International Journal of Otorhinolaryngology and Head and Neck Surgery
Singh J et al. Int J Otorhinolaryngol Head Neck Surg. 2022 Jun;8(6):506-510
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

DOI: https://dx.doi.org/10.18203/issn.2454-5929.ijohns20221389

Original Research Article

Safety and quality protection of cochlear implantation during the COVID-19 pandemic

Jyoti Singh, Shruti Jha, Alekh Kumar, Rakesh Kumar Singh*

Department of ENT, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India

Received: 21 March 2022
Revised: 30 April 2022
Accepted: 02 May 2022

***Correspondence:**
Dr. Rakesh Kumar Singh,
E-mail: rksent5@gmail.com

ABSTRACT

Background: With the emergence of the COVID-19 pandemic, there has been an urgent need to formulate guidelines for safety during aerosol-generating surgeries like cochlear implantation. Although elective, these procedures are crucial to prelingually deaf children so they can develop speech and language skills. Our study is based on guidelines we formulated for cochlear implantation during the COVID-19 pandemic, emphasizing the need for utilizing reverse transcription-polymerase chain reaction (RT-PCR), isolation, and proper protective equipment that is safe yet practical.

Methods: This study was carried out between February 2020 and December 2021. Forty-nine cochlear implantations were carried out at our center following our guidelines during three safe windows when the R factor was <1. All patients underwent serial RT-PCR testing, proper isolation, and were operated on by surgeons who used effective and practical protective equipment.

Results: None of the 49 patients who underwent cochlear implant surgery or the health care workers involved in their care developed clinical features or tested positive for COVID-19 postoperatively. There were also no cases of readmission for COVID-19 after the patients' discharge from the hospital.

Conclusions: Cochlear implantation is an essential procedure that can be safely carried out during a pandemic if guidelines are followed ardently and personal protective equipment is used effectively.

Keywords: COVID-19, Cochlear implantation, Personal protective equipment, Otology

INTRODUCTION

Since the beginning of the COVID-19 pandemic in March 2020, there has been an urgent need for health care systems to customize their mitigation of treatment strategies to provide safe and effective treatment of other diseases. Some conditions require urgent care despite a pandemic emergency strategy. These conditions, especially those that require elective or semi-elective surgeries, necessitate timely strategies so that there is not a negative impact on human health. There are many semi-elective procedures that are necessary to prevent negative disease modulation and achieve favorable outcomes. One such group of patients are pre-lingually deaf children who are being planned for cochlear implantation, which should preferably be done within 3 months.[1] In these patients, postponing treatment will delay speech and language development and will affect the patient's social and academic functioning and ultimately their quality of life.[2] Of note, emergency cochlear implantation is advised before impending ossification in cases of post-meningitis hearing loss.[3]

In response to the COVID-19 pandemic, health care providers have needed to alter their practices, conserve resources, and limit contagion to healthy patients as well

as hospital staff. Therefore, safe surgical practices must be pursued amidst the pandemic, including preoperative screening alongside strategies to limit the generation of virus-containing aerosol during surgery. Over the past 2 years, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, has mutated and spread in a waveform in each geographic area. The commencement of each wave and its turnover is best determined by the reproducibility (R) factor.[4] The R factor establishes the pace of disease spread at a given time. If it is <1, then the disease spread in the community is under control at the beginning of a wave or the spread is declining at the end of a wave. An R factor >1 indicates the disease is spreading rapidly in the community. When the R factor is low, it may provide an opportunity for health care providers to perform elective or semi-elective surgeries, including cochlear implantation.

