

REGULAR ARTICLES

Modifiable risk factors for SIDS in Germany: Results of GeSID

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Abstract

Background: The incidence of sudden infant death syndrome (SIDS) has been falling in Germany over the last decade. However, little is known about the prevalence and the importance of well-known risk factors in Germany since a local prevention campaign in 1992. **Design:** A 3-y, population-based, case-control study was conducted in half of Germany, consisting of 333 cases. All sudden and unexpected deaths in infancy, if they fitted the inclusion criteria, were included in the study. Parental interview was carried out soon after the death, and three living control infants, matched for age, gender, region and sleep time, were recruited. **Results:** The prevalence of placing infants prone to sleep was only 4% in the control group, but this was associated with a markedly increased risk of SIDS (adjusted odds ratio, aOR = 6.08). Other modifiable risk factors for SIDS were: maternal smoking during pregnancy, breastfeeding for less than 2 wk (aOR = 1.71) and co-sleeping (aOR = 2.71), while using a pacifier during the last sleep reduced the risk (aOR = 0.39).

Conclusions: Previously recognized risk factors for SIDS also occur in Germany. Despite knowledge about the major modifiable risk factors for SIDS, these factors are still present in Germany. To reduce the incidence of SIDS in Germany, a continued effort is needed to inform all parents about preventable risk factors for SIDS.

Key Words: SIDS, case-control study, risk factors

Introduction

In the year 2002, a total of 359 infants died in Germany with the diagnosis of sudden infant death syndrome (SIDS) [1], and SIDS is still the leading cause of death after the post-neonatal period. The incidence has dropped from 1.5 to 0.6 per 1000 live births in 1990 and 2000, respectively, but the mortality of SIDS in Germany remains much higher than in the neighbouring Netherlands (0.12/1000).

In many international studies [2–5] as well as in the German Westphalian Cot Death Study [6], risk factors were identified, such as prone sleeping position, smoking of the mother during pregnancy and heat

stress. This knowledge was used in the early 1990s for prevention campaigns, and subsequently the incidence of SIDS declined significantly in all these countries where campaigns had been organized. However, there was never a nationwide campaign in Germany, but localized promotion of side and supine and later of supine-only sleep position.

Few studies about the prevalence and magnitude of risk factors have been undertaken after the “back to sleep” campaigns of the early 1990s [7,8]. The epidemiology of SIDS might have changed significantly now that more infants sleep supine or on their side. This study was therefore undertaken to determine the

prevalence and magnitude of risk factors for SIDS in Germany following the prevention campaign.

Methods

A population-based case-control study was conducted in 11 out of 18 states in the Federal Republic of Germany, with 18 centres involved. The study area during the first 18 mo was the service area of 13 institutes of legal medicine, which was then extended to 18 institutes. In that area, 50% of all births in Germany occur. The study was conducted from November 1998 to October 2001. All 18 centres had the approval of their local medical ethics committees, and the state data protection officer gave permission to recruit controls in each state. All cases of sudden and unexpected deaths in the first year of life after the first 7 d were to be reported to the study centre in Muenster. The emergency department doctors, police departments or forensic pathologists reported cases as soon as they knew them. The study centre then asked the parents for participation. For each case, three control infants were matched for region, age (± 2 wk), gender and reference sleep. The control infants were recruited through the same or a neighbouring local birth registration office where the case was registered. Control infants were born 4–6 wk after the case infant, so that by the time the interviews were done, they had the same age as the index case (± 2 wk). If one control family refused to participate, another family was recruited. If more than three controls agreed to participate, the three controls with the best age matching were chosen by the study centre. All cases were autopsied by forensic pathologists according to a standardized autopsy protocol, which included extended virology, microbiology, neuropathology and histology. The method of case reporting, the recruitment of control families and the autopsy protocol have been described in detail previously [9].

Parents of cases and controls were interviewed with a standardized questionnaire in their homes. The questionnaire consisted of 106 questions about family history, the infant's medical history, sleeping environment, cigarette and alcohol use of the parents, feeding of the infant and socio-demographic aspects.

