

## Longitudinal Study of Sleep Behavior in Normal Infants during the First Year of Life

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**Study Objectives:** To longitudinally examine sleep patterns, habits, and parent-reported sleep problems during the first year of life.

**Methods:** Seven hundred four parent/child pairs participated in a longitudinal cohort study. Structured interview recording general demographic data, feeding habits, intercurrent diseases, family history, sleep habits, and parental evaluation of the infant's sleep carried out at 1, 3, 6, 9, and 12 months

**Results:** Nocturnal, daytime, and total sleep duration showed a high inter-individual variability in the first year of life associated with changes in the first 6 months and stability from 6 to 12 months. Bedtime was at around 22:00 and remained stable at 6, 9, and 12 months of age. Approximately 20% of the infants had more than 2 awakenings and slept more often in the parent bed. Nearly 10% of the infants were considered as having a

problematic sleep by parents and this significantly correlated with nocturnal awakenings and difficulties falling asleep.

**Conclusions:** Sleep patterns change during the first year of life but most sleep variables (i.e., sleep latency and duration) show little variation from 6 to 12 months. Our data provide a context for clinicians to discuss sleep issues with parents and suggest that prevention efforts should focus to the first 3-6 months, since sleep patterns show stability from that time point to 12 months.

**Keywords:** sleep habit, sleep ecology, sleep problems, infants  
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Sleep patterns and sleep structure show significant changes during the first year of life; the circadian rhythm is not established in the first months, and sleep is distributed throughout the day and night with a basic rest/activity cycle, similar to that of fetal life. At 1-2 weeks of age the fetal circadian rhythms starts to fade away and, at 1-2 months, the circadian activity rhythm develops with colic as the first sign of circadian rhythmicity; at 3-4 months of age, infants are entrained to the 24-h cycle and melatonin production is stable. At 6-9 months, wakefulness increases, daytime naps are established, and finally, at 12 months 70% to 80% of infants sleep mostly at night.<sup>1</sup>

Total sleep time decreases with age, linked to the gradual disappearance of daytime sleep and consolidation of nighttime sleep. Sadeh et al.<sup>2</sup> demonstrated that daytime sleep is mostly determined by maturation (age), whereas nocturnal sleep is better predicted by ecological factors. More specifically, studies of infant sleep correlates showed that intense parental involvement and reduced self-soothing skills may interfere with nighttime sleep consolidation.<sup>2,3</sup> Not only major developmental steps are determined by the interaction between maturational processes and ecological factors; sleep-wake patterns are also heavily influenced by biological and cultural factors, and therefore the concept of "normal sleep" varies according to cultural

### BRIEF SUMMARY

**Current Knowledge/Study Rationale:** To our knowledge, most of the data on the sleep pattern development in the previous reports were derived from longitudinal studies designed to collect different information but not exclusively intended to assess sleep structure and ecology. Our study represents the first longitudinal analysis of sleep patterns during the first year of life in the Italian population.

**Study Impact:** Sleep duration showed a high inter-individual variability in the first year of life, but most sleep variables showed little variation from 6 to 12 months. Our data suggest that prevention should focus to the first 3-6 months.

backgrounds.<sup>2,4</sup> Recent research showed that children from predominantly-Asian (P-A) countries had significantly later bedtimes, shorter total sleep times, increased parental perception of sleep problems, and were more likely to room-share than children from predominantly-Caucasian (P-C) countries/regions.<sup>4</sup> Parentally defined sleep problems were clearly a universal issue primarily based on cultural norms: approximately one-half of all parents in P-A countries/regions and one-quarter of parents in P-C countries perceive that their child has a sleep problem.<sup>4</sup>

Different studies in several countries have shown that the most common sleep complaints during early childhood are

excessive night awakenings and difficulties falling asleep, present in 20% to 30% of children during the first 3 years of life.<sup>2,5-9</sup> Conversely, some characteristics of sleep patterns do not vary in different cultures: the course of age-related developmental changes<sup>1,6,8,10-12</sup> and the extremely large interindividual variability in sleep duration, particularly during the first year of life.<sup>1,2</sup>

