Current Estimates of Cochlear Implant Utilization in the United States

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Objective: To present key data from a private marketing report that characterizes U.S. cochlear implant (CI) utilization, potential CI candidate and recipient population sizes, and CI market growth.
Patients: Individuals who may benefit from CI and CI recipients in the United States.
Interventions: Cochlear implantation.
Main outcome measures: CI utilization, potential CI candidate and recipient population sizes, and CI market size and value.
Results: As of 2015, a cumulative 170,252 people (240,056 devices) had undergone cochlear implantation in the United States. In the year 2015, approximately 30% of devices were implanted in bilateral CI patients, through simultaneous or sequential implantation. When considering traditional audiometric CI candidacy criteria (patients with severe to profound sensorineural hearing loss in the better hearing ear), utilization rates among the population who may benefit from CI approximated 12.7%. When considering expanded criteria including individuals with single-sided deafness or asymmetrical hearing loss (severe to profound hearing loss in the worse hearing ear), utilization rates approximated 2.1%. In 2015, there was a net increase of 20,093 individuals who may have benefited from CI who had not undergone CI, adding to the group of about 1.3 M untreated audiometric CI candidates who existed prior to that year. The CI market was valued at $450.8 M in 2015, with an average device selling price of $25,701 per device.
Conclusions: CI utilization rates remain low among individuals who meet audiometric criteria for CI. Although the *annual proportion* of CI recipients to new audiometric candidates has increased, the *total population* of untreated audiometric CI candidates continues to rise. **Key Words:** Cochlear implant—Epidemiology—Market—Penetrance—Price—Utilization.

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INTRODUCTION

While hearing loss is increasingly recognized as an important and actionable health condition, untreated hearing loss remains prevalent today (1–3). Although cochlear implants (CI) can be used to treat severe to profound sensorineural hearing loss in many cases, it is widely understood that CI utilization among the eligible U.S. population is low. Current market utilization estimates are dependent upon voluntary reports from CI manufacturers or a private marketing report (4,5). A previous report from 2010, produced by iData Research Inc. (6), a private market research firm, serves as the source of perhaps the most commonly cited CI prevalence rate of about 6% (7–14). Although this statistic is widely referenced in the literature, the source of data and the underlying methodology used to derive this estimate is not publicly available. Establishing accurate and comprehensive CI utilization estimates in the United States is critical toward understanding and implementing clinical outreach programs, informing research effort, and driving relevant legislative changes. The present study updates and makes publicly available the most recent CI market report by iData Research Inc. in an effort to improve the understanding of patient access to care, guide practice management, and direct research efforts.

METHODS

Description of Market Report

The U.S. CI market trends and projections were sourced from the U.S. Market Report Suite for Hearing Devices published by iData Research Inc in 2016 (most recent available report) which includes the study period from 2013 to 2015 (15). iData Research Inc. is a private market research firm, and market reports are available to the public for purchase. While the raw data used in the development of the presented marketing models

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TABLE 1. *Cochlear implant market size from 2013 to 2015 (Traditional Criteria)*

Year	Total U.S. Population	Total U.S. Population Meeting Traditional Audiometric CI Criteria[a]	Total CIs Implanted	Annual New CIs Implanted	Total CI Recipients	Annual New CI Recipients	Total Untreated Population Meeting Traditional Audiometric CI Criteria
2013	317,083,319	1,266,214	200,103	–	139,396	–	1,126,818
2014	319,428,475	1,301,380	219,505	19,402	154,581	15,185	1,146,799
2015	321,773,631	1,337,144	240,056	20,551	170,252	15,671	1,166,892

[a]Bilateral severe-to-profound sensorineural hearing loss (>70 dB pure tone average).
''–'' indicates data not available; CI, cochlear implant.

are proprietary, sources for these data included U.S. Census and hospital statistics (CPT and billing codes), academic publications, investor presentations, U.S. Securities and Exchange Commission filings, and procedural databases. Procedural and diagnostic data were evaluated by CPT and ICD code at the national, hospital and physician level. The market models additionally included both data and expert opinion from leading and emerging hearing device manufacturers and distributors. The average selling price reflects the price that the CI manufacturer charges the purchaser (hospital or surgical practice). In the years following the publication of the report, iData Research Inc. confirmed accuracy of market forecasts through cross-verification of estimates and projections with purchase order data from a sample of over 1700 U.S. healthcare facilities. Study data was obtained from iData Research and was independently analyzed; the iData Research team was not involved in the interpretation of the report, writing of this manuscript, or funding of this study.