The other important factor that influences institutional mitigation of COVID-19 is the sensitivity of the diagnostic tools to detect the virus and its variants. The gold standard diagnostic determinant of this virus is the reverse transcriptase-polymerase chain reaction (RT-PCR), whose specificity is almost 100%. However, its sensitivity varies between 70% and 80%, which can be increased up to 99% if the test is done on two consecutive days. Considering this fact in policy and decision-making for surgical intervention is essential to increase significantly the number of operations performed in virus-free environments. To achieve this goal, the medical administration has designed a number of modifications to be used during surgical procedures, especially those that generate aerosols. The main modification is the use of personal protective equipment (PPE), including gloves, medical masks, goggles or face shields, gowns, shoe covers, and N95 or equivalent respirators. Several other modifications have been reported during this pandemic for otological microsurgery such as the use of tent and double draping, among others.[5] The use of PPE is one of the myriad factors to mitigate the transmission of hospital-acquired infections and protect both the surgeon and the patient.[6] There have been many studies focussing on the effectiveness of PPE, tents, double drapes, etc., in protecting patients and health care workers from infected droplets and aerosols, but very few studies have been conducted on the impact of a surgeon's performance during an otologic procedure. Visibility impairment due to goggle fogging, glaring caused by a face shield and goggles, increased fatigue due to excessive sweating, and increased working distance over the microscope because of the use of bulky goggles, leading to a reduced surgical view, are all examples of problems a surgeon has to face while performing any microsurgery. Cochlear implantation is a high-precision surgery that requires posterior tympanotomy, exposing the round window niche, and visualising the round window for correct insertion of the electrode array in the scala tympani. It requires focussed and clear visualisation of the surgical area, a factor that is considerably hampered while wearing full PPE. There is an urgent need to formulate strategies to overcome the difficulties which come with wearing PPE.[7]

This study implemented a strategical algorithm that was followed for every patient undergoing cochlear implantation. This ensured that the patient and the operating theatre staff were not exposed to the SARS-CoV-2 virus without compromising or delaying the treatment in pre-lingually deaf children. This study also focussed on the efficacy of RT-PCR testing combined with isolation of both the patient and his/her attendant as well as the use of the povidone-iodine solution as a handwashing solution, antiseptic paint, and in irrigation fluid along with modifying the use of PPE in such a way that it did not hamper the surgical view and accuracy of the surgery.

METHODS

This retrospective data analysis was carried out at the Indira Gandhi institute of medical sciences between January 2020 and December 2021. Forty-nine patients underwent cochlear implantation during this period at our centre. Each surgery was carried out by following our institutional protocol formulated specially for cochlear implant surgeries. All the candidates meeting the criteria for cochlear implantation, after obtaining clearance from various concerned departments as well as after proper vaccination, were called for admission. The study was conducted after the obtaining emergency approval from the member secretory of the institutional ethics committee.

Before admission

History was taken regarding any symptoms, exposure, or contact with people infected with COVID-19. The patients then underwent mandatory blood investigations and chest X-rays and all candidates underwent RT-PCR testing. Samples were collected by an otolaryngologist or a well-trained staff member to increase the specificity of the test. The collected samples were sent in viral transport media to the microbiology department of our institute. Until the sample, serological, and radiological reports were obtained, the patient was admitted to the institutional common isolation ward. After COVID-19 was ruled out, the patient was then shifted to the ENT ward in an isolation room. If the patient tested positive for COVID-19, they were referred to the COVID-19 management centre.

In the ENT ward

Patients along with a single attendant were kept in an isolation room, the vitals of both the patient and attendant, including temperature, oxygen saturation (SpO_2), and respiration rate, were taken, patients were posted for surgery with two consecutive days of negative

RT-PCR results and a negative antigen test, twenty-four (24) hours before the surgery, the patient was encouraged to the gargle povidone-iodine four to five times.

Operative conditions

Hand hygiene protocols as recommended were augmented by the use of povidone-iodine scrub (7.5% w/v), PPE included a surgical gown, N95 mask/respirator, surgical cap, and a double layer of surgical gloves, antiseptic painting with povidone-iodine solution (10% w/v) was done, 20 ml of 10% povidone-iodine was added to 500 ml of normal saline for irrigation during mastoidectomy, the drilling speed was maintained at 10000-15000 rpm, the bone dust generated during drilling was collected by proper closed suctioning.

Post-operative course

Patients were discharged on the fifth postoperative day and were advised to isolate at home for 14 days. They underwent antigen testing on the 21st postoperative day. If negative, the cochlear device was switched on. Speech therapy was performed as a mix of both online and offline sessions.

