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Original Research Article

Innovation for CI surgery and habilitation in the COVID era: the MERF, Tamil Nadu experience

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ABSTRACT

Background: Cochlear implantation (CI) is a safe and effective procedure for management of severe-profound hearing loss. Complications are uncommon, but when present, should be identified and managed appropriately. The CI and its habilitation services were halted during this time period. Through this article we have tried to showcase how our institute resumed the CI surgeries and managed its complications as well as how we tackled the problems faced in auditory habilitation of CI candidates.
Methods: This was a retrospective review of the challenges in cochlear implantation and its complications during the COVID pandemic. A safe management plan was formulated. All patients were thoroughly evaluated and complications were classified as minor or major and were managed medically or surgically, based on its severity. Postoperative auditory habilitation challenges were also tackled with innovative approaches to habilitation.
Results: A stringent protocol was followed during the pandemic. Wound infection, biofilm, device failure were the complications encountered. All challenges and complications were dealt with by an experienced CI surgeon appropriately with successful outcomes.
Conclusions: During the pandemic, it was essential to deal with all the challenges in CI and its complications taking all necessary precautions. Complications of CI, although not common required prompt and effective management for optimal outcomes.

Keywords: Cochlear implantation, Challenges, Complications, COVID pandemic

INTRODUCTION

The outbreak of COVID 19 was officially announced as pandemic by the World Health Organization in March 2020.[1] Viral detection was noted in both symptomatic as well as asymptomatic patients.[2] The aerosol generating procedures of otolaryngology were considered to be potentially hazardous due to the contagious nature of the virus. With the national guidelines calling for the cancellation of all the elective procedures and further the anthropause due to complete social lock down measures resulted in drastic slowdown of services provided in the field of implantation otology. A protocol was recommended to classify the ENT procedures into emergencies, semi-emergent and elective, to proceed with theatre allocation, whilst following COVID protective measures to perform the surgeries. CI was one of the vital services which was affected during these times. Delaying seemingly elective procedures as well as discontinuity in post-operative habilitation can have an immense consequence in the quality of life and potential long-term health of a deaf child.[3] The Cochlear Implant Group of India (CIGI) recommends that the surgical and hearing habilitation services in pediatric age group should not be delayed beyond 3 months from the time of diagnosis.[4] Later Indian Speech-Language and Hearing Association (ISHA) published the guidelines for teleservice for habilitation during the COVID pandemic.[5] Our

implantation otology and audiology team came up with a protocol to tackle the new challenges faced during COVID pandemic and we resumed implantation services by March 2020. In this article, we present our protocol for management of surgeries related to cochlear implantation and their habilitation during the surge and fall of COVID cases over the last 2 years and the surgical complications encountered during the same.

METHODS

This was a retrospective study performed at a tertiary ENT care centre of South India between March 2020 to February 2022, including 105 patients who underwent CI and surgeries related to CI.

The surgical indications for cochlear implantation were profound hearing loss due to congenital causes or acquired causes such as sudden sensorineural hearing loss, ototoxicity, otosclerosis, trauma, chronic otitis media, etc. All the patients were followed up for a period of one year. The protocol formed and followed by our centre is as follows. Institutional ethic committee approval was obtained.

Protocol

The protocol laid down by our team mainly aimed at preventing the chances of COVID infection amongst the implant team members as well as our patients during the course of care. The protocol also aimed to ensure effective habilitation with strict adherence to local COVID control policies, which was reinforced with the help of spoke and hub model which was followed by our institute for habilitation for telemedicine services. The patients were grouped into different risk strata as follows-

Risk stratification of patients during COVID pandemic:

Urgent

Treatment of post-operative infection, biofilms [done even if the reproducibility (R) factor of COVID pandemic wave was more than 1].

Semi-urgent

Done only if the R factor of COVID pandemic wave was less than 1- removal of infected CI, cochlear ossification requiring CI, young child- CI a neurolinguistic emergency, and CI before the age of 6 years as Government funding (TNCMCHIS) is provided only up to the age of 6 years.

