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Original Article

Feasibility of Day Surgery for Cochlear Implantation under Conscious Sedation with Same-Day Fitting

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OBJECTIVES: To evaluate the feasibility of performing cochlear implantation under conscious sedation (CS) as day surgery with same-day fitting.

MATERIALS and METHODS: All patients underwent cochlear implantation under CS between November 2017 and April 2018. The data collected included demographic information, preoperative clinical characteristics, surgical details, postoperative fitting information, and side effects, if any.

RESULTS: Nine patients had 11 cochlear implants (CIs) placed under CS (2 patients received bilateral CIs). One patient's data were excluded from the audiological results because conversion to general anesthesia (GA) was necessary. One patient (11%) vomited just before the end of the procedure. Seven patients had uneventful procedures. Eight (88%) patients were discharged home the same day. There was a statistically significant difference in recovery time between the CS group and the GA group ($t=-2.26$, $df=12$, $p<0.05$). In the CS group, there was no statistically significant change in the maximum comfortable loudness level for all electrodes from the day of the surgery to the following day. However, there was a statistically significant difference in the threshold levels of all electrodes from the day of the surgery to the following day ($Z=-2.04$, $N=120$, $p<0.05$). Further analysis revealed a statistically significant difference in the four most apical electrodes ($Z=-3.496$, $N=40$, $p<0.0001$), but not in the middle or basal electrodes.

CONCLUSION: Cochlear implantation can be performed under CS with careful patient selection. This approach facilitates same-day fitting and day surgery by minimizing comorbidity.

KEYWORDS: Cochlear implant, local anesthesia, early fitting

INTRODUCTION

Cochlear implantation is a hearing rehabilitation procedure for patients with sensorineural hearing loss who do not benefit from hearing aids [1,2]. Over time and with increasing experience, cochlear implantation practices have changed over the last two decades. These approaches and different surgical techniques have been described in the literature [3].

Cochlear implantation is usually performed under general anesthesia (GA) as standard practice worldwide. A few studies have considered the use of conscious sedation (CS) because of the patient's age or contraindications for GA during cochlear implantation [4,5]. Surgery with CS or local infiltration only is a well-established technique for various surgical specialties, including otology, and many otologists utilize this technique when performing mastoidectomy, stapes surgery, or tympanoplasties [6].

With the development of minimally invasive surgical procedures and technical advances in the CI device itself, early fitting of the cochlear implant (CI) has become possible [7,8]. Next-day activation of CI has been found to be feasible without affecting healing or negatively impacting the physiological processes of the cochlea [7]. Early activation of the CI can provide a practical and convenient option for CI recipients who need to travel to their CI center. Even next-day activation can be costly or impractical for some CI recipients and families residing in cities other than that of their CI center. Costs can arise from the need to pay for accommodations and/or apply for a leave of absence from work or from school for their siblings.

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We aimed to evaluate the feasibility of performing cochlear implantation under CS as a standard practice upon request by adult patients. Patients with different indications for cochlear implantation were evaluated in this study. In addition, we aimed to evaluate for the first time the possibility of providing initial audiological fitting of CIs in the recovery room and discharging patients on the same day with the external speech processor turned on, a process that is facilitated when CIs are implanted under CS.

MATERIALS AND METHODS

This was a retrospective chart review conducted at a reference cochlear implant center between November 2017 and April 2018. The study was approved by the Institutional Review Board at The University Medical City. All patients who underwent cochlear implantation under CS were included in this review. The collected data included demographic information, perioperative reports, surgical notes, surgical times, and postoperative follow-up data. The patients were classified into two groups: those who underwent surgery under CS with same-day fitting (CS group) and those who underwent surgery under GA with next-day fitting (GA group). Audiological data were collected to evaluate the clinical feasibility of same-day fitting compared with our routine fitting (next-day fitting). The evaluated parameters were impedance telemetry, threshold (THR) level, and maximum comfortable loudness (MCL) level. Patients with claustrophobia, anxiety, hesitation, and obstructive sleep apnea were excluded. All patients received SYNCHRONY CI System devices from Med-El, Innsbruck, Austria.

All patients in the CS group were matched for age group and, to the extent possible, cochlear implantation duration with patients who underwent surgery under GA with next-day fitting. $p<0.05$ were considered statistically significant. The data were statistically analyzed using IBM SPSS Statistics for Mac, version 23 (IBM Corp., Armonk, NY, USA).

