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Early activation of a late sequential cochlear implant systematic review

Abstract

Early activation of Cochlear Implant (CI) is a technique where the processor is activated in less than 4 weeks. In this way, time and costs are reduced in the process of functional restoration of hearing. On the other hand, a late sequential cochlear implant is one where the second CI is implanted at a different surgical time than the first and the user's age is greater than 7 years. The aim of systematic review is to analyze the available information on the effects of early activation after late sequential cochlear implant surgery. Systematic literature search was performed, in databases, of studies about the effects of early activation of late sequential CI and early activation of CI in terms of quality of life, hearing and language from the years 2012 to June 2022. Fifteen publications were included in the clinical evidence review for early CI activation review, but no articles were found for review on the topic of early activation of late sequential CI. The review identified early CI activation as a safe and reliable procedure where the effects are positive on quality of life, hearing and speech by electrophysiological and auditory perceptual recordings. However, no information about the effects on early activation of late sequential CI is recognized.

Keywords: early activation, cochlear implant, sequential, late, impedance, complications

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Abbreviations: UCI, unilateral cochlear implant; BCI, bilateral cochlear implant; EC, early activation; CA, conventional activation; ECAP, electrically evoked compound action potential; EG, experimental group; CG, control group; MCL, most comfortable listening level; DR, dynamic range; BTE, behind-the-ear; OTE, off-the-ear

Introduction

Cochlear implants (CI) are devices that allow electrical stimulation of the auditory nerve through the interpretation of sound stimuli.1 It is a surgical medical treatment of hearing loss that requires surgery and subsequent auditory and speech rehabilitation.2 The benefit of CIs depends on different factors, among them, the unilaterality or bilaterality and the moment of implantation stand out, considering the age. For this reason, the aim of Bilateral Cochlear Implants (BCI) is to obtain similar levels in binaural hearing. Research has suggested advantages in terms of sound source localization, speech recognition and intelligibility in noisy environments, binaural summation, the shadow effect, and the squelch effect.3-7 For pediatric users, the BCI reduces the auditory effort causing an impact on language development, at expressive and comprehensive levels.8,9

Bilateral implantation can be performed using two surgical techniques, sequential and simultaneous. In the sequential BCI each ear has an independent surgery, in other words, in two surgeries, where there can be a difference from months to years in between. On the contrary, in the simultaneous BCI the implants are placed in the same surgery.10 Likewise, these types of implantations differ according to surgical risks, lengths of stay and procedures, preoperative and postoperative care and economic costs.11,12 In the same way, from an audio logical perspective, in hearing performance and voice recognition in noisy environments and speech in noise, the performance is higher for simultaneous BCI.8,12 However, in adults with postlocutive deafness where the auditory pathways are mature, there is no difference in the results of simultaneous and sequential BCI.13

Sequential Bilateral adaptation is required when the hearing loss presents a degree of residual hearing considering that simultaneous implantation means a hearing deprivation phase while the processors are activated. It is important to clarify that sequential BCI does not present disadvantages in binaural hearing, but it does in therapeutic rehabilitation measures, since these may change according to the individual's needs when the second fitting is performed.7

Similarly, an important factor for sequential BCI is the time interval between CIs. Considering that the cochlear nucleus nerve may not develop without stimulation and therefore tends to degeneration and to apoptosis; as a matter of fact, it may have negative effects in its maturation and survival. For the same reason, it has been identified that there is a greater benefit in speech development and linguistic competence when the second CI is implanted before the age of 2.14

However, different studies indicate that inter-implant time should be less than 5 years for the second CI not to affect language outcomes.12 Despite this, adequate functioning of the two CIs has been identified in the ability to perceive speech in quiet and noisy environments, with children whose inter-implant time averaged 5.5 years and in the second CI the outcomes were close to those of the first implant.15 In the same way, in children whose inter-implant period was between 1 and 12 years, the functioning of the second CI improved significantly over time, in word recognition tasks in noise and in a noisy environment. Likewise, in children with inter- implant between 8 to 12 years, small improvements in word recognition in noisy environments were identified when using both CIs.16