Delayed

Adult patients requiring CI, excluding post meningitis cases (delayed up to 6 months and operated after relaxation of lockdown)

Pre-operative measures

Patients diagnosed and worked-up for CI and enlisted for the surgery were contacted over telephone based on the risk stratification and urgency of care. Over the telephonic conversation, the details of residence (to delay cases from red/orange containment zone as per Govt till situation improves), history of travel to containment zones, contact with COVID positive patients, history of symptoms suggestive of COVID (fever, cough, rhinitis, body ache etc.), and vaccination status were enquired. Those who were unlikely to be infected based on tele-verification, were called for preanesthetic assessment. During this visit a proposed date of surgery was fixed and patients/bystanders were counselled about the change in hospital protocol, and to strictly adhere to the new COVID control protocol laid by the government.

Written informed consent for the routine surgery with additional stress on post-operative risk due to COVID infection if contracted, as well need for strict follow up for habilitation were explained and taken from all patients. The patient and bystander were subjected to COVID testing - RT-PCR from certified lab 24 hours prior to the procedure and admission was done only after confirmation of COVID negative status. The number of elective cases were kept to a maximum of one case per operation theatre (OT) to minimize the chances of infection. All the patients and bystanders wore surgical mask and followed strict hand hygiene during the stay in the hospital. The barrier nursing care was given in COVID free wards. COVID screening was also done for the CI team at regular intervals.

Intra-operative

All the patients underwent the proposed surgery under general anaesthesia. General anaesthesia was given with COVID precautionary protocols. The surgical team strength was kept to the bare minimum to avoid exposure and risk of COVID infection. All members wore personal protective equipment recommended. The surgical team entry was in the following order - first the anaesthetist and technician shift and intubate the patient under COVID precautions, following which the surgeon and nurse enter and start the procedure. Audiologist for intraoperative audiological assessment entered only after implant placement. Aerosolization due to mastoid drilling was contained with the help of double microscope cover technique (Figure 1), setting the micromotor speed to the lowest, and laminar flow with HEPA filters.[4] The patients were discharged on post-op day 2 and were advised to maintain home isolation till the first follow-up.

Post-operative

All operated patients underwent regular wound care with COVID precautions.

Audiological habilitation

Habilitation post operatively was amongst the most challenging aspects of CI during the pandemic. Habilitation in person was preferred over the teletherapy whenever possible. The in person habilitation was conducted as per the guidelines proposed by our audiology institute.[6]

For teletherapy during the peak of the pandemic, the guidelines laid by Ministry of health and family welfare, Govt of India and Indian speech and hearing association were followed. During the interpeak relaxation, children were also assessed in person while following COVID precautions at our audiology institute for fine-tuning their implant, trouble-shooting and escalation of therapy sessions.

Remote mapping and programming of device, satellite centres at multiple locations over the state (Hub and spoke model), counselling and educating the parents over video conferencing and micro group video conferencing for sharing experiences with previously operated CI kids and their parents which were all practiced successfully by us during normal times. Implementing these during the COVID times ensured a good positive approach and compliance of parents to the CI habilitation program during the pandemic.

Management of complications

The post-operative complications such as surgical site infection, hematoma, seroma, skin flap necrosis etc. were considered as cases requiring urgent care. If the medical line of management failed, patients would be taken up for surgical correction on priority basis. Complications such as device failure (soft device failure or hard device failure) were categorized under semi-urgent cases, they underwent explantation and reimplantation as elective surgery with all COVID precautions mentioned as above.

Figure 1: Intra-operative measures taking during COVID pandemic.

All the data collected was processed and analysed using Statistical Package for Social Science (SPSS) version 16.0 and a p value of 0.05 was considered to be statistically significant value.

