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Assessment of self-selection bias in a pediatric unilateral hearing loss study

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Abstract

Objective—To examine the differences between participants and non-participants in a study of children with unilateral hearing loss that might contribute to selection bias.

Study Design—Case-control study

Setting—Academic pediatric otolaryngology practice

Subjects and Methods—Comparison of clinical and socio-demographic characteristics between the 81 participants and 78 non-participants with unilateral hearing loss in a case-control study.

Results—Compared to non-participants, the study participants were younger but diagnosed at an older age. Participants were more likely to have been diagnosed through a primary care screen and have normal ear anatomy, and less likely to have an attributed etiology for their unilateral hearing loss or tried assistive hearing devices. No other significant demographic, socioeconomic or clinical differences were identified.

Conclusions—Self-selection bias may jeopardize both internal and external validity of study results and should be evaluated whenever possible. Methods to minimize self-selection bias should be considered and implemented during the planning stages of clinical studies.

Keywords

bias; volunteer; selection bias; hearing loss; unilateral hearing loss; children; recruitment

INTRODUCTION

Self-selection bias, or volunteer bias, is error due to systematic differences between the characteristics of participants and non-participants in clinical studies, particularly if these studies are generalized to the entire targeted population. As a sub-type of selection bias, self-selection bias may occur if research subjects select, or un-select themselves for a study.¹

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Whereas selection bias is a potential problem in all types of clinical research, self-selection bias impacts primarily prospective studies. Recruiting an unbiased patient sample population is vital for the scientific rigor of medical research, yet recruiting and retaining participants often represent the most difficult tasks in clinical research. Because non-participation and attrition are inevitable, it is important to examine their impact on a study's internal validity and generalizability.² Self-selection bias threatens internal validity when there are differences between study groups, such as with differential drop-out between arms of a randomized controlled trial. The external validity or generalizability of studies is compromised when the differences between those who do and do not participate suggest that the participants do not represent the target population. Studies with low levels of participation or high drop-out rates are more vulnerable to self-selection bias than those with high participation rates or low drop-out.³

In an ongoing prospective case-control study named the Unilateral Hearing Loss in Children Study (UHLCS), we have recruited and tested fewer than 50% of the eligible subjects. This raises the possibility of selection bias since participants in the study may not be representative of the larger group of children with unilateral hearing loss (UHL) seen in our clinic or in the general population. While researchers have reported findings of educational problems in children with UHL, selection biases in these studies may have lead to overestimates in the proportion that experience problems in school. Limited data exist about the effect of UHL upon the acquisition of speech and language skills. Additionally, little is known about which children with UHL might benefit from intervention or amplification to avoid academic delay. Previous studies in this area suffer from small sample sizes, lack of rigorous controls, and little longitudinal follow-up.⁴ In order to investigate these issues a large case-control study was undertaken comparing children with UHL to control siblings with normal hearing on standardized measures of achievement, language and behavior. Whether the findings of this study are generalizable will depend on how well the study participants represent the broader target population of children with UHL.

Upon learning what will be required of them during a research study, many eligible subjects or their parents decline participation, thus potentially leading to systematic differences between those who do and do not participate. It is critical to elucidate the characteristics of participants⁵ because it remains unclear how these characteristics may impact the generalizability of the findings of the UHLCS. Those who volunteer may represent one end of the target population spectrum in terms of age, motivation, activity level and other correlates of health. Although all samples are composed of volunteers, those who agree to be part of a random sample (such as in a national health survey) are not self-selected, and thus are likely to represent the target population. This is not necessarily true in the case of non-random samples or groups with a high non-participation rate.⁶ Self-selection bias can compromise the external validity or generalizability of the research if the participation pattern is not uniform.⁷ Research on this topic suggests that the decision to participate is based on multiple factors⁵ that include the method of recruitment; family and medical histories; exposures and disease status; questionnaire structure; and method and number of contacts. Conflicting results of the effect of other factors on participation have been reported, including age, gender, race, education level, and the use of incentives.⁸

The objective of this study was to determine whether non-participants were different from participants in any systematic way, such as in socio-demographic and other baseline characteristics, that could bias the results of the UHLCS. We hypothesized that we would find no significant differences between participant and non-participant groups suggesting that we had failed to recruit our target population.