A cross-sectional survey published in 1996 on approximately 3,000 participants<sup>6</sup> reported that Italian children sleep less than children of the same age living in some other European and US countries<sup>13-15</sup> and show a later sleep onset time that is significantly associated with shorter nighttime sleep duration, without an increase in daytime sleep. In agreement with this study, another recent survey showed that, in normal infants and children from the United Kingdom, total sleep duration steadily fell from 13 hours 12 min during infancy to 9 hours 49 min at 11 years of age; compared to earlier studies, the younger children in this cohort slept for a shorter period. Also, high interindividual variability has been found in sleep duration, which ranges 10-17 hours in early infancy, but only from 8.5 to 11 hours at 11 years of age.<sup>16</sup>

The aims of this study were: (1) to provide a longitudinal picture of the typical sleep patterns of Italian infants during the first year of life, and (2) to evaluate the influence on sleep patterns of ecological factors over time.

## METHODS

### Recruitment

A group of Italian family pediatricians belonging to a pediatric association (*Associazione Pediatri in Gruppo*, APEG), evenly distributed over the entire national territory, was recruited to participate voluntarily in the study. Each pediatrician agreed to enroll the first consecutive infants undergoing routine health visits from March 2011 to August 2012, according to the following inclusion criteria: (a) Italian or foreigner newborn; (b) full-term; (c) Apgar score > 8 at 5 minutes, and (d) informed consent to the interview from both parents.

Exclusion criteria were: (a) presence of serious medical diseases, malformations, neurological, or psychiatric disorders; (b) intercurrent disease that would require drug treatment affecting sleep (e.g., steroids, antihistamines); and (c) infants of non-Italian ethnic groups whose parents had problems in understanding and speaking Italian.

The institutional review board of each region of the participating pediatricians approved the study. All parents provided written informed consent before enrollment. Parents enrolled received phone calls regularly to maintain contact and interest in the study.

### Structured Interview

Trained research assistants administered questionnaires to the mothers through structured telephone interviews when the infants were aged 1, 3, 6, 9, and 12 months. The questionnaires were developed based upon previous validated sleep instruments and adapted from several scales.<sup>5,6,8</sup>

The interview contained approximately 50 items, including specific questions about sleep and waking behaviors. The interview was structured in progressive steps consisting of: (a)

general demographic data, feeding habits, intercurrent diseases, presence of infantile colic; (b) family history for diseases potentially related to sleep (depression, headache, anemia, sleep disorders, restless legs syndrome); (c) sleep habits (bedtime, wake time, naps, nighttime awakenings, sleep latency, daytime sleep); and (d) parental perception of overall sleep problems. No data on sleep duration and napping were collected at the first observation at 1 month because of the extreme variability of feeding habits and because a specific routine was not yet established by the mothers. Nighttime sleep duration was calculated from bedtime and wake time. Total sleep duration was the sum of nighttime and daytime sleep duration.

The interviewer asked about any intercurrent disease, and if necessary postponed the interview until a healthy period. The interview was composed of questions with dichotomous answers, of closed questions (with categorical answers: i.e., sleeping arrangement: infant crib in parents room, infant crib in a separate room alone, infant crib in a separate room with siblings, in parents bed; sleep initiation methods: alone, breastfeeding, hold in arms, rocked, pacifier, bottle feeding, other). Some questions were measured by analog scale (i.e., "Do you consider your child sleep as a problem?" 0 = *absolutely no* to 10 = *absolutely yes*), and some were open-ended. Data on sleep habits were asked regarding the average of the 7 days preceding the interview.

Colic was defined as episodes of crying > 3 h/day for > 3 days a week for a 3-week duration in an otherwise healthy child between the ages of 2 weeks and 4 months.<sup>17</sup> The parental perception of overall sleep problems was evaluated through a visual analog scale 0-10 (0 = no problem; 5 = discomforting; 7 = distressing; 10 = severe). We considered as problematic those who rated the sleep problem of their infant as  $\geq 7$ .

