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Optymalizacja leczenia oraz prognozowanie (wczesnych i odległych) wyników badania słuchu u chorych operowanych z powodu przewlekłego zapalenia ucha środkowego.

Praca doktorska

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Żyj tak, jakbyś miał umrzeć jutro.
Ucz się tak, jakbyś miał żyć wiecznie."

Mahatma Gandhi

Spis treści:

Streszczenie w języku polskim 4
Wstęp 4
Cele pracy 6
Cele szczegółowe pracy 6
Materiał i metody 7
Omówienie publikacji 7
Podsumowanie wyników i wnioski 11
Abstract in English 13
Introduction 13
Aims 15
The specific aims covered 15
Material and methods 15
Publication overview 16
Summary of results and conclusions 19
Załączniki 21

Streszczenie w języku polskim

Osiągnięcie naukowe stanowi monotematyczny cykl trzech powiązanych tematycznie publikacji dotyczących operacji na uchu środkowym w przebiegu przewlekłego zapalenia ucha środkowego:

1. Boron A., Wiatr A., Skladzien J., Wiatr M.: The effect of preserved stapedial superstructure on hearing improvement; Otolaryngol Pol 2020; 74 (1): 17-22.
2. Boron A., Skladzien J.: Long-term results of a hearing test in patients operated for chronic otitis media; Otolaryngol Pol 2020; 74 (1-7); DOI: 10.5604/01.3001.0014.1581 (Advanced online publication)
3. Boron A, Skladzien J, Wiatr M. Pre- and Post-operative Speech Audiometry Evaluation in Patients with Chronic Otitis Media. J Int Adv Otol 2020; 16(2): 241-7.

Wstęp

Pod pojęciem ucha środkowego rozumiemy przestrzenie powietrzne kości skroniowej tj. jamę bębenkową, komórki powietrzne wyrostka sutkowatego oraz bliższą jamie bębenkowej części trąbki słuchowej o ścianach kostnych. W prawidłowym uchu środkowym wymienione przestrzenie komunikują się ze środowiskiem zewnętrznym drogą trąbki słuchowej, która odpowiedzialna jest za ich prawidłowy drenaż i wentylację.

Przewlekłe zapalenie ucha środkowego (PZUŚ) charakteryzuje się: przewodzeniowym upośledzeniem słuchu, możliwą perforacją błony bębenkowej, a – w aktywnej formie – okresowym lub stałym wyciekiem z ucha. Czynnikami ryzyka PZUŚ są: nawracające ostre zapalenia ucha środkowego, niewłaściwa antybiotykoterapia, zaburzenie funkcji trąbki słuchowej, rozszczep podniebienia, płeć męska oraz dodatni wywiad rodzinny w kierunku zapalenia występującego u rodziców i krewnych.

Leczeniem z wyboru PZUŚ jest operacja, której zakres zależy od rodzaju i rozległości zmian patologicznych. Głównymi celami leczenia chirurgicznego są: usunięcie zmian chorobowych, przywrócenie drenażu i wentylacji ucha środkowego, poprawa słuchu oraz dążenie do zabezpieczenia ucha środkowego od wody, celem polepszenia komfortu życia chorego.

Operacje tympanoplastyczne, bo takim mianem określa się operacje ucha środkowego, dzieli się na zamknięte i otwarte, w zależności od zachowania tylno-górnej ściany przewodu

słuchowego zewnętrznego. Zabiegi w obrębie ucha środkowego obejmują: plastykę przewodu słuchowego zewnętrznego (kanaloplastyka), plastykę błony bębenkowej (myringoplastyka), a – przy uszkodzeniu łańcucha kosteczek słuchowych – także ich rekonstrukcję (ossikuloplastyka). W leczeniu przewlekłego zapalenia ucha środkowego wyróżnia się trzy możliwe drogi dojścia chirurgicznego: przezprzewodowe, przeduszne i zamałżowinowe. W rekonstrukcji błony bębenkowej jako materiał wykorzystuje się ochrzęstną lub powięź skroniową powierzchowną, stosując metodę jej podkładania. W rekonstrukcji łańcucha kosteczek słuchowych, w zależności od stopnia uszkodzenia układu przewodzącego ucha środkowego, wykorzystuje się materiał własny chorego (np.: domodelowane kowadełko, palisada z chrząstki chorego itp.) lub protezki alloplastyczne. Z punktu widzenia poprawy słuchu istotne jest zachowanie prawidłowo ruchomego strzemiączka oraz samowentylującej się jamy bębenkowej drogą trąbki słuchowej.

Ze względu na złożoność zabiegów w obrębie ucha środkowego, stworzono międzynarodowy konsensus w sprawie kategoryzacji operacji tympanoplastycznych (International Otology Outcome Group, 2018r). W klasyfikacji uwzględniono chirurgię wyrostka sutkowatego oraz chirurgię jamy bębenkowej. W zakresie wyrostka sutkowatego uwzględniono: liczbę operacji (pierwsza, „second look", rewizja), rodzaj dojścia do wyrostka, rozległość mastoidektomii, obecność rekonstrukcji przewodu słuchowego zewnętrznego oraz ewentualną obliterację wyrostka. W zakresie chirurgii jamy bębenkowej uwzględniono: rodzaj dojścia, stan i rodzaj rekonstrukcji błony bębenkowej oraz sposób rekonstrukcji łańcucha kosteczek słuchowych.

Podobny konsensus dotyczący definicji, klasyfikacji oraz stopnia zaawansowania perlakowego zapalenia ucha środkowego powstał w 2017 roku (EAONO/JOS Joint Consensus Statements).

Pośród metod diagnostyki zaburzeń słuchu istotną rolę odgrywają badania subiektywne takie jak audiometria tonalna oraz audiometria słowna. Audiometria tonalna jako badanie przesiewowe pozwala oszacować stopień niedosłuchu oraz wskazać jego rodzaj. Badaniem opisującym wydolność zmysłu słuchu w aspekcie porozumiewania się z innymi osobami jest audiometria mowy. Mowa jest wartościowym parametrem w diagnostyce narządu słuchu ze względu na szeroki zakres częstotliwości wahający się pomiędzy 20 Hz a 20 kHz. Badanie to pozwala ocenić nie tylko wydolność części przewodzeniowej i odbiorczej narządu słuchu ale także wydolność ośrodkowych procesów rozumienia sygnału mowy. Audiogram mowy przedstawiany jest w postaci wykresu odnosząc się do tak zwanej krzywej wzorcowej uzyskanej od osób z prawidłowym słuchem. Procentowy odsetek

rozumienia mowy nanosi się na osi rzędnych w odniesieniu do natężenia dźwięku zaznaczanego na osi odciętych. Autorem pierwszego testu do audiometrii mowy był H. Fletcher w 1929r. W Polsce po raz pierwszy podobny materiał opracowali w 1953 r. Zakrzewski, Suwalski, Antkowski.

Podstawą diagnostyki przedoperacyjnej oraz oceny po przeprowadzonym leczeniu chirurgicznym schorzeń ucha środkowego jest audiometria tonalna. W diagnostyce przewlekłego zapalenia ucha środkowego rzadko skupiamy się na ocenie rozumienia mowy, zwykle oceniając audiometrię tonalną. Wynik audiometrii mowy jest wyrazem społecznej wydolności narządu słuchu.

Cele pracy

Głównym celem rozprawy doktorskiej jest określenie wczesnych (6 – miesięcznych) i odległych (około 10 – letnich) wyników badania słuchu pacjentów operowanych z powodu przewlekłego zapalenia ucha środkowego oraz próba odpowiedzi na pytanie czy i jak czas wpływa na odległe wyniki badania słuchu.

Cele szczegółowe pracy

1. Próba określenia najbardziej optymalnego sposobu przeprowadzenia zabiegu, tak aby uzyskać długotrwałą stabilizację choroby, najlepszą poprawę słuchu oraz polepszenie komfortu życia chorego.
2. Ocena wpływu reoperacji na wynik badania słuchu.
3. Ocena stopnia rozumienia mowy wyrażonego przez badanie audiometrii mowy przed i w odległej kontroli po zabiegu operacyjnym.
4. Ocena wpływu przewlekłego zapalenia ucha środkowego na występowanie nagłej głuchoty śródoperacyjnej i pooperacyjnej.
5. Określenie czy przewlekłe zapalenie ucha środkowego wpływa na powstanie niedosłuchu o charakterze odbiorczym.
6. Ocena wpływu rekonstrukcji układu przewodzącego ucha środkowego na ucho wewnętrzne (zmiana krzywej progowej kostnej po operacji ucha).
7. Ocena roli zachowanej suprastruktury strzemienia na wyniki badania słuchu.

Materiał i metody

Badanie zrealizowane było w Oddziale Klinicznym Otolaryngologii Szpitala Uniwersyteckiego w Krakowie.

W ramach pracy doktorskiej przeanalizowano dokumentację medyczną pacjentów operowanych z powodu przewlekłego zapalenia ucha środkowego w latach 2005-2014.

W ocenie słuchu wykorzystano audiogram tonalny wykonany przed zabiegiem operacyjnym, 6 i 12 miesięcy po zabiegu oraz w odległym, 10-letnim okresie obserwacji. Audiogram słowny wykonany został przed zabiegiem oraz w odległej około 10 – letniej kontroli. Dodatkowo każdy pacjent wypełnił ankietę, która opisywała zgłaszane dolegliwości i został zbadany przez specjalistę otolaryngologa. Uzyskane wyniki poddano analizie statystycznej. Za poziom istotności przyjęto $p < 0.05$.

Uzyskano zgodę Komisji Bioetycznej CM UJ na przeprowadzone badania.

Wyniki przedstawiono w trzech publikacjach:

W pracy pt.: „**Wpływ zachowanej suprastruktury strzemiączka na poprawę słuchu**” (*Boron A., Wiatr A., Skladzien J., Wiatr M.: The effect of preserved stapedial superstructure on hearing improvement; Otolaryngol Pol 2020; 74 (1): 17-22*) przeanalizowano dokumentację medyczną oraz wyniki badań słuchu uzyskane od 294 kolejnych pacjentów operowanych z powodu przewlekłego zapalenia ucha środkowego w latach 2009 – 2013. Do dalszej analizy uwzględniającej ocenę roli zachowania suprastruktury strzemiączka kwalifikowało się 96 pacjentów w przedziale wiekowym od 17 do 74 lat. Grupa składała się z 51 kobiet i 45 mężczyzn podzielonych na 3 podgrupy różniące się zakresem uszkodzeń łańcucha kosteczek słuchowych i wynikającą z niego techniką rekonstrukcji :

1. Przeszczep błony bębenkowej umieszczony na nienaruszonym, prawidłowo ruchomym strzemiączku
2. Przeszczep błony bębenkowej umieszczony na ruchomej płytce strzemiączka (palisada chrząstek między płytką strzemiączka a przeszczepem błony bębenkowej)
3. Domodelowane kowadełko umieszczone na nienaruszonym, prawidłowo ruchomym strzemiączku

Poprawę słuchu oceniano jako zamknięcie średniej rezerwy ślimakowej (dla 500Hz, 1000Hz i 2000Hz) w świetle zmian stwierdzanych w uchu środkowym oraz przeprowadzonej rekonstrukcji.

Wielkość pooperacyjnej poprawy słuchu zmniejsza się wraz z rosnącym stopniem uszkodzenia łańcucha kosteczek słuchowych. Najmniej korzystny wpływ przeprowadzonej rekonstrukcji zaobserwowano u pacjentów z uszkodzeniem suprastruktury strzemiączka. Pośród omawianych podgrup najgorsze efekty w zestawieniu z pozostałymi grupami, mierzone zmieniejszeniem rezerwy ślimakowej, obserwowano u chorych, u których możliwa była jedynie myringostapedopeksja.

Zachowanie nieuszkodzonego strzemiączka ma zasadnicze znaczenie dla uzyskania poprawy słuchu, stwarza możliwość domodelowania własnej kosteczki chorego i umieszczenia jej na strzemiączku, pod odtworzoną błoną bębenkową. Daje to również możliwość wykorzystania protezki typu PORP.

Należy zauważyć, że w przypadkach poważnego uszkodzenia łańcucha kosteczek słuchowych przedoperacyjna wartość rezerwy ślimakowej może być mniejsza niż wartość pooperacyjna. Jest to spowodowane udziałem zmian patologicznych w drodze transmisji dźwięku między błoną bębenkową a okienkiem owalnym.

W pracy pt.: **„Odległe wyniki badania słuchu u pacjentów operowanych z powodu przewlekłego zapalenia ucha środkowego”** (*Boron A., Skladzien J.: Long-term results of a hearing test in patients operated for chronic otitis media; Otolaryngol Pol 2020; 74 (1-7); DOI: 10.5604/01.3001.0014.1581*) analizowano dane uzyskane od 79 pacjentów, którzy zgłosili się do odległej kontroli po leczeniu chirurgicznym z powodu przewlekłego zapalenia ucha środkowego. W ocenie słuchu wykorzystano audiogram tonalny wykonany przed zabiegiem operacyjnym, 6 miesięcy po zabiegu oraz w odległym okresie obserwacji.

