ORIGINAL ARTICLE

ABSTRACT

Hearing loss associated with repeated MRI acquisition procedure-related acoustic noise exposure: an occupational cohort study

Suzan Bongers,¹ Pauline Slottje,^{1,2} Hans Kromhout¹

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¹Division of Environmental Epidemiology, Institute for Risk Assessment Sciences, Utrecht University, Utrecht, The Netherlands ²Department of General Practice and Elderk Car VII University

and Elderly Car, VU University Medical Centre, Amsterdam, The Netherlands

Correspondence to

Professor Hans Kromhout, Division of Environmental Epidemiology, Institute for Risk Assessment Sciences, Utrecht University, P.O. Box 80.176, 3508 TD, Utrecht, The Netherlands; h.kromhout@uu.nl

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Objective To study the effects of repeated exposure to MRI-related acoustic noise during image acquisition procedures (scans) on hearing.

Methods A retrospective occupational cohort study was performed among workers of an MRI manufacturing facility (n=474). Longitudinal audiometry data from the facility's medical surveillance scheme collected from 1973 to 2010 were analysed by studying the association of cumulative exposure to MRI-related acoustic noise from voluntary (multiple) MRI scans and the hearing threshold of the volunteer.

Results Repeated acoustic noise exposure during volunteer MRI scans was found to be associated with a small exposure-dependent increased rate change of hearing threshold level (dB/year), but the association was only found related to the number of voluntary MRI scans and not to modelled cumulative noise exposure (dB*hour) based on MRI-system type. The increased rate change of hearing threshold level was found to be statistically significant for the frequencies 500, 1000, 2000, 3000 and 4000 Hz in the right ear.

Conclusions From our longitudinal cohort study, it appeared that exposure to noise from voluntarily MRI scans may have resulted in a slight amount of hearing loss. Mandatory use of hearing protection might have prevented more severe hearing loss. Lack of consistency in findings between the left and right ears and between the two exposure measures prohibits definitive conclusions. Further research that addresses the study's methodological limitations is warranted to corroborate our findings.

INTRODUCTION

MRI is a rapidly developing diagnostic technology with a development towards higher static magnetic field (SMF) strength systems and increased application worldwide¹⁻³ and in the Netherlands.⁴ SMFs are constant fields (having a frequency of 0 Hz), which do not change in intensity or direction over time, in contrast to low and high frequency alternating fields.⁵ MRI equipment and magnetic resonance (MR) procedures have been developed and employed in clinical and research settings for more than 30 years. Technology has evolved continuously, resulting in increases in SMF strength and in stronger switched gradient magnetic fields (SGMFs).⁶ SGMFs are produced during an image acquisition procedure when the current in the gradient coils is switched on and off rapidly, causing

What this paper adds

- Current (patient) exposure limits for acoustic noise levels during MRI procedures are based on recommendations for hearing loss prevention based on the risk for permanent noise-induced hearing loss caused by long-term occupational exposures, while exposure during an MRI procedure may be relatively short and incidental.
- This retrospective occupational cohort study focused on effects from (cumulative) short-term exposure to acoustic noise related to MRI image acquisition procedures.
- MRI-related acoustic noise exposure was found to be associated with a small exposuredependent increased hearing threshold.
- Further research efforts focusing on effects of MRI-related acoustic noise exposure on hearing are warranted to corroborate these findings.

in turn quick changes in amplitude and polarity of the gradient magnetic fields. Activating the SGMF constitutes the main source of MRI-related acoustic noise that can be at levels above 99 dB(A), exceeding exposure limits for patients and repeated exposure may lead to permanent hearing impairment.⁷

The largest groups of MRI-related noise-exposed workers are found in clinical and research settings where MRI techniques are being applied.⁴ Technicians and engineers developing and producing MRI-systems are presumed to be at higher risk of MRI-related exposure, since they may spend more time near MRI-systems⁸ and may be exposed to higher noise levels as special sound insulation measures,^{7 9} if applicable to system type, may not yet be in place in functional systems during the production process. To reduce exposure to acoustic noise, these workers are instructed to, when possible, leave the MRI room during an image acquisition procedure (hereafter referred to as a scan). During a scan the SGMF is applied and workers are instructed to wear hearing protection devices (HPDs) as required. Subjects of MRI scans (ie, patients or volunteers) are considered to experience the highest acoustic noise exposure levels as they have to remain stationary within the bore of the MRI-system. To study the potential hearing effects of repeated MRI-related acoustic noise exposure, a retrospective occupational cohort study



was initiated among workers of an MRI manufacturing facility, who volunteered for scans during the development and manufacturing of MRI-systems.

