Randomized Controlled Trial of a Car Safety Seat Insert to Reduce Hypoxia in Term Infants

WHAT’S KNOWN ON THIS SUBJECT: Brief periods of low oxygen saturation are common in infants while restrained in car safety seats. There is some evidence that an insert that allows the infant head to rest in a neutral position in sleep may reduce hypoxic episodes.

WHAT THIS STUDY ADDS: This randomized controlled study shows that the insert reduced numbers of obstructive apneas and the severity of desaturation events but did not significantly reduce the overall rate of moderate desaturations.

abstract

OBJECTIVE: To test the hypothesis that a foam plastic insert that allows the infant head to rest in a neutral position in sleep may prevent obstruction of the upper airway and thus reduce episodes of reduced oxygenation in term infants in car seats.

METHODS: Healthy full-term babies were randomized to be studied during sleep while restrained in an infant car safety seat either with or without the insert, with continuous polysomnographic recordings with sleep video.

RESULTS: Seventy-eight infants (39 in each group) had polysomnogram recordings at a mean of 8 days of age. Both groups showed a small fall in mean hemoglobin oxygen saturation (SpO₂) over the first hour of sleep. There was no difference between insert and no insert in the rate of moderate desaturations (a fall in SpO₂ ≥4% lasting for ≥10 seconds, mean ± SEM, 17.0 ± 1.5 vs 17.2 ± 1.5/hour), or mean SpO₂ during sleep. The insert was associated with a significant reduction in the rate of obstructive apnea (0.3 ± 0.1 vs 0.9 ± 1.5/hour, P < .03), the severity of desaturation events (minimum SpO₂ 82% ± 1% vs 74% ± 2%, P < .001), and time with SpO₂ <85% (0.6% ± 0.3% vs 1.8% ± 1.4%, P = .03).

CONCLUSIONS: In full-term newborn infants, a car seat insert that helps the head to lie in a neutral position was associated with reduced severity of desaturation events but not the overall rate of moderate desaturations. Pediatrics 2013;132:326–331

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KEY WORDS: infant, car seat, oxygenation, airway, device, insert, apnea

ABBREVIATION: SpO₂—hemoglobin oxygen saturation

Dr McIntosh helped design the study, obtained written parental consent, collected and tabulated the data, and drafted the initial manuscript; Dr Tonkin conceptualized and helped design the study, supervised sleep data analysis, and reviewed and revised the manuscript; Dr Gunn supervised the design and execution of the study, performed the final data analysis, and edited and critically reviewed the manuscript; and all authors approved the final manuscript as submitted.

This trial has been registered at http://www.anzctr.org.au (identifier 12612000976886)

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Infant car safety seats are vital to protect young infants from injury and death in motor vehicle accidents, and their use is legally mandated in many countries, including New Zealand.1 Despite their major benefits for injury, it is well established that preterm infants and term infants with preexisting health conditions have a high risk of episodes of apnea and reduced hemoglobin oxygen saturation (SpO2) while restrained in infant car safety seats2–4 or car beds.5,6 Disturbingly, there is compelling evidence that mild desaturations are also common in healthy full-term infants.6–9 For example, Merchant et al reported that term infants showed a decline in mean SpO2 from 97% in the supine position to 94% after 60 minutes in their car safety seats; 8% had SpO2 values of <90% for longer than 20 minutes.6 Similarly, Kornhauser et al found that the time that infants’ SpO2 was <95% increased from 6.5% while lying in crib to 24% while restrained in a car seat.6

Supporting possible clinically important consequences from these relatively mild falls in oxygenation that are observed under controlled circumstances, we reported that 8 healthy, full-term infants developed an apparent life-threatening event while they were restrained in their car seat.10 Additionally, confirming previous anecdotal reports of sudden unexpected deaths of term infants who were restrained in semi-reclined car safety seats,11 a Canadian population study detailed ~10 deaths of 409 in the first year of life that were unexplained after detailed investigation occurred in sitting devices, mainly infant car seats.12 Although this suggests that, fortunately, such events are uncommon, these cases were healthy, predominantly born at term, and most were less than one month of age.12

We have previously shown that the increased incidence of episodic oxygen desaturation in preterm infants placed in semirect upright infant car seats compared with lying in cots was associated with flexion of the head on the body, leading to marked narrowing of the upper airway on respiration timed lateral radiographs.13 Supporting a critical role for upper airway compromise, the frequency of episodes of reduced oxygenation was markedly reduced by a simple foam plastic insert placed behind the infant’s back, with a slot that allowed the large infant occiput to rest behind the spinal line in the neutral plane.13 In term infants, a small nonrandomized pilot study suggested that the insert was associated with a significant reduction in the rate of mild apnea (from a median of 9.2 to 4.4 events/hour).9

In the current study, we tested in a prospective randomized controlled trial whether a simple foam plastic insert could prevent episodes of reduced oxygenation in healthy young term infants restrained in a car safety seat.

