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ORIGINAL ARTICLE

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German study on sudden infant death (GeSID): design, epidemiological and pathological profile

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Abstract The German study on sudden infant death (GeSID) is a multi-centre case-control study aiming at the assessment of etiological factors and risk factors of SIDS. This report describes the study design and the methods applied and presents some general findings. Between 1998 and 2001, 455 cases of sudden and unexpected death of infants aged between 8 and 365 days were recruited into the study. The study comprised at least 11 out of the 16 German states with 18 centres involved. In 1999 and 2000, 75% of all SIDS cases registered with the Federal Office of Statistics (ICD 10/R95, *n*=384) in the study area were recruited into the study (*n*=286). A standardised autopsy including extended histology, microbiology, virology, toxicology and neuropathology investigations was carried out. Of the parents 82% (*n*=373) agreed to fill in an extensive questionnaire containing 120 questions reflecting all important aspects of the infant's development. For each SIDS case, the parents of three living control infants were interviewed. These controls were matched for age, gender and region (*n*=1,118). The response rate of the controls was 58.7%. Data were linked with medical records obtained from obstetrics departments, the children's hospitals, and general practitioners. Death scene investigation was performed in 4 study areas (cases: *n*=64, controls: *n*=191). All cases were classified into one of 4 categories using defined criteria: 7.3% of the children were assigned to category 1 (no pathological findings: SIDS), 61.1% to category 2 (minor findings: SIDS+), 20.4% to category 3 (severe findings: SIDS+) and 11.2% to category 4 (findings which explained the death: non-SIDS). In case conferences the previous history and circumstantial factors were included and an extended category (E-cat.) was defined. The consideration of these factors for the final classification is of great importance in the causal explanation of some cases. An analysis of 18 main variables in cases of categories 1–3 (SIDS) compared to the cases of category 4 (non-SIDS) showed significant differences for the sleeping position, coughing the day before death and breast-feeding indicating that the cases of both groups should be separated for further analyses.
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Keywords Sudden infant death syndrome (SIDS) · Standardised investigation protocol · Pathological and extended categories · Case-control study

A list of the collaborating authors and institutes is given in the appendix.

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Introduction

In Germany, sudden infant death syndrome (SIDS) is still the leading cause of death in infancy after the neonatal period. While the incidence dropped in the 1990s from 1.4 per 1,000 live births (*n*=1,283) to 0.6 in the year 2000 (*n*=482), the SIDS mortality rate is still much higher in Germany, than for example in the Netherlands (0.17‰) [1, 2].

In various international studies as well as in the Westfalian Cot Death Study [3, 4], risk factors such as the

prone sleeping position, smoking of the mother during pregnancy and overheating of the infant were identified [5, 6, 7, 8, 9] and highlighted in prevention campaigns leading to a significant decrease in the SIDS incidence [1, 10, 11, 12].

Based on these results, the German Federal Ministry for Science and Education supported the GeSID (German study on sudden infant death) to investigate SIDS in Germany. This interdisciplinary project started with a pilot study in 1996/1997 and the data collection period for the main study was performed from November 1998 to October 2001 as a multi-centre case-control study in 11 federal states with 18 centres involved.

Methods

Study area

Initially 13 forensic pathology institutes co-operated with the study centre. Because of the decreasing SIDS incidence the area was extended in mid-2000 to 18 centres in 11 states (Table 1). This area covered about 50% of Germany as well as 50% of all births.

All 18 centres obtained the approval of their local medical ethics committees and the control recruitment in each state was accepted by the state data protection officer.

Study population

All infants who seemed to die suddenly and unexpectedly from the results of necropsy were to be reported to the study centre by the emergency doctor, the pediatrician, the general practitioner or by police officers. Exclusion criteria were:

- Death prior to 8 days or later than 12 months after birth
- Cases where death was expected due to known diseases
- Unnatural deaths
- Parents had insufficient knowledge of the German language so that informed consent could not be obtained.

