

The German case–control scene investigation study on SIDS: epidemiological approach and main results

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Abstract The present study, which was part of the German SIDS Study (GeSID), enrolled sudden infant death syndrome (SIDS) cases and population controls and obtained objective scene data via specifically trained observers shortly after discovery of each dead infant. Infants who had died suddenly and unexpectedly at ages between 8 and 365 days were enrolled in five regions of Germany between November 1998 and October 2001. Shortly after discovery of each dead infant, a specially trained doctor of legal medicine visited the bereaved family at home. Data were obtained by measurements and observations. Dead infants underwent a standardised autopsy, additional information being obtained by

standardised parent interviews. Investigation of the sleep environment and wake-up scene in matched controls followed the same protocol. A total of 52 SIDS cases and 154 controls were enrolled, 58% were boys, and median age of cases vs. controls was 126 vs. 129 days. Risk factors in the sleeping environment were pillow use (adjusted OR 4.3; 95%CI 1.6–11.6), heavy duvets (OR 4.4; 1.5–13.3), soft underlay (OR 3.0; 1.1–8.7), face covered by bedding (OR 15.8; 2.5–102.1) and entire body covered by bedding (OR 35.5; 5.5–228.3). Using a standardised protocol, including objective measurements of the sleep environment and a case–control design, this study was able to confirm many risk factors for SIDS.

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Sudden infant death syndrome (SIDS, ICD-10 R95.0) is still the leading “cause” of post-neonatal death in many countries including Germany [1, 2]. This is true even after a pronounced decline in German SIDS mortality rates since the identification of the prone sleeping position as a major risk factor. This has resulted in a downward trend from about 1.5 cases per 1,000 live births in the late 1980s to 0.4 cases per 1,000 live births in 2005. Over this time, a decline in the prevalence of prone sleeping has also been observed [3, 4]. Nevertheless, SIDS remains a major threat, with 482 cases in Germany in 2000 and 298 cases in 2007.

Modifiable risk factors for SIDS identified by epidemiological research in the 1990s were located, predominantly, in the sleep environment of infants. As well as the now well-established risk factor of the prone sleeping position [5], overheating by clothing or heating devices [6], soft mattresses [7] and bedding material [8] were all found to be associated with SIDS. Most studies about the sleep environment, however, had some methodological limitations: either they included only SIDS cases, without any reference data from the general population, or they obtained all information by parent interview [9–12]. This second limitation may introduce a major source of recall bias particularly in case–control studies. The aim of this study was to overcome these limitations by obtaining objective scene data via specifically trained observers shortly after discovery of a dead infant and by enrolling SIDS cases and suitable population controls in a case–control study design.

This scene investigation was a sub-study of the German Study on Sudden Infant Death (GeSID) [13] and was performed as an additional module in some of the GeSID study areas. The study aim was to identify risk factors in the sleep environment supporting the hypothesis that hypoxia, rebreathing and/or hyperthermia may be causal mechanisms of death.

Materials and methods

Study background

The GeSID study has been described in detail elsewhere [13] and included a number of projects dealing with pathology, physiology and epidemiology [14, 15]. In brief, infants who had died suddenly and unexpectedly at ages between 8 and 365 days were enrolled in 11 federal states of Germany between November 1998 and October 2001. The area covered about 50% of the country and about 50% of births. Dead infants underwent a standardised autopsy in accordance with the European guidelines for medico-legal

autopsies [16], including a full external and internal examination, an analytical toxicology scheme and microbiological and virological tests. Additional information was obtained by standardised parent interviews and questionnaires sent to any doctor who had seen the infant before study enrolment. For each infant, the cause of death was ascertained in a multidisciplinary case conference using all available information and applying a modified version of the classification proposed by Taylor and Emery [17] which is very similar to the San Diego definition [18]. For each case, three living controls were randomly selected from registration offices in or near the community where the case had lived, matched to cases on age and gender. Parent interviews and medical information were obtained in the same way as employed for SIDS cases. Socioeconomic status (SES) was assessed using education, job title and available household income and classified into three categories according to the method of Winkler [19].

The scene investigation study

The scene investigation study was performed in four of the 18 GeSID study areas covering the Hannover/Oldenburg region in Lower Saxony and the federal states of Hamburg, Saxony-Anhalt and Thuringia. In these areas, nine million inhabitants resided and there were 76,500 infant births each year in the late 1990s. Therefore, 120 SIDS cases were expected to occur within the 2 years. Power estimations were carried out using STPLAN 4.1 (University of Texas, Houston, TX, USA) with an expected 100 cases and 300 controls. Error probabilities were set to 0.05 for alpha and 0.20 for beta, yielding smallest detectable relative risks (odds ratios) of 2–3 for any risk factor with a prevalence between 5% and 50%.

