PREVALENCE OF COCHLEAR IMPLANTS IN EUROPE: WHAT DO WE KNOW AND WHAT CAN WE EXPECT?

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Abstract

Background: Cochlear implantation is the major beneficial treatment of bilateral profound deafness in children and adults, but there are big differences in utilisation between European countries.

Materials and method: Statistical data on the number of implanted persons are obtained each year by Euro-CIU (the European Association of Cochlear Implant Users). This study models the trends and gives an overview of the current number of cochlear implants in 16 European countries; our model predicts the future demand on cochlear implants in children and adults.

Results: The degree of utilisation of cochlear implantation by suitable children and adults varies considerably between the European countries. Most less affluent East European countries focus on the implantation of children rather than adults. Although adult recipient numbers are growing, it has been estimated that less than 10% of adult candidates in Europe receive a CI. There is little to no scientific data available on late onset, or progressive, hearing loss in children or adults.

Conclusion: It is possible to estimate the yearly number of CI candidates in a country, but we don't yet have enough reliable data to put into our model. Because of the underutilisation of cochlear implants, especially in adults, we have to work on raising the general awareness of the benefits of cochlear implants, and its improvement in quality of life, based on cost-effectiveness data and on guidelines for good clinical practice.

Keywords: cochlear implants • prevalence • deafness

PRESENCIA DE IMPLANTES COCLEARES EN EUROPA: ¿QUÉ ES LO QUE SABEMOS Y QUÉ PODEMOS ESPERAR?

Resumen

Historial/fondo: Los implantes cocleares son el mejor método de tratamiento de la sordera bilateral del grado avanzado tanto en niños como y en adultos. Sin embargo, existen diferencias significativas en su uso en diferentes países europeos.

Materiales y métodos: La Asociación Europea de Usuarios de Implante Coclear (European Association of Cochlear Implant Users) recopila todos los años los datos estadísticos sobe el número de personas con implante coclear. Estos estudios están creando las tendencias y proporcionan una visión general del número actual de implantes cocleares en 16 países europeos. Nuestro modelo predice la futura demanda de implantes cocleares en niños y adultos.

Resultados: El grado del uso de implantes cocleares en niños y adultos difiere significamente entre distintos países europeos. La mayor parte de los países menos prósperos de Europa del Este se concentra más en insertar implantes en niños que en adultos. Aunque el número de beneficiarios adultos de este método sigue creciendo, se estima que se procederá a insertar implantes en tan sólo un 10% de candidatos adultos. Los datos científicos referentes a la aparición tardía de problemas de sordera o sobre el desarrollo de pérdida de audición en niños y adultos o no son del todo accesibles, o son pocos.

Conclusiones: Es posible estimar el número anual de candidatos para insertar el implante coclear a escala nacional, sin embargo no disponemos aún del número suficiente de datos fidedignos para nuestro modelo. Dado que no se aprovecha del todo los implantes cocleares, sobre todo en adultos, tenemos que trabajar, en base a los datos sobre la economía y los principios dela buena práctica clínica, para mejorar los conocimientos generales sobre los beneficios que ofrecen los implantes y la mejora de la calidad de vida que pueden aportar,

Palabras clave: implantes cocleares • divulgación • sordera

РАСПРОСТРАНЕНИЕ УЛИТКОВЫХ ИМПЛАНТАТОВ В ЕВРОПЕ: ЧТО МЫ ЗНАЕМ И ЧТО МЫ МОЖЕМ ОЖИДАТЬ?

Изложение

Почва: Улитковые имплантаты – это полезнейший способ лечения двусторонней глухоты глубокой степени у детей и взрослых. Однако существует значительная разница в их использовании в отдельных европейских странах.

Материал и методы: Европейская Ассоциация Пользователей Улитковых Имлантатов (European Association of Cochlear Implant Users) собирает ежегодные статистические данные относительно количества имплантированных людей. Эти исследования формируют тренды и снабжают данными относительно актуального количества улитковых имплантатов в 16 европейских странах. Наша модель предвидит будущий спрос на улитковые имплантаты среди детей и взрослых.