Średnie przewodnictwo kostne (dla częstotliwości 500Hz, 1000Hz i 2000Hz) przed wszystkimi rodzajami zabiegów wynosiło 31,8 dB, SD – 16,3; nie różniło się istotnie ($p = 0,355$) po 6 miesiącach od zabiegu (32,8 dB, SD 17,3), natomiast istotnie się pogarszało ($p < 0,001$) w odległej 10-letniej kontroli, wynosząc 43,4 dB, SD – 23. Średnie przewodnictwo powietrzne przed zabiegami to 57,6 dB, SD – 18,2; istotnie poprawiło się we wczesnej kontroli, wynosząc 50,5 dB, SD – 19,5 przy $p < 0,001$. W odległej kontroli ponownie uległo pogorszeniu do wartości 61,3 dB, SD – 22,9 i istotnie różniło się od wczesnego okresu pooperacyjnego ($p < 0,001$). Rezerwa ślimakowa przed zabiegami wynosiła średnio 26,4 dB, SD – 12,4; uległa istotnemu ($p < 0,001$) zmniejszeniu w okresie

pooperacyjnym, wynosząc 17,6 dB, SD – 11,4. Poziom rezerwy ślimakowej utrzymywał się na podobnym poziomie w odległej kolejnej kontroli.

Nie zaobserwowano istotnie gorszych wyników ani w przewodnictwie kostnym, ani powietrznym, ani w poziomie rezerwy ślimakowej u pacjentów z perlakiem i/lub ziarniną zapalną w porównaniu do chorych bez zmienionej chorobowo śluzówki ucha środkowego w odległej obserwacji.

22 chorych (27,8 %) wymagało reoperacji. Liczba ponownych zabiegów wahała się od 1 do 5 u pojedynczego pacjenta. Średnie przewodnictwo kostne w grupie bez reoperacji i w grupie reoperowanej nie różniło się statystycznie. Natomiast przewodnictwo powietrzne było istotnie statystycznie gorsze w grupie reoperowanej i wynosiło 70,8 dB w porównaniu do 55,6 dB w grupie bez reoperacji; p = 0,015. W związku z tym, rezerwa ślimakowa była istotnie większa w grupie reoperowanej (p = 0,014).

W przeprowadzonym badaniu głuchota śródoperacyjna oraz przypadki nagłej głuchoty wyniosły około 1%.

Celem pracy pt.: ”**Pre and Post Operative Speech Audiometry Evaluation in Patients with Chronic Otitis Media**” (*Boron A., Skladzien J., Wiatr M. Pre- and Post-operative Speech Audiometry Evaluation in Patients with Chronic Otitis Media. J Int Adv Otol 2020; 16(2): 241-7)* była analiza odległych (około 10- letnich) wyników leczenia chirurgicznego w aspekcie poprawy słuchu wyrażonego przez audiogram mowy u pacjentów operowanych z powodu przewlekłego zapalenia ucha środkowego.

Wyniki rozpatrywano w kontekście przeprowadzonej tympanoplastyki, porównując ucho operowane do zdrowego oraz analizując zmienność audiogramu mowy uzyskanego przed i w odległym czasie po operacji.

Celem przeprowadzenia analizy audiogramów mowy wprowadzono podział pacjentów wg maksymalnego poziomu głośności podawanych słów wyrażonego w dB przy którym obserwowany odsetek rozumienia mowy był największy.

Grupa I : 0 – 40 dB

Grupa II : 41–70 dB

Grupa III : 71 – 100dB

W grupie pierwszej zaproponowanego podziału poziomu głośności w audiometrii mowy różnica maksymalnego rozumienia mowy w odległej kontroli po zabiegu wynosiła 99,7 % w uchu zdrowym „versus” 97,1 % w uchu operowanym. W grupie II różnica ta również była niewielka tj. 96,6% w uchu zdrowym „versus” 95,2 % w uchu operowanym. Dopiero

w grupie III gdzie poziom głośności wykorzystywanych w teście słów był powyżej 70 dB różnica wynosiła 77,1 % w uchu zdrowym „versus" 47,1 % w uchu operowanym, przy istotności p = 0,02.

Nie obserwowano istotnego statystycznego pogorszenia słuchu ucha zdrowego w 10 letnim okresie obserwacji.

Przeprowadzone leczenie chirurgiczne najlepiej wpływa na poprawę rozumienia mowy w grupie II (poziom głośności 41-70 dB), dla p=0,011. W grupie tej po operacji maksymalny procent rozumienia mowy wzrósł z 72,9 % przed zabiegiem do 95,2 % po latach od wykonania procedury. Zgoła odmiennie wygląda sytuacja w grupie chorych, gdzie w wykonywanej przed zabiegiem audiometrii mowy poziom głośności był >70dB. Wtedy po latach od zabiegu % rozumienia spada z 71,4% do 47,1%. Dla poziomu głośności <40 dB w audiometrii mowy (grupa I), po latach % rozumienia mowy pozostaje na podobnym poziomie lub nieznacznie się zwiększa (91,8% przed „versus" 97,1% po zabiegu).

W analizie audiogramu mowy uwzględniono również rodzaj przeprowadzonego zabiegu operacyjnego. Zaproponowano podział przeprowadzonych zabiegów w zależności od wykonanej tympanoplastyki.

Zabieg 1 (n = 19): Austin-Kartush A (M+ I-S+)/tympanoplastyka typu II

Zabieg 2 (n = 13): Austin-Kartush A (M-I-S+)/tympanoplastyka typu II (z użyciem PORP)

Zabieg 3 (n = 20): Austin-Kartush O/tympanoplastyka typu I

Zabieg 4 (n = 27): Austin-Kartush C/tympanoplastyka typu III

Nie stwierdzono różnic istotnych statystycznie miedzy zabiegami 1,2,3 oraz 4 zestawiając wyniki uzyskane w audiometrii mowy wykonanej po około 10 latach od zabiegu jeżeli głośność uzyskania najlepszego zrozumienia była poniżej 70 dB, przy p = 0,055. Analiza pokazała, że głębokie uszkodzenie łańcucha kosteczek słuchowych (zabieg nr 4) charakteryzuje gorsze rozumienie mowy w porównaniu z innymi zabiegami jeżeli poziom głośności podawanych słów był powyżej 70 dB (grupa III), przy p = 0,002.

Podsumowanie wyników i wnioski

1. Upływ czasu w przewlekłym zapaleniu ucha środkowego z uszkodzeniem łańcucha kosteczek słuchowych negatywnie wpływa na niedosłuch typu odbiorczego poprzez pogorszenie przewodnictwa kostnego w odległej kontroli (10 – letniej) mimo jego stabilnego utrzymania we wczesnym etapie poopercyjnym. W odległej kontroli mimo początkowej poprawy, obniżeniu ulega również przewodnictwo powietrzne, przy zachowanej i stabilnej w czasie rezerwie ślimakowej. Wynika to z negatywnego wpływu toksycznych czynników stanu zapalnego na ucho wewnętrzne oraz możliwego negatywnego wpływu zaburzonej mechaniki ucha środkowego na ucho wewnętrzne.

Najlepsze rokowanie co do poprawy słuchu spośród przeprowadzonych tympanoplastyk cechuje myringoplastykę, w której mamy zachowany i prawidłowo ruchomy łańcuch kosteczek słuchowych.

2. Reoperacja pogarsza odległe wyniki badania słuchu w porównaniu do operacji wykonanej po raz pierwszy. Nie zaobserwowano gorszego rokowania co do utrzymania się stabilnej w czasie poprawy słuchu w przypadku perlaka i/lub ziarniny zapalnej w porównaniu z prawidłową śluzówką ucha środkowego.

3. Operacja na uchu środkowym przynosi najlepsze efekty w poprawie rozumienia mowy jeżeli głośność podawanych słów w audiometrii mowy w okresie przedoperacyjnym zawiera się między 41-70 dB. Po zabiegu na uchu środkowym istotnie statystycznie pogarsza się % rozumienia mowy jeżeli głośność przedoperacyjnie podawanych słów jest > 70 dB. Stąd, najgorsze rezultaty w audiometrii mowy dotyczą pacjentów z największym uszkodzeniem łańcucha kosteczek słuchowych, u których wieloletni przewlekły proces zapalny najbardziej negatywnie wpłynął na ucho wewnętrzne.

4. W przeprowadzonych badaniach stwierdzono, że ryzyko nagłej głuchoty śródoperacyjnej oraz powikłanie pooperacyjne w postaci całkowitej utraty słuchu pozostaje na porównywalnym z innymi autorami poziomie około 1 % pacjentów operowanych z powodu przewlekłego zapalenia ucha środowego.

5. Przewlekłe zapalenie ucha środkowego, szczególnie w aktywnej formie, może mieć wpływ na powstanie niedosłuchu typu odbiorczego. Obserwuje się tą prawidłowość porównując ucho operowane z uchem zdrowym. Zawsze należy jednak pamiętać, iż etiologia niedosłuchu odbiorczego jest wieloczynnikowa. Upływ czasu, narażenie na hałas oraz inne schorzenia współistniejące przyczyniają się również do zaburzenia słuchu o typie czuciowo-nerwowym.

6. Zachowany, prawidłowy łańcuch kosteczek słuchowych, a przede wszystkim brak aktywnego stanu zapalnego, wpływa na zachowanie prawidłowej funkcji ucha wewnętrznego, umożliwia utrzymanie fizjologicznego wzmocnienia dźwięku zapewnianego przez dźwignię jaka tworzy układ łańcucha kosteczek słuchowych. W przypadku tympanoplastyki typu III, którą charakteryzuje znaczne uszkodzenie układu przewodzącego ucha środkowego, stwierdzono, w odległej kontroli pooperacyjnej, istotne statystycznie pogorszenie przewodnictwa kostnego dla częstotliwości rezonansowej łańcucha kosteczek słuchowych (2000 Hz) w porównaniu z tympanoplastyką typu I, dla której pozostaje ona stabilna w czasie.

7. Zachowane, prawidłowo ruchome strzemiączko ma kluczowe znaczenie dla poprawy słuchu obserwowanej po operacji w przebiegu przewlekłego zapalenia ucha środkowego. Obecność tylko ruchomej płytki strzemiączka jest niekorzystnym czynnikiem prognostycznym poprawy słuchu w tympanoplastykach. Wielkość rezerwy ślimakowej mierzona przed operacją ucha często nie odzwierciedla nasilenia zaawansowania procesu chorobowego, w tym stopnia zniszczenia kosteczek słuchowych i tylko na jej podstawie nie można prognozować poprawy słuchu po leczeniu operacyjnym.

Abstract in English

The scientific achievement is a monothematic series of three related publications on middle ear surgery in the course of chronic otitis media:

1. Boron A., Wiatr A., Skladzien J., Wiatr M.: The effect of preserved stapedial superstructure on hearing improvement; Otolaryngol Pol 2020; 74 (1): 17-22.
2. Boron A., Skladzien J.: Long-term results of a hearing test in patients operated for chronic otitis media; Otolaryngol Pol 2020; 74 (1-7); DOI: 10.5604/01.3001.0014.1581 (Advanced online publication)
3. Boron A., Skladzien J., Wiatr M. Pre- and Post-operative Speech Audiometry Evaluation in Patients with Chronic Otitis Media. J Int Adv Otol 2020; 16(2): 241-7.

Introduction

By the middle ear, we mean the air spaces of the temporal bone, i.e. the tympanic cavity, the mastoid air cells and the proximal part of the Eustachian tube with bone walls. In the normal middle ear, these spaces communicate with the external environment through the Eustachian tube, which is responsible for their proper drainage and ventilation.

Chronic otitis media (COM) is characterized by conductive hearing loss, possible perforation of the tympanic membrane and periodic or permanent otorrhea in active form. The risk factors in COM are recurrent acute otitis media, inadequate antibiotic therapy, impaired Eustachian tube functions, cleft palate, male gender and a positive family history of inflammation in parents and relatives.

The treatment of choice for COM is surgery, the scope of which depends on the type and extent of the pathological changes. The primary aim of surgical treatment is: removal of lesions, restoration of drainage and ventilation of the middle ear, improvement of hearing and striving for protection of the middle ear from water in order to improve the patient’s quality of life.

Tympanoplasties, as this is the term used for middle ear surgery, are divided into canel wall up and canal wall down depending on the behavior of the posteroanterior wall of the external auditory canal. Middle ear procedures include plastic surgery of the external auditory canal (canaloplasty), plastic surgery of the tympanic membrane (myringoplasty), and in the case of the ossicular chain damage also their reconstruction (ossiculoplasty). The treatment of

chronic otitis media involves three possible ways of surgical approach: transcanal, intra-aural, and extra-auricular. Reconstruction of the tympanic membrane involves the use of the perichondrium or temporal fascia as graft material, using the underlay technique. In the reconstruction of the ossicular chain, depending on the degree of damage to the middle-ear conductive system, graft materials from the patient's own body (e.g. modeled incus, palisade from the patient's cartilage, etc.) or alloplastic prostheses are used. From the perspective of hearing improvement, it is essential to preserve adequate stapes mobility and self-ventilation of the tympanic cavity through the Eustachian tube.

