

VA RR&D Merit Review

Project Title: Comprehensive Ototoxicity Monitoring Program for VA: A Randomized Trial

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Objectives:

The ongoing goal of our ototoxicity monitoring program of research has been to implement an evidence-based, efficacious program into the VA healthcare system. Early detection of ototoxicity provides oncology an opportunity to reconsider the treatment plan before hearing loss becomes handicapping, and to provide aural rehabilitation to reduce the impacts of handicapping hearing loss incurred as a necessary consequence of treatment. Investigators at the NCRAR have developed high-performance high-frequency portable instrumentation, evidence-based, sensitive, and time efficient strategies for monitoring, and model-based tools for use before treatment to predict a patient's risk for ototoxicity, or during treatment of Veterans who become too ill, to provide a reliable hearing test. These advances lay the groundwork for an ototoxicity monitoring program applicable for achieving a range of clinical objectives, and for testing all patients regardless of frailty or ability to reliably take a hearing test using conventional methods

Plan:

The proposed study tests this new approach for guideline-concordant ototoxicity monitoring implemented as a portable, comprehensive program of evidence-based protocols for VA healthcare (Comp-VA program). Research objectives are: to compare the effectiveness of ototoxicity monitoring implemented using Comp-VA and standard of care testing (SOC) with regard to (1) improving Veterans' hearing and quality of life outcomes and use of audiological rehabilitation services and (2) assisting Oncologists in chemotherapeutic planning and counseling. In order to achieve these objectives, we propose a randomized trial conducted at the Portland VA Medical Center. We plan to recruit a total of 320 Veterans undergoing cisplatin chemotherapeutic treatment over 4 years and 120 control subjects

Methods:

Program Evaluation: Hearing testing prior to treatment will be done by an NCRAR research audiologist not associated with the intervention groups in order to establish eligibility, enroll and randomize each subject into one of two study arms. At 5 weeks and at one year post-randomization hearing will be re-tested in order to obtain an estimate of longitudinal trends in hearing and quality of life assessment. Use of audiological services following treatment from the randomized subjects will be tracked. Finally, data will also be collected at each treatment interval to track use of counseling tools and oncology personnel treatment decisions.

Proposed Intervention Groups: Serial measurements from subjects receiving cisplatin prior to treatment who are randomized to the Comp-VA group will be obtained at each treatment interval and at one-month post-treatment. Auditory testing will be done on the Chemo Unit and will include otoscopy, immittance testing, automated air conduction hearing testing, and distortion product otoacoustic emissions (DPOAEs). The SOC group will receive the current standard of care: full audiometric evaluations (otoscopy, immittance testing, air conduction and bone conduction hearing testing, speech audiometry, and DPOAEs) in a sound-treated booth before chemotherapy with any further testing done by oncology request. Additional data will also be collected from control subjects who are similar in age and are tested at intervals similar to the chemotherapy subjects

Relevance to VA mission:

Prevention and rehabilitation of hearing loss and tinnitus, the two most commonly awarded service-connected disabilities, are high priority initiatives in VA. If trends continue, over 4000 Veterans will receive cisplatin this year with up to half sustaining a permanent hearing shift and nearly 40% developing new tinnitus. Since most of these Veterans begin treatment with significant hearing loss, even minor hearing shifts substantially influence communication. This research has the capability of reducing the medical, legal, emotional and socioeconomic consequences of a potentially preventable hearing loss and will ultimately allow Veterans to retain a better post-treatment quality of life following chemotherapy.

MeSH Terms: ototoxicity monitoring, hearing, DPOAE