Statical analysis and tools

The data was analysed using the MS office 2019 excel spreadsheet (Microsoft Corp., Remond, WA) and the program IBM SPSS 28.0.0 (SPSS Inc., Chicago, IL). The mean, standard deviation (SD), and range of each parameter was computed.

RESULTS

From January 2020 to December 2022, there were 49 cases of cochlear implantation at our centre.

Surgeries were performed when the R factor was <1 and halted when it rose above 1. Seven patients underwent cochlear implantation between January 2020 to mid-June 2020, the first safe window when the R factor was <1. No surgery was performed between mid-June 2020 to mid-October 2020 (R factor was >1), regarded as the first locking period. Twenty-one patients subsequently underwent cochlear implantation from mid-October 2020 to March 2021, considered the second safe window. Surgeries were halted from April 2021 to June 2021, when the R factor rose above 1 (the second locking period). The third safe window was from July 2021 to till December 2021, during which time twenty-one surgeries were performed (Graphs 1 and 2).

Out of the forty-nine patients, thirty-three are male and sixteen are female. When following our institutional protocol for surgical management during the COVID-19 pandemic, none of the patients undergoing cochlear implantation or the health care workers associated with the surgery tested positive for the virus.

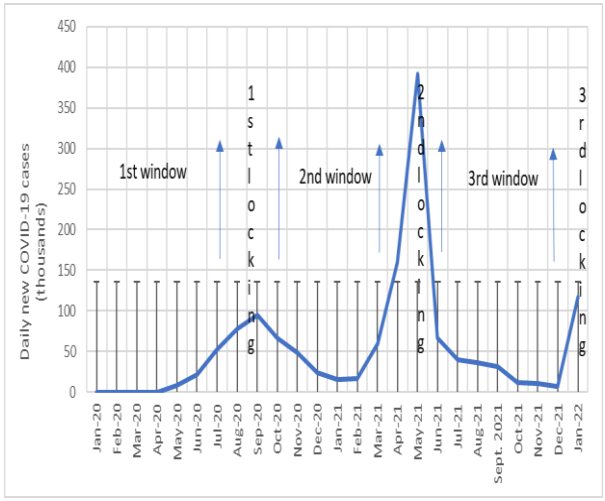

Figure 1: The trend of daily new COVID-19 cases (virtual representation of the trend in India is based upon the graphic representation from covid19tracker.in).

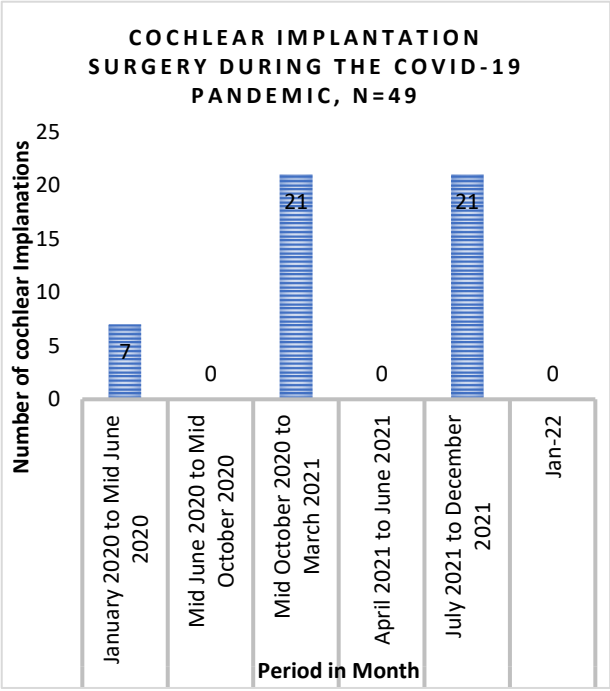

Figure 2: Surgeries were performed when the R factor was <1 and halted when it was >1 (virtual representation of the trend in India is based upon the graphic representation of covid19tracker.in).

