

in a simulated moving vehicle Renu Arya, ¹ Georgina Williams, ¹ Anna Kilonback, ¹ Martin Toward, ² Michael Griffin, ²

Is the infant car seat challenge useful? A pilot study

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► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/ archdischild-2016-310730).

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Received 18 February 2016 Revised 23 June 2016 Accepted 27 June 2016 Published Online First 30 September 2016

ABSTRACT

Background and objective The American Academy of Pediatrics recommends that preterm infants complete a predischarge 'car seat challenge' observation for cardiorespiratory compromise while in a car seat. This static challenge does not consider the more upright position in a car or the vibration of the seat when the car is moving. This pilot study was designed to assess the cardiorespiratory effects of vibration, mimicking the effect of being in a moving car, on preterm and term infants.

Methods A simulator was designed to reproduce vertical vibration similar to that in a rear-facing car seat at 30 mph. 19 healthy newborn term and 21 preterm infants, ready for hospital discharge, underwent cardiorespiratory measurements while lying flat in a cot (baseline), static in the seat (30°), simulator (40°) and during motion (vibration 40°).

Results Median test age was 13 days (range 1-65 days) and median weight was 2.5 kg (IQR: 2.1-3.1 kg). Compared with baseline observations, only the total number of desaturations was significantly increased when infants were placed at 30° (p=0.03). At 40°, or with vibration, respiratory and heart rates increased and oxygen saturation decreased significantly. Profound desaturations <85% significantly increased during motion, regardless of gestational age.

Conclusions This is the first study to assess the effect of motion on infants seated in a car safety seat. Term and preterm infants showed significant signs of potentially adverse cardiorespiratory effects in the upright position at 40°, particularly with simulated motion, not identified in the standard challenge. A larger study is required to investigate the significance of these results.

INTRODUCTION

Infant car safety seats are used for infants from birth up to 10 kg. They may be too big to effectively secure low-birthweight or preterm infants who are discharged home from neonatal intensive care units (NICUs), at weights of 1.8-2.5 kg.¹ In these seats, the prominent occiput of a preterm infant may push the head forward, particularly during sleep, potentially causing airway obstruction. Studies have shown that premature infants are prone to drops in blood oxygen saturation, and apnoea or hypoventilation when restrained in car seats,²⁻⁴ in up to 60% of infants studied.⁵ The American Academy of Pediatrics (AAP) recommends that all preterm infants should undergo monitoring in a car seat before discharge—for apnoea, bradycardia or desaturations, ⁶ ⁷ and many UK hospitals follow this advice. The significance and potential impact of these problems is not

What is already known on this topic?

- ► Some infants seated in car safety seats show signs of cardiorespiratory compromise.
- The infant car seat challenge is used in neonatal units to determine if the infant can travel safely in a car.
- The static challenge does not take into account the more upright position of the seat or the effect of motion when the car is moving.

What this study adds?

- This is the first study to carry out the car seat challenge in a simulated moving car seat.
- Infants showed signs of cardiorespiratory compromise, which were undetected in the static car seat challenge.
- The moving challenge may be a better test to determine if infants can travel safely in a car seat but further research is required.

clear,8 9 but there have been reports of deaths of infants who have been left in a sitting position, including in car seats-both on journeys, and when parents have used it as an alternative to a pushchair or cot for the infant to sleep in. 10-13

One survey noted that 94% of infants, below 5 months of age, spent over 30 min a day in seating devices including car seats.¹⁴ The mean was 5.7 ±3.5 hours. There have been no studies looking at the effects on infants over such prolonged periods in a sitting position.

There are no universal guidelines on implementing the car seat challenge, 15-17 and commonly the angle of the back of the car seat to the horizontal is not reported although in a vehicle it should be 40°-45° for maximum protective effect. In our hospital, the challenge is routinely performed with the car seat placed on the floor, using the carrying handle for stability (like many UK units surveyed, see online supplementary appendix 1). The angle of the seat's back to the floor is approximately 30°, which is flatter than the position in a vehicle.

