ORIGINAL PAPER DOI: 10.5935/0946-5448.20190013

International Tinnitus Journal. 2019;23(2):74-78.

A National Iranian Cochlear Implant Registry (ICIR): cochlear implanted recipient observational study

Nader Saki[1]
Arash Bayat[1]
Soheila Nikakhlagh[1]
Majid Karimi[1]
Mohammad Nikafrooz[2,3]
Ahmad Daneshi[4]
Masoud Motesadi Zarandi[5]
Mohammad Ajalloueyan[6]
Seyed Basir Hashemi[7]
Mohammad Mehdi Ghasemi[8]
Ali Eftekharian[9]
Seyyed Hamidreza Abtahi[10]
Maryam Amizadeh[11]
Farhad Farahani[12]
Masoud Naderpour[13]

ABSTRACT

Background and Objective: Patients who receive cochlear implants (CIs) constitutes a significant population in Iran. This population needs regular monitor on long-term outcomes, educational placement and quality of life. Currently, there is no national or regional registry on the long term outcomes of CI users in Iran. The present study aims to introduce the design and implementation of a national patient-outcomes registry on CI recipients for Iran. This Iranian CI registry (ICIR) provides an integrated framework for data collection and sharing, scientific communication and collaboration in CI research.

Methods: The national ICIR is a prospective patient-outcomes registry for patients who are implanted in one of Iranian centers. The registry is based on an integrated database that utilizes a secure web-based platform to collect response data from clinicians and patient's proxy via electronic case report forms (e-CRFs) at predefined intervals. The CI candidates are evaluated with a set of standardized and non-standardized questionnaires prior to initial device activation (as baseline variables) and at three-monthly interval follow-up intervals up to 24 months and annually thereafter.

Results: The software application of the ICIR registry is designed in a user-friendly graphical interface with different entry fields. The collected data are categorized into four subsets including personal information, clinical data, surgery data and commission results. The main parameters include audiometric performance of patient, device use, patient comorbidities, device use, quality of life and health-related utilities, across different types of CI devices from different manufacturers.

Conclusion: The ICIR database could be used by the increasingly growing network of CI centers in Iran. Clinicians, academic and industrial researchers as well as healthcare policy makers could use this database to develop more effective CI devices and better management of the recipients as well as to develop national guidelines.

Keywords: Iran; cochlear implant registry.

[1]Hearing Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
[2]Department of Education, University of Farhangian Teacher Education, Chamran Branch, Iran
[3]Special Education Organization, Tehran, Iran
[4]ENT and Head & Neck Research Center and Department, The Five Senses Institute, Iran University of Medical Sciences, Tehran, Iran
[5]Department of Cochlear Implant Center and Otorhinolaryngology, Tehran University of Medical Sciences, Tehran, Iran
[6]Department of Otorhinolaryngology, Baqiyatallah University of Medical Sciences, Tehran, Iran
[7]Department of Otorhinolaryngology, Shiraz University of Medical Sciences, Shiraz, Iran
[8]Sinus and Surgical Endoscopic Research Center, Mashhad University of Medical Sciences, Mashhad, Iran
[9]Department of Otorhinolaryngology, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[10]Department of Otolaryngology, Isfahan University of Medical Sciences, Isfahan, Iran
[11]Department of Otorhinolaryngology Head and Neck Surgery, Kerman University of Medical Sciences, Kerman, Iran
[12]Hearing Disorders Research Center, Hamadan University of Medical Sciences, Hamadan, Iran
[13]Department of Otorhinolaryngology Head and Neck Surgery, Tabriz University of Medical Sciences, Tabriz, Iran
*Send correspondence to:
Nader Saki
Department of hearing research center. Ahvaz Jundishapur University of Medical Sciences, Iran. E-mail: ahvaz.ent@gmail.com Tel:+986133738283.
Paper submitted to the ITJ-EM (Editorial Manager System) on June 16, 2019; and Accepted on July 18, 2019

