Three groups of five Chinchillas laniger each were given a 2-day regimen comprising five doses of D-met (200 mg/kg/dose) intraperitoneally (IP) starting 2, 2.5, or 3 days prior to noise exposure. A control group (n = 5) received five doses of equivalent volume saline IP starting 2.5 days prior to noise exposure.
RESULTS: ABR threshold shifts from baseline to day-21 post-noise exposure were reduced in all D-met groups versus controls, reaching significance ($p < 0.05$) in the 3-day group. D-met groups showed reduced OHC loss relative to controls at day-21 post-noise exposure, reaching

significance ($p < 0.05$) at all frequency regions in the 3-day group and at the 2, 4, and 8 kHz frequency regions in the 2.5-day group.
CONCLUSIONS: D-met administration in advance of noise-exposure, without further administration, significantly protects from noise-induced ABR threshold shift and OHC loss.

Therapeutic effects of orally administrated antioxidant drugs on acute noise-induced hearing loss.
Free Radic Res. 2013 Nov 28. [Epub ahead of print] PubMed PMID: 24182331.

Choi CH, Du X, Floyd RA, Kopke RD.
Department of Otolaryngology-Head and Neck Surgery, University of Texas Health Science Center at San Antonio, San Antonio, TX; and Department of Audiology and Communication Sciences, Washington University School of Medicine, St. Louis, MO.

OBJECTIVE: The objective of this study was to investigate the dose-dependent therapeutic effect of the orally administrated antioxidant drugs [4-hydroxy alpha-phenyl-tert-butylnitrone (4-OHPBN) and N-acetyl-L-cysteine (NAC)] on acute noise-induced hearing loss because oral administration is the most commonly used method of drug administration due to its convenience, safety, and economical efficiency.
METHODS: Thirty chinchilla were exposed to a 105 dB octave band noise centered at 4 kHz for 6 h and randomly assigned to a control group (saline only) and three experimental groups [4-OHPBN (10 mg/kg) plus NAC (20 mg/kg), 4-OHPBN (20 mg/kg) plus NAC (50 mg/kg), and 4-OHPBN (50 mg/kg) plus NAC (100 mg/kg)]. The drugs were orally administrated beginning 4 h after noise exposure and then administered twice daily for the next 2 days. Permanent auditory brainstem response threshold shifts, distortion product otoacoustic emission threshold shifts, and the percentage of missing outer hair cell were determined.
RESULTS: The oral administration significantly reduced permanent hearing threshold shift, distortion product otoacoustic emission threshold shift, and the percentage of missing outer hair cell in a dose-dependent manner.
DISCUSSION: This result demonstrates that orally administered drugs can treat acute noise-induced hearing loss in a dose-dependent manner. This suggests that oral administration was effective in treating acute noise-induced hearing loss as in intraperitoneal administration.

Is noise-induced cochlear neuropathy key to the generation of hyperacusis or tinnitus?
J Neurophysiol. 2013 Nov 6. [Epub ahead of print] PubMed PMID: 24198321.

Hickox AE, Liberman MC.
Purdue University.

Perceptual abnormalities such as hyperacusis and tinnitus often occur following acoustic overexposure. Although such exposure can also result in permanent threshold elevation, some individuals with noise-induced hyperacusis or tinnitus show clinically normal thresholds. Recent work in animals has shown that a "neuropathic" noise exposure can cause immediate, permanent degeneration of the cochlear nerve despite complete threshold recovery and lack of hair cell damage (Kujawa and Liberman, 2009; Lin et al., 2011). Here, we ask whether this

noise-induced primary neuronal degeneration results in abnormal auditory behavior, based on the acoustic startle response (ASR) and prepulse inhibition (PPI) of startle. Responses were measured in mice exposed either to a "neuropathic" noise or to a lower intensity, "non-neuropathic" noise, and in unexposed controls. Mice with cochlear neuropathy displayed hyper-responsivity to sound, evidenced by enhanced ASR and PPI, while exposed mice without neuronal loss showed control-like responses. Gap PPI tests, often used to assess tinnitus, revealed limited gap detection deficits in mice with cochlear neuropathy only for certain gap-startle latencies, inconsistent with the presence of tinnitus "filling in the gap". Despite significantly reduced wave 1 of the auditory brainstem response, representing cochlear nerve activity, later peaks were unchanged or enhanced, suggesting compensatory neural hyperactivity in the auditory brainstem. Considering the rapid post-exposure onset of both cochlear neuropathy and exaggerated startle-based behavior, the results suggest a role for cochlear primary neuronal degeneration, per se, in the central neural excitability that could underlie the generation of hyperacusis.

