Sudden Infant Death With External Airways Covered
Case-Comparison Study of 206 Deaths in the United States
N. J. Scheers, PhD; C. Mitchell Dayton, PhD; James S. Kemp, MD

Objective: To study factors associated with sudden infant deaths occurring with the external airways (ie, nose and mouth) covered by bedding.

Design: Case-comparison study of infants dying with vs those dying without the external airways covered.

Setting: Death-scene investigation and reconstruction at the site of death using an infant mannequin; 18 metropolitan areas.

Participants: Caregivers for a consecutive sample of infants who died of sudden infant death syndrome (SIDS). Complete data from 206 of 382 eligible cases.

Main Outcome Measures: Among infants dying suddenly and unexpectedly, an analysis of whether sociodemographic risk factors for SIDS, sleep practices, or bedding increased the risk of dying with the external airways covered.

Results: Data were analyzed by using univariate and 2 types of multivariate risk analysis, logistic regression and latent class. Of the victims, 59 (29%) were found with the external airways covered. Conventional risk factors for SIDS did not affect the risk of death with the external airways covered. Factors increasing the risk of death with the external airways covered included prone sleep position (odds ratio [OR], 2.86) and using soft bedding (OR, 5.28), such as comforters (OR, 2.46) and pillows (OR, 3.31). Infants at low risk for death with the external airways covered slept in the prone position, but rarely on a pillow, comforter, or other bedding that allowed a pocket to form beneath the face. All 9 infants who were positioned supine or on one side for sleep and found with the external airways covered had turned and were found dead in the prone position.

Conclusions: Sudden infant deaths with the external airways covered were common in the United States when most infants slept prone. Soft bedding, including pillows and comforters, increased the risk that an infant who died would be found with the external airways covered. Therefore, these items should not be placed near infants, regardless of the sleep position.

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Editor’s Note: This is one case for soft findings (eg, pillows, comforters) being of great significance.

Catherine D. DeAngelis, MD

Research conducted in other countries shows that sleeping with the head and face covered,1-3 using certain items of soft bedding,4-5 and sleeping in the prone position6-7 increase the risk of sudden infant death syndrome (SIDS). There are no controlled studies from the United States of the interactions among head and face covering, bedding, and sleep position. However, case series from the United States suggest that infants are at increased risk for death when they sleep on certain items of bedding, eg, waterbeds and sleeping bags, because the infants were found with the head covered, particularly the face, nose, and mouth.8-9 Physiological studies have shown that many of the bedding items cause substantial thermal stress or rebreathing of exhaled gases.9-16 Thus, epidemiological data from abroad and limited clinical and physiological studies from the United States and elsewhere suggest that soft bedding covering the entire head or just the face can pose a risk for sudden death among infants. Indeed, before the recent “Back-to-Sleep” campaign, perhaps 30% of sudden infant deaths in the United States occurred with the infant prone and with the external airways (ie, nose and mouth) covered.10-17-19

We report a case-comparison study conducted in the United States of infants dying suddenly and unexpectedly. For the study, we divided the infants into 2 groups. Group 1 included infants (n=59) who died...
RISK FOR SIDS, SLEEP PRACTICES, AND DEATH-SCENE INVESTIGATION

The CPSC study interviews were conducted by investigators experienced with face-to-face interviews about product-related matters. In addition, the CPSC staff attended a 2-day program given by the St Louis investigators and other specialists in SIDS. The program emphasized how to conduct a thorough, but empathetic, death-scene investigation and how to avoid bias in the interview.