The interviewer filled the interview form directly online; for each of the 5 time-points, and the average time for the administration of each interview was approximately 15 min.

Socioeconomic status was derived by calculating the Hollingshead Four Factor Index based on both parents' levels of occupation and education.<sup>18</sup> If both parents were employed, the Hollingshead scores were added and divided by 2 to receive a combined score that was then divided into 3 homogeneous categories (low, middle, and high).

As reported in a previous study<sup>19</sup> the questionnaires were not completely parallel because developmental changes required modification of item content (e.g., some items such as colic were not significant at 9-12 months of age) and the range of response options.

### Software

The software specifically arranged for this study made it possible to manage and recognize automatically the registration and access of users with different access levels. The program randomly assigned each infant to one of the interviewers. Data entry by the interviewer was driven on the basis of predetermined options, and the data in the network were transferred in certified encrypted mode. The software consisted of 5 structured forms, one for each age, with assisted compilation: dichotomous and closed questions had pull-down menus with responses for categorical variables; questions with analog scales had pull-down menus with 0-10 values.

## RESULTS

## Statistical Analysis

Descriptive analysis (frequencies, means, and standard deviation [SD]) was conducted for demographic and sleep variables. Comparisons between continuous distributions were carried out by means of the analysis of variance (ANOVA). The Pearson correlation coefficient was also used. ANOVA was used to compare across ages the following continuous variables: (1) sleep latency, (2) nighttime sleep, (3) duration and number of nighttime awakenings; (4) total sleep time, (5) daytime sleep (naps), (6) bedtime, (7) rise time, and (8) parental perception of overall sleep problems. The Bonferroni post hoc analysis was used to test for specific age group differences. Frequency data for parent report of a nonspecific sleep problem were calculated at 1, 3, 6, 9, and 12-month assessments, and correlation with sleep behavior domains was evaluated. A two-tailed significance threshold of  $p < 0.05$  was adopted across all analyses. All statistical analyses were performed using the software STATISTICA 6.1 (StatSoft Inc., Tulsa, OK).

The analysis on developmental trajectories of nighttime sleep, daytime sleep, and total sleep time was conducted within the latent growth curve (LGC) framework using Mplus 5.1.<sup>20</sup> For each variable, we tested a series of nested models positing different growth trajectories. The models were compared with each other using the  $\chi^2$  difference test. For all models, 2 latent factors (i.e., the intercept and the slope) were specified from the 4 repeated measures of the variables of interest (3, 6, 9, and 12 months). The intercept represents the baseline of each variable (i.e., 3 months). The slope gives the growth rate of the variables over time (from 3 to 12 months). This allows us to examine mean-level changes of the variables considered. Model 1 (strict stability or no growth model) includes only the intercept. This model assumes that no change occurred at all over the 4 time points. Model 2 posits a linear pattern of change over time. Model 3 assumes a nonlinear growth where the form of the change across time is not specified a priori (nonlinear growth).

To evaluate the fit of a structural model, we used the standard  $\chi^2$  index of statistical fit that is routinely provided under maximum likelihood estimation of parameters, as well as several indices of practical fit, including the root mean square error of approximation (RMSEA), the Tucker-Lewis index (TLI), and the comparative fit index (CFI). CFI and TLI values  $> 0.90$  were considered evidence of good fit, as was RMSEA value  $< 0.08$ .<sup>21,22</sup>

To take into account the role of sleep ecology measures at 1 month (sleep initiation method—*independent and non-independent*—and sleeping arrangements), type of feeding (breast fed and bottle fed), and demographic variables (child gender and socioeconomic status), we added those predictors in the best model of developmental trajectory for each variables (i.e., nighttime sleep, daytime sleep, and total sleep time). The non-independent method included breastfeeding, holding, rocking, while the independent method included pacifier and falling asleep alone.

