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0530 2016017311

Datum 8 februari 2016
Betreft Herzien advies als bedoeld in artikel 114 Zorgverzekeringswet

Zaaknummer
2015143793

Onze referentie
2016017311

Uw referentie
G47 201500566

Uw brief van
12 november 2015

Geachte mevrouw

Hierbij bevestig ik de ontvangst van het verslag van de hoorzitting.

Na kennisneming van het verslag heeft Zorginstituut Nederland het verslag en bijgevoegde stukken voor een medische beoordeling voorgelegd aan zijn medisch adviseur. Deze heeft de stukken bestudeerd en deelt het volgende mee.
Verzoeker heeft bij de hoorzitting een tweetal documenten aangedragen. Het eerste document is een caseserie van 6 Duitse soldaten met eenzijdige doofheid die zijn behandeld met een CI. Het tweede document is een verslag van een beslissing van het "Bundessozialgericht" inzake een hulpmiddel niet zijnde een Cochleair implantaat. Op basis geven de stukken en het verslag geen nieuwe informatie op grond waarvan een heroverweging van het standpunt is aangewezen. Het eerdere advies blijft gehandhaafd, aldus de medisch adviseur.

Uit het verslag komen geen feiten of omstandigheden naar voren die Zorginstituut Nederland aanleiding geven het voorlopig advies te herzien.
U kunt het voorlopig advies met bovenstaande aanvulling bij deze als definitief beschouwen.

Hoogachtend,

2015005566 16 DEC. 2015

Zorginstituut Nederland

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0530.2015159039

Datum 15 december 2015
Betreft Advies als bedoeld in artikel 114 Zorgverzekeringswet

Zaaknummer
2015143793

Onze referentie
2015159039

Uw referentie
G47 201500566

Uw brief van
12 november 2015

Geachte voorzitter, commissie,

U hebt op 12 november 2015 aan Zorginstituut Nederland advies gevraagd als bedoeld in artikel 114, derde lid Zorgverzekeringswet. Verzoeker en verweerder hebben een geschil over het plaatsen van een cochleair implantaat (links) uit te voeren in Gent (België).
Bij uw adviesaanvraag hebt u ons ook een kopie van het dossier gestuurd, maar een verslag van de hoorzitting ontbreekt nog. Zorginstituut Nederland brengt daarom een voorlopig advies uit, dat nog aangepast kan worden als uit het verslag van de hoorzitting nieuwe feiten of omstandigheden naar voren komen.

Medische beoordeling
Na kennisneming van het geschil heeft Zorginstituut Nederland dit dossier voor een medische beoordeling voorgelegd aan zijn medisch adviseur. Deze heeft de stukken bestudeerd en deelt het volgende mee.

Achtergrond
Verzoeker heeft al enkele jaren last van zijn linkeroor. Hij is hieraan tweemaal geopereerd. Na de tweede operatie is doofheid ontstaan aan het linkeroor van verzoeker. Ook kreeg hij last van duizeligheid. Naar aanleiding van deze klachten heeft verzoeker zich gewend tot een KNO arts in het UZ Gent. De klachten bleken te worden veroorzaakt door een perforatie van het trommelvlies van het linkeroor. Op 13 augustus 2014 is een ingreep uitgevoerd, waarmee onder meer voornoemde perforatie is hersteld. De doofheid is echter blijvend. Aangezien het linkeroor van verzoeker nu gezond is, kan volgens de behandelend arts een deel van de functie van het oor met behulp van een cochleair implantaat worden hersteld. Hierdoor kan de oorsuizing, waarvan verzoeker last heeft worden hersteld.

De KNO arts heeft in een brief van 3 oktober 2015 verklaard dat de klachten van verzoeker voornamelijk bestaan uit slechthorendheid links waarbij deze problematiek op de voorgrond komt in omgevingslawaai, geroezemoes en groepsevenementen. Ook het lokaliseren van geluid is problematisch.

Spraakverstaan wordt sterk bemoeilijkt wanneer achtergrondgeluid aanwezig is. Bij zijn werk als sluismeester is zowel de communicatie met collega's als via apparatuur zeer moeilijk. Naast de gehoorproblematiek heeft verzoeker nu continu last van oorsuizen. Door het plaatsen van een CI kan de problematiek van het oorsuizen worden verlicht.

Ter ondersteuning van zijn aanvraag en standpunt heeft verzoeker zijn vier studies aangedragen. Drie van de artikelen betreft case series (Jacob 2011, Kleine Punte 2011 en Vermeire 2008)[1] en een review (Giardina 20..). In een onderzoek is gekeken naar eenzijdige doofheid in combinatie met tinnitus(Vermeire 2008).