Anesthetic protocol

All patients were evaluated in the preanesthesia clinic. In the holding area, lidocaine and prilocaine cream (5% Emla) was applied over the facial nerve electrode insertion sites, the external auditory canal, and the postauricular area for 30 minutes. These areas were covered with a transparent medical dressing (Tegaderm) to keep the cream in place.

MAIN POINTS

- The cochlear implant procedure can be performed safely for adult patients, including those who are not contraindicative for general anesthesia.
- Performing cochlear implant surgery as day surgery is more effective for patients and institution.
- Early next-day fitting of the sound processor should be performed routinely for cochlear implant patients.
- Same-day fitting of sound processor might be a convenient option especially for patients from long distance; further studies with a larger number of participants are needed.

Operative monitoring included oxygen delivery through a nasal cannula at a rate of 2-3 L/min, electrocardiography, pulse oximetry, capnography, and noninvasive blood pressure monitoring. Intraoperatively, conscious sedation was induced using an intravenous dexmedetomidine infusion at a dose of 0.2-0.4 mcg/kg/min as appropriate to maintain a minimum mean blood pressure of 60 mmHg.

Patient preparation

In the operating room, each patient was placed comfortably in the supine position, and viscoelastic gel pads were placed under the legs with a compressor for deep vein thrombosis prophylaxis. The patient's face was uncovered and tilted comfortably to the opposite side. Facial monitoring was performed in all cases; for patients undergoing bilateral implantation, we used only two-channel facial nerve monitoring at the midline of the face at the level of the eyebrows and the philtrum to stimulate both sides. One staff member sat in front of the patient to facilitate communication and obtain feedback. The nurse and surgeon and all instruments were placed on the surgical side. A metallic bar was used to hold the drape as a curtain to separate the surgical side from the patient's view.

Surgery

The operative area was prepared with povidone. A drape was applied as previously described. An auricular block using 10 mL of 1% lidocaine with 1/100,000 epinephrine was used as LA. A standard 3-cm postauricular incision with a periosteal Palva flap was elevated, and a standard mastoidectomy with a facial recess approach was used to insert the electrode through the round window after removing the niche.

Intraoperative impedance and field telemetry (IFT) for all electrodes were collected (via Maestro 6 with the MAX Programming Interface from Med-El, Innsbruck, Austria) at high intraoperative stimulation levels down to zero.

Audiological measurements and fittings

IFT measurements were performed intraoperatively, in the recovery room, and postoperatively at 1 day and 2, 4, 6, and 8 weeks. Impedance (kOhm) telemetry was measured from Channel (CH) 1 to CH 12 using Maestro 6 software.

The default strategy used was FS4-p (parallel signal processing). The THR and MCL levels were measured for all electrodes [1-12] using a train of biphasic pulses. A loudness scale was used to measure the MCL level. The lower end of the frequency range was reduced to 70 Hz for all patients; the compression ratio of the automatic gain control was set at the default 3:1 ratio. The patients were given progressive programs until a stable program was reached; they were asked to initially use the program downloaded to the P1 position of the speech processor before using P2 and so on. The program downloaded to P1 was tested for comfort and quality before it was downloaded with each device in live mode; both devices were tested in live mode in cases of bilateral cochlear implantation.

Statistical Analysis

All statistical analyses were performed using the Statistical Packages for the Social Sciences (SPSS) Statistics for Mac, version 23 (IBM Corp., Armonk, NY, USA). According to the Shapiro–Wilk's test, the

data for the IFT, THR level, and MCL level were not normally distributed. Hence, the two groups were compared using the Mann–Whitney test, and the Wilcoxon signed-rank test was used to compare values from consecutive fitting sessions within each group.

RESULTS

A total of 11 CIs (9 patients) were implanted under CS. Three cases were second implants, two patients underwent bilateral cochlear implantation, two cases were first implants, and two patients had single-sided deafness. Seven patients were male, and two patients were female. The age range was 25 to 68 years, with a mean age of 38.7 years. One patient (11%) required conversion to GA; this patient's data were excluded from the audiology results, but the patient was included in the study as a case of an intraoperative complication. One patient (vomited just before the end of the procedure; seven patients had uneventful procedures. Eight (88%) patients were discharged home the same day; one of the nine patients without medical issues was hospitalized as an inpatient until the following day at his own request.

The *t*-test was used to compare the anesthesia induction time and recovery time (from the time of skin closure to the time the patient was awake) for the CS group and the GA group. The mean induction time was 22.2 minutes for the CS group and 19 minutes for the GA group, with no statistically significant difference between the two groups ($p<0.237$). The mean recovery time was 2.6 and 7.6 minutes for the CS and GA groups, respectively. The *t*-test revealed a statistically significant difference in the recovery time between the two groups ($t=-2.26$, $df=12$, $p<0.05$).