Audiometric CI Candidacy Criteria

Market models utilized traditional audiologic criteria to identify individuals who may benefit from CI in the United States (15). Importantly, a CI candidate in this study was defined as an individual who may receive benefit from CI based on audiometric criteria. Assuming anatomy amenable to implantation, adults who met the following criteria were considered traditional audiometric candidates: postlingual onset of bilateral severe-to-profound sensorineural hearing loss (>70 dB), minimal to no benefit from appropriately fitted hearing aids, <50% ipsilateral sentence recognition in quiet, and < 60% contralateral sentence recognition in quiet. Children with bilateral profound sensorineural hearing loss between 9 months and 2 years were considered candidates, while those over 2 years of age with bilateral severe to profound hearing loss were considered candidates. Additionally, lack of progress in auditory skills development and poor speech perception scores (<30% for those able to participate in testing) despite appropriately fitted hearing aids informed inclusion for CI candidacy. iData modeling for traditional candidate estimates utilized data from national epidemiologic studies cross-referenced and augmented with representative regional hospital data.

Notably, patients with single-sided deafness or asymmetric hearing loss with residual hearing were not considered CI candidates as a part of the iData Research Inc. marketing report. To provide the prevalence of CI in the setting of expanded CI criteria, the authors utilized U.S. Census population data to estimate the number of individuals with severe to profound hearing loss in the worse hearing ear (2.5% of the U.S. population over the age of 12) (16,17). Specifically, rates of severe-to-profound hearing loss in the worse ear cited in the National Health and Nutritional Examination Survey (NHANES) database were adjusted with updated U.S. Census data to account for population growth between the time of the NHANES data and the study period (16,17).

RESULTS

Between 1984 and 2015, a total of 170,252 U.S. adult and pediatric patients underwent cochlear implantation, accounting for 240,056 devices (Table 1). The numbers of annual implantations and those estimated to receive benefit from CI under traditional criteria steadily increased during the study period from 2013 to 2015. In 2015, approximately 30% of devices were implanted in bilateral CI patients through either simultaneous or sequential implantation.

CI utilization estimations were performed using the total number of CI recipients as the numerator and estimates for both the traditional and expanded criteria populations of individuals who may benefit from CI as the denominators. In 2015, the number of CI recipients totaled 170,252, while the number of traditional audiometric CI candidates totaled 1,337,144, resulting in a utilization of 12.7% amongst individuals who met traditional audiometric criteria for CI (Fig. 1). Notably, the increasing CI utilization rate over the 3-year study period can be attributed to the relative growth rate of the CI recipient and potential candidate populations; the

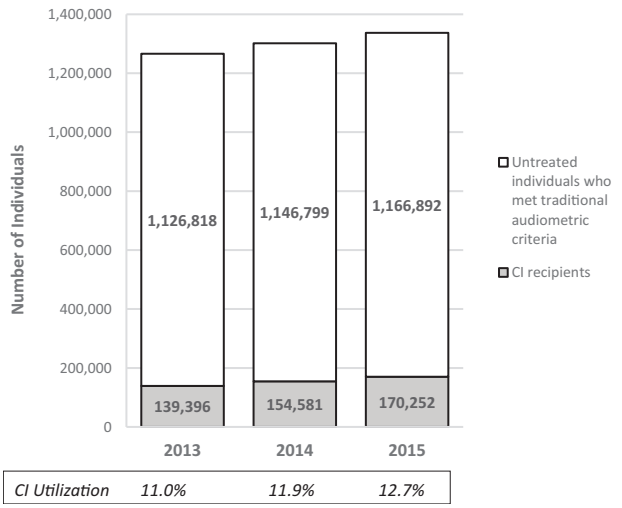

FIG. 1. Cochlear implant utilization over time. Patients who met traditional audiometric criteria for CI during the study period (2013–2015) are represented.