On the other hand, age at implantation ends up being the primary predictor in spoken language development when using CI.17 since during the sensitive period, before the age of three, the brain is able to establish connections between auditory speech input and language development.18 So, auditory pathways are subject to neural plasticity, but when not stimulated, its function changes.18,19 For the same reason, it is necessary to mention the classification according to the age of implantation, where an early CI is less than 3.5 years and a late CI is greater than 7 years.20

Although the literature mentions that there is a greater auditory and linguistic benefit after early implantation, it does not assume the total inexistence of CI benefits after the established age.21 Therefore,

it has been described that patients with prelingual deafness whose implantation was after adolescence have benefits in recognizing voice and words in open context, where in logopedic evaluations the results were similar to the preoperative evaluation, after two years. They also presented a change to auditory-verbal communication; however, these changes were not significantly reflected in young people between the ages of 15 and 19.22 Similarly, quality of life is improved by the second implant despite the time of implantation in terms of sound perception, speech production, self-esteem, activity, social interaction, general well-being, daily life functioning and emotion.23

Continuing with the process, after implantation, the first stimulation is performed between 2 to 6 weeks considering the healing process of the incision site and the reduction of inflammation.24 In this process patients have the opportunity to listen to sounds through their devices, and for this purpose programming is carried out with the specific stimulation parameters according to the receiver's ear.24,25

Currently, first activation is being performed in a shorter time considering that in different countries implant centers are limited and unavailable, therefore waiting for the recommended period may not be practical, especially for families who are located in other regions than the place where the CI should be received.24 Consequently, early activation is a technique that aims to restore hearing as soon as possible after CI surgery, that is to say, days later without waiting for wound healing to complete.7,11 Therefore, it would not take into account the recommended time for CI adaptation which is at least 4 weeks after the surgical procedure.26

Likewise, early fitting of the sound processor is a procedure that has been shown to be feasible and safe. Also, it has been demonstrated that it does not have significant disadvantages compared to the standard healing phase. Furthermore, it significantly reduces the time between surgery and the first fitting compared to the conventional fitting, allowing to acquire hearing experience much earlier and thus start the auditive rehabilitation.27

The aim of systematic review is to analyze the available information on the effects of early activation after late sequential cochlear implant surgery.

Methods

The research is an integrative, observational, retrospective study between 2012 and 2022. The search for the literature review was conducted in biomedical information databases: Pubmed, Medline, Science Direct, Mendeley, Scielo, Scopus, among others. Studies were included, in any language, of retrospective, prospective, cross-sectional, observational, comparative type with data before and after early activation of late sequential cochlear implantation in children and adults. The studies had to consider aspects such as auditory and linguistic achievement, quality of life and feasibility. On the other hand, animal studies, abstracts or conference proceedings and non-systematic reviews were excluded. Finally, the search terms were "late sequential cochlear implant", "early activation", "switch-on" and "early fitting" and their Spanish equivalents, which were combined with the Boolean operators "AND" and "OR" to establish the search equations.

Results

The literature review only identified one citation published in the period from 2012 to June 7, 2017. It was verified if the article corresponded to the subject of the literature review taking into account the title and abstract. However, the study found did not address the topic of early activation of late sequential cochlear implantation. Additionally, the search was made in different databases to cross-check the information, however, no relevant article was found, as the most important terms were specifically presented in the search browsers. It is necessary to clarify that there was no need to apply filters, since most of the databases indicated the non-existence of articles on the subject and in two databases (Pubmed and Embase) the article which described the above process was found.

For this reason, it was decided to search for the important elements of the research topic separately (early activation and cochlear implant) and to perform the corresponding review. Consequently, we searched, under the same criteria, in order to verify the existing results and the types of implants according to their age at implantation (early or late) and the surgical procedure for bilateral CI (simultaneous or sequential). In each search engine and depending on the number of articles it was necessary to apply filters such as date of publication, type of study performed and publication. At a general level, the possible results were identified by means of Boolean keys, yielding 68 articles, of which 14 were duplicates and therefore eliminated. The titles and abstracts of the possible articles were then read for screening purposes, resulting in the exclusion of 38 articles that were not considered relevant for the review because these did not address the topic of early activation of CI. For this reason, only 16 articles were read in full; however, one of the articles was omitted because the link led to a page where the article was not displayed. Finally, from the reading, 15 publications were selected and included in this review (Figure 1).

