ORIGINAL ARTICLE

Identification of risk factors for hearing impairment in newborns: a hospital based study

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ABSTRACT

Aim To identify risk factors for hearing impairment presented in neonates born in Cantonal Hospital Zenica (CHZ) and to estimate their influence on outcome of hearing tests in Newborn Hearing Screening (NHS).

Methods Retrospective-prospective study was done at the Department of Gynaecology and Maternity. The NHS was performed with transitory evoked otoacoustic emissions (TEOAE) during a six-month period using "Titan" device (Interacoustics, Denmark). The questionnaire was written for the purpose of getting more structured basic information about every newborn and to identify risk factors for hearing impairment. Chi-square test was used to investigate the difference between experimental and control group refer incidence.

Results A total of 1217 newborns was screened for hearing impairment of which 259 (21.28%) with one or more known risk factors for hearing impairment. The following risk factors for hearing impairment were identified during the study period: family history of permanent childhood hearing impairment in 42 (3.45%) newborns, prematurity in 39 (3.21%), low APGAR scores in 29 (2.40%), asphyxia in 31 (2.55%), hyperbilirubinemia in 41 (3.37%), admission of ototoxic medication (aminoglycosides) after birth in 155 (12.74%).

Conclusion There were many serious risk factors for hearing loss identified in this study. Identification of risk factors for hearing impairment in neonates is necessary because a follow up of the children with risk factors is very important.

Key words: neonatal screening, hearing loss, otoacoustic emissions, follow up

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INTRODUCTION

Hearing is the most vital of all senses in newborns. Almost all information from surroundings newborns get by sound perception. Good hearing is crucial for the development of speech and language in children (1). Permanent childhood hearing impairment (PCHI) is a very serious health problem for every society (2). The incidence of bilateral hearing loss in newborns is 1-3 cases per 1000 live births in well baby nursery (WBN) and 2-4 per 1000 infants admitted at neonatal intensive care unit (NICU) (3).

Early diagnosis of hearing impairment in young children has been carried out through universal neonatal hearing screening (UNHS) programs in Europe since 1998 (2). In the USA in 2014, 96.1% of newborns had their hearing screened before the age of one month (4). The UNHS is based on a systematic/structured hearing assessment in newborns. The goal of the UNHS is early detection and diagnosis of permanent hearing loss in newborns. Early diagnosis is necessary for early intervention and adequate auditory rehabilitation with use of hearing aids and/or cochlear implants (CI). The importance of NHS is to start hearing rehabilitation 3-4 months after birth, enabling optimal conditions for child development (5).

In countries without an organized NHS, the average age of a child when permanent hearing loss is recognized is about 30 months (6,7). This is very late for appropriate early rehabilitation. Unfortunately, children with mild or moderate hearing impairment are usually not identified until school time in these countries (8). Neonatal hearing screening programs may be either "high risk" population based or "universal" (9). It has been proven that 50% of children with hearing impairment come from the population of children without known risk factors for hearing impairment (2).

Risk factors for the PCHI which are most commonly described in the literature are intrauterine infections, low birth weight, craniofacial malformations, bacterial meningitis, ototoxic drugs, hyperbilirubinemia (≥20mg/dl), low APGAR score (< four at first minute or < six at fifth minute), mechanical ventilation longer than five days as well as various syndromes with hearing loss (3,10). Genetic mechanisms are the most common cause of hearing loss and are represented in almost 50% of children with hearing impairment in the prelingual age (11). The incidence of permanent hearing impairment in premature infants is higher than in neonates born in the predicted term (12). Permanent hearing loss occurs in approximately 10% of prematurely born babies (13,14). Follow up of children with risk factors for hearing impairment until the age of three years is recommended (15). Therefore, identification of these children with risk factors for hearing loss in very early childhood is very important.

This study was done as groundwork for implementing a NHS program in Cantonal Hospital Zenica (CHZ). Nowadays in CHZ hearing impairment is diagnosed earliest at 2-3 years of child's age, when speech and language ability is already permanently affected. The PCHI with delayed-onset is more common in children with some known risk factors (3,5). Therefore, it is very important to identify risk factors for hearing impairment in newborns, so we can follow up those children until the age of three years according to the recommendation of the Joint Committee of Infant Hearing (5).