RESULTS

In the CPSC study, 414 potential cases were identified in which SIDS was the initial or preliminary diagnosis. Of the original 414 cases, 64 were not included in the study, as further review showed that in 13 cases, death was due to suffocation (eg, wedging of the head and body, head entrapment, or overlying by a person in the same bed), and in 51 cases, other causes of death were found by examining the histological specimens (eg, respiratory infections, 27; “undetermined,” 6; hypoxic-ischemic encephalopathy, 5; heart disease, 3; and dehydration, 2). Cases in which another diagnosis became apparent after the examination of histological specimens were referred from 11 sites, and no site-specific

with their external airways covered and group 2 included infants (n=147) who died with the external airways uncovered. We chose the case-comparison approach to compare the circumstances of their deaths because it increased the likelihood that we would identify factors associated with death with the external airways covered. We did not use the familiar case-control method commonly used in SIDS research to identify factors associated with death per se. Rather, we chose the case-comparison approach, with deceased rather than living control infants, because we were interested in determining whether certain sleep practices and bedding factors, such as prone sleep position and soft bedding, and risk factors for SIDS, such as winter season and prematurity, might distinguish the 2 groups.

Our results show that sudden infant deaths with the head covered, in the United States, occurred most often with parts of the front, rather than the back, of the head covered, and that deaths with the nose and mouth covered were more frequent among infants sleeping in the prone position on soft bedding. Our results emphasize the potential role of bedding and are pertinent to modifiable SIDS-related sleep practices in the United States.
physically, the presence of a pocket that persisted after the mannequin was lifted off the bedding suggested that the bedding was soft and malleable. The depth of the pocket was measured, and the absence of any discernible impression was recorded as “no pocket.” The St Louis study did not document the presence or absence of a pocket created by the mannequin in all the study bedding, and less information was available about antecedent illness. For most of the deaths in group 1, the bedding was tested as a cause of rebreathing of exhaled gases. The methods and results of these tests have been reported in detail.

Data from the CPSC study were reviewed for consistency with data from medical examiners’ investigations. Although differences were unusual (3 of 59 in group 1), when there were important discrepancies, the data from the mannequin reconstruction were used.

STATISTICAL ANALYSIS

Analyses were based on comparisons between the 59 infants in group 1 and the 147 infants in group 2, and the results are shown in Table 2 through Table 5. Unadjusted odds ratios were calculated for group 1 vs group 2 by using the standard risk factors for SIDS listed in Table 1 and by using the possible risk factors associated with bedding. The bedding factors considered are shown in Tables 4 and 5.

Both univariate and adjusted odds ratios were computed using SPSS for Windows 6.14 (SPSS, Inc, Chicago, Ill). The latent class analyses were done using software described in detail.

Two types of multivariate analyses were used: logistic regression and latent class analysis. These analyses were used to conservatively address 4 principal hypotheses and to conservatively address 4 principal hypotheses and questions about group 1 deaths (external airways covered). Moreover, whether (1) a link exists between the prone sleep position and the death of infants in group 1; (2) deaths in group 1 were more likely on bedding with the physical properties of softness and malleability; (3) specific items of bedding used by infants from the United States increased the risk of death of group 1 infants; and (4) the SIDS-related sociodemographic risk factors affect the risk of death for group 1 infants.

From the multivariate logistic regression, 2 models were developed, with 3 steps in the development of each model (Table 5). From the latent class analysis, 3 subtypes were identified within the total sample of 206 (Figure 3).

Multivariate logistic regression analysis was performed with stepwise selection to identify variables associated with the group 1 deaths for 2 separate models (Table 5). Dichotomous variables (eg, prematurity and sex) were coded as 1 for present or 0 for absent. Cases from St Louis with missing data for pocket formation and illness were coded as zero (ie, “no pocket formation” and “no illness”). Two models were then developed, and the relevant results are shown in Table 5.

Model 1 (Table 5) assessed the significance of bedding-related variables after the effects of significant risk factors for SIDS had been held constant. Three steps were used in developing this model, using stepwise procedures on each step. The first-step variables included all risk factors listed in Table 1, except sleeping in the prone position. The second-step variables included variables related to the infant’s sleep environment: a blanket, a comforter, a pillow, or a sheet under the infant; bedding over the infant; formation of a pocket when the mannequin was positioned; bed sharing with another person; and a prone sleeping position. The third-step variables included interactions among the significant first- and second-step variables. Model 2 (Table 5) assessed the significance of bedding-related variables after the effects of all risk factors for SIDS had been held constant.