TABLE 2. *Cochlear implant and hearing aid recipients from 2013 to 2015*

Year	Total Number of CI Recipients	Total Number of HA Recipients	CI:HA Recipient Proportion
2013	139,396	8,084,990	0.017
2014	154,581	8,250,838	0.019
2015	170,252	8,486,780	0.020

CI indicates cochlear implant; HA, hearing aid.

numerator (CI recipients) exhibited larger proportional growth compared to the denominator (CI candidates). Despite the growing number of annual new CI recipients between 2013 and 2015, the number of individuals who met traditional audiometric criteria for CI grew by a greater absolute number with overall population growth resulting in a growing cohort of untreated potential CI candidates.

Importantly, the iData Research marketing report only considered traditional CI audiometric criteria in the above analysis. Broadening audiometric criteria to include patients with single-sided deafness and asymmetrical hearing loss expanded the potential CI candidate population to approximately 8.05 M individuals, with a resultant utilization rate of 2.1% in 2015.

The CI market has demonstrated steady growth in value during the study period. While initially valued at $409.3 M in 2013, the market expanded to $450.8 M in 2015. In contrast, device prices have steadily declined over the study period, resulting in an average selling price of $25,701 per device in 2015. Despite consistent growth, the CI market represents a small portion of the hearing device industry volume, as the vast majority of the population with hearing loss are hearing aid candidates (Table 2). Notably, however, the proportion of CI recipients to hearing aid recipients increased from 1.7% to 2.0% during the study period, suggesting that the annual CI market percentage growth rate surpassed that of the hearing aid market.

DISCUSSION

As the indications for CI continue to broaden, so does the size of the prospective population of individuals who may receive benefit from CI. Reflective of advancing device technology, surgical technique, and programming parameters, CI candidacy indications have significantly expanded in the last decade to include patients with greater degrees of residual hearing (10,18–21), those with unilateral hearing loss (22,23), and younger pediatric patients (22,24,25). A growing population of individuals who meet audiometric criteria for CI increases the denominator in the utilization proportion, resulting in a smaller overall utilization rate. This study provides a range of CI utilization from 2.1% and 12.7%, which reflects two extremes employing expanded and traditional audiometric criteria, respectively. Arguably more important than cross-sectional prevalence, variation in the proportion of new CI recipients to new CI candidates over time determines how quickly we may ''close the gap'' in the under-penetrated CI candidate population. In 2015 alone, there was a net increase of 20,093 individuals who met traditional audiometric criteria who had not undergone CI, adding to the cohort of about 1.3 M untreated individuals meeting traditional audiometric criteria who existed prior that year. In other words, the total number of audiometrically eligible people who do not receive an implant within the United States continues to grow annually, even when using traditional audiometric criteria. When considering more liberal, expanded criteria, the cohort of untreated individuals who meet audiometric criteria for CI is significantly larger (about 8 M individuals), and is projected to grow proportionally with the aging U.S. population (26–28). Interestingly, the growing proportion of CI to hearing aid recipients may reflect the expanding CI candidacy criteria to include patients with residual or asymmetric hearing loss who were once only hearing aid candidates. Support for this theory, however, requires more granular detail with respect to hearing aid recipients and severity of hearing loss (Table 2).