Результаты: Степень использования улитковых иплантатов у детей и взрослых значительно отличается в европейских странах. Большинство менее состоятельных стран Восточной Европы более сосредотачивает внимание на имплантировании детей чем взрослых. Несмотря на то, что число взрослых получателей этого метода растет, оценивается, что в Европе иплантируется менее 10% взрослых кандидатов. Научные данные относительно позднего появления или развития тугоухости у детей и взрослых совсем недоступные или их мало.

Выводы: Возможна оценка годового количества кандидатов на вживление улиткового имплантата на территории страны, но у нас еще нет достаточного количества достоверных данных для нашей модели. По причине неполного использования улитковых имплантатов, особенно у взрослых, мы должны работать над улучшением общего сознания относительно пользы, возникающей из применения улитковых имплантатов и улучшения качества жизни, на основании данных, касающихся экономности и принципа хорошей клинической практитки.

Ключевые слова: улитковые имплантаты • распространение • глухота

ROZPOWSZECHNIENIE IMPLANTÓW ŚLIMAKOWYCH W EUROPIE: CO WIEMY I CZEGO MOŻEMY SIĘ SPODZIEWAĆ?

Streszczenie

Tło: Implanty ślimakowe są najkorzystniejszym sposobem leczenia obustronnej głuchoty głębokiego stopnia u dzieci i dorosłych. Istnieją jednak znaczące różnice w ich wykorzystaniu w poszczególnych krajach europejskich.

Materiał i metody: Europejskie Stowarzyszenie Użytkowników Implantów Ślimakowych (European Association of Cochlear Implant Users) gromadzi coroczne dane statystyczne na temat liczby osób implantowanych. Badania te kształtują trendy i dostarczają przeglądu aktualnej liczby implantów ślimakowych w 16 krajach europejskich. Nasz model przewiduje przyszłe zapotrzebowanie na implanty ślimakowe wśród dzieci i dorosłych.

Wyniki: Stopień wykorzystania implantów ślimakowych u dzieci i dorosłych znacznie różni się między krajami europejskimi. Większość mniej zamożnych krajów Europy Wschodniej bardziej skupia uwagę na implantowaniu dzieci niż dorosłych. Pomimo, że liczba dorosłych beneficjentów tej metody rośnie, szacuje się, że implantowanych zostaje w Europie niespełna 10% dorosłych kandydatów. Dane naukowe na temat późnego pojawiania się lub rozwoju niedosłuchów u dzieci i dorosłych nie są dostępne wcale lub jest ich niewiele.

Wnioski: Możliwe jest oszacowanie rocznej liczby kandydatów do wszczepienia implantu ślimakowego na terenie kraju, ale nie posiadamy jeszcze wystarczającej ilości wiarygodnych danych do naszego modelu. Ze względu na niepełne wykorzystanie implantów ślimakowych, zwłaszcza u dorosłych, musimy pracować nad polepszeniem ogólnej świadomości dotyczącej korzyści wynikających z zastosowania implantów ślimakowych oraz poprawy jakości życia, w oparciu o dane na temat oszczędności oraz zasady dobrej praktyki klinicznej.

Słowa kluczowe: implanty ślimakowe • rozpowszechnienie • głuchota

Background

Attempts to provide hearing by electrical stimulation of the auditory system have a long history. Interest in electrical methods of stimulating hearing started in the late 18th century when Alessandro Volta discovered the electrolytic cell [1]. The initial optimism surrounding this bioelectrical approach was followed by a period of skepticism as

its applications were invasive and required ongoing critical evaluation. Presently, cochlear implants are the result of intensive research over the last five decades [2].

Initial efforts concentrated on the use of cochlear implants with postlingually deaf adults who had knowledge of spoken language, whose auditory system had already been stimulated, and who were able to give consent. In 1990 the American Food and Drug Administration (FDA) approved the Nucleus device for use with children aged 2–17 years. Since then, cochlear implant candidacy criteria have gradually expanded. In the case of children, initially only those who were totally deaf, had normal intelligence, and had a normal cochlea could receive a cochlear implant [3]. Now, children and adults are being implanted who have amounts of residual hearing [4], additional needs, and even malformed cochleas [1]. Children are also being implanted at much younger ages because there is a clear correlation between age at implantation and speech recognition ability [5].