A temporary threshold shift¹⁰ and decreased otoacoustic emissions¹¹ were found after a single exposure to MRI-related noise, but this is the first study to focus on long-term hearing effects associated with (repeated) MR-volunteer scan-related noise exposure.

METHODS

Study population

Workers of a medical imaging device manufacturing facility in the Netherlands were selected using historical company records on employment, participation in MR-volunteer scans and occupational health examinations. The cohort was defined as all workers who had been employed at the manufacturing facility for at least 1 year (365 days) between 1984 (year of inception of the facility's MR-business unit) and 2010 and had at least one MR-volunteer scan recorded. MR-volunteers could be employed at all business units of the manufacturing facility and not only at the MR-business unit. Workers with at least two complete audiometry measurement records with at least 2 years between the first and final measurement were selected for the current analyses (n=474). (See figure 1 and the Audiometry section for further details.)

Data from occupational health examinations

Historical medical records from the manufacturing facility's health surveillance scheme were analysed to assess whether workers exposed to MRI-related acoustic noise may show increased hearing threshold levels (HTLs) over time. Data from the following two types of occupational health examinations were used for analyses:

- 1. MR-related periodic occupational health examinations (MRrelated examination) for certain categories of workers of the MR-business unit and for workers who underwent MRvolunteer-scans.
- 2. Periodic occupational health examinations for workers aged 50 and up (age-related examination).

From the onset of MRI production in 1984, the manufacturing facility has provided periodic examinations for its workers working in the vicinity of MRI-systems or acting as MR-volunteers.

MR workers categorised by the manufacturing facility as high exposed (\geq 4 hours/week) and low exposed (<4 hours/week) to MRI-related SMF received an MR-related examination on start and termination of holding an SMF exposed job. In addition to examinations on start and termination, high exposed workers also received an examination every 2 years until mid '90s and every 3 years from then onwards. MR-volunteers received examinations similar to high SMF exposed workers every 2–3 years, and in addition after undergoing 40 MR-volunteer scans. The purpose of the MR-related examinations was to offer auditory testing to MRI-related acoustic noise exposed workers and to monitor the health of SMF exposed workers as a precaution.

All workers of the manufacturing facility aged 50 years or higher were offered voluntary health examinations every 2–4 years. Age-related examination records from MR-volunteers were included in this study.

All of the above-mentioned examinations were performed by a trained occupational physician or nurse in the service of an external Health and Safety Service commissioned by the manufacturing facility. Aside from audiometric testing, the examination included blood cell count, cardiac rhythm (ECG, heart rate), systolic and diastolic blood pressure, height and weight and lung function (age-related examinations only); however, only records on audiometry, blood pressure, height and weight were sufficiently comprehensive for longitudinal analyses.

From the mid-90s, data from the health examinations were entered directly into an electronic database. The paper medical records from 1970 until the mid-90s were manually entered into the digital database between 2009 and 2010 for the purpose of this study. To account for human error during data entry, all data in the digital database were screened for anomalous values. Records with possible entry errors were manually compared with the original paper records and corrected when necessary.

Audiometry

Audiometry was carried out by an occupational nurse in a sound-attenuating booth (background noise <20 dB(A)) present at the occupational physician's office. No information was available on the differences in equipment used over time. Workers had to have had no exposure to a noisy environment up to 30 min prior to the test and workers with a non-removable (cochlear or other hearing) implant were excluded from audiometric tests. The threshold of hearing, the minimum sound level an ear can hear with no other sound present, was measured for pure tone frequencies of 0.5, 1, 2, 3, 4, 6 and 8 kHz in each ear. Measurements started with the right ear unless hearing in the left ear was known to be better and commenced with the other ear after completing measurements of all seven frequencies.

A total of 474 workers, of which 57 (12%) were female workers, had at least two audiometric tests with ≥ 2 years between the earliest and the final measurement record. A minimum of 2 years between measurements was *a priori* chosen for the main analyses, because MR-related examinations took place at 2–3 years interval.

To account for loss of hearing caused by ageing, the age at first audiometric test was included in the analyses. The annual change in HTL (Δ dB/year) was estimated for each measured frequency by subtracting the HTL value of the first record from the HTL value of the final record (Δ dB) and subsequently dividing it by the number of years between the first and final record.