Latent class analysis was used as an aid to interpret the data because it has the potential to identify subgroups (latent classes) within the sample of 206 cases. Infants within the subgroups identified by latent class analysis were at more risk (or less) risk for death with the external airways covered. The latent class analysis was based on 6 dichotomous variables, the 3 risk factors identified in the logistic regression analysis (Table 5), and the outcome variable, external airways covered (yes or no). The latent class analysis yields a prediction of the fraction of the total sample with low risk or varying degrees of increased risk for death with external airways covered.

Differences were apparent. Of the 350 remaining CPSC cases, death-scene investigations were conducted for 176. The remaining 174 cases were not included in the study for the following reasons: (1) the person who found the infant dead could not be contacted (67 cases [38.5%]); (2) the person who found the infant dead was unwilling to be interviewed (73 cases [42.0%]); (3) the infant’s face position was not established reliably (15 cases [8.6%]); and (4) miscellaneous reasons (19 cases [10.9%]). Each CPSC site contributed approximately the same proportion to the cases that were included or not included in the study.

In St Louis, 30 of 32 potential cases were included, bringing the total number of cases for analysis to 206, ie, 206 cases in which complete postmortem and death-scene investigations led to the conclusion by the medical examiner or coroner that the death was due to SIDS. The median interval from death until a CPSC interview was 16 days; 89% were done within 2 months (ie, 61 days; range, 0-203 days); for St Louis, the mean±SD interval was 9.0 ± 7.7 days. For the CPSC data, the set of SIDS-related sociodemographic risk factors was not realizable (15 cases [8.6%]); and (4) miscellaneous reasons (19 cases [10.9%]). Each CPSC site contributed approximately the same proportion to the cases that were included or not included in the study.

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Table 1. Odds Ratios for Risk Factors for SIDS and External Airways Covered*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Cases (N = 206)</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioned prone to sleep</td>
<td>146 (70.9)</td>
<td>2.95†</td>
<td>1.34-6.48</td>
</tr>
<tr>
<td>Change in behavior during previous 48 h</td>
<td>56 (27.2)</td>
<td>1.87</td>
<td>0.97-3.60</td>
</tr>
<tr>
<td>Medication during previous 24 h</td>
<td>43 (20.9)</td>
<td>1.48</td>
<td>0.72-3.04</td>
</tr>
<tr>
<td>Boys</td>
<td>121 (58.7)</td>
<td>1.26</td>
<td>0.68-2.35</td>
</tr>
<tr>
<td>Respiratory illness</td>
<td>92 (44.7)</td>
<td>1.17</td>
<td>0.64-2.15</td>
</tr>
<tr>
<td>Premature (&lt;37 wk's gestation)</td>
<td>46 (22.3)</td>
<td>1.16</td>
<td>0.59-2.27</td>
</tr>
<tr>
<td>Birth weight &lt;2500 g</td>
<td>52 (25.2)</td>
<td>1.15</td>
<td>0.58-2.28</td>
</tr>
<tr>
<td>Age, 120 d or younger</td>
<td>165 (82.1)</td>
<td>1.12</td>
<td>0.52-2.41</td>
</tr>
<tr>
<td>Maternal smoking during pregnancy</td>
<td>78 (37.9)</td>
<td>0.77</td>
<td>0.41-1.45</td>
</tr>
<tr>
<td>Winter season (September 21 to March 20)</td>
<td>123 (59.7)</td>
<td>0.72</td>
<td>0.40-1.34</td>
</tr>
<tr>
<td>Major illness or injury since birth</td>
<td>48 (23.3)</td>
<td>0.68</td>
<td>0.32-1.45</td>
</tr>
<tr>
<td>Never breast-fed</td>
<td>141 (68.4)</td>
<td>0.56</td>
<td>0.30-1.06</td>
</tr>
<tr>
<td>Mother's age, younger than 20 y</td>
<td>63 (30.6)</td>
<td>0.54</td>
<td>0.27-1.10</td>
</tr>
<tr>
<td>Minority</td>
<td>130 (63.1)</td>
<td>0.54‡</td>
<td>0.29-0.99</td>
</tr>
</tbody>
</table>

* SIDS indicates sudden infant death syndrome.
† Data are given as number (percentage).
‡ Significant at P = .05.

