"Repository of Cochlear Implant Information" (ROCII): A Multi-Institutional REDCap Database

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Objectives

1. To thoroughly describe the creation of a medical database to serve as a roadmap for future database creation
2. To describe how a clinical question can be answered using a medical database, specifically the impact of obesity on unilateral cochlear implant (CI) surgical time and postoperative outcome, measured by the AZBio Sentence Test.

Introduction

In 2022, a REDCap database entitled the Repository of Cochlear Implant Information (ROCII) was created at Rush University Medical Center to better understand the processes and outcomes of cochlear implantation. There are numerous variables that affect patient performance prior to and following cochlear implantation, and there is an assortment of evaluations to assess performance. However, there is a lack of standardized protocol for assessing post-implant progress amongst institutions. Such pitfalls complicate the understanding of success following cochlear implantation. Comprehensive analysis of multiple variables across multiple institutions is critical in decision-making as it has the potential to affect candidacy, device selection, and performance prediction.

The first clinical question ROCII examined was the association between BMI and CI surgical time as well as postoperative (postop) outcome. It was previously described that obese patients (BMI >=30.0) who underwent surgical procedures, across many specialties, experienced increased time in the operating room, increased postop complications, increased readmission rates, and longer hospital admissions following surgery.[1,2,3,4] Obesity had a similar effect on otolaryngologic procedures such as tracheostomy and sleep apnea surgeries, [5,6] however few studies have demonstrated the impact of obesity on cochlear implantation.

Database Design

All data is de-identified with a unique record ID. Static data, including demographics, social history, and hearing history, is collected a single instance per patient. All aspects of patient demographics are captured including name, MRN, date of birth, date of death, gender, preferred language, zip code, race, ethnicity, BMI, marital status, etc. Repeatable data, including surgical data and longitudinal improvement in hearing performance with audiogram, AzBio, CNC, and surveys, is collected several instances per patient. We enabled 'repeatable instances' for longitudinal data points to allow for infinite instances to be inputted per instrument (ie. audiograms), organized chronologically by date. This provides flexibility for differences in protocols amongst institutions and patient follow up.

Methods

A retrospective case control study from a tertiary academic center was performed and data was managed using a REDCap database [7,8]. Patients included were adults (age >=18 years) who had primary, unilateral cochlear implantation from October 2012 to 2022. The following data were exported from ROCII: BMI, age, surgical time (procedure start to procedure finish), preop AZBio score in quiet, and postop AZBio score in quiet. Patients who had bilateral cochlear implantation on the same day were excluded from analysis due to confounding surgical time, as well as patients who underwent CI revision surgery. Only patients who qualified for CI using the AZBio Sentence Test in quiet were selected for analysis.

Patients were stratified into three groups based on BMI (<25, 25.0-29.9, >=30.0). Differences in surgical time were analyzed between groupings using the mixed effect model. Surgical time was analyzed based on patient age for comparison. Of the same patient cohort, CI outcome, measured by AZBio postop score change (postop score - preop score), was analyzed using BMI groupings and patient age with the mixed effect model. Patients required a minimum of one preop and one postop AZBio score in quiet for analysis.

Table 1. Surgical Time vs. BMI.

Surgical Time vs BMI								
						Mixed effect model		
BMI Group	N	Mean	Std Dev	Minimum	Maximum	Comparison	Estimate	P-value
BMI<25 (reference group)	50	127.5	26.69	75	181			
BMI 25.0-29.9	50	127.52	24.29	84	179	BMI 25.0-29.9 vs BMI<25	0.1133	0.9833*
BMI>=30.0	45	132	27.21	81	209	BMI>=30.0 vs BMI<25	4.4268	0.4367**

*Compared to patients with BMI<25, patients with BMI 25.0-29.9 had a higher surgical time on average, but the difference was not statistically significant.

**Compared to patients with BMI<25, patients with BMI>=30.0 had a higher surgical time on average, but the difference was not statistically significant.

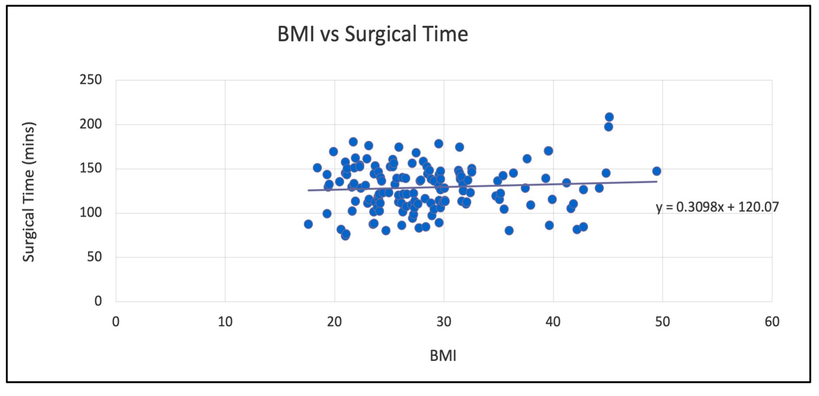
Table 2. AZBio Postop Score vs. BMI.

AZBio post-op change vs BMI								
						Mixed effect model		
BMI Group	N	Mean	Std Dev	Minimum	Maximum	Comparison	Estimate	P-value
BMI<25 (reference group)	29	56.66	29.23	1	96			
BMI 25.0-29.9	22	61.32	32	3	99	BMI 25.0-29.9 vs.BMI<25	4.5119	0.5847*
BMI>=30.0	23	73.65	23.5	4	98	BMI>=30.0 vs. BMI<25	16.8747	0.0637**

*Compared to patients with BMI<25, patients with BMI 25.0-29.9 had a higher AZBio post-op change on average, but the difference was not statistically significant.

**Compared to patients with BMI<25, patients with BMI>=30.0 had a higher AZBio post-op change on average, but the difference was not statistically significant.

Figure 1. BMI vs Surgical Time



Results

The mean BMI (n=145) was 28.52, and the mean surgical time was 128.9 minutes. The BMI<25 reference group (n=50) and the BMI 25.0-29.9 group (n=50) had an identical mean surgical time of 127.5 minutes. The BMI>=30.0 group (n=45) had a mean surgical time of 132 minutes, however this difference was not statistically significant when compared to the reference group (p=0.4727). The mean AZBio postoperative score change (n=74) was 63.32. The BMI<25 reference group (n=29) had a mean postoperative change of 56.66. The BMI 25.0-29.9 group (n=22) and BMI>=30.0 group (n=23) had mean postoperative changes of 61.32 and 73.65 respectively, however these differences were not statistically significant compared to the reference group (p=0.5847, 0.0637).

Discussion

BMI and age did not have a significant effect on CI surgical time and were therefore not contraindications for implantation. Additionally, BMI and age did not have a significant effect on CI post-operative outcomes, measured by the AZBio Sentence Test. As BMI increased, mean surgical time and postop hearing test performance both trended upwards, but neither significantly.

The ultimate goal of ROCII is to facilitate a deeper, more wholistic understanding of the evaluation process, postop outcomes, and patient experience of cochlear implantation. To best accomplish this, ROCII will need to be implemented across multiple institutions and increase its power.

References

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Want to be a part of data collection using ROCII? Contact:

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