Audiology results

The electrodes were also divided into apical, middle, and basal groups [9-11]. Apical electrodes were defined as electrodes (E) E1 to E4, middle electrodes as E5 to E8, and basal electrodes as E9 to E12.

Impedance and field telemetry

Within the CS group, there was an initial statistically significant decrease in the impedances for all electrodes when they were tested the day of the surgery in the recovery room compared with intraoperative impedances ($Z=-8.679$, $N=120$, $p<0.0001$). This finding was followed by a significant increase in the impedances the following day ($Z=-5.255$, $N=120$, $p<0.0001$) and a week later ($Z=-3.215$, $N=120$, $p<0.0001$). After the first 2 weeks, no statistically significant changes were seen up to 8 weeks postoperatively. This was true for apical, middle, and basal electrodes, as shown in Figure 1.

The Mann–Whitney U test showed no significant difference between the CS and GA groups at any test interval.

Threshold level

Within the CS group, there was a statistically significant difference in the THR level for all electrodes when tested on the day of the surgery in the recovery room compared with the next-day measurements ($Z=-2.04$, $N=120$, $p<0.05$). However, further analysis revealed a statistically significant change in the THR level between the same-day fitting and the next-day fitting in the apical region only ($Z=-3.496$, $N=40$, $p<0.0001$) and not in the middle or basal regions.

The THR level was stable with no statistically significant changes for all electrodes at the 6th week postoperatively when compared with that at the 8th week postoperatively.

The Mann–Whitney U test showed a significant difference in the initial activation program between the CS and GA groups ($U=4698.5$, $p<0.0001$), but there was no difference for later sessions.

Maximum Comfortable Loudness level

In the CS group, there was no statistically significant change in the MCL level for all electrodes when tested the day of the surgery in the recovery room compared with the next-day measurements. This was true for all regions.

Two weeks postoperatively, the MCL level was unstable; there were statistically significant changes in the MCL level for all electrodes at the 6th week postoperatively compared with that at the 8th week postoperatively ($Z=-3.858$, $N=120$, $p<0.0001$). However, further analysis revealed different patterns across the different regions, with significant changes in the MCL level at the 6th week postoperatively compared with that at the 8th week postoperatively in the apical ($Z=-2.768$, $N=120$, $p<0.01$) and middle ($Z=-2.567$, $N=120$, $p<0.01$) regions but not in the basal region. The MCL level was stable by the 6th week postoperatively, with no significant changes compared with that by the 8th week postoperatively; however, the MCL level was not stable between the 4th and 6th week postoperatively in the basal region ($Z=-2.821$, $N=120$, $p<0.01$).

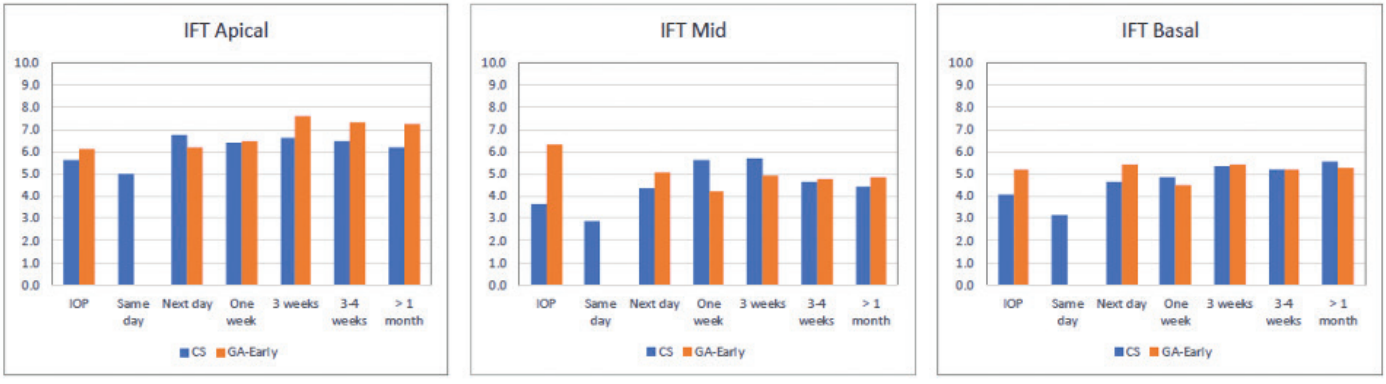

Figure 1. The progression of impedance field telemetry (IFT) in both groups of early fitting (conscious sedation (CS) vs general anesthesia (GA)) in three cochlear duct parts.