MR-volunteer acoustic noise exposure

In order to estimate MRI-related acoustic noise exposure for MR-volunteers, the different sound pressure levels (SPLs) resulting from the operating MRI-system was taken into account. The acoustic noise is the result of electromagnetic forces on the conductors of the gradient coil and the sound level is different (higher) for MRI-systems with a higher SMF and/or with a stronger gradient system installed.³⁷¹² The position of the subject inside the bore of the MRI-system, and the type of image acquisition sequences run on the MRI-system during a scan influence the SPL.³⁶⁷ Variation over time of the MRI-system type and gradient power was difficult to determine retrospectively, and therefore an average value for the SPL per system type was used as a proxy for the complex noise exposure. On current (2016) systems, the expected SPL is displayed in the user interface of those systems, but this was not available for older systems nor recorded during each MR-volunteer scan.

To protect workers and patients, the exposure limit of SPL produced by an MRI-system is regulated. Exposure of MR-volunteers was assumed to be equal to that of patients and MR-volunteers had the same exposure limit set as patients; 99 dB(A) is the maximum average sound level at a patient's



Figure 1 The composition of the magnetic resonance (MR)-volunteer population among workers of an MRI manufacturing facility with at least one scan recorded up to and including 2010 (n=968). From these, MR-volunteers with at least two complete audiometric tests with at least 2 years between the first and final measurements (n=474) from examination records were selected for the main analysis. Of this main analytical sample, 237 had additional self-reported questionnaire data available on confounders and were included in subgroup analyses. Sensitivity analyses were performed on MR-volunteers with at least 1 year and at least 3 years between audiometric tests, respectively. Numbers in percentages reflect the portion of the original MR-volunteer population (n=968).

ear allowed by the basic safety standard for medical devices IEC 60601-2-33,¹³ which takes into account the short exposure time (average of 1 hour) and the non-daily character of patient exposure.

Date, duration, MRI-system type and additional comments when appropriate of each MR-volunteer scan were registered as part of the MR-volunteer programme and MR-volunteer scan records were provided by the manufacturing facility. The duration of an MR-volunteer scan was 1 hour for 71% of the scans and was set to 1 hour for scans with missing duration (13% of scans). The duration of 12.5%–2.5% of scans was respectively less than or more than 1 hour. Data on system type were missing for 13% of relevant scan entries and the missing data were imputed with an average maximum noise exposure level based on annual production numbers, provided by the manufacturer, on different system types of the year corresponding with that of the scan date.

Two measures of MR-volunteer-related noise exposure were used:

1. Cumulative MRI-related acoustic noise exposure (dB*hour)

2. Cumulative number of MR-volunteer scans

Cumulative exposure to noise was calculated, using energetic dB addition.¹⁴ For this study, the 3 Tesla (T) cylindrical MRI-system was taken as reference for which the maximum allowed average exposure level during a scan of 1 hour was set at 99 dB(A). Based on field strength, structure (cylindrical or open) and the time period of system production, an estimated average maximum SPL of a routine clinical scan procedure was established as follows per system type:

3 T cylindrical system: $L_{Aeq, 1h} = 99 \text{ dB(A)}$ (REF)

1.5 T cylindrical system: $L_{Aeq, 1h} = REF-3 dB(A) = 96 dB(A)$ 1.0 T cylindrical/open system: $L_{Aeq, 1h} = REF-6 dB(A) = 93 dB(A)$ 0.5 T: cylindrical system: $L_{Aeq, 1h} = REF-9 dB(A) = 90 dB(A)$ Individual cumulative noise exposure (dB*hour) was esti-

mated by first summation of SPLs of all MR-volunteer scans up to and including the year of final audiometric test. Consequently, log₁₀ of the sum of all relevant scan sound pressure values was estimated:

cumulative MR volunteer noise exposure =
$$10 * log_{10} \left[\sum_{i=1}^{n} ti \left(\frac{L_{Aeqi}}{10} \right) \right]$$

Where n is the total number of scans until the end of the year of final examination, ti is the duration of individual scan i in hours, and LACO is the estimated 1 hour A-weighted root mean square value (RMS) of SPL related to the system type used for scan i.