The aim of this study was to identify risk factors for hearing impairment which present in newborns delivered at the Cantonal Hospital Zenica and to evaluate their influence on the outcome of hearing tests during NHS. This type of the study has not been performed until now in the Cantonal Hospital Zenica.

PATIENTS AND METHODS

Patients and study design

This study was retrospective-prospective and implemented at the Department of Gynaecology and Maternity in collaboration with Ear, Nose and Throat (ENT) Department of the Cantonal Hospital Zenica (CHZ).

Newborn hearing screening (NHS) was performed in neonates born in CHZ during the six-month period from 1st February to 31st July 2016. Neonates were divided into two groups depending on whether they had a risk factor for hearing impairment or not. Newborns were placed in the experimental group with some known risk factors for the occurrence of hearing impairment or in the control group without known risk factors for hearing impairment.

Parental permission was always obtained before performing NHS. Only one mother did not allow hearing screening of her baby.

Hearing screening was performed by experienced staff of medical technicians and physicians from ENT department in CHZ.

An approval of the CHZ Ethics Committee for the implementation of all necessary procedures was obtained before the beginning of the study.

Methods

For the purpose of getting more structured information about every newborn in this study a questionnaire was designed. The initial part of the questionnaire contains contact information of a newborn's parents. The focus of the questionnaire was about pregnancy (whether it was the first pregnancy, the way of conception, use of medication during the pregnancy), way of delivery (natural way or Caesarean section); about the newborns - APGAR score (appearance/skin colour, pulse rate, grimace/reflex irritability, activity/muscle tone, respiration effort), gender, asphyxia, hyperbilirubinemia, prematurity (gestational age ≤ 36 weeks), birth weight, ototoxic medication after birth, family history of permanent childhood hearing impairment (PCHI), stay in the Neonatal Intensive Care Unit (NICU) longer than five days, craniofacial anomalies, findings associated with a syndrome known to include hearing loss and the presence of other known risk factors for hearing impairment in the newborn.

The questionnaires were filled out by the examiners for each newborn. The data were taken from protocols of the Department of Gynaecology and Maternity and by interviewing the mothers. All data were saved into an Excel database for further evaluation.

Diagnostic methods. Transient evoked otoacoustic emissions (TEOAE) with automatic display of results, without the need of evaluation of the test results by the clinician, was used for NHS. That is most commonly used method for initial hearing test in NHS. This method is safe and harmless for newborns with a high percentage of specificity and sensitivity (16).

The TEOAE is an objective, non-invasive diagnostic method with very short time of performance, from a few seconds to a maximum of a few minutes. The TEOAE test primarily shows the status of the outer hair cells in the inner ear. The TEOAE test has been performed by inserting a probe with soft tip into the ear of the newborn. The probe is equipped with a small speaker and a microphone. A click sound stimulus characteristic for the TEOAE test is emitted from the speaker. Those sounds cause movements of the basilar membrane in the cochlea and that excite outer hair cells to generate sound. These newly generated sounds, otoacoustic emissions (OAE) are recorded with a microphone placed in the probe in the external auditory channel.

The "Titan" device (Interacoustics, Denmark) has been used. The device automatically evaluates the result of the test based on predefined test parameters (test length, the required OAE signal strength at individual frequencies, satisfactory signal to noise ratio, signal reproducibility). The result "pass" appears on display if OAEs are recorded in the ear as normal finding. If OAEs are not recorded in the ear, the test result that appears on display is "refer".

Statistical analysis

The data were recorded in the original program "Ottoacces" by "Interacoustics" and subsequently copied and processed in the Microsoft Excel database. Standard descriptive methods of statistics were used. The $\chi 2$ test was used to investigate the difference between experimental and control group. The significance level for all statistical tests was set at the p value < 0.05. IBM-SPSS version 20.0 was used for the statistical analysis.

RESULTS

A total of 1217 neonates were screened for hearing impairment during the period of six months, from 1st February to 31st July 2016. Neonates were placed at the Well Baby Nursery (WBN), 930 (76.42%) or at the Neonatal Intensive Care Unit (NICU), 287 (23.58%) depending on their health conditions.