Controls and recruitment of the controls

Two local registry offices in the area where the infant had died were approached and each was asked to select five control infants matched for age, gender and the geographical region. These control infants had been born 4–6 weeks after the case infant, so by the time the interview was done they had the same age as the index case. From these controls the first 3 giving informed consent and who did not fulfil the following exclusion criteria were selected:

- Age less than 8 days or more than 1 year
- Infant admitted to hospital prior to the time of interview
- Infants who were fatally ill
- Infant was a SIDS surviving twin
- Informed consent could not be obtained.

Interview

The questionnaire consisted of 106 questions dealing with major topics such as family and child history, socio-demographic factors, sleeping situation, feeding of the infant, cigarette and alcohol consumption of the parents during pregnancy and after birth. In an annex data on antenatal obstetrician visits of the mother, vaccinations received by the infant, and so-called well-baby check-ups are given. The socio-economic questions were based on "MONICA" (Monitoring Trends and Determinants in Cardiovascular Diseases, Augsburg Cohort Study 1984–1995) [13] and social status was calculated according to the modified "Scheuch Index" [14]. The questionnaire was filled in by trained interviewers who visited the parents at their homes. For quality control, interviews were recorded on tape with the consent of the parents and every 10th interview was checked for accuracy.

Additional information

The physician who made the well-baby check-ups filled in a questionnaire containing 20 questions relating to health status and threatment, vaccination status, and suspected child abuse and/or neglect. The delivery clinic was asked to provide the discharge documents, containing information about previous pregnancies, delivery mode of the index case and the Apgar score. If a child had been admitted to hospital, the related records were also evaluated.

Table 1 Institutes of Legal Medicine participating in the project, cases examined and response rate for interviews

Institues of Legal Medicine	Months of cooperation	Region in Germany	Cases per area	Autopsy only	Interview and autopsy	Response rate
Aachen	36	West	23	7	16	70%
Berlin East/West	16	East	21	4	17	81%
Dortmund	16	West	6	2	4	67%
Düsseldorf	16	West	8	0	8	100%
Erlangen	16	South	20	8	12	60%
Essen	36	West	24	6	18	75%
Frankfurt a. M.	33	South	43	8	35	81%
Freiburg	34	South	18	4	14	78%
Halle[a]	35	East	13	0	13 (12[a])	100%
Hamburg[a]	36	North	18	2	16 (10[a])	89%
Hannover[a]	35	North	56	8	48 (21[a])	86%
Heidelberg	34	South	22	6	16	73%
Jena[a]	35	East	18	5	13 (12[a])	72%
Kiel	33	North	17	1	16	94%
Magdeburg[a]	35	East	11	0	11 (9[a])	100%
Munich	34	South	74	17	57	77%
Münster	36	West	57	4	53	93%
Potsdam	16	East	6	0	6	100%
Total			455	82	373 (64[a])	82%

[a]Death scene investigation performed.

A 10-point questionnaire was applied if a child had been previously monitored.

Morphological investigations

A standardised autopsy protocol (SAP) was introduced to all study centers involved (ESM Tables. I–IV, Fig. 1). This SAP is in accordance with the European guidelines for medico-legal autopsies [15] and closely reflects the international standardised autopsy protocol [16] as well as protocols used in other studies on SIDS [5, 17, 18]. The autopsy included a thorough external examination, a complete internal examination (ESM Table I), extensive histology (ESM Table II, Fig. 1), a full analytical toxicology scheme (ESM Table III), and microbiology and virology (ESM Table IV).

Histology

A total of 20 samples were taken from defined organs and tissues and were further processed into 90 microsections for different staining methods (ESM, Table II, Fig. 1). The first assessment was made in the department performing the autopsy. The validation of these findings was done at the study centre by an experienced histologist using coded slides. The histology was evaluated qualitatively and quantitatively (grading) and every 10th case was sent to an expert in paediatric pathology for confirmation. A weighted kappa index was calculated to evaluate the interreader agreement.