The Mann–Whitney U test showed a significant difference in the initial activation program between the CS and GA groups (U=3851, p<0.0001) at 2 weeks (U=5291.5, p<0.05), 4 weeks (U=4265.5, p<0.0001), and 6 weeks postoperatively (U=4054, p<0.0001) but not at 8 weeks postoperatively.

DISCUSSION

Our study group (11 CIs) included patients with different conditions and indications for cochlear implantation: bilateral simultaneous, sequential, and unilateral implantation and single-sided deafness.

Of the patients, 88% were discharged home the same day; one patient without medical issues was hospitalized as an inpatient until the following day at his own request.

One patient vomited during the electrode insertion, which may have occurred as a result of autonomous nervous system stimulation triggered by the stimulation of the vestibular system; this side effect might be avoided with very slow insertion, avoidance of applying suction to the round window, and gentle opening of the round window. Both patients with single-sided deafness were anxious during surgery, especially during drilling, and one patient required conversion to GA intraoperatively because the patient could not handle the stress of the procedure. In our opinion, the following groups of patients are amenable to cochlear implantation under CS: 1) patients who meet the criteria for cochlear implantation; 2) patients older than 18 years, so the patient can legally and mentally decide for him- or herself the preferred type of anesthesia; 3) patients with medical contraindications for GA; and 4) a preoperative understanding of expectations and cooperative and calm behavior.

The anesthesia induction time was longer in the CS group than in the GA group, although the difference was not statistically significant (p<0.237). Although less preparation was necessary for the CS group than for the GA group, we reflected on the results when starting each new procedure, and we spent considerable time communicating with the anesthesia team every time the team was involved. However, the recovery time was significantly shorter in the CS group than in the GA group, as the patients were already awake (p<0.012)

Cochlear implantation under CS is an interesting procedure for patients, surgeons, and health care institutions for different reasons. CS allows the patient to be fully awake immediately after surgery; thus, many patients prefer CS because this technique offers less risk and a faster recovery from surgery than GA [7]. Minimally invasive surgery that provides the same quality of management is of interest to surgeons. Many institutions are interested in CS to facilitate day procedures that increase turnover at hospitals. Mawby et al. [12] safely treated 116 patients undergoing cochlear implantation as day cases without any complications or readmissions.

A few interoperative considerations are important; for example, it is best to have a staff member sit in front of the patient because during drilling, it is not possible to hear the patient's complaints. Furthermore, it is preferable for the patient to have someone to contact throughout the procedure for reassurance.

The beauty of surgery under LA is that this technique allows facial nerve function to be monitored throughout the procedure, and the staff member sitting in front of the patient for communication can also inform the surgeon if he or she observes any facial contractions.

In the recovery room, patients were given time to rest after surgery and were fitted with an external processor. Because these CI recipients were awake, most of them were excited to return home after surgery and to be able to hear through their device. Hamerschmidt et al. [13] found that surgery under CS is more cost effective than surgery under GA. This kind of surgery should be performed only when surgeons have a great deal of experience and must be prepared to convert to GA if necessary

According to Hu et al. [9], there was an initial decrease in the impedances for all electrodes, followed by an increase. However, the timelines were different; in their study, they did not test the impedances again on the day of surgery. Therefore, they reported the decrease in impedances the following day and the increase 1 week later. However, in our study, there was a significant increase the following day given that the initial stimulation occurred on the day of surgery. The initial decrease in the impedances could be due to air bubbles or an early intracochlear inflammatory process, considering that this decrease occurred on the same day as surgery in our population. The initial increase following this decrease in the impedances could be secondary to poststimulation changes that altered the biophysical properties of the cochlea. This finding would explain why the increase in the impedances occurred the following day in our study, but not in the study by Hu et al. [9]. In addition, our findings were supported by Lin et al. [14], who reported an increase in impedances for all electrodes when tested the next day as compared with intraoperative values. Considering that Hu et al. used Nucleus 24RECA implant system, which is closer to the modiolus than Med-El's lateral wall electrodes used in this study and that of Advanced Bionics' Hi Focus1J electrode used in the study by Lin et al.[14] study, which could provide more space for fibrosis.