Depending whether the neonates have risk factors for hearing impairment or not, they were divided in two groups regardless of where they were placed, at the NICU or WBN. There were 44 (16.99%) more male newborns with risk factors for hearing impairment noted during the study period (Table 1).

Table 1. Distribution of newborns with or without risk factor (RF) for hearing loss according to gender

Group of neonates	No (%) of neonates			
	Total	Males	Females	Gender missed to note
With RF	259 (21.28)	151 (58.30)	107 (41.31)	1 (0.39)
Without RF	958 (78.72)	491 (51.25)	466 (48.64)	1 (0.11)
Both groups	1217 (100)	642 (52.75)	573 (47.09)	2 (0.16)

Risk factors for hearing impairment identified in the study included family history of permanent childhood hearing impairment (PCHI), prematurity, low APGAR score, asphyxia, hyperbilirubinemia, admission of ototoxic medication after birth, stay at the NICU longer than five days, low birth weight, craniofacial anomalies, findings associated with a syndrome known to include hearing loss. There were 259 (21.28%) of the total number of screened newborns with one or more known risk factors for hearing impairment (Table 2).

Family history of hearing impairment. From 259 newborns with risk factors for hearing impairment there were 42 (16.22%) families with known heredity for PCHI. There were 16 (38.10%) relatives with impared hearing from the father's side and 26 (61.90%) relatives with impaired hearing from the mother's side.

A total of 223 (19.10%) out of 1217 newborns had the 'refer' result on the first hearing screening. There were seven (3.13 %) neonates in this group with 'refer' result on the first hearing test, three (42.86%) on both ears, one (14.29%) on the right ear only, and three (42.86%) on the left ear only. On the second hearing test six (85.71%) of those newborns had the 'pass' result and one (14.29%) newborn was lost for the follow up (did not complete the next hearing test).

Prematurity. Prematurity was documented in 39 (15.06%) out of 259 newborns with the risk factor for hearing impairment. The youngest premature newborn was born in the 32nd week of pregnancy. There were 10 (4.48 %) neonates in this group with the 'refer' result on the first hearing test (of all 223 newborns with the 'refer' result). 'Refer' results on both ears were recorded in five (50%) newborns, one (10%) on the right ear only and four (40%) were with the 'refer' result on the left ear only. On the second hearing test, four (40%) of those newborns had the 'pass' result and three (30%) had the 'pass' result on the third hearing test. Three (30%) newborns were lost for the follow up.

APGAR scores ≤ four at first minute or ≤ six at fifth minute. APGAR score was not noted in eight (0.66%) out of the 1217 newborns. Among 1209 newborns whose APGAR score was noted, 29 (2.40%) had a low score, while the lowest APGAR score was two in the first and five in the fifth minute. There were five (2.24%) neonates in this group with 'refer' result on the first hearing test of all with the 'refer' result. The 'refer' result on right ear only was noted in three (60%) newborns, two (40%) newborns were with the 'refer' result on the left ear only. On the second hearing test four (80%) of those newborns had the 'pass' result and one (20%) newborn was lost for follow up.

Asphyxia. In the study there were 31 (2.55%) out of 1217 newborns with diagnosed asphyxia. All newborns diagnosed with asphyxia were admitted in NICU. There were five (16.13%) neonates in this group who had the 'refer' result on the first hearing test of all with the 'refer' result. The 'refer' result on both ears was recorded in two (40%) newborns, one (20%) newborn had the 'refer' result on the right ear only and two (40%) were with the 'refer' result on the left ear only. On the second hearing test four (80%) of

Table 2. Distribution of risk factors for hearing impairment in neonates according to gender and results of the hearing tests