Current FDA guidelines permit cochlear implantation in the US in children aged 2 years and older with severe to profound deafness (i.e., pure tone average thresholds >70 dB HL), and in children 12–23 months of age with profound deafness (i.e., pure tone average threshold >90 dB HL). The guidelines for adults permit implantation if open-set aided word perception scores with well-fitted hearing aids is less than 20–30% [6]. As cochlear implant devices continue to improve, as does our knowledge, the criteria regarding the degree of hearing loss and performance with a hearing aid that warrants consideration of a cochlear implant, will also continue to evolve. Nevertheless, general questions about the applicability will persist: there will always be the need to evaluate the patient's medical, audiological, and psychosocial/habilitative conditions.

The criteria mentioned above apply for 'conventional' cochlear implants. However, presently there are more and more people receiving cochlear implants for high frequency hearing loss where their low-frequency acoustic hearing is preserved. This type of cochlear implant is often referred to as a hybrid cochlear implant or as combined electric and acoustic stimulation (EAS) [7–9]. Unilateral or single-sided deafness (SSD) is another promising application for cochlear implants. Implanting these patients has the potential to enhance their ability to communicate, to suppress their tinnitus, and to increase their quality of life [4].

This study gives an overview of the current number of conventional cochlear implants in 16 European member countries of Euro-CIU (the European Association of Cochlear Implant Users) and develops a model to predict future demand.

Prevalence of hearing loss

In February 2013 the World Health Organization (WHO) reported that about 5% of the world's population has a disabling hearing loss (328 million adults and 32 million children), the majority of which live in low- and middle-income countries. Approximately one-third of people over 65 years of age are affected by disabling hearing loss. The prevalence in this age group is greatest in South Asia, the Asia-Pacific, and sub-Saharan Africa [10]. Of the total group of hearing-impaired people, about 10% have a severe to profound hearing loss. About half of them are over 65 years of age and less than 4% are younger than 18 [11].

The estimated prevalence of permanent bilateral childhood hearing impairment (>40 dB HL) varies from 1 to 1.4 per 1000 for newborns and increases to 1.62–1.68 per 100 at the age of 16 [12]. The prevalence of severe and profound hearing loss in children increases uniformly with age; this is because of non-diagnosis at screening, post-natal acquisition of hearing loss, late onset of progressive hearing loss, and immigration of children born in countries without neonatal hearing screening [13]. Of all newborns who have bilateral hearing loss, 25–30% have a profound loss (>90 dB HL) and 20–25% a severe loss (71–90 dB HL) [11,14], which means 45% are CI candidates based on the current pediatric FDA guidelines.

Concerning the prevalence of permanent adult hearing loss, a national survey in the UK [15] is still the best and most detailed study. Their data show that 0.4% have a hearing loss exceeding 85 dB HL and 0.3% a hearing loss exceeding 95 dB HL.

Materials and method

Accessibility to cochlear implants in Europe

Each year the European Association of Cochlear Implant Users (Euro-CIU) asks their members to collect data on the number of implantees in their country [16]. In 2011, Euro-CIU had 23 national CI-user associations as member and altogether they represented more than 100,000 implantees. Out of these 23 countries, 16 were able to forward their data on the number of CI-users in their country. The collected data differ in reliability because some countries have a centralised government registration system (Austria, Netherlands, Belgium, Switzerland, UK, and Turkey), while others receive data directly from the CI-centres (Sweden, Denmark, Finland, Luxemburg, Italy, Estonia, Slovak Republic, and Hungary); in a few countries data are kept confidential by government and/or CI-centres (Germany, France).

Results

Number of cochlear implant users in Europe

Figure 1 gives an overview of the total number of implantees per million inhabitants until 2011 in 16 European countries participating in this study. It is clear that there are large individual differences within Europe, both in children (age <18 years) as well as in adults (>18 years).