No published studies have monitored infants in moving vehicles, so there is no data on whether infants experience more or less cardiorespiratory compromise when travelling. Hence, it is unknown whether the 'car seat challenge' as currently



To cite: Arya R, Williams G, Kilonback A, et al. Arch Dis Child Fetal Neonatal Ed 2017;**102**:F136-F141.

performed has any validity as a means of distinguishing between an infant who can safely travel in a car or one who is at risk of adverse effects during such a journey.

STUDY DESIGN AND METHODOLOGY Study aims

This pilot study investigated the physiological effects on healthy term and preterm infants placed in a static car seat at 30° and 40°, and whether the motion of a moving vehicle had any adverse or beneficial effects. It replicates the normal routine of a parent preparing and taking their infant on a car journey.

Study design

Ethical approval was granted. Informed written consent was obtained from both parents of participating infants. Mothers in late pregnancy attending antenatal clinics were informed about the study. Interested mothers of healthy infants were visited 12–24 hours after delivery to obtain consent. Given that many term infants were discharged within hours after normal delivery, many infants recruited were delivered by caesarean section. Healthy term or preterm infants on NICU shortly due for discharge were also eligible.

Exclusion criteria included unwell infants, those with known congenital anomalies, cardiorespiratory disease or hypotonia from any cause.

All infants in the study were due to take a similar (non-monitored) journey home in a car seat within days of the study.

Study protocol

After random allocation to one of two protocols (to investigate test order), the infants underwent physiological monitoring for 30 min in a car seat in each of the three positions.

Protocol A:

- I. on a horizontal surface, seating angle 30° (static)
- II. on the simulator, seating angle of 40° (static)
- III. on the simulator, seating angle of 40° with movements to simulate being in a car travelling at 30 mph (motion).

Protocol B:

- I. on the simulator, seating angle 40° (static)
- II. on the simulator, seating angle 40° (in motion)
- III. on a horizontal surface, seating angle 30° (static).

Each of these conditions was compared with baseline—a period before testing when the infant was asleep supine in a cot, for up to 90 min after a feed.

As all infants were due to go home within days of testing, for the 30° position, the infants' own car seats were used. All infants underwent testing at 40° in the stationary vibration rig.

The two protocols were designed to determine whether any identified physiological disturbances observed were more likely to be a consequence of being in the car seat, the angle of the car seat or the presence of movement, including identifying any effect from infant sleep state, or the possible effects of being in a car seat for a long period.

Motion simulator

A motion simulator was developed to reproduce vertical vibration broadly representative of that at the base of a car safety seat fixed in a rear-facing position in the back seat of a small family car (see figure 1 and online supplementary video 1). The angle of fixation was approximately 40° to the horizontal, using the standard Isofix system. The simulator was designed, manufactured and tested by the Human Factors Research Unit within the Institute of Sound and Vibration Research at the University of Southampton and received ethical approval for use in

neonates. The simulator reproduced the vertical vibrations from travelling at 30 mph on a straight urban road, excluding braking, acceleration or going over bumps (see online supplementary appendix 2).

Infant monitoring

Physiological recordings were made using a 'capnocheck' recording system (Oxi-pulse sleep capnograph, Pulmolink UK) allowing continuous recording of inspiratory and expiratory carbon dioxide levels (EtCO₂), oxygen saturation (SpO₂), respiratory rate (RR) and heart rate (HR), sampled at 1 s intervals. The monitor has an artefact rejection programme designed to cope with movement. All infants were constantly observed by an experienced neonatal nurse and/or doctor. A report was generated for each infant in each position using the PROFOX Respiratory Oximetry Software.

If any significant episodes of apnoea (more than 15 s) or oxygen desaturation (<85% for more than 20 s) were observed, the test was immediately stopped. These pragmatic cut-offs were chosen to minimise responses to minor, artefactual or self-limiting apnoea or desaturation while ensuring a prompt response to more significant episodes and minimising any risk to the infant. Resuscitation equipment and trained personnel were available immediately.

