# SMOKING AND ALCOHOL DRINKING DURING PREGNANCY. THE RELIABILITY OF RETROSPECTIVE MATERNAL SELF-REPORTED INFORMATION

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**SUMMARY**

*Background:* The reliability of retrospective maternal self-reported information regarding smoking and alcohol drinking during pregnancy seemed necessary to be checked.

*Methods:* Two groups of congenital abnormalities were selected for the study from the population based Hungarian Congenital Abnormality Registry. The prevalence of smoking and drinking during the study pregnancy was measured in the mothers of 81 cases affected with isolated orofacial cleft and 537 cases with congenital limb deficiencies, and in their matched control pairs without any defect by maternal self-reported retrospective information through a mailed structured questionnaire. In the second step the latter data were checked by an independent personal interview of fathers and other family members at the home visit or in our department using the same structured questionnaire.

*Results:* The family consensus indicated the low reliability of retrospective maternal self-reported information concerning smoking in the mothers of cases but not in mothers of controls. However, the comparison of retrospective maternal self-reported data and information of close relatives indicated a reported bias concerning the drinking of alcohol beverages during pregnancy in both controls and cases.

*Conclusions:* Since retrospective maternal self-reported data had low reliability, therefore, data of smoking and alcohol drinking were not collected for the data set of the Hungarian Case-Control Surveillance of Congenital Abnormalities between 1980 and 1996.

*Key words:* smoking during pregnancy, alcohol drinking during pregnancy, case-control analysis, reliability of retrospective maternal information.

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## INTRODUCTION

The population-based Hungarian Case-Control Surveillance of Congenital Abnormalities (HCCSCA) (1) between 1980 and 1996 contains the largest case-control data set in the world with 22,843 cases with congenital abnormalities (CAs) and 38,151 matched controls without CAs. This case-control data set has been extensively used in international collaborations for the study of possible associations between unsuccessful pregnancy outcomes (CAs, preterm birth, intrauterine growth retardation) and the exposures to drugs or other potential teratogenic-fetotoxic environmental factors.

Potential confounders, such as maternal age, birth order, marital and socioeconomic status of mothers, acute and chronic maternal disorders, medicine (drug and pregnancy supplement) intakes have been taken into consideration at the statistical analysis. However, data were not collected regarding alcohol drinking and smoking during pregnancy, though typical fetal alcohol syndrome (2-4) or fetal alcohol effect (5) are well-known, in addition the adverse effect of maternal smoking for fetal development was also recognized because the rate of intrauterine growth retardation (6-8), fetal (e.g. miscarriages) and infant death (9), some CAs, e.g. limb deficiencies (10) and oral clefts (11) was higher in newborn infants born to smoking mothers. We were aware of these and other risks, nevertheless we did collect data on alcohol drinking and smoking of pregnant women studied because of the low validity of retrospective maternal self-reported information in two previous studies (12,13).

This weakness of the HCCSCA was sometimes critized since maternal smoking and alcohol drinking during pregnancy partly may have an association with unsuccessful pregnancy outcomes, partly may modify as confounders some other associations. We agree with this opinion, however, our decision can be understood only on the basis of our experiences. Thus, the objective of our paper is to report the unpublished results of two previous studies (12,13).

## METHODS

*Cases* affected with specified CAs were identified from the records of the national-based data set of the Hungarian Congenital Abnormality Registry (HCAR) (14) for our validation studies. Notification by physicians of cases with CAs to the HCAR was mandatory.

*Control* infants without CA were selected from the National Birth Registry (NBR) of the Central Statistical Office. Two controls were matched to each case according to sex, birth week in the year when the case was born and district of parent's residence.

Among pregnant women, never smoked, ex-smokers (women who stopped smoking before the study pregnancy) and smokers during the study pregnancy were differentiated. At the evaluation of smoking during the study pregnancy, the number of cigarettes smoked per day, type of cigarettes, duration of smoking by gestational months and the smoking habit of fathers were considered. (The data of fathers are not evaluated here.) Four groups of mothers were classified according to the drinking habit during the study pregnancy: abstinents (never drink), occasional drinkers (to drink from once during pregnancy to once a week), regular drinkers (more than one drink per week) and daily drinkers (to drink once or more per day). Among alcohol beverages, beer, wine and hard drinks were separated, and drinking was evaluated according to gestational months.

