

Rationing Rotational Magnet Cochlear Implant Technology in a Single Payer Healthcare System

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Abstract

Introduction: In a publicly funded health care system, fiscally responsible management of any program is required. This is especially pertinent as evolving technology and associated incremental costs, places pressure on device availability within a fixed funding envelope. The application of rotational magnet technology and associated escalating surgical wait times must be justified to patients and the single-payer system. We present a single cochlear implant center's attempt at a rationing schema for magnetic resonance compatible cochlear implantation. Contrasting approaches to rationing care are evaluated and deliberated.

Methods: Based on a comparison of magnetic resonance imaging (MRI) rates within the general population to our cochlear implant (CI) cohort, we attempt the development of a decision-making schema that maximizes the number of patients to receive a CI while rationing the distribution of a rotational magnet technology to similarly situated individuals most likely to benefit.

Results: We elect to provide rotational magnet technology to select patient cohorts. This is based on the dominant imaging needs of these populations and the probability of requiring recurrent imaging studies. We consider this an ethical approach grounded in the egalitarian principle of equality of opportunity within cohorts of patients.

Conclusion: Given finite resources, increasing per unit cost will unavoidably extend wait times for adult patients. Our approach does not afford similar implant devices for all patients, but rather all similarly situated individuals. Therefore, access to a scarce medical resource requires program rigor and a formalized policy around candidacy for emergent technology.

Keywords

cochlear implant, Otolaryngology, rotational, magnet, single, payer

Introduction

A core component to all cochlear implant (CI) systems is the magnet housed within the internal receiver-stimulator. While crucial in allowing the external sound processor to communicate with the internal array, the magnet also presents two challenges, it generates a shadow during imaging and it may require removal prior to magnetic resonance imaging (MRI). Historically, when an MRI was required, the magnet was surgically removed and replaced following the imaging study. This process was resource intensive and resulted in a period of anacusis for the patient.^{1,2,3,4}

With over 400 000 annual CI recipients globally, it is inevitable that cochlear implant candidates will encounter the need for imaging and in some cases, require regular MRI throughout their lifetime.⁵

There are currently three CI devices that do not require manipulation of the magnet for MR image acquisition.

These manufactures employ rotational magnet technology (RMT) that allows the recipient to undergo MRI at 1.5 and 3.0 Tesla (T) without the need for head wrap or magnet removal.^{6,7} These magnets rotate 3-dimensionally, regardless of the direction and orientation of the MRI magnetic field.⁸ The reduction in torque on the implant also ensures

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patients do not feel any discomfort during the procedure.⁹ The benefits of RMT are apparent in permitting MR acquisition without the additional work for technologists and surgeons before and after imaging.⁹ Further, it prevents the need for a period of anacusis, even if brief.

With new technology, comes the added cost of research, development, and production, which is absorbed by the consumer. For our CI center, the incremental cost is currently US \$2000.

The Canada Health Act of 1984 established a federal cost sharing program within the universal health care system to standardize services across the country.¹⁰ The goal is to provide comprehensive care that is universal, with each province or territory acting as a single-payer insurer.¹¹ The federal government provides national standards of care, however the actual administration and delivery is highly decentralized.¹² Standards of care are established within the public system for elective procedures such as cochlear implantation.¹³

In a publically funded health system, a CI program is implicitly mandated to positively impact an individual's health within a fiscally responsible framework. As a result, our implant center is tasked with managing resources to maximize function; being mindful of the best implant device options for individual patients. As a single-payer, each provincially administered implant program operates under a fixed medical device budget and must negotiate pricing contracts with implant manufacturers. Given finite resources, increasing per unit cost will unavoidably extend wait times for adult patients as more expensive technology will impact purchases within a given fiscal year. Therefore, access to a scarce medical resource requires program rigor and a formalized policy around candidacy.

We present a single CI center's working considerations and an attempt at an evidenced-based approach to rationing decisions with respect to RMT and the associated incremental cost.¹⁴

Theories of Distributive Justice

A consistent, principled, and transparent methodology is required for evaluating potential cases using rotational magnet technology within a single-payer health care model. Any approach can be characterized as transactional between several inherent ethical principles. Whenever a patient is forced to wait to receive a medical good the justifications to address the delay in treatment should be explicit to the patient, the system and the political context. An ideal system would consistently result in the same prioritization given to any similarly situated individual patient.

