Randomized clinical trial of an oscillating air mattress in preterm infants: Effect on apnea, growth, and development

To investigate claims that oscillating mattresses reduce apnea of prematurity and improve growth and neurobehavioural development, we performed a randomized clinical trial using a predetermined sample size. Preterm infants weighing from 750 to 1750 gm at birth were randomly assigned, by 250 gm strata, to either a conventional mattress (n = 63) or to an air mattress (n = 59) oscillating at 14 to 16 regular pulses per minute. Infants remained on the oscillating air mattress for at least 7 days or until 34 weeks postmenstrual age. Apneic episodes occurred and required treatment equally in the two groups; this lack of an effect was seen for both sexes and all weight groups. Both weight and energy intake were similar. Neurobehavioral development as shown by sleep state, habituation testing, and behavioral assessment at term, 3, 6, and 12 months was similar in the two groups. There was no difference in the incidence of neurologic abnormalities. We conclude that an oscillating air mattress has no prophylactic value in reducing apnea and does not enhance growth and development. (J PEDIATR 1986;109:857-64)

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Oscillating water beds are used in some centers with the aim of reducing apnea of prematurity. The impetus for this novel treatment was an observation by Korner et al.[1,2] that oscillating water beds reduced apnea. Not all subsequent studies have confirmed this finding[3,4]; indeed we have shown that the oscillating water bed is not as effective as theophylline in the treatment of apnea of prematurity.[5] However, the potential for reducing apnea remains clinically appealing. It has been suggested, in addition, that the oscillating water bed may mimic some aspects of uterine stimulation,[6,7] possibly proprioceptive, which may be a biologic mechanism for enhancing brain maturation,[8,9] improving growth rate,[10] and promoting quiet sleep.[11,12] The evidence is not conclusive, and these propositions require further investigation.

See related article, p. 828.

BW	Birth weight
CPAP	Continuous positive airway pressure
CT	Computed tomography
IPPV	Intermittent positive pressure ventilation
IVH	Intraventricular hemorrhage
OAM	Oscillating air mattress
REM	Rapid eye movement (sleep)

Most previous studies have used short-term crossover designs to examine the effects of an oscillating mattress.[2,3] However, only a conventional randomized clinical trial can provide evidence of changes in growth and long-term

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effects and a true measure of the size of the effects, allowing clinical relevance to be assessed. We report a randomized clinical trial with four objectives: to determine whether an oscillating mattress (1) prevented the development of apnea of prematurity to a clinically significant degree; (2) resulted in differences in growth (weight gain) either resulting from or independent of variations in energy intake; (3) produced differences in the organization of sleep and behavioral state in the early weeks of life; and (4) resulted in acceleration of development in the first 12 months of life. We examined also the incidence of neurologic abnormalities in each group at 1 year of age.

METHODS

Preterm infants weighing 750 to 1750 gm at birth who were breathing spontaneously were eligible for the study. Infants who had major congenital malformations and those who had documented grade 3 or 4 intraventricular hemorrhage by routine ultrasound[13] or CT scans were not eligible for the study. Infants receiving IPPV were assessed prospectively and were included only if they had been weaned from the ventilator by 84 hours of age and had been breathing spontaneously for 12 hours prior to enrollment. All infants were enrolled before 5 days of age.

We used a table of random numbers in blocks of two per stratum to allocate the infants to the OAM or control group after stratifying by 250 gm BW groups. Written consent was obtained from the parents of infants of both groups after random allocation.[14] The study was approved by the Research and Ethics Committee of our hospital. A record was kept of all eligible infants who did not participate in the study.

Infants assigned to the experimental group were nursed in an incubator and placed on an oscillating air mattress (Gaymar Industries, Orchard Park, N.Y.). The OAM produces a longitudinal wave motion similar to that of a water bed, although it is likely that the wave length may be more constant and the frequency more regular. We preferred the OAM because it was easier to vary the infant's position and to control temperature. The oscillations generated in the mattress were maintained at approximately 14 to 16 regular pulses per minute. Before stopping the OAM we reduced the frequency and amplitude for 24 hours. We continued to nurse the infants on an OAM even if theophylline, CPAP, or IPPV were considered necessary during the study. Infants in the control group were placed on a conventional mattress in an incubator. In both groups the babies stayed in the study for a minimum of 7 days or until discharge to a convalescent unit at around 34 weeks postmenstrual age.

