

Infant Deaths and Injuries Associated with Wearable Blankets, Swaddle Wraps, and Swaddling

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Objective To assess risks involved in using wearable blankets, swaddle wraps, and swaddling.

Study design This was a retrospective review of incidents reported to the Consumer Product Safety Commission between 2004 and 2012.

Results A total of 36 incidents involving wearable blankets and swaddle wraps were reviewed, including 10 deaths, 2 injuries, and 12 incidents without injury. The median age at death was 3.5 months; 80% of the deaths were attributed to positional asphyxia related to prone sleeping, and 70% involved additional risk factors, usually soft bedding. Two injuries involved tooth extraction from the zipper. The 12 incidents without injury reported concern for strangulation/suffocation when the swaddle wrap became wrapped around the face/neck, and a potential choking hazard when the zipper detached. All 12 incidents involving swaddling in ordinary blankets resulted in death. The median age at death was 2 months; 58% of deaths were attributed to positional asphyxia related to prone sleeping, and 92% involved additional risk factors, most commonly soft bedding.

Conclusion Reports of sudden unexpected death in swaddled infants are rare. Risks can be reduced by placing infants supine and discontinuing swaddling as soon as an infant's earliest attempts to roll are observed. Risks can be further reduced by removing soft bedding and bumper pads from the sleep environment. When using commercial swaddle wraps, fasteners must be securely attached. (*J Pediatr* 2014;164:1152-6).

In its 2011 policy statement and technical report, the American Academy of Pediatrics (AAP) noted that the incidence of sudden infant death syndrome (SIDS) has decreased significantly since its 1992 recommendation that infants be placed in a nonprone position for sleep. This decline in the rate of death has plateaued, however, and other causes of sleep-related deaths in infants have increased in frequency.^{1,2} In 2011, the AAP expanded its recommendations for an overall safe sleeping environment for infants, rather than focusing solely on SIDS. These recommendations include supine positioning, breastfeeding, room sharing without bed sharing, immunizations, consideration of pacifier use, and avoidance of soft or loose bedding, smoke/alcohol/drug exposure, and overheating. The recommendations on avoiding soft or loose bedding note that infant clothing designed to keep the infant warm without posing a risk of entrapment or head covering may be used.^{1,2} In addition, swaddling is a frequently used technique to calm infants^{3,4} and to encourage supine sleeping.^{5,6}

Various forms of infant clothing designed to avoid loose blankets, and thus purportedly decrease the risk of SIDS, have become available in recent years. These include such items as infant sleeping bags (commonly referred to as wearable blankets) and swaddle wraps, which are wearable blankets with bands of fabric that can be wrapped around the infant. Indeed, more than 5 millions swaddle wraps have been sold in the US (personal communication, William Schmid, Halo Technologies, Inc, Minnetonka, Minnesota). The use of wearable blankets has been prevalent in Europe, and 1 case-control study found an association between the use of wearable blankets and a decreased incidence of SIDS, possibly because it facilitated supine placement and reduced rolling to the prone position.⁷ No subsequent studies have confirmed this finding, however, and there are no published data on the use of the newer swaddle wraps.

In the present study, we reviewed data collected by the Consumer Product Safety Commission (CPSC) pertaining to deaths, injuries, and potential injuries in infants with wearable blankets and swaddle wraps, as well as those swaddled in ordinary blankets, to assess the associated risks and to suggest strategies for minimizing these risks.

Methods

We conducted a retrospective review of infant deaths, injuries, and potential injuries involving wearable blankets, swaddle wraps, and swaddling occurring between September 2004 and July 2012 as reported to the CPSC. We used the

AAP	American Academy of Pediatrics
CPSC	Consumer Product Safety Commission
SIDS	Sudden infant death syndrome

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Freedom of Information Act to access data from 3 CPSC databases, including Death Certificates, Injury and Potential Injury Incidents, and In-Depth Investigations. Reporting to the CPSC is voluntary, and reports can be submitted by police and fire departments, insurance investigators, medical examiners and healthcare workers, manufacturers and retailers, and consumers.⁸ In addition, the CPSC conducts its own investigations into specific cases, which may include interviews with family members and other witnesses.

For all cases, we collected demographic information, infant position, type and mechanism of injury or potential injury, cause of death when applicable, and presence of known SIDS risk factors, such as smoke exposure, presence of soft bedding, or bed sharing. Each case was analyzed for hazard patterns. This study received exemption from review by the Institutional Review Board of Children's National Medical Center.