The socio-economic status (SES) of the families was calculated based on the modified Scheuch index, using household income, school education and current working position [10,11]. Extra warming during the last sleep was defined as a hot water bottle in the infant's crib or the infant's cot less than 1.5 m from an activated heater. Single mother indicates that the mother lived neither with the father nor with a new partner at the time of the baby's death/interview. Breastfeeding was defined as breastfeeding for more than 2 wk. For the five cases younger than 2 wk, if

they were still breastfed at the time of death, they were categorized as breastfeeding for > 2 wk.

After collecting the information, the cases were reviewed by a panel of experts, consisting of a forensic pathologist, a histologist, a paediatrician, a microbiologist and an epidemiologist. Cases were categorized according to the findings in the autopsy into four categories: (I) no signs of disease; (II) minor signs of disease; (III) major signs of disease; (IV) definite cause of death [9].

All data were entered into a database and analysed in SAS 6.12 (Statistical Analysis System). Univariate analysis and multivariate analysis were done using conditional logistic regression [12]. The multivariate model includes all variables which were found significant at the 5% level in the univariate analysis, except gestational age, as this was closely related to birth-weight.

Results

During the 3-y period, 455 infants died suddenly and unexpectedly and were entered into the study. Cases with extraneous causes of death, such as filicides or accidents, were not included. Of the 455 cases, an explained cause of death was identified in 51 (category IV), and 404 were classified as SIDS (categories I–III) [9]. Of the 404 SIDS cases, 333 (82.4%) families were interviewed. During the 3-y period, we approached 2702 control families, and 58.7% agreed to participate. For this analysis we excluded the matched controls of the explained deaths, controls for the cases that were not interviewed and families that were not needed because three other families had already been interviewed. Interviews were carried out soon after the death (mean 39 d). Thus, 333 SIDS infants (categories I–III) and the matched 998 control infants are the subject of this analysis.

SIDS occurred most frequently at the age of 2–5 mo (59%) and, as described in other studies on SIDS, male infants (60.4%) had a higher risk than females [13–15]. Table I shows the effectiveness of matching.

The risk of SIDS was inversely proportional to the age of the mother and the socio-economic status of the family (Table II). A positive association with SIDS was also found for the numbers of previous live births. Infants of mothers who did not live with the husband or a partner had an increased risk of SIDS. However, after adjustment for potential confounders, the ethnicity of the mother and/or father did not affect the risk of SIDS.

Maternal smoking during pregnancy was associated with an increased risk. A clear dose-response relationship could be established (1–9 cigarettes/d: adjusted odds ratio, aOR = 1.66; 10–19/d aOR = 2.76; and 20+/d aOR = 3.43).

Low birthweight was associated with SIDS (Table III).

Table I. The number (and percentage) and *p*-values of matching variables.

Variable	Cases (%) <i>n</i> =333	Controls (%) <i>n</i> =998	<i>p</i> -value χ^2
Sex of infant			
Male	201 (60.4)	602 (60.3)	0.99
Female	132 (39.6)	396 (39.7)	
Age of infant (wk)			
≤12	114 (34.2)	317 (31.8)	0.79
13–25	129 (38.7)	387 (38.8)	
26–38	60 (18.0)	193 (19.3)	
39+	30 (9.0)	101 (10.1)	
Mean (wk)	19.1	20.5	
SD	12.1	11.8	
Reference sleep			
Morning	71 (21.3)	256 (25.7)	0.38
Afternoon	37 (11.1)	118 (11.8)	
Evening	28 (8.4)	73 (7.3)	
Night	197 (59.2)	551 (55.2)	
Season			
Summer (May–Oct.)	157 (47.2)	508 (50.9)	0.24
Winter (Nov.–April)	176 (52.9)	490 (49.1)	
Region			
East	38 (11.4)	113 (11.3)	0.97
West	295 (88.6)	885 (88.7)	

Infants placed prone to sleep were at a markedly increased risk of SIDS compared with those placed supine (aOR=6.08) (Table IV). However, the side sleeping position was not associated with an increased risk of SIDS (aOR=0.82). Infants placed on the side or supine to sleep who turned to the prone position and were found in that position (secondary prone) were at increased risk of SIDS (OR=8.28, 95% CI: 5.05–13.59 and aOR=22.76, 95% CI: 9.25–55.98, respectively). Thirty-nine (40%) of the cases put down on their side and 29 (32%) of the cases put down on their back turned prone.