The study duration and criteria for the use of theophylline and IPPV were similar for both groups. Theophylline was given in a standard dosage[15] to infants who had 10 or more apneic spells per 24 hours or who had two episodes requiring ventilation with bag and mask. Weight to nearest gram was recorded daily (Scale-Tronix 4004 infant scale, Scale-Tronix, Inc., White Plains, N.Y.). Infants were fed with expressed human milk, SMA 20 (Wyeth Laboratories), or Special Care Formula (Ross Laboratories), and actual intakes were recorded daily. No attempts were made by the investigators to alter the neonatal management in any way.

Cardiorespiratory impedance monitors were used on all infants throughout the study (HP 78021B and 7807C, Hewlett-Packard, Fullerton, Calif.). A respiratory pause of $\geq$15 seconds or a heart rate $\leq$100 beats per minute triggered the alarm; nurses recorded apnea, bradycardia, cyanosis, and need for cutaneous stimulation or bagging with mask. Recordings on a cardiorespirograph (HP 8025B Cardiorespiratory Recorder, Hewlett-Packard) were made for 6-hour periods to confirm the nurses' records between study days 1 to 3, 4 to 7, 8 to 12, and after 13 days. The recordings were examined by an observer blind to the treatment to detect pauses in breathing of 10 to 19 seconds, $\geq$20 seconds, and short pauses accompanied by bradycardia. No attempt was made to distinguish between central and obstructive apnea. In a previous study[2] only 3% of apneic episodes were considered obstructive in origin, and both forms appeared to respond equally well to the oscillations.

Behavioral and developmental assessments of infants. A 90-minute examination of the infants' sleep and behavioral state was made just before and again 24 hours after weaning from the OAM. The initial assessment could not be performed blind; a blind examiner made the second assessment. Corresponding times were chosen for the sleep assessments of the control group. The observations were made during the interval between feeds. During every minute the observers classified the infants' behavioral state using a standard rating scale[16]; interobserver agreement had been shown to be better than 90% for these observers for all states.

The Albert Einstein Neonatal Neurobehavioural Scale,[17] which consists of 20 test items and five summary scores, was used during a first follow-up visit at the expected date of delivery. At 3 months corrected age, the babies were given a test of cardiac habituation to an auditory stimulus. A 500 Hz tone at 80 dB was presented for 20 successive trials; the tone lasted 2.5 seconds, and the trials were approximately 30 seconds apart.[18] At 6 and 12 months corrected age, the Bayley Scales of Infant Development[19] were administered to all infants. Weight, body

Table I. Demographic data and neonatal course

	Oscillating air mattress (n = 59)	Control (n = 63)		Oscillating air mattress (n = 59)	Control (n = 63)
Birth weight (gm) ($\bar{X} \pm SD$)	1294 ± 266	1299 ± 241	CPAP and/or IPPV		
Gestational age (wk) ($\bar{X} \pm SD$)	30.5 ± 3.2	31.0 ± 2.7	n	20	12
Social class* ($\bar{X} \pm SD$)	3.4 ± 1.1	3.5 ± 1.2	%	34	19
Maternal education			Patent ductus arteriosus		
<High school	19	26	n	13	16
High school	18	14	%	22	25
College/university	17	19	Sepsis		
Unknown	5	4	n	16	12
Small for gestational age			%	27	19
n	14	17	Intraventricular hemorrhage, grade 3 or 4 (after enrollment)		
%	24	27	n	5	4
Apgar score			%	8	6
1 Minute			Hydrocephalus		
Median	5	6	n	5	5
Range	1-9	1-9	%	8	8
5 Minutes			Age at enrollment (day) ($\bar{X} \pm SD$)	3.1 ± 1.6	1.8 ± 1.1
Median	8	8	Duration of study (day)		
Range	3-10	4-10	Median	17.3	18.4
Respiratory distress syndrome			Range	7-68	7-51
n	24	26			
%	41	41			

*Hollingshead AB. Two-factor index of social positions. New Haven, Conn.: Yale University Press, 1969.

length, and head circumference were recorded and a standard neurologic and physical examination was performed by a pediatrician. All the posttreatment assessments were performed blind.

