Published in final edited form as:

J Pediatr. 2014 May ; 164(5): 1152–1156. doi:10.1016/j.jpeds.2013.12.045.

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

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Abstract

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

Study design—Retrospective review of incidents reported to the Consumer Product Safety Commission in 2004–2012.

Results—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 deaths were attributed to positional asphyxia related to prone sleeping. 70% had 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 potential choking hazard when the zipper detached. All 12 incidents involving swaddling in ordinary blankets resulted in death. The median age was 2 months; 58% of deaths were attributed to positional asphyxia related to prone sleeping. 92% involved additional risk factors, most commonly soft bedding.

Conclusions—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.

Keywords

SIDS; suffocation; injury

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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 significantly decreased since its 1992 recommendation that infants be placed to sleep in a non-prone position. However, this decline in the rate of death has plateaued, 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 only 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, or overheating. The recommendations on avoiding soft or loose bedding note that infant clothing that is designed to keep the infant warm without posing a risk of entrapment or head covering may be used.^{1, 2} In addition, swaddling is frequently used as a strategy 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 to decrease the risk of SIDS, have become available in recent years. These include items such 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 1 million swaddle wraps have been sold in the U.S. (personal communication, William Schmid, Halo Technologies). The use of wearable blankets has been prevalent in Europe, and one case-control study found that use of a wearable blanket was associated with a decreased incidence of SIDS, possibly because it facilitated supine placement and reduced rolling to the prone position.⁷ However, no subsequent studies have confirmed this, and there are no data about the use of the newer swaddle wraps. To that end, we reviewed data collected by the Consumer Product Safety Commission (CPSC) pertaining to deaths, injuries, and potential injuries of infants in wearable blankets and swaddle wraps, as well as those swaddled in ordinary blankets, to assess the risks therein, 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 that occurred between September of 2004 and July of 2012 as reported to the CPSC. We used the 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 health care 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, position of the infant, 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

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 sleep sack), 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

There were ten reported cases of infants who died in incidents involving wearable blankets and swaddle wraps. All but 2 were associated with swaddle wraps; 1 was associated with a wearable blanket, and 1 was unspecified. The median age of death was 3.5 months (interquartile range (IQR), 3 months – 5 months); 4 were female and 6 male. Nine were white and 1 was Hispanic. The cause of death in 80% was attributed to positional asphyxia due to prone sleeping. In 7 of these 8 cases, the infant was placed supine or on the side and rolled to prone; one was placed prone. Two reported deaths had undetermined causes of death. 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 (5) and bumper pads (3). For 3 infants, no known environmental risk factors in the sleep environment were documented. In only 1 of the 10 reported deaths was misuse of the swaddle wrap or wearable blanket associated. In this 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 resulted in death. The median age of the infants was 2 months (IQR, 1 month – 3.5 months); 8 were female and 4 male. Four were white, 3 black, 1 biracial, 1 Asian, and 3 unknown race/ethnicity. The assigned cause of death in 7 cases was positional asphyxia related to prone sleeping; 1 of these infants was laid prone, and the other 6 rolled to prone from supine while swaddled. In four other reports, the infants died from suffocation or mechanical asphyxia related to soft bedding, and in one report, the infant died from hyperthermia related to over-bundling with ambient temperature >90°F. Eight of the infants were placed in a crib, portable crib, or bassinet; 2 were in a car seat; 1 was on an adult bed; and 1 sleep location was unknown. Risk factors present in the sleep environment included blankets other than the swaddle blanket (10), pillows (3), and bumper pads (3). One infant was known to be bed-sharing, one was sleeping unrestrained in the car seat, and two had documented secondhand smoke exposure. For one infant, no known environmental risk factors in the sleep environment were documented.

Injuries and Incidents without Injury Associated with Wearable blankets

There were 2 reported injuries associated with wearable blankets; one infant was 9 months old and the other 15 months old. Both injuries occurred when the zipper snagged on a tooth, resulting in accidental tooth extraction. In addition, there were 2 reports about a potential choking hazard when part of the zipper became detached from the wearable blanket. These

infants were 6 months and 7 months of age; both were female. Of note, one manufacturer subsequently changed the zipper design for its wearable blanket, so that the zipper pull is now a solid tab that will not snag primary teeth.

Incidents without Injury Associated with Swaddle Wraps

There were 10 reports from concerned individuals about 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 if 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 months – 2.8 months).