The Fiduciary Ideal places the trust of the patient in a professional and ascribes that this individual will always act in the best interest of the patient.⁵ This is irrespective of the potential impact that such actions might have on other

persons.⁶ Juxtaposed is the evolving role of physician as a health care resource manager.^{5,7,8} The competing needs of a patient are uniquely at odds with the needs of a fiscally conservative program, requiring physicians to both plan for and execute prioritization decisions that may negatively impact their own patients.

There are a host of approaches to best allocate a social good across populations.¹⁵

A utilitarian approach attempts to maximize benefit for the community. Here, the benefits to society supersede the individual.^{15,16} The substantial benefits to the individual and the community, extending to include even the tax base, are considered and contrasted against exceptional device cost.

A deontological approach surmises that health care entitlements arise from ascribed patient rights. Equally situated individuals have an equal right to health services.¹⁷

Further, the liberal egalitarian approach argues that patient responsibility for individual health outcomes must be measured against external factors that are generally regarded as being outside of a patient's control.¹⁸ An important distinction in this approach is that while individual lifestyle choice should be a factor to care, it should never be considered as a barrier to treatment. In essence, patients are responsible for their choices, but not the consequences of those decisions.¹⁸

More recently there is the attempt to apply social justice theories to macro level health economics. Inherent within this construct is the idea that not all health care resources can be provided to all patients.¹⁹ Health service delivery must consider the entire span of an individual's life and allocate accordingly. This schema acknowledges the inherent discrimination; however age-related transitions through life apply to all individuals, regardless of sex or race.

Program Specific Imaging Following Cochlear Implantation

All cochlear implant recipients over the last 6 years were reviewed under existing research ethics board approval (University of Manitoba: H2015:209 (HS18623)). The data encapsulates 257 recipients, 283 ears and 1027 years of follow up. All images acquired in this Health System reside in a single imaging data base. We have subsequently reviewed all post implantation images acquired. There were a total of 272 images acquired.

All indications for imaging were reviewed with site specific specialists in Neurology, General Surgery, Thoracic Surgery, and Radiology. A total of 142 images were believed would have benefited from MR imaging over the CT acquired (Figure 1).

Subsequently a plot of MR need across age was developed (Figure 2). This illustrates greatest need for imaging in the 6th and 7th decades of life. Data from a 2003 Ontario provincial report on age-related MR utilization mirrors our

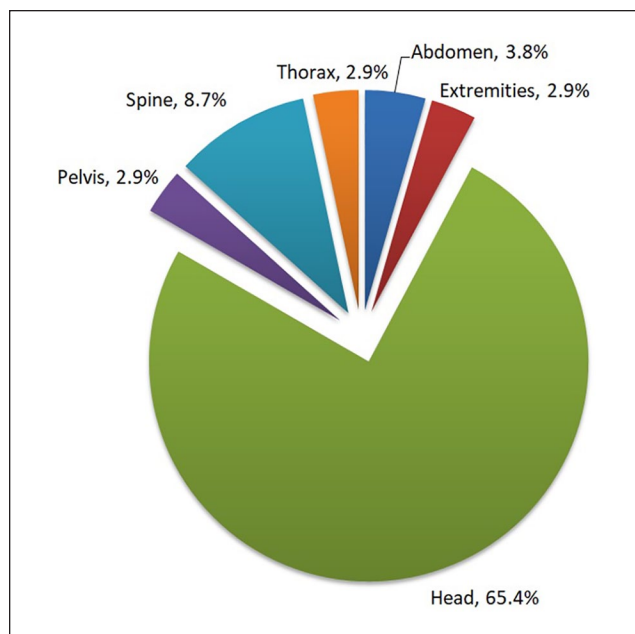


Figure 1. A single CI center's post-CT imaging disease site locations that would likely have benefited from MRI as contrasted to the acquired CT. A total of 142 out of 272 post-operative scans identified.

programs experience with a left skewed bell curve and greatest imaging rates in mid to late life.²⁰

Our Approach

We practice in a highly scrutinized medical environment where cost-utility factors heavily. Our program has historically long wait times. Escalating wait times, even if to improve post-operative imaging capacity, will be unacceptable to patients and the single-payer. Any change in volume needs to be explicitly justified.

We attempt to develop a program specific schema which maximizes the number of patients to receive a cochlear implant while rationing the distribution of a rotational magnet.

Our approach is predicated on the following considerations;

- The benefit of rotational magnet technology and the implication to patients is apparent.
- Requests for increasing the existing funding envelope to permit all patients to have an MR compatible device will be declined.
- Currently MR imaging is very common, however, may not be required in all cases.
- Pediatric implantation is associated with the longest duration of use with the probability that this patient cohort will require the highest number of re-implantation procedures.