Sample size calculations and statistical analysis. We estimated a priori a sample size sufficient to detect three outcome variables (apnea, growth, and development). The largest sample size, required to demonstrate a reduction from 50% to 25% in the number of infants who had at least 1 day with five or more apneic episodes ($\alpha = 0.05, \beta = 0.20$ for a one-tailed test) was 45 per group. We planned to enroll a larger sample to ensure that we had sufficient numbers of those at highest risk <1250 gm BW.

The statistical methods used were chi-square analyses with adjustment for multiple sampling where appropriate for the Einstein test, analysis of variance for the habituation scores, Bayley scores, and sleep state periods, and unpaired t tests for weight gain and apnea.

RESULTS

Study population and clinical course. During a 16-month period from June 1982, we enrolled 122 infants: OAM group 59, control group 63. During the same period, 107 infants were not eligible for enrollment because of death (27), IPPV for ≥84 hours (59), grade 3 IVH (two), early transfer to peripheral hospitals (six), and for logistic reasons such as distance, adoption, lack of monitors and OAM (13); only five parents refused to participate in the study (OAM 2, control 3).

There were no statistically significant differences between the two groups in sociodemographic characteristics or in neonatal problems (Table I). The age at enrollment and the median duration of the study were similar for both groups. Only six infants in the OAM group and five in the control group were enrolled for less than 2 weeks. The duration of hospitalization in the neonatal unit was similar. There were no in-hospital deaths.

Documentation of apnea and bradycardia. Twenty-eight (47.5%) infants in the OAM group and 31 (49.2%) in the control group never had a day with five or more apneic episodes. Clinically significant apnea occurred and was treated to a similar extent in both groups. IPPV was used to treat apnea in three infants in the OAM group and one infant in the control group. The proportions of infants who were given theophylline for more than 10 apneic episodes in a single 24-hour period were similar (OAM 18, control 22) and the mean duration of treatment with theophylline did not differ (OAM 27 ± 19 days, control 23 ± 17). There was no difference in the incidence of apnea within birth weight groups (Table II), nor in the proportions of episodes that resolved spontaneously and those that required stimulation. There was a consistent trend toward

Table II. Episodes of apnea and bradycardia* recorded by nursing staff

Birth weight (gm)	Study day				
	1-5	6-10	11-15	16-20	21-25
750-999					
OAM	6.4 ± 3.9	6.4 ± 5.0	7.0 ± 4.9	6.2 ± 3.3	3.7 ± 4.0
Control	3.6 ± 4.3	7.3 ± 5.9	5.2 ± 4.6	3.8 ± 4.1	2.7 ± 2.7
1000-1249					
OAM	2.3 ± 1.9	3.2 ± 2.8	3.5 ± 3.5	4.4 ± 6.3	1.9 ± 2.1
Control	4.0 ± 3.8	5.7 ± 7.5	4.0 ± 4.8	3.0 ± 4.2	3.5 ± 3.4
1250-1499					
OAM	3.0 ± 2.8	2.8 ± 2.6	2.1 ± 2.7	1.8 ± 1.9	—
Control	2.8 ± 3.2	2.6 ± 2.4	1.5 ± 1.7	1.0 ± 1.6	—
1500-1750					
OAM	1.2 ± 1.6	1.2 ± 1.9	0.9 ± 1.6	1.1 ± 1.8	—
Control	2.4 ± 2.1	0.8 ± 1.3	0.5 ± 0.9	0.5 ± 0.9	—

Values represent mean ± SD.
OAM, oscillating air mattress.
*Episodes of apnea/24 hours, including both those that terminated spontaneously and those necessitating stimulation.