Breastfeeding for less than 2 wk was associated with an increased risk (aOR=1.71). The use of a pacifier in the last sleep was associated with a reduced risk of SIDS (aOR=0.39).

Co-sleeping with an adult was associated with a significantly increased risk of SIDS (aOR=2.71). Table V shows the relationship between maternal smoking and co-sleeping. However, there was not a statistically significant interaction between maternal smoking and co-sleeping (*p*=0.35).

Table II. The number (and percentage) and odds ratios related to maternal factors.

Variable	Cases (%) <i>n</i> =333	Controls (%) <i>n</i> =998	Univariate OR (95%CI)	Multivariate OR (95%CI)
Maternal age in years (at delivery)				
≥30	97 (29.1)	631 (63.2)	1.00 (Ref.)	1.00
25–29	78 (23.4)	267 (26.8)	1.99 (1.40–2.81)	2.16 (1.31–3.57)
20–24	98 (29.4)	90 (9.0)	7.58 (5.12–11.22)	4.01 (2.07–7.78)
<20	60 (18.0)	10 (1.0)	50.0 (21.95–113.92)	18.71 (6.00–58.32)
Family status				
Not single	265 (79.6)	966 (96.8)	1.0 (Ref.)	1.00
Single	68 (20.4)	32 (3.2)	7.45 (4.73–11.73)	2.38 (1.10–5.12)
Ethnicity				
Both European ^a	270 (82.3)	898 (90.3)	1.0 (Ref.)	1.00
Father European ^a	7 (2.1)	25 (2.5)	0.96 (0.41–2.26)	0.54 (0.13–2.30)
Mother European ^a	26 (7.9)	33 (3.3)	2.62 (1.55–4.43)	1.28 (0.53–3.10)
Neither European ^a	25 (7.6)	39 (3.9)	2.17 (1.27–3.70)	0.70 (0.28–1.77)
Missing	5	3		
Smoking in pregnancy, cig./d				
Nil	120 (36.0)	784 (78.6)	1.0 (Ref.)	1.00
1–9	87 (26.1)	149 (14.9)	3.28 (2.37–4.55)	1.66 (1.02–2.70)
10–19	79 (23.7)	46 (4.6)	10.43 (6.70–16.22)	2.76 (1.42–5.35)
≥20	47 (14.1)	19 (1.9)	16.64 (8.93–30.99)	3.43 (1.39–8.46)
Previous live births				
Nil	111 (33.3)	468 (46.9)	1.0 (Ref.)	1.00
1	132 (39.6)	385 (38.6)	1.42 (1.05–1.89)	3.12 (1.86–5.24)
2	44 (13.2)	105 (10.5)	1.78 (1.16–2.69)	1.83 (1.29–2.60)
≥3	46 (13.8)	40 (4.0)	5.0 (3.04–8.12)	1.91 (1.46–2.49)
Socio-economic status of the family				
Upper	36 (10.9)	383 (38.5)	1.0 (Ref.)	1.00
Middle	131 (39.6)	536 (53.8)	3.18 (2.05–4.92)	1.58 (0.89–2.82)
Lower	164 (49.6)	77 (7.7)	31.58 (18.52–53.89)	3.00 (1.35–6.69)
Missing	2	2		

^a Central European.

Table III. The number (and percentage) and odds ratios related to infant factors.