All predictor variables, except socioeconomic status, were encoded as dummy variables (i.e., breast fed = 1 and bottle fed = 0; sleep initiation method independent = 1 and non-independent = 0; own room alone/with siblings = 1 and in crib in the parents room or in parents bed = 0; girls = 1 and boys = 0).

A total of 81 pediatricians entered the study. They were evenly distributed throughout the Italian territory (14 out of 20 regions). The distribution of infants recruited was fairly similar throughout the country, with a slight prevalence of subjects from Northern Italy: North 328 subjects (43.1%), Center 201 subjects (26.5%), and South 231 subjects (30.4%). Each pediatrician recruited an average of 9 infants (min 1, max 21) for a total of 760 infants meeting inclusion criteria.

The infants underwent regular health visits by the pediatricians who recruited the infants, and the pediatricians reported any intercurrent illness. Fifty-six (7.4%) dropped out: 7 subjects because they took drugs affecting sleep (antihistamines); 12 subjects did not have time for the interview; 36 parents refused to continue the interviews; 1 subject moved to another country.

The final sample included 704 infants evenly divided by gender ( $n = 347$  females, 49.3%;  $n = 357$  males, 50.7%) for a total of 3,520 completed questionnaires. For 703 of these infants, both mother and father were living together at birth (1 father abandoned the family at the 7<sup>th</sup> month of pregnancy). During the survey we recorded the separation of parents in only 3 cases: 1 at 3 months, 1 at 9 months, and 1 at 12 months. Sibship size was 43.9% single children, 44.3% with 1 sibling, and 11.8% with  $\geq 2$  siblings.

**Table 1** highlights the demographic characteristics of the sample. A positive family history was found for (a) mood disorders in 5.3% (4.3% in the mothers, 0.7% in the fathers, and 0.3% in both parents); (b) headache in 27.1% (15.5% in the mothers, 8.9% in the fathers, and 2.7% in both parents); (c) anemia in 14.1% (12.2% in the mothers, 1.6% in the fathers, and 0.3% in both parents); and (d) restless legs syndrome in 8.1% (4.5% in the mothers, 2.8% in fathers, and 0.7% in both parents).

Feeding on demand was adopted by 86.8% of mothers at 1 month; breastfeeding was adopted by 63.4% at 1 month and gradually decreased to 16.2% at 12 months; formula feeding by 13.8% at 1 month and increased to 44.6% at 12 months; mixed feeding by 22.9% at 1 month and gradually decreased to 9.5% at 12 months.

## Sleep Habits and Behavior

Colic affected 53.8% of the infants in the first month of life, decreasing to 17.9% at the age of 3 months. The severity level of colic was assessed via an analog scale (0-10); mean values (SD) were 6.2 (1.74) at 1 month and 6.1 (1.85) at 3 months, without statistically significant difference between the 2 ages. At 1 month, colic was defined as severe (score  $\geq 1$ SD in the analog scale 0-10) in 23.5% at 1 month and in 19.0% at 3 months. The majority of colic initiated after 5 p.m. (80.2% at 1 month and 74.6% at 3 months).

The percentage of infants who fell asleep alone was fixed at around 20% to 25% during the first year of life while approximately 80% needed support to fall asleep (breast, holding, rocking, pacifier). The sleep initiation methods seemed to remain constant over time (**Table 2**). **Table 2** shows that most of the infants in the first 3 months of life slept in a crib/bed in the parent room and 50% of them remained there until 12 months

of age. More than 10% of infants shared a bed with parents at 3-6 months, with a gradual increase to 18% at 9 and 12 months.