The results indicate that same-day fitting after cochlear implantation under CS is feasible without a significant difference in the MCL level between same-day and next-day measurements. However, considering the significant changes in the THR level between the same-day and next-day measurements, especially in the apical region for those who had CIs placed under CS, next-day fine-tuning and refitting of the CI speech processor might be preferable to optimize fitting of the CI. In addition, no significant differences between the CS and GA groups were found in the impedance telemetry, THR level, or MCL level at 8 weeks postoperatively.

Most of our cases were done with a minimal 3-cm postauricular incision away from the hair follicles with a tight pocket bed, and since we started performing this technique, wound-related infection and postoperative edema were greatly reduced. In light that some of our patients were hesitant to put the behind-the-ear processor in the 1st week post-CI near the wound, only the magnet was placed while the processor was attached at the clothes using a long cable.

Moreover, early activation is known in our center with many studies in this field [7,15], and it was successful by all means (patient satisfaction, audiologists' performance), and it gives us more understanding on what is going on inside the cochlea. Impedance field audiometry and stimulation or fitting parameter comparison between the early

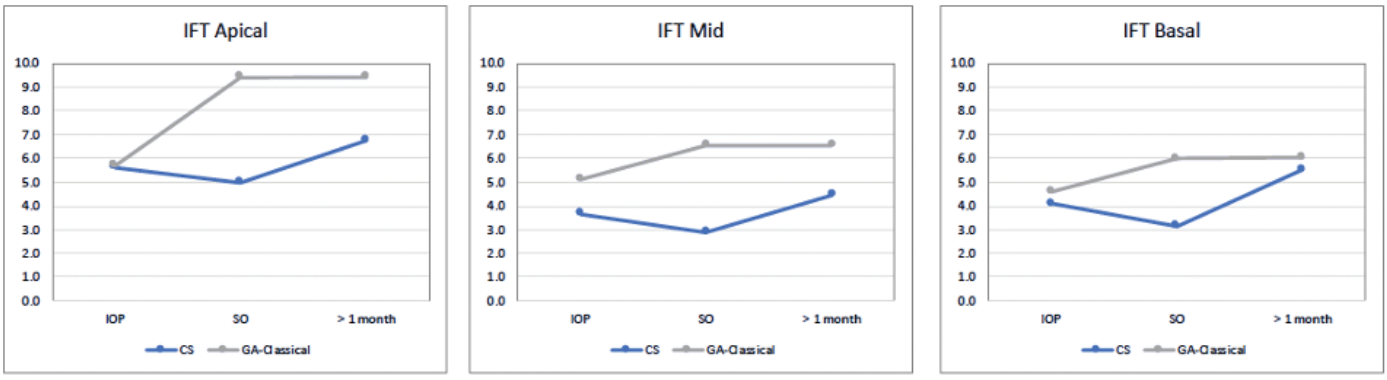

Figure 2. Impedance field telemetry (IFT) comparison between early fitting group (conscious sedation (CS)–same-day fitting) vs general anesthesia (GA)–late-classical fitting patients (1 month switch on (SO)) in SO days and 1-month postoperative within three cochlear duct parts.

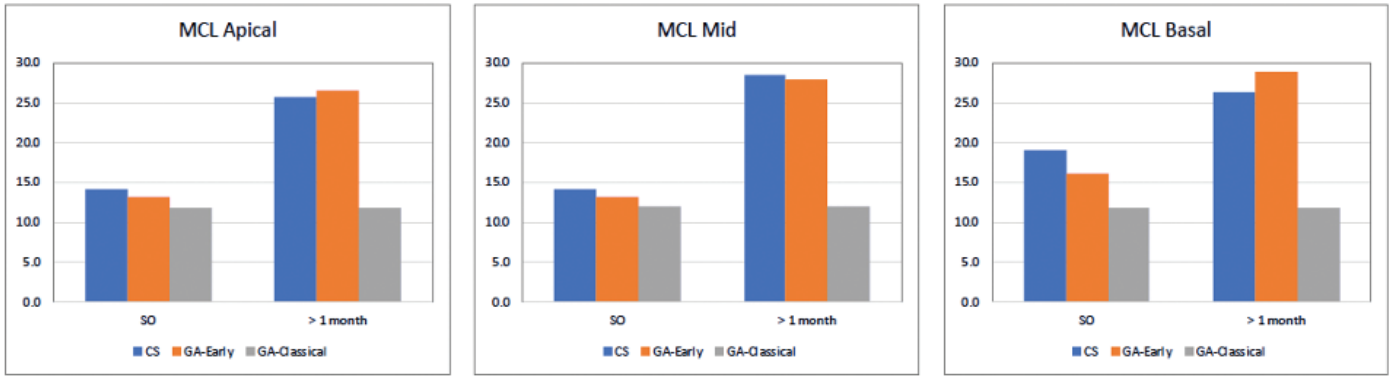

Figure 3. Maximum comfortable loudness (MCL) level comparison between conscious sedation (CS)–same-day fitting vs general anesthesia (GA)–early fitting group (next-day switch on (SO)) vs GA–late-classical fitting patients (1-month SO) in SO days and 1-month postoperative within three cochlear duct parts.