METHODS
Ethics approval was granted by Northern X Regional Ethics Committee. Healthy infants born between 37 and 42 weeks’ gestation with no known current medical complications were studied between the fourth and eleventh day of life. The parents of the infants were initially approached by the attending midwife or family doctor for consideration of enrollment in this study either in pregnancy or before discharge from hospital. Written consent was obtained, and a brief questionnaire was completed with the mothers.

Trial Design
The primary outcome was the frequency of moderate apneic events, defined as a fall in the infant’s SpO2 by ≥4% for ≥10 seconds. Secondary outcomes included the frequency of obstructive and hypopnea apneas, frequency of desaturations in active and quiet sleep, mean SpO2, minimum SpO2, the proportion of time in which SpO2 saturation was >95%, and the proportion of sleep time <85%. Finally, we examined whether there was a fall in SpO2 over time.

Study power was based on an estimated control incidence of 2 moderate falls in SpO2 per hour, with an SD of 2.9 Thus, 80 infants was required to have an 80% chance of detecting a two-thirds reduction with the insert. Randomization codes were pregenerated and supplied in numbered, sealed envelopes that were opened on the day of the study. Infants were assigned to be studied in a car seat (Designer 22, SE, LX Delux Infant Seat, Dorel Juvenile Group, Auckland, NZ) either with a 25-mm-thick fabric covered foam plastic insert in place (Happi Insert, SIDS New Zealand, Waiuku, New Zealand; http://shop.sids.org.nz/happi_baby_car_seat_insert.html, Fig 1) or no insert. The insert is constructed with a 9-cm-wide slot in the foam to allow the infant’s occiput to rest in a plane behind the infants’ back, with support of the head by the foam insert on each side of the head, with the goal of enabling the Frankfort plane (a line from the lower orbital margin to the auditory canal placed at 90° to the spine) to be maintained.14 The insert’s position can be adjusted to accommodate infants up to at least 6 months of age.

Data Recording
The infants were studied in their family’s home. Each infant had polysomnogram (Sandman Pocket 2008, Sleep Diagnostics, Tyco Healthcare, Lane Cove, Australia) monitoring leads attached and was placed in the same car seat by the same investigator. The car seat was placed on a flat surface with the back of the car seat at 45° from horizontal for the duration of the study. Nappy rolls were placed at the sides but not around the head of the infant to help to position them, and the seat belt was fastened and tightened to allow
1 finger to fit between the baby and the belt. Studies were started shortly after each baby had been fed. The infants were allowed to fall asleep, and then they were continuously observed while a polysomnogram and sleep video was recorded for the duration of their sleep. Polygraphic recordings were made of heart rate, chest and abdominal expansion by plesiometry bands, nasal thermistor for airflow, pulse oximetry from the foot, eye movements by electro-oculogram, and sleep video recording.

Analysis of polysomnograms using the Sandman Elite V9.2 software was performed by the same unblinded researcher, strictly following the criteria described by Anders. Only recording time in which the baby was asleep was analyzed. If a pacifier was used to settle the infant to sleep, then only sleep without the pacifier was used for analysis. Thirty-second epochs were used during analysis. Desaturations were identified if there was a drop ≥4% SpO₂. Brief desaturation events were defined as a fall in SpO₂ lasting >4 seconds but <10 seconds, and moderate desaturation events were defined as a fall lasting for ≥10 seconds.