Statistical analyses

In this pilot study, we aimed to recruit 20 term and 20 preterm infants. No studies in a vibrating car seat have been conducted; hence, the nature, frequency and magnitude of any adverse effects were unknown. The sample size was pragmatic, by each infant acting as his/her own control (ie, each being studied in each condition—static and moving), and this should generate CIs for potential discernible treatment effects to help inform a larger study. It is unknown whether the movement of a simulated car journey would make such effects more or less likely or severe.

The sampled values for all parameters were imported into an Excel spreadsheet, and all analyses were conducted using SPSS V23.

The mean values obtained in each condition for each infant for SpO₂, EtCO₂, HR and RR were used as point estimates (ie, as single-value units of interest). Given the small numbers and skewed nature of the data a non-parametric approach was



Figure 1 Car seat motion simulator with controls.

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Figure 2 One preterm infant who flopped forward during 'motion'.

used for the paired data (Wilcoxon test). The McNemar's test was used for categorical paired data. For looking at differences in test order the Mann-Whitney and χ^2 tests were used. Every infant was to undergo three study positions randomly assigned as per protocol and data from each study were compared with the baseline observation period in the cot.

Similar comparisons were made for the frequency and duration of dips in saturation (a fall in $SpO_2 \ge 4\%$ lasting for ≥ 10 s and SpO_2 below 85% for at least 4 s), episodes of apnoea (pauses of > 10 s) and bradycardia (< 100 bpm in preterms, < 60 bpm in term infants).

RESULTS

Infant demographics

Forty infants were studied; 21 preterm (53%) and 22 were male (55%). The median gestational age was 36 weeks (IQR: 31–39 weeks), ranging from 27 weeks 5 days to 41 weeks 5 days. The median birth weight was 2.5 kg (IQR: 1.5–3.2 kg) ranging from 0.8 to 4.8 kg. Seventeen infants were born by normal vaginal delivery (42.5%), 10 by elective (25.0%) and 13 by emergency caesarean section (32.5%).

Data at testing

The median age at testing was 13 days (IQR: 6–33 days) ranging from 1 day after birth to 65 days. Preterm or very low-birthweight infants were tested when they were mature enough

Outcome variable	Position	N	Median	IQR	p Value*
Heart rate (bpm)	At rest in cot	39	145	127–155	Ref group
	30°	36	143.5	126.5-156.8	0.69
	40°	39	150	135–158	0.01
	In motion	37	150	129–157.5	0.047
Oxygen saturation (%)	At rest in cot	39	96	93–97	Ref group
,,	30°	36	94.5	93–96	0.42
	40°	39	94	92–96	0.03
	In motion	37	93	91–95	0.0003
Number of desaturations <85% in 30 min (n)	At rest in cot	39	1	0–7	Ref group
	30°	36	3	0.3–7	0.12
	40°	38	4	0–6	0.17
	In motion	35	6	1–11	0.001
Total number of desaturations (n)	At rest in cot	39	26	19–36	Ref group
(fall in SpO ₂ ≥4% lasting for ≥10 s per hour)	30°	36	33	22–41	0.03
(p-22 p	40°	39	32	24–37	0.005
	In motion	36	39	28–46	< 0.0001
Respiratory rate (breaths per minute)	At rest in cot	38	42	39–50	Ref group
	30°	35	45	39–49	0.12
	40°	38	48	38.8-55	0.0004
	In motion	36	46.5	41-50.8	0.009
End-tidal CO ₂ (kPa)	At rest in cot	38	4.58	3.99-5.13	Ref group
	30°	35	4.56	3.88-5.07	0.84
	40°	38	4.61	4.13-5.08	0.32
	In motion	36	4.65	4.20–5.14	0.38
Outcome variable	Position	N	n	Per cent	p Value
One or more bradycardias (n)	At rest in cot	39	4	10.3	Ref group
	30°	36	2	5.6	0.62
	40°	39	2	5.2	0.62
	In motion	37	3	8.1	0.68
One or more apnoeas (n)	At rest in cot	39	6	15.4	Ref grou
	30°	36	1	2.8	0.13
	40°	39	2	5.1	0.45
	In motion	37	0	0	0.13