Risk factors	No (%) of neonates						
	Total	Males	Females	Refer result of the test 1	Refer result of the test 2	Refer result of the test 3	Lost to follow-up
Family history of permanent childhood hearing loss	42 (3.45)	23 (54.76)	19 (46.24)	7 (16.67)	1 (2.38)	0 (0)	1 (2.38)
Prematurity	39 (3.21)	20 (51.28)	19 (48.72)	10 (25.64)	6 (15.38)	3 (7.69)	3 (7.69)
Apgar scores of ≤4 in first minute or ≤6 at fifth minute;	29 (2.40)	19 (65.52)	10 (34.48)	5 (17.24)	1 (3.45)	0 (0)	1 (3.45)
Asphyxia	31 (2.55)	22 (70.97)	9 (29.03)	5 (16.13)	1 (3.23)	0 (0)	1 (3.23)
Hyperbilirubinemia	41 (3.37)	27 (65.85)	14 (34.15)	6 (14.63)	1 (2.44)	0 (0)	1 (2.44)
Ototoxic medications	155 (12.74)	92 (59.35)	63 (40.65)	23 (14.84)	4 (2.58)	0 (0)	4 (2.58)
NICU Stay ≥ 5 days	125 (10.27)	76 (60.80)	49 (39.20)	30 (24.00)	9 (7.2)	0 (0)	9 (7.2)
Birth weight	28 (2.30)	13 (46.43)	15 (53.57)	12 (42.86)	3 (10.71)	0 (0)	3 (10.71)
Craniofacial anomalies	1 (0.08)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)
Findings associated with a syndrome known to include hearing loss	1 (0.08)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)

those newborns had the 'pass' result and one (20%) newborn was lost for follow up.

Hyperbilirubinemia. There were 41 (3.37%) out of 1217 neonates with diagnosed hyperbilirubinemia. Phototherapy was performed for seven (17.07%) out of 41 newborns. Therapy with blood exchange transfusion was not required in any of the neonates. There were six (2.69%) neonates in this group with the 'refer' result on the first hearing test of all with the 'refer' result. The 'refer' result on both ears was obtained in one (16.67%) newborn, two (33.33%) newborns had the 'refer' result on the right ear only and three (50%) newborns had the 'refer' result on the left ear only. On the second hearing test five (83.33%) of those newborns had the 'pass' result and one (16.67%) newborn was lost to follow up.

Ototoxic medications. Gentamycin (aminoglycosides) is the only ototoxic medication that was used for the treatment of newborns in the study period. A total number of 155 (12.74%) from 1217 screened neonates was treated with gentamycin (Table 3). There were 23 (10.31%) neonates in this group with the 'refer' result on the first hearing test of all with the 'refer' result. The 'refer' result on both ears were found in four (17.39%) newborns, eight (34.78%) newborns had the 'refer' result on the right ear only and 11 (47.83%) were with refer result on the left ear only. On the second hearing test 19 (82.61%) of those newborns had the 'pass' result and four (17.39%) newborns were lost for the follow up.

Table 3. Duration of gentamycin therapy in neonates in neonatal intensive care unit (NICU) and well-baby nursery (WBN)

Gentamycin therapy duration	No (%) of neonates		
	NICU	WBN	Total
>five days	42 (14.64)	4 (0.42)	46 (3.78)
Five days	25 (8.71)	13 (1.40)	38 (3.12)
< five days	37 (12.89)	34 (3.66)	71 (5.84)
Total	**104 (36.24)**	**51 (5.48)**	**155 (12.74)**

Newborns who stayed in NICU for five days and longer. There were 125 (10.27%) out of 1217 neonates who were in NICU for five days and longer. There were 30 (13.45%) neonates in this group with the 'refer' result on the first hearing test of all with the 'refer' result. The 'refer' result on both ears was found in six (20%) newborns, six (20%) newborns had the 'refer' result on the right ear only and 18 (60%) newborns were with the 'refer' result on the left ear only. On the second hearing test 21 (70%) of those newborns had the 'pass' result and nine (30%) newborns were lost for the follow up.

Low birth weight (LBW). The lowest birth weight of all newborns recorded in this study was 1600 g and the highest one was 5460 g (mean value 3485.44; SD±498.99). The birth weight less than and equal to 2500 g was documented in 28 (2.30%) newborns. One (3.57%) newborn was in WBN with birth weight 2500 g while 27 (96.43%) were at the NICU. Of these 27 newborns, three (11.11%) were with a birth weight below 2000 g (1880 g, 1830 g and 1600 g, respectively). There were 12 (5.38%) neonates in this group with the 'refer' result on the first hearing test of all with the 'refer' result. The 'refer' result on both ears was recorded in four (33.33%) newborns, five (41.67%) newborns had the 'refer' result on the right ear only and three (25%) were with the 'refer' result on the left ear only. On the second hearing test nine (75%) of those newborns were with the 'pass' result and three (25%) newborns were lost for the follow up.