METHODS

This study is a case-control study utilizing medical record review of all children who were eligible to participate in UHLC study between January 2005 and December 2006, and who had been seen at least once in the Washington University Medical Center/St. Louis Children's Hospital (SLCH) pediatric otolaryngology clinic. Study eligibility criteria include UHL with pure tone average (PTA) ≥ 30 dB in one ear and normal hearing (PTA < 20 dB) in the other ear; age 6 to 12 years between 2005 and 2009; sensorineural hearing loss or "permanent" mixed or conductive loss (i.e., no surgical treatment planned that could bring hearing to normal levels before leaving elementary school); no medical problem causing cognitive impairment (e.g., Down syndrome, congenital cytomegalovirus infection); and availability of medical records. The UHLCS is an NIH-funded case-control study that compares children with UHL to siblings with normal hearing on standardized measures of academic achievement and speech-language attainment, controlling for cognitive ability. Recruitment and testing began in 2005 and is anticipated to continue through mid-2010.

We extracted non-participant data from clinical charts and participant data from research charts. Data collected included demographic (e.g., age, gender, race) and socioeconomic (e.g., median household income and health insurance type) information, as well as past medical history, audiometric data, and pertinent laboratory or imaging study results. Patients classified themselves into racial and ethnic groups. We estimated the distance from SLCH to the zip code listed for the subject's home address using www.mapquest.com. Zip codes rather than exact street address were used because street addresses were not available for all of the patients. An estimate of each subject's household income based on their home zip code was obtained using 1999 U.S. Census Bureau data (http://factfinder.census.gov/home/saff/main.html?_lang=en). We derived the PTA for each ear by averaging the hearing thresholds at 500, 1000, 2000, and 4000 Hz. Each of the demographic and socioeconomic variables were examined because they have been shown to be confounders in other clinical studies. The clinical baseline variables were chosen to be examined as possible confounders or effect modifiers of the outcomes examined in the UHLCS.

Data were compiled in a Microsoft Access database and imported into SPSS version 15.0 (Lead Technologies Inc, Charlotte, NC) for statistical analysis. CIA version 2.0 (CIA Software, Bristol, United Kingdom) was also used to calculate 95% confidence intervals (CI). We used student's t-tests, chi-square and Fisher exact tests to compare the characteristics of participants and non-participants. A two-tailed alpha level of 0.05 was used to determine statistical significance.

We obtained institutional review board approval and waiver for informed consent from the Washington University Medical Center Human Research Protection Office (HRPO) before beginning this study.

RESULTS

Demographic information

We identified 159 eligible patients (81 participants and 78 non-participants) and reviewed their charts. Three additional non-participants identified through financial records had no outpatient clinic chart because they had been seen as inpatient consults only; they were not eligible for this review. The reasons for non-participation included: inability to contact the eligible subject (incorrect address and/or phone numbers), $n=25$; parent declined participation, $n=19$; no eligible control sibling, $n=4$; and other reason or unknown, $n=30$.

Demographic data is shown in Table 1. No significant differences in sex, race distribution, adoption status, type of health insurance, or median household income were found. Those who did not participate were older and had more siblings than the study participants, and lived farther from the medical center.

Medical History

Past medical history for the participant and non-participant groups is summarized in Table 2. Past medical history was not available for 2–10% of the non-participants. Data concerning refractive or other eye problems in the non-participant group was largely unavailable and was not evaluated. Non-participants suffered from more recurrent ear infections and sinusitis, and were more likely to have undergone tympanoplasty in the past. However, there were no other significant differences in past medical history between groups.