INTRODUCTION

Hearing loss affects all age groups and about 5.3% of the world's population suffer different types and degrees of hearing loss, of which 9% are children. The global prevalence of hearing impairment, defined as an average hearing loss of 20 decibels Hearing Level (dBHL) or more in the better ear, is about 1.4% in children aged 5-14 years. The global prevalence of severe-to-profound hearing loss, defined as hearing loss of 61 dBHL or greater in the better ear, is about 4.8% among 0-1 years and 6.4% among children aged 1-4 years. There are different strategies for treatment of children with hearing impairments. The gold standard interventions used for treatment of patients with a permanent hearing impairment are Cochlear Implants (CIs) and bone conduction implants. CI is the recommended and most commonly used treatment for children with a permanent and severe to profound bilateral Sensorineural Hearing Loss (SNHL). A CI is a small electronic device that help patients to partially restore hearing through converting acoustic signals into electrical pulses that stimulate the auditory nerves directly via electrodes in close contact to the auditory nerve fibers[1,2]. Although the overall auditory and speech functions of CI recipients gradually improve following the implantation, some patients receive little or no benefit from CIs even after many years of daily use of the device[3,4]. Different factors have been reportedly to contribute to the overall outcomes of CIs including duration of deafness, age at onset of deafness, implantation age, duration of implant use, length of daily device use, and preoperative level of residual hearing[5-8]. It has been demonstrated that properly designed and executed, clinical data registries can provide a real-world view of clinical practice, patient outcomes, safety, and comparative effectiveness[9,10]. A well-designed patient registry can serve as a powerful tool to monitor the course of disease, to yield insights into variations in treatment and outcomes, to describe care patterns including appropriateness of care and disparities in the delivery of care, to yield insights into risk factors for adverse outcomes, and to measure quality of care[11-13]. Developing and implementing a longitudinal observational clinical registry for CIs in health-care services possesses several benefits for clinicians and patients Improving patient management and securing the medical records; improving clinical practice through standardized CI protocols; documenting the usefulness and effectiveness of CI in real-world settings; determining influential factors on prognosis and quality of life in CI recipients; creating a national network of centers contributing to CI procedures; providing a comparative benchmark reports to stakeholders; conducting exploratory research based on the registry database; and adapting effective healthcare policies[14-19]. Children who receive CIs constitute a significant population in Iran. This population needs regular monitor on long-term outcomes, educational placement and quality of life. Despite the importance of a clinical registry on the long term outcomes of CI users, there is no national or regional CI registry in Iran. The present study aims to design and implement a national patient-outcomes registry on CI recipients for Iran. The Iranian Cochlear Implant Registry (ICIR) is a longitudinal prospective registry initiated to facilitate communication, improve care, and create a framework for aggregate data sharing in CI research. There is no national or regional registry on the long term outcomes of CI users in Iran. Therefore, the present study aims to introduce the design and implementation of a national patient-outcomes registry on CI recipients for Iran. This CI registry provides an integrated framework for data collection and sharing, scientific communication and collaboration in CI research. This CI registry provides an integrated framework for data collection and sharing, scientific communication and collaboration in CI research in a national level in Iran. This paper introduces the study design, methodology, and future directions of the registry.

MATERIALS AND METHODS

Study Design: The ICIR is a prospective, longitudinal, and observational study conducted nationally across multiple cochlear implant centers in Iran. This is an ongoing regular observations of the patients who undergoing CIs to collect the predefined data from different standardized and non-standardized questionnaires.