**Table 1**—Demographic features of the study sample.

	n (%)
Sample size	704 (100.0)
Gender, % girls	347 (49.3)
No other sibs	309 (43.9)
1 sibling	312 (44.3)
≥ 2 siblings	83 (11.8)
Italian nationality – mother	654 (92.9)
Italian nationality – father	672 (95.4)
Ethnic group (mother)	
White/Caucasian	690 (98.0)
Hispanic	9 (1.3)
African	3 (0.4)
Asian	2 (0.3)
Ethnic group (father)	
White/Caucasian	694 (98.6)
Hispanic	5 (0.7)
African	5 (0.7)
Asian	0 (0.0)
Maternal education at birth	
Postgraduate/college degree	235 (33.4)
High school degree	344 (48.9)
Less than high school degree	125 (17.8)
Paternal education at birth	
Postgraduate/college degree	167 (23.7)
High school degree	343 (48.7)
Less than high school degree	194 (27.6)
Socioeconomic status	
High	247 (35.1)
Middle	205 (29.1)
Low	252 (35.8)

**Figure 1** illustrates the changes in nocturnal, daytime, and total sleep time showing a very high standard deviation in the first 3 months that decreased with increasing age. The comparison of sleep variables across ages showed significant age differences for all measures (**Table 3**). For sleep latency only, the age groups between 3 and 6 months were significantly different from each other. From 3 months on, nocturnal sleep increased but tended to remain stable at around 590 min from 6 to 12 months; post hoc analysis showed that night sleep duration was not significantly different in the age groups (6, 9, and 12 months). Daytime sleep significantly tended to decrease (from 200 min to 121 min) from 3 to 12 months, resulting in a significant decrease of total sleep time from the initial 766 min down to 710 min at 12 months. Accordingly, the number of daytime naps decreased significantly from a mean of 3.4 at 3 months to 1.9 at 12 months. Bedtime at 6, 9, and 12 months differed from that at 1 and 3 months, but did not differ between them, being stable at around 22:00. A progressive delay in the waking up hours in the morning was evident, but statistical significance was reached only at 9 months, compared to 1 month.

Approximately 50% of infants had an average of 1-2 awakenings per night, while > 2 awakenings were present in 9% at 3 months, 21% at 6 months, 26% at 9 months, and 17% at 12 months. Bedtime difficulties were reported by 15% at 1 month, 11% at 3 months, 17% at 6 months, 16% at 9 months, and 14% at 12 months (**Figure 2**). The distribution of nighttime awakenings differed according to the infant sleeping arrangements (i.e., parent bed, crib in the parent room, own room with siblings, and own room alone) at 3, 6, 9, and 12 months. Infants with > 2 nighttime awakenings slept more often in the parent bed than infants without awakenings, at 3 months ( $\chi^2(9) = 43.480, p = 0.001$ ; 2% vs. 1%, respectively), 6 months ( $\chi^2(9) = 54.024, p = 0.001$ ; 6% vs. 2%, respectively), and 9 months ( $\chi^2(9) = 43.633, p = 0.001$ ; 8% vs. 3%). At 12 months, infants without awakenings slept more in their own room alone and less in the parent bed ( $\chi^2(9) = 43.480, p = 0.001$ ; 8% vs. 3%, respectively).

**Table 2**—Prevalence of sleep initiation methods, sleeping arrangements, and sleeping difficulties.

	1 month n (%)	3 months n (%)	6 months n (%)	9 months n (%)	12 months n (%)
<b>Sleep initiation methods</b>					
Alone	110 (15.6)	172 (24.4)	166 (23.6)	128 (18.2)	146 (20.8)
Breastfeeding	231 (32.8)	117 (16.6)	130 (18.5)	105 (14.9)	67 (9.5)
Hold in arms	247 (35.1)	217 (30.8)	228 (32.4)	280 (39.8)	272 (38.6)
Rocked	67 (9.5)	101 (14.3)	72 (10.2)	70 (9.9)	72 (10.2)
Pacifier	30 (4.3)	80 (11.4)	84 (11.9)	73 (10.4)	65 (9.2)
Bottle feeding	6 (0.8)	9 (1.3)	3 (0.4)	14 (2.0)	13 (1.9)
Other	13 (1.8)	8 (1.1)	21 (3.0)	34 (4.8)	69 (9.8)
<b>Sleeping arrangement</b>					
Parents bed	74 (10.5)	60 (8.5)	81 (11.5)	129 (18.3)	124 (17.6)
Crib in the parents room	589 (83.7)	562 (79.8)	461 (65.5)	381 (54.1)	380 (54.0)
Own room with siblings	11 (1.6)	28 (4.0)	61 (8.7)	85 (12.1)	88 (12.5)
Own room alone	30 (4.3)	54 (7.7)	101 (14.3)	109 (15.5)	112 (15.9)
<b>Sleeping difficulties</b>					
Bedtime difficulties	105 (14.9)	75 (10.6)	117 (16.6)	110 (15.6)	97 (13.8)
Night awakenings > 2	234 (33.2)	62 (8.8)	144 (20.5)	179 (25.4)	123 (17.5)