Discussion

In this review of CPSC data, we found that reports of injury and death associated with wearable blankets, swaddle wraps, and swaddling in ordinary blankets are rare. Over 1 million swaddle wraps have been sold in the United States, with only 18 cases reported to the CPSC in 8 years involving swaddle wraps. Nonetheless, there are hazard patterns that are noteworthy.

More than two-thirds (68%) of the 15 reported infant deaths associated with wearable blankets, swaddle wraps, and swaddling in ordinary blankets were attributed to positional asphyxia. Two of these infants were placed prone, and the other 13 (87%) rolled to prone from either the supine or side position. The risk of infant death increases more than tenfold if the infant is either placed or rolls into the prone position when swaddled - far more than if the infant is prone and unswaddled.^{9, 10} The median age of infants who rolled to the prone position was 4 months, with the youngest only 5 weeks, despite 4 months being the approximate age when it is generally expected that infants will begin to roll. It is possible, given that 5 weeks is a very young age for an infant to roll, that the original sleep position was inaccurately reported; however, it is notable that several 3-month-olds were also reported to have rolled to prone. This is also despite Gerard's suggestion that the physical confines of swaddling may prevent infants rolling to the prone position from supine.^{10, 11} It is presumed that prone-lying infants, when swaddled, cannot use their upper body to change their head and body position if they are in an asphyxiating situation.

Of the deaths of infants swaddled in ordinary blankets, one-third were attributed to suffocation due to soft bedding. Furthermore, of the total 22 deaths in the study, only one had no sleep environment risks, such as soft bedding (blankets, pillows) and bumper pads. It is important that the infant sleep environment be clear of soft and loose bedding, which can present a suffocation risk to the infant, even when swaddled.

The AAP Task Force has noted that swaddling, when incorrectly applied, can result in covering of the infant's head and/or neck, and possibly strangulation.¹ In this study, one 2 month old infant swaddled in an ordinary blanket was found dead with the swaddling blanket covering the mouth and nose; death in this case was attributed to mechanical asphyxia. Several incidents were reported in which swaddle wraps, even though correctly

used, were found around the infant's face and/or neck, creating a potential suffocation or strangulation risk.

Hyperthermia is a known risk factor for SIDS,⁵ and it is possible that swaddling may increase the likelihood of hyperthermia.¹¹ Swaddling may have contributed to the death of a 13 day-old infant who was found swaddled tightly in an environment where the ambient temperature was >90 degrees Fahrenheit; this death was attributed to hyperthermia.

Previous studies have found that very tight swaddling may increase problems associated with developmental dysplasia of the hip,^{12–15} and may also cause reduced lung capacity.^{11, 16, 17} However, no incidents with either of these concerns were reported.

We acknowledge the limitations of this study, largely due to the data source. Because CPSC investigations are conducted in response to specific complaints from consumers, this creates a bias in the data. In addition, the consumer has to identify the product used; it is possible that our search terms did not identify all of the incidents associated with these products. Different brands of wearable blankets and swaddle wraps encompass a variety of designs, and ordinary blankets used for swaddling may include blankets of all thicknesses and sizes; as the brand names of products were redacted and because we did not have full descriptions of the blankets in these incidents, we could not discern different hazard patterns with different product brands. Furthermore, the reviewed cases do not represent a complete accounting of such deaths, as reporting to the CPSC is voluntary. Because we cannot determine the number of infants who use wearable blankets and swaddle wraps or who are swaddled in ordinary blankets, and because these data represent an unknown percentage of these deaths, this database cannot be used to calculate the relative risk of death associated with these products. Finally, there is much variability in the amount of information available for each case, with some reports being completed from documents only and others with additional information provided by witnesses and/or law enforcement officers. Eleven of the cases included medical examiners' complete reports, all of which included the scene investigation and the postmortem examination.