Conclusie van verweerder
De verweerder concludeert dat een cochleair implantaat bij enkelzijdig gehoorsverlies en tinnitus geen behandeling is die voldoet aan de stand van de wetenschap en praktijk en daarmee van verzoeker zorg. Door verzoeker is aangevoerd dat de onderhavige behandeling inmiddels voldoet aan de stand van wetenschap en praktijk. De adviserend geneeskundige van verweerder heeft bij een recente search in de literatuur geen nieuwe studies aangetroffen die zijn gepubliceerd na de uitspraak van het Zorginstituut in 2014. Er zijn wel publicaties beschikbaar van case series en kleine prospectieve follow up studies zonder gerandomiseerde controlegroep. De follow up duur van deze studies is echter beperkt. Zodoende is, zoals beschreven in het advies van het Zorginstituut, de gepubliceerde literatuur over het plaatsen van een cochleair implantaat bij mensen met een eenzijdige doofheid en tinnitus klachten van zeer lage kwaliteit. De onderhavige behandeling voldoet bij deze indicatie dus niet aan de stand van de wetenschap en praktijk. De door verzoeker aangehaalde studies betreffen alleen de indicatie eenzijdige doofheid. Enkelzijdige doofheid is niet aan te merken als ernstig dubbelzijdig perceptief gehoorsverlies. Bovendien is er bij verzoeker niet alleen sprake van eenzijdige doofheid maar ook van tinnitus.

Beoordeling
De studies aangedragen door verzoeker zijn van oudere datum en daar waar passend gewogen in het eerdere standpunt van het Zorginstituut. In 2014 heeft het Zorginstituut een standpunt geformuleerd ten aanzien van effectiviteit van directe en indirecte hersenstimulatie bij tinnitus. Het Cochleair implantaat was een van de onderzochte interventies. Het rapport is toegevoegd aan het dossier.

In het standpunt van 2014 is aangegeven dat het Zorginstituut een RCT met blindering van patiënt en onderzoeker bij CI's niet kan verwachten maar dat vergelijkende studies wel mogelijk zijn. In de reactie op het standpunt in 2014 hebben beroepsgroepen geconcludeerd dat op dat moment de eindconclusie t.a.v. CI bij tinnitus wel gerechtvaardigd is. Daarnaast gaven beroepsgroepen aan dat

[1] Giardina et al, Cochlear implants in single side deafness. Review
Jacob et all 2011,The Koblenz experience in treating single sided deafness with cochlear implants. case serie
Kleine Punte et al 2011 cochleair implantationa as a durable tinnitus treatment in single-sided deafness. case serie
Vermeire K 2008, Binaural hearing after cochlear implantation in subjects with unilateral sensorineural deafness and tinnitus case serie.

bij beoordeling van de literatuur onderscheid gemaakt moet worden naar het doel van een CI, een CI voor verbetering van de spraakverstaanbaarheid bij ernstige slechthorendheid of een CI als TI (Tinnitus Instruments).

Het Zorginstituut heeft een update van de literatuur sinds 2013 uitgevoerd in Medline. Het Zorginstituut concludeert dat er sinds 2014 wel enkele nieuwe cases series zijn gepubliceerd (4, 7,8,12). Er zijn geen vergelijkende studies gepubliceerd zoals hierboven vermeld. Enkele studies betreffen andere indicaties of andere onderzoeksvragen (2,3,5,6,) en een review (10).
In 2014 is een meta-analyse gepubliceerd door Blasco et al (9). bij personen met eenzijdige acute doofheid en tinnitus. Een CI kan een effectieve interventie zijn bij deze indicatie maar vergelijking van deze effecten met gebruikelijke behandelingen (Contralateral Routing of Sound Systems (CROS) en Bone Conduction Devices (BCD) is aangewezen. Ook Vlastarakos et al 2014
In 2015 is deel I van de studie van Arts et al (1) gepubliceerd: "Tinnitus Suppression by Intracochlear Electrical Stimulation in Single Sided Deafness: a prospective clinical trial". In deze studie wordt onderzocht wat de onderliggende mechanismen zijn bij tinnitus supressie, maskering door geluid of aanpassingen door plasticiteit van de hersenen. De conclusie bij deze 10 onderzochte personen is dat het aanbieden van hardere geluiden meer effect hebben dan zachtere geluiden (maskering). Wat dit betekent op langere termijn is nog niet bekend.
In deel II worden t.z.t. de lange termijn effecten van intracochleare electrische stimulatie gepubliceerd.

In 2015 is ook het study protocol gepubliceerd van de CINGLE studie (www.trialregister.nl, NTR4580) (13). In deze studie worden de gebruikelijke behandelingen bij eenzijdige doofheid, (Contralateral Routing of Sound Systems (CROS) en Bone Conduction Devices (BCD) vergeleken met een Cochleair Implantaat naar spraakverstaan in ruis, geluidlokalisatie, tinnitus en kwaliteit van leven. De effectiviteit en kosteneffectiviteit van de interventie wordt onderzocht.

Zoals de verweerder ook al heeft geconcludeerd is er op dit moment onvoldoende bewijs beschikbaar om te concluderen dat het standpunt uit 2014 moet worden aangepast. Vergelijkend onderzoek naar huidige behandelingen met reguliere hulpmiddelen bij eenzijdige doofheid met tinnitus is aangewezen. Een herbeoordeling van dit standpunt is aangewezen na publicatie van de resultaten van de hiervoor beschreven trials (voor literatuursearch zie bijlage).