From the onset of the MR-volunteer programme and during every scan procedure, MR-volunteers wore mandatory HPDs consisting of earmuffs, which were sometimes, but not always, supplemented with inserted earplugs to reduce acoustic noise exposure. The use of earplugs in addition to earmuffs was mandatory for MRI-systems with a magnet strength of 3 T (strongest MRI-system type produced at the manufacturing facility during the study period). The attenuation of earmuffs was specified by the manufacturer as 20 dB(A) and as 28 dB(A) for earplugs. Combined use was estimated to offer an additional reduction up to 3 dB(A). In practice, the attenuation of the HPDs will have been dependent on the proper fit and maintenance of the devices¹⁵ and may have been less than reported by manufacturers of these devices.¹⁶

Due to uncertainty regarding efficiency of HPD use and application, hearing protector attenuation was considered equal for all MR-volunteers. When assuming adequate attenuation through the use of HPDs, the cumulative number of MR-volunteer scans was considered a reasonable proxy for a best case scenario in which average acoustic noise levels would be reduced to below 99 dB(A). Estimated cumulative noise exposure (cumulative dB*hour) of MR-volunteer scans reflected a worst case scenario as it was based on a maximum noise average exposure level driven by magnet strength, and was not adjusted for possible protective effects of hearing protection.

Supplemental data on smoking behaviour, alcohol consumption and use of HPDs

Data on potential confounders were collected through a questionnaire among current and former MR-volunteers in 2010 and 2011.¹⁷ Figure 1 shows that 237 MR-volunteers with ≥ 2 vears between first and final audiometric test had complete questionnaire records on smoking behaviour, alcohol consumption and self-reported exposure to occupational noise and use of HPDs.

A smoker was defined as a person who reported having smoked more than 100 cigarettes (approximately five packages) in their lifetime. An average number of cigarettes smoked per day or week was reported over 10-year age periods (aged ≤ 19 , 20–29, 30–39, 40–49, 50–59 and ≥ 60 years) and an average number of pipes smoked per day or week over all years of age was reported. One pipe was considered equivalent to 2.5 cigarettes.¹⁸ Reported starting and (when applicable) quitting age of smoking were combined with reported smoking rates to estimate (cumulative) pack-years ((number of cigarettes smoked per day/20)×number of years smoked) up until the end of the year of final audiometric test. The estimated pack-year value did not account for periods of smoking cessation as no information was available on duration and time period of cessation.

Alcohol consumption was assessed for workers who reported consuming alcoholic beverages at least once a month. Thirty-one workers reported no alcohol consumption. Data were collected on starting and (if applicable) quitting age and the number of units of alcoholic beverages consumed on average per week at specific age periods (aged ≤ 19 , 20–39, 40–59 and ≥ 60 years). See ref. 17 for a detailed description of alcohol unit count of different beverages. A count of 1 to ≤ 14 units/week was scored as low alcohol consumption and a count of >14 units/week was scored as high alcohol consumption. The cumulative number of years of self-reported low and high alcohol consumption was estimated up until the end of the year of final audiometric test. Years of low and high alcohol consumption were set to 0 for workers reporting no alcohol consumption.

The questionnaire-based self-reported job history records included information on jobs held at the manufacturing facility and elsewhere, whether each individual job was performed in a noisy environment and, if yes, whether HPDs (ie, earmuffs or earplugs) were used always, sometimes or never while working in a noisy environment. The cumulative number of years working in a noisy environment while always, sometimes or never using HPDs was estimated up until and including the year of final audiometric test.

Statistical analyses

One-sample binominal test and one-sample median test were applied to compare binominal and continuous data on characteristics, respectively, between the original MR-volunteer population and the subpopulations used for further analyses.

The main analysis performed in the main analytical sample (n=474) consisted of two linear regression models, which were used to assess the association between change in HTL per year $(\Delta dB/y)$ and either cumulative MR-volunteer noise exposure (dB*hour) or cumulative number of MR-volunteer scans. Two sensitivity analyses were performed to explore the influence of the minimal time between first and final audiometric test, comparing the regression results of the main analytical sample (cut-off ≥ 2 years between first and final audiometric test) with a less or a more restrictive cut-off (≥ 1 year (n=496) and ≥ 3 year (n=441)) (figure 1).

Subpopulation analysis was performed in the subpopulation with additional questionnaire data to explore potential confounding (comparing within this subgroup linear regression results adjusted for smoking, alcohol consumption and self-reported occupational noise exposure and use of HPDs while at work with unadjusted results.

Analyses were performed with SAS V.9.2 (SAS Institute, Cary, North Carolina, USA) and a p value of <0.05 was considered to be statistically significant.