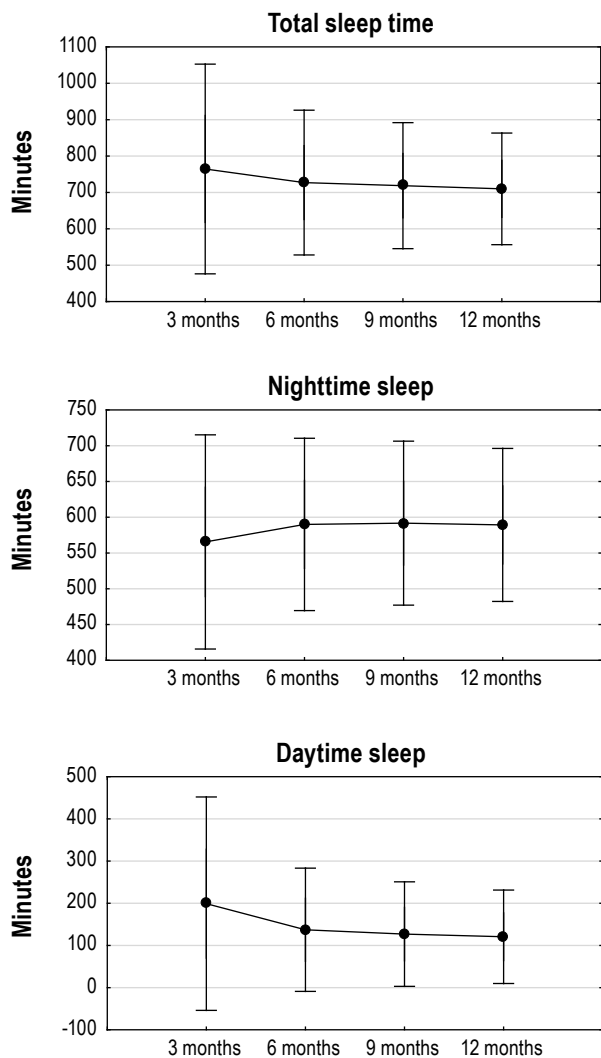
Since the method of sleep initiation (independent or non-independent) has been reported to influence sleep behavior and disturbances, we analyzed the differences in sleep duration of these 2 groups of infants (Table 4). As expected, independent infants slept longer than non-independent subjects at 3 and 6

months, while no significant difference was found at 9 and 12 months except for daytime sleep that was longer in the independent group at 12 months.