The main study started on 1 April 1999 and ended on 31 October 2001. This was preceded by a feasibility study lasting 6 months, followed by optimisation of the protocol, approval by institutional ethics committees and data protection officials, intensive training of all investigators and the provision of the information needed to alert doctors, paramedics and the police in the study areas. Case enrolment occurred as follows: Shortly after discovery of each dead infant, the paramedics or the police informed the nearest department of legal medicine from where a specially trained forensic pathologist visited the bereaved family in their home (or wherever the infant had died). Data were obtained mainly by observation, according to a standardised protocol. Information on how the infant was found (including covering of the head and body by bedding), and what may have been changed since then, was obtained by structured parent interview.

There was an extensive protocol for cases in which the death scene could be visited within 6 h after discovery and

a reduced version for cases where a home visit took place between 6 and 72 h after discovery. All variables expected to have potentially changed within 6 h (most importantly room temperature) were omitted in the reduced protocol. The extensive protocol included:

- Temperatures of the room, the heating device, the body and outdoors;
- Dimensions of the room and the cot;
- Type, dimensions and weight of all bedding;
- Type, dimensions and softness of the mattress/underlay;
- Type of infant clothing;
- Pacifiers or other items found in the cot;
- Devices in the vicinity of the cot;
- Information on doors and windows (dimensions and whether open or closed during sleep).

Temperatures were measured in degrees Celsius using electronic thermometers (Testo Type 112, Testo, Lenzkirch, Germany) with different probes for air, surfaces and rectum (in cases) and were read to one decimal place. The air temperature was taken at the infant's sleeping position. Since doors and windows are often opened after discovery of a dead infant, and thus later measurements may not represent the true condition during sleep, the air temperature was additionally taken in a wardrobe or a drawer of the same room and nearest to the place where the infant had slept [20]. The temperature of any heating device was taken by contact with the surface probe, either at the hot water inflow of the radiator or at the top of any other hot surface. Ambient air temperature was taken outside the entrance door of the house, 1 m above ground. When direct sunlight was present, an appropriate place in the shade was chosen. The body temperatures of controls were measured by a digital ear thermometer (ThermoScan pro LT, Thermoscan, San Diego, CA, USA) and read to one decimal place, rather than being taken rectally, so as not to endanger acceptance by parents. Date and time were always noted when taking any temperature.

All distances were measured in metres, read to three decimal places (millimetres), using an ultrasound distance metre (Fennel Dimension Master Plus, Calculated Industries, Carson City, NV, USA) for room dimensions or a folding ruler for shorter distances. The weight of any item was measured in kilograms, read to three decimal places, using an electronic scale (CWE 7745, Soehnle, Murrhardt, Germany) with an effective range from 40 g to 15 kg.

The softness of the underlay was measured by taking the distance, in millimetres, that a 2-kg weight sank in at three points diagonally across the cot and at the point where the infant's head had been, using a specially designed device (Fig. 1). The 2-kg weight was a metal cylinder with a diameter of 6 cm, a circular ground surface of 28.3 cm² and an effective ground pressure of 70.7 g/cm². Photographs of

the scene were taken with instant cameras (Polaroid or digital) to further elucidate the sleep environment, covering the following perspectives:

- Overview from the door into the room,
- Overview from the opposite side of the room,
- Site where the infant had been found dead or had slept last (cot, bed, perambulator etc.),
- Infant in the clothes worn when found dead or after the last sleep,
- Infant without clothes (cases only),
- Additional photos as appropriate.

The same investigator who had visited the respective case visited the matched controls. Visits were arranged at short notice on the day the control infant had reached the same age as the matched case and at a time of the day which would allow observation of the control infant waking up from the same sleep (night, morning, midday or afternoon sleep) in which the case had died (the reference sleep). Investigation of the sleep environment and wake-up scene in controls followed the same protocol used in cases, except for any items concerned with death. In both cases and controls, written informed consent was obtained at the first visit before any investigation was carried out.