The evaluation of validity regarding the data collection of smoking and alcohol drinking during pregnancy was part of our previous case-control studies in orofacial clefts (12) and in congenital limb deficiencies (10,13). The relevant part of methods and materials regarding validation studies were not mentioned in our previous papers, therefore we summarize these details here. In Hungary it was not a practice to ask a permission for such kind of studies from ethical committees during the study period. However, parents of cases and controls were informed about the general objectives of the studies and they had, of course, right to refuse their participation.

At the statistical analysis, prevalence odds ratio (POR) with 95% confidence interval (CI) was used for categorical data using the software SAS version 8.02 (SAS Institute Ins., Cary, North Carolina, USA).

**Cases with Orofacial Clefts and their Matched Controls**

Cases with isolated orofacial clefts (OFS), i.e. cleft lip with or without cleft palate and posterior cleft palate born between 1970 and 1976 were identified from the HCAR in 1977 and their matched controls were selected from the NBR in 1977.

Necessary data including smoking and alcohol drinking were collected by a reply-paid structured questionnaire mailed to the mothers of cases and controls immediately after their selection nearly on the same time. Completed questionnaires were returned on average in 1.4 and 1.8 months and information was available for 88% of cases and for 84% of controls after the exclusion of families with wrong or new unknown addresses, respectively. District nurses prepared for the study visited mothers of cases with OFC born in 1976 and their first matched controls 2–5 months after the return of questionnaires in the frame of a sociological study. Among others, data on lifestyle: smoking and alcohol drinking before, during and after the pregnancy studied were collected through a personal interview using the same structured questionnaire independently both from mothers and fathers, in addition from grandmothers if they lived together with the family in the same flat. The latter occurred in 18% of cases and 12% of controls. After the data collection, their information was discussed together to achieve a *"family consensus"*, and these data were considered as referent. The data of previous mailed questionnaire filled in by mothers were not shown and discussed. Three case and six control families did not cooperate, thus three cases were dropped out while these six controls were replaced by the "second" control families.

**Cases with Congenital Limb Deficiencies and their Matched Controls**

Cases with congenital limb deficiencies (CLD) born between 1975 and 1984 were identified from the HCAR and their matched controls from the NBR. In general there was 6 months delay in the selection of controls after the reporting of cases to the HCAR. Data of exposures including smoking and alcohol drinking were collected by the reply-paid structured questionnaire mailed to the mothers of cases and controls immediately after the report of cases to the HCAR and the selection of controls from the NBR. Completed questionnaire was returned on average in 1.0 and 1.2 months and information was available for 93% of cases and 87% of controls after the exclusion of families with wrong and new unknown addresses, respectively.

After the return of questionnaires, cases with their families were invited to visit our Department. (The major aim was to examine all cases and to check personally the diagnoses of CLD.) The first matched controls of cases with CLD were visited at home by our coworker. Eleven first controls did not cooperate, thus the second one's selected were visited. At the visit of case families in our Department or at the home visit of control families, the data of maternal smoking and drinking habit during the study pregnancy were collected through a personal interview using the same structured questionnaires independently from the mothers and her husbands without the knowledge of data in the previously filled-in questionnaire by mothers. The differences regarding maternal smoking and alcohol drinking were discussed with the parents of cases and controls to achieve a family consensus and it was then used as reference value. However, there was no agreement in these maternal data between parents in 33% of case families and 12% of control families. In these families the data of husbands were considered as reference concerning maternal smoking and drinking habit during the study pregnancy. The personal interview was performed both in the parents of cases in our Department and in the parents of controls at home visit by the same qualified social worker. The average time interval between the birth of cases and personal interview was 11 months, while it was 21 months in the control group.

## RESULTS

**Cases with Orofacial Clefts and their Controls**

Both the number of cases with isolated OFC (including 630 and 179 liveborn infants with cleft lip with or without cleft palate and posterior cleft palate, respectively) and their matched controls was 809.