Results

A total of 36 cases were reviewed. There were 5 cases (including 1 death, 2 injuries, and 2 potential injuries) involving wearable blankets, 18 cases (including 8 deaths and 10 potential injuries) involving swaddle wraps, 1 case (resulting in death) involving an unspecified product (either a swaddle wrap or wearable blanket), and 12 cases (all resulting in death) involving infants swaddled in ordinary blankets. Brands and manufacturers of all products were redacted.

Deaths Associated with Wearable Blankets and Swaddle Wraps

Ten infants died in incidents involving wearable blankets and swaddle wraps (Table I). All but 2 of these cases were associated with swaddle wraps; 1 case was associated with a wearable blanket, and 1 case was unspecified. The median age of death was 3.5 months (IQR, 3-5 months). Four infants were female and 6 were male; 9 were white and 1 was Hispanic. In 8 cases (80%), the cause of death was attributed to positional asphyxia related to prone sleeping. In 7 of these 8 cases, the infant was placed supine or on the side and rolled to prone; in the other case, the infant was placed prone. In 2 reported deaths, the cause was undetermined. Eight infants were placed in a crib, portable crib, or bassinet; 1 was in a car seat; and 1 was in a glider seat.

Risk factors present in the sleep environment included soft bedding (n = 5) and bumper pads (n = 3). For 3 infants, no known environmental risk factors in the sleep environment were documented. Only 1 of the 10 reported deaths was associated with misuse of the swaddle wrap or wearable blanket. In that case, the mother had removed the Velcro wrap from the product and continued to use it after the 5-month-old infant had outgrown the swaddle wrap.

Deaths Associated with Swaddling in Ordinary Blankets

There were 12 reported incidents involving infants who were swaddled in ordinary blankets, all of which resulted in death

(Table II). The median age of these infants was 2 months (IQR, 1-3.5 months). Eight were female and 4 were male; 4 were white, 3 were black, 1 was biracial, 1 was Asian, and 3 were of unknown race/ethnicity. In 7 cases, the assigned cause of death was positional asphyxia related to prone sleeping. One of these infants had been laid prone, and the other 6 had rolled to prone from supine while swaddled. Four infants died from suffocation or mechanical asphyxia related to soft bedding, and 1 infant died from hyperthermia related to overbundling with an ambient temperature >90°F. Eight of the infants had been placed in a crib, portable crib, or bassinet. Two infants were in a car seat; 1 infant was on an adult bed; and for 1 infant the sleep location was unknown. Risk factors present in the sleep environment included blankets other than the swaddle blanket (n = 10), pillows (n = 3), and bumper pads (n = 3). One infant was known to be bed sharing, 1 was sleeping unrestrained in the car seat, and 2 had documented secondhand smoke exposure. For 1 infant, no known environmental risk factors in the sleep environment were documented.

Injuries and Incidents Without Injury Associated with Wearable Blankets

Two reported injuries were associated with wearable blankets, 1 in an infant aged 9 months and the other in an infant aged 15 months. Both injuries occurred when the zipper snagged on a tooth, resulting in accidental tooth extraction. In addition, there were 2 reports of a potential choking hazard when part of the zipper became detached from the wearable blanket. These 2 infants, both females, were aged 6 months and 7 months. Of note, one manufacturer subsequently changed the zipper design for its wearable blanket, so that the zipper pull is now a solid tab that cannot snag primary teeth.

Incidents Without Injury Associated with Swaddle Wraps

There were 10 reports from concerned individuals of potential injury associated with swaddle wraps when part of the swaddle wrap had become wrapped around the infant's face and/or neck. This usually occurred when the infant's arms and/or legs came out of the swaddle wrap, and the wrap was pushed up to the face and/or neck (Figure). The median age of the infants involved was 1.4 months (IQR, 0.8-2.8 months).

Discussion

In this review of CPSC data, we found that reports of injury and death associated with wearable blankets, swaddle wraps, or swaddling in ordinary blankets are rare. More than 5 million swaddle wraps have been sold in the US to date, and only 18 cases involving swaddle wraps have been reported to the CPSC in 8 years. Nonetheless, some hazard patterns are noteworthy.

More than two-thirds (68%) of the 15 reported infant deaths associated with wearable blankets, swaddle wraps,

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