Given the complexity of middle ear surgery, an international consensus has emerged on the categorization of tympanoplasty (International Otology Outcome Group, 2018). The classification included surgery of the mastoid and middle ear (tympanic). When it comes to the mastoid process, the number of operations (first, second look, revision), approach taken to the mastoid process, range of mastoidectomy, presence of reconstruction of the external auditory canal and possible obliteration of the mastoid process were included. In terms of middle ear surgery, the type of access to the tympanic cavity, the state and type of tympanic membrane reconstruction and the method of reconstruction of the ossicular chain were taken into account.

A similar consensus regarding the definition, classification and severity of cholesteatoma was established in 2017 (EAONO/JOS Joint Consensus Statements).

Subjective tests, such as tonal and speech audiometry, play an important role in the diagnosis of hearing abnormalities. Used for screening, tonal audiometry makes it possible to estimate the degree of hearing loss and to indicate its type. Speech audiometry, in contrast, can help evaluate hearing by characterizing its communication performance. Speech audiometry enables the assessment of conductive and sensory aspects of the hearing organ, providing some insight into the central auditory processing function. Speech comprehension is a valuable parameter in the assessment of hearing pathology. The frequency of human speech ranges from 20 Hz (Hertz) to 20 kHz (Kilohertz). A speech audiogram is plotted onto the reference curve obtained from people with normal hearing, with the percentage of correctly comprehended presented speech stimuli as the ordinate and sound volume as the abscissa. The first speech audiometry text was developed by H. Fletcher in 1929 .The first Polish speech audiometry text was developed in 1953 by Zakrzewski, Suwalski, Antkowski.

Pre- and post-operative assessment of patients with middle ear pathologies mainly relies on tonal audiometry. When assessing patients with chronic otitis media (COM), we hardly ever focus on speech comprehension, with clinical decision-making usually based on

tonal audiometry. However, speech audiometry reflects the social aspects of auditory performance.

Aims

The main aim of the study was to determine the early (6-month) and late (10-year) hearing test results in patients operated on for chronic otitis media and to try to answer the question whether and how time affects the long-term hearing test results.

The specific aims covered

1. An attempt to determine the most optimal method of carrying out the procedure, so as to obtain long-term stabilization of the disease, the best improvement in hearing and improvement of the patient's quality of life.
2. Assessment of the impact of reoperation on the hearing test result.
3. Assessment of the level of speech understanding expressed by the examination of speech audiometry before and in remote control after surgery.
4. Assessment of the influence of chronic otitis media on the occurrence of sudden intraoperative and postoperative deafness.
5. Determining whether the chronic otitis media affects the appearance of sensorineural hearing loss.
6. Assessment of the impact of the middle ear conducting system reconstruction on the inner ear (change of the bone threshold curve after ear surgery)
7. Assessment of the role of the preserved stapedial superstructure on the hearing test results.

Material and methods

The study was performed at the Department of Otolaryngology in the University Hospital in Cracow.

As part of the doctoral dissertation, the medical documentation of patients operated on for chronic otitis media in 2005-2014 was analyzed.

The evaluation of hearing involved the use of a pure – tone audiogram made before the surgery, 6, 12 months after the surgery and in the distant 10 – year observation period. Speech audiometry was made before the procedure and during a 10 – year long follow-up. Furthermore, each patient filled in the questionnaire describing the reported complaints and was examined by an otolaryngologist. The obtained results were subjected to statistical analysis. The level of significance was $p < 0.05$.

The Bioethics Committee of the Medical College of the Jagiellonian University was approved for the research.

Results were presented in three papers

The paper: „***The effect of preserved stapedial superstructure on hearing improvement"*** (Boron A., Wiatr A., Skladzien J., Wiatr M.: The effect of preserved stapedial superstructure on hearing improvement; Otolaryngol Pol 2020; 74 (1): 17-22) analyzed the medical records and the results of hearing tests obtained from 294 consecutive patients operated on due to chronic otitis media in the years 2009-2013. In order to assess the role of the preserved superstructure of stapes, 96 patients aged 17 to 74 were eligible for further analysis. The group consisted of 51 women and 45 men divided into 3 subgroups differing in the extent of damage to the ossicular chain and the resulting reconstruction technique:

1. tympanic graft placed on intact stapes;
2. tympanic graft placed on stapedial footplate (cartilage palisade between the footplate and the tympanic graft);
3. modelled incus placed on intact stapes.

Hearing improvement was defined as closing the air-bone gap (at 500Hz, 1000Hz and 2000Hz) in the light of the changes found in the middle ear and performed reconstruction.

The amount of postoperative hearing improvement decreases with the increasing degree of damage to the ossicular chain. The least beneficial effect of the performed reconstruction was observed in patients with damage to the stapes suprastructure. The mean postoperative air-bone gap values in the discussed subgroups were much better than in the subgroups, where only myringostapedopexy was possible due to extensive damage to the ossicular chain and the local disease process.

Among the analyzed subgroups, the worst effects in comparison with the other groups, measured by the reduction of the air-bone gap, were observed in patients with possible only myringostapedopexy.

The behavior of an undamaged stapes is essential to improve hearing, it makes it possible to model the patient's own bones and place it on the stapes, under the restored eardrum. It also makes it possible to use a PORP type prosthesis.

It should be noted that in cases of severe damage to the ossicular chain, the pre-operative air-bone gap may be less than the post-operative value. It is caused by pathological changes in the way of sound transmission between the eardrum and the oval window.

The paper: ”***Long-term results of a hearing test in patients operated for chronic otitis media***.” (Boron A., Skladzien J.: Long-term results of a hearing test in patients operated for chronic otitis media; Otolaryngol Pol 2020; 74 (1-7); DOI: 10.5604/01.3001.0014.1581) analyzed data obtained from 79 patients who reported for long-term follow-up after surgical treatment due to chronic otitis media. The evaluation of hearing involved the use of a pure-tone audiogram made before the surgery, 6 months after the surgery and in the distant observation period.

The mean bone conduction before all type of surgery was 31.8 dB, SD 16.3, it did not differ significantly ($p = 0.355$) 6 months after surgery (32.8 dB SD 17.3), but it got worse significantly ($p < 0.001$) in long – term 10 – year follow – up at 43.4 dB, SD 23. The mean air conduction before surgery was 57.6 dB, SD 18.2, it significantly improved in the early follow-up at 50.5 dB SD 19.5, at $p < 0.001$. In long-term follow-up it got worse again to 61.3 dB SD 22.9 and was significantly different from the early postoperative period ($p < 0.001$). The air-bone gap before surgery averaged 26.4 dB SD 12.4, and it decreased significantly ($p < 0.001$) in the postoperative period at 17.6 dB SD 11.4. The air – bone gap level remained at a similar level in long – term follow – up.

No significantly worse results were observed in bone or air conduction, or the air – bone gap level in patients with cholesteatoma and/or granulation tissue compared to patients without a diseased middle ear mucosa in long – term follow – up.

22 patients (27.8%) required reoperation. The number of repeated treatments ranged from 1 to 5 in a single patient. The average bone conduction in the non – reoperated group and in the reoperated group did not differ statistically. In contrast, air conduction was statistically significantly worse in the reoperated group and equaled 70.8 dB compared to

55.6 dB in the non – reoperated group, p = 0.015. Therefore, the air – bone gap was significantly higher in the reoperated group (p = 0.014)

In our study, intraoperative deafness and sudden deafness was at about 1%.

The aim of the work: ***Pre and Post Operative Speech Audiometry Evaluation in Patients with Chronic Otitis Media***" (Boron A., Skladzien J., Wiatr M. Pre- and Post-operative Speech Audiometry Evaluation in Patients with Chronic Otitis Media. J Int Adv Otol 2020; 16(2): 241-7) was to analyze long-term (about 10 – years) functional outcomes (i.e., improvement in speech audiometry) of surgical treatment in patients with chronic otitis media.

The findings were analyzed in the context of tympanoplasty, comparing the treated and the contralateral (healthy) ears, and analyzing the differences between pre- and post-operative speech audiograms.

In order to analyze speech audiograms, we divided the patients into the following groups on the basis of the maximum hearing loss (expressed in dB of the words given in speech audiometry) for which the best speech comprehension was achieved.

Group I: 0 – 40 dB

Group II: 41 – 70 dB

Group III: 71 – 100 dB

In group I, identified on the basis of hearing loss for which the best results were achieved in long time control in speech audiometry, the maximum speech comprehension was 99.7% in the healthy ear and 97.1% in the treated ear. In group II, the between – ear difference was also small (96.6% in the healthy ear „versus" 95.2% in the treated ear). Only in group III, where best responses were achieved for the hearing loss above 70dB, the difference was significant – 77.1% vs. 47.1% in the healthy and treated ears, respectively, p = 0.02.

There was no significant hearing impairment in the contralateral (untreated) ear over the mean 10 – year follow – up.

The performed surgery best improved the speech comprehension in group II (hearing loss 41 – 70 dB), where the best attained percentage of speech comprehension increased from 72.9% (pre – operative) to 95.2% at the end of the follow – up (p = 0.011). The situation was quite different in patients who attained the best pre – operative speech audiometry results for the hearing loss above 70 dB. At the end of the follow – up, the speech comprehension in this group dropped from 71.4% preoperatively to 47.1%. In group I (best

speech audiometry results for the hearing loss up to 40 dB), the percentage of speech comprehension remained at a similar level or increased slightly (91.8% preoperatively vs. 97.1% at the end of the follow – up).

Speech audiograms were also analyzed against the type of surgery performed. We assumed a division based on the extent of tympanoplasty performed.

Procedure 1 (n = 19): Austin-Kartush A (M+ I-S+)/tympanoplasty type II

Procedure 2 (n = 13): Austin-Kartush A (M-I-S+)/tympanoplasty type II (with use PORP)

Procedure 3 (n = 20): Austin-Kartush O/tympanoplasty type I

Procedure 4 (n = 27): Austin-Kartush C/tympanoplasty type III

A comparison of post-operative speech audiograms demonstrated no significant differences between procedures 1, 2, 3, and 4 in patients who presented the best speech comprehension at the hearing loss below 70 dB (p=0.055). However, it also demonstrated that significant damage to the ossicular chain induced by procedure 4 was associated with worse speech comprehension than other procedures if the hearing loss for the best attained speech audiogram was above 70 dB (group III, p=0.002).

Summary of results and conclusions

1. The passage of time in chronic otitis media with damage to the ossicular chain has a negative impact on sensorineural hearing loss expressed by a decrease in bone conduction in the remote (10-years) control despite its maintenance in the early postoperative stage. In remote control, despite the initial improvement, the air conduction also decreases, with the air-bone gap maintained and stable over time. This is due to the negative impact of toxic inflammatory factors on the inner ear and the influence of impaired mechanics of the middle ear on the inner ear.

   Among the performed tympanoplasties, the best prognosis for hearing improvement is myringoplasty, where the ossicular chain is preserved and properly movable.
2. Reoperation worsens the long-term results of a hearing test compared to the first operations. There was no worse prognosis for hearing improvement stable over time in cholesteatoma and/or granulation tissue in the middle ear compared to normal mucosa.
3. Middle ear reconstructive surgery offers the maximum improvement in speech comprehension at the hearing loss of 41-70 dB in the preoperative speech audiometry. After surgery on the middle ear, the % speech understanding deteriorates statistically

significantly if the volume of preoperatively administered words is > 70 dB. Hence, the worst results in speech audiometry concern patients with the greatest damage to the ossicular chain, in whom the long-term chronic inflammatory process had the most negative impact on the inner ear.

4. In the conducted research it was found that the risk of sudden intraoperative deafness and the postoperative complication in the form of complete hearing loss remains at a comparable level with other authors, about 1% of patients operated on due to chronic otitis media.
5. Chronic otitis media, especially in the active form, may contribute to sensorineural hearing loss. This regularity is observed when comparing the operated ear with the healthy ear. However, it should always be remembered that the etiology of sensorineural hearing loss is multifactorial. The passage of time, exposure to noise and other comorbidities also contribute to sensorineural hearing impairment.
6. A correct ossicular chain, and above all the lack of active inflammation, helps maintain the proper function of the inner ear, and enables the physiological amplification of sound provided by the lever that creates the ossicular chain to be maintained. In the case of tympanoplasty type III, which is characterized by significant damage to the conducting system of the middle ear, a statistically significant deterioration of bone conduction was found, in distant control, for the ossicular chain resonance frequency (2000 Hz) compared to type I tympanoplasty for which it remains stable over time.
7. Preservation of an intact, fully mobile stapes is the key for hearing improvement after middle ear surgery. The presence of only the stapedial footplate is a negative prognostic factor of hearing improvement after tympanoplasty. The size of the air – bone gap assessed prior to surgery may not reflect the severity of disease – induced damage, including the degree of ossicular destruction, and cannot, therefore, be used as the only prognostic factor of postoperative hearing improvement.

Załączniki

1. Boron A., Wiatr A., Skladzien J., Wiatr M.: The effect of preserved stapedial superstructure on hearing improvement; Otolaryngol Pol 2020; 74 (1): 17 – 22.
2. Boron A., Skladzien J.: Long – term results of a hearing test in patients operated for chronic otitis media; Otolaryngol Pol 2020; 74 (1–7); DOI: 10.5604/01.3001.0014.1581 (Advanced online publication).
3. Boron A, Skladzien J, Wiatr M.: Pre – and Post – operative Speech Audiometry Evaluation in Patients with Chronic Otitis Media. J Int Adv Otol 2020; 16(2): 241 – 7.