for discharge. The postmenstrual age at testing ranged from 34 weeks 3 days to 42 weeks 4 days. The median weight was 2.5 kg (IQR: 2.1–3.1 kg) ranging from 1.6 to 4.8 kg.

We aimed to test each infant in each condition for 30 min but interruptions from infant care procedures meant that the actual times varied and not all tests were completed in a few cases. The baseline recordings with the infant placed supine in a cot ranged from 17 to 120 min with a median of 60 min; thus, the results were adjusted to a standard 30 min or per unit of time tested.

Many infants put their chin on their chest during testing but three infants slumped forward during vibration (see figure 2). Their position was left while they maintained normal oxygen saturations to observe what would happen. They lifted their head up briefly at intervals but could not maintain this position.

Outcome for all infants

Table 1 shows the outcomes for all infants comparing measurements at rest in the cot (reference group) with the three other positions. The only significant difference in the outcome variables comparing baseline to the 30° position was a higher number of total desaturations at 30°.

However, infants in the static 40° position and in motion had significantly higher HR and RR, lower SpO₂ and more total desaturations, compared with baseline. In motion, episodes of desaturation <85% were also significantly increased, a median

of six episodes versus one when at rest. Episodes of bradycardia and apnoea were slightly but not significantly more common at rest. EtCO₂ level rose slightly but non-significantly at 40° and in motion.

Term versus preterm

Preterm infants were older at testing (median 25 days, range 7–65 days) compared with term infants (median 6 days, range 1–15 days).

Table 2 shows the same outcomes as in table 1 but for term infants only. The numbers are smaller, hence the potential for significance is reduced, but the direction of the differences persisted and was similar in term and preterm infants.

Term infants placed in the static 40° position had significantly higher HR and RR and lower SpO_2 . In motion, the increased HR did not reach significance compared with baseline but the RR was significantly higher, the SpO_2 significantly lower and the number of desaturations was increased.

Table 3 shows the same outcomes as in table 1 but for preterm infants only. The differences are in the same direction but slightly less marked compared with term infants.

In comparison with term infants baseline HRs were much higher, and although the rates increased sequentially when the infants were seated at 30°, 40° and in motion these differences were not statistically significant compared with baseline. The median SpO₂ dropped from baseline but was only significant

Outcome variable	Position	N	Median	IQR	p Value
Heart rate (bpm)	At rest in cot	19	127	116–149	Ref grou
	30°	18	127	115.3-142.8	0.65
	40°	19	138	126–144	0.03
	In motion	18	131	123.5–143.8	0.16
Oxygen saturation (%)	At rest in cot	19	95	92–97	Ref grou
	30°	18	93.5	93–95.3	0.11
	40°	19	94	91–96	0.04
	In motion	18	93	91–95	0.01
Number of desaturations <85% in 30 min (n)	At rest in cot	19	1	0.5-1.5	Ref grou
()	30°	18	2.5	0-6.5	0.06
	40°	19	4	0–7	0.06
	In motion	17	2	0.5–8	0.04
Total number of desaturations (n)	At rest in cot	19	25	13–36	Ref gro
(fall in $SpO_2 \ge 4\%$ lasting for ≥ 10 s per hour)	30°	18	31	22–42	0.08
, , , , ,	40°	19	31	23–36	0.049
	In motion	17	35	24–45	0.01
Respiratory rate (breaths per minute)	At rest in cot	18	43	37.5-52.3	Ref gro
	30°	17	47	37.5–52	0.28
	40°	18	51	39.8-56.3	0.009
	In motion	17	49	39.5–55	0.02
End-tidal CO ₂ (kPa)	At rest in cot	18	4.25	3.72-4.73	Ref gro
<u>-</u> ` '	30°	17	4.51	3.81-4.88	0.55
	40°	18	4.47	3.79-5.11	0.15
	In motion	17	4.21	3.73–5.09	0.38
Outcome variable	Position	N	N	Per cent	p Value
One or more bradycardias (n)	At rest in cot	19	3	15.8	Ref grou
	30°	18	1	5.6	0.48
	40°	19	2	10.6	1.00
	In motion	18	3	16.7	1.00
One or more apnoeas (n)	At rest in cot	19	3	15.8	Ref gro
	30°	18	1	5.6	0.62
	40°	19	0	0	0.25
	In motion	18	0	0	0.25