Participants were diagnosed with hearing loss at an older age than non-participants (Table 3). Non-participants were more likely to have had their hearing loss identified via primary care screening or as the result of parental suspicion than participants. Participants were less likely to have tried assistive listening devices, including frequency-modulation assistive devices (FM systems), hearing aids, or BAHA. Non-participants are more likely to have had a history of otitis media and tympanic membrane perforations as attributed etiologies, but participants were less likely to have a known cause for hearing loss. Significantly less was recorded and ascertained regarding progression of hearing loss; follow up; use of genetic testing; the congenital or hereditary nature of the hearing loss; and presence of speech and language problems in non-participants (data not shown).

Physical Examination

While the participants and non-participants were quite similar on their head and neck examination, there were significant differences in their ear examinations (Table 4). Non-participants were more likely to have an abnormal external auditory canal (EAC) or tympanic membrane, preauricular pit, and microtia than participants. This corresponds with the increased percentage of known etiology for UHL among the non-participants versus participants.

Audiologic data

Participant and non-participant groups were similar in their audiologic evaluations, particularly in degree and side of UHL (Table 5). Audiograms were incomplete (e.g., limited number of pure tone thresholds) for six non-participants. Non-participants had right UHL in 50% while participants had right UHL in 52% ($P = 0.82$). Non-participants were more likely to have a conductive or mixed hearing loss (47% vs. 23% for participants, $P = 0.002$), which corresponds to the greater proportion of non-participants who had known middle ear or auricular abnormalities.

DISCUSSION

In this study of self-selection bias, we found several significant differences between the participants and non-participants that might limit generalizability of the UHLCS. Among the demographic variables, participants were slightly younger, had fewer siblings, and lived significantly closer to the study site than non-participants. Those living farther distances from the hospital (and in rural areas) may be less inclined to participate in a study when considerable travel is necessary.⁹ We speculate that in larger families with many children, participation in observational studies may not rank highly on a list of family priorities. We deliberately used median household income based on zip code as a surrogate of direct ascertainment of family income; although this surrogate may result in misclassification bias, it is not clear whether this would lead to over- or under-estimation of incomes. Demographic and socioeconomic factors,

known to play a significant role in the health status of an individual, were generally equivalent across the two groups.¹⁰ Although individuals of lower socioeconomic status, African American or other minority group are often less likely to participate in clinical research and health surveys,^{5, 11} our participants and non-participants were similar with respect to these variables.

Participants and non-participants varied across multiple aspects of medical history and hearing-related history which might account for differing motivations for participation in research. Older age at diagnosis, greater percentage of unknown etiology, less parental suspicion of UHL, and fewer trials of using assistive listening device suggest that participants or their parents were still seeking more information and answers about how to cope with UHL. Extant literature indicates that 39% of clinical research participants do so to improve their own health care.¹² For many participants, the cause of hearing loss was unknown, whereas non-participants were more likely to have UHL attributed to otitis media, tympanic membrane perforation, or microtia/aural atresia—well-known etiologies of conductive hearing loss with the possibility of surgical repair. This suggests that non-participants may have perceived little benefit to participation in a clinical research study. Structural abnormalities of the ears (e.g., tympanic membrane perforation, atresia) were more prevalent in the non-participants, which accompany the known causes of UHL. Alternatively, a parent of a child with microtia may wish to shift the focus of attention away from this abnormality, and therefore refused participation in this study.¹³

In prospective clinical studies such as the UHLCS, self-selection bias may jeopardize internal and external validity.¹⁴ Selection bias may arise from at least three mechanisms: lack of participation, missing information in some covariates (and thus exclusion from analyses) and cohort attrition (dropouts or losses to follow-up).⁸ Although our study examined self-selection bias in a case-control study, self-selection bias can plague any prospective clinical study design, including randomized control trials. The CONSORT statement acknowledges that evaluating for recruitment and selection biases are pertinent to clinical trials; it endorses the use of a flow diagram to indicate the number of patients recruited, enrolled, and reasons for non-enrollment, as a means of addressing and acknowledging selection bias.¹⁵

