ANALYSIS OF CLINICAL RECORDS AS A MEANS TO VALIDATE NON-INVASIVE ASSESSMENT OF INTRACRANIAL PRESSURE USING THE CEREBRAL AND COCHLEAR FLUID PRESSURE (CCFP) ANALYZER

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INTRODUCTION

Visual impairment / intracranial pressure (VIIP) is a top risk for human spaceflight, yet there are no reliable means to monitor intracranial pressure (ICP) noninvasively, particularly inflight. A lumbar puncture (LP) procedure is invasive, thus not a viable option for inflight monitoring. LP’s have only been performed postflight and are reserved for crewmembers exhibiting significant VIIP symptoms. Development and validation of a noninvasive means of measuring ICP would result in collection of data that could define the involvement of elevated ICP in the VIIP syndrome. There are few technologies capable of monitoring ICP noninvasively, and none have a strong record of “real world” use. The cerebral and cochlear fluid pressure analyzer (CCFP) (Marchbanks Measurement Systems, UK) measures tympanic membrane displacement (TMD) in both evoked and passive modes. These TMD waveforms change in response to ICP alterations, allowing a noninvasive means to monitor ICP changes. This technology relies on a patent cochlear aqueduct, which has been reported to become nonpatent in an age-dependent manner, although this rate is controversial.

The CCFP analyzer provides a potential option for monitoring ICP changes both terrestrially and inflight; spaceflight worthy units have been designed and assembled for a prior shuttle detailed test objective (DTO) and commercial units have been developed based on this design, which reduces the time required to prepare the instrument for flight. However, additional clinical validation of this device is necessary to better understand the device’s utility. The Ear and Balance Institute (Covington, LA) has over 1,000 patients tested with the CCFP, roughly 500 of which have had LP. Analysis of these tests can help validate the potential use of this technology as a surrogate measure of ICP. The purpose of this retrospective clinical study is to examine this unique CCFP and LP data set in order to identify characteristics that could contribute to follow-on studies employing the CCFP analyzer.

METHODS

This study is a retrospective review and analysis of Ear and Balance Institute patient data. Personnel at the Ear and Balance Institute reviewed physical and electronic charts and compiled data into a de-identified spreadsheet. Charts selected for inclusion in the data set have CCFP and LP measures within several days of each other and no medical interventions between measures. The data were sent to the team in Houston who are performing analyses with input from Ear and Balance Institute clinicians. The analysis has several components that will be combined to address the specific aims: 1) evaluate both evoked and passive TMD waveforms as measured by CCFP and compare with LP; 2) describe the inter- and intra-patient variability of the TMD measurements to evaluate CCFP utility as a direct surrogate measure for ICP (as opposed to using CCFP as a tool to monitor ICP changes in individual patients); and 3) determine the age-dependent distribution of cochlear aqueduct patency.

DISCUSSION

Data collection is complete and analysis is ongoing. Because the CCFP is being used as a screening tool by the clinic, many patients have begun medical intervention between the time of the CCFP test and the LP or have already been undergoing treatment. Another caveat associated with this analysis is that CCFP measures have not been collected at the same time as LP. To address these issues, analysis will focus on patients whose LP was performed in close temporal proximity to CCFP, and those who have no interventions between measures. These factors have reduced the number of charts available for analysis (~70 out of ~1000 available with CCFP and LP measures). Due to the fact that all patients in this study will have had an intervention between repeated CCFP tests, intra-patient variability analysis will be limited to a coarse metric indicating whether CCFP results have shifted in the “correct” direction and are still consistent with available LP data. Nearly all patients in this database have ear-related pathology, with the largest contributors being superior semicircular canal dehiscence (~50%), and perilymph fistula (~65%) that likely affect CCFP response. Data were originally collected as a clinical screening method and not as a controlled investigation therefore the certainty of results correlating CCFP and LP will not be as high as could be expected from a well-designed prospective study. However, this study is expected to yield essential information about the CCFP method including high-certainty data regarding 1) cochlear aqueduct patency rates, 2) general utility of the CCFP as an ICP screening tool, 3) clinical factors that affect repeatability and reliability, and 4) factors to be considered in planning prospective studies comparing CCFP and invasively acquired ICP data.