Protective effect of dexmedetomidine on noise-induced hearing loss.
Laryngoscope. 2013 Oct 1. doi: 10.1002/lary.24425. [Epub ahead of print] PubMed PMID: 24114834.

Wen J, Xiao Y, Bai YX, Xu M.
Department of Anesthesiology, The First Affiliated Hospital of Medical College of Xi'an Jiaotong University, Xi'an, China.

PURPOSE: Noise generated by instruments, such as mastoid or craniotomy drills, may cause hearing damage by reducing the cochlear blood flow (CoBF). This study investigated whether dexmedetomidine can lessen noise-induced hearing loss (NIHL) in a guinea pig model.
STUDY DESIGN: Animal study using noise stimulation and measurement of hearing and CoBF in guinea pigs.
METHODS: Guinea pigs (n = 8 animals/group) were treated by saline vehicle (control group), dexmedetomidine (1, 3, and 10 μg/kg dex groups), saline and noise (noise group), or 3 μg/kg dexmedetomidine and noise (dex+noise group). For noise exposure, octave band noise at 124 dB sound pressure level was administered to animals for 2 h. Blood pressure (BP) and CoBF were monitored continuously. Auditory function was measured by the auditory brain-stem response (ABR) before and 1, 3, 8 h, and 10 d after noise exposure. Plasma norepinephrine (NE) was measured at baseline and 30, 60, 90, and 120 min after noise exposure by high-performance liquid chromatography (HPLC).
RESULTS: Noise exposure caused temporary and permanent hearing damage. Dexmedetomidine concentrations of 1 and 3 μg/kg dose-dependently improved CoBF. Administration of 10 μg/kg dexmedetomidine drastically reduced BP and CoBF. Pretreatment with 3 μg/kg dexmedetomidine alleviated the noise-induced reduction in CoBF and improved hearing function by decreasing the permanent and temporary threshold shifts.
CONCLUSION: Dexmedetomidine displayed protective effects against NIHL in this animal model, suppressing activation of the sympathetic nervous system and improving CoBF. These findings could have clinical relevance and deserve further investigation.

RECENTLY PUBLISHED LITERATURE

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Department of Otolaryngology-Head and Neck Surgery, University of Texas Health Science Center at San Antonio, San Antonio, TX; and Department of Audiology and Communication Sciences, Washington University School of Medicine, St. Louis, MO.

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Institut national de santé publique du Québec; École d'orthophonie et d'audiologie, Université de Montréal; and Département de médecine sociale et préventive, Université Laval, Québec.

Ribbon synapse plasticity in the cochleae of Guinea pigs after noise-induced silent damage.
PLoS One. 2013 Dec 9;8(12):e81566. doi: 10.1371/journal.pone.0081566. PubMed PMID: 24349090; PubMed Central PMCID: PMC3857186.
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Department of Physiology and Pharmacology, Medical College of Southeast University, Nanjing, China; School of Human Communication Disorders, Dalhousie University, Halifax, Canada; Department of Otolaryngology, 6th Affiliated Hospital, Jiaotong University, Shanghai, China; and Department of Physiology and Pharmacology, Medical College of Southeast University, Nanjing, China.
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Tonotopic reorganization and spontaneous firing in inferior colliculus during both short and long recovery periods after noise overexposure.
J Biomed Sci. 2013 Dec 9;20(1):91. doi: 10.1186/1423-0127-20-91. PubMed PMID: 24320109.
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Department of Otolaryngology-Head and Neck Surgery, Chinese PLA General Hospital, Beijing 100853, China. labrat304@gmail.com.

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Weldon School of Biomedical Engineering, Purdue University, 206 South Martin Jischke Drive, West Lafayette, IN 47907, USA.; Department of Speech, Language, and Hearing Sciences, Purdue University, 500 Oval Drive, West Lafayette, IN 47907, USA.; and Weldon School of Biomedical Engineering, Purdue University, 206 South Martin Jischke Drive, West Lafayette, IN 47907, USA; Electronic address: mheinz@purdue.edu.