Neuropathology

The "routine" examination was based on the SAP (ESM Tables I and II).

Toxicology

Body fluids, tissue samples and stomach contents were taken (ESM Table III) and toxicological analysis was performed for the following substances:

1. Ethanol, methanol, acetone, iso-propanol; blood/serum; headspace gas chromatography [18], cut-off 20 µg/ml
2. Carboxyhaemoglobin; cardiac blood, photometry [19]
3. Amphetamines, cannabinoids, cocaine, opiates; acetone extract from cardiac blood, immunology screening [20]
4. General unknown analysis [21] for the detection of antiepileptic drugs (carbamazepine, phenobarbital), benzodiazepines and metabolites, hypnotics (e.g. diphenhydramine), antidepressants (e.g. amitriptyline, maprotiline), neuroleptics, opiates and other analgetic drugs; blood, liver tissue, determined by gas chromatography mass spectrometry after enzymatic cleavage of metabolites and an extraction procedure.

Microbiology/virology

Virology screening was done for the detection of defined viruses by PCR methods in the tracheal mucosa (influenza A+B, parainfluenza virus, adenovirus, respiratory syncytial virus and cytomegalovirus) and in the stool (adenovirus, enterovirus, rotavirus, ESM Table IV).

Microbiology was carried out using conventional techniques for the detection of bacteria in smears taken from defined regions and tissue samples (ESM Table IV).

Data management and statistics

All data were entered with a case-related code number. Data recording and statistical analysis were performed at the study centre using the SAS (Statistical Analysis System, version 6.12) software.

Table 2 Pathology categories and criteria for diagnoses

Pathology category	Results of autopsy
P-cat. 1	Without pathological findings from autopsy and additional investigations
P-cat. 2	With minor pathological findings in autopsy and investigations
	Minor infections of the respiratory tract
	Rhinitis, otitis media, pharyngitis, tracheitis
	Bronchitis, mild/intermediate forms of peribronchitis
	Mild/intermediate forms of bronchiolitis and of interstitial pneumonia
	Tonsillitis
	Mild abnormalities and congenital deformations
	Mild forms of hepatitis/ hepatosis
	Enteritis without exsiccosis
	Mild forms of nephritis/ nephrosis
	Local infection with cytomegalovirus
	Mild forms of metabolic disorders without symptoms
P-cat. 3	Severe findings
	Metabolic disorders
	Interstitial pneumonia showing bacterial superinfection
	Severe bronchiolitis
	Enteritis with exsiccosis
	Pericarditis/myocarditis, especially of the borderline type
	Mild forms of meningo-encephalitis
P-cat. 4	Clear cause of death
	Bronchopneumonia
	Interstitial pneumonia with carditis
	Severe meningo-encephalitis
	Major congenital disorders
	Generalised infection
	Myocarditis with sarcolysis

Case conferences

A review committee consisting of a forensic pathologist, a paediatrician, a histologist, a microbiologist and an epidemiologist reviewed all cases to determine the cause of death and to assign a case to a specific category, using a modified version of the classification proposed by Taylor and Emery [22]. As the information derived from cases with a parental interview was much more detailed than that from cases lacking an interview, a second category was introduced. Cases were allocated to a P-cat. (pathological category), and interviewed cases to an E-cat. (extended category), based on the pathological findings, the previous history and the circumstances of the death (Tables 2 and 3).

Results

Case recruitment

Comparison of the data from the Federal Offices of Statistics and the cases registered in the study reveals that the

Table 3 Extended categories (E-cat.) with additional information on pathological categories and criteria deduced from information on the circumstances of the death and the previous history

Extended category	Previous history and circumstances of the death
E-cat. 1	P-cat. 1 and no unusual previous history
E-cat. 2	P-cat. 1 or 2 in addition with minor findings in circumstances and previous history Infection 48 h prior to death Fever <40°C rectal Malnutrition
E-cat. 3	P-cat. 1–3 and severe findings Fever≥40°C rectal Vomiting and/or diarrhoea >24 h Possible suffocation in soft bedding No feeding: ≥12 h until 12th week of life, ≥14 h after the 12th week of life
E-cat. 4	P-cat. 1–4 and findings explaining the death Case reports Emergency doctor measured rectal temperature of 42°C Body weight loss over several weeks with clear signs of dystrophy