The prevalence of smokers was somewhat higher (21.3%) in the total OFC sample than in their controls (18.9%) on the basis of retrospective maternal self-reported information (Table 1). This difference is explained mainly by the proportion of light (1-10 cigarettes per day) smokers. The prevalence of self-reported maternal smokers did not show significant difference between the total samples of cases and controls born in 1976. However, the prevalence of maternal smokers based on maternal self-reported

*Table 1. Prevalence of cigarette smokers and alcohol drinkers among pregnant women in the total samples and selected samples of cases and controls born in 1976 based on the retrospective maternal information, in addition in selected samples based on the family consensus after the personal interview of the fathers and grandmothers*

| Smoking (cig/day) and drinking habit | Total samples based on maternal information | | | | Selected samples of cases and controls born in 1976 based on maternal information | | | | | | | | Selected samples of cases and controls born in 1976 based on family consensus | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Cases with OFC (N=809) | | Matched controls (N=809) | | Cases with OFC (N=81) | | POR with 95% CI | | Matched controls (N=81) | | POR with 95% CI | | Cases with OFC (N=81) | | POR with 95% CI | | Matched controls (N=81) | | POR with 95% CI | |
| Smoking | No. | % | No. | % | No. | % | POR | 95%CI | No. | % | POR | 95%CI | No. | % | POR | 95%CI | No. | % | POR | 95%CI |
| Never | 637 | 78.7 | 656 | 81.1 | 62 | 76.5 | referent | | 67 | 82.7 | referent | | 52 | 64.2 | referent | | 65 | 80.2 | referent | |
| 1–10 | 112 | 13.8 | 89 | 11.0 | 13 | 16.0 | 0.8 | 0.4–1.6 | 8 | 9.9 | 1.1 | 0.5–2.4 | 16 | 19.8 | 0.7 | 0.3–1.5 | 9 | 11.1 | 0.9 | 0.3–2.3 |
| 11–20 | 35 | 4.3 | 42 | 5.2 | 4 | 4.9 | }1.0 | 0.4–2.3 | 4 | 4.9 | }1.1 | 0.5–2.5 | 8 | 9.9 | }0.4 | 0.1–1.1 | 5 | 6.2 | }0.8 | 0.3–2.5 |
| 21- | 25 | 3.1 | 22 | 2.7 | 2 | 2.5 | | | 2 | 2.5 | | | 5 | 6.2 | | | 2 | 2.5 | | |
| Total | 172 | 21.3 | 153 | 18.9 | 19 | 23.4 | 0.9 | 0.5–1.5 | 14 | 17.2 | 1.1 | 0.6–2.0 | 29 | 35.8 | 0.5 | 0.3–1.1 | 16 | 19.8 | 0.8 | 0.4–1.9 |
| Drinking Never | 611 | 75.5 | 554 | 68.5 | 63 | 77.8 | referent | | 56 | 69.1 | referent | | 44 | 54.3 | referent | | 43 | 53.1 | referent | |
| Occasional | 192 | 23.7 | 250 | 30.9 | 16 | 19.7 | 1.2 | 0.7–2.2 | 24 | 29.6 | 1.1 | 0.6–1.7 | 31 | 38.3 | **0.4** | **0.2–0.7** | 37 | 45.7 | **0.5** | **0.3–0.9** |
| Regular | 6 | 0.7 | 5 | 0.6 | 2 | 2.5 | }0.3 | 0.1-1.6 | 1 | 1.2 | }0.5 | 0.1-4.4 | 5 | 6.2 | }0.2 | 0.0–1.1 | 1 | 1.2 | }0.8 | 0.0–12.6 |
| Daily | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | | 0 | 0.0 | | | 1 | 1.2 | | | 0 | 0.0 | | |
| Total | 198 | 24.5 | 255 | 31.5 | 18 | 22.2 | 1.1 | 0.7-2.0 | 25 | 30.9 | 1.0 | 0.6-1.7 | 37 | 45.7 | **0.3** | **0.2–0.7** | 38 | 46.9 | **0.5** | **0.3–0.9** |