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ORIGINAL ARTICLE

The effect of preserved stapedial superstructure on hearing improvement

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT:

Backgrounds: Ossiculoplasty can be carried out in a number of ways, depending on the anatomical and functional conditions encountered during otosurgery and the experience of a given centre.

The objective: The objective of the study was to analyse treatment effects in terms of postoperative hearing improvement in patients with chronic otitis media, with a particular emphasis on stapedial superstructure preservation.

Methods: The records of 294 consecutive patients undergoing their first ENT surgery due to chronic otitis media at the Department of Otolaryngology in Cracow, in 2009–2013 were analysed. In order to assess the role of preserved stapedial superstructure, 96 patients were eligible for further analysis.

Results: The analysis points to a significant hearing improvement after ossiculoplasty with the preserved stapedial superstructure as compared with the patients after footplate mobilisation. On the other hand, the research results point to significantly smaller hearing improvement in those patients, in whom only stapes was preserved, as compared with those, in whom a more extensive reconstruction of the ossicular chain was possible.

Conclusion: The air-bone gap measured before otosurgery often fails to reflect the extent of abnormalities and cannot, therefore, be considered as the only prognostic factor for postoperative hearing improvement.

KEYWORDS: chronic otitis media, stapedial superstructure, tympanoplasty

INTRODUCTION

Optimisation of surgical management in otology has always been an important issue. Different centres prefer various surgical approaches to the temporal bone, in particular regarding the preservation and potential reconstruction of the posterosuperior wall of the external auditory canal and tympanoplasty or ossiculoplasty.

The aims of ear surgery involve removing abnormalities, improving the function of the Eustachian tube and reconstruction of bone conduction pathway. Another objective is, if clinically feasible, to reconstruct the posterosuperior wall of the external auditory canal in patients undergoing open tympanoplasty. Tympanoplasty procedure may also involve canaloplasty, myringoplasty, and – in the event of damage to the auditory ossicles – ossiculoplasty.

The aim of ossiculoplasty is to reconstruct and restore normal anatomical relationships between the auditory ossicles. It is usually performed along with myringoplasty. There is a number of surgical techniques applicable to ossiculoplasty, depending on the structural and functional status of the middle ear and experience of a surgeon. However, the key determinant of the ossicle reconstruction method is the degree of damage. Ossiculoplasty can be performed under local or general anaesthesia. Local anaesthesia offers an advantage of a visual and verbal contact between the patient and the surgeon during surgery, and an associated possibility to perform an intraoperative subjective assessment of hearing improvement. Should the improvement be unsatisfactory, there is a possibility to directly reposition the ossicular chain and re-establish its continuity. A number of ossiculoplasty classifications are available. Each of them emphasizes the role of preserved and mobile stapes in ensuring hearing improvement. Zini proposed a classification of ossiculoplasty procedures depending on the location of damage within the ossicular chain [1]. Fisch described a number of basic situations characterised by the preservation of different ossicles, proposing an alternative approach to re-establishing the continuity of the ossicular chain in each of the described situations.

In his classification of ossiculoplasty, Fisch identifies three groups of patients depending on the expected functional outcome [2]. The prognosis is the poorest in patients in whom only stapes is preserved out of the entire ossicular chain. The expected postoperative air-bone gap in these patients is approximately 30dB. The functional prognosis depends on the air-bone gap, pressure equalisation ability of the Eustachian tube, wound healing and absence of effusion in the tympanic cavity [3, 4].

AIM

To perform a prospective analysis of functional outcomes in patients with chronic otitis media treated surgically at the Depart-

ment, with particular emphasis on the status of the stapedial superstructure.

MATERIAL AND METHODS

Medical records of 294 consecutive patients undergoing their first ENT procedure due to chronic otitis media at the Department of Otolaryngology, Collegium Medicum of the Jagiellonian University in Kraków in 2009–2013 were reviewed.

The youngest patient was 6, and the oldest was 80 years old. The mean age was 40.84 years. A total of 160 women and 134 men were enrolled. Transcanal approach was chosen in 146 (49.66%) cases, whereas retroauricular approach was chosen in 148 (50.34%) cases.

Closed tympanoplasty was performed in 216 patients, whereas 78 patients underwent open tympanoplasty. The extent of surgery was limited to the tympanic cavity only in 60 cases. In order to access and properly visualise the disease-affected middle ear cavity, attico-antro-mastoidectomy was performed in 120 patients (Fig. 1.). In 14 cases, due to significantly advanced disease, the treatment involved radical ear surgery without Eustachian tube closure. This subset was excluded from further analyses due to a low number of cases.

Perichondrium was the most often used for tympanic membrane reconstruction. Temporalis fascia was used less often. Cartilageperichondrial composite graft was used in a few cases (Fig. 2.).

Hearing improvement was defined as closing the air-bone gap (at 500Hz, 1000Hz and 2000Hz) as a result of surgically-induced structural improvement confirmed postoperatively in an ENT assessment. The assessment was based on audiometry testing carried out directly prior to surgery as well as at 6 and 12 months postoperatively. Analysing treatment outcomes, subsets of patients were identified, depending on the ossicular chain reconstruction type.

In order to assess the role of the preserved superstructure of stapes, 96 patients were eligible for further analysis, divided into 3 subsets (Tab. I.):

- tympanic graft placed on intact stapes;
- tympanic graft placed on stapedial footplate (cartilage palisade between the footplate and the tympanic graft);
- modelled incus placed on intact stapes.

The results were analysed statistically. When interpreting the results of the observations, the results were extrapolated onto all patients with otitis media undergoing surgical treatment at the Department during the predefined timeframe.

RESULTS

The results of 96 patients at the age range of 17 to 74 years were analysed. The group consisted of 51 women and 45 men classified into 3 subsets, which differed in the extent of damage to the ossicular chain and the resulting reconstruction technique. The long-term functional effect, defined as the change in the mean air-bone gap, was assessed for the 3 subsets and comparisons were made. The three assessment time points included baseline (T0), as well as at 6 and 12 months postoperatively.

Tab. I. Study sample characteristics by subset.

SUBSET	NUMBER OF PATIENTS	TYPE OF OSSICULOPLASTY
1	32	tympanic graft placed on intact stapes
2	38	tympanic graft placed on stapedial footplate (cartilage palisade between the footplate and the tympanic graft)
3	26	modelled incus placed on intact stapes

Tab. II. Mean air-bone gap prior to treatment in analysed subsets.

SUBSET NO.	X 0	SD 0
1.	32.08	10.32
2.	38.68	10.36
3.	33.28	11.25

Tab. III. Mean air-bone gap 6 months postoperatively in analysed subsets.

SUBSET NO.	X 6	SD 6
1.	26.77	10.76
2.	35.26	9.77
3.	25.98	6.83

Tab. IV. Mean air-bone gap at 12 months postoperatively in analysed subsets.

SUBSET NO.	X 12	SD 12
1.	25.10	10.99
2.	35.44	14.35
3.	25.33	7.39

The following abbreviations were used:

X – mean air-bone gap,
X0 – mean air-bone gap prior to treatment,
X6 – mean air-bone gap at 6 months postoperatively,
X12 – mean air-bone gap at 12 months postoperatively,
SD – standard deviation.

The ANOVA for the baseline status yielded the results as shown in Tab. II., $P < 0.05$.

Our measurements confirmed that the mean air-bone gap differed significantly between the subsets at baseline (T0 time-point). This means that prior to treatment there had already been significant differences in the air-bone gap between the subsets, which reflected the extent of middle ear damage at baseline.

The mean air-bone gap in subset 2 was significantly larger than in the remaining subsets. This means that due to the most severe damage of the ossicular chain in subset 2, where only mobile stapedial footplate was present, the air-bone gap was the largest, compared to the two remaining subsets. The mean air-bone gap in subset 1 was significantly larger than in subsets with the pre-

served ossicular chain. This means that the preoperative air-bone gap was significantly larger in patients in whom only the stapes bone was preserved, than in those with less severe damage to the ossicular chain.

This finding confirms the association between the degree of hearing loss, expressed as the extent of damage to the ossicular chain and the amount of cochlear reserve (air-bone gap). The ANOVA for the air-bone gap in individual subsets at 6 months postoperatively yielded the results as shown in Tab. III., $P < 0.05$.

The analysis demonstrated that the mean air-bone gaps differed between the subsets ($P < 0.05$). The mean air-bone gap in subset 2 was significantly larger than in other subsets (just as it was at baseline). The above finding confirms the role of absent stapedial superstructure as a negative prognostic factor in assessing hearing improvement at 6 months following tympanoplasty.

The mean air-bone gap in subset 1 was significantly larger than in subsets with the fully preserved ossicular chain. The above finding confirms a significant association between the hearing improvement and the status of the ossicular chain, indicating that the best functional outcomes are achieved in patients with the least damage to the auditory ossicles and their preserved continuity. The ANOVA for the air-bone gap in individual subsets at 12 months postoperatively yielded the results as shown in Tab. IV., $P < 0.05$.

There were significant differences in the mean air-bone gaps between the subsets.The mean air-bone gap in subset 2 was significantly larger than in all other subsets. This confirms little effect of ossiculoplasty in patients with damaged stapes.

The mean air-bone gap in subset 1 was significantly larger than in subsets with the preserved ossicular chain and significantly smaller than in subset 2. Longer follow-up of 12 months demonstrated a significantly better hearing improvement after ossiculoplasty in patients with preserved stapedial superstructure as compared to those with mobile stapedial footplate, yet without the superstructure.

On the other hand, the current findings emphasize significantly smaller hearing improvement in patients with preserved stapes bone only, as compared to those, in whom a more effective ossicular chain reconstruction was possible.The ANOVA for time-dependence of the air-bone gap size was carried out in an attempt to ascertain whether the changes in the mean air-bone gap in each subset observed at 6 and 12 months were and remained significant.

The within-group design was used to assess changes in the air-bone gap in each subset (Tab. V.).In subset 1, there were no significant differences between the mean air-bone gap size at 6 and 12 months as compared to baseline.

In subset 2 there were no significant differences between the mean air-bone gap size at 6 and 12 months as compared to baseline, which indicates no surgically-induced hearing improvement.

The results observed in subsets 1 and 2 unequivocally confirm that severe damage to the ossicular chain with only stapes bone (or only stapedial footplate) preservation is often associated with no functional improvement after middle ear surgery. Radical excision of lesions to achieve dry ear should be the priority in those patients.

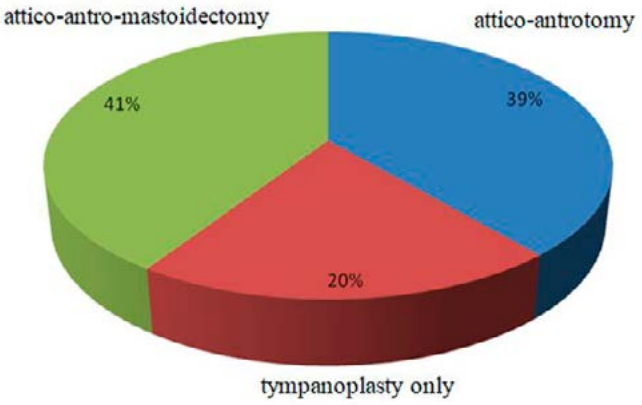

Fig. 1. The extent of temporal bone surgery.

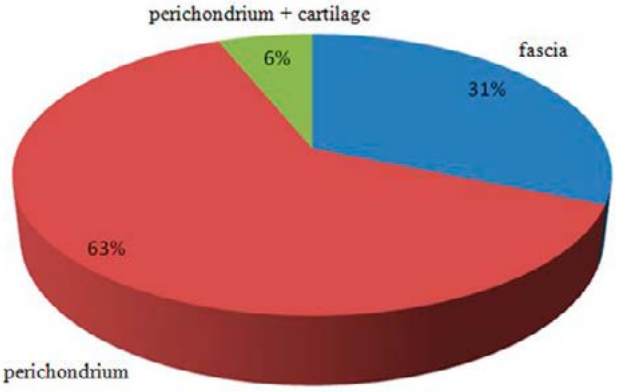

Fig. 2. The frequency of using various graft types in tympanoplasty.

Using an autologous modelled ossicle (incus), placed on the head of the preserved and mobile stapes (subset 3) to re-establish the continuity of the ossicular chain resulted in a significant change of the air-bone gap from baseline to month six postoperatively ($P = 0.046$), which supports this reconstructive technique. In the same subset, there were no significant differences in the mean air-bone gap between 6 and 12 months postoperatively, which demonstrates sustained effect of surgically induced hearing improvement.

The use of modelled incus resulted in significant hearing improvement.