Table 4 Case recruitment in relation to the data of the Federal Office of Statistics with the diagnosis "SIDS" (ICD 10; R95) and the total infant mortality after the 7th day of life

Year	Total infant mortality in the study region	SIDS cases registered by the National Office of Statistics (ICD 10, R95)	SIDS cases registered in the study
	N	N	N (%)
1999	746	199	134 (67.3)
2000	710	185	152 (82.2)
Total	1,456	384	286 (74.5)

recruitment rate was 67.3% out of 384 cases in 1999 and 82.2% out of 286 cases in 2000 (Table 4).

Parents interview

Cases

Of the 455 cases recruited into the study, 82 parents did not consent to participate in the interview (18%). The interview was held 31 days after death on average.

Controls

Proportions of response, contact and co-operation were calculated according to the definitions of Slattery et al. [23]. Overall, 2,702 families were contacted, and 58.7% finally agreed to participate.

For the age-matching criterion the overall difference in mean age was 1 week (mean age of cases 19 weeks, controls 20 weeks).

Clinical documentation

Of thepaediatricians 69 did not complete the questionaire and 34 infants had never been seen by a doctor. The response rate to the questionnaire was therefore 95.3%. Discharge letters were requested for 378 admissions to children's hospitals (response rate 93.4%, *n*=354).

A total of 1,491 discharge letters from delivery clinics were requested. Data on 16 home deliveries could not be obtained and 8 hospitals refused to participate (response rate 98%).

Histology

For the differences between interreader variability of the histological diagnosis the weighted kappa index [24] was used. The final diagnosis of the institute and the second opinion in the study centre were compared for 433 cases (for 22 cases only 1 result was obtained): the weighted kappa index was calculated as κ=0.67 (95% CI: 0.61–0.73). The comparison of the second and third diagnoses (*n*=120) gave a similar level of agreement (κ=0.57; 95% CI: 0.45–0.69).

Case conferences

Pathomorphological classification of cases (P-cat.)

All cases were classified by the committee into 1 of 4 categories using defined criteria (Table 2). Of the children 7.3% were assigned to category 1 (no pathological findings: SIDS), 61.1% to category 2 (minor findings: SIDS+), 20.4% to category 3 (severe findings: SIDS+) and 11.2% to category 4 (findings which explained the death: non-SIDS). The distribution of cases with or without interview into the 4 categories did not differ significantly (Tables 5 and 6).

Extended classification by E-category (E-cat.)

The E-cat. was introduced to consider the previous history, the circumstances of death as well as pathological findings (Table 3). Example: an infant with an upper air-

Table 5 Pathomorphological classification for all cases (*n*=455)

Category	P-cat. 1	P-cat. 2	P-cat. 3	P-cat. 4
Cases	n=33 7.25%	n=278 61.10%	n=93 20.44%	n=51 11.21%

Table 6 Pathomorphological (P-cat.) and extended classification (E-cat.) for interviewed cases (n=373)

Category	P-cat. 1	P-cat. 2	P-cat. 3	P-cat. 4	Total E-cat
E-cat. 1	7	0	0	0	7 (1.9%)
E-cat. 2	12	115	0	0	127 (34.1%)
E-cat. 3	11	108	78	0	197 (52.8%)
E-cat. 4	0	2	0	40	42 (11.3%)
Total P-cat.	30 (8.0%)	225 (60.3%)	78 (20.9%)	40 (10.7%)	373