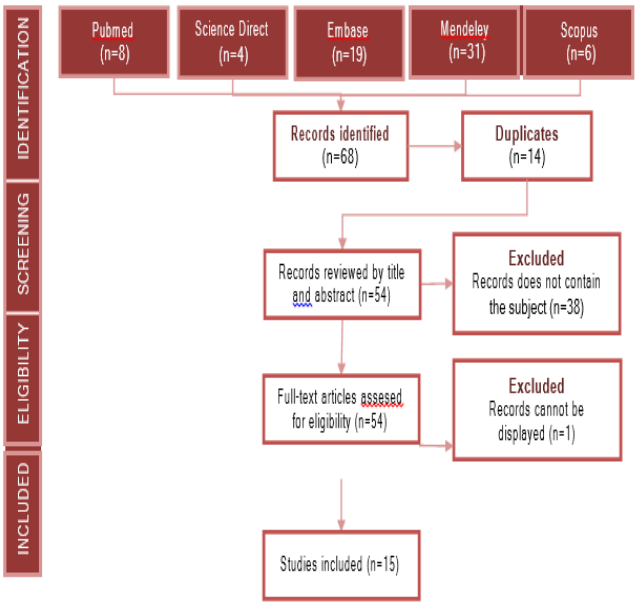

Figure 1 PRISMA flow chart - literature review.

Table 1 presents the articles taking into account the author, title and year of publication and Table 2 shows the general characteristics of the articles selected for the review, taking into account the population (pediatric and/or adult), the CI either the manufacturer, the system, the electrode or the processor that was implanted, the type of activation (early or late), the objective of the research, the results according to the aspects that were evaluated and the time in which the respective evaluations were carried out.

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Table 1 Authors, year of publication and title of articles

Authors	Year	Title
Marsella P, Scorpecci A, Pacifico C, Resca A, Vallarino, M, Ingrosso, & Luchenti S.[38]	2014	Safety and functional results of early cochlear implant switch-on in children.
Alsabellha R, Hagr A, Al-Momani MO & Garadat S.[41]	2014	Cochlear implant device activation and programming: 5 dayspostimplantation
Wolf A, Schnabl J, Edlinger S, Pok S, Schoerg P & Sprinzl G[28]	2015	Postoperative changes in telemetry measurements after cochlear implantation and its impact on early activation.
Chen J, Chuang A, Sprinzl G, Tung T & Li L.[40]	2015	Safety and feasibility of initial frequency mapping within 24 hours after cochlear implantation
Hagr A, Garadat, S, Al-Momani, M, Alsabellha R, Almuhawas F.[41]	2015	Feasibility of one-day activation in cochlear implant recipients
Hu H, Chen J, Tsai C, Chen H, Tung T & Li L.[29]	2017	Evolution of impedance field telemetry after one day of activation in cochlear implant recipients
Günther S, Baumann U & Stöver T.[42]	2018	Early Fitting in Cochlear Implantation: Benefits and Limits
Batuk M, Yarali M, Cinar B, Kocabay A, Bajin M, Sennaroglu G & Sennaroglu L.[26]	2019	Is early cochlear implant device activation safe for all on-the-ear and off-the-ear sound processors?
Sun, C, Chang, C, Hsu, C, & Wu, H.	2019	Feasibility of early activation after cochlear implantation
Aldhafeeri A, Saleh S, Almuhawas F & Hagr A.[31]	2020	Feasibility of day surgery for cochlear implantation underconscious sedation with same-day fitting
Sunwoo W, Jeon H & Choi B.[35]	2021	Effect of initial switch-on within 24 hours of cochlear implantation using slim modiolar electrodes
Bruschke S, Baumann U & Stöver T.[27]	2021	Long-Term Follow-Up of Early Cochlear Implant Device Activation
Wei J, Tung T & Li L.[43]	2021	Evolution of impedance values in cochlear implant patients after early switch-on
Alhabib S, Abdelsamad Y, Yousef M, Alzhrani F & Hagr A.[32]	2021	Effect of early activation of cochlear implant on electrodeimpedance in pediatric population
Saoji A, Adkins W, Graham M & Carlson M.[33]	2022	Does early activation within hours after cochlear implant surgery Influence electrode impedances?