DISCUSSION

Our observations show that in patients who did not need ossiculoplasty as well as those in whom bone destruction enabled using long columella technique or partial ossicular replacement prosthesis (PORP), the mean air-bone gap values at baseline fell in the range of 24.77–31.87 dB. The mean postoperative air-bone gaps in the discussed subsets were significantly better than in the subsets where due to the extensive damage to the ossicular chain and local disease process, only myringostapedopexy was possible. The

Tab. V. Mean air-bone gap at baseline (surgery day) as well as at 6 and 12 months postoperatively for each analysed subset. SD – standard deviation.

TIME FROM SURGERY (MONTHS)	AIR-BONE GAP SUBSET 1	SD SUBSET 1	AIR-BONE GAP SUBSET 2	SD SUBSET 2	AIR-BONE GAP SUBSET 3	SD SUBSET 3
0	32.08	10.32	38.68	10.36	33.28	11.25
6	26.77	10.76	35.26	9.77	25.98	6.83
12	25.1	10.99	35.44	14.35	25.33	7.39

above findings emphasize the crucial role of proper diagnosis and thorough eligibility assessment before performing elective surgery [5–9]. At the same time, they indicate that with less advanced ossicular pathology, the air-bone gap is not always an accurate predictor of expected postoperative hearing improvement, which is a novel finding.

At the stage of treatment planning and assessing eligibility for surgery, other signs and symptoms become crucial as potential predictors of hearing improvement. It is exemplified in a prognostic classification proposed by Bellucci [10]. The author emphasizes the role of such factors as dry ear, incidence and type of effusion, Eustachian tube patency, clinical response to medical treatment of flare-ups, and concomitant structural abnormalities.

If severe damage to ossicular chain is found intraoperatively, with only stapes preserved, and in particular if stapedial superstructure is also damaged, a single-stage reconstruction does not offer satisfactory effect [6, 8, 11]. Radical excision of pathological lesions should be a priority in these patients. Once it is accomplished, reconstructive surgery can be attempted, often as the second step of a two-stage procedure. In an attempt to restore proper anatomical relationships, a potential reconstruction of the posterosuperior wall of the external auditory canal should also be considered [12].

The amount of hearing improvement decreases with the increasing extent of damage to the ossicular chain, which was also confirmed by the current analysis [13–15]. The least favourable effect was observed in patients with damage to the stapedial superstructure. As confirmed by other authors, preservation of intact stapes is of key importance in hearing improvement, as it offers a possibility to use modelled autologous incus and placing it on the stapes under the reconstructed tympanic membrane [14–17]. Partial ossicular replacement prosthesis (PORP) can be used in such cases.

It should be noted that in cases with severe damage to the ossicular chain, the preoperative air-bone gap may be smaller than the postoperative one. It is caused by involvement of pathological lesions in sound transmission between the tympanic membrane and the oval window.

It is believed that hearing improvement may not be achieved in approximately 60% of patients with damaged stapedial superstructure [18–19].

In the analysed subset, a cartilage palisade was formed on the stapedial footplate. These patients, however, did not achieve a significant change in the mean air-bone gap.

Currently, a number of prostheses are available to be placed on the stapedial footplate, in order to ensure a complete reconstruction of the ossicular chain. The presented results, supported with long-term clinical experience, demonstrate that the reconstruction of the entire ossicular chain is still a current issue in otologic surgery.

Here, it should be mentioned that, according to many authors, otologic surgery outcomes tend to worsen with time [20–21]. Very good outcomes of ear surgery measured with the closure of the air-bone gap, are no longer observable in the follow-up assessments after a dozen or more years.

CONCLUSIONS

1. The size of the air-bone gap assessed prior to surgery may not reflect the severity of disease-induced damage and cannot, therefore, be used as the only prognostic factor of postoperative hearing improvement;

2. Preservation of an intact, fully mobile stapes is the key for hearing improvement after middle ear surgery;

3. The presence of only the stapedial footplate is a negative prognostic factor of hearing improvement after tympanoplasty.

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ORIGINAL ARTICLE

Long-term results of a hearing test in patients operated for chronic otitis media

Authors' Contribution:
A–Study Design
B–Data Collection
C–Statistical Analysis
D–Data Interpretation
E–Manuscript Preparation
F–Literature Search
G–Funds Collection

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ABSTRACT:

Introduction: Chronic otitis media is characterized by tympanic membrane perforation and conductive hearing loss. In the active form of this disease, there will also be periodic or permanent otorrhea. With a number of surgical techniques available depending on intraoperative findings, otosurgery is the treatment of choice in such cases, the extent of which depends on the type and extent of the pathological changes.

Material and Method: We carried out an analysis of 79 patients with chronic otitis media undergoing surgery at the Department of Otolaryngology, Jagiellonian University Medical College in Kraków between 2005 and 2014. Total audiometry was used as a part of hearing assessment, before the surgery, 6 months after the surgery and in the distant 10-year observation period. In addition, each patient completed the questionnaire and was examined by an otolaryngologist.

Results: The analysis included 79 patients operated on due to chronic otitis media. The mean bone conduction (for frequencies 500,1000 and 2000 Hz) before surgery was 31.8 dB, it did not differ significantly ($p = 0.355$) after 6 months after surgery (32.8 dB), while it significantly increased ($p < 0.001$) in a distant 10-year control of 43.4 dB. The mean air conduction (for frequencies 500, 1000 and 2000 Hz) before the procedure was 57.6 dB, it significantly improved in the early control by 50.5 dB, at $p < 0.001$. In long-term follow-up it increased again to 61.3 dB and was significantly different from the early postoperative period ($p < 0.001$). The mean air-bone gap for frequencies 500, 1000 and 2000 Hz before surgery was on average 26.4 dB, it was significantly ($p < 0.001$) reduced in the postoperative period by 17.6 dB. The level of air-bone gap remained at a similar level in distant control.

Conclusions: (1) A completely preserved ossicular chain in the absence of active chronic otitis media is the best prognosis for stable hearing improvement over the years with normal inner ear function; (2) Reoperation worsens the long-term results of a hearing test compared to the first operation.

KEYWORDS: chronic otitis media, long-term postoperative hearing improvement, tympanoplasty

ABBREVIATONS

COM – chronic otitis media
PORP – partial ossicular replacement prosthesis
TORP – total ossicular replacement prosthesis

INTRODUCTION

Chronic otitis media (COM) is characterized by conductive hearing loss, possible perforation of the tympanic membrane and periodic or permanent otorrhea in active form. The risk factors in COM are recurrent acute otitis media, inadequate antibiotic therapy, impaired Eustachian tube functions, cleft palate, male gender and a positive family history of inflammation in parents and relatives.

The treatment of choice for chronic otitis media is surgery, the scope of which depends on the type and extent of the pathological changes. The primary aim of surgical treatment is: removal of lesions, restoration of drainage and ventilation of the middle ear, improvement of hearing and protection of the middle ear from water in order to improve the patient's quality of life.

Tympanoplasties, as this is the term used for middle ear surgery, is divided into canel wall up and canal wall down depending on the behavior of the posteroanterior wall of the external auditory canal. Middle ear procedures include plastic surgery of the external auditory canal (canaloplasty), plastic surgery of the tympanic membrane (myringoplasty), and in the case of the ossicular chain damage also their reconstruction (ossiculoplasty).

The treatment of chronic otitis media involves three possible ways of surgical approach: transcanal, intra-aural, and extra-auricular. Reconstruction of the tympanic membrane involves the use of the perichondrium or temporal fascia as graft material, using the underlay technique.

In the reconstruction of the ossicular chain, depending on the degree of damage to the middle-ear conductive system, graft materials from the patient's own body (e.g. modeled incus, palisade from the patient's cartilage, etc.) or alloplastic prostheses are used. From the perspective of hearing improvement, it is essential to preserve adequate stapes mobility and self-ventilation of the tympanic cavity through the Eustachian tube.

Given the complexity of middle ear surgery, an international consensus has emerged on the categorization of tympanoplasty.

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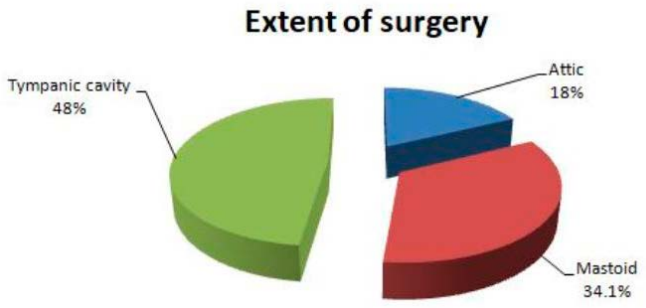

Fig. 1. The extent of surgery in the study sample.

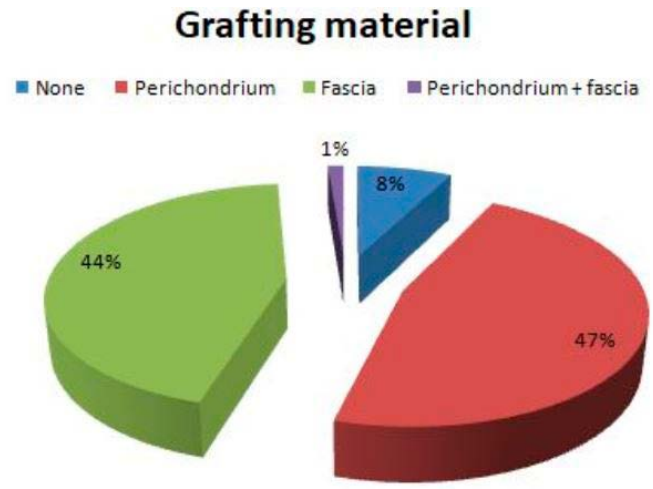

Fig. 2. Type of grafting material used for tympanic membrane reconstruction.

The classification included surgery of the mastoid and middle ear (tympanic). When it comes to the mastoid process, the number of operations (first, revision, second look), approach taken to the mastoid process, range of mastoidectomy, presence of reconstruction of the external auditory canal and possible obliteration of the mastoid process were included. In terms of middle ear surgery, the type of access to the tympanic cavity, the state and type of tympanic membrane reconstruction and the method of reconstruction of the ossicular chain were taken into account [1].

In the literature we encounter the analysis of effects of surgical treatment of chronic otitis media, however, studies assessing such long-term results (10 years) that will be included in the proposed project are scarce.

AIM

A prospective analysis of early and distant otosurgical results in patients operated due to chronic otitis media was performed.

MATERIAL AND METHOD

The material examined data obtained from 79 patients who reported for long-term follow-up after surgical treatment due to chronic otitis media at the Department of Otolaryngology CM UJ in 2005–2014. The youngest patient was 27 and the oldest was 78. The average age was 57.1. The study group consisted of 51 women and 28 men. 40 patients (50.6%) underwent surgery in the right ear and 38 (49.4%) in the left ear. In the study group, 57 patients (72.2%) were operated for the first time and did not require further surgery, while 22 (27.8%) required reoperation. In 27 subjects (34.2%) preaurical access was chosen, while in 52 (65.8%) we used extra-auricular access.

The evaluation of hearing involved the use of a pure-tone audiogram made before the surgery, 6 months after the surgery and in the distant 10-year observation period. Furthermore, each patient filled in the questionnaire and was examined by an otolaryngologist.

The obtained results were subjected to statistical analysis. The level of significance was $p < 0.05$.

RESULTS

The analysis included 79 patients. According to the survey, 38 patients (48%) reported subjective hearing improvement after otosurgery during long-term follow-up, while the remaining 41 patients (52%) did not experience hearing improvement, neither did they report a reduced sense of hearing. 25 patients (31.6%) required hearing care, of which 17 (21.5%) with air conduction hearing aids, while 8 patients (10.1%) were qualified to wear bone conduction devices on the operated ear, which resulted in significant subjective improvement of hearing. One patient suffered from sudden deafness of the operated ear, which occurred 3 years after the surgery. The implemented conservative treatment did not bring any improvement.

2 patients (2.5%) reported postoperative taste disorders in the early postoperative period. No facial nerve palsy was noted, but intraoperative deafness was found in 1 patient (1.25%). 33 patients (41.7%) reported tinnitus before surgery. In most cases it decreased, and only 4 patients (5%) had increased tinnitus. 23 patients (29%) experienced dizziness, which decreased after the surgery.

The majority of patients (74.6%) reported recurrent acute otitis media since childhood. Only 5 patients (6.3%) had adenotomy, no patient had a cleft palate, which is a major risk factor for EMP. In 4 patients (5%) surgery was required in the case of otogenic meningitis.

Preoperative perforation of the tympanic membrane occurred in 77 patients (97.5%), but in long-term follow-up its presence was found in 17 patients (21.5%). Twenty-five subjects (31.6%) had retraction pockets in long-term follow-up. Otorrhea in the operated ear appeared in 13 patients (16.5%), on average 3 years after surgery.

79 otosurgeries were performed. The procedure limited to the tympanic cavity was performed in 38 patients, while in the remaining individuals (41 patients) it had to be extended to other middle ear spaces (Fig. 1.).

In 52 patients (66%) there were no pathological changes in the middle ear, while in the remaining 27 (34%) cholesteatoma masses or inflammatory granulomatous lesions were removed.

Perichondrium and/or fascia of temporal muscle were used for reconstruction of the tympanic membrane (Fig. 2.).

The analysis focused primarily on long-term hearing outcomes.

Patients were divided into groups depending on the tympanoplasty performed.