Bradycardia was determined by electrocardiogram and pulse by a reduction to <90 beats per minute. Epochs were marked as “arousal” or “movement” as described by Anders when the change in state lasted >50% of the epoch. Sleep stages of “active,” “quiet,” and “indeterminate” sleep were determined. Respiratory events were determined as follows: “obstructive apnea” indicated a desaturation event associated with a reduced airflow to <10% at thermistor, with increased respiratory effort; “central apnea” indicated a desaturation event with airflow <10% and no respiratory movements over 2 respiratory cycles; “mixed apnea” had characteristics of both obstructive and central apnea; and “hypopnea” was defined as a desaturation with <50% airflow. To assess changes over time after the start of sleep, polysomnogram data were analyzed in 30-minute intervals.

**Data Analysis**

Comparisons between groups were made by Mann-Whitney U test (SPSS v12, Chicago, IL). Changes over time were compared with Wilcoxon signed-rank test. Data are mean (SEM).

**Results**

Eighty-one full-term infants were recruited. One infant was excluded before randomization because of a concurrent respiratory infection. Eighty infants were randomized, 39 infants to the insert and 41 to no insert. Two infants in the no-insert group never slept and were excluded from additional analysis. There were no significant demographic differences (Table 1). At the time of recruitment, a third of families (27 of 80) were concerned about their baby’s positioning in the car seat, most because of observed “head flop” (19 of 27), the awkward sitting position (2 of 27), or that baby was not able to breathe easily (3 of 27). More than half the families were using a “non-approved” positioning device in their infants’ car seat (46 families used a head roll, and 8 reported other devices); only 27 families were using no positioning device.

**Sleep Analysis**

Infants were studied at a mean of 8 days of age. There were no significant differences between groups in total sleep time, time in active sleep, or rates of movement (Table 2) or arousal. Brief desaturation events were common, particularly in active sleep. Insert use had no significant effect on numbers of moderate desaturation events (Fig 2) or proportion of time with saturation ≥95%. However, the insert was associated with a marked reduction in severity of desaturation events as shown by improved minimum SpO₂ with the insert (Table 2). The rate of obstructive respiratory events was reduced by insert use but not central, mixed, or hypopnea events (Table 2). Consistent with these findings, the proportion of time with SpO₂ <85% was significantly reduced (Table 2). There was a significant fall in mean SpO₂ between the first and second 30-min
interval \( (P < .001, \text{Fig 3}) \) that was not affected by the insert. Similarly, the mean minimum Sp\(\text{O}_2\) also fell after the first 30 min \( (P = .038, \text{data not shown}) \). There was no significant change in Sp\(\text{O}_2\) thereafter.

**DISCUSSION**

The current study suggests that contrary to our original hypothesis, an insert designed to help maintain the head upright did not reduce the overall rate of desaturation events or affect average oxygenation in full-term babies sleeping in a car safety seat. However, encouragingly, use of the insert was associated with a marked reduction in the severity of desaturation events and the total duration of deoxygenation to <85%. Furthermore, infants sleeping in the car seat with the insert had fewer obstructive apneic events, supporting the hypothesis that the insert can help reduce obstruction of the upper airway.\(^9\)\(^{10}\)\(^{13}\)

Consistent with previous studies,\(^3\)\(^6\)\(^9\)\(^{10}\)\(^{13}\) episodes of transient mild to moderate desaturation were common in otherwise healthy full-term infants restrained in car safety seats. Kornhauser and colleagues, for example, have elegantly shown that term infants have many more desaturations in a car seat than while resting in a crib (mean 17 vs 6 per hour), with significantly lower mean and minimum oxygen saturations.\(^9\) The current study confirms a similar rate of moderate desaturations during sleep. Car seats are essential for the safe transportation of infants. It is of concern that >90% of infants are reported to spend >30 min a day in their car seat, often for sleep outside of the car.\(^6\)

As previously reviewed, there is now compelling evidence that intermittent hypoxia is associated with behavioral problems and adverse effects on development and school performance.\(^17\) Furthermore, car seat use has been associated with at least some otherwise unexplained sudden deaths in term infants.\(^12\) Thus, given the evidence from these studies that car seat use is associated with a marked increase in desaturations, we believe that caregivers should be strongly advised that car seats should not be used for infant sleep outside of the car.