Several of the parameters examined in the participants were not examined in the non-participants because considerably less information was available for the non-participants. Most of these characteristics were elements of past medical history which were missing from the clinical otolaryngology chart.¹⁶ For example, prematurity at birth, a risk factor for congenital hearing loss, was not addressed in many patient charts. We are unable to comment on the differences in the frequency of speech or language evaluations, the types of speech or language problems, and types of interventions used, between the two groups. Ophthalmologic examination is usually recommended to rule-out syndromic causes of hearing loss, assess vision status (including refractive errors) and to investigate methods of optimizing sensory information for individuals who have fewer modes of sensory input.¹⁷ We did not expect to find educational data about the non-participants as it is not routinely ascertained in a clinical appointment.

Audiologic similarities between participants and non-participants imply that patients with left- and right-sided UHL were equally inclined to participate in the study. Both groups had similar degrees of hearing loss as measured by PTA. Therefore, the results of the UHLCS concerning sidedness and degree of hearing loss will likely be generalizable to the spectrum of children with UHL seen in a pediatric otolaryngology practice. Non-participants demonstrated more conductive hearing loss caused by a potentially temporary condition, such as tympanic membrane perforation, while participants demonstrated more sensorineural or mixed UHL caused by an unknown etiology. This difference reassures us that the exclusion criteria for the

UHLCS, excluding subjects whose UHL may resolve in the near future, have been effective. Nevertheless, the predominance of children with sensorineural UHL makes us less able to generalize the results of the UHLC study to children with long-term conductive UHL, such as from aural atresia or ossicular problems.

In this study, we chose to use research charts as sources of data for the participants and clinical charts as sources of data for the non-participants. This introduces the possibility of information bias, which is the error that may occur when the method of data collection is different between study groups. For this study, the primary effect of the information bias is likely to be misclassification of the exposure or disease status of a non-participant, or missing data, because the clinical charts did not contain all the information we gathered in the research charts. Unfortunately, we cannot correct the potential information bias without enrolling the non-participants; instead, we documented when data were missing and acknowledge this as a limitation of this study.

The use of rigorous recruitment and subject retention techniques has aided in controlling self-selection bias. The extant literature provides little guidance on management of self-selection bias in case-control studies. The primary modes of recruitment employed in the UHLCS include recruitment letters and phone calls to potential participants from the pediatric otolaryngology clinic and local school districts. Our ability to enroll just over 50% of recruited individuals is similar to the statistic that 58% of patients are likely to participate in a study when they are initially recruited by telephone, following screening of clinical charts.¹⁸ The UHLCS uses monetary incentives as well as a small toy gift for each child participant at each visit. Once enrolled, each subject receives a reminder phone call 2 days prior to each scheduled study appointment. The study coordinator often rescheduling subjects multiple times to facilitate participation. In addition, participants who do not have adequate means of transportation to the study site are provided with taxi vouchers. These methods of recruitment and retention have been successful methods of controlling for selection bias utilized in other studies.

Despite these efforts, investigators may still wonder whether their subject sample is representative of the target population and thus whether their study is generalizable. Investigations studying those who were recruited but chose not to participate can give insight into the characteristics subject to selection bias. To exemplify from the otolaryngology literature, Paradise et al¹⁹ compared results of tonsillectomy in children with chronic tonsillitis from a parallel randomized trial and non-randomized cohort whose parents chose their child's treatment. They found that the effects of tonsillectomy were similar in both the randomized trial and the non-randomized group. In contrast, Fortnum et al found significant demographic differences among children with profound hearing impairment who did and did not undergo cochlear implantation.²⁰ They concluded that comparison of outcomes and generalizations of results of studies require adjustment for differences in study population characteristics to better estimate the effectiveness of interventions. In an effort to assess the role of selection bias, future studies may also benefit from conducting parallel randomized and non-randomized trials, or collecting information on key variables, such as socioeconomic status or disease severity, that are most likely to contribute to overall bias and threaten internal and external validity. Sensitivity analyses may then be used to determine whether differential characteristics of participants and non-participants might produce significant differences in a study's results.