- The oldest cohort of implanted patients will generally have the shortest duration of device employ, and not require few re-implantation procedures.
- Greatest MR needs are in mid to late life stages.
- There are implant candidates with medical conditions that have absolute imaging needs.
 - Meningitis, Neurofibromatosis Type II (NF2), vestibular schwannoma, craniofacial anomalies, malignancy, traumatic brain injury (TBI), seizure disorder, auditory neuropathy spectrum disorder (ANSD), and syndromic patients.

We elect to apply imaging needs as significant if there is a greater than 10% probability of requiring an MRI during the life of the device. Ten percent is arbitrary and was determined at the discretion of our program.

We have generated a construct (Figure 3) with the use of these considerations. It borrows from the fiduciary ideal, as well as utilitarian and deontological philosophies. A rotational magnet will be provided to a) all individuals with concurrent health issues requiring additional or routine/regular imaging and b) adults between 45 and 75 years of age.

This is an explicitly ageist approach. However, with the application of current social justice approaches, when pediatric patients are re-implanted later in life, owing to anticipated device failure, they would then receive an MR compatible implant. Older individuals have lived a long life without limitation in access to imaging. Further, within our cohort of recipients, the extremes of life have the fewest imaging needs. Individuals with specific concurrent health issues are considered distinct as they are more likely to necessitate imaging.

Program Specific Impact of RMT Implementation on Patient Wait-Times

The application of the above schema to our cohort suggests that 54% of CI recipients would receive a RMT device.

- Sixteen patients would be considered to have absolute MR imaging needs.
 - Eight of these patients would otherwise not have received a RMT based on age.
- Historically 53.5% of our recipients are between the ages of 45 and 75 years of age.

For our program, the incremental cost of applying a rotational magnet to these two cohorts would be \$42 000 USD (\$56 000 CAD) annually. This would reduce our surgical CI volumes by at minimum three devices, or roughly 7% per annum.

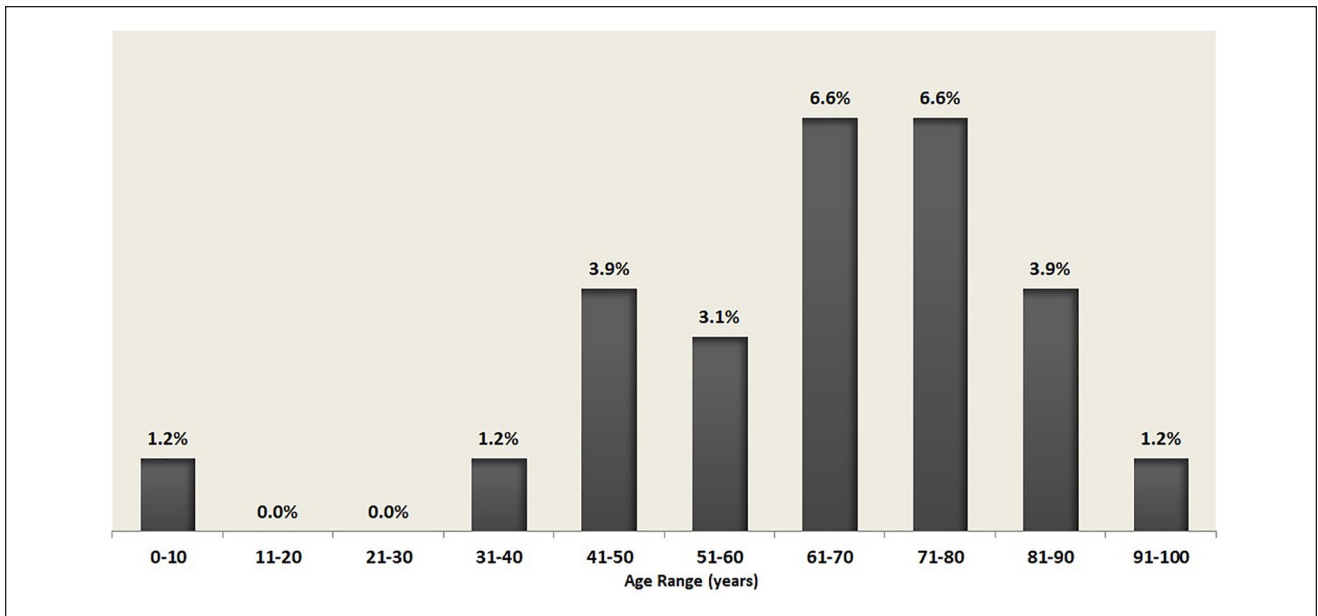


Figure 2. Post-implantation MR imaging needs identified in cochlear implant recipients by age.