Participants: Patients who undergoing unilateral or bilateral CI surgery are eligible to be included in the ICIR database. They will be recruited consecutively if they meet the following inclusion criteria: severe to profound bilateral SNHL, little or no useful benefit from hearing aids, no radiological or medical contraindications, appropriate expectations and commitment from client and family, and appropriate access to educational and rehabilitation services to ensure success following the implantation. This study will be implemented through a secure, web-based, registry platform through which clinicians and patient's relatives could administer response data via e-CRFs at consistent time intervals. Obtaining written consent form on participating and collecting data on the database is compulsory prior to the patient enrolment in the registry. The consent form is obtained from a parent, guardian or the caregiver with legal responsibility for the implanted child, prior to the child's enrolment in the registry. Those cases with missing data at predefined intervals or fragmented data, difficulty to complete the different registry fields, as well as those subjects who refuse consent to the use of their data will be excluded from the study.

Observation period: In order to extract and collect clinically-reliable data and to enable comparisons of repeated measures over time intervals, the participants will be followed at regular intervals at 30, 60, 90, and 180 days and annually thereafter for 4 consecutive years and the following factors are monitored and recorded: auditory performance, speech and language development and/

or associated complications including non-invasive or invasive auditory diagnostic tests post-operative medical problems or device failure.

Structure of the database: The software application of the ICIR registry is designed in a user-friendly graphical interface with different entry fields. The collected data are categorized into four subsets including personal information, clinical data, surgery data and commission results. The main parameters include audiometric performance of patient, device use, patient comorbidities, device use, and health-related utilities across different types of CI devices from different manufacturers.

The data collected can be subdivided into four principal subsets (supplement 1).

Personal Information: This subset provides fields for registry of all records, such as personal details, clinical case-history (etiology of deafness, deafness onset-time, use of hearing devices, auditory system assessments (external/middle ear condition, hearing thresholds, auditory nerve function, auditory cortical function), evaluation of speech and language skills (speech perception abilities, language development), and psychological data (family support, behavioral skills, attention and concentration status, IQ,).

Clinical Data: This subset of data concerns clinical information related to "Hearing", "Speech and Language", and "Psychology" data. These components are necessary to trace the clinical profile of the CI user and to check the impact of CI usage on auditory performance, speech and language development, and improvement of quality of life.

Surgery Data: This subset of data includes information relative to preoperative and post-operative information including surgical techniques, duration of surgery, number of inserted electrodes, intraoperative measures (neural and impedance telemetry), intraoperative complications, and postoperative complications.

Commission: In this section, all related experts according to their level of access and based on the results of the examinations will register their comments on the candidate for CI, to specify if the applicant is a suitable candidate for surgery or not.

RESULTS

Electronic-Case Report Form (e-CRF) design: The logical framework of the ICIR registry is set-up as a series of evaluation tools in the format of eCRFs that are completed through data entry via the electronic platform according to the predetermined evaluation schedule of the study. The supplement 1 contains eCRFs presented as different subsets. The paper copies of the eCRFs can be downloaded and printed from the study platform at any time, ultimately for completion, and storage. Technical implementation of this projects including both the practical the maintenance aspects. the practical aspect will concern the generation of the internet-based standardized e-CRF, ongoing queries development, data-clearing and production of descriptive and analytical reports while the maintenance aspect will concern the hosting server, system back-up, and module's connection. Source data verification will be performed to identify transcription errors. The system will periodically check for congruence and completion, and send warning messages aimed at correcting any input mistakes made by users.

Data management: The ICIR is designed and implemented as a secure, web-based database that allows investigators across different CI centers to enroll their patient's information into the database, allocate study identifier numbers and record clinical data according to predefined criteria. All records will be backed-up on a secure server once per day for the last 30 days, and once per month for the last 12 months. The database contains different subsets and field topics that only authorized project administrators can store, share and communicate the data. The data could be directly transferred into EXCELL software. Five variables will be presented as proportions or frequency tables. Continuous variables will be reported as means and standard deviation. For the baseline analysis, the auditory performance, speech and language perception, hearing thresholds (with or without amplification devices) for each CI patient will be recorded across different time points. Analysis of variance (ANOVA) tests will be conducted to compare mean scores across one or more variables that are based on *repeated* observations. Multivariate linear and logistic regression will be utilized to evaluate the independent associations between auditory and speech performances and possible effective factors.