Variable	Cases (%) <i>n</i> = 333	Controls (%) <i>n</i> = 998	Univariate OR (95%CI)	Multivariate OR (95%CI)
Gestational age (wk)				
≥ 38	244 (73.7)	859 (86.2)	1.00	
36–37	48 (14.5)	103 (10.3)	1.60 (1.11–2.31)	
30–35	28 (8.5)	28 (2.8)	3.73 (2.12–6.53)	
< 30	11 (3.3)	6 (0.6)	6.74 (2.46–18.49)	
Missing	2	2		
Birthweight (g)				
≥ 3500	86 (26.0)	476 (47.8)	1.0	1.00
3000–3499	111 (33.3)	324 (32.5)	1.90 (1.38–2.61)	1.97 (1.24–3.12)
2500–2999	75 (22.7)	158 (15.9)	2.62 (1.82–3.75)	1.78 (1.03–3.06)
1500–2499	41 (12.4)	32 (3.2)	7.18 (4.17–12.34)	2.81 (1.16–6.78)
< 1500	18 (5.4)	6 (0.6)	15.12 (5.83–39.22)	10.67 (2.10–54.17)
Missing	2	2		

The presence of a pillow was identified as a risk factor in the univariate analysis, but this was not associated with SIDS after adjustment for potential confounders. Similarly, extra heating was associated with SIDS in the univariate analysis but not after adjustment.

Discussion

The German SIDS study is the only population-based case-control study on SIDS in Germany since the prevention campaigns of 1992. The study in 18 centres used a standardized autopsy protocol. The response

rate of parental interviews of cases was high (82%), and while the response rate of the controls was still acceptable (58.7%), it was less than expected but reflects a tendency of non-response seen in other population-based studies in Germany [16]. Maternal age at delivery was higher in the controls than among pregnant women in the perinatal dataset in 2000 for the study area (i.e. age > 30 y: 63.2% vs 53.9%, respectively). However, smoking was more prevalent in the controls than in the perinatal dataset (21.4% vs 17.1%, respectively) [17]. Although there is some evidence to suggest selection bias, the effect is likely to be quite

Table IV. The number (and percentage) and odds ratios related to postnatal factors.

Variable	Cases (%) <i>n</i> = 333	Controls (%) <i>n</i> = 998	Univariate OR (95%CI)	Multivariate OR (95% CI)
Breastfeeding > 2 wk				
Yes	165 (49.6)	827 (82.9)	1.0 (Ref.)	1.00
No	168 (50.5)	171 (17.1)	5.36 (3.97–7.23)	1.71 (1.06–2.77)
Position placed to sleep				
Supine	91 (28.1)	490 (49.4)	1.0 (Ref.)	1.00
Side	97 (29.9)	462 (46.5)	1.12 (0.79–1.58)	0.82 (0.52–1.28)
Prone	136 (42.0)	41 (4.1)	16.62 (10.38–26.61)	6.08 (3.33–11.08)
Missing	9	5		
Pacifier used during last sleep				
No	194 (59.0)	450 (45.3)	1.0	1.00
Yes	135 (41.0)	543 (54.7)	0.57 (0.44–0.74)	0.39 (0.25–0.59)
Missing	4	5		
Co-sleeping with an adult				
No	285 (85.6)	909 (91.1)	1.0 (Ref.)	1.00
Yes	48 (14.4)	89 (8.9)	1.80 (1.21–2.66)	2.71 (1.44–5.10)
Pillow in infant's bed				
No	211 (64.1)	793 (79.9)	1.0 (Ref.)	1.00
Yes	118 (35.9)	200 (20.1)	2.41 (1.80–3.23)	1.03 (0.66–1.59)
Missing	4	5		
Extra warming during last sleep				
No	276 (83.9)	891 (90.8)	1.0 (Ref.)	1.00
Yes	53 (16.1)	90 (9.2)	2.01 (1.37–2.96)	1.70 (0.91–3.16)
Missing	4	17		

Table V. Interaction between co-sleeping and maternal smoking.