Quality control, data processing and statistics

On arrival at the study centre, all forms were checked for completeness and consistency. Data were then entered into an SIR dbms database (SIR Pty Ltd, Terrey Hills, NSW, Australia) and validated by a complete second data entry. After additional crosschecks of data quality, descriptive and analytical statistics were computed using the packages SPSS (SPSS Inc, Chicago, IL, USA) and SAS (SAS Institute, Cary, NC, USA). Group differences between cases and controls were tested for statistical significance using a *t* test, a χ^2 test or a *U* test, all two-sided, according to the distribution of the data under examination. Any *P*

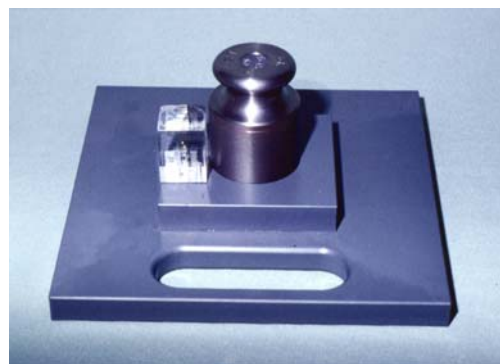


Fig. 1 Device used to measure mattress softness

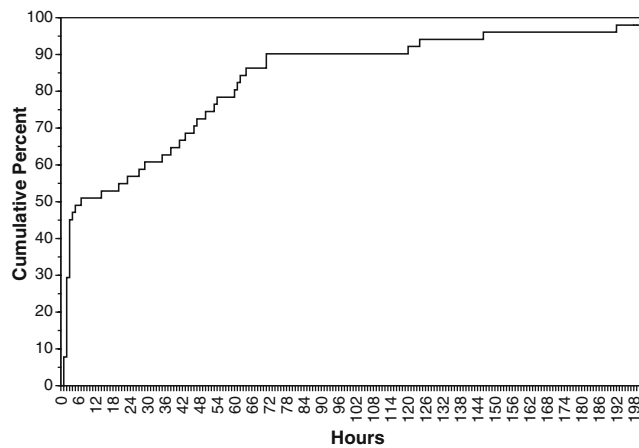


Fig. 2 Cumulative frequency distribution of time intervals between infant found dead and scene investigation in SIDS cases

values below 0.05 were considered statistically significant. Adjusted odds ratios (OR) and their 95% confidence intervals (95%CI) were estimated by conditional logistic regression in strata of matched case–control quartets. Whenever these models tended to be unstable due to low number of cases in certain analyses, unconditional logistic regression was used and additional adjustments were made for matching factors.

Results

Description of study participants

During the 30-month study period, notifications of 84 sudden deaths were received and 64 (78%) could be enrolled. In the remaining cases, either no scene investigation could be performed due to late notification or parents refused study participation. Matched controls participated with a 52% response, but for two cases, only two instead of three matched controls could be found. Out of the enrolled 64 cases, no autopsy had been performed in one case and a sufficient cause of death been ascertained by multidisciplinary case conferences in another 12 cases. In the final count, 52 SIDS cases and their matched controls were available for statistical analysis. The cumulative frequency distribution of time intervals between infant found dead and beginning of scene investigation is shown in Fig. 2. Thirty per cent of death scenes could be investigated within 2 h, 50% within 6 h and 72.5% within 48 h. There was one extreme outlier of 559 h, which was still included due to the low number of cases.

Basic characteristics of cases and controls are shown in Table 1. Fifty-eight per cent of cases were boys, with a mean age at death of 147 days (median 126 days, range 11–348 days). Controls had a mean age of 157 days (median 129 days, range

Table 1 Basic characteristics of SIDS cases and controls

	Cases (<i>n</i> =52)		Controls (<i>n</i> =154)		<i>P</i> value
	Mean	SD	Mean	SD	
Infant age (days)	146.6	90.7	156.9	88.4	0.416 ^a
Mother's age (years)	26.3	7.2	31.2	4.4	<0.001 ^a
Father's age (years)	30.0	8.6	34.1	4.9	<0.001 ^a
Socioeconomic status ^b					<0.001 ^c
Low (%)	65.4		4.6		
Medium (%)	30.8		64.1		
High (%)	3.8		31.4		
Nationality					0.532 ^c
German (%)	88.0		92.2		
Other (%)	12.0		7.8		

^a Mann–Whitney *U* test

^b Winkler's index [19]

^c χ^2 test

30–378 days) and were thus slightly older on the day of the home visit. On average, control parents were 5 years older than parents of cases, which may at least in part be attributed to differences in SES; almost two thirds of cases had a low SES in comparison to 4.6% in controls. Conversely, 31% of controls had a high SES compared to only 3.8% of cases.