- Surgery no. 1 (n = 19): Austin-Kartush A [M+I-S+] / Type II tympanoplasty;
- Surgery no. 2 (n = 13): Austin-Kartush A [M-I-S+] / Type II tympanoplasty (using PORP);
- Surgery no. 3 (n = 20): Austin-Kartush O / Type I tympanoplasty;
- Surgery no. 4 (n = 27): Austin-Kartush C / Type III tympanoplasty.

Comparing pure-tone audiograms made before surgery and in long-term follow-up after tympanoplasty for surgeries no. 1, 2 and 4, statistically significant worse mean bone conduction was observed after many years' observation with comparable mean air conduction and significantly smaller air-bone gap (Tab. I.).

Analyzing the follow-up long-term audiogram for surgery no. 3, there is no substantial decline in bone conduction after many years, while air conduction decreases at p = 0.059, which is close to significance. After many years, the air-bone gap decreases significantly (Tab. II.).

No statistical difference was observed in preoperative audiograms between treatments, either in air conduction, bone conduction or air-bone gap. However, in long-term follow-up after surgery there was a significant difference in bone conduction for a frequency of 2000 Hz between surgery no. 3 (tympanoplasty type I) of 35.8 dB and surgery no. 4 (tympanoplasty type III) of 55.9 dB at p = 0.036. Additionally, for surgery no. 4 there was statistically significantly worse air conduction at each frequency compared to surgery no. 3, on average for surgery no. 3 it was 46.7 dB and for surgery no. 4 it was 69.1 dB, at p = 0.022.

In long-term follow-up, the average cochlear reserve after surgery no. 1 is statistically significantly smaller than after surgery no. 2 and 4 (Tab. III.).

The further phase of the research consisted in comparing early and distant treatment results, assessing their change over time (Tab. IV.).

The mean bone conduction before surgery was 31.8 dB, SD 16.3, it did not differ significantly (p = 0.355) 6 months after surgery (32.8 dB SD 17.3), but it increased significantly (p < 0.001) in long-term 10-year follow-up at 43.4 dB, SD 23. The mean air conduction before surgery was 57.6 dB, SD 18.2, it significantly improved in the early follow-up at 50.5 dB SD 19.5, at p < 0.001. In long-term follow-up it increased again to 61.3 dB SD 22.9 and was significantly different from the early postoperative period (p < 0.001). The air-bone gap before surgery averaged 26.4 dB SD 12.4, and it decreased significantly (p < 0.001) in the postoperative period at 17.6 dB SD 11.4. The air-bone gap level remained at a similar level in long-term follow-up.

Tab. I. Comparison of pure-tone audiograms taken before and at long-term follow-up after surgery no. 1 (tympanoplasty type II), no. 2 (tympanoplasty type II (using AfterRP) and 4 (tympanoplasty type III). SD – standard deviation.

SURGERY	MEAN CONDUCTION FOR FREQUENCIES 500, 1000, 2000 HZ	STUDY	AUDIOGRAM		WILCOXON TEST
			MEAN	SD	
No. 1 (n = 19)	bone	Before	30.0	12.0	**p = 0.002**
		After	42.8	23.3	
	air	Before	56.3	18.1	p = 0.396
		After	58.5	25.4	
	air-bone gap	Before	27.9	8.4	**p = 0.007**
		after	15.7	14.5	
No. 2 (n = 13)	bone	before	31.9	7.6	**p = 0.005**
		after	41.3	10.2	
	air	before	62.8	15.5	p = 0.889
		after	62.8	16.3	
	air-bone gap	before	30.9	16.4	**p = 0.05**
		after	21.5	12.5	
No. 4 (n = 27)	bone	before	36.5	23.7	**p = 0.003**
		after	49.1	27.0	
	air	before	61.2	22.9	p = 0.048
		after	69.1	25.5	
	air-bone gap	before	27.7	13.1	**p = 0.025**
		after	19.9	13.8	

Tab. II. Comparison of pure-tone audiograms taken before and at long-term follow-up after surgery no. 3 (tympanoplasty type I). SD – standard deviation.

SURGERY	MEAN CONDUCTIVITY AT 500, 1000, 2000 HZ	STUDY	AUDIOGRAM		WILCOXON TEST
			MEAN	SD	
No. 3 (n = 20)	Bone	before	32.1	15.8	p = 0.370
		After	34.3	18.8	
	Air	before	50.7	19.9	p = 0.059
		After	46.7	25.5	
	air-bone gap	before	19.1	10.9	**p < 0.001**
		after	7.8	8.7	

Tab. III. Mean air-bone gap in long-term postoperative follow-up depending on the conducted procedure. N – number of patients.

SURGERY	N	AVERAGE AIR-BONE GAP FOR 500, 1000 AND 2000 HZ		ANOVA KRUSKAL-WALLIS	MULTIPLE COMPARISON TEST
		MEAN	DEVIATION		
1	19	15.7	14.5		**2#3 p = 0.019**
2	13	21.5	12.5	**p = 0.008**	
3	20	7.8	8.7		**3#4 p = 0.021**
4	27	19.9	13.8		

Further evaluation examined whether pathological masses within the middle ear have an impact on audiometric results. No significantly worse results were observed in bone or air conduction, or the air-bone gap level in patients with cholesteatoma and/or granulation tissue compared to patients without a diseased middle ear mucosa in long-term follow-up. No advantage of the material

Tab. IV. Comparison of early and long-term otosurgical treatment results in patients with chronic otitis media. SD – standard deviation.

CONDUCTIVITY	FREQUENCY	STUDY	MEAN	SD	FRIEDMAN ANOVA	0–10 L	6 M-10 L	0–6 M
bone	Mean (500, 1000 and 2000 Hz)	before	31.8	16.3	**p < 0.001**	**p < 0.001**	**p < 0.001**	p = 0.355
		6 months after	32.8	17.3				
		10 years after	43.4	23.0				
air	Mean (500, 1000 and 2000 Hz)	before	57.6	18.2	**p < 0.001**	p = 0.334	**p < 0.001**	**p < 0.001**
		6 months after	50.5	19.5				
		10 years after	61.3	22.9				
air-bone gap (mean)		before	26.4	12.4	**p < 0.001**	**p < 0.001**	p = 0.385	**p < 0.001**
		6 months after	17.6	11.4				
		10 years after	15.9	12.9				

Tab. V. Comparison of the impact of reoperation on audiogram outcomes in long-term follow-up. SD – standard deviation; N – number of patients.

CONDUCTIVITY	FREQUENCY	REOPERATIONS	N	AUDIOGRAM		WILCOXON TEST
				MEAN	SD	
bone	Mean for 500, 1000 and 2000 Hz	no reoperation	57	40.6	21.1	p = 0.212
		reoperation/s	22	47.8	25.2	
air	Mean for 500, 1000 and 2000 Hz	no reoperation	57	55.6	24.6	**p = 0.015**
		reoperation/s	22	70.8	24.4	
air-bone gap (mean)		no reoperation	57	13.4	11.6	**p = 0.014**
		reoperation/s	22	23.0	15.6	

used for reconstruction of the tympanic membrane was observed. Both the fascia of temporal muscle and perichondrium yielded comparable results of hearing tests in the conducted study.

The next part of the study compared the effects of reoperation on hearing outcomes. 22 patients (27.8%) required reoperation. The number of repeated treatments ranged from 1 to 5 in a single patient. The average bone conduction in the non-reoperated group and in the reoperated group did not differ statistically. In contrast, air conduction was statistically significantly worse in the reoperated group and equaled 70.8 dB compared to 55.6 dB in the non-reoperated group, p = 0.015. Therefore, the air-bone gap was significantly higher in the reoperated group (p = 0.014) (Tab. V.).

DISCUSSION

In otosurgical procedures, in addition to removing lesions and restoring proper ventilation of the middle ear, it is also important to obtain the best possible hearing in the operated ear. The development of new operating techniques and increasingly modern equipment allow for better functional results.

In surgery no. 1 (type II tympanoplasty) where at least 2 bone elements were preserved, surgery no. 2 (type II tympanoplasty using PORP) and surgery no. 4 (type III tympanoplasty), deterioration of bone conduction at all frequencies was observed in long-term follow-up. This stems from the adverse impact of toxic factors of inflammation on the inner ear, the possible effect of noise on the organ of Corti during lifting of the temporal bone, and the effect of impaired air conduction on the inner ear. Numerous authors have pointed out that surgical treatment of conductive hearing loss can result in damage to the inner ear secondary to stapes manipulation and damage due to noise emitted by the drill [2–4]. There are rare reports of total deafness during otosurgeries, estimated at 0.2% to 1% of cases [4, 5]. In our study, intraoperative deafness was at about 1%.

Edfeldt et al. believe that the only factors worsening postoperative hearing prognosis are reoperation and stapes injury requiring the use of a TORP prosthesis [6]. This is also confirmed by our view.

In long-term follow-up, as a result of a worsened bone conduction in the course of the illness and the passage of years, and thus damage to the inner ear, a decrease in cochlear reserve is observed with slightly altered air conduction. Many researchers consider that the most crucial factors affecting the long-term outcome of ossiculoplasty are persistent middle ear disease such as cholesteatoma, atelectasis, and Eustachian tube dysfunction. Such factors are often indications for reoperation and, as a consequence, worse hearing results [7, 8].

In surgery no. 3, where only myringoplasty was performed while the ossicular chain was preserved, the adverse impact of inflammation on the inner ear was minor, and the improvement in hearing expressed after the postoperative reduction of the air-bone gap was the largest and stable over time. The preserved ossicular chain and, above all, the lack of active inflammation, affects the maintenance of normal inner ear function. It allows to maintain the physiological sound amplification provided by the lever system that forms the chain of auditory ossicles.

No significant statistical differences were observed in preoperative audiograms in bone and air conduction, and air-bone gap. On average,

after 10 years of follow-up, bone conduction for 2000 Hz for surgery no. 4, in which the conduction element is most damaged, is statistically significantly worse compared to surgery no. 3, where it is completely preserved. 2000 Hz is the resonance frequency of the ossicular chain and its restoration is visible for myringoplasty itself. The difference also stems from the extent of the procedure, an active inflammatory process affecting the inner ear that occurs in the most locally advanced chronic middle ear inflammation [9]. Pareschi et al. noticed a reduced sense of hearing in long-term follow-up after surgery in the course of chronic granulomatous otitis media. After an initial improvement in the 6-month follow-up, if the stapes were preserved during surgery, there was a deterioration in pure-tone audiometry. In the absence of stapes, there was no significant difference in the audiogram after 6 months and 10 years [10, 11]. Our analysis did not involve any worse audiometry results depending on the pathological tissue within the middle ear, but only on damage within the ossicular chain and the reconstruction used. However, the preservation of stapes is a major prognostic factor for hearing improvement. According to other reports, the most important factor in postoperative hearing improvement beside the stapes is the presence of the handle of the malleus [12]. This is supported by our results.

An adverse prognostic factor for postoperative hearing improvement is any subsequent surgical intervention. The most common cause of reoperation is recurrence or persistent cholesteatoma. In literature, recurrence of cholesteatoma is estimated between 2% and 18% [10, 13, 14], while in our study, the recurrence of cholesteatoma was 15%. There are two ways to treat recurrence: as incomplete removal in the course of a single procedure or creating a new cholesteatoma from a retraction pocket [10]. Other risk factors include poor condition of the middle ear mucosa, the patient's age, and a lack of hearing improvement after previous operations [6, 10, 15, 16].

The mean cochlear reserve after surgery is subject to the greatest closure at surgery no. 3 (myringoplasty) and is 7.8 dB; it is statistically significantly smaller than in surgery no. 2 – 21.5 dB and surgery no. 4 – 19.9 dB. After surgery no. 1, the reserve is 15.7 dB. On this basis, it can be concluded that a completely preserved ossicular chain or such with damage to only one bone element guarantees a smaller auditory reserve that is stable over time.

CONCLUSIONS

1. A completely preserved ossicular chain in the absence of active chronic otitis media is the best prognosis for stable hearing improvement over the years with preserved normal ear function;

2. Reoperation worsens the long-term results of a hearing test compared to the first operation;

3. In long-term follow-up, as a result of the progressive deterioration of bone conduction in the course of the disease, a decrease in air-bone gap is observed with slightly changed air conduction;

4. There was no worse prognosis for hearing improvement in cholesteatoma and/or granulation tissue in the middle ear compared to normal mucosa.

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Original Article

Pre- and Post-operative Speech Audiometry Evaluation in Patients with Chronic Otitis Media

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OBJECTIVES: The primary function of the human auditory system is to ensure proper speech comprehension. Speech audiometry enables the assessment of the conductive and the sensory aspects of the ears, providing some insight into the central auditory processing function.

MATERIALS and METHODS: We conducted an analysis of 79 patients with chronic otitis media (COM) undergoing surgery at the Department of Otolaryngology, Jagiellonian University Medical College, in Kraków between 2005 and 2014. Tonal audiometry and speech audiometry were used as part of the hearing assessment. The pre-operative and long-term post-operative findings were compared, focusing mainly on speech audiometry.