### Developmental Trajectory of Nighttime Sleep, Daytime Sleep, and Total Sleep Time

Table 5 showed that, for all 3 variables (nighttime sleep, daytime sleep, and total sleep time), the best fit was a non-linear growth model (Model 3). Figure 1 shows the trajectories for the 3 variables across the 4 time points (from 3 to 12 months). The final nonlinear model for nighttime sleep suggested an increase from 3 to 12 months of nighttime sleep (mean intercept = 566.439,  $p < 0.001$ ; mean slope = 21.803,  $p < 0.001$ ). Conversely, daytime sleep (mean intercept = 199.590,  $p < 0.001$ ; mean slope = -0.79.206,  $p < 0.001$ ) and total-time sleep (mean intercept = 763.638,  $p < 0.001$ ; mean slope = -0.54.402,  $p < 0.001$ ) showed a decrease over time. For each variable, the variances of the intercept and slope were significant for nighttime ( $b$  intercept = 844.416,  $p = 0.001$ ;  $b$  slope = 423.775,  $p = 0.001$ ), daytime ( $b$  intercept = 9181.675,  $p = 0.001$ ;  $b$  slope = 7926.039,  $p = 0.001$ ), and total sleep time ( $b$  intercept = 8841.209,  $p = 0.001$ ;  $b$  slope = 6358.287,  $p = 0.001$ ), suggesting that children started out with different levels of sleep duration and did not follow the same trajectories.

Figure 1—Sleep duration across the first year of life.



Data are shown as means (lines) and standard deviations (mean ± 1.96\*SD)

Figure 2—Percentage of infants with 0, 1-2, and ≥ 3 nighttime awakenings at 3, 6, 9, and 12 months of age.

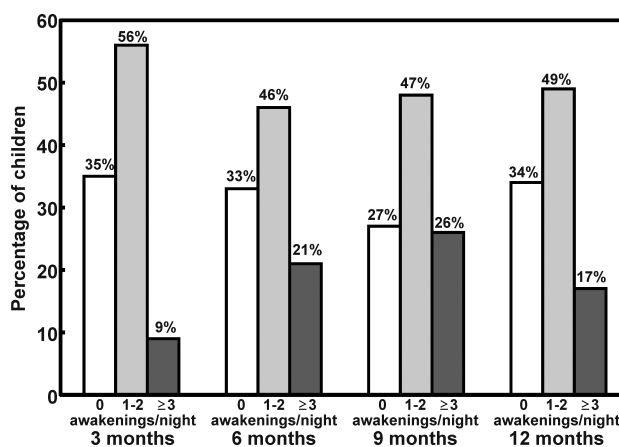


Table 3—Sleep variables and sleep problems across age groups.

	3 months	6 months	9 months	12 months	F	Partial $\eta^2$
Sleep latency (min)	15.3 (12.50)	13.8 (10.40)	14.9 (12.03)	14.7 (11.53)	3.003*	0.01
Nighttime sleep (min)	565.7 (76.82)	590.1 (61.68)	591.8 (58.53)	589.3 (54.57)	108.535***	0.13
Daytime sleep (min)	200.0 (129.18)	138.2 (74.83)	127.2 (63.32)	120.6 (56.50)	169.471***	0.19
Total sleep time (min)	765.8 (147.85)	728.4 (102.00)	719.0 (88.45)	709.9 (78.31)	53.185***	0.07
N. daytime naps	3.4 (1.04)	2.8 (0.81)	2.3 (0.68)	1.9 (0.53)	608.572***	0.46
Bedtime	22.0 (0.97)	21.7 (0.88)	21.7 (0.88)	21.7 (0.82)	140.737***	0.17
Rise time	7.4 (1.09)	7.5 (1.02)	7.6 (1.01)	7.5 (0.92)	5.776***	0.01
N. nighttime awakenings	1.1 (1.09)	1.5 (1.49)	1.8 (1.78)	1.4 (1.40)	80.278***	0.10

Values are represented as mean (SD). \*  $p < 0.05$ , \*\*\*  $p < 0.001$ .

In each non-linear model, the effects of feeding, sleeping arrangements, gender, and socioeconomic status were not predictive for sleep duration. Only the sleep initiation method (0 = non-independent, 1 = independent) significantly predicted both the intercept and the slope of nighttime, daytime, and total sleep time. In particular, at 3 months (i.e., the intercept) the independent group compared to the non-independent group reported longer nighttime ( $\beta = 0.22, p < 0.05$ ), daytime ( $\beta = 0.17, p < 0.001$ ), and total sleep time ( $\beta = 0.23, p < 0.001$ ) duration. Moreover, daytime sleep and total sleep time tended to decrease more over time (from 3