Characteristics of the sleep environment

Characteristics of the sleep environment in cases and controls are presented in Table 2. A pillow for the infant's head was used during reference sleep by 41% of cases vs. 18% of controls ($P<0.001$). Although there were virtually no differences in the frequency of duvet use, duvets turned out to be significantly heavier in cases than in controls (average weight 1,397 vs. 820 g, $P<0.001$). The size and

Table 2 Characteristics of infants' sleep environment

	Cases	Controls	<i>P</i> value
Pillow used in reference sleep (%)	41.2	18.2	<0.001 ^a
Duvet used in reference sleep (%)	88.5	89.6	0.79 ^a
Mean size of duvet (cm ² , SE)	11,568 (869)	9,010 (332)	0.11 ^b
Mean volume of duvet (cm ³ , SE)	84,413 (11,501)	64,648 (6,300)	0.44 ^b
Mean weight of duvet (g, SE)	1,397 (114)	820 (40)	< 0.001 ^b
Specific weight of duvet (g/m ² , SE)	1,731 (221)	1,253 (78)	0.018 ^b

SE standard error

^a χ^2 test

^b Mann–Whitney *U* test

volume of duvets tended to be lower in controls, but these differences failed to reach statistical significance. The specific weight of duvets, however, calculated as grams per square metre (g/m^2), was significantly lower in controls (1,252 vs. 1,731 g/m^2 , $P=0.018$). There was no difference in the distribution of different duvet fillings (e.g. synthetic fibres, down or wool).

In the conditional logistic model, pillow use was associated with a crude odds ratio of 4.9 (95%CI 2.26–10.41), which lost statistical significance after adjustment for infant age, SES and nationality (OR 2.9, 95% CI 0.8–10.5; Table 3). When using the unconditional model, adjusting for matching factors and the above confounders, the result remained statistically significant (OR 4.3, 95%CI 1.6–11.6).

Duvet weight was dichotomised at a median of 819.5 g. Use of heavier duvets in reference sleep was associated with a crude sevenfold risk of SIDS (OR 7.3, 95%CI 2.7–19.5), which was reduced to 4.2 (0.8, 22.4) and lost statistical significance after adjustment for infant age, SES and nationality in the conditional model. Again, the unconditional logistic model revealed a statistically significant fourfold risk of SIDS even after adjustment for confounders and matching factors (OR 4.4, 95%CI 1.1–13.3).

Softness of the underlay, measured as the distance a 2-kg weight sank in, turned out to be greater in cases than in controls. Dichotomised at its median value, conditional logistic regression revealed a crude odds ratio of 2.7 (1.2, 6.3), which lost statistical significance after adjustment for infant age, SES and nationality (OR 4.3, 95%CI 0.8–23.7).

Adjusted unconditional logistic regression, however, still showed a threefold risk of SIDS associated with a soft underlay (OR 3.0, 5%CI 1.1–8.7).

According to parent interviews and demonstrations at the death scene, 52% of cases were found with their heads covered by bedding, in contrast to only three control infants (2%). When found dead, 30% of cases were found to be completely covered by bedding, but only two (1%) of the controls were found to be completely covered when the wake-up scene was observed. In the conditional logistic models, face covering was associated with a crude 33-fold, and an adjusted 16-fold, risk of SIDS (OR 15.8, 95%CI 2.5–102.1). Complete covering of the body was associated with a crude OR of 39. The adjusted odds ratio could only be calculated by unconditional logistic regression and was 35.5 (95%CI 5.5–228.3).

Discussion

This is the first case–control study that has included an observational scene investigation in both cases and controls and has identified pillow use, heavy duvets, a soft underlay and head covering by bedding as important and potentially preventable risk factors for SIDS. Because almost all information was obtained by standardised measurements taken by trained doctors of legal medicine, rather than by asking parents retrospectively, a major recall bias is highly unlikely. Every effort has been made to obtain data from cases and controls in a comparable manner. However, some degree of information bias cannot be completely excluded.

Table 3 Characteristics of bedding and covering and their associated risk of SIDS

	Cases	Controls	cLR ^a	cLR ^b	uLR ^c
Pillow used in cot					
No	30	123	1.0	1.0	1.0
Yes	21	27	4.9 (2.3–10.4)	2.9 (0.8–10.5)	4.3 (1.6–11.6)
Weight of duvet (g)					
≤819.5	9	81	1.0	1.0	1.0
>819.5	35	55	7.3 (2.7–19.5)	4.2 (0.8–22.5)	4.4 (1.5–13.3)
Softness of underlay (distance a 2-kg weight sinks in)					
≤14.5 mm	14	72	1.0	1.0	1.0
>14.5 mm	27	72	2.7 (1.2–6.3)	4.3 (0.8–23.7)	3.0 (1.1–8.7)
Infant face found covered					
No	23	145	1.0	1.0	
Yes	25	3	33.2 (7.8–140.5)	15.8 (2.5–102.1)	
Infant found completely covered					
No	35	145	1.0		1.0
Yes	15	2	39.2 (5.2–298.1)	–	35.5 (5.5–228.3)

^a Conditional logistic regression; crude odds ratios

^b Conditional logistic regression; odds ratios adjusted for infant age, SES, nationality

^c Unconditional logistic regression; odds ratios adjusted for matching factors (gender, study region, infant age), SES, nationality

Even when made at short notice, an appointed visit to control parents was a different situation from the unexpected discovery of a dead infant.