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Outcome variable	Position	N	Median	IQR	p Value
Heart rate (bpm)	At rest in cot	20	151.5	145–159	Ref grou
	30°	18	153	143.8–158.2	0.88
	40°	20	156	150.3–158	0.20
	In motion	19	157	150–163	0.21
Oxygen saturation (%)	At rest in cot	20	96	93–97	Ref grou
	30°	18	96	93.5–97.3	0.71
	40°	20	94.5	94–96	0.34
	In motion	19	94	91–95	0.01
Number of desaturations <85% in 30 min (n)	At rest in cot	20	5	0–8	Ref grou
	30°	18	3	1–8.25	0.69
	40°	19	4	2–6	0.85
	In motion	18	7.5	1.8–14.3	0.02
Total number of desaturations (n)	At rest in cot	20	28	22–36	Ref grou
	30°	18	33	23–41	0.21
	40°	20	34	25–37	0.07
	In motion	19	38	36–51	0.001
Respiratory rate (breaths per minute)	At rest in cot	20	42	40–48.8	Ref grou
	30°	18	44	38–49.3	0.42
	40°	20	48	37–53	0.02
	In motion	19	45	41–48	0.45
End-tidal CO ₂ (kPa)	At rest in cot	19	4.99	4.18–5.5	Ref gro
	30°	18	4.67	4.05–5.19	0.36
	40°	20	4.71	4.23–5.22	0.85
	In motion	19	4.79	4.60–5.14	0.68
Outcome variable	Position	N	n	Per cent	p Value
One or more bradycardias (n)	At rest in cot	20	1	5.0	Ref grou
	30°	18	1	5.6	0.48
	40°	20	0	0	1.00
	In motion	19	0	0	1.00
One or more apnoeas (n)	At rest in cot	20	3	15	Ref gro
	30°	18	0	0	0.25
	40°	20	2	10	0.62
	In motion	19	0	0	1.00

during motion. The number of desaturations was much higher among preterm infants (5) at baseline and rose significantly during motion. RR showed a significant increase at 40° but not when in motion. EtCO₂ levels were higher in all positions, with fewer bradycardic events and a similar number of apnoeic events, but no significant differences between positions.

The order of testing did not affect the results.

DISCUSSION

This is the first study of its kind looking at the physiological cardiorespiratory response in infants seated in a moving car seat.

We have shown that the simulation rig is safe to use and identified physiological disturbances not seen under static conditions in many infants. It may thus be a more accurate predictor of potential cardiorespiratory risk compared with the standard car seat challenge.

The finding that significant potentially adverse physiological effects were more frequent when the infant was at 40° and in motion than when at 30° regardless of which test came first suggests that it is the more upright position and the addition of movement that is responsible rather than an effect of a prolonged period in the sitting position.