RESULTS: At the end of the mean 10-year follow-up, a significant percentage worsening in speech comprehension from the baseline was demonstrated in group III (hearing loss > 70 dB(decibels)), as compared with the remaining groups. There was a significant (p=0.017) difference in speech comprehension between the treated and contralateral ears, with the mean maximum speech comprehension rates of 80% in the treated ear versus 92% in the contralateral ear.

CONCLUSION: We demonstrated a correlation between the findings of tonal audiometry and speech audiometry. The severe damage caused by chronic middle ear diseases not only leads to conductive hearing loss but also acts as a significant contributor to poor speech comprehension in a long-term follow-up. The speech comprehension in a healthy ear is significantly better than in a diseased ear. Middle ear reconstructive surgery offers the maximum improvement in speech comprehension at the hearing loss of 41 to 70 dB in speech audiometry.

KEYWORDS: Speech audiometry, chronic otitis media, tympanoplasty

INTRODUCTION

The human auditory sense is intended to ensure accurate speech perception and comprehension. Subjective tests, such as tonal and speech audiometry, play an important role in the diagnosis of hearing abnormalities. Used for screening, tonal audiometry makes it possible to estimate the degree of hearing loss and to indicate its type. Speech audiometry, in contrast, can help evaluate hearing by characterizing its communication performance. Speech audiometry enables the assessment of conductive and sensory aspects of the hearing organ, providing some insight into the central auditory processing function. Speech comprehension is a valuable parameter in the assessment of hearing pathology. Although the frequency of human speech ranges from 20 Hz (Hertz) to 20 kHz (Kilohertz) [1,2], some authors indicate these frequencies to be between 14 Hz and 14 kHz for national languages. If it corresponds to the "range of speech intelligibility," it is between 1 Hz and 4 kHz [2,3]. A speech audiogram is plotted onto the reference curve obtained from people with normal hearing, with the percentage of correctly comprehended presented speech stimuli as the ordinate and sound volume as the abscissa. Speech audiometry text may contain monosyllabic words, multisyllabic (bisyllabic, trisyllabic, or more) words, numbers or even sentences [3]. They are always typical of the language spoken by a given population. The first speech audiometry text was developed by H. Fletcher in 1929 [3]. The first Polish speech audiometry text was developed in 1953 by Zakrzewski, Suwalski, Antkowski, and Suwalski [4].

Pre- and post-operative assessment of patients with middle ear pathologies mainly relies on tonal audiometry. When assessing patients with chronic otitis media (COM), we hardly ever focus on speech comprehension, with clinical decision-making usually based

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on tonal audiometry. However, speech audiometry reflects the social aspects of auditory performance.

Chronic otitis media is a common ear disease that manifests as conductive hearing loss. In the active form of this disease, there will also be periodic or permanent otorrhea and tympanic perforation.

With a number of surgical techniques available depending on intraoperative findings, otosurgery is the treatment of choice in such cases. The goals for surgery for COM are eradication of the disease (safe ear), grafting of the perforation, if it exists (dry ear), and reconstruction of the ossicular chain (hearing ear), together with well-aerated ear [5].

The aim of the study was to analyze long-term functional outcomes (i.e., improvement in speech audiometry) of surgical treatment in patients with COM.

MATERIALS AND METHODS

We carried out an analysis of 79 patients with COM undergoing surgery between 2005 and 2014. Patients with incomplete medical records, who did not report for control, and those operated for otosclerosis or middle ear tumor were excluded. Patients who did not consent to a hearing test and did not completed the questionnaire were excluded. The youngest patient was 27 years old, and the oldest one was 78 years old, with the mean age of 57.1 years. Fifty-one women and 28 men were enrolled. Forty of them (50.6%) had their right ear operated on, and 38 of them (49.4%) had the left ear operated on. Fifty-seven (72.2%) patients underwent their first surgery and did not require any further procedure, whereas 22 (27.8%) patients were re-operated. In 27 (34.2%) patients, the endaural approach was chosen, whereas in 52 (65.8%) patients, the postauricular approach was used.

On the basis of the questionnaire completed during the remote control, only 2 patients (2.5%) reported post-operative taste disturbances. No facial nerve palsy was noted, but perioperative deafness was found in 2 patients (2.5%). Tinnitus before the surgery was reported by 33 patients (41.7%). In most cases it decreased; only 4 patients (5%) reported increase in tinnitus. Twenty-three patients (29%) experienced dizziness.

Thirty-eight patients (48%) reported subjective hearing improvement after otosurgery, and the remaining 41 patients (52%) did not notice hearing improvement or even reported deterioration. Twenty-five patients (31.6%) required hearing aid, of which, 17 (21.5%) required air conduction hearing aids, and bone-anchored hearing aid (BAHA) was inserted in the ears of 8 patients (10.1%). One patient suffered from sudden deafness of the operated ear 3 years after the surgery. The implemented treatment did not bring any improvement.

MAIN POINTS

- Severe damage in COM contributes to poor speech comprehension.
- Speech comprehension is always better in healthy ear.
- Reconstruction of middle ear gives the best improvement in speech comprehension at the hearing loss of 41-70 dB in speech audiometry.

Most patients (74.6%) reported recurrent otitis media from childhood. Only 5 patients (6.3%) had adenoidectomy in daycare; no patient had a cleft palate. In 4 patients (5%), the indication for surgery was otogenic meningitis.

Pre-operative tympanic membrane perforation occurred in 77 patients (97.5%), of which the tympanic membrane defect of over 50% occurred in half of the patients. In remote control, perforations were diagnosed in 17 patients (21.5%), 10-80% in size. In contrast, 25 patients (31.6%) had retraction pockets in long control. Otorrhea from the operated ear appeared in 13 patients (16.5%), 3 years after the surgery, on the average.

Pure tone audiometry and speech audiometry were used as a part of hearing assessment. The tests were performed with an audiometer equipped with TDK 39® (MIDIMATE 622, Madsen, Dybendalsvænget, Taastrup, Denmark). The pre-operative and long-term post-operative findings were compared. The follow-up duration was from 5 to 14 years.

In order to analyze speech audiograms, we divided the patients into the following groups on the basis of the maximum hearing loss (expressed in dB of the words given in speech audiometry) for which the best speech comprehension was achieved.

Group I: 0-40 dB
Group II: 41-70 dB
Group III: 71-100 dB

In order to ensure reliable analyses, the patient groups were comparable in terms of patient number and their mean age.

All the patients consented to the surgery and participation in the study, and the approval of the Local Bioethical Committee was obtained to conduct the study (no. 122.6120.206.2016).

Statistical Analysis

Statistical analysis was performed with a significance level of 5%. Statistica software (ANOVA; Statistica, StatSoft, Krakow, Poland) was used for statistical analysis.

RESULTS

The outcomes of 79 patients were analyzed. Canal wall-up (CWU) tympanoplasty was performed in 52 patients and canal wall-down (CWD) tympanoplasty in the remaining 27 patients. The procedure was limited to tympanotomy in 38 patients and in the remaining 41 patients to atticotomy or atticoantromastoidectomy (Figure 1).

No abnormalities of middle ear lining were demonstrated in 52 patients. In the remaining 27 cases, inflammatory granulation and/or cholesteatoma removal was required.

For the tympanic membrane reconstruction, temporalis fascia graft and/or cartilage perichondrium were used (Figure 2).

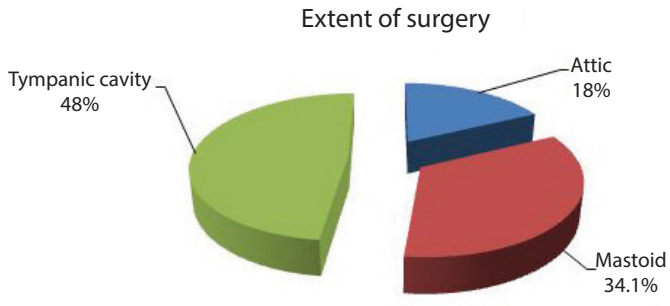

Figure 1. The extent of surgery in the study sample.

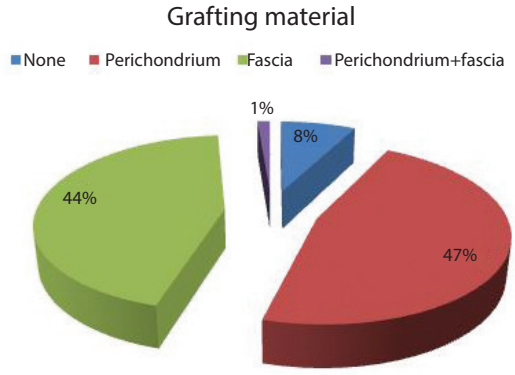

Figure 2. Type of grafting material used for tympanic membrane reconstruction.

In an attempt to evaluate treatment outcomes in terms of changes

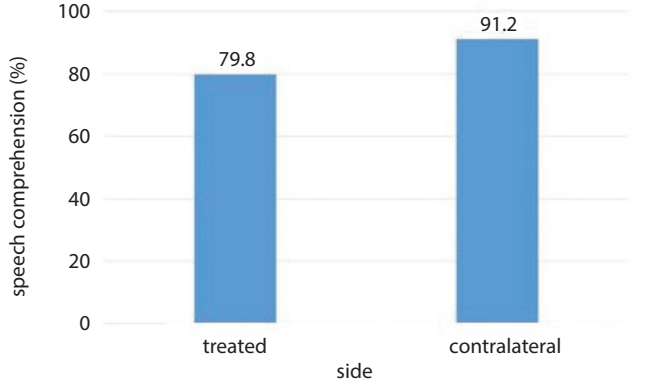

Figure 3. The mean maximum difference in speech comprehension between the treated ear and the contralateral ear.

in the social hearing performance, further analysis was based on speech audiograms. No studies are available to address this aspect of hearing assessment in patients with COM.

Pure tone audiometry and speech audiometry were performed preoperatively and postoperatively in each enrolled patient. The pre-operative audiograms were compared with those obtained at the end of 5-14 days of follow-up.

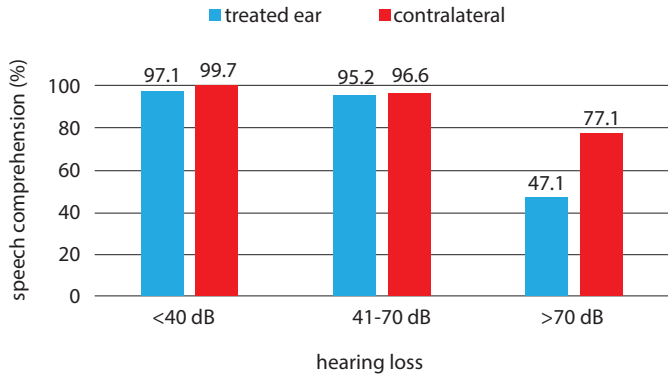

Figure 4. Speech comprehension in treated and untreated ears for different hearing loss levels.

Table 1. Speech comprehension levels in different hearing loss level groups assessed preoperatively and postoperatively

Hearing loss	Before surgery Speech comprehension level (%)	After surgery Speech comprehension level (%)	p
I (up to 40 dB)	91.8	97.1	p=0.86
II (41-70 dB)	72.9	95.2	p=0.011
III (above 70 dB)	71.4	47.1	p=0.135

The findings were analyzed in the context of tympanoplasty, comparing the treated and the contralateral (healthy) ears, and analyzing the differences between pre- and post-operative speech audiograms. Speech audiometry values in the second, untreated ear compared with changes in speech comprehension in the operated ear enabled to eliminate inter-individual variability with time. The assumption behind this is the second ear could be the point of reference for the changes in speech comprehension tests performed long after ear surgery.

There was a significant (p=0.017) difference in speech comprehension between the treated and contralateral ears, with the mean maximum speech comprehension rate of 79.8% in the treated ear versus 91.2% in the contralateral (untreated) ear (Figure 3).

There was no significant hearing impairment in the contralateral (untreated) ear over the mean 10-year follow-up.

The two-way analysis of variance (ANOVA), with assessed ear (treated vs. untreated) and hearing loss (three ranges) as independent variables, demonstrated no significant difference in speech comprehension over time in groups I and II. However, in group III, there was a significant change in speech comprehension during the follow-up period (Figure 4).

Further analysis focused on comparing pre- and late post-operative speech audiograms. The performed surgery best improved speech comprehension in group II (hearing loss 41-70 dB). In group III (above 70 dB), speech comprehension deteriorated, whereas in group I (hearing loss up to 40 dB), the percentage of speech com-

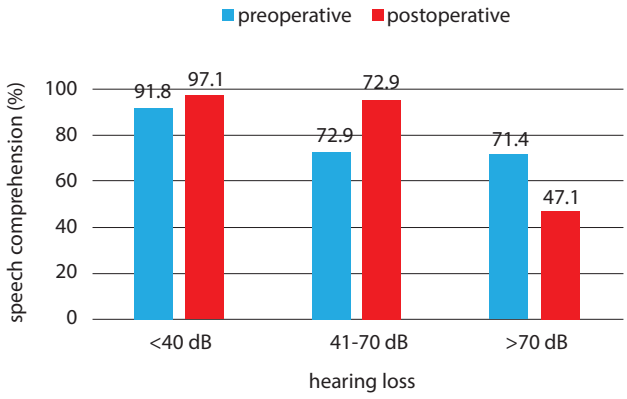

Figure 5. Speech comprehension levels in different hearing loss level groups assessed preoperatively (blue) and postoperatively (red).