Conclusie
Op dit moment voldoet een CI bij de indicatie eenzijdige doofheid met tinnitus niet aan de stand van de wetenschap en praktijk. Herbeoordeling van het standpunt uit 2014 is aangewezen na afronding van de hierboven genoemde studies, aldus de medisch adviseur.

Juridische beoordeling
Zorginstituut Nederland heeft kennisgenomen van de stukken en beoordeeld of verweerder terecht het gevraagde heeft afgewezen. Op basis van de tussen partijen overeengekomen zorgverzekering, is Zorginstituut Nederland het met verweerder eens dat verzoeker niet in aanmerking komt voor het gevraagde. In artikel A.3.2. van de overeengekomen zorgverzekering is bepaald dat de inhoud en omvang van de zorg wordt bepaald door de stand van de wetenschap en praktijk. Dit komt overeen met hetgeen daarover bij en krachtens de

Zorgverzekeringswet is bepaald. Gelet op het advies van de medisch adviseur voldoet een CI bij de indicatie eenzijdige doofheid met tinnitus niet aan de stand van de wetenschap en praktijk.

Ten slotte merkt Zorginstituut Nederland nog op dat de adviestaak van Zorginstituut Nederland beperkt is tot de vraag of een verzekerde aanspraak heeft op een verstrekking of een vergoeding op grond van de basisverzekering. Het advies van Zorginstituut Nederland kan dus geen betrekking hebben op een beslissing van een zorgverzekeraar op basis van de aanvullende verzekering.

Hoogachtend,

Zorginstituut Nederland
Pakket

Datum
15 december 2015

Onze referentie
2015159039

Cochleair implantaat bij tinnitus en eenzijdige gehoorschade
Searchdatum: 24-11-2015
Update van ME-TA search van 13-10-2013

Medline

("Cochlear Implants"[Mesh] OR "Cochlear Implantation"[Mesh] OR (cochlea*[tiab] AND (implant*[tiab] OR device*[tiab] OR prosthe*[tiab])))
AND
("tinnitus"[mesh] OR tinnit*[tiab] OR (ear*[tiab] AND (buzz*[tiab] OR ring*[tiab] OR roar*[tiab] OR click*[tiab] OR puls*[tiab])))
Filter: vanaf 13-10-2013

Selectiecriteria: eenzijdige doofheid (SSD) en tinnitus

1. Arts RAGJ, George ELJ, Griessner A, et al. Tinnitus Suppression by Intracochlear Electrical Stimulation in Single-Sided Deafness: A Prospective Clinical Trial - Part I. Audiol Neurootol 2015; 20: 294-313.
Abstract: Cochlear implantation is a viable treatment option for tinnitus, but the underlying mechanism is yet unclear. Is the tinnitus suppression due to the reversal of the assumed maladaptive neuroplasticity or is it the shift in attention from the tinnitus to environmental sounds and therefore a reduced awareness that reduces tinnitus perception? In this prospective trial, 10 patients with single-sided deafness were fitted with a cochlear implant to investigate the effect of looped intracochlear electrical stimulation (i.e. stimulation that does not encode environmental sounds) on tinnitus, in an effort to find optimal stimulation parameters. Variables under investigation were: amplitude (perceived stimulus loudness), anatomical location inside the cochlea (electrode/electrodes), amplitude modulation, polarity (cathodic/anodic first biphasic stimulation) and stimulation rate. The results suggest that tinnitus can be reduced with looped electrical stimulation, in some cases even with inaudible stimuli. The optimal stimuli for tinnitus suppression appear to be subject specific. However, medium-to-loud stimuli suppress tinnitus significantly better than soft stimuli, which partly can be explained by the masking effect. Although the long-term effects on tinnitus would still have to be investigated and will be described in part II, intracochlear electrical stimulation seems a potential treatment option for tinnitus in this population
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1421-9700
PM:26227468

2. Hassepass F, Hassepass F, Arndt S, et al. Cochlear implantation for hearing rehabilitation in single-sided deafness after translabyrinthine vestibular schwannoma surgery. Eur Arch Otorhinolaryngol 2015; aheadofprint Oct 23.
Abstract: The aim of the study was to investigate the option of cochlear implantation (CI) in resultant single-sided deafness associated with unilateral translabyrinthine resection of sporadic vestibular schwannoma (VS). This is a retrospective study performed at Tertiary Care Academic Centre. Following extensive counselling regarding the potential for delayed CI, translabyrinthine VS

resection was performed and an intracochlear placeholder was inserted to allow later CI in 11 patients who showed intraoperative microscopic confirmation of preserved cochlear nerve anatomy. Follow-up magnetic resonance imaging (MRI) and promontory testing were performed 1 year after surgery to confirm the absence of VS recurrence and viable cochlea. Confirmed CI candidates underwent a second procedure where the placeholder was removed and the CI inserted (4/11). Preimplant unaided and CI-aided evaluations at 12 and 24 months were performed for subjective and objective hearing outcomes. Tinnitus suppression was also measured for implant on and off effects. Available audiological data for three patients demonstrated significant hearing benefits for 'speech from deaf/implanted side, noise from the normal-hearing side' in all three patients and localisation ability improved for 2/3 patients. Subjective findings presented similar results. For the two patients with preimplant tinnitus, complete suppression occurred during active CI. CI is beneficial for hearing rehabilitation and tinnitus reduction in SSD patients with remaining viable cochlear nerve after translabyrinthine VS surgery. Counselling on the risks of intracochlear placeholder insertion and the inherent limitations for ongoing MRI investigations of VS recurrence is essential
Pub. type: JOURNAL ARTICLE
ISSN: 1434-4726
PM:26498948