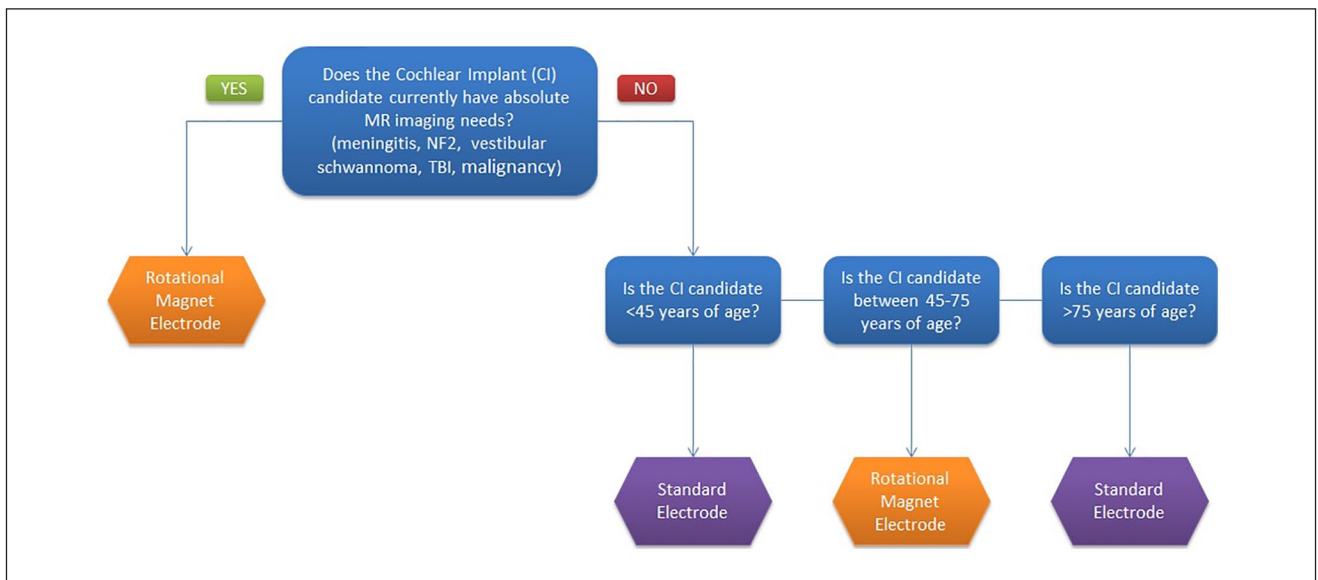


Figure 3. Flowchart for application of RMT for cochlear implant candidates.

The most appropriate lens is not to consider the impact per annum, but over the life of a program. Specifically, 5 years from implementation, we can extrapolate that this would result in any new CI candidate having to wait an additional 30%. This is a best case scenario as it does not factor for the aging demographic, evolving bilateral paradigm, implantation for single-sided deafness and a pending wave of re-implantation following the natural loss of older devices in otherwise younger individuals.

If we had otherwise elected to provide a rotational magnet to all patients, this would impact the wait list by 5.5 devices per annum and reduce throughput by 14% annually. Again, at 5 years this would represent a 62% increase in overall wait times.

The implications of adding rotational magnet technology will significantly impact patient wait times. We do consider RMT an important advance that should be implemented. While a difference of 7% to 14% in surgical volumes can be

viewed as absorbable, it has as significant impact on patient wait times for a discrete CI Program with a fixed funding envelope.

Summary

We have elected to explicitly disclose our current practice as we believe that pragmatic discussion around the fair allocation of a limited resource is substantive and timely. The predicted evolution of health systems around the globe and the shape of future medical practice will be heavily influenced by both the macro and micro level resource dependent decisions we currently face. We believe that physicians must assume a leadership role in this discussion, and failure to do so may compromise our future influence in such matters.

We consider this an ethical approach grounded in the egalitarian principle of equality of opportunity within cohorts of patients. In doing so, patient wait times are extended. This does not afford similar implant devices for all patients but rather all similarly situated individuals. We intend to monitor the adjusted wait times for the global surgical waitlist and accordingly attempt to procure additional funding to offset this change.

This model of allocation will be of interest to other cochlear implant programs and other similarly situated bodies that are also called upon to ration health care services.


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