Most prior studies citing CI utilization refer to the marketing report published by iData Research Inc. in 2010 (7–14). Few studies beyond this have attempted to estimate CI utilization in the United States. Using Census 2000 data, Bradham et al. estimated CI prevalence among children aged 12 months to 6 years to be approximately 55% (29). Importantly, this study did consider rates of cochlear nerve aplasia and severe neurological deficits in children and excluded these potential candidates, however, it was unable to account for other reasons that would potentially prevent individuals from undergoing CI, and utilization rates may have changed in this population over the last two decades. Goman et al. estimated both hybrid and conventional CI audiometric candidacy in adults aged 60+ using NHANES data from 2001 to 2012 (30). In the age group 60+, it was estimated that 1.9 M individuals would meet traditional audiometric criteria in 2020, aligns with population growth rates and our estimates of traditional audiometric candidates in 2015. Unfortunately, while this study did evaluate audiometric profiles in the United States, it did not provide rates of CI utilization. In contrast, the current study estimates CI utilization and includes a majority of the U.S. population.

When attempting to establish accurate estimates of CI utilization, the influence of evolving audiometric CI candidacy criteria and population dynamics have considerable ramifications. Practices across the United States demonstrate significant variability in CI evaluations, candidacy criteria, and surgical preferences, which have broad implications on estimates of locoregional CI utilization (18,31). To address these variations, the present study provides two extremes, using both expanded and traditional candidacy criteria, in order to capture a CI utilization range more reflective of the variable practices

in the United States. In both estimates, the numerator includes all CI recipients (regardless of indication), as granular information including individual candidacy criteria were not available in the iData Research Inc. marketing report. Consequently, the traditional CI utilization rate of 12.7% likely includes some CI recipients who met expanded criteria, suggesting that 12.7% may be an overestimate. Furthermore, the denominator (CI candidate population) in the expanded criteria CI utilization rate was derived from U.S. Census estimates of hearing loss severity, which excluded children under the age of 12 (17). Including the population of children under the age of 12 with severe to profound hearing loss in the worse hearing ear would likely result in a CI utilization rate less than 2.1%. Although some CI centers treated SSD with CI prior to FDA approval in 2019, this was not routine practice during the study period nor is it in current day. Many SSD patients choose to utilize alternative options such as bone-anchored implants or contralateral routing of sound (CROS) hearing aids, or forego hearing rehabilitation altogether. This point emphasizes an important limitation of this study in that the CI utilization estimates provided are based on audiometric candidacy criteria, but do not consider individual reasons for undergoing or foregoing CI. Importantly, there is a significant difference between whether an individual *could* or *should* undergo implantation and the above utilization analyses do not take individual clinical decision-making into consideration. Patient factors such as comorbidities (e.g., overall health and dementia), duration of deafness, and desire to receive hearing treatment may result in a smaller denominator, and therefore a larger real utilization rate. Moreover, audiometric CI candidacy calculations include members of the Deaf community, who may hold different views regarding hearing rehabilitation. Finally, market report estimates were derived from proprietary models developed by iData Research Inc.; consequently, granular information about the derivation of these figures is unavailable. While these estimates may have some limitations, the above CI utilization range is comparable to prior estimates of CI prevalence in the United States (5–7).

Importantly, this study demonstrates that CI utilization remains low among individuals who meet audiometric criteria in the United States. This data can be used to support efforts aimed to improve CI utilization in the United States including patient outreach, research, and systematic changes that emphasize the importance of hearing health. Prior work has demonstrated considerable differences in utilization and access across patient geographic distribution, socioeconomic status, and age groups owing to pediatric screenings, referral patterns, and insurance coverage (7,32–34). As a limitation, this market report does not provide utilization rates in relation to these variables, and more detailed data evaluating the distribution of CIs across the country and subpopulations are critical in designing programs to improve healthcare access.

CONCLUSION

The approximate U.S. CI utilization rate likely falls between 2% and 13%, which reflect a range using expanded and traditional audiometric CI criteria, respectively. Although the *annual proportion* of CI recipients to new audiometric candidates has increased, the *total population* of untreated individuals who may benefit from CI continues to rise. While this study supports prior work that suggested substantial under-utilization of CI in the United States, a more granular understanding of this complex market and patient population is required to develop actionable steps to improve penetrance and access to care.

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