Workplace

Table 1 Characteristics of MR-volunteer population (n=968) with \geq 1 scan record up until and including 2010 and the populations used for analyses: MR-volunteers with \geq 2 years between first and final audiometric test (n=474) and the subpopulation with addition data on confounders (n=237). Percentages indicate a proportion within each (sub)population

	Original MR-volunteer population: MR-volunteers with≥1 recorded scan	Main analytical sample: MR-volunteers with≥1 scan and≥2 years between first and final audiometric test	Subgroup analytical sample: MR-volunteers with≥1 scan, ≥2 years between first and final audiometric test and additional data on confounders
N° (% total MR-volunteer population)	968 (100%)	474 (49%)	237 (24%)
Male, N° (%)	820 (85%)	417 (88%)	208 (88%)
Age at first MR-volunteer scan, median (range)	37 (18–62)	37 (19–59)	38 (25–58)
Year of birth, median (range)	1969 (1932–1987)	1959 (1936–1985)***	1958 (1936–1985)***
Age at first audiometric test, median (range)	-	36 (17–58)	36 (18–56)
Age at last audiometric test, median (range)	-	47 (24–65)	47 (24–65)
Time between first and last audiometric test, median (range)	-	7.1 (2.0–36.2)	8.6 (2.0–36.2)*
Number of MR-volunteer scans until end of year of last audiometric test, median (range)	-	22.5 (1–177)	30 (1–177) *
Cumulative noise exposure from MR- volunteer scans (dB*hour) until end of year of last audiometric test, median (range)	-	109.3 (99.0–118.1)	110.3 (90.0–118.1) *
N° (ever) Smokers, (%)	-	-	108 (46%)
Pack-year, median (range)	-	-	9.6 (0.1–56)
N° MR-volunteers reporting low alcohol consumption, (%)†			189 (80%)
Years of low alcohol consumption, median (range)	-	-	15 (1–39)
N° MR-volunteers reporting high alcohol consumption, (%)†			61 (26%)
Years of high alcohol consumption, median (range)	-	-	11 (2–32)
N° MR-volunteers reporting occupational exposure to noise+no use of HPD			16 (7%)
Years occupational exposure to noise+no use of HPD	-	-	4.5 (1–22)
N° MR-volunteers reporting occupational exposure to noise+sometimes use of HPD (%)			21 (9%)
Years occupational exposure to noise+sometimes use of HPD	-	-	3 (1–31)
N° MR-volunteers reporting occupational exposure to noise+always use of HPD (%)			24 (10%)
Years occupational exposure to noise+always use of HPD	-	-	3.5 (1–21)

*p<0.05, one-sample median test between the study main analytical sample and the subgroup analytical sample, ***p<0.001 one-sample median test between the main analytical sample or the subgroup analytical sample and the original MR-volunteer population, †The categories of workers reporting low and high alcohol consumption are not mutually exclusive since it was possible for workers to both report periods with low and periods with high alcohol consumption.

RESULTS

Population characteristics

Figure 1 shows the size of the original MR-volunteer population at the manufacturing facility and the subpopulations used for analyses and table 1 shows the characteristics of these populations for age, gender and MRI-related noise exposure.

The main analytical sample and the subpopulation with additional data on confounders both appeared to be older in general (based on birth year) when compared with the original MR-volunteer population, but no statistical difference was observed for the age at first MR-volunteer scan. The subpopulation with additional data on confounders had on average a higher amount of noise exposure (cumulative dB*hour and number of scans) and more time between audiometric tests when compared with the main analytical sample, although the differences are small. Incomplete medical records and missing data contributed to the subpopulation size of <50% of the original MR-volunteer population and the questionnaire providing additional confounder data had a 50% participation rate among MR-volunteers,¹⁷ but the study populations appeared to be a representative sample of the original population based on gender distribution and age at first MR-volunteer scan.

Acoustic noise exposure and hearing loss

No significant association was found between cumulative MR-volunteer noise exposure (dB*hour) and rate change of

Table 2 Linear regression model-based estimates of intercept (β 0) and regression coefficient for MR-volunteer-related noise exposure (β 1) expressed as cumulative modelled noise exposure (dB*hour) for MR-volunteers with \geq 2 years between first and final audiometric test (n=474). β 0 represents the intercept (increase of hearing threshold level (HTL) per year (Δ dB/y)), while β 1 represents the additional effect on increase of HTL per year of one unit change of cumulative noise exposure (dB*hour) and confounders β 2 and β 3 represent the additional effect of one unit change of age at first audiometric test (year) and the additional effect of being male, respectively