RESULTS

A total of 105 patients underwent cochlear implantation surgery between March 2020 and February 2022 at our centre. The age range was as young as 1 year to 64 years (mean age- 6 years). The male: female ratio was 1.2: 1. We encountered complications among 9 of our patients (8.6%). Device failure was the most encountered complication (4 cases), followed by wound infection (3 cases) and biofilm (1 case) respectively (Figure 2).

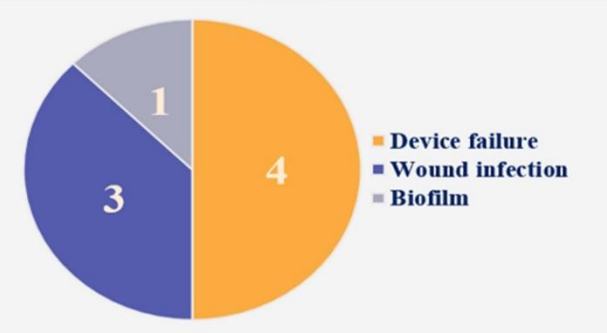

Figure 2: Distribution of various complications encountered in the study population.

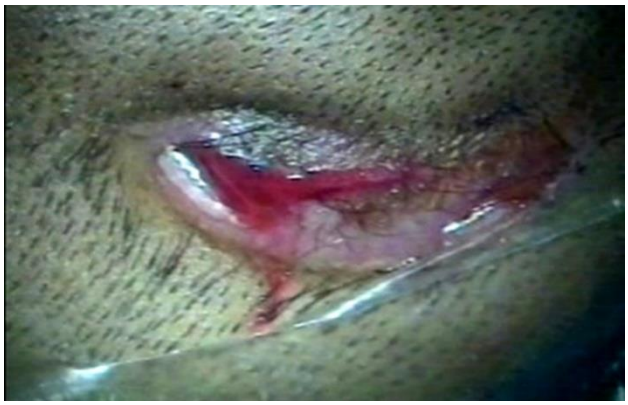

Figure 3: A case of wound infection in an implantee.

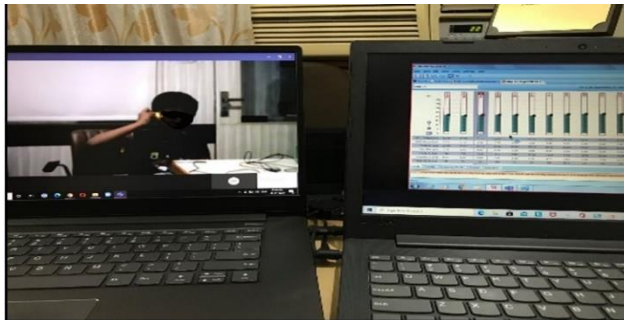

Figure 4: Tele-mapping done for cochlear implantee during the pandemic.

The 4 cases of device failure underwent explantation and reimplantation. 3 cases of wound infection (Figure 3) were managed medically with IV antibiotics and twice daily dressings. 1 case of biofilm was treated with rifampicin.

The distribution of the cases over the course of the pandemic is shown in Table 1. The mean pre-operative CAP score was 1 and the mean post-operative CAP score was 2 at the end of 6 months and 5 at the end of 12 months. This was found to be statistically significant ($p>0.05$) reflecting the no significant difference in the benefit of cochlear implantation during the COVID pandemic despite the remote habilitation offered in these COVID times, due to the continuous effort by our team and support from motivated parents. The rate of surgical complications were similar to pre-COVID era rates of our centre (p value>0.05).

Table 1: Distribution of cochlear implant related surgeries done during each COVID pandemic peaks and inter-peak period.