Effect of SIDS

The risk factors for SIDS rarely had a significant effect on whether an infant was found with the external airways covered (Table 1). However, there were 2 important exceptions: (1) In general, infants in minority groups were less likely to die with the external airways covered. (2) Being placed prone for the “last sleep” before death increased the odds ratio (OR) for death with the external airways covered to almost 3. Changes in behavior suggestive of illness tended to be more common in group 1 infants (OR, 1.87; 95% confidence interval [CI], 0.97-3.60, not significant). Almost the same percentage of infants in group 1 (43 [73%]) as infants in group 2 (94 [64%]; χ² = 4.22, P = .24) habitually slept in the prone position. This finding is analogous to one noted in several other studies of sleep practices and SIDS, ie, there is a weaker effect on the risk for SIDS if the infant habitually slept prone compared with having slept prone on the night of death.35–37

Additional Effect of Sleeping Position

Table 3 shows, in greater detail, that being positioned prone for the last sleep is associated with a much higher rate of dying with the external airways covered compared with being positioned on one side or supine (χ² = 6.79, P ≤ .009). All 9 infants in group 1 who were positioned to sleep on one side or supine had turned to the prone position but were not found with external airways covered.

Although the data are not shown, only 2 infants in group 1 were found on one side or in the supine position. Of the infants in group 1 who were found in the prone position, 5 had their heads turned to the side; 52 infants in group 1 who were found in the prone position had their heads in the vertical or nearly face down position, and, thus, were positioned face down, or nearly so, at the time of death.

Effect of Bedding

Table 4 shows the unadjusted ORs for bedding factors linked to deaths in group 1. Of the infants in group 1, 27 (46%) were sleeping on comforters; only 34 (23%) of the infants in group 2 were sleeping on comforters. Of group 1 infants, 14 (24%) were sleeping on pillows; only 19 (13%) in group 2 were sleeping on pillows. In group 1, after the mannequin was lifted off the bedding, a pocket 1 to 4 inches deep was found in 21 cases (36%); in 6 cases (10%), the pocket was between ½ and 1 inch deep; thus, a pocket...
infants were sleeping on sheepskins. Only 82 (40%) of death with the external airways covered.

was left in 27 cases (46%). In group 2, a pocket was discernible in only 21 (14.3%) of 147 deaths. Multiple layers of bedding beneath the infant were associated with increased risk (≥2 layers vs 1 or no layer on the mattress or fixed sleeping surface); layers of bedding over the infant (≥1 vs none) were not associated with an increased risk of death with the external airways covered.

Four deaths (2 from each group) occurred while the infants were sleeping on sheepskins. Only 82 (40%) of the 206 infants were found in sleeping environments designed for infants (eg, bassinets or cribs). The remainder were sleeping on adult beds (74 infants [36%]), sofas (21 [10%]), waterbeds (6 [3%]), or the floor (6 [3%]) or in playpens (10 [5%]). Of the 206 infants, 70 (34%) were sharing a bed with another person at the time of death, including 48% of black infants, 21% of white infants, and 22% of Hispanic infants (χ²=8.97, P ≤.003 for all subgroups). None of the sleep arrangements had a significant effect in group 1 deaths except sharing a bed; fewer infants who shared a bed were included in group 1 (corrected χ²=4.54, P = .03).

Bedding from infants in group 1 was collected to study the relation to rebreathing of exhaled gases in 36 cases (61%). By using animal and mechanical testing models, 24 (67%) of the bedding caused marked rebreathing.

MODELS RESULTING FROM MULTIVARIATE RISK ANALYSES

Multivariate Logistic Regression Analyses

Table 5 shows the adjusted OR for the 2 models derived from the logistic regression analysis. Three steps were used in the development of each model. For model 1, in the first step, only race, among 13 conventional risk factors for SIDS, was significantly related to death in group 1 after the 13 risk factors were entered using stepwise procedures. In the second step, holding race constant and using stepwise procedures, the risk of death in group 1 was significantly increased if the infant was positioned on a soft item that left a pocket, prone for the last sleep, or on a pillow, or on a comforter. In the third step, there were no significant interactions among the first- and second-step variables shown in Table 5. For model 2, all 13 standard risk factors for SIDS were forced into the model in step 1. Results were essentially the same as with model 1; the same 4 bedding-related variables were significantly related to death in group 1 after all risk factors for SIDS had been held constant. However, in step 1 no risk factor for SIDS was significantly related to death in group 1; therefore, with the exception of race, these results are not shown in Table 5.