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Department of Occupational Medicine and Epidemiology, National Institute of Occupational Health, PO Box 8149 Dep, N-0033 Oslo, Norway.
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KU Leuven, Department of Neurosciences, ExpORL , Leuven , Belgium.

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Center for Neurological Studies, Novi, MI, USA.; Department of Radiology, Wayne State University School of Medicine, Detroit, MI, USA.; and Department of Communication Sciences & Disorders, Wayne State University, 207 Rackham, 60 Farnsworth, Detroit, MI 48202, USA. Electronic address: cacacea@wayne.edu.

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Eur Arch Otorhinolaryngol. 2013 Oct 20. [Epub ahead of print] PubMed PMID: 24141521.
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a School of Health and Rehabilitation Sciences , The University of Queensland , Brisbane , Australia.

FUNDING OPPORTUNITIES

Refer to the HCE website (http://hearing.health.mil/Research/FundingInformation.aspx) for additional hearing-related research funding opportunities.

NIDCD Research Grants for Translating Basic Research into Clinical Tools (R01)

Award Organization: National Institutes of Health

Announcement #: PAR-14-009

Date Released: May 23, 2014

Date Closed: May 25, 2014

Web site: http://grants.nih.gov/grants/guide/pa-files/PAR-14-009.html

The NIDCD is encouraging applications which translate basic research findings into clinical tools for better human health in the NIDCD mission areas of hearing, balance, smell, taste, voice, speech and language. The intent of this Funding Opportunity Announcement (FOA) is to provide a new avenue for basic scientists, clinicians and clinical scientists to jointly initiate and conduct translational research projects. The scope of this FOA includes a range of activities to encourage translation of basic research findings which will impact the diagnosis, treatment and prevention of communication disorders. Multi-institutional, multi-disciplinary, and academic-industrial collaborations studies are encouraged. This FOA is not intended for health services/outcome studies, the extension of ongoing clinical research studies, the optimization of current clinical protocols, or pre-translational studies. Connection to the clinical condition must be clearly established and the outcomes of the grant must have practical clinical impact.

CLINICAL TRIALS

Source: www.clinicaltrials.gov (December 2013)

A Simplified Patient-Centered Educational Tool for Improved Hearing-Aid Outcomes
This study is not yet open for participant recruitment.
Study NCT01940705
Information provided by (Responsible Party): Department of Veterans Affairs
Study Start Date: December 2013
First Received on September 9, 2013

Hearing loss is the second most prevalent service-connected disability among Veterans. Hearing aids are the most common technological intervention for hearing loss. The VA, therefore, spends a considerable amount of money on them. Despite these expenditures, there are some Veterans who do not use their hearing aids successfully. Research has demonstrated that this inconsistent use may be related to a patient's inability to effectively take care of, and use, hearing aids. The proposed investigation will compare the effectiveness of three different tools for enhancing the educational efforts (hearing-aid orientation) typically provided by clinical audiologists when dispensing hearing aids. Each of these educational tools were developed using established methods for improving patient-provider communication. We hypothesize that the use of these tools will result in better hearing-aid outcomes for our Veteran patients than using the current standard-of-care procedures.

Observation of Benefits for Patients Implanted With a Hearing Implant of the Company Cochlear (IROS)
This study is currently recruiting participants.
Study NCT02004353
Information provided by (Responsible Party): Cochlear
Study Start Date: July 2011
First Received on November 26, 2013

The purpose of this study is to collect patient related benefit data following treatment for permanent hearing loss with a hearing implant from the company Cochlear over a period of 2 years post treatment. Assessment of benefits is based on standard questionnaires of hearing ability and quality of life in general.

Post-market Clinical Follow-up of a Magnetic Bone Conduction Implant (Cochlear Baha Attract System)
This study is not yet open for participant recruitment.
Study NCT02022085
Information provided by (Responsible Party): Cochlear Bone Anchored Solutions
Study Start Date: February 2014
First Received on September 16, 2013

The rationale behind this post-market clinical follow-up investigation is to collect data regarding the usability and clinical performance of the Baha Attract System in subjects with hearing impairment that are candidates for Baha surgery:

- to evaluate the efficacy of the Baha Attract System in terms of hearing performance compared to the unaided situation and compared to a pre-operative test situation using the sound processor on a Baha Softband;
- to evaluate the mid- and long-term safety of the Baha Attract System.