CONCLUSIONS

We found several demographic and clinical differences between participants and non-participants in the UHLCS that may represent sources of selection bias. Self-selection bias can jeopardize internal and external validity (generalizability) of study results. Methods to minimize self-selection bias should be considered and implemented during the planning stages

of clinical studies. We have described some methods to help control and minimize selection bias, and evaluate its effect in prospective clinical studies.

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Table 1

Demographic and socioeconomic information about the participants (n=81) and non-participants (n=78).

Characteristic	Participants	Non-participants	Mean or % Difference (95% CI)	P value
Male sex, n (%)	40 (49)	45 (58)	-8 (-23, 7)	0.30
Age in years, mean	8.7 (1.8)	9.6 (2.3)	0.9 (0.2, 1.6)	0.007
Race, n (%)				0.10
African American	14 (17)	14 (18)		
Caucasian	58 (72)	53 (68)		
Asian	4 (5)	1 (1)		
American Indian/ Alaskan Native	0 (0)	2 (3)		
Other	4 (5)	1 (1)		
Unknown	1 (1)	6 (8)		
*Number of siblings, mean (SD)	1.7 (1.1)	3.9 (3.7)	2.1 (1.3, 3.0)	<0.001
*Adopted, n (%)	8 (10)	2 (3)	7 (-1, 16)	0.09
Type of Insurance, n (%)				0.53
None	1 (1)	0 (0)		
Medicaid	22 (27)	21 (27)		
Private	56 (69)	49 (63)		
Medicaid and Private	2 (3)	2 (3)		
Median household income in \$, mean (SD)	45,151 (17,768)	42,543 (17,118)	-2607 (-8213, 2997)	0.36
Distance from SLCH in miles, mean (SD)	35.8 (37.5)	50.4 (51.9)	14.6 (0.1, 29.2)	0.04

CI, confidence interval; SD, standard deviation

* Data were missing for 4 non-participants regarding adoption status, and 26 non-participants regarding numbers of siblings.

Table 2

Past medical history of participants (n=81) and non-participants (n=78)

Characteristic	Participants	Non-participants *	% Difference (95% CI)
Recurrent ear infections, n (%)	26 (32)	46 (62)	-30 (-44, -14)
Sinusitis, n (%)	6 (7)	16 (22)	-14 (-26, -3)
Asthma, n (%)	20 (25)	15 (20)	4 (-9, 17)
Prior ear tubes, n (%)	26 (32)	28 (37)	-5 (-19, 10)
Prior tympanoplasty, n (%)	0 (0)	13 (17)	-17 (-27, -9)
Other ENT surgeries, n (%)	18 (22)	27 (36)	-14 (-28, 0)
Currently taking medications, n (%)	39 (48)	29 (41)	7 (-9, 22)

* Data were missing for 4 non-participants for recurrent ear infections, sinusitis, and other ENT surgeries; 5 for asthma; 2 for prior ear tubes; 3 for prior tympanoplasty; 8 for currently taking medications.