Ethical issues: All procedures of this study were approved by the local Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (AJUMS), Ahvaz, Iran (Registration Code: U94124) which were in complete accordance with the ethical standards and regulations of human studies of the Helsinki declaration (2014). For database management and to ensure the confidentiality and privacy of the patients, the subjects are registered in the web-based platform and the predefined data are collected using the electronic data capture (EDC) system. The 'Act on the Protection of Personal Information' (Act No. 57 of 30 May 2003) and related notifications are applied to patient information. All personnel involved in conducting the study will routinely follow this act and ensure the confidentiality of all subjects' information and the privacy of all subjects.

DISCUSSION

The ICIR registry is designed and implemented to collect demographic clinical and patient-related outcomes information from newly patients who underwent CI

operation, and presented for routine management. In fact, the ICIR provides a unique opportunity for improving the evidences regarding to the auditory, speech and language outcomes in CI recipients. The main objectives of this ICIR are as follows: To longitudinally monitor the improvements of auditory performance in children undergoing CIs using standard questionnaires. To provide patient-outcomes data to set regulations and policies for effective managements and treatment for CI users, and to compare the long-term CI benefits on different aspects including educational placement, quality of life and patient satisfaction in unilateral, bilateral and bimodal configurations. It seems that development of an electronic registry specific to CI would serve to provide information regarding current clinical-practice models and patient outcomes in the field of hearing sciences. It has been indicated that successful registry development will provide essential clinical and cost-effectiveness data for policy and guidelines development[19-21]. A well-designed disease registry could improve patient safety and allow commissioners and service providers to monitor quality, monitor auditory and speech development, and identify variations in practice[22-24]. The ICIR has the potential to be used as a multi-center web-based registry system. Then, it allows us to develop national research collaborations and to collect data on broad populations and evaluate outcomes in real time. Furthermore, ICIR provides a basis for every CI center to design their own set of patient profiles, outcomes data and accordingly follow their own research favorites which may result in scientific publications. the ICIR platform on regular assessment of the outcomes is designed so that to reduce the potential recall bias, with a recall memory period of one month requested at each assessment interval.

CONCLUSION

This paper introduces the design, rationale and methodology of the ICIR registry. This database addresses the requirements for developing a successful national registry of CIs to support research interests of clinicians and academics. This information will be utilized for a wide range of stakeholders including otolaryngologists, radiologists, audiologist, speech pathologists, psychologists, and policy makers for the acceptance and selection of CI devices for the management of hearing loss. This purposefully designed clinical registry would also help to improve healthcare quality and safety and help patients make decisions about their care.

ACKNOWLEDGMENTS

This study was supported financially by Deputy of Research and Technology of Iranian Ministry of Health and Education and Ahvaz Jundishapur University of Medical Sciences.

CONFLICT OF INTEREST

The Author declares no potential conflict of interest on publishing this paper.