The mechanism(s) of this recurrent hypoxia are not fully established. In this

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**TABLE 1** Demographic Data

<table>
<thead>
<tr>
<th></th>
<th>Insert, ( n = 39 )</th>
<th>Control, ( n = 39 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, M:F</td>
<td>18:21</td>
<td>20:19</td>
</tr>
<tr>
<td>Ethnicity, Maori:Pacifica/New Zealand European:other</td>
<td>3:0:34:2</td>
<td>6:1:30:2</td>
</tr>
<tr>
<td>Maternal age at birth, y</td>
<td>33.0 ± 0.6</td>
<td>30.7 ± 1.0</td>
</tr>
<tr>
<td>Mode of delivery, vaginal:cesarean</td>
<td>34:5</td>
<td>27:12</td>
</tr>
<tr>
<td>Gestation at birth, wk</td>
<td>39.6 ± 0.2</td>
<td>39.6 ± 0.2</td>
</tr>
<tr>
<td>Birth wt, g</td>
<td>3457 ± 94</td>
<td>3503 ± 71</td>
</tr>
<tr>
<td>Age at study, d</td>
<td>7.9 ± 0.3</td>
<td>8.1 ± 0.3</td>
</tr>
</tbody>
</table>

Data are mean ± SEM or \( n \), F, female; M, male.

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**TABLE 2** Effect of Insert on Sleep and Oxygenation Indices

<table>
<thead>
<tr>
<th></th>
<th>Insert</th>
<th>No Insert</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep time, min</td>
<td>113.9 ± 5.5</td>
<td>110.7 ± 5.58</td>
<td>.8</td>
</tr>
<tr>
<td>Active sleep, min</td>
<td>65.7 ± 3.3</td>
<td>64.2 ± 4.6</td>
<td>.77</td>
</tr>
<tr>
<td>Movement episodes</td>
<td>9.1 ± 1.0</td>
<td>11.9 ± 1.2</td>
<td>.12</td>
</tr>
<tr>
<td>Moderate desaturation, (/h)</td>
<td>17.0 ± 1.5</td>
<td>17.2 ± 1.5</td>
<td>.92</td>
</tr>
<tr>
<td>Active sleep desaturation, (/h)</td>
<td>24.4 ± 12.2</td>
<td>25.7 ± 2.4</td>
<td>.7</td>
</tr>
<tr>
<td>Quiet sleep desaturation, (/h)</td>
<td>2.0 ± 0.4</td>
<td>3.1 ± 0.5</td>
<td>.08</td>
</tr>
<tr>
<td>Respiratory events, (/h)</td>
<td>8.4 ± 0.7</td>
<td>10.3 ± 1.0</td>
<td>.14</td>
</tr>
<tr>
<td>Obstructive apnea, (/h)</td>
<td>0.3 ± 0.1</td>
<td>0.9 ± 1.5</td>
<td>.03</td>
</tr>
<tr>
<td>Central events, (/h)</td>
<td>1.2 ± 1.8</td>
<td>1.6 ± 2.6</td>
<td>.52</td>
</tr>
<tr>
<td>Mixed events, (/h)</td>
<td>0.9 ± 1.3</td>
<td>0.9 ± 1.2</td>
<td>.81</td>
</tr>
<tr>
<td>Hypopnea, (/h)</td>
<td>5.9 ± 0.5</td>
<td>6.8 ± 0.7</td>
<td>.45</td>
</tr>
<tr>
<td>Mean Sp(\text{O}_2), %</td>
<td>96.7 ± 0.4</td>
<td>97.0 ± 0.4</td>
<td>.44</td>
</tr>
<tr>
<td>Minimum Sp(\text{O}_2)</td>
<td>82.0 ± 1.0</td>
<td>74.7 ± 1.6</td>
<td>.001</td>
</tr>
<tr>
<td>Minimum Sp(\text{O}_2), active sleep</td>
<td>82.2 ± 1.0</td>
<td>73.7 ± 2.4</td>
<td>.001</td>
</tr>
<tr>
<td>% Sp(\text{O}_2), ≥85%</td>
<td>67.5 ± 4.6</td>
<td>73.0 ± 4.7</td>
<td>.54</td>
</tr>
<tr>
<td>% Sp(\text{O}_2), ≥85% and &lt;95%</td>
<td>31.9 ± 4.5</td>
<td>25.3 ± 4.5</td>
<td>.52</td>
</tr>
<tr>
<td>% Sp(\text{O}_2), &lt;85%</td>
<td>0.6 ± 0.3</td>
<td>1.8 ± 1.4</td>
<td>.03</td>
</tr>
</tbody>
</table>