In most West European countries, there are about 200 implanted persons per million inhabitants. However in East European countries like Slovak Republic, Estonia, and Hungary the figure is 50–75 implantees/million. This difference might relate to limited funding and/or the fact that cochlear implantation in Eastern Europe started later. In some of these countries cochlear implants for adults are not reimbursed (or only minimally). According to an estimate of the German CI Association (DCIG), Germany

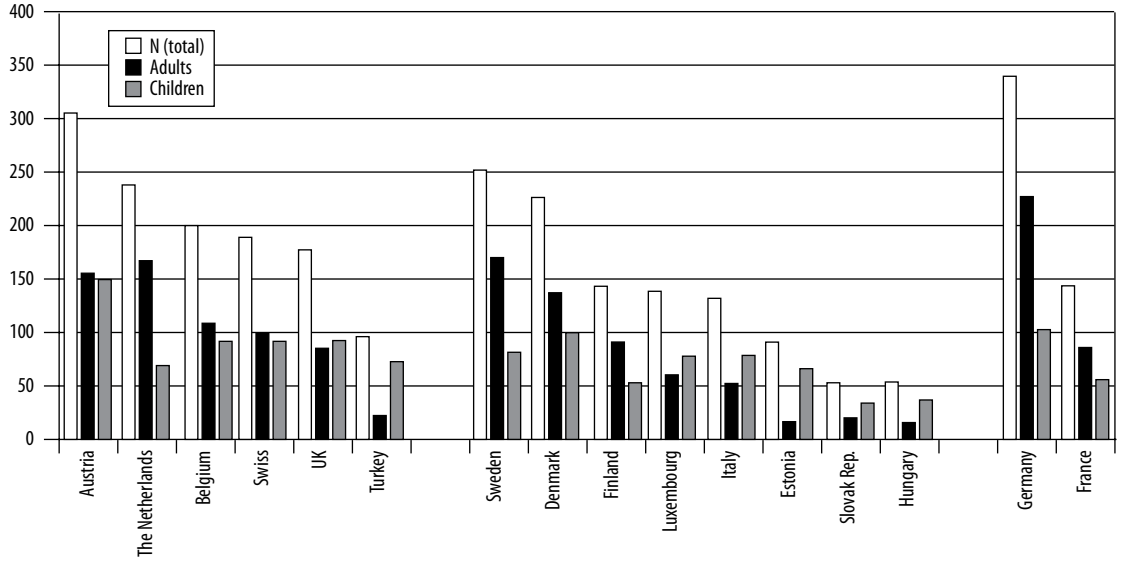

Figure 1. Total number of implantees per million inhabitants by 2011

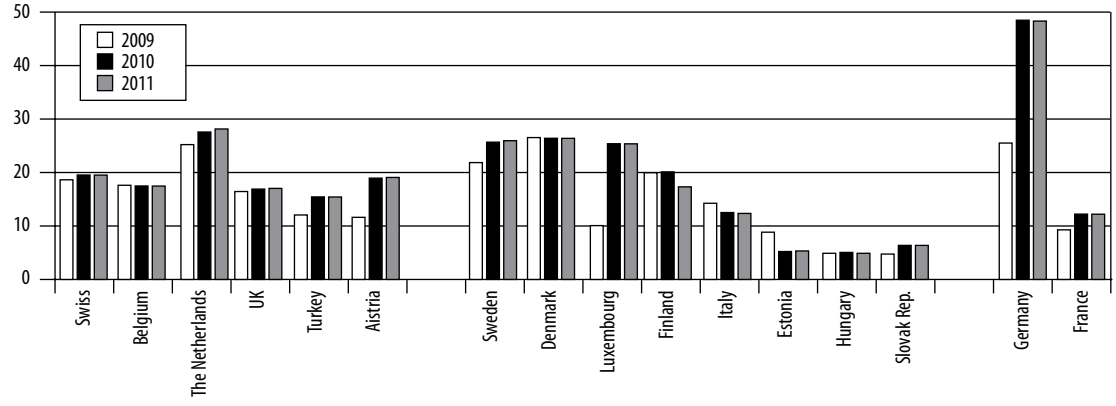

Figure 2. Total number of implantations per million inhabitants in 2009, 2010, and 2011

has more than 300 implanted persons per million inhabitants. Reimbursement policy also causes large differences in the ratio of the number of implanted children (reimbursed in most European countries) and the number of adults (reimbursed in fewer countries). Estonia, Slovac Republic, Turkey, Hungary, and Italy focus on the implantation of children rather than adults.