DISCUSSION

Otolaryngologists are at a high risk of hospital-acquired infection with SARS-COV-2, which resides and colonises within the nasopharynx and oropharynx, the primary sites handled by these doctors. Cochlear implantation, which requires mastoid drilling that

generates aerosols potentially carrying viruses, exposes not only the surgeon but also the assistant, nurses, anaesthetists, and operating theatre staff. Heavy viral loads have been found in the mastoid antrum and mastoid air cells that reach via the eustachian tube.[8] If infected with this high viral load, the incubation period of the disease decreases, and the damage to the lungs increases. The maximum distance of particle spread can range from 30 to 208 cm in otological surgeries.[9]

To prevent otolaryngologists and operating staff from getting infected with the high viral load, RT-PCR testing and proper use of PPE are mandatory. RT-PCR is the gold standard test for SARS-CoV-2. While almost all people who test positive for the virus will have the disease (given the near 100% specificity of the test), there is a risk of false negatives who have the disease but test negative, thus giving a false sense of security.[10] To increase the sensitivity of the RT-PCR test to detect a person with COVID-19, it has to be repeated in the case of clinical suspicion. In our study, we performed an initial RT-PCR at the time of admission in an asymptomatic patient. When their results were negative, they were kept in an isolated ENT ward to prevent hospital-acquired exposure. Their temperature, pulse rate, respiration rate, and SpO_2 were assessed every 8 hours. After this isolation, they were subjected to RT-PCR testing on two consecutive days. A repeat RT-PCR test would detect false negatives and increase the sensitivity above 99 percent.

Cochlear implantation requires high precision, accuracy, and a focussed mind of an operating surgeon. While wearing a PPE kit will certainly protect from SARS-CoV-2, it has disadvantages during such delicate surgery. These include decreased visibility and glaring due to fogging by goggles/face shield, heavy goggles acting as a barrier between the eyes and the microscope, increasing the working distance, and excessive sweating under the PPE kit, leading to exhaustion.[11] Jaiswal et al noted that eye goggles severely restrict vision, which could decrease the efficacy of a surgeon, increase complications such as damage to vital structures (dura, sigmoid, ossicles), and prolong the operative time-and thus potential exposure to the virus.[12] In our study, after confirming the patient is a true negative (clinical assessment, and repeat RT-PCR testing), which means it is minimal or no COVID-19 virus harboured in the nasopharyngeal or oropharyngeal region and the mastoid antrum and air cells of the patient, they were posted for cochlear implantation.

Alongside the steps that preceded the emergence of COVID-19-proper hand scrubbing with povidone-iodine (7.5% w/v) and antiseptic painting with povidone-iodine (10% w/v)-a few more modifications have been made amidst the COVID-19 pandemic: povidone-iodine gargle 24 hours before surgery, continuous use of a microscope to maintain a safe working distance, mixing povidone-iodine with the irrigation fluid, and decreasing the speed of drill to 10000-15000 rpm while drilling the mastoid bone. We have also demonstrated that minimal PPE in the form of an N95 mask or respirator with a proper seal, a head cap, a double layer of gloves, and the usual surgical gown is sufficient during surgery without compromising the efficacy of surgery, but only if our proposed preoperative institutional protocol is strictly followed. We must keep in mind that all elective surgeries including cochlear implantation must be kept on hold when the infection rate is high, and surgery can only be resumed when a flat curve is achieved for about 1 month. While the mortality rate for COVID-19 has been reported as approximately 4%, there have been reports of postoperative mortality as high as 50% in patients who develop COVID-19 symptoms perioperatively.[13,14] This factor must be kept in mind before commencing surgery.

Out of 49 patients operated on during the 2 years of this study, none of the surgeons, assistants, or other staff members was infected with SARS-CoV-2. This means that following the guidelines proposed by our institution, we can safely perform cochlear implantation without compromising the surgical outcome or the safety of the patient and the operating staff. This will also ensure a better quality of life for the patients.

Limitations

It was a retrospective data analysis of the cochlear implantation done in our institution from January 2020 to December 2021 of 49 cases. The prospective observational study is required in more cases to come to a further scientific conclusion.