We cannot exclude that some parents may have intentionally changed the sleep environment or tidied their infant's sleeping room for the visiting doctor, which could have introduced some degree of non-conservative bias. It will be noticed that controls were, on average, about 10 days older than cases on the day of the home visit; this potential bias was adjusted in the logistic model and thus is unlikely to have substantially influenced the results.

Due to declining infant mortality rates, the number of cases eventually enrolled was lower than expected, resulting in a loss of study power or in an increase of the smallest detectable relative risk, respectively. Also the death scene investigation could be carried out within 6 h of discovery of the dead infant in only half of the cases. In the cases where this was not possible, a number of variables, such as temperature measurements, were likely to have changed and therefore were not obtained. This means that any associations with small magnitudes of effect may have failed to reach statistical significance. The use of unconditional logistic regression for individually matched data is unusual and may bias any effect estimates towards the null to some degree. However, this conservative bias is not substantial and may be acceptable in a situation where conditional logistic regression does not yield any results due to low numbers of cases.

The participation of 52% in controls was disappointing. Though studies with low response proportions may, in principle, be less biased than studies with high response proportions [21], there is evidence that lower educated parents were less willing to consent to be enrolled in this study. After adjusting for SES, however, we feel that any residual bias is unlikely to be able to change results substantially.

This study involved case parents at a time of great emotional pressure, which was also experienced by the investigators. Even in the acute situation of having so very recently found that their infant had died, none of the bereaved parents declined the home visit. Many parents were grateful to have someone around them who was familiar with this distressing situation and who could be approached for advice. For this reason, it is felt that this study provided a benefit to participating parents that was, at least partly, able to compensate for the extra stress arising from taking part. Investigators made sure that all data were obtained in a standardised way before addressing any advice to parents.

In our study, use of a pillow in the cot was associated with a fourfold increase in the risk of SIDS. Several other studies had similar findings [10, 22–24], although another

one did not identify pillow use as a risk factor [25]. Pillows may be of particular risk for infants sleeping in the facedown position [26]. Carleton et al. [27] found a high degree of rebreathing and CO₂ retention in experimental settings with infant mannequins lying facedown on a pillow or other bedding material. Most preventive measures aiming at reducing SIDS rates recommend that pillows should not be used on infants' beds [28, 29].

There was no difference in the frequency of duvet use between cases and controls; a heavy duvet, however, turned out to be a major risk factor for SIDS in this study. Not only were duvets in cases larger, the specific weight was also higher than in controls. The use of a duvet has previously been identified as a risk factor for SIDS [8, 30] and may have a higher impact on infants sleeping in a non-prone position [31]. This could be explained by a higher thermal insulation [32] or a higher likelihood of having the face covered by a heavy duvet [33]. Whatever the cause, the use of any duvet, quilt or pillow should be discouraged as a preventive measure for SIDS [29].

The softness of mattresses and any underlay was higher in cases than in controls. This is in accordance with other studies [7, 34]. In the Chicago Infant Mortality Study, a soft sleeping surface was associated with an increased risk of SIDS [10]. In that study, however, data were collected by parental report rather than by objective measurements. Experimental evidence suggests that soft bedding may result in rebreathing and CO₂ retention in infants sleeping prone [27, 35–37] and this has been hypothesised as a potential death mechanism in SIDS [38].

Cases were much more likely to be found with their face or whole body covered by bedding than controls. Covering has been found to be a risk factor for SIDS in some earlier studies [39–43]. Covering of the head by bedding during sleep is associated with accumulation of CO₂ around the face [33, 44], as well as with a higher body temperature and significant changes in autonomic balance [45]. Present advice given to parents includes the fact that infants should not be in a situation where they are able to become covered by bedding [28, 29, 46]; use of a sleeping bag is one way of achieving a safe situation [30].

Conclusions

Using a standardised protocol, including objective measurements of the sleep environment, and a case–control design, this study could confirm many well-established risk factors for SIDS. In addition, our data suggest that heavy duvets or quilts may further increase the risk of SIDS. The methods used in this study are recommended for inclusion in a standard protocol for scene investigation in sudden unexpected infant deaths [47].

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Conflict of interest statement All authors declare that there are no competing interests.

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