*Table 2. Prevalence of smokers and alcohol drinkers among pregnant women of the two study groups on the basis of maternal self-reported information, and of cross-interview of fathers*

| Smoking (cig/day) and drinking habit | Maternal information | | | | Cross-interview of fathers | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Cases with CLD (N=537) | | Matched controls (N=537) | | Cases with CLD (N=537) | | POR with 95% CI | | Matched controls (N=537) | | POR with 95% CI | |
| Smoking | No. | % | No. | % | No. | % | POR | 95%CI | No. | % | POR | 95%CI |
| Never | 413 | 76.9 | 445 | 82.9 | 369 | 68.7 | referent | | 437 | 81.4 | referent | |
| 1-10 | 93 | 17.3 | 69 | 12.8 | 106 | 19.7 | 0.8 | 0.6-1.1 | 76 | 14.2 | 0.9 | 0.6-1.3 |
| 11-20 | 31 | 5.8 | 23 | 4.3 | 59 | 11.0 | **}0.4** | **0.3-0.7** | 24 | 4.5 | }0.9 | 0.5-1.7 |
| 21- | 0 | 0.0 | 0 | 0.0 | 3 | 0.6 | | | 0 | 0.0 | | |
| Total | 124 | 23.1 | 92 | 17.1 | 168 | 31.3 | **0.7** | **0.5-0.9** | 100 | 18.6 | 0.9 | 0.7-1.2 |
| Drinking Never | 462 | 86.0 | 447 | 83.2 | 438 | 81.6 | referent | | 429 | 79.9 | referent | |
| Occasional | 73 | 13.6 | 88 | 16.4 | 92 | 17.1 | 0.8 | 0.5-1.0 | 104 | 19.4 | 0.8 | 0.6-1.1 |
| Regular | 2 | 0.4 | 2 | 0.4 | 6 | 1.1 | }0.3 | 0.0-1.2 | 4 | 0.7 | }0.5 | 0.0-2.3 |
| Daily | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 | | | 0 | 0.0 | | |
| Total | 75 | 14.0 | 90 | 16.8 | 99 | 18.4 | **0.7** | **0.5-0.9** | 108 | 20.1 | 0.8 | 0.6-1.1 |

information was lower (POR: 0.5, 95% CI: 0.3-1.1) than that of maternal smoking estimated by the family consensus in the selected samples of cases with OFC. A somewhat higher number of light smokers (less than 10 cigarettes per day) was found, however, the prevalence of more than 10 daily cigarette smokers doubled (from 7.4% to 16.1%) among case mothers on the basis of the family consensus. Of 5 heavy smokers (more than 21 cigarettes per day), three were ascertained due to the family information members. Similar differences were not seen among controls.

There was a somewhat lower prevalence of drinkers in the total OFC sample than in the total control sample (see Table 1). The data of total and 1976 samples based on retrospective maternal information did not show significant difference. However, the family consensus indicated a more frequent maternal consumption of alcohol beverages during the study pregnancy both in the groups of cases and controls explained mainly by the higher prevalence of occasional drinkers. The prevalence of regular drinkers was also somewhat higher among the mothers of cases with OFC. In addition one daily drinker was reported by family members in the OFC sample.

**Cases with Congenital Limb Deficiencies and their Controls**

The evaluated number of cases with CLD and their matched controls was 537.

Table 2 shows a higher prevalence of smokers during pregnancy based on the retrospective maternal self-reported information in the group of cases with CLD than in the group of their matched controls. However, there was a further increase in the prevalence of maternal smokers in the group of cases with CLD and a redistribution towards the heavy smokers on the basis of personal interview of parents (family consensus) and sometimes only of fathers. There was no change in the data of control mothers.

The prevalence of drinkers was nearly similar in the case and control groups. However, there was a higher prevalence of total maternal consumption of alcohol beverages in both study groups on the basis of personal interview of parents or only of fathers compared with the data based on maternal self-reported information (see Table 2). This increase was more obvious in the group of cases. One daily drinker was also ascertained with the help of father in the group of cases.

## DISCUSSION

Our analysis aimed to show the low reliability of retrospective maternal self-reported information obtained by questionnaire regarding smoking during pregnancy in the case groups of OFC and CLD and alcohol drinking during pregnancy in both the case group with CAs and control group without CA.