	Right ear								
Frequency (Hz)	Intercept (△dB/	Intercept (∆dB/year)		MR-volunteer-related noise exposure (cumulative dB*hour)		Age at first audiometric test		Sex (male)	
	β	SE	β	SE	β2	SE	β	SE	
500	-0.1	1.5	-0.011	0.014	0.008	0.007	0.7*	0.2	
1000	-0.8	1.3	0.001	0.012	0.008	0.006	0.5*	0.2	
2000	-1.6	1.5	0.010	0.014	0.002	0.007	0.6*	0.2	
3000	-2.0	1.6	0.016	0.014	0.002	0.008	0.4	0.2	
4000	-0.7	1.8	0.005	0.017	0.001	0.009	0.4	0.3	
6000	0.7	2.0	-0.003	0.018	0.007	0.009	0.0	0.3	
8000	2.2	2.2	-0.020	0.020	0.030*	0.011	0.0	0.3	
	Left ear								
500	0.1	1.3	-0.013	0.012	0.011	0.006	0.7***	0.2	
1000	-1.8	1.2	0.007	0.011	0.017*	0.006	0.6*	0.2	
2000	-1.3	1.4	0.006	0.012	0.010	0.007	0.4	0.2	
3000	-1.0	1.4	0.004	0.013	0.010	0.007	0.7*	0.2	
4000	-1.1	1.6	0.001	0.014	0.018*	0.008	0.9***	0.2	
6000	-4.2*	2.0	0.037	0.018	0.028*	0.009	0.0	0.3	
8000	-2.5	2.1	0.011	0.019	0.045*	0.010	0.8*	0.3	

*p <0.05, ***p <0.001.

HTL (dB/year) (table 2). Number of MR-volunteer scans per year was found to be associated with a significant rate change of HTL (0.007–0.008 dB/year per MR-volunteer scan) for the frequencies 500–4000 Hz in the right ear, but not in the left ear (table 3).

The results of the linear regression model (table 3) were used to model the increase of hearing threshold attributable to MR-volunteer scan-related acoustic noise exposure based on the cumulative number of MR-volunteer scans observed within the MR-volunteer study population. Figures 2A and 2B illustrate

Table 3 Linear regression model-based estimates of intercept (β 0) and regression coefficient for MR-volunteer-related noise exposure (β 1) expressed as number of MR-volunteer scans for MR-volunteers with \geq 2 years between first and final audiometric test (n=474). β 0 represents the intercept (increase of hearing threshold level (HTL) per year (Δ dB/y)), while β 1 represents the additional effect on increase of HTL per year per one MR-volunteer scan and confounders β 2 and β 3 represent the additional effect of one unit change of age at first audiometric test (year) and the additional effect of being male, respectively

	Right ear								
Frequency (Hz)	Intercept (∆d	Intercept (∆dB/year)		MR-volunteer-related noise exposure (number of scans)		Age at first audiometric test		Sex (male)	
	β _o	SE	β1	SE	β₂	SE	β₃	SE	
500	-1.4***	0.3	0.007*	0.003	0.006	0.007	0.7*	0.2	
1000	-0.9*	0.3	0.007*	0.003	0.007	0.006	0.5*	0.2	
2000	-0.7*	0.3	0.007*	0.003	0.001	0.007	0.5*	0.2	
3000	-0.4	0.3	0.007*	0.003	0.001	0.008	0.4*	0.2	
4000	-0.3	0.4	0.008*	0.004	0.000	0.009	0.3	0.3	
6000	0.4	0.4	-0.001	0.004	0.007	0.009	0.0	0.3	
8000	0.1	0.5	-0.004	0.005	0.030*	0.011	0.1	0.3	
	Left ear								
500	-1.3***	0.3	0.004	0.003	0.010	0.006	0.7***	0.2	
1000	-1.1***	0.3	0.004	0.003	0.016*	0.006	0.6*	0.2	
2000	-0.7*	0.3	0.005	0.003	0.009	0.007	0.3*	0.2	
3000	-0.6*	0.3	0.003	0.003	0.009	0.007	0.7*	0.2	
4000	-1.1*	0.3	0.003	0.003	0.018*	0.008	0.9***	0.2	
6000	-0.3	0.4	0.005	0.004	0.027*	0.009	0.0	0.3	
*n <0.05 ***n <0.001									

*p <0.05, ***p <0.001.