In Figure 2, an overview of the total number of implantations per million inhabitants in 2009, 2010, and 2011 is given, showing that the data during these years is fairly constant. The figures for Germany in 2010 and 2011 are most probably contaminated by double counting of large numbers of bilaterally implanted persons, since bilateral implantation started on a large scale in 2010. Therefore, it was decided that the German data were not further considered in this study. The 'best' performing countries reach a yearly total number of 15–30 implantations (adults and children) per million inhabitants. However, some East European countries reach only 5 per million.

The 2011 data differentiated for children and adults is shown in Figure 3. In most European countries the number of adults that received a cochlear implant in 2011 was 10–20 per million inhabitants. The number of pediatric implantations shows smaller individual differences, and falls into the range of 6–10 per million in most European countries.

Publications relating to various West European countries show that in these countries 80–95% of all deaf newborns receive cochlear implants [5,17,18]. However, this is not the case in France, Estonia, Slovak Republic, and Hungary where the implantation level is less than 5 children/year/million inhabitants.

In presenting data on pediatric cochlear implantation we have to take into account the differences in birth rate between European countries. In 2011 the mean annual European birth rate was 10.3 per 1000, with the lowest value 8.3 for Germany and the highest 17.5 for Turkey [19].

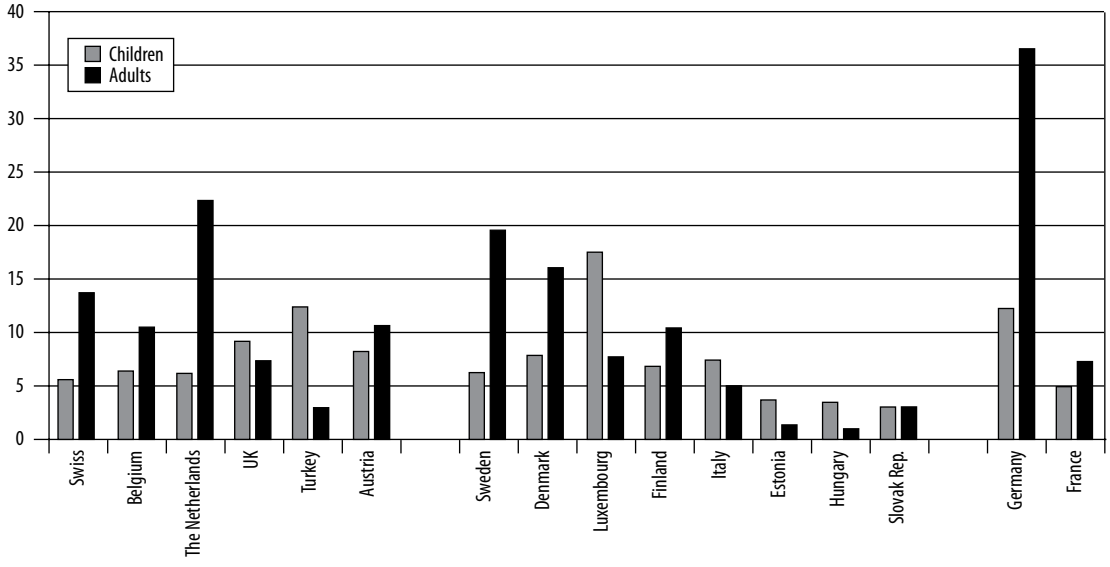

Figure 3. Implantations per year (per million) for children and adults in 2011

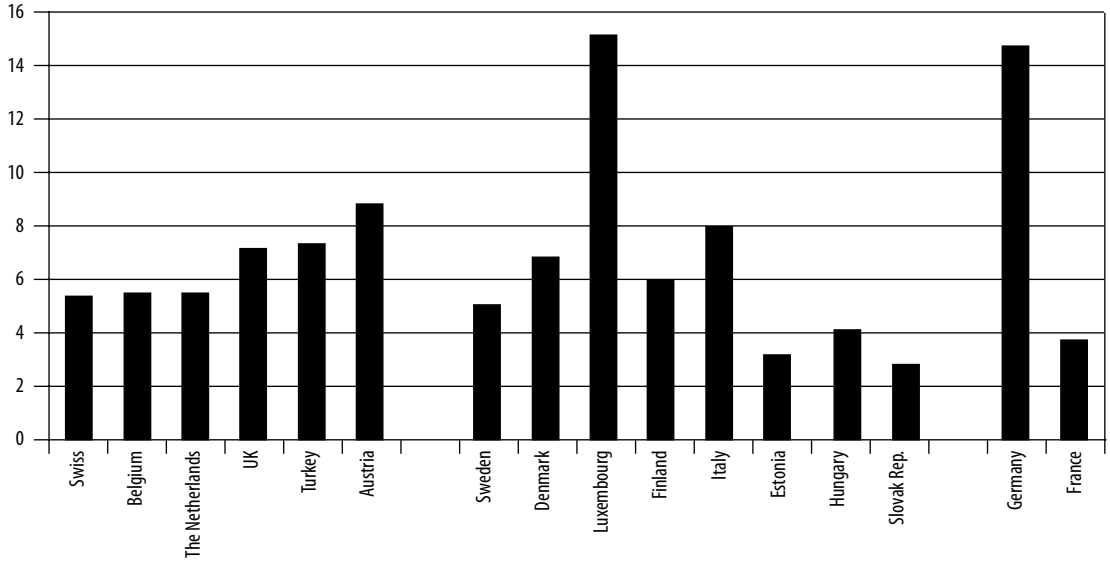

Figure 4. Yearly number of implantations per 10,000 newborns in 2011

Hence, a better way to compare the performances of pediatric implantation in various countries is the number of implants per number of newborn children. This number is easily obtained by dividing the number of children implanted per million inhabitants by the birth rate, as shown in Figure 4.