3. Kloostra FJJ, Arnold R, Hofman R, et al. Changes in tinnitus after cochlear implantation and its relation with psychological functioning. Audiol Neurootol 2015; 20: 81-9.
Abstract: This study retrospectively assessed the prevalence of tinnitus in cochlear implant patients and the changes after implantation in 212 patients implanted between 2000 and 2009. Patients were included at least 6 months after implantation and received 2 sets of questionnaires, one about the situation before implantation and one about the situation after implantation. Mostly standardized questionnaires assessed tinnitus handicap (Tinnitus Handicap Inventory, THI, and Tinnitus Handicap Questionnaire, THQ), tinnitus characteristics, hearing loss (Abbreviated Profile of Hearing Aid Benefit) and anxiety/depression (Hospital Anxiety and Depression Scale). Of the approached patients, 117 completed the full sets of questionnaires and 35 completed a short version. Preoperative tinnitus was reported by 51.3% of these patients, of which 55.6% reported a reduction or cessation of their tinnitus after implantation. However, 8.2% of the patients with tinnitus reported a postoperative deterioration of their tinnitus. In addition, among the patients without preoperative tinnitus, 19.6% reported the start of tinnitus after implantation. The self-reported change of tinnitus correlated with the pre- and postoperative scores on the THI and THQ. The THQ showed slightly more changes in scores after cochlear implantation compared to the THI. Overall hearing handicap and feelings of anxiety and depression decreased after implantation. In conclusion, tinnitus is reduced after cochlear implantation in an important part of the patients, but in a small part implantation has a negative effect on tinnitus. When tinnitus starts after implantation, the tinnitus handicap is mild
Pub. type: Journal Article
ISSN: 1421-9700
PM:25531170

4. Mertens G, Mertens G, De Bodt M, et al. Cochlear implantation as a

long-term treatment for ipsilateral incapacitating tinnitus in subjects with unilateral hearing loss up to 10 years. Hear Res 2015; 331: 1-6.
Abstract: INTRODUCTION: The authors previously demonstrated that tinnitus resulting from unilateral hearing loss (UHL) can be treated with electrical stimulation via a Cochlear Implant (CI). The study aimed to do a long-term (LT) evaluation of CI in subjects suffering from UHL and accompanied incapacitating tinnitus up to 10 years. The primary focus of the study is on LT tinnitus reduction. SUBJECTS: LT evaluation was derived from 23 subjects suffering from UHL and accompanied incapacitating tinnitus (Pre-operative Tinnitus Loudness Visual Analogue Scale (VAS) score >6/10). They were cochlear implanted at a median age of 55 years (22-71 yr) and had 8 years (3-10 yr) experience with their CI at the LT testing. The subjects were categorized into two groups: a Single-Sided Deaf Group (SSD) and an Asymmetric Hearing Loss Group (AHL). The SSD group comprises subjects with contralateral normal hearing (i.e. air conduction pure tone average (PTA0.5, 1, 2 and 4 kHz) </= 30 dB HL) and the AHL group subjects with contralateral mild to moderate hearing loss (i.e. air conduction PTA0.5, 1, 2 and 4 kHz > 30 dB HL). METHODS: In order to obtain a LT structural overview of the CI use in UHL subjects, a structured interview was conducted including questions about daily amount of CI use, residual inhibition of the tinnitus after switch off, tinnitus type, etc. The VAStinnitus loudness and the Tinnitus Questionnaire were obtained pre-operatively, one, three, six, 12, and 36-months post-operatively and at the long-term test interval (8 (3-10 years) post-operative). The Hyperacusis Questionnaire was administered in the CION and the CIOFF condition. RESULTS: The structural interview revealed that all patients (23/23) still wear their CI seven days a week, eight (3-10) years after cochlear implantation. It appeared that in all subjects but one CI switch-on is the first act when rising and CI switch-off is the last act before bedtime. In the SSD group, tinnitus suppression is still the primary benefit reported (83%), whereas in the AHL the majority of the subjects (55%) report that the primary benefit shifted to improved hearing. In the majority of the subjects the tinnitus reduction starts within 1 min (in 70% of the cases) and the residual inhibition after CI switch-off is less than a minute (in 65% of the cases). The VAS and TQ scores significantly improved up to three months after the first-fitting and remain stable up to the LT test interval. The median score on the Hyperacusis Questionnaire was 17 (7-36) in the CIOFF condition and improved to 23,5 (12-39) in the CION condition in the SSD group. CONCLUSION: This is the first study to report on LT results in a large number of UHL CI users, up to 10 years. Structured interviews shows that 100% of the subjects wears their CI seven days a week. The tinnitus reduces significantly up to three months after the first-fitting and the tinnitus reduction remain stable up to the LT test interval. The SSD group report tinnitus reduction as the primary benefit, whereas the majority of the AHL group report improved hearing as the primary benefit, eight (3-10) years after implantation. In addition to the tinnitus reduction, the CI provides also a benefit regarding reported
Pub. type: JOURNAL ARTICLE
aheadofprint
ISSN: 1878-5891
PM:26433053