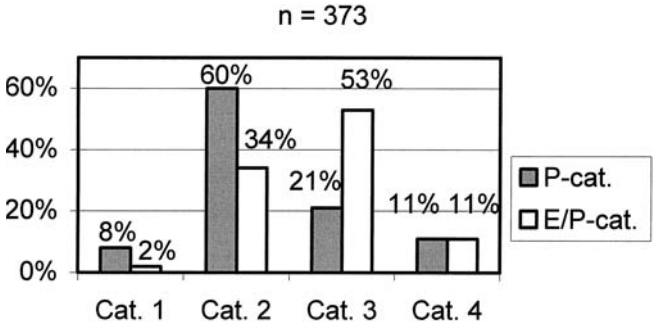

Fig. 1 Shifts in the classification of cases (P-cat.) due to the introduction of E-cat

way infection graded P-cat. 2 had been found dead with a rectal temperature of 42.5 C°. Hyperthermia was considered to be the cause of death. Final classification: E-cat. 4. The 82 cases lacking an interview were classified as P-cat. only. The distributions of the combined E-cat and P-cat. revealed either no difference (P-cat. 4 and E-cat. 4; 11%) or only minor differences in category 1 (P-cat. 8%, E-cat 2%) (Table 6). Major shifts were observed between categories 2 (P-cat. 60%, E-cat. 34%) and 3 (P-cat. 21%, E-cat. 53%). The combination of pathology and previous history with regard to the circumstances of death led to a decrease in category 2 and consequently to a significant increase in category 3 (Fig. 1).

Discussion

A total of 45 million inhabitants, 54.9% of the total population of Germany, live in the study areas. At 430,000 the annual number of births is approximately 55.7% of the overall number. Taking into account that some states were fully covered in the investigation, that all major geographical regions of Germany were included, and that the proportions of rural and urban regions were well balanced, and reflected those of the whole of Germany, the study area can be considered as being representative for the whole of Germany.

To determine the incidence of SIDS in the study area, the reported cases were compared with the annual data of the Federal Office of Statistics which suggest a high rate of case recruitment into the study for the years 1999 and 2000 of 74.5% (official data for 2001 are not available at present) [1].

The rate of parental consent of case families to the interview was high (82%), suggesting reliable findings re-

Table 7 Pathological categories and distribution of main variables (n=373)

Variable	P-cat. 1 n=30 (8.0%)	P-cat. 2 n=225 (60.3%)	P-cat. 3 n=78 (20.9%)	P-cat. 4 n=40 (10.7%)	Cochran-Armitage trend test p-value	P-cat. 1–3/ P-cat. 4 Fisher's Exact test
Age of infant (<90 days)	9 (30)	78 (34.7)	27 (34.6)	20 (50)	0.09	0.06
Gender (male)	23 (76.7)	130 (57.8)	48 (61.5)	20 (50)	0.14	0.24
Season (May–October)	18 (60)	103 (45.8)	36 (46.1)	13 (32.5)	0.05	0.09
Time of death (night)	13 (43.3)	138 (61.3)	46 (59)	22 (55)	0.80	0.62
Maternal age (<21 years)	10 (33.3)	59 (26.2)	17 (21.8)	7 (17.5)	0.09	0.33
Parents central European	24 (80)	182 (80.9)	64 (82.1)	34 (85.0)	0.97	0.83
Maternal school education <10 years	16 (53.3)	138 (61.4)	49 (62.8)	20 (50)	0.63	0.23
Smoking during pregnancy	20 (66.7)	144 (64)	49 (59)	24 (60)	0.55	0.61
Previous live births (=0)	14 (46.7)	74 (32.9)	23 (29.5)	10 (25)	0.07	0.37
Gestational age (<38 weeks)	10 (33.3)	57 (25.6)	20 (25.6)	9 (22.5)	0.43	0.71
Birth weight (<2500 g)	6 (20)	36 (16)	17 (21.8)	4 (10)	0.63	0.27
Breastfeeding	16 (53.3)	105 (46.7)	44 (56.4)	29 (72.5)	0.01	0.01
Position placed to sleep (prone)	15 (50)	94 (41.8)	27 (34.6)	7 (17.5)	0.001	0.003
Extra warming	5 (17.2)	35 (15.6)	13 (16.7)	6 (15.8)	0.99	1.00
Co-sleeping	3 (10)	34 (15.1)	11 (14.1)	9 (22.5)	0.23	0.24
Pacifier (last sleep)	13 (43.3)	90 (40.0)	32 (41)	16 (40)	0.76	1.00
Head covered	7 (24.1)	62 (27.8)	23 (30.7)	6 (15)	0.51	0.17
Coughing the day before death	2 (6.7)	24 (10.7)	9 (11.5)	12 (30)	0.002	0.001