Although most West European countries show implantation numbers of 5.5–8.5/10,000 newborns, it doesn't mean that all these implanted children were born deaf. It is generally accepted that 1–1.2‰ of all newborns have a bilateral hearing loss [20] of which a minimum of 45% is severe to profound. Hence, only 3–4/10,000 are directly referred for implantation. The other 3 or 4/10,000 implanted children are those who were missed/not referred by the neonatal hearing screening, or who suffer progressive or late onset hearing loss. These data are in line with the paediatric UK data, which show that 40–50% are implanted under the age of 3 (most of them born deaf) and 50–60% are implanted between 3 and 17 years old, most of them having a progressive or late onset hearing loss [18]. The reason for the high number in Luxemburg in 2011 is that in this small country (only 500,000 inhabitants) a few implants more or less per year make a big difference in percentage.

Number of potential CI-candidates

Looking at the current selection criteria for cochlear implantation, nearly every child and adult with a bilateral profound hearing loss (>85–90 dB), a functioning auditory nerve, and good health is a potential CI candidate. They can be born deaf or have a sudden or progressively

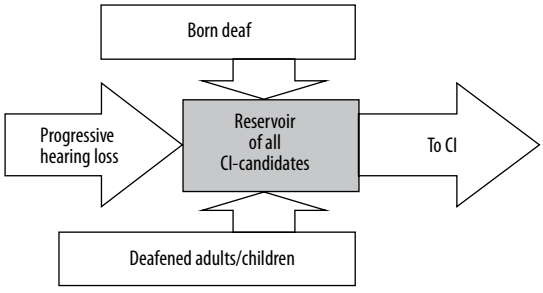

Figure 5. Flow diagram of potential CI candidates

acquired hearing loss, as depicted in Figure 5 in which all possible CI candidates are placed together in a reservoir. Only a certain percentage of candidates will be implanted, depending on the local reimbursement system, selection criteria (e.g. good physical condition and motivation), and awareness of the possibilities and benefits of cochlear implants.

Based on the above flow diagram, we tried to find an answer to the question of whether the implantation capacity in a country is sufficient to keep pace with the demand.