Table III. Documentation of apnea and bradycardia by cardiorespiratory recordings

Study day	n	Apnea ≥20 seconds		Apnea 10-19 seconds		Apnea ≥10 + bradycardia	
		OAM	Control	OAM	Control	OAM	Control
1-3							
OAM	32	0.3 ± 0.6	0.3 ± 0.6	1.9 ± 3.3	2.8 ± 3.9	0.7 ± 1.3	0.8 ± 2.0
Control	24						
4-7							
OAM	16	0.3 ± 0.8	0.6 ± 0.2	6.7 ± 16.2	4.9 ± 19.7	1.1 ± 2.0	0.4 ± 0.5
Control	29						
8-12							
OAM	24	0.1 ± 0.2	0.2 ± 0.3	2.2 ± 3.9	1.5 ± 1.7	0.4 ± 1.0	0.4 ± 0.6
Control	21						
≥13							
OAM	15	0.1 ± 0.2	0.2 ± 0.3	1.4 ± 1.3	3.8 ± 8.6	0	0
Control	14						

Values represent mean ± SD number of apneic episodues/baby/hour.
OAM, oscillating air mattress.

decreasing numbers of apneic episodes with increasing age and with increasing birth weight. The lack of any difference between the two groups was similar in males and females.

The cardiorespirograph records showed that occurrences of apnea of shorter (10 to 19 seconds) and longer (≥20 seconds) duration and of apnea accompanied by bradycardia did not differ significantly between the two groups at any time (Table III). The finding that the two groups did not differ in episodic apnea recorded by cardiorespirogram suggests that the lack of any differences in the clinical recordings cannot be attributed to biased recording by nurses (who could not be made blind to the maneuver). On comparing the cardiorespirograph records with nursing records for the apneic episodes seen on the same periods, we found similar results for the OAM and the control groups. As in other studies, an objective recording showed more apneic spells than were reported in the nursing charts.[20] The proportion of apneic episodes reported by nurses was one fourth to one third that of the number detected by cardiorespirograph recordings..

Weight gain. There was no significant difference between the groups in either weight or energy intake at any stage during the study (Table IV). This finding was consistent within 250 gm BW strata. The infants in the OAM group entered the study 1 day later; by day 8 the infants in the OAM group matched the control group in weight. The lower mean weight in both groups at day 22

Table IV. Weight and energy intakes

Study day	OAM n	OAM Weight (gm)	OAM Energy intake (kJ/kg/day)	Control n	Control Weight (gm)	Control Energy intake (kJ/kg/day)
1	59	1219 ± 270	278 ± 127	63	1269 ± 230	187 ± 101
8	58	1232 ± 280	449 ± 91	62	1218 ± 235	435 ± 84
15	44	1296 ± 303	445 ± 99	45	1293 ± 277	455 ± 69
22	24	1258 ± 326	460 ± 86	22	1258 ± 315	461 ± 135

Values represent mean ± SD.
OAM, oscillating air mattress.

Table V. Bayley Scales of Infant Development

	6 Months*		12 Months*	
	OAM (n = 48)	Control (n = 50)	OAM (n = 44)	Control (n = 48)
Mental Development Index	95.8 ± 14	96.5 ± 16	100.1 ± 23	97.0 ± 16
Psychomotor Development Index	99.1 ± 14	96.6 ± 12	95.2 ± 16	90.3 ± 15

Values represent mean ± SD.
*Corrected age.

compared with day 15 reflects the tendency for smaller infants to remain in the study for a longer period. Infants were losing weight at the time of admission to the study and regained their birth weight at a median age of 15 days (OAM 16.4 ± 6.8, control 14.4 ± 5.8, not significant). The mean daily weight gain after regaining birth weight was 18.8 ± 7.0 gm/day in the OAM group and 20.1 ± 7.7 gm/day in the control group. We examined the data for those infants who remained in the study for at least 10 days after regaining birth weight, and found no difference in the initial and terminal weights and energy intakes.

Sleep state observation before and 24 hours after completion of study protocol. The proportions of time spent waking, in quiet sleep, in transitional sleep, and in active (REM) sleep were similar in both groups, as was the number of changes of state (Figure). No differences were seen between the two groups when they were stratified by birth weight, and no shift was seen in the sleep-state pattern between the last day on the study and 24 hours after completion of the study. The amount of time spent on the OAM had no detectable effect in altering the organization of sleep.