Discussion

The results of the present review show that the objectives of the analysis of available information on the effects of early activation after late sequential cochlear implant surgery have been met. The systematic search for early activation of late sequential CI, taking into account evidence-based practice, presents a limitation in terms of quantity and access to the information investigated in the databases used. This is reflected in the lack of documentation, within the databases, demonstrating the effects of early activation in late sequential CI. Therefore, it indicates a field available for research considering the relevance of these aspects in auditory and linguistic development; communicative and cognitive competence; and the quality of life of the user. Although, in order to verify the results mentioned above, the search was repeated with the topic restricted to "early activation in cochlear implantation", that is, in a general way.

The article does not present the age specifically; an approximation was made taking into acount the mean of the groups and their standard deviation.

From the review, it is possible to establish that CI activation can be performed from the same day or 24 hours after the surgical procedure according to the research conducted by.28-33 However, it should be mentioned that the other investigations differ in terms of the time of early activation (EA), product of the healing process, or the study objectives. Nevertheless, all the initial adjustments were between the same day and less than 14 days, meeting a shorter time than conventional activation (CA), this means 4 weeks. This suggests that there is no need to wait for the conventional time to perform the initial activation, as long as the suggestions and recommendations for early activation of the CI are followed.

For this reason, it is recognized that early activation is a safe and feasible procedure, which does not cause possible additional complications that may occur in standard or conventional activation, and thus does not interfere with the standard CI procedure. Likewise, in the study by Günter et al.34 the participants suggest a high satisfaction with the procedure, that increases after 3 months. Thus, according to Bruschke, Baumann, & Stöver21 and Chen, Chuang, Sprinzl, Tung, & Li,29 early activation benefits patients by reducing

time and costs, decreasing the uncertainty of the surgery results, and developing speech recognition faster.

Taking into account that impedance is a factor that will be reflected in sound quality and speech perception and sonority35 the effect of early activation on impedance evolution is manifested with variable results since some suggest that there are no significant differences between EA and CA or that the behavior of impedance differs between them, where in the majority, it indicates that impedance stabilizes earlier in EA. Additionally, it should be rescued that in the study by Saoji, et al.33 where early activation is in 2 groups (5 hours and one day), the behavior is similar in relation to the decrease in impedance, but with different values. On the other hand, discrepancies were found in the impedance results according to the IC manufacturer and the activation group. Consequently, in the study of Günter, et al.34 the impedance results of Cochlear CIs in the EA group are lower versus the CA group, while the impedance of Med-El CIs do not present significant differences versus Cochlear. Thus, there is a possibility that impedance fluctuations may be associated with the electrode array and manufacturers due to a change in the cochlear microenvironment, which in turn affects postoperative hearing preservation.36

As with the general impedance, the results of the impedance according to the apical, middle, and basal electrodes are variable. Alhabib, et al.32 reports differences between the EA and CA groups with lower impedances in the first one for all electrodes, and Sunwoo, et al.35 reports differences, for intraoperative measurements, between basal and apical electrodes, with higher impedance in the basal electrodes. In view of the above-mentioned, impedance values may indicate higher or lower sound quality depending on the frequencies stimulated if the electrode is apical, middle or basal. Additionally, the electrically evoked compound action potential (ECAP) being an intraoperative marker of auditory nerve function and postoperative marker of speech perception,37 is not affected in early activation. However, according to Marsella, et al.,38 although there are no significant differences between EA and CA and the behavior is similar, the values differ, before and after the switch on session for both groups. Likewise, according to the review articles, in tone audiometry and speech recognition, early activation does not alter the results in auditory threshold and speech perception since, in the former, there are no significant differences between preoperative and postoperative EA and CA; and in the latter, there is no difference in the values in the Multisyllabic word test and the Monosyllabic word test.