CONCLUSION

For cochlear implantation, the time of operative intervention is crucial since the early intervention provides the best outcome. Hence, the operation cannot be delayed for a long time due to the COVID-19 pandemic that showed an urgent need to formulate guidelines for safety. Moreover, the surgical procedure must be carried out without compromising the quality of the surgery which was faced with modifications in the surgical setting during this pandemic. The present study is unique in its own type because the adopted protocol was highly protective and safe and maintained the quality of the surgery with an excellent outcome.

ACKNOWLEDGEMENTS

Author would like to thanks to prof. (Dr) Ramesh Chandra Deka, professor emeritus, department of ENT of Indira Gandhi institute of medical sciences for his reluctant guidance to formulate all aspects of this manuscript. We extend our thanks to prof. (Dr.) N. R. Biswas, the director and prof. (Dr) Manish Mandal, medical superintendent for providing the administrative support and hospital materials to conduct this study. We are immensely grateful to the patients and their relatives for their faith and support to us in this difficult pandemic period.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Skarzynski H, Lorens A, Dziendziel B. Resumption of cochlear implant surgery under COVID-19 pandemic conditions. Life (Basel). 2021;11(9):929.
2. Mohammed H, Kennedy L, Whitehead D, Ahmad N, Banerjee A. A prospective study on the feasibility of cochlear implantation during the coronavirus disease 2019 crisis and trends of assessment: experience in a UK centre. J Laryngol Otol. 2021;135(1): 21-7.
3. Vaid N, Vaze V, Gokhale N, Kothadiya A. Cochlear implant surgery during the Covid pandemic lockdown-the KEM Hospital, Pune experience. Indian J Otolaryngol Head Neck Surg. 2020;1-4.
4. Reproduction number (R) and growth rate (r) of the COVID-19 epidemic in the UK: methods of estimation, data sources, causes of heterogeneity, and use as a guide in policy formulation. The Royal Society. 2020. publishedonlineSep9. Available at: https://royalsociety.org/-/media/policy/projects/set-c/set-covid-19-R-estimates.pdf. Accessed on 25 March, 2021.
5. Lawrence RJ, O'Donoghue G, Kitterick P. Recommended personal protective equipment for cochlear implant and other mastoid surgery during the COVID-19 era. Laryngoscope. 2020;130(11):2693-99.
6. Jessop ZM, Dobbs TD, Ali SR. Personal protective equipment for surgeons during COVID-19 pandemic: systematic review of availability, usage and rationing, Br J Surg. 2020;107(10):1262-80.
7. Khan MM, Parab SR, Paranjape M. Repurposing 0.5% povidone iodine solution in otorhinolaryngology practice in COVID-19 pandemic. Am J Otolaryngol. 2020;41(5):102618.
8. Mick P, Murphy R. Aerosol-generating otolaryngology procedures and the need for enhanced PPE during the COVID-19 pandemic: a literature review. J Otolaryngol Head Neck Surg. 2020;49:29.
9. Favre NM, McIntyre KM, Kuo CC. Mitigation of particle spread during mastoidectomy: a systematic review. Cureus. 2021;13(10):e19040.
10. Goudouris ES. Laboratory diagnosis of COVID-19. J Pediatr (Rio J). 2021;97(1):7-12.
11. Agarwal A, Agarwal S, Motiani P. Difficulties encountered while using PPE kits and how to overcome them: an Indian perspective. Cureus. 2020;12(11):e11652.
12. Jaiswal V, Fraser L, Wardrop P. Ocular protection not used during elective cochlear implant and mastoid surgery during Covid-19 era. Laryngoscope. 2021; 131(4): E1286. doi:10.1002/lary.29150
13. Grech V. Unknown unknowns-COVID-19 and potential global mortality. Early Hum Dev. 2020;144:105026
14. Aminian A, Safari S, Razeghian-Jahromi A, Ghorbani M, Delaney CP COVID-19 outbreak and surgical practice: unexpected fatality in perioperative period. Ann Surg. 2020;272:e27-9.

Cite this article as: Singh J, Jha S, Kumar A, Singh RK. Safety and quality protection of cochlear implantation during the COVID-19 pandemic. Int J Otorhinolaryngol Head Neck Surg 2022;8:506-10.