We tested infants for up to 30 min—a relatively short journey time; however, some had frequent (up to 16) significant desaturations (<85% for ≥4 s) during this time. The vibration test

reproduced motion in a straight line—no bumps, turns, braking or acceleration, so this probably underestimates the effect of travelling on real roads. Previous studies of infants in static car seats have noted that cardiorespiratory problems increase in frequency with longer periods in a car seat. ¹ 18

All infants in our study were healthy but the effects in infants with cardiorespiratory disease or hypotonia may be more marked, as has been shown in the static car seat challenge.¹⁹

The low muscle tone and prominent occiput of preterm infants may lead to neck flexion and possible airway obstruction when in a car seat, 20 and this may be exacerbated by motion. Some preterm infants with recurrent desaturations flopped forward in an extremely flexed position during motion, raising their heads intermittently but could not maintain a raised head position. The head and shoulders came forward despite shoulder straps, which may be too long for smaller infants allowing some forward movement.² While head supports with cut-outs over the occipital area have been shown to reduce neck flexion,²¹ further research using them during motion is indicated. Parents often leave their infant alone in the back seat when travelling, and on long journeys the infant may slump forward in this way, resulting in respiratory compromise. Our findings suggest that it may be beneficial on a long journey for an adult to sit with the infant in the back of the car or use a mirror to observe the infant's position.

This small-scale pilot study was designed to identify any potential adverse effects of a more upright position and of motion on infants in car seats. Limitations are its small size, lack of randomisation of the infants studied, the lack of formal sleep state monitoring and the limited time each infant spent in a car seat.

We have shown potential changes in cardiorespiratory stability during periods in which the infant is in a more upright position than usually used in static car seat challenges, and the exacerbation of these effects during simulated movement in some infants. We cannot be certain of the clinical significance or potential risks posed by the changes we have identified, which could be a consequence of position, restraint, movement or a combination of all three. The infants in the supine position were not restrained (as they would be in a car bed); thus, we cannot assess the effects of restraint in this position.

More research is needed to quantify these effects, and to investigate how best to avoid them if they are clinically significant. In particular, there is a need for larger studies to investigate the effect of increasing infant age (and thus size), and duration of journey time, together with simulating the effects of changes in vehicle speed and direction.

The importance of protecting infants in the event of a moving vehicle accident must be emphasised, and infant car seats must be used whenever infants travel in cars (as per UK law),²² ²³ but these findings support the AAP guideline that infant car seats should not be used as a routine infant sleep environment.²⁴

CONCLUSIONS

This is a unique pilot study—the first to look at the physiological effect of vibration on infants in a car safety seat. The standard static car seat challenge currently used in hospitals does not reflect the angle or motion of the journey undertaken by the infant. The infant, in a seat placed at the more upright 40° position plus vibration experienced in a car, shows significantly increased HR, RR and decreased SpO₂. Simulating motion reveals a striking increase in potentially clinically significant oxygen desaturations. Surprisingly these differences were similar in term and preterm infants.

The motion simulator offers the possibility of further investigation of the potential benefits and limitations of various designs of infant car seats. This may lead to a revision of current recommendations for testing infants' suitability for travel in an infant car seat and also have implications for the design of car seats for newborn infants.

Acknowledgements Thanks to the nursing staff (particularly SN Rebecca Thomas and SN Joanne Newell) at the Great Western Hospitals NHS Trust NICU for their help in carrying out the car seat challenges. Video clip courtesy of Matthew Hill and BBC Points West.

Contributors RA conceived and designed the study, obtained ethical approval and funding and performed data analysis. MT and MG designed and built the vibration simulator and obtained ethical approval for its use. AK, GW and RA participated in the enrolment of patients, performing the challenges and data collection. PF contributed to the design of the study with technical advice plus data analysis. PB undertook the statistical analysis. RA, PF and PB wrote the paper with critical revision from all authors.

Funding Supported by a grant from the Lullaby Trust (formerly the Foundation of the Study of Infant Deaths) project number 259.

Competing interests None declared.

Patient consent Parental/quardian consent obtained.

Ethics approval Approval was obtained from West of England Research Ethics Committee (no. 11/h0106/1) and from Southampton University Human Experimentation Safety and Ethics Committee for the safety and use of the vibration simulator in humans

Provenance and peer review Not commissioned; externally peer reviewed.

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