Data are mean ± SEM. Moderate desaturations were defined as a fall of ≥4% for ≥10 seconds. \(/h\), indicates frequency per hour.
study, we hypothesized that because the occiput of newborn infants commonly protrudes behind their spinal line, there is forward pressure on the head when they are restrained against a flat surface, leading to excessive forward flexion and thus pressure of the chest on the less stable infant jaw and consequent backward movement of the tongue, narrowing the upper airway.\textsuperscript{13,18}

Supporting this hypothesis, Kornhauser et al found a borderline increase in obstructive apnea in the car seat compared with the crib,\textsuperscript{6} and in the current study, an insert designed to provide a slot for the infant’s occiput was associated with significant reduction in obstructive apnea. Sleep video and direct observation in this study revealed that obstructive apnea appeared to be related to neck flexion but that many infants had neck flexion without apparent obstruction.

However, in contrast to our previous trial of this insert in preterm infants,\textsuperscript{13} there was no overall reduction in numbers of desaturation events. In part, this may simply reflect that term infants have greater head control, even in sleep, and so were able to move their heads to alleviate obstruction. Alternatively, in part, our observations suggest that the insert tested here may not have provided a deep enough slot for the occiput of all full-term infants. Consistent with this, some infants developed head flexion despite the insert. Additional studies are essential to assess whether a thicker insert or other modifications might be more effective in reducing head flexion without compromising car seat safety.

Finally, it is important to consider additional mechanisms, such as restriction of pulmonary expansion by the restraining straps, inactivity of the intercostal muscles of the rib cage during rapid eye movement sleep,\textsuperscript{19} and pressure on the diaphragm from the sitting position, that might reduce tidal volume.\textsuperscript{20} This would be consistent with the fall in mean (and minimum) oxygenation over time in the current study and previous reports.\textsuperscript{6,7} Furthermore, the great majority of apneic events occurred in active sleep, with few during quiet (or indeterminate) sleep.\textsuperscript{9}

Thus, the reduction in skeletal muscle tone during active sleep may have allowed greater forward flexion of the head on to the chest, leading to greater narrowing of the upper airway.\textsuperscript{21–23}

Some limitations of the current study should be considered. The study lacked power to investigate the impact of the insert on the relatively infrequent deep reductions in saturation. As a physical intervention, the study was not blinded, potentially allowing bias; to reduce this possibility, the traces were independently reviewed by an author not involved in obtaining the original recordings. Infants were not monitored during transport, although there is evidence that sleeping in a car seat in the family home is important in its own right.\textsuperscript{16} Furthermore, the mean duration of sleep in the current study was relatively short in absolute terms.

**CONCLUSIONS**

This study shows that a simple car seat insert was useful in reducing the severity of desaturation events but not the rate of desaturations. Given both the significant rate of events and the fall in mean oxygenation over time, the current study strongly reinforces recommendations that even with such an insert, young infants should never be left unattended in car seat carriers,\textsuperscript{10} or indeed any seat device, and that car seat use should be restricted to the minimum time required for essential travel.

**ACKNOWLEDGMENTS**

We thank the infants and their families who participated in this trial and Mrs Penelope Harrison, midwife.

**NOT JUST A PRETTY STONE:** My wife’s engagement ring displays a tiny sapphire. While to us the stone represents our commitment to one another, to other people it tells a story of the earth. As reported in The New York Times (Science: June 13, 2013), gems can tell us a great deal of information about the earth’s history and plate tectonics. It turns out that gems are forged deep within the earth, with each type of gem requiring specific elements such as aluminum or carbon, heat, and pressure. Some gems (like sapphires and rubies) are formed when mountains arise, while others (such as a form of jade) are forged deep beneath the ocean. Rubies are made when tectonic plates collide; one plate is submerged under another and subjected to massive pressure and heat. In this pressure cooker, shale (the rock that often surrounds the plates) can produce crystals of aluminum and oxygen. These crystals are known as sapphires. If a crystal is pushed under pressure to the surface, chromium atoms may replace some of the aluminum atoms, giving it a pink or red color—resulting in what we call a ruby. Interestingly, few gemstones are older than 600 million years. One possible explanation for this is that plate tectonics may be a relatively recent phenomenon in earth’s history—starting approximately one billion years ago. While I cannot be sure under which ancient mountain my wife’s sapphire was formed, I do know that it still looks good on her.

*Note by WWR, MD*
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