Despite the limitations of this study, we can draw some preliminary conclusions regarding infant safety when using wearable blankets or swaddle wraps, and when swaddled. Many of these preliminary conclusions echo the recommendations in the 2011 AAP policy statement, as swaddling does not diminish the need for an overall safe sleep environment. As noted above, the risk of death increases if the swaddled infant is placed in or rolls into the prone position; thus, infants should always be placed in the supine position when swaddled. Swaddling should not be used once rolling attempts by the infant (swaddled or unswaddled) are observed. It is unclear whether this risk is decreased for infants in wearable blankets whose arms are free, and one report suggests that wearable blankets may reduce the possibility of rolling to the prone position.⁷ Swaddling may increase the risk of head covering, strangulation, and overheating, so particular care must be taken to avoid these risks when swaddling an infant. In addition, it is important to ensure a safe sleeping environment in an approved crib or bassinet, free of soft bedding or other objects that can lead to suffocation, for both swaddled and un-swaddled infants. Parents should maintain caution when using commercial swaddle wraps, ensuring that all Velcro or other fasteners

are securely attached. Finally, swaddle wraps could potentially be made safer if manufactured with fasteners that cannot be easily detached by infants, to avoid any risk of entrapment, head covering, or dental injury.

Acknowledgments

Funded by the National Institutes of Health (P20MD000198) and the Maternal and Child Health Branch, Health Resources and Services Administration (R40MC21511). The authors declare no conflicts of interest.

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Figure.
Demonstration of mechanism of potential injury with swaddle wrap

Table 1
Deaths Associated with Wearable Blankets and Swaddle Wraps (total: 10 infants)

Age	Sex	Race/Ethnicity	Wrap Type	Location	Position	Hazards	Cause of death
3 days	F	Hispanic	Swaddle wrap	Bassinet	Supine	None	Undetermined
2 mos	M	White	Wearable blanket	Infant glider seat (unrestrained)	Side	Found with face partially covered by side of glider seat	Undetermined
3 mos	F	White	Wearable blanket	Crib	Prone	Thick blankets & pillows under baby	Positional asphyxia
3 mos	M	White	Swaddle wrap	Car seat on floor	Sitting in seat; rolled out of seat to prone	Floor covered with piles of clothes, blankets, pillows	Positional asphyxia
3 mos	M	White	Unknown	Crib	Side; rolled to prone	Placed in sleep positioner between foam wedges, blanket by head, crib bumper pads	Positional asphyxia
4 mos	M	White	Swaddle wrap	Portable crib	Supine; rolled to prone	Soft homemade foam pad instead of mattress	Positional asphyxia
5 mos	M	White	Swaddle wrap	Crib	Supine; rolled to prone	Wrap was removed from product; extra blanket wrapped around baby, crib bumper pads, toys in crib	Positional asphyxia
5 mos	F	White	Swaddle wrap	Crib	Supine; rolled to prone	Crib bumper pads	Positional asphyxia
5.5 mos	F	White	Swaddle wrap	Portable crib	Supine; rolled to prone	Unknown	Positional asphyxia
6.5 mos	M	White	Swaddle wrap	Portable crib	Supine; rolled to prone	Unknown	Positional asphyxia

Table 2

Deaths Associated with Swaddling in Ordinary Blankets (total: 12 infants)

Age	Sex	Race/Ethnicity	Sleep location	Position	Hazards	Cause of Death
13 days	F	Unk	Car seat	Sitting in car seat	Sleeping in car seat, covered with quilt, room temperature in 90s	Hyperthermia
2 weeks	F	Biracial	Crib	Supine, with head on standard adult pillow	Crib bumper pads, multiple blankets, pillows, stuffed animals; smoke exposure	Suffocation
3 weeks	M	White	Adult bed	Supine, with head on nursing pillow	Pillow, comforter; bed-sharing	Suffocation
5 weeks	F	White	Bassinet	Supine; rolled to prone	Fleece blanket	Positional asphyxia
1.5 mos	F	Black	Bassinet	Prone	Blankets and stuffed animals	Suffocation
2 mos	F	White	Unknown	Unknown - found with swaddling blanket covering nose and mouth	Unknown	Mechanical asphyxia
2 mos	F	Black	Bassinet	Supine; rolled to prone	Multiple blankets, crib bumper pads, clothes	Positional asphyxia
2.5 mos	F	White	Car seat	Sitting face-up in car seat, but flipped to prone and head-down	Sleeping unstrapped in car seat,	Positional asphyxia
3 mos	M	Black	Bassinet	Prone	Multiple blankets, smoke exposure	Positional asphyxia
4 mos	M	Unk	Portable crib	Supine; rolled to prone	Soft comforter folded underneath baby	Positional asphyxia
4.5 mos	F	Asian	Crib	Supine; rolled to prone	Additional blanket, pillow	Positional asphyxia
8 mos	M	Unk	Crib	Supine; rolled to prone	Large blanket for swaddling, comforter, crib bumper pads	Positional asphyxia