Community-Based Kiosks for Hearing Screening and Education

This study is enrolling participants by invitation only.
Study NCT01963104
Information provided by (Responsible Party): M. Patrick Feeney, Portland VA Medical Center
Study Start Date: September 2013
First Received on September 12, 2013

The overall goal of the project is to evaluate innovative, cost-effective, community-based automated hearing screening and education methods to motivate individuals with mild-to-moderate hearing loss to enter the hearing healthcare system.

Evaluation of Hearing Preservation in Adults With Partial Low-Frequency Hearing Implanted With the HiFocus™ Mid-Scala Electrode

This study is not yet open for participant recruitment.
Study NCT01959152
Information provided by (Responsible Party): Advanced Bionics
Study Start Date: October 2013
First Received on October 8, 2013

The purpose of this study is to determine the feasibility of preserving low-frequency acoustic hearing in adults with a moderate degree of hearing loss in the low frequencies and severe-to-profound hearing loss in the mid-to-high frequencies who are implanted with the HiRes™ 90K Advantage implant with HiFocus™ Mid-Scala electrode.

Clinical Study of Cochlear Implants in Adults with Asymmetrical Hearing Loss

This study is currently recruiting participants.
Study NCT02004535
Information provided by (Responsible Party): Washington University School of Medicine
Study Start Date: April 2006
First Received on November 26, 2013

The objective of this study is to investigate benefits of binaural hearing for non-traditional cochlear implant candidates (with Asymmetric Hearing Loss). Asymmetric candidates are patients with severe to profound hearing loss in one ear and better hearing in the other ear. (One ear is deaf and the other ear has better hearing and in most cases uses a hearing aid.) The investigators hypothesize that cochlear implantation of the poorer ear provides a functional increase in word and sentence understanding in quiet or noise, perceived benefit, localization

ability, and other measures of auditory performance relative to use of the better hearing ear alone.

Maximizing Language Development in Children With Hearing Loss
This study is currently recruiting participants.
Study NCT01963468
Information provided by (Responsible Party): Megan Roberts, Northwestern University
Study Start Date: October 2013
First Received on October 11, 2013

The purpose of this study is to evaluate the effects of early intervention on language skills for children with hearing loss.

Gamma Knife Radiosurgery vs Initial Conservative Treatment for Vestibular Schwannoma Patients With Preserved Hearing, a Prospective Randomized Study
This study is currently recruiting participants.
Study NCT01938677
Information provided by (Responsible Party): Petter Forander, Karolinska Institutet
Study Start Date: April 2013
First Received on September 5, 2013

The effect of Gamma knife radiosurgery (GKRS) on hearing loss, in patients with vestibular schwannoma (VS) and preserved hearing is still unclear. Retrospective data indicate that the hearing is preserved in most patient years after the gamma knife treatment. Recent prospective data suggests that radiosurgery could be a hearing preserving treatment for these patients. The main objective of this study is to evaluate if GKRS can inhibit progression of hearing loss in patients with VS. Patients with preserved hearing will be offered to participate in the study and randomized ether to GKRS or initial conservative treatment for their vestibular schwannoma. They will then be followed with scheduled magnetic resonance image (MRI) and audiometry and evaluated after one, three and five years after treatment.

Neuromodulation Techniques in the Treatment of Chronic Tinnitus With Hearing Loss
This study has been completed.
Study NCT01944501
Information provided by (Responsible Party): Joaquim Brasil-Neto, University of Brasilia
Study Start Date: March 2012
First Received on September 9, 2013

This study aimed at trying transcranial magnetic stimulation and transcranial direct current stimulation as potential treatments to decrease tinnitus in patients with significant hearing loss.

Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans
This study is not yet open for participant recruitment.
Study NCT02019888

Information provided by (Responsible Party): Department of Veterans Affairs
Study Start Date: March 2014
First Received on December 18, 2013

The accurate assessment of auditory status is critical for planning treatment for Veterans with hearing loss to include medical and audiological management. Current physiologic tests of auditory function in the standard clinical audiological test battery for Veterans have limited sensitivity in detecting some middle-ear disorders, and do not include a direct test of cochlear function. Recent studies have shown promise for new wide-bandwidth (WB) tests of absorbance for improved sensitivity in the assessment of middle-ear function including acoustic reflex testing. The addition of WB tests of cochlear function included in the WB test battery provides an opportunity to improve audiological diagnosis of a range of hearing disorders in Veterans. The automation provided by the WB test battery could provide additional benefits in reducing the duration of the evaluation, leaving more time for evaluation of test findings and counseling. Results from this study may lead to the improvement of audiological care for Veterans with hearing loss.

Congenital Cytomegalovirus: Efficacy of Antiviral Treatment (CONCERT 2)
This study is currently recruiting participants.
Study NCT02005822
Information provided by (Responsible Party): Dr. Ann C.T.M. Vossen, Leiden University
Study Start Date: October 2013
First Received on December 4, 2013

The objective of the trial is to investigate whether early treatment with oral valganciclovir of infants with both congenital cytomegalovirus infection and sensorineural hearing loss can prevent progression of hearing loss.

Montelukast for Children With Chronic Otitis Media With Effusion (COME): A Double-blind, Placebo-controlled Study
This study is not yet open for participant recruitment.
Study NCT01967498
Information provided by (Responsible Party): Tel-Aviv Sourasky Medical Center
Study Start Date: November 2013
First Received on October 17, 2013

The purpose of our double-blind, placebo controlled study is to test the hypothesis that montelukast therapy might be associated with improved hearing in certain sub populations of children suffering from OME.

The Effects of Gevokizumab in Corticosteroid-resistant Subjects With Autoimmune Inner Ear Disease
This study is currently recruiting participants.
Study NCT01950312
Information provided by (Responsible Party): XOMA (US) LLC

Study Start Date: August 2013
First Received on September 20, 2013

The purpose of this study is to determine if gevokizumab therapy may be an alternate therapy in patients with steroid resistant Autoimmune Inner Ear Disease.

Latanoprost for the Treatment of Menière's Disease
This study is currently recruiting participants.
Study NCT01973114
Information provided by (Responsible Party): Synphora AB
Study Start Date: October 2013
First Received on October 17, 2013

The purpose of the study is to evaluate the dose regimen, efficacy and safety of latanoprost for the treatment of Menière's disease.

Clinical and Genetic Examination of Usher Syndrome Patients' Cohort in Europe (EURUSH)
This study is currently recruiting participants.
Study NCT01954953
Information provided by (Responsible Party): Centre Hospitalier National d'Ophtalmologie des Quinze-Vingts
Study Start Date: September 2013
First Received on September 18, 2013

This study aims to characterize Usher patients in order to correlate this data with genetic information.
Tasks:
- Standardization and improvement of Usher syndrome diagnosis: refine and elaborate special tests of visual and otological function in association with genotype that enable to determine the most significant markers for Usher disease progression and therapeutic effect.
- Perform genotype and phenotype correlations in Usher syndrome patients
- Develop and maintain database for phenotypically and genotypically well-characterized patient cohorts, suitable for future therapeutic trials

Mini-Mental State (MMS-LS) and Sign Language
This study is currently recruiting participants.
Study NCT02005679
Information provided by (Responsible Party): Lille Catholic University
Study Start Date: June 2011
First Received on November 22, 2013

In France the prevalence of pre-lingual deafness is between 1 and 1.4 per 1000 habitants, and according to very conservative estimates, about 44 000 deaf persons use the sign language. Additionally, the prevalence of dementia in France is close to 1% (850 000 dements for a total

population of 65 millions). The prevalence of dementia in pre-lingual deaf adults has also been described and is between 1 and 1.4 /100 000 habitants.

The Mini Mental State Examination (MMSE) of Folstein is a test recommended to perform the cognitive evaluation for the detection of mental disorders including dementia, and a consensual French version exists prepared by GRECO (Group of Research and Cognitive Assessments). However, to date, there are no simple, rapid and validated screening tests to study cognitive disorders in deaf persons who use the sign language. The only tests available allow a late diagnosis avoiding an optimal treatment of the patients.

http://hearing.health.mil/EducationAdvocacy/Newsletters.aspx