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Patient Oriented Research Unit

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To Whom It May Concern,

The following is my report on studies of internal pressures imposed by a Halo Sleep Sack Swaddle on infant manikins and a living infant.

Methodology: A standard water manometer was used to measure pressure (cm H^2O) [1]. A Mylar balloon was partially filled with air and wrapped around the manikins and infant [1]. The balloon plus manikin or infant was placed in the Halo Sleep Sack Swaddle. Pressure measurements were made with arms encased by the swaddle and arms out.

Measurements were made under two conditions. First, the swaddle was tightened firmly with the Velcro(R) straps. The force used is what I estimate a prudent caretaker would use to swaddle a newborn infant. This relates to my experience with nurses swaddling infants in hospitals where I work as a neonatologist. The second method used exceptional force to tighten the swaddle. This is termed as "tight as possible".

Results: (See Table- Last Page)

Comment: These data suggest that the pressure increased with increasing chest circumference and also pressures increased with arms out of the swaddle than pressures with arms in. Why this is so is unclear. Several mechanical factors are possible.

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A previous swaddling study indicated that when the pressure exerted by a swaddle on an infant's abdomen and chest during quiet sleep was increased to 7.05 ± 0.06 cm H^2O, average respiratory rate increased from 43.2 to 51.6 BPM [1]. However, there was no change in heart rate or arterial oxygen saturation. In REM sleep, an average pressure increase of 6.9 ± 0.6 was not accompanied by a change in respiratory rate or oxygen saturation, but did result in heart rate (134 vs. 131 BPM).

In the smaller manikin, using the "arms out" pressure data for comparison with prior measurements in living infants; in both situations ("firm" v.s. "as tight as possible") we would not expect swaddling to have much, if any, effect on respiration [1]. We would expect no effect on oxygen saturation, which would be the critical indicator of impending suffocation. Comparisons with the larger manikin and older infant in the "firm" swaddle situation also would suggest no compromise to respiration. Only with "as tight as possible" pressures in the larger mannequin and infant would we expect to see moderate changes in heart or respiratory rates, but again no change in the critically important oxygen saturation measurements.

Regarding the pressure exerted by a swaddle, it is worth noting that in past studies of living infants, high pressures were well tolerated [1]. More over, studies of traditional swaddling techniques indicate that swaddle pressures can reach 9 cm H^20 with no evidence of respiratory impairment [1]. Furthermore, although several adverse effects of swaddling have been noted such as increased susceptibility to hip dysplasia or pneumonia, sudden unexplained death has not been noted to be a consequence when infants are swaddled lying on their backs [2]. In fact, swaddling infants who sleep on their backs appears to further reduce the risk of sudden unexplained infant death [2].

References

1. Gerard CM, Harris KA, Thach BTT. Physiologic Studies in Swaddling: An ancient childcare practice, which may promote the supine for infant sleep. J Pediatr, 2002;141:398-404. June
2. Ponsonby A, Dwyer T, Gibbons LE, et al. Factors potentiating the risk of Sudden Infant Death Syndrome associated with prone position. N Eng J Med 1993;329:377-382.

	*CHEST Circumference	*LENGTH	+ARMS-IN Firmly	+ARMS-IN Tight (as possible)	+ARMS-OUT Firmly	+ARMS-OUT Tight (as possible)
Manikin #1	28.8	39.5	0.7 (0.6-0.8)	2.2 (2.0-2.5)	2.7 (2.4-3.0)	4.1 (3.5-5.5)
Manikin #2	36.5	46.5	1.5 (1.2-2.5)	2.0 (1.7-2.3)	3.2 (2.5-3.7)	7.6 (3.5-9.5)
3 month old Infant wt.=15.2 lbs	48.3				5.5 (4.7-6.0)	8.1 (5.0-10.0)
	*cm	*cm	+cm H^2O Average (range)		+cm H^2O Average (range)	

Sincerely,

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