Craniofacial anomalies. Cleft lip without cleft of the palate was found in one male newborn. On the first hearing test in this newborn the 'refer' result on the left ear only was noted. On the second hearing test the result was 'pass' on both ears.

Findings associated with a syndrome known to include hearing loss. Polydactyly of the right hand (*polydactilia mani dextri*) was the only anomaly noted. On the first hearing test in this newborn 'pass' result on both ears was noted.

A total of 223 (19.10%) newborns were with the 'refer' result on the first hearing screening test, of which in the experimental group there were 99 (44.40%) newborns and in control group there were 124 (55.60%) newborns. From all 259 newborns in the experimental group 99 (38.22%) were with the 'refer' result on the first hearing test. In the control group there were 958 newborns and 124 (12.94%) of them had the 'refer' result on the first hearing test ($p<0.001$).

The frequency of the 'refer' results within each of the groups with a certain risk factor for hearing impairment (e. g. prematurity - 10 newborns with the 'refer' result of 39) did not show statistical significance.

A total of 85 (38.12%) out of 223 newborns with the 'refer' result on the first hearing screening were lost for the follow up, of which in the expe-

rimental group there were 22 (25.88%) and 63 (74.12%) in control group. Loss to follow up in the experimental group was 8.49% and 6.58% in the control group.

DISCUSSION

It has been estimated that approximately 10 to 12% of newborns have a risk factor for hearing impairment and 2.5 to 5% have sensorineural hearing loss (9). In this study 259 (21.88%) newborns with the risk factors for hearing impairment have been identified. Some of the neonates were with more than one of the known risk factors for hearing impairment.

Reportedly, gender does not affect hearing outcome (3), which is confirmed in our study.

The family history of hearing loss was identified in 3.45% of newborns in this study, with 3.13 % newborns with the 'refer' result on the first hearing screening. Similar results were reported previously (1.4%, 2.62% and 3%) in studies from India (17, 18, 19). The conclusion of a large retrospective study was that children with a family history of hearing loss should be followed up during the childhood even after good (pass) results on the NHS (20).

A total of 3.21% premature newborns (gestational age ≤ 36 weeks) was noticed in this study, of which almost 25% were with the referring result, and all of them were with the 'pass' result on both ears after the third hearing test. Regina et al. study showed that almost 2% of premature newborns had hearing impairment (18). A study by Sun et al. showed 34.09% of diagnosed hearing impairments in the premature infant group (21). In a systematic review by Beswick et al. prematurity was recognized as a risk factor for hearing impairment (22).

Low APGAR score was identified in 2.40% of newborns in this study. Regina M et al., Gouri et al. and Maqbool et al. reported a frequency of hearing impairment of 10.52%, 16.7% and 12.5%, respectively in newborns with low APGAR score, concluding that APGAR score ≤5 in the first minute was a significant risk factor for hearing impairment (3,18,19). Results from Vohr et al. showed low APGAR scores in 13.9% of newborns in the NICU and in 2.8% newborns in WBN (23). In our study only 3.45% (one newborn) with low APGAR score was at the WBN and 96.55% were at the NICU.

Asphyxia was identified in 2.55% of newborns in our study. In a systemic review by Borg et al. asphyxia at birth was not correlated with hearing loss in babies with complicated deliveries (24). The same conclusion was made by Regina et al. (18). Quite the opposite Sun et al. registered asphyxia in 40% of newborns with diagnosed hearing loss (21). Also Hille et al. reported severe birth asphyxia as independent risk factors for hearing loss in neonates (25).

In our study hyperbilirubinemia was identified in 3.37% of newborns. Sensory neural hearing loss and auditory neuropathy spectrum disorder may occur due to hyperbilirubinemia because of induced neurotoxicity (26). Hyperbilirubinemia in 26.37% of newborns with hearing impairment was reported in the literature (21). In the study from India 30% of children with suspected hearing loss were with diagnosed hyperbilirubinemia (3).