5. Mertens G, Hofkens A, Punte AK, et al. Hearing performance in single-sided deaf cochlear implant users after upgrade to a single-unit speech processor. Otol Neurotol 2015; 36: 51-60.

Abstract: INTRODUCTION: Single-sided deaf (SSD) patients report multiple benefits after cochlear implantation (CI), such as tinnitus suppression, speech perception, and sound localization. The first single-unit speech processor, the RONDO, was launched recently. Both the RONDO and the well-known behind-the-ear (BTE) speech processor work on the same audio processor platform. However, in contrast to the BTE, the microphone placement on the RONDO is different. The aim of this study was to evaluate the hearing performances using the BTE speech processor versus using the single-unit speech processor. Subjective and objective outcomes in SSD CI patients with a BTE speech processor and a single-unit speech processor, with particular focus on spatial hearing, were compared. METHODOLOGY: Ten adults with unilateral incapacitating tinnitus resulting from ipsilateral sensorineural deafness were enrolled in the study. The mean age at enrollment in the study was 56 (standard deviation, 13) years. The subjects were cochlear implanted at a mean age of 48 (standard deviation, 14) years and had on average 8 years' experience with their CI (range, 4-11 yr). At the first test interval (T0), testing was conducted using the subject's BTE speech processor, with which they were already familiar. Aided free-field audiometry, speech reception in noise, and sound localization testing were performed. Self-administered questionnaires on subjective evaluation consisted of HISQUI-NL, SSQ5, SHQ, and a Visual Analogue Scale to assess tinnitus loudness and disturbance. All 10 subjects were upgraded to the single-unit processor and retested after 28 days (T28) with the same fitting map. At T28, an additional single-unit questionnaire was administered to determine qualitative experiences and the effect of the position of the microphone on the new speech processor. RESULTS: Equal hearing outcomes were found between the single-unit speech processor: median PTA(single-unit) (0.5, 1, 2 kHz) = 40 (range, 33-48) dB HL; median Speech Reception Threshold in noise = -1.00 (range, -8.50 to +1.00) dB SNR; median Root Mean Square Error of sound localization = 45 (range, 19-139) degrees; HISQUI = 128 (range, 106-180); SHQ = 68 (range, 45-83); SSQ5 = 6 (range, 3-9) and the BTE speech processor: median PTA(BTE) (0.5, 1, 2 kHz) = 41 (range, 30-53) dB HL; median Speech Reception Threshold in noise = -0.25 (range, -7.00 to +4.00) dB SNR; median Root Mean Square Error of sound localization = 38 (range, 26-164) degrees; HISQUI = 144 (range, 120-183); SHQ = 56 (range, 47-85); SSQ5 = 6 (range, 3-9). The results in the condition with the single-unit speech processor were not significantly influenced by the position of the microphone. CONCLUSION: The study showed that long-term BTE speech processor SSD users are able to be upgraded to a single-unit speech processor without compromising their speech performance, aided hearing thresholds, sound localization, objective speech quality, hearing abilities, sound localization, and tinnitus reduction. Microphone position on the single-unit speech processor did not influence the outcomes measures. Moreover, after a short time of experience, 80% of the users preferred the single-unit processor

Pub. type: Clinical Trial
Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1537-4505
PM:25406874

6. Olze H. [Cochlear implants and tinnitus]
Cochleaimplantate und Tinnitus. HNO 2015; 63: 291-7.
Abstract: The cochlear implant became a very successful method of hearing rehabilitation for patients with profound sensorineural hearing loss. The benefits of the CI extend beyond the medical success and positively influence social and psychosocial areas, reflected by an improved HRQoL. Furthermore, variety of studies demonstrated that the tinnitus severity improves in 46-95 % of cases following the cochlear implantation. However, the parameters investigated in such studies are not always standardized or addressed by validated questionnaires, which explains the high outcome variation between the studies. The relationships between HRQoL and tinnitus distress before and after cochlear implantation have not been well studied. Nevertheless, it is believed that the improvement in HRQoL following CI affects particularly tinnitus.However, an existing tinnitus can also worsen or occur for the first time after the surgery. Since neither tinnitus frequency nor tinnitus loudness correlate with the tinnitus-induced distress, the measurement of HRQoL, distress factors, stress reactions and psychiatric comorbidities appears to be the meaningful assessment of positive or negative effects of CI on tinnitus.Initial studies demonstrated that also patients with unilateral hearing loss may benefit from CI supply, as shown by an improvement in HRQoL and reduction of tinnitus-induced distress. For those patients, who despite CI implantation experience severe tinnitus, there is an option of tinnitus-specific CI-fitting and tinnitus-specific therapy with psychosomatic and psychological approaches, and- in addition- a treatment of possible mental comorbidities
Pub. type: English Abstract
Journal Article
ISSN: 1433-0458
PM:25862623