Latent Class Analysis

The latent class analysis was done to identify subgroups of infants with similar sleep practices within the sample of 206 cases. Results are shown in Figure 3. The subgroups and the predicted size of each were based on 6 dichotomous variables: sleeping in the prone position, 4 sleep practice variables from Table 5, and the outcome variable, external airways covered (yes or no). We calculated 2-, 3-, and 4-class latent class models for the 6-way frequency table. The 3-class model was chosen because it provided the best fit to the frequencies.
Results of death-scene investigations of 206 sudden unexpected infant deaths in the United States are presented. We document factors associated with death when the external airways are covered by bedding. These findings are the first direct evidence from epidemiological studies that infants positioned to sleep prone are more likely to die with the external airways covered. More than half of these infants were found dead on a comforter and on pocket-forming bedding. The representation of infants classified as minorities in the subgroups was as follows: low-risk, 70%; risk-pillow, 80%; and risk-comforter, 36%.

The 3-group latent class model predicted that 42% of the infants in the risk-pillow subgroup and 67% of the infants in the risk-comforter subgroup would be in group 1. Thus, the model predicted that 29.0% of the 206 cases would be in group 1 (actual rate, 28.6% [59/206]).

**COMMENT**

Results of death-scene investigations of 206 sudden unexpected infant deaths in the United States are presented. We document factors associated with death when the external airways are covered by bedding. These findings are the first direct evidence from epidemiological studies that infants positioned to sleep prone are more likely to die with the external airways covered. Although this may seem predictable, linkage between sleeping in the prone position and death with the external airways covered has not been established. That prone positioning increased the likelihood for death with the external airways covered was assumed but not studied earlier. We also explored the effect of risk factors for SIDS and the type of bedding used and whether the risk factors for SIDS or the type of bedding explained the risk of dying with the external airways covered.

Compared with infants in group 2, bedding beneath the infants in group 1 was soft and more likely to be sufficiently malleable to form a pocket beneath the infant (Tables 4 and 5, Figures 3, B, and 3, C). These findings were consistent with the studies of the physical properties of the bedding in cases of SIDS and with reports showing that pillows and soft bedding increased the risk for SIDS. Furthermore, the results shown in Tables 4 and 5 and Figures 3, B, and 3, C, identify specific soft and malleable items and indicate that comforters and pillows enhance the risk of death with the external airways covered. These results are analogous to the results of studies conducted in New Zealand and Australia, in which soft bedding, such as sheepskins and items filled with natural fibers, caused marked increases in the OR for sudden death while in the prone position.

Individual risk factors for SIDS did little to increase the risk of death with the external airways covered. However, a trend was noted toward an increased risk of death with the external airways covered with changes in behavior within 48 hours of death, including irritability and sleeping more; perhaps these changes were associated with blunting of arousal, abnormal behavioral responses to carbon dioxide, or thermal stress in the sleep environment. Among factors having nonsig-
nificant effects, the rate of death with the external airways covered was not higher during the colder months. This is surprising, because reduction in use of the prone sleeping position has been followed, in other countries, by loss of the winter peak in rates of SIDS. In the present study, the percentage of deaths during the winter months was similar (59.7%) to the percentage in an earlier US study (58.7%). In one explanation for no winter peak in deaths with the external airways covered is that infants in the United States do not use bedding during winter that is softer or that causes more rebreathing of exhaled gases than the bedding used during summer. If this is correct, and rebreathing exhaled gases is an important explanation for deaths in the prone position, the loss of the winter peak in SIDS may be less clear in the United States, when few infants sleep prone.