Albert Einstein Neurobehavioural Assessment Scale at term. Chi-square analysis with Yates correction showed no significant differences between the OAM and control groups.

Habituation test at 3 months corrected age. During the test of habituation to a tone, the heart rate slowed in both groups at the start of the series of tones. There were no significant differences between the two groups in either the initial decline in heart rate or the gradual reappearance of the baseline heart rate during the sequence of 20 trials.

Follow-up at 6 and 12 months corrected age. At the 6-months visit, 81% of the OAM group and 79% of the control group attended; at 12 months the proportions were 75% and 76%, respectively. Information about neurologic status and anthropometric measurements were available from the family physician for three infants in the OAM group who did not attend and for eight infants in the control group. Eleven infants failed to attend both the 6- and 12-months follow-up visits: two moved away, seven lived too far away, and two died in accidents. These 11 infants did not differ in any salient respect in their initial state from those who did attend the follow-up visits.

There were no differences in weight, body length, and head circumference between the groups at their 3-, 6-, and 12-months visits. At 12 months, four infants in the OAM group had definite neurologic problems; one infant had suspect neurologic findings of hypotonia and delayed motor development, which at 2 years were assessed as normal. Six infants in the control group had definite neurologic problems. The Bayley Scales of Infant Development revealed no differences in the Mental or Psychomotor Development Indexes between the OAM and control groups at 6 or 12 months (Table V).

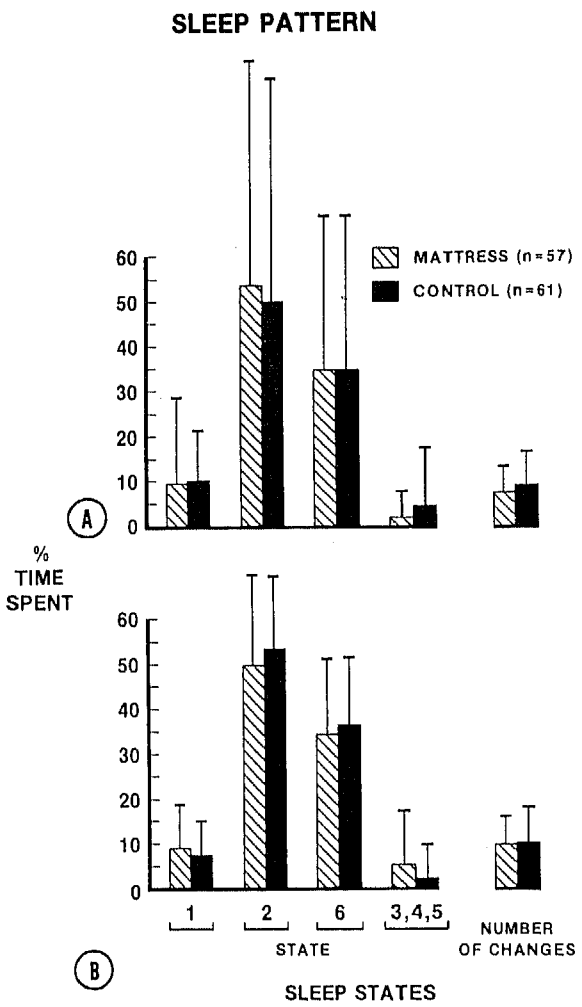

Figure. Proportion of time observed spent in quiet sleep *(1)*, REM sleep *(2)*, indeterminate sleep *(6)*, and waking *(3, 4, 5)* immediately before end of study (A) and 24 hours after completion of study (B).

DISCUSSION

Our study showed that the oscillating air mattress failed to prevent or reduce apnea, improve growth, or alter growth and development.

This study differs from others in two important aspects: design, and use of an oscillating air mattress rather than a water bed. Most other studies have used a crossover design[2,3] and may therefore be very sensitive methods of detecting small but biologically important effects. Such studies cannot be used to examine long-term (or even post-study) effects, and the biologic effects may not have any clinical relevance. In addition, the periodic changes in the maneuver in such a crossover design may themselves be the stimulus for triggering a response. Because our aim was to detect a clinically relevant and effective benefit, we chose a randomized trial and a sample of sufficient size to detect a prescribed effect. This resulted in a larger study than any previously reported. Although the study was designed to be 80% certain of detecting a 50% reduction in apnea, the results actually allow us to say that it was large enough to have detected a relative risk reduction in the occurrence of apnea of 25% if it had occurred ($\alpha = 0.05$, one tailed). An alternative way of expressing the strength of this finding is by hypothesis testing for equivalence.[21] The similarity between the two groups in the incidence of apnea, when subjected to such an analysis,* allows us to state with 95% confidence that the two treatments are equivalent.