7. Ramos Macias A, Falcon Gonzalez JC, Manrique M, et al. Cochlear implants as a treatment option for unilateral hearing loss, severe tinnitus and hyperacusis. Audiol Neurootol 2015; 20 Suppl 1: 60-6.
Abstract: Tinnitus is an incapacitating condition commonly affecting cochlear implant (CI) candidates. The aim of this clinical study is to assess the long-term effects of CI treatment in patients with severe-to-profound, sensorineural, unilateral hearing loss (UHL) and incapacitating tinnitus. We performed a prospective Cochlear company-sponsored multicentre study in five Spanish centres. Sixteen patients with UHL and incapacitating tinnitus, which was indicated by a Tinnitus Handicap Inventory (THI) score >58%, received a Nucleus(R) CI in their deaf ear. The study design includes repeated within-subject measures on hearing, tinnitus, hyperacusis and quality of life up to 12 months after initial CI fitting. In addition to hearing loss and tinnitus, all patients suffered from hyperacusis. Most patients had a sudden hearing loss and received a CI within 2 years after their hearing loss. Preliminary 6-month, post-CI activation data of 13 subjects showed that the majority of patients perceived a subjective benefit from CI treatment, which was assessed using the THI, a Visual Analogue Scale of tinnitus loudness/annoyance and the Speech, Spatial and Qualities of Hearing Scale. Preliminary 12-month data of 7 subjects showed that most patients also perceived a degree of relief from their hyperacusis. One patient showed no improvements in any of the applied scales, which could be explained by partial insertion of the electrode due to obstruction of the cochlea by otosclerosis. In conclusion, CI can successfully be used in the treatment of UHL

patients with accompanying severe tinnitus and hyperacusis. Implantation resulted in hearing benefits and a durable relief from tinnitus and hyperacusis in the majority of patients. These findings support the hypothesis that pathophysiological mechanisms after peripheral sensorineural hearing loss are at least partly reversible when hearing is restored with a CI
Pub. type: Journal Article
ISSN: 1421-9700
PM:25997672

8. Tavora-Vieira D, Marino R, Acharya A, et al. The impact of cochlear implantation on speech understanding, subjective hearing performance, and tinnitus perception in patients with unilateral severe to profound hearing loss. Otol Neurotol 2015; 36: 430-6.
Abstract: OBJECTIVES: This study aimed to determine the impact of cochlear implantation on speech understanding in noise, subjective perception of hearing, and tinnitus perception of adult patients with unilateral severe to profound hearing loss and to investigate whether duration of deafness and age at implantation would influence the outcomes. In addition, this article describes the auditory training protocol used for unilaterally deaf patients. DESIGN: This is a prospective study of subjects undergoing cochlear implantation for unilateral deafness with or without associated tinnitus. METHODS: Speech perception in noise was tested using the Bamford-Kowal-Bench speech-in-noise test presented at 65 dB SPL. The Speech, Spatial, and Qualities of Hearing Scale and the Abbreviated Profile of Hearing Aid Benefit were used to evaluate the subjective perception of hearing with a cochlear implant and quality of life. Tinnitus disturbance was measured using the Tinnitus Reaction Questionnaire. Data were collected before cochlear implantation and 3, 6, 12, and 24 months after implantation. RESULTS: Twenty-eight postlingual unilaterally deaf adults with or without tinnitus were implanted. There was a significant improvement in speech perception in noise across time in all spatial configurations. There was an overall significant improvement on the subjective perception of hearing and quality of life. Tinnitus disturbance reduced significantly across time. Age at implantation and duration of deafness did not influence the outcomes significantly. CONCLUSION: Cochlear implantation provided significant improvement in speech understanding in challenging situations, subjective perception of hearing performance, and quality of life. Cochlear implantation also resulted in reduced tinnitus disturbance. Age at implantation and duration of deafness did not seem to influence the outcomes
Pub. type: Journal Article
ISSN: 1537-4505
PM:25594387

9. Blasco MA and Redleaf MI. Cochlear implantation in unilateral sudden deafness improves tinnitus and speech comprehension: meta-analysis and systematic review. Otol Neurotol 2014; 35: 1426-32.
Abstract: OBJECTIVE: In recent years, otologists have begun to place cochlear implants into nonfunctioning ears after sudden unilateral hearing loss. Patients in these trials demonstrate differing degrees of hearing loss in the unimplanted ear. Few studies have examined the role of implantation in patients with normal hearing in the unimplanted ear. To understand if this practice benefits these patients in terms of tinnitus, sound localization, and speech understanding, the available world literature is reviewed. DATA SOURCES: MEDLINE, Embase, and