Nine infants died with the external airways covered after turning to the prone position from one side or the supine position (Table 3). This suggests that caregivers should use firm bedding and that soft bedding is dangerous, regardless of the initial sleep position of the infant.

One third of the infants died while they shared a bed with another person, including 48% of black infants. Nevertheless, significantly fewer infants died with external airways covered while sharing a bed than while sleeping alone. One interpretation of this finding is that sharing a bed may interrupt the sequence leading to death with the external airways covered. It also is plausible that the external airways of infants who died while sharing a bed were covered at the time of death, but the position of the external airways was changed before they were found dead. Our findings about sharing a bed and death with the external airways covered merit study because it is our impression from previous studies that shared adult beds are more likely than standard infant beds to be softer and to have other physical properties associated with deaths in the prone position.

In some cases, the interval between death of the infant and the site visit was several days. Because there are no reports on effects of recall bias on recollection of death with the external airways covered, we can only speculate whether the person who found the infant dead would preferentially report that the infant died with the external airways covered. One study of sleep position showed no bias in favor of recalling that the infant was placed in the prone position; whether the external airways were covered was not the focus in that study, however.

We used a case-comparison approach, rather than a case-control study. For a case-control study, appropriate controls would have been unexpected deaths not diagnosed as SIDS; however, this type of control group is unacceptable for the present study because it is very small and heterogeneous. More important, the case-comparison approach worked, by identifying factors associated with death with the external airways covered. Finally, if another case-control study had been done with living infants as controls, the results would have likely been consonant with ours, because only 2% to 4% of living infants habitually sleep in the prone position with their faces straight down, while 28.6% of our cases were found dead with the external airways covered, and almost all had their faces in the straight down or nearly straight down position. Why 20% to 50% of infants are found dead with the face down when only 2% to 4% sleep that way is likely explicable by a peculiar susceptibility of some infants who eventually lie face down on bedding that is soft or forms a pocket.

Some have claimed that the face-down posture is agonal and, thus, not instrumental in sudden death with the external airways covered. However, reports of witnessed unexpected deaths of 26 infants did not mention the infants turning into the face-down position. Moreover, acceptance of the face-down posture as agonal requires an explanation of why it is more likely to occur on soft items that form pockets. Finally, Waters et al showed that living infants in their own beds spontaneously positioned their faces so that their external airways were covered. This position sometimes caused striking abnormalities in oxygen saturation and partial pressure of carbon dioxide.

We used latent class analysis (Figure 3), a type of multivariate risk analysis, to detect subtle subgroups within the 206 cases. The subgroups were based on the risk for death with the external airways covered, the type of bedding used, the sleep position, and status within a minority group. We thus described 2 at-risk subgroups and 1 low-risk subgroup. The at-risk subgroups (risk-pillow and risk-comforter) accounted for virtually all deaths in group 1. The 2 subgroups associated with increased risk differed in important ways from the low-risk subgroup. Infants at low risk for death with the external airways covered often slept in the prone position but rarely on a pillow, comforter, or bedding that allowed a pocket to form (Figure 3, A). Compared with the low-risk subgroup, the risk-pillow subgroup (Figure 3, B) was more likely to have used bedding that allowed formation of a pocket, to have slept on a pillow, and to be from a minority group. Infants in the risk-comforter subgroup were most likely to have been positioned for sleep on a comforter or other bedding that permitted pocket formation (Figure 3, C). Thus, latent class analysis suggests simple strategies to reduce deaths with the external airways covered among minorities, although being a minority infant reduced the general risk for death with the external airways covered. As shown in Figures 3, B, and 3, C, many minority infants died with the external airways covered on pillows and comforters (80% and 36%, respectively).

Interest in factors affecting the risk for minority infants is warranted because the proportion of SIDS in many cities in the United States is much higher among poor black infants even since initiation of the “Back to Sleep” campaign. Furthermore, black infants continue to sleep in the prone position on bedding, including pillows, that increases risk of death with the external airways covered. Therefore, the latent class analysis suggests that, because black parents persist in positioning their infants prone for sleeping, they should not use pillows, comforters, or any malleable item that allows pocket formation.

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