First, let us look at the situation in The Netherlands (16.8 million inhabitants) as an example, and investigate what would be the result of transferring its implantation rate to other West European countries if there were equal conditions of early hearing screening, age distribution, and level of income.

Children

The number of newborns in The Netherlands is presently about 185,000 per year, of which 1–1.2‰ (i.e., 185–220 children) have a bilateral hearing loss [21]. Of these newborns it is assumed that approximately 45% (approx. 60 children) have a severe to profound bilateral hearing loss [11,13], qualifying them for implantation.

According to Raine (2013), 50% of the total group of deaf children (age up to 17 years) are not recognised at birth, leading to an extra number of 60. We therefore expect around 120 paediatric CI candidates per year. Looking at the data of The Netherlands collected by CION (Cochlear Implant Overleg Nederland) in 2013, we note that 106 children (88%) received a CI in 2010, 97 (81%) in 2011, and 79 (65%) in 2012, which means that on average about 80% of paediatric CI candidates receive a CI in The Netherlands. This is comparable to the situation in the Flanders area of neighboring Belgium [22] and higher than the 50% rate in the US [23].

Adults

As mentioned earlier, the study of Davis (1995) on the incidence of hearing loss in the adult UK population is still the best and most detailed available. He reported that in the age group 18–80 year olds, 0.4% had a hearing loss >85 dB HL and 0.3% had a profound hearing loss above 95 dB HL. Extrapolating, we estimate that 0.33% have a hearing loss above 90 dB. So using the Davis data we can estimate the number of CI candidates within any adult population in Western Europe.

We take The Netherlands as an example, a country with 16.8 million inhabitants of which 13.7 million are aged >18 years [22]. Based on the Davis data and the >90 dB HL inclusion criterion, there are 44,500 adult CI candidates. From the data of CION [25], we learn that until 2012, 3176 adults in the Netherlands have cumulatively received a CI. This means that only 7% of all adult CI candidates in The Netherlands (with thresholds >90 dB) have received a CI. This percentage is comparable to that in the US, where until 2009 less than 6% of Americans, who could have benefited from a CI, received one [23].

We have shown how it is possible to estimate the total number of adult CI candidates in a country based on the Davis data. However, it is also interesting to measure the yearly number of new adult CI candidates, as we did for the children, making it possible to estimate the implantation capacity necessary to keep pace with the yearly growth of demand. Obtaining the yearly number of CI candidates in a country is rather complex and has to take account of changes in demography over time. From the 1995 Davis data we learn that in the age groups 18–30 and 31–40 the percentage prevalence of >90 dB hearing loss is rather small; however, after 10 years the age group of 31–40

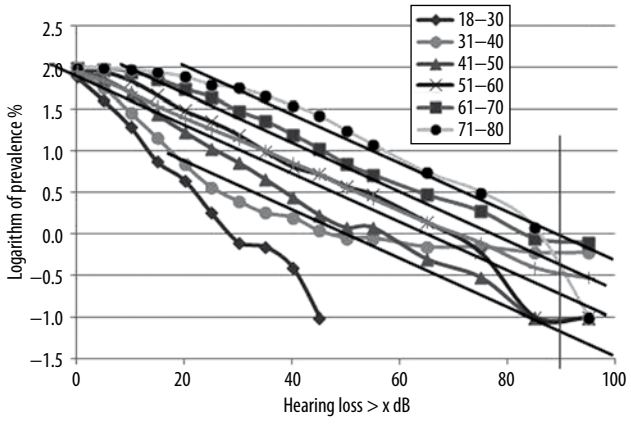

Figure 6. Logarithm of per cent prevalence of hearing loss by age group, based on the study of Davis (1995)

Table 1. Calculation model for measuring the yearly increase of people passing the 90 dB HL threshold in The Netherlands