10 MR-volunteer scans ····∎··· 20 MR-volunteer scans ····▲··· 40 MR-volunteer scans ····▲··· 60 MR-volunteer scans

Figure 2 Increase in hearing threshold (dB) attributable to MR-volunteer scan exposure modelled for a 10-year period and based on a linear regression model (table 3) corrected for age at first audiometric test and gender. The noise exposure levels were based on a total of 10, 20, 40 and 60 MR-volunteer scans which corresponded with the 25th, 50th, 75th and 90th exposure percentile cut-off points of the total number of MR-volunteer scans among MR-volunteers with \leq 2 years between first and final audiometric test. Modelled contribution of MR-volunteer-related noise exposure is significant (p<0.05) for the frequencies 500, 1000, 2000, 3000 and 4000 Hz in the right ear (A) but not in the left ear (B).

what the estimated effect per year amounts to over a period of 10 years for different total cumulative number of scans, ranging from <1 dB increase in the right and left ear for a total of 10 MR-volunteer scans and up to 5 dB in the right ear for a total of 60 MR-volunteer scans.

Sensitivity analyses exploring the effect of cut-off point between the minimum amount of time between first and final audiometric test suggested that a lower cut-off point (≥ 1 year) introduced a noticeable observational noise to the measurement data, while a higher cut-off point (\geq 3 years) resulted in similar results as those with the main analytical sample. When completing the linear regression model with MR-volunteers with ≥ 1 year between measurements (n=496), results were inconsistent with the aforementioned found associations (online supplementary tables 4.1-2). Limiting the model to MR-volunteers with \geq 3 years between measurements (n=441) resulted in no significant association with cumulative MR-volunteer noise exposure (dB*hour), but showed a similar association with number of scans as was seen for the MR-volunteers with ≥ 2 years between measurements, and additionally a significant association between exposure and an increase in rate change of HTL (dB/ year) and 500 and 1000 in the left ear (see online supplementary tables 5.1-2).

When adjusted for smoking, alcohol consumption and self-reported noise exposure during work, a similar association between number of MR-volunteer scans and increase in rate change of HTL (dB/year) was observed in both ears, but the association was statistically significant only for 1000 Hz in the right ear (see online supplementary tables 6.1–2). Other confounders such as self-reported exposure to occupational noise (combined with no use of HPDs) and smoking were associated with an increased rate change of HTL (dB/year), while alcohol consumption (both low and high) and the use of HPDs (always and sometimes) were, especially in the right ear, associated with a protective effect.

DISCUSSION

Our study is unique as it studied prospectively collected information on hearing thresholds that could be associated with estimates of repeated exposure to MRI-related acoustic noise during voluntary MRI scans among workers from an MRI manufacturing plant. The repeated exposures were associated with increased HTL in the right ear for the frequency range of 500-4000 Hz. Noise exposure during MRI procedures is of interest as exposure limits for patients, the main recipients of MRI scans, are conservative and based on recommendations for occupational exposures that are inherently chronic,^{67 12} while an MRI procedure (for an MR-volunteer) produces a relatively short-term exposure (on average up to 1 hour) to acoustic noise. Our study suggests that the conservative exposure limits for patients, recommending or instructing the use of hearing protection when exposed to a noise level of 80 or 85 dB(A), respectively, is exceeded,¹² may be sufficiently conservative. While use of HPDs was mandatory during all MR-volunteer scans, we still found that the number of undergone voluntary MRI scans was associated with a small, but statistically significant increase of HTL in especially the right ear, particularly for the lower frequency range of 500-4000 Hz. Although high acoustic noise levels up to 114-115 dB(A) have been recorded during MRI procedures,⁹ measured noise levels are generally within permissible exposure limits.^{7 9} Most MRI acoustic output occurs at frequencies up to 1500 Hz,⁷ which may explain why MR-volunteer scan-related noise exposure was found to be associated with an increase in HTL mainly for the lower frequency range of hearing. In contrast, impact noise¹⁹ and occupational noise²⁰ induced hearing loss are more commonly found to affect hearing first at 3000-4000 Hz and the latter will furthermore progress to 6000 Hz and then more slowly to 8000 and 2000 Hz. Aging-related hearing loss also affects the upper hearing range,²¹ which may be a reason the (modest) effect of

MRI-related noise exposure among volunteers wearing HPD during scanning was only visible for the lower frequencies.

Whereas a significant association was found between number of MR-volunteer scans and increased rate change of HTL, estimated cumulative noise exposure (dB*hour) (uncorrected for the use of HPDs), did not appear to be associated with a significant increased rate change of HTL. A plausible explanation might be the adequate use of mandatory HPDs during the scan procedure reducing noise exposure to similar levels regardless of MRI-system type. Exposure estimation was also based on a maximum exposure average to simulate a worst -case scenario to avoid introducing uncertainty caused by variance in average exposure levels between different MRI models of the same field strength.