Now, within the early activation recommendations, magnet strength is an important factor, since it should be constantly monitored because inadequate magnet strength can cause discomfort such as headache, skin irritation and flap infections.34 This is the reason why, research differ regarding the change of the magnet, while for Günter, et al,34 there is a reduction, of the magnet strength, of 35% in the EA group, for Hagr, et al.24 users used the standard magnet. On the other hand, Bruschke, et al.27 suggest that there are no significant differences between the EA and CA groups, as well as between Cochlear and Med-El, however, in Cochlear there is a higher frequency of magnet change for the early activation group.

Returning to the limitations of the review "early activation in cochlear implantation", it was identified that the lack of documentation on late sequential cochlear implantation and early activation is associated with the superficial presentation of the demographic characteristics of the participants and its relation to cochlear implantation. This is reflected in the fact that the studies do not indicate whether the implantation was early or late and, in the case of research with users whose implantation is bilateral, they do not present whether it was sequential or simultaneous, as well as the inter-implantation period in sequential bilateral CI.

It is important to mention that these aspects are directly related to CI functionality, since deprivation is an indicator of auditory pathway activation14 which, in turn, is a determining factor in the rehabilitation process.36,39 Hence, the benefit obtained by the subject because of the type and modality of CI is examined, in terms of binaurality, sound source localization, head shadow effect, Squelch effect, speech understanding and intelligibility in noisy environments, costs, quality of life, among others.

For the same reason, in the more general review it was identified that there are variables that were not taken into account in the analysis of the results and that influence the CI performance. In the articles there is no correlation between the ages of the population (children and adults), i.e., there is no report on the effects of early activation as a function of age, although in 53% of the investigations the sample is of adults and children. Likewise, as previously mentioned, the documentation of early activation regarding the manufacturer, electrodes, systems and/or CI processors requires further study considering the variability of the results, which may be due to the fact that CI manufacturers have different procedures for the positioning of the electrodes inside the cochlea, and, consequently, it impacts the results of early activation as for the performance of this procedure an a traumatic insertion of the electrodes is recommended.

Finally, it should be mentioned that although there are results regarding ECAP, tonal audiometry and speech perception in early CI activation, the supporting documentation is especially scarce. Therefore, it is necessary to continue investigating early activation behavior and thus provide a higher degree of reliability.

Conclusion

This paper reports on the documentation on early activation in cochlear implantation, allowing to identify the impact of early activation or adaptation in terms of impedance, speech recognition, complications, safety, hearing threshold, electrically evoked compound action potentials (ECAP) and satisfaction with the procedure in both children and adults.

According to the above, early CI activation is safe, feasible and reliable, not only by medical criteria but also from the perception of the implanted subject, since high levels of satisfaction with the procedure are presented. On the other hand, the impedance presents a variable behavior that tends to stabilize, in an early stage, in regard of conventional activation, and thus quickly establish a sound quality according to the user's needs. As for the auditory threshold and the electrically evoked compound action potential, the results indicate that they are not altered with activation in a shorter time than previously established.

However, it should be mentioned that the information found is scarce and nonexistent when referring to late sequential cochlear implantation because the articles do not specify the results according to the

moment of implantation, that is, early or late; the type of cochlear implant, unilateral or bilateral; in case of bilateral, if it is simultaneous or sequential; and also, the inter-implantation period. Therefore, it is recommended to continue addressing the topic and to deepen in predictive factors such as age of implantation, binaurality, type of surgical procedure, CI manufacturer, system and implanted electrodes in relation to early activation. Considering the relevance of the time interval between implants and the presence of a second CI considering

the simultaneity or sequentially of this, thinking about the effects it may produce on the functioning of the second CI, auditory function and language development. Additionally, it is appropriate conducting research on the results in relation to the manufacturers, the system, the processor and the CI systems since, as mentioned, it may suggest differences that impact the performance of CI users.

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