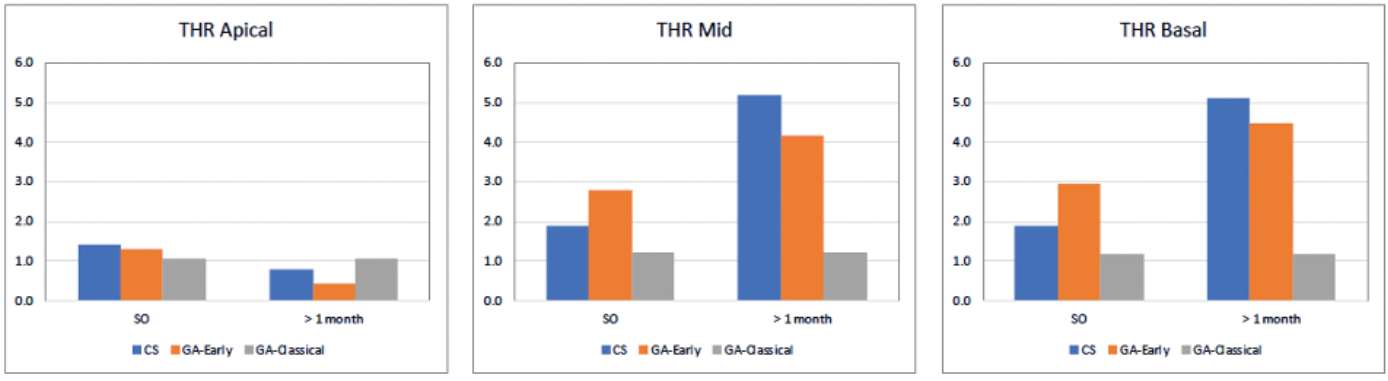

Figure 4. Threshold (THR) comparison between conscious sedation (CS)–same-day fitting vs general anesthesia (GA)–early fitting group (next-day switch-on (SO) days) vs GA–late-classical fitting patients (1-month SO days) in SO days and 1-month postoperative within three cochlear duct parts.

fitting group (same day) in the CS group with the late-classical fitting group (1 month) provides evidence that early stimulation reduces the impedance values as shown in Figure 2. One explanation might be related to the reduction of the intracochlear fibrosis production by early stimulation. Another expected advantage for MCL fitting parameter was faster improvement, because a 1-month period of stimulation is enough to get adapted to the sound and provides the patients fitted early with a 1-month advantage over classically fitted CI recipients. In addition, theater room noise did not affect the program in the CS early group activation group during switch on as demonstrated in the lack of statistically significant change between the MCL levels on the day of surgery and on the next day, which was also supported by comparison results between the early activation group and the GA classical fitting group (Figure 3). Lastly, the changes in THR levels at the apical electrodes in the early fitting group after 1 month from the implants were minimal as compared with those in the mid and basal electrodes (Figure 4). Early fitting can enable stable cochlear implantation programs as early as 6 weeks postoperatively, with stable THR levels in all regions by the 6th week postoperatively. This could provide a great advantage in the postoperative rehabilitation program, especially if we consider that traditional fitting of CIs does not occur until the 4th-6th week postoperatively.

Our limitation in this review was the small sample size. It would be interesting to see the results of same-day fitting after day cochlear implantation under CS in a study with a large sample size in the future.

CONCLUSION

Cochlear implantation can be performed under conscious sedation as an option for some cases and only in adult patients. The procedure can be safely performed as day surgery. Although same-day initial fitting of the CI is an option for CI recipients when CS is used, next-day fine tuning is recommended to optimize fitting.

Ethics Committee Approval: Ethics committee approval was received for this study from the Institutional Review Board of King Saud University, collage of medicine, Riyadh, Saudi Arabia (Project No: E14-1170).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

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Conflict of Interest: The authors have no conflict of interest to declare.

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