Ototoxic medications exposure was the major risk factor identified in this study. More than half of the newborns with the risk factor for hearing impairment received ototoxic medication during this study. In a study by Zamani et al. majority of diagnosed hearing impaired children were treated with ototoxic medication and with hyperbilirubinemia as a risk factor (27). In the study by Mayer et al. most of the children with diagnosed hearing impairment were with low birth weight (<1500 g) and exposure to ototoxic medication as a risk factor for hearing impairment (28). Results in a study from China showed that 41.30% of newborns with hearing impairment received ototoxic medicines (21). In our study 12.74% of neonates received gentamycin and more than half of the newborns treated with ototoxic medication received this therapy for at least five days. Similar results were published in a study from India where 45% of neonates referred to tertiary care hospital because of suspected hearing loss were treated with ototoxic medicines for longer than five days (3).

In the presented study 10.27% of newborns were in the NICU for five days and longer, which was almost half (43.55%) of all newborns who were placed in the NICU. In guidelines from the Join Committee of Infants Hearing (JCIH) staying at the NICU longer than five days is confirmed as a risk factor for hearing impairment (5). In a study by Regina et al. 68.42% of hearing impaired newborns were at the NICU for more than 24

hours suggesting that admission to the NICU for more than 24 hours is a significant risk factor for hearing impairment among neonates (18). Length of newborns' stay at the NICU should be seriously observed regarding the follow up after NHS.

Birth weight less than 1500 g is considered to be a risk factor for the occurrence of hearing loss (5). Newborns included in this study had birth weight greater than 1500 g with lowest birth weight of 1600 g. Regina et al. reported 28.94% of hearing impaired newborns with birth weight <1500 g (18), Vohr et al showed low birth weight in 17.8% of newborns with hearing impairment (23). On the other hand, in a study by Ohl et al. birth weight < 1500g together with premature birth (< the 34th week of pregnancy) did not show a statistically significant impact on hearing loss (29).

Craniofacial anomalies were identified in 0.08% of newborns in our study. Craniofacial anomalies are an important risk factor for conductive hearing loss (29). In a study from India 5% of all children referred to tertiary care referral hospital because of suspected hearing impairment had craniofacial anomalies (3). Anomaly of the right hand in 0.08% (one) of newborns was found in our study. This anomaly can occur in Wardenburg syndrome type III (Klein-Wardenburg syndrome) and it is well known that hearing impairment might be one of the symptoms in this syndrome (30).

In this study 11.2% more newborns with the 'refer' result on the first hearing test were in the control group of newborns (the group without risk factors for hearing impairment) indicating that risk factors for hearing impairment had an influence on the outcome of the first hearing test in the NHS. It is very possible that the time of performance of the test (31) and the presence of amnion liquid or debris in ear canal or in middle ear (32) could play an important role for high 'refer' result too.

The results of Yoshikawa et al. have shown that infants with congenital infection, chromosomal aberration and central nervous system abnormality had a significantly higher incidence of the 'refer' results in hearing screening; authors did not find a statistically significant difference between the pass and the refer groups in the NICU, birth weight (<2200 g), gestational age, the values of total serum bilirubin, Apgar score and ototoxic drug use (14).

A limitation of the study was relatively short time of the study period and a relatively small sample. Further studies, with lager sample size, are needed for better insight in the importance of hearing assessment in newborns with risk factors for hearing impairment. The lack of experience in the NHS diagnostic procedures was another limiting factor in this study, since until now the NHS was not performed in the Cantonal Hospital Zenica. Many infants who were lost for follow-up due to lack of legal obligation of the parents to bring their newborns to the next hearing tests was another limitation in the study.

In conclusion, many serious risk factors for hearing loss are identified in this study, which is of great importance because the follow-up of the children with risk factors is very important. Our data indicate that risk factors for hearing impairment have influence on the outcome of the first hearing test in the NHS. The use of ototoxic medication and length of stay at the NICU as major identified risk factors for hearing impairment in this study should be seriously observed in the future.

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TRANSPARENCY DECLARATION

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