The magnitude of increased rate change of HTL associated with MR-volunteer scan-related acoustic noise exposure is found to be greater in the right-side ear. The difference in outcome between the two ears cannot be explained by noise exposure during MR-volunteer scans, which is measured to be of equal level at both ears by the manufacturer. On the other hand, a case of unilateral hearing loss affecting the right ear most after MRI-related noise exposure has been reported,²² although the underlying mechanism was unclear. The audiometric measurement protocol used at the manufacturing facility may have played a role in the difference observed between ears. The protocol instructs that measurement start with the right ear, which may have introduced measurement error through confounding with gaining test experience²¹ and may have led to an underestimation of effect on hearing in the left ear.

The detailed historical company records on MR-volunteer scans, which facilitated estimation of MRI-related acoustic noise exposure, which is a strength of the study. Another strong point is the analysis on a subpopulation for which additional data on potential confounders like smoking, alcohol consumption and use of HPDs during work were available. The potential confounders did affect the HTL, but did not considerably affect the association between MRI-related acoustic noise exposure during voluntary scans and the rate with which HTL changed per year.

The small sample size and thus limited statistical power are a limitation of the study, but the study covers 92% of the original MR-volunteer population with data on two audiometric tests available. The original cohort and the audiometric data are unique as no other study with data on (repeated) MRI-related acoustic noise exposure is known to exist. Another limitation of this study is the lack of information on the gradient systems that drive noise production,^{7 12} and lack of noise measurement data. Although data on gradient system and use of HPDs (another factor influencing exposure) were missing, company records did provide solid documentation on number of performed MR-volunteer scans per MR-volunteer and magnet strength during scans, which allowed for some degree of exposure contrast between different MRI-systems. The magnet strength was used to estimate a maximum exposure average without correction for use of HPDs, which might have been an overestimation of exposure and may have led to an underestimation of the effect of exposure. When making the assumption that proper hearing protection was applied during all MR-volunteer scans and thus all MR-volunteers were exposed to the same average noise level per scan (below 99 dB(A)), the cumulative number of MR-volunteer scans was considered a sufficient proxy for MR-volunteer scan-related noise exposure.

The data available for this study originate from the manufacturing facility's (precautionary) health surveillance programme and were originally not collected for research purposes. The quality of the available data was not optimal due to the lack of a uniform data collection protocol, but sound enough to demonstrate the association between age, a well-established risk factor for hearing loss.^{23 24} Gender is another known contributing factor to risk of age-related hearing loss,^{21 24 25} which is also observed in our study where male MR-volunteers are found to have up to a 0.9 dB higher increase of HTL per year compared with female MR-volunteers. Despite the low statistical power of the analyses within the subpopulation with data on additional potential confounders, the direction of association between the potential confounders and change in HTL is consistent with results of several other studies.^{26 27}

CONCLUSION

We found a positive association between exposure to MRI scans and HTL increase per year among MR-volunteers at an MRI manufacturing facility. The study period covered the early pioneer years until recent days in MRI manufacturing (1984–2010). Presently, diagnostic and medical intervention techniques relying on MRI-technology have been on the rise,¹² which has led to increased noise exposure for staff of medical and research facilities working with MRI-technology, workers involved in MRI manufacturing and patients.

The effects of MRI-related acoustic noise exposure on hearing were expected to be small as the mandatory use of HPDs should have reduced exposure within acceptable limits and the results support the expected protective effect of HPDs. Instruction on proper use of HPDs during MRI scans remains important to use the full protection HPDs have to offer.

The results of our study indicated that MRI-related acoustic noise may increase HTL in MR-volunteers; however, the magnitude of the increase was relatively small (even at up to 60 scans), especially compared with other factors like age and gender. Continued screening of exposed MR-volunteers as part of a standard hearing conservation programme is advisable considering the current trend of increased use of MRI-technology and the development of (louder) MRI-systems with stronger magnets.

Lack of consistency in findings between the left and right ears and between the two exposure measures prohibits definitive conclusions. The current trend of increased use of MRI-technology warrants further research efforts looking into long-term effects of MRI-related acoustic noise exposure and further studies should address this study's methodological limitations to corroborate our findings.

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Suzan Bongers, Pauline Slottje and Hans Kromhout

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