Cochrane databases were searched for publications from database inception to June 1, 2013, without restriction of language. STUDY SELECTION: A search of multiple medical databases was performed to identify articles reporting cases series of cochlear implantation for unilateral hearing loss. Subjects were included for analysis only if the course of hearing loss was acute and rapidly progressive, if the loss was severe to profound, and if the contralateral ear had normal hearing. DATA EXTRACTION AND SYNTHESIS: Nine appropriate articles were identified, in which 36 patients met our inclusion criteria. Three meta-analyses were performed: of tinnitus (22 patients); of the lowest signal-to-noise ratio, which still allowed 50% sentence understanding (16 patients); and of sentence understanding at a fixed signal-to-noise ratio (12 patients). These found that measures of tinnitus reduction and decreased signal-to-noise ratios to still allow 50% speech discrimination were statistically significantly reduced. Systematic review of subjective changes of tinnitus in 27 patients, speech understanding in 16 patients, and sound localization in 16 patients found 96%, 100%, and 87% were improved, respectively. CONCLUSION: Cochlear implantation in unilateral sudden hearing loss with a normal functioning contralateral ear might prove to be an effective therapy. Tinnitus is reduced as is the signal-to-noise ratio, which still allows 50% speech discrimination. All patients felt that they localized sound better, and most felt that they understood speech better. Further studies should be conducted to compare the success of hearing rehabilitation of cochlear rehabilitation and traditional modalities such as contralateral routing of signal and bone-anchored hearing aids
Pub. type: Journal Article
Meta-Analysis
Review
ISSN: 1537-4505
PM:24786540

10. Tokita J, Dunn C, Hansen MR. Cochlear implantation and single-sided deafness. Curr Opin Otolaryngol Head Neck Surg 2014; 22: 353-8.
Abstract: PURPOSE OF REVIEW: Recently, more patients with single-sided deafness (SSD) have been undergoing cochlear implantation. We review recent studies and case reports to provide an overview of the efficacy of cochlear implants to rehabilitate patients with SSD with regards to sound localization, speech discrimination, and tinnitus suppression. RECENT FINDINGS: There are a growing number of studies evaluating the effect of cochlear implantation for rehabilitation of the deficits associated with SSD over the past several years as more centers offer this treatment modality to patients with SSD. Although individual studies have few patients and are underpowered, the vast majority report improvement in sound localization, speech understanding in quiet and noise, and tinnitus. In some cases, the outcomes with cochlear implant appear superior to those achieved with other devices, including contralateral routing of sound devices and osseointegrated implants. SUMMARY: Although cochlear implant is not a Food and Drug Administration-approved treatment for SSD, several recent studies show improvements in speech understanding, sound localization, and tinnitus. Because of the low number of cases, it is difficult to conclusively compare outcomes achieved with cochlear implants and those provided by other devices. However, on the basis of encouraging early results and the unique ability to restore binaural sound processing, a growing number of centers offer cochlear implants as treatment for SSD. Forthcoming studies will help define outcome expectations in different populations

Pub. type: Journal Article
Research Support, N.I.H., Extramural
Research Support, Non-U.S. Gov't
Review
ISSN: 1531-6998
PM:25050566

11. Vlastarakos PV, Nazos K, Tavoulari EF, et al. Cochlear implantation for single-sided deafness: the outcomes. An evidence-based approach. Eur Arch Otorhinolaryngol 2014; 271: 2119-26.
Abstract: The aim of the present paper is to critically review the current evidence on the efficacy of cochlear implantation as a treatment modality for single-sided deafness (SSD), and/or unilateral tinnitus. Systematic literature review in Medline and other database sources was conducted along with critical analysis of pooled data. The study selection includes prospective and retrospective comparative studies, case series and case reports. The total number of analyzed studies was 17. A total of 108 patients with SSD have been implanted; 66 patients due to problems associated with SSD, and 42 primarily because of debilitating tinnitus. Cochlear implantation in SSD leads to improved sound localization performance and speech perception in noise from the ipsilateral side with an angle of coverage up to (but not including) 90(degrees) to the front, when noise is present in the contralateral quartile (Strength of recommendation B). Speech and spatial hearing also subjectively improve following the insertion of a cochlear implant (Strength of recommendation B); this was not the case regarding the quality of hearing. Tinnitus improvement was also reported following implant placement (Strength of recommendation B); however, patients need to be advised that the suppression is mainly successful when the implant is activated. The overall quality of the available evidence supports a wider use of cochlear implantation in SSD following appropriate selection and counseling (overall strength of recommendation B). It remains to be seen if the long-term follow-up of large number of patients in well conducted high quality studies will confirm the above mentioned results
Pub. type: Journal Article
Review
ISSN: 1434-4726
PM:24096818

12. Tavora-Vieira D, Marino R, Krishnaswamy J, et al. Cochlear implantation for unilateral deafness with and without tinnitus: a case series. Laryngoscope 2013; 123: 1251-5.
Abstract: OBJECTIVES/HYPOTHESIS: To investigate cochlear implantation (CI) in patients with unilateral deafness with and without tinnitus. STUDY DESIGN: Prospective case series of patients undergoing cochlear implantation for unilateral deafness and tinnitus in a tertiary academic unit. METHODS: Nine postlingually deafened subjects with unilateral hearing loss, with and without tinnitus ipsilaterally, and functional hearing in the contralateral ear were implanted with a standard electrode. Speech perception in noise was tested using the Bamford-Kowal-Bench presented at 65 dB SPL. The Speech, Spatial, and Qualities (SSQ) of Hearing Scale was used to evaluate the subjective perception of hearing outcomes, and the Tinnitus Reaction Questionnaire assessed the effect on tinnitus. RESULTS: All patients were implanted with the Med-El Flex soft electrode, Innsbruck, Austria. They are regularly wearing the speech processor and find it beneficial in improving their ability to hear, particularly in noise.