The benefits of our validation studies are (i) the population--based (ii) large data sets of cases with CAs and (iii) matched controls without any CA (iv) in the homogenous ethnic (European-Caucasian) Hungarian population. (v) The validation procedure was based on standarized personal interview using a structured questionnaire. Our approaches have also drawbacks. (i) The number of cases with OFC born in 1976 and their controls evaluated on the basis of both maternal self-reported information and of family consensus based on a personal interview was low, therefore the statistical power was limited. However, the study of cases with CLD and their matched controls represented unselected large population-based data set. (ii) There was a relatively long time interval between the study pregnancy and data collection, in addition (iii) there was some time delay in the collection of data from controls. (iv) We had no option to validate these habits on the basis of biochemical markers (as cotinine in the urine of smokers and high density lipoprotein cholesterol in the plasma of drinkers).

At present smoking of females is not considered as an inappropriate habit in Hungary. Maternal self-reported data regarding their smoking during the pre- and postconceptional period was reliable in our previous study (15). However, recently the fetal risks of this lifestyle factor during pregnancy have become well-known and the mothers of cases with CAs might have guilty feeling and/or they did not want to confess their smoking and/or to accept any association between the CA of their babies and their smoking during pregnancy. Thus many of them did not give adequate information concerning smoking after the birth of malformed babies. Similar experience was not found in the mothers of healthy babies, i.e. in the control group. The prevalence of smokers in our control groups corresponded well to the rate of smokers in the Hungarian pregnant population during the study period (16).

The drinking of alcohol beverages was a shame for females in the past, though recently there has been some change in the social judgement of this lifestyle habit (17). However, the high risk of alcohol drinking during pregnancy for the fetuses has become well-known. This can explain the fact that the mothers of both cases and controls reported a lower occurrence of drinking during pregnancy compared with the information of other family members, in general fathers. However, this reporting bias was more obvious in the mothers of cases with CA than in the mothers of controls without any CA. The proportion of different drinking habits in our control mothers corresponded to the previously published Hungarian prevalence of occasional, regular and daily drinkers during pregnancy (17).

The findings of these two studies can probably be extrapolated for other CAs as well.

In general our experiences agree with the results of studies in other countries. The low self-reported smoking rates and high self-reported quit rates for smoking and alcohol found in several studies raised concerns about the validity of self-report of these behaviours (7, 18-20). Studies that biochemically validate tobacco exposure suggest that pregnant women may either fail to disclose or underreport their use of cigarette during pregnancy (21, 22). Many studies tested the accuracy of self-reports regarding alcohol consumption and it showed differences depending on sex, socioeconomic status, cultural background (23-27). Underreporting of alcohol use in pregnancy remains a significant obstacle to reliable data collection (28). However, Little et al. (29) found no substantial inaccuracies in pregnant women's self-reported alcohol consumption after verification using physical examinations and blood chemistry. Self-administered questionnaires have generally been found to be more sensitive in identifying alcohol use than interviewer-administered questionnaires in non-pregnant subjects (30). However, the self-administered questionnaire showed only in 76.6% sensitivity, though specificity was 92.8% in pregnant women regarding alcohol consumption during pregnancy (31).

The inclusion of maternal smoking and drinking habits among confounders is important in the analytical epidemiological studies

regarding pregnancy outcomes. However, there is a reporting bias, in addition these variables need differential confounding adjustment at the comparison of cases and controls. The findings of our validation studies therefore faced us a difficult dilemma at the establishment of the HCCSCA in 1979: to collect data with low reliability regarding self-reported smoking habit during the study pregnancy by the mothers of cases with CAs and to evaluate invalid data of maternal drinking during pregnancy in both case and control mothers or to omit these data from our structured questionnaire and data analysis. (Unfortunately the prospective data of antenatal logbook did not contain this information in the past.) We therefore decided to omit these variables from the questionnaire of the HCCSCA (1).

In 1997 the data collection of the HCCSCA was changed, families of cases and controls are visited by regional nurses at home and the necessary data including smoking and alcohol use are collected through a structured questionnaire on the basis of personal interview of mothers and fathers. Parallel with this public health project we conduct a new validation study regarding maternal smoking and drinking within the EUROCRAN-project of cases with orofacial clefts and their controls.

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