lating to the epidemiology of SIDS. The average time interval between death and interview of 31 days has logistical reasons but was in the range of other studies (ECAS 34 days [11], NZ study 28 days [25]). It has been shown in other SIDS studies that such a time interval did not influence the results, because parents are able to remember in great detail what happened around the time of the infants death [26, 27].

The overall response rate of controls (58.7%) was similar to response rates of other German studies [28]. In a sample of 54,000 deliveries from Westfalia [29] we found similar data for maternal smoking during pregnancy and for birth weight of the infants as well as for maternal age as in the present study, indicating that the controls are representative. However, a more detailed examination of these data will follow with the ongoing analyses.

The κ-values for interreader variability of the histological diagnoses demonstrate the quality of the standardised morphological investigations and the use of unique diagnostic criteria.

Case ascertainment was thoroughly done using four categories. The Nordic study [30], the CESID study [31] and the European Concerted Action on SIDS (ECAS) [17] used three categories. In order to be able to compare the data collected in this study with the data of the Westfalian Cot Death Study [32], we used the same system again. The categories 2 and 3 used in the German study correspond with the borderline SIDS or SIDS+ cases in these three other major studies.

Epidemiological analysis

To determine the strategy of the analysis in the case control study, we analysed the distribution of 18 main factors for SIDS in the categories defined. The statistical test applied to compare the subgroups 1–3 and 4 resulted in significant differences in 3 main variables:

- Breast-feeding showed an increase in P-cat. 4 (Table 7)
- The prone position was a more common sleep-related pattern in P-cats. 1–3. There seemed to be a gradual decrease of this risk factor in relation to an increase in the severity of pathological changes. From a pathophysiological point of view, this correlation seems highly plausible. On the other hand this link confirms the importance of the prone position as a contributing factor.
- Coughing the day before death: the stepwise increase in coughing from P-cat. 1 to P-cat. 4 correlated as a symptom with the severity of upper airway infections. This also confirms the accuracy of the grading of the pathological findings (κ-index 0.67).

From the results (Table 7) it can be seen that the cases in P-cat. 1–3 show similarities (SIDS cases). The statistical tests suggest that the epidemiological profiles of the cases in subgroup 4 differ from those of the other groups. These cases (P-cat. 4) were therefore excluded from further epidemiological analysis of SIDS cases and will be analysed separately.

Among the 455 cases autopsied, only 7% remained without significant findings in the pathology investigation scheme (Table 5). This figure is further decreased if the combined P/E-cat. criterium is applied (Table 6). Only approximately 2% of all cases investigated were without findings in the pathology scheme as well as in the previous history. Only 36% of cases with the combined score E-cat. failed to offer an adequate explanation for the fatal outcome. In particular the shift between categories 2 and 3 in the combined score shows that the consideration of circumstantial factors and the previous history is of great importance in the causal explanation of sudden unexpected death in infancy.

In conclusion a detailed investigation as carried out in the GeSID study can contribute to explaining the cause of death in a considerable number of cases compared to a routine autopsy alone and is a prerequisite for a high quality of epidemiological case-control studies. Some risk factors for SIDS gradually change as more pathological findings were detected by extensive postmortem investigations (Table 7). Therefore a more detailed epidemiological analysis of the moderately large categories of death is necessary to demonstrate statistically significant trends, and statistically significant differences between subgroups and to develop focused prevention strategies.

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Appendix

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