Age	Population in millions		Prevalence of HL >90 dB	Numbers of HL >90 dB		Increase after 10 years
	2000	2010	%	2000	2010	
21–30	2,240		**0**	0		0
31–40	2,620	2,170	**0,052**	1362	1130	1130
41–50	2,507	2,718	**0,120**	3008	3216	1854
51–60	1,967	2,088	**0,300**	5901	6264	3256
61–70	1,475	1,923	**0,660**	9735	12691	6791
71–80	0,936	1,210	**1,368**	12804	11325	1590
81–90	0,365	0,448	**3,146**	11482	14094	1290
91–100	0,126	0,199	**7,236**	(9117)	14399	2917
Total 21–90	12,110			44292		
Total 31–100		10,756			63119	18828
Survival% 31–100 y		88.8				
Total survivors 21–90				39331		**23788**
Increase per year						**2379**

years old is transferred into the age group of 41–50 years old and the prevalence of >90 dB HL is no longer negligible. The increase in prevalence of HL >90 dB over 10 years can also be obtained from the Davis data as plotted in Figure 6.

As an example, in Table 1 we compare the situation in The Netherlands in the years 2000 and 2010. The population is divided into 10-year age groups and the demographic data of the Dutch population [24] are shown in columns 2 and 3. Note that after 10 years, the population in each of the original age groups transfers into the next age group. The detailed calculation of the total number of people with a >90 dB HL is performed in a differential mode, i.e. the number of people *N* is divided into 10-year age groups and the number is multiplied by the average prevalence of that group (column 4) as determined from Figure 6. The calculated number of people with a HL >90 dB per age group is given in columns 5 and 6 for the years 2000 and 2010; the increase in the number of people with a HL >90 dB between 2000 and 2010 is given in column 7.

The change in the distribution of the original population is indicated by the 'survival' ratio, which is calculated as the quotient of the total numbers of people in 2000 and 2010 in the age groups 21–100 and 31–100 years old respectively. The population aged 20+ years was 12.110 million in 2000. This group becomes the population aged 30+ years old in 2010 and decreases to 10.756 million. This means that the survival ratio of the 2000 population of 20+ is 10.756/12.110=88.8%, migration and other factors included. The total increase in the number of people with a HL >90 dB between the years 2000 and 2010 is corrected for this survival ratio, and the outcome shows a total increase of approximately 24,000 CI candidates in 10 years' time. Thus the yearly flux of CI candidates with a hearing loss above 90 dB HL is approximately 2400 per year into the 'reservoir', or 200 per million inhabitants aged 31–90 years old. To empty the reservoir the number of implantations has to be larger than the yearly flux. For The Netherlands this means that more than 2400 adult CI candidates should be implanted per year, given no further constraints.

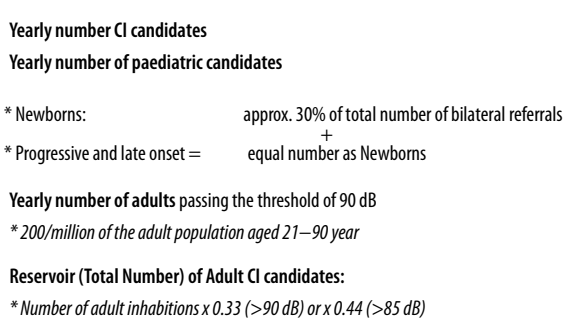

Figure 7. How to estimate the number of CI candidates in your country

Comparing the actual yearly number of CI surgeries for adults in The Netherlands, i.e. 391 in 2012 [25], with the calculated yearly flux of 2400 of the age group 31–90, the present yearly number of implanted adults is only 16% of the calculated flux.

To summarise, it is possible to estimate the yearly number of CI candidates for children and adults in a country and to estimate the total number of adult CI candidates, as is shown in Figure 7.

Conclusions

The data from Euro-CIU has shown that there is a considerable variation in CI utilisation within Europe. Because of the underutilisation of cochlear implants, especially in adults, we have to work on raising the general awareness of the benefits of cochlear implants and its improvement in quality of life, based on cost-effectiveness data and on guidelines for good clinical practice.

It is possible to estimate the yearly number of CI candidates in a country, but we don't have enough reliable data to put into our model. A new research project would be welcomed to estimate the demand for cochlear implantation more precisely, as well as to obtain more insight into the hearing problems of our recent population of adolescents and of the increasing number of elderly people.

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