Decrease of tinnitus perception and an improvement of sound localization sounds were also reported by these patients. CONCLUSION: In our case series, CI was successful for all nine patients, with improvement of speech recognition in noise, self-perceived improvement of hearing, and for tinnitus control. Several factors such as deafness duration, age of deafness onset, the presence of residual hearing, patient motivation, and the rehabilitation intensity need to be further investigated in order to understand their impact on performance after implantation. LEVEL OF EVIDENCE: 4
Pub. type: Comparative Study
Journal Article
ISSN: 1531-4995
PM:23553411

Study protocol

13. Peters JPM, Van ZA, Smit AL, et al. CINGLE-trial: Cochlear implantation for sINGLE-sided deafness, a randomised controlled trial and economic evaluation. **Study protocol.** BMC Ear Nose Throat Disord 2015; 15: 3.
Abstract: Background: Individuals with single-sided deafness (SSD) have problems with speech perception in noise, localisation of sounds and with communication and social interaction in their daily life. Current treatment modalities (Contralateral Routing of Sound systems [CROS] and Bone Conduction Devices [BCD]) do not restore binaural hearing. Based on low level of evidence studies, CROS and BCD do not improve speech perception in noise or sound localisation. In contrast, cochlear implantation (CI) may overcome the limitations of CROS and BCD, as binaural input can be restored. Promising results have previously been achieved on speech perception in noise, sound localisation, tinnitus and quality of life. Methods and design: A single-center Randomised Controlled Trial (RCT) was designed to compare all treatment strategies for SSD. One hundred and twenty adult single-sided deaf patients (duration of deafness >3 months and maximum 10 years; pure tone average at 0.5, 1, 2, 4 kHz, deaf ear: threshold equal to or more than 70 dB, better ear: threshold of maximum 30 dB) will be included in this trial and randomised to CI, 'first BCD, then CROS' or 'first CROS, then BCD'-groups. After the trial period, patients in the two latter groups may choose with which treatment option they continue. Outcomes of interest are speech perception in noise, sound localization, tinnitus and quality of life. These outcomes will be measured during a baseline visit and at follow up visits, which will take place at 6, 12, 18, 24, 36, 48 and 60 months after onset of treatment. Furthermore, an economic evaluation will be performed and adverse events will be monitored. Discussion: This RCT allows for a comparison between the two current treatment modalities for single-sided deafness and a new promising treatment strategy, CI, on a range of health outcomes: speech perception in noise, sound localization, tinnitus and quality of life. Additionally, we will be able to answer the question if the additional costs of CI are justified by increased benefits, when compared to current treatment strategies. This study will inform health policy makers with regard to reimbursement of CI. Trial registration: Netherlands Trial Register (www.trialregister.nl): NTR4580
ISSN: 1472-6815

1. AETNA. Tinnitus Treatments. 2015. Geraadpleegd in December 2015 via http://www.aetna.com/cpb/medical/data/400_499/0406.html.

2. ANTHEM. Cochlear Implants and Auditory Brainstem Implants. 2015. Geraadpleegd in December 2015 via http://www.anthem.com/ca/medicalpolicies/policies/mp_pw_a050199.htm.
A cochlear implant is considered investigational and not medically necessary for all other indications when the above criteria are not met, including but not limited to treatment of any of the following:
- auditory neuropathy spectrum disorders (ANSD)
- tinnitus in individuals who do not also have bilateral severe-to-profound hearing loss (sensorineural deafness)
- unilateral deafness

3. CIGNA. Cochlear and Auditory Brainstem Implants. 2015. Geraadpleegd in December 2015 via http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0190_coveragepositioncriteria_cochlear_and_auditory_brainstem_implants.pdf.
Cigna does not cover a traditional cochlear implant for the treatment of tinnitus in an individual who does not also have profound or severe sensorineural deafness/hearing loss warranting the need for traditional cochlear implantation because such use is considered experimental, investigational or unproven.

4. DGHNO. Cochlea-Implantat Versorgung und zentral-auditorische Implantate . 2012. Geraadpleegd in December 2015 via http://www.awmf.org/uploads/tx_szleitlinien/017-071l_S2k_Cochlea_Implant_Versorgung_2012-05_01.pdf.
Eine weitere Indikation besteht bei einseitiger Horstorung mit CI-Indikation mit und ohne Tinnitus und erheblicher Einschrankung der Lebensqualitat (van de Heyning et al 2008; Arndt et al. 2011).