		Cases (%) <i>n</i> = 333	Controls (%) <i>n</i> = 998	Univariate OR (95% CI)	Multivariate OR (95% CI)
Co-sleeping	Maternal smoking				
No	No	106	714	1.00	1.00
No	Yes	179	195	2.90 (1.8–4.6)	1.94 (1.24–3.05)
Yes	No	14	70	1.97 (0.9–4.5)	2.20 (0.99–4.91)
Yes	Yes	34	19	7.72 (3.0–19.9)	6.44 (2.62–15.81)

small, and adjustment for socio-economic factors in the multivariate analysis would have largely corrected for this.

Despite the fact that Germany never had a nationwide “back to sleep” campaign, localized prevention campaigns and news coverage brought the message to large segments of the population. Schlaud reported that the prone sleeping prevalence dropped in Germany from 37.6% in 1991 to 8.7% in 1995 [18]. In our control population only 4% of control infants were placed prone to sleep. This correlates with a decreasing incidence in SIDS between 1995 and 2000. However, 40% of the cases were still put down prone for their sleep. As in the German Westphalian Cot Death Study [19] and the Tasmanian [20] study, we found no increased risk for the side-sleeping position. A striking finding was the increased risk of SIDS for infants placed supine or on their side who subsequently turned to the prone position (secondary prone).

Maternal smoking during pregnancy was much more prevalent in the mothers of the SIDS infants than in the control group. Furthermore, a dose effect was seen, with the risk increasing with increasing number of cigarettes smoked. A detailed analysis on the effect of smoking including paternal smoking will be reported later.

Co-sleeping is a well-recognized risk factor for SIDS. However, some promote co-sleeping, as it is associated with an increased rate of breastfeeding [21]. Several studies [22,23] have found that co-sleeping was a risk factor only when the mother smoked. It is more controversial as to whether co-sleeping is a risk factor for SIDS for infants of mothers who are non-smokers, although Carpenter have recently shown that this group of infants are at increased risk of SIDS when they are less than 8 wk of age [24]. In our data, co-sleeping with an adult was a strong risk factor for SIDS. Although there was not a statistically significant interaction between smoking and co-sleeping in this dataset, the data are consistent with this interaction.

Bottle-feeding has been described by several large studies as being a risk factor for SIDS after adjustment for socio-economic and other factors [22,25–27]. Our study is in agreement with these studies. When a pacifier was used during the last sleep, we found a significant protective effect on SIDS. This is also in accordance with several studies [4,28,29]. However,

there is disagreement as to whether using a pacifier should be promoted or not.

In our dataset, a pillow in the bed of the infant increased the risk only in the univariate analysis; in the multivariate model it was no longer significant. Many authors have described the possibility of the re-breathing of air if the head of the infant sinks into a soft pillow [30]. Further evidence is expected from the death-scene investigation in a subgroup of our study as they collected detailed information on bedding material.

Other studies have highlighted the danger of keeping babies too warm during their sleep [27]. In contrast, in this study, extra warming of the infant during his/her last sleep increased the risk of SIDS only in the univariate analysis, but in the multivariate analysis the increased risk did not reach statistical significance. We will explore the sleeping environment of the infants in more detail at a later stage.

Conclusions

The German SIDS study presents data on SIDS in Germany several years after risk factors have been identified and disseminated in Europe. Despite the fact that prone sleeping position has been a recognized risk factor for more than a decade, placing infants prone to sleep still occurs in Germany. It appears that there is a group of young families who are unaware of this risk factor. Knowledge of the harmful effects of maternal smoking on infant health is well known, but mothers are either unable to change their smoking behaviour or chose to ignore the health message. Knowledge of other preventable risk factors, like the prone sleeping position, bed sharing and lack of breastfeeding, needs to be distributed to each young family. The young mothers of today were teens when the first information about risk factors was distributed. There is a need for repeated and focused prevention campaigns in Germany to reduce the SIDS incidence further.

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