Table 3

Hearing-related past medical history for participants (n=81) and non-participants (n=78)

Characteristic	Participants	Non-participants	% Difference (95% CI)
Mean Age at Diagnosis, years (SD)	4.6 (2.5)	3.7 (2.9)	-0.9 (-1.8, -0.1)
[†] Hearing loss identification, n (%)			
Newborn screening	5 (6)	10 (13)	-7 (-16, 3)
School screening	33 (41)	24 (31)	10 (-5, 24)
Primary care screening	7 (9)	21 (27)	-18 (-30, -6)
Parental suspicion	12 (15)	43 (55)	-40 (-52, -26)
Audiogram for ear infections	11 (14)	16 (21)	-7 (-19, 5)
*CAPD/ADHD evaluation	0 (0)	3 (4)	-4 (-11, 1)
Other	14 (17)	16 (21)	-4 (-16, 9)
[†] Trial of amplification, n (%)			
FM system	23 (28)	52 (67)	-38 (-51, -23)
Hearing Aid	16 (20)	28 (36)	-16 (-29, -2)
Other	1 (1)	2 (3)	-1 (-8, 4)
BAHA	1 (1)	10 (13)	-12 (-20, -4)
[†] Cause of hearing loss, n (%)			
Otitis Media	1 (1)	28 (36)	-35 (-46, -24)
Tympanic membrane perforation	0 (0)	17 (22)	-22 (-32, -13)
Otosclerosis	0 (0)	2 (3)	-3 (-9, 2)
Trauma	6 (7)	5 (6)	1 (-8, 10)
Meningitis	3 (4)	1 (1)	2 (-4, 9)
Microtia or aural atresia	2 (3)	10 (13)	-10 (-20, -2)
Temporal bone abnormality	25 (31)	18 (23)	8 (-6, 21)
Other	16 (20)	24 (31)	-11 (-24, 2)
Unknown	34 (42)	15 (19)	23 (8, 36)
Temporal bone CT obtained, n (%)	53 (65)	56 (72)	6 (-20, 8)

*CAPD/ADHD, central auditory processing disorder/attention-deficit hyperactive disorder

[†]Multiple answers possible, thus total may exceed 100%

Table 4

Physical examination characteristics for participants (n= 79) and non-participants (n=74)*.

Characteristic	Participants	Non-participants	% Difference (95% CI)
Auricle n (%)			
Normal	77 (98)	62 (84)	14 (4, 24)
Preauricular pit	0 (0)	6 (8)	-8 (-17, -2)
Microtia	2 (3)	10 (14)	-11 (-21, -2)
Abnormal position	0 (0)	6 (8)	-8 (-17, -2)
External Auditory canal n (%)			
Normal	77 (98)	41 (55)	42 (30, 54)
Tortuous or stenotic	0 (0)	14 (19)	-19 (-29, -10)
Blind pouch	1 (1)	8 (11)	-10 (-19, -2)
Tympanic Membrane n (%)			
Normal	71 (90)	47 (64)	26 (13, 39)
Abnormal**	4 (5)	19 (26)	-21(-32, -9)
Tube	3 (4)	18 (24)	-21(-32, -10)
Other	7 (9)	10 (14)	-5 (-15, 6)
Nose n (%)			
Normal	79 (100)	71 (96)	4 (-1, 11)
S/P cleft repair	0 (0)	2 (3)	-3 (-9, 2)
Other	0 (0)	2 (3)	-3 (-9, 2)

* Physical examination data were unavailable for several non-participants.

** Abnormal tympanic membrane includes: monomeric, retracted, presence of a retraction pocket, dull, immobile, and middle ear fluid

Table 5

Audiologic data from 79 participants and 72 non-participants*.

Pure tone average (PTA) in dB	Participants mean (SD)	Non-Participants mean (SD)	Mean Difference (95% CI)	P value
Overall Right ear hearing	45 (40)	40 (39)	-5 (-18, 8)	0.45
Severity of Right UHL (total n=74)	79 (24)	74 (33)	-5 (-18, 9)	0.48
Overall Left ear hearing	38 (38)	36 (34)	-2 (-14, 10)	0.74
Severity of Left UHL (total n=77)	72 (30)	65 (25)	-7 (-20, 6)	0.28

* Missing data due to the unavailability of complete audiograms for 6 non-participants.