REFERENCES

1. Lenarz T, Muller L, Czerniejewska WH, Varela HV. Patient-related benefits for adults with cochlear implantation: a multicultural longitudinal observational study. Audiol Neurotol. 2017:22:61-73.
2. Niparko JK, Tobey EA, Thal DJ, Eisenberg LS, Wang NY. Spoken language development in children following cochlear implantation. JAMA. 2010;303:1498-506.
3. Saki N, Yadollahpour A, Moniri S, Karimi M, Bayat A, Abshirini H, et al. Investigating the impacts of cochlear implantation on the happiness and self-esteem of mothers of children with severe hearing loss. Int J Mental Health Addict. 2017;15:288-94.
4. Mederake MB. Early intervention and assessment of speech and language development in young children with cochlear implants. Int J Pediatr Otorhinolaryngol. 2012;76:939-46.
5. Causon A, Verschuur C, Newman TAA. Retrospective analysis of the contribution of reported factors in cochlear implantation on hearing preservation outcomes. Otol Neurotol. 2015;36:1137-45.
6. Chen S, Karamy B, Shipp D, Nedzelski J, Chen J, Lin V. Assessment of the psychosocial impacts of cochlear implants on adult recipients and their partners. Cochlear Implants Int. 2016;17:90-7.
7. Dunn CC, Walker EA, Oleson J. Longitudinal speech perception and language performance in pediatric cochlear implant users: the effect of age at implantation. Ear Hear. 2014;35:148-160.
8. Ching TY, Dillon H, Marnane V, Hou S, Day J, Seeto M, et al. Outcomes of early- and late-identified children at 3 years of age: findings from a prospective population-based study. Ear Hear. 2013;34:535-52.
9. Mandavia R, Knight A, Phillips J, Mossialos E, Littlejohns P, Schilder A. What are the essential features of a successful surgical registry? A systematic review. BMJ Open. 2017;7:e017373.
10. Hickey GL, Cosgriff R, Grant SW. A technical review of the United Kingdom National Adult Cardiac Surgery Governance Analysis 2008-11. Eur J Cardiothorac Surg. 2014;45:225-33.
11. Bulusu VR, Fullarton J, Leahy M. Rationale and design of a UK database for a rare cancer type: the GEM Registry for gastrointestinal stromal tumours. Br J Cancer. 2013;109:1403-7.
12. Mojarrab S, Rafei A, Akhondzadeh S, Jeddian A, Jafarpour M, Zendehdel K. Diseases and health outcomes registry systems in I.R. Iran: successful initiative to improve public health programs, quality of care, and biomedical research. Arch Iran Med. 2017;20:296-303.
13. Newton J, Garner S. Disease Registers in England. England: Institute of Health Sciences, University of Oxford. 2002.
14. Berrettini S, Arslan E, Baggiani A, Burdo S, Cassandro E, Cuda D, et al. Registry for the collection of data in cochlear implant patient. Acta Otorhinolaryngol Ital. 2011;31:328-40.
15. Ou H, Cleary P, Sie K. Assessing the immunization status of pediatric cochlear implant recipients using a state-maintained immunization registry. Otolaryngol Head Neck Surg. 2010;143:487-91.

16. Schafer EC, Grisel JJ, de Jong A, Ravelo K, Lam A, Burke M, et al. Creating a framework for data sharing in cochlear implant research. Cochlear Implants Int. 2016;17:283-92.

17. Formeister EJ, Forgues M, Adunka OF. An online database to improve clinical operation and scientific data collection in a pediatric hearing loss practice. Otol Neurotol. 2015;36:788-92.

18. Sanderson G, Ariyaratne TV, Wyss J, Looi V. A global patient outcomes registry: cochlear paediatric implanted recipient observational study (Cochlear™ P-IROS). BMC Ear Nose Throat Dis. 2014;14:1-10.

19. Mandavia R, Knight A, Carter AW, Toal C, Mossialos E, Littlejohns P. What are the requirements for developing a successful national registry of auditory implants? A qualitative study. BMJ Open. 2018;8:e021720.

20. Patrick H, Sims A, Burn J. Monitoring the use and outcomes of new devices and procedures: how does coding affect what Hospital Episode Statistics contribute? Lessons from 12 emerging procedures 2006-10. J Public Health. 2013;35:132-38.

21. Larsson S, Lawyer P, Garellick G. Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. Health Aff. 2012;31:220-27.

22. 'Dowd A. Government considers a national implant register in review of cosmetic procedures. BMJ. 2012;345:e5574.

23. Breakwell LM. Understanding the need for spinal registries: Lee Break well reviews the importance of registries in spinal research and explains why the British Association of Spinal Surgeons (BASS) has decided to set up its own registry. Eur Spine J. 2013;22:5-6.

24. Goldberg AJ, MacGregor A, Spencer SA. An information revolution in orthopaedics. J Bone Joint Surg Br. 2012;94:454-58.