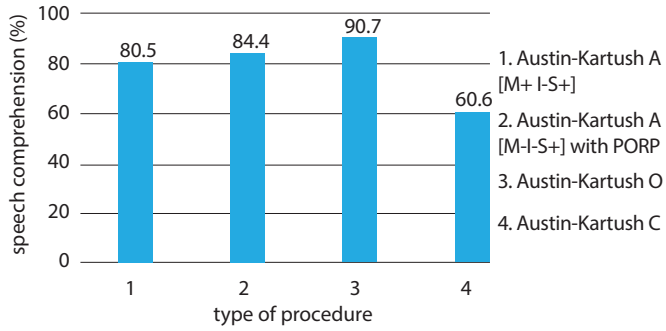

Figure 6. Speech comprehension levels in groups based on the extent of auditory ossicle reconstruction.

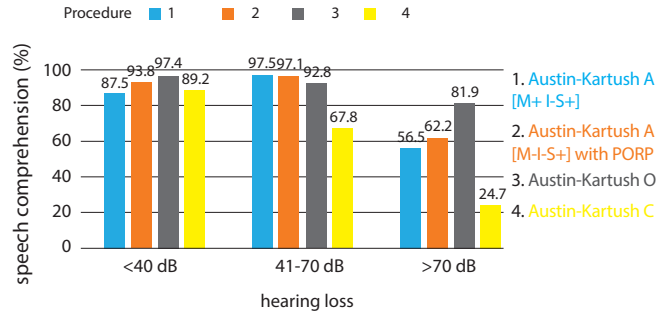

Figure 7. Speech comprehension levels in groups based on the extent of ossicle reconstruction depending on hearing loss, for which the best speech audiogram was obtained.

prehension remained at a similar to the pre-operative level (Figure 5, Table 1).

Speech audiograms were also analyzed against the type of surgery performed. We assumed a division based on the extent of tympanoplasty performed. We used Austin-Kartush classification/Wullstein classification.

Procedure # 1 (n = 19): Austin-Kartush A (M+ I-S+)/tympanoplasty type II
Procedure # 2 (n = 13): Austin-Kartush A (M-I-S+)/tympanoplasty type II (with use PORP)
Procedure # 3 (n = 20): Austin-Kartush O/tympanoplasty type I
Procedure # 4 (n = 27): Austin-Kartush C/tympanoplasty type III

Statistical analysis with ANOVA demonstrated a significant difference ($p<0.0001$) between the surgery type-based groups. Patients after procedure # 4 had significantly worse speech comprehension than those after other procedures (Figure 6).

Further analysis with two-way ANOVA included hearing loss (groups 1-3) and the extent of surgery (procedures #1-#4) as independent variables (Figure 7).

A comparison of post-operative speech audiograms demonstrated no significant differences between procedures #1, #2, #3, and #4 in patients who presented the best speech comprehension at the hearing loss below 70 dB ($p=0.055$). However, it also demonstrated that significant damage to the ossicular chain induced by procedure #4 was associated with worse speech comprehension than other procedures if the hearing loss for the best attained speech audiogram was above 70 dB (group III, $p=0.002$).

In the next step, correlations were determined between tonal and speech audiograms in the hearing loss-based groups. The correlation between the two audiograms was weak in group I (hearing loss up to 40 dB), moderate in group II (hearing loss 41-70 dB), and very strong in group III (hearing loss above 70 dB) (Figures 8 and 9). In each case, the correlation coefficient was negative, which indicated an inverse association.

The correlation between air conduction and speech audiometry and the correlation between bone conduction and speech audiometry were comparable. The results are presented in Table 2.

DISCUSSION

The beneficial effect of middle ear reconstruction on the inner ear (including the contralateral, untreated inner ear) was discovered and documented by Professor Jan Miodoński in 1956 in his paper entitled "Fenestracja poza otosklerozą. Fenestracje nietypowe, drenaż cysterny" (Fenestration in diseases other than otosclerosis, atypical fenestration, and drainage of the cisterna) [6]. The effect of middle ear mechanics on the inner ear function has been studied for many years. There are reports of a significant improvement in bone conduction in some patients after ossiculoplasty and stapedotomy, which is a measure of the effect of middle ear mechanics on the organ of Corti [7-9].

Simple and inexpensive diagnostic tools, such as tonal or speech audiometry, may facilitate analysis of different aspects of surgery (surgical approach to the temporal bone, selection of reconstructive material, etc.), indicating treatment efficacy in reconstructing the sound conductive system in the middle ear and restoring the effect of middle ear mechanics on the function of the inner ear.

In group I, identified on the basis of hearing loss for which the best results were achieved in speech audiometry, the maximum speech comprehension was 99.7% in the healthy ear and 97.1% in the treated ear. In group II, the between-ear difference was also small (96.6% in the healthy ear versus 95.2% in the treated ear). Only in group III, where best responses were achieved for the hearing loss above 70

Table 2. Correlation between audiometry findings and speech comprehension at three volume levels

Conduction	Frequency	Hearing loss					
		up to 40 dB (n=88)		41–70 dB (n=105)		above 70 dB (n=115)	
Bone	500 Hz	r = –0.2625	Weak	r= -0.4382	Moderate	r= –0.6103	Strong
	1000 Hz	r = –0.3352	Weak	r= –0.3585	Weak	r= –0.6552	Strong
	2000 Hz	r = –0.1482	Very weak	r= –0.3158	Weak	r= –0.6954	Strong
	Moderate	r = –0.2829	Weak	r= –0.4221	Moderate	r= –0.6896	Strong
Air	500 Hz	r = –0.3173	Weak	r= –0.3563	Weak	r= –0.6259	Strong
	1000 Hz	r = –0.2815	Weak	r= –0.3482	Weak	r= –0.6827	Strong
	2000 Hz	r = –0.1144	Very weak	r= –0.3197	Weak	r= –0.7081	Strong
	Moderate	r = –0.1537	Very weak	r= –0.4049	Moderate	r= –0.7312	Strong

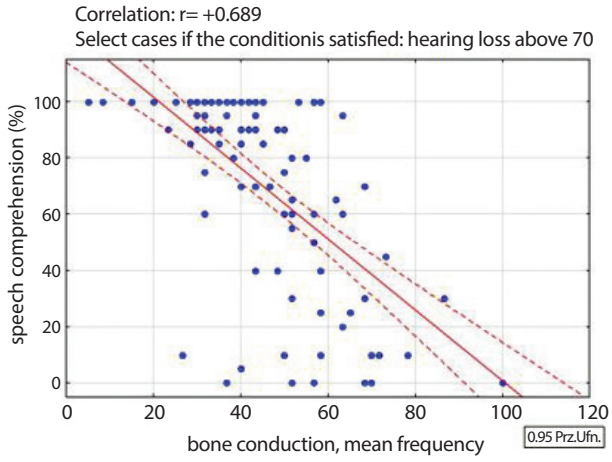

Figure 8. Correlation between the mean bone conduction and speech audiometry in group III with the best attained audiogram at the hearing loss over 70 dB.

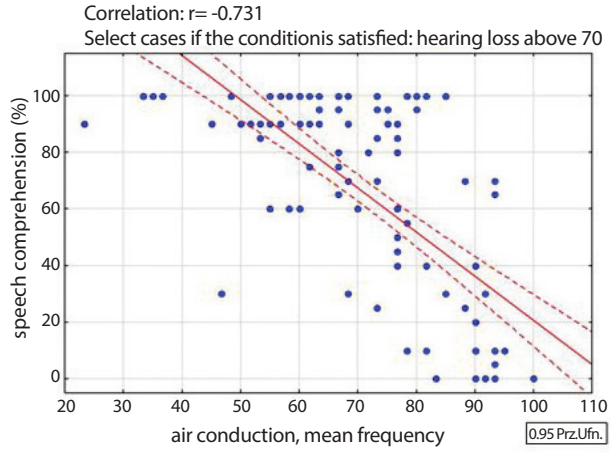

Figure 9. Correlation between the mean air conduction and speech audiometry in group III with the best attained audiogram at the hearing loss over 70 dB.

dB, the difference was significant—77.1% vs. 47.1% in the healthy and treated ears, respectively, p=0.02.

This confirms that speech comprehension in the contralateral (i.e., untreated, healthy) ear is significantly superior to that in the treated ear. Therefore, the improvement in speech audiometry was only significant for the hearing loss above 70 dB. This finding confirms that the treated ear is more prone to inner ear damage. This may result from the spread of inflammation from the middle ear to the inner ear, the effect of exposure to noise during drilling into the temporal bone, and the fact that abnormal acoustic wave transmission may affect the damage to the organ of Corti [10-12]. In contrast, in distant control, worse speech understanding in group III (hearing loss > 70 dB) occurs on both sides, which suggests that not only the type of otosurgery affects hearing results but also observation time, possible exposure to noise, inflammation, or excessive unheated ear load.

The performed surgery best improved the speech comprehension in group II (hearing loss 41-70 dB), where the best attained percentage of speech comprehension increased from 72.9% (pre-operative) to 95.2% at the end of the follow-up (p=0.011). The situation was quite different in patients who attained the best pre-operative speech audiometry results for the hearing loss above 70 dB. At the end of the follow-up, the speech comprehension in this group dropped from 71.4% preoperatively to 47.1%. The difference, albeit large, was not significant (p=0.13), attributable to the high variability of speech comprehension obtained in this group. In group I (best speech audiometry results for the hearing loss up to 40 dB), the percentage of speech comprehension remained at a similar level or increased slightly (91.8% preoperatively vs. 97.1% at the end of the follow-up). The above finding indicates that the pre-operative speech audiometry result is a prognostic factor for the post-operative social auditory performance. This perspective on hearing improvement after middle ear surgery in patients with COM is an original observation.

If the best speech audiometry results were achieved for the hearing loss above 70 dB (group III), speech comprehension was significantly worse after procedure #4 as compared with the remaining procedures (p=0.002). The largest difference in post-operative speech comprehension levels was between procedure #3 (tympanoplasty type I) and procedure #4 (tympanoplasty type III), which caused the greatest damage to the sound conductive system. Patients who underwent tympanoplasty type III had a long-term (since childhood) history of COM (91%), which favored the possible toxic, inflammatory metabolic products of the middle ear to act on the internal ear.

No patient had a history of cleft palate, which is an important risk factor for COM. In 4 patients (5%), the indication for surgery was otogenic meningitis, which increased the inner ear damage. In addition, dizziness partly resulted from a semicircular canal fistula, which decreased after surgery and also had an influence on the inner ear function. Moreover, reoperations are a negative prognostic factor for hearing improvement.

Another factor that worsens speech understanding is age-related hearing damage. In the study group, the average age of patients was 57.1 years, and the majority of respondents (79.7%) were older than 50 years.

The effect of otosurgery on the inner ear function has been debated for a number of years. Vartiainen et al. [13] did not observe any post-operative changes in bone conduction in 92% of their patients undergoing middle ear surgery owing to COM. In the remaining 5% of patients, the improvement in bone conduction was significant, reflecting the functional improvement in the inner ear. Only the intact middle ear sound conductive system favorably affects bone conduction. In practice, it comes down to improved bone conduction in patients treated for otosclerosis (marked by the presence of the Carhart notch) and COM, yet only those with a preserved or only slightly impaired ossicular chain.

Many researchers reported a link between the middle ear pathology and inner ear function [14,15]. Severe COM with cholesteatoma, mucosal abnormalities in the inner ear, and an impaired ossicular chain negatively affect the inner ear. They all impact the ossicular chain mechanism, which is reflected in speech audiograms [15, 16]. As demonstrated in our study, the worst post-operative speech audiometry results were shown in patients with a long history of COM, after procedure # 4 and after reoperation, which are negative prognostic factors for hearing improvement. In some studies, the only factor that affects hearing loss is reoperation and damage to the stapes. The reason for reoperation is residual or recurrent disease and no hearing improvement [17, 18]. To date, there have been no studies to analyze speech audiograms in patients with COM. The available speech audiometry research focuses mainly on different types of tests such as speech audiometry in silence and speech-in-noise tests or assessing the beneficial effect of a cochlear implant or hearing aid on speech comprehension [19,20].

Our analysis sheds new light on post-operative social hearing performance in patients with COM.

CONCLUSION

Whereas speech audiogram correlates with bone and air conduction for all hearing loss levels, it is not linked to the air-bone gap (ABG). The speech comprehension in the healthy ear is significantly better than in the diseased ear. A significant decrease in speech comprehension at above 70 dB is noted after middle ear surgery, which results from the inflammatory damage to the inner ear, reflected by the presence of loudness recruitment. Middle ear reconstructive surgery offers the maximum improvement in speech comprehension at the hearing loss of 41-70 dB in speech audiometry. There is a correlation between severe sensorineural hearing loss and worse speech audiometry results. The severe damage caused by chronic middle ear diseases not only leads to conductive hearing loss but also acts as a significant contributor to poor speech comprehension in the long-term follow-up.

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