The nature of the stimulation used in our study consisted of regular oscillations generated by an air mattress. It is possible that the infants may habituate to the regular motion and lose their initial response; additional stimuli, such as the auditory inputs used in other studies, may be needed[10,22] to produce a clinically useful effect.

The data now available on the effects of an oscillating water bed are confusing. Korner et al.[1] first showed a decrease in the incidence of apnea by using an irregularly cycled oscillating water bed; in a well-designed but small randomized study to test the safety of an oscillating water bed, preterm infants who had been allocated to the oscillating water bed had fewer apneic episodes than controls did. A subsequent polygraphic study by the same authors used a crossover design; in this study[2] 6-hour blocks on the oscillating water bed alternated with 6-hour blocks off the oscillating water bed, for a total of 24 hours. Eight infants with clinically observed apnea showed a statistically significant reduction in apneic episodes when they were on the oscillating water bed. Tuck et al.,[23] who also used a crossover design, found fewer apneic episodes in preterm infants while the oscillating water bed was in motion. Jones,[3] using a similar design, found that the oscillating water bed, with or without oscillations, had no effect on apnea or bradycardia. Subsequently Korner[4] was unable to elucidate the mechanism of reduction of apnea on the oscillating water bed, because she had difficulty obtaining infants who were stable enough to complete a 48-hour study protocol without further intervention. We encountered similar problems in an earlier study[5] in which

*Hypothesis testing for equivalence tests, not the usual null hypothesis of no difference (which may then be found to be not proved and therefore the treatment to be effective), but instead the hypothesis that a given difference Δ *is* present. If the true difference is less than Δ, the treatments can be said for all practical purposes to be equivalent.

a higher proportion of infants with apnea randomized to the oscillating water bed needed mechanical respiratory support compared with a control group assigned to theophylline therapy.

More recently, investigators have attempted to determine whether oscillating water beds improve the organization of sleep and possibly ameliorate the adverse effects of stimulant drugs.[24] Edelman et al.[12] studied the sleep pattern of 12 preterm infants. They noted that, while on the oscillating water bed, infants had significantly more quiet sleep and reduced fussiness and crying compared with control periods. In another study[11] apnea was not reduced but water bed oscillation significantly improved the infants' sleep and motility; it promoted quiet and active sleep and resulted in fewer state changes and less jittery movements. Burns et al.,[22] who used sound stimulation as well as an oscillating water bed, noted changes in sleep following the withdrawal of the additional stimulation. Inasmuch as we found no difference in sleep states or behavioral pattern, we conclude that, in the form in which we used the OAM—regular oscillations not augumented by other stimuli—the oscillations provide no useful clinical benefit.

In contrast to the study by Kramer and Pierpont,[10] we found no improvement in growth. Indeed, calculation of the confidence interval for the difference between the means in growth rate results in confidence limits that include zero, again suggesting (as do the apnea data) that not only is there no difference between the groups, they are likely to be equivalent. It is not possible to determine the mechanism of weight gain in the Kramer study (which used auditory stimuli as well as oscillations), because the report did not include information on energy intake. Burns et al.,[22] in a study very similar to that of Kramer, did not show changes in growth attributable to oscillations.

This study showed that at term, 3, 6, and 12 months age the OAM conferred no long-term advantage, although in other studies additional stimuli appear to have enhanced development in premature infants.[25] Many of the studies have used more than one kind of additional stimulation, and the observations were sometimes made by observers who were not blind.

We conclude that the prophylactic use of an oscillating air mattress offers no benefits in reduction of apnea or enhanced growth and neurobehavioral performance. Although we did not observe any adverse effects, its usefulness in the clinical management of preterm infants seems limited.

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