Duration	No. of CI	Challenges	Medical management of complication	Surgical management of complication
March-November 2020 (first COVID wave)	6	Wound infection-2 Device failure-3	2	Explanation and reimplantation-3
December 2020-March 2021	36	Biofilm-1 Device failure-1	-	Explanation and reimplantation-1
April-August 2021 (second COVID wave)	18	Wound infection-1	1	-
September-October 2021	20	-	-	-
November 2021-February 2022 (third COVID wave)	25	Wound infection-1	1	-

DISCUSSION

The COVID virus made an unprecedented attack in December 2019, following which the access to hearing services was challenging. It came to a standstill with complete social lockdown on March 24th 2020 and with official orders to stop elective surgeries at medical health care facilities. This psychologically as well as functionally affected CI patients and their families globally during the pandemic

Early identification and correction are crucial for development of age-appropriate speech and language development.[7] The COVID pandemic put a halt to screening, diagnosis and treatment for hearing impaired children within their critical age for hearing restoration. There is also a stringent criteria of ≤6 years cut-off for being eligible to receive a CI under the Tamil Nadu Chief Minister's Comprehensive Health Insurance Scheme (TN CMCHIS), due to which there was a fear of a few of the candidates becoming time-lapsed for CI funding.

This work reflects our experience of Cochlear implantation during the pandemic and measures taken by our institute to run the CI program smoothly, despite the adverse situation worldwide. We attempted to understand the main challenges faced by our patients in availing the CI related services and aimed at providing solutions to the same during the COVID pandemic. The fear of contracting the infection, difficulty in access to services due to public restrictions, the lack of knowledge and experience with teleconsultation were the key challenges our institute aimed at solving in a systematic manner, thanks to the technological knowhow and infrastructure we already possessed as the successful hub and spoke model of pre-COVID times.[8] With the case risk stratification followed by our institute, we could prioritize on which CI patient should receive medical/surgical attention without increasing the risk of COVID infection. We performed 105 cochlear implantations during the last 2 years as compared to the usual count of 150-170 implants/year during pre-COVID times. Although the mortality rate of COVID is reported to be around 4%, it was noted that postoperative mortality can be as high as 50% among those who develop COVID symptoms peri-operatively.[9] Hence our primary goal was to continue the Cochlear implant program without increasing risk to our patients or personnel. None of our implantees developed COVID in the post-operative period and there was no post-operative mortality. We encountered post-operative complication among 9 cases (8.2%). The complication rates are similar to other studies which were done prior to COVID pandemic.[10] In our study, device failure was most encountered complication (4 cases), followed by wound infection (3 cases) and biofilm (1 case) respectively. The 4 cases of device failure underwent explantation and reimplantation. 3 cases of wound infection were managed medically with IV antibiotics and twice daily dressings. 1 case of biofilm was treated with rifampicin.

For audiological habilitation, when in person therapy was not possible, teletherapy, tele-habilitation (Figure 4), remote mapping, and satellite habilitation centres were helpful to ensure continuation of habilitation even in the peak of the COVID pandemic. Various studies have shown teletherapy to be an effective tool for auditory habilitation during the pandemic.[11,12] Ironically, some studies have

shown that when compared with in person therapy, teletherapy was not as effective.[13] Our CI habilitation works on 'the hub and spokes' model which was shown to be an effective method to improve the rate of habilitation attendance in the pre-pandemic period. Having such a model also proved to be advantageous during the COVID pandemic. It enabled to make habilitation available at these satellite centres, which reduced the travel duration, expenses as well as the risk of the patient's exposure to COVID. As expected, due to the lockdown, spare parts non availability and problems in delivering it to these satellite centres were hindering the habilitation which were eventually resolved. All the patients had satisfactory audiological outcomes with CI similar to pre pandemic results.

CONCLUSION

The impact of the COVID pandemic constituted several challenges to cochlear implantation and management of its complications. During the pandemic, safety was paramount; hence it was essential to take all necessary precautions. Formulating a strategy with stringent protocols helped to effectively deal with the challenges of CI (complications were not due to COVID) during the COVID pandemic. As a silver lining to our implant program, our pre-existent tele-services via the hub and spoke model, were of great help for our CI habilitation unit to tide over these unprecedented COVID times, without compromising implant services. This innovative protocol stands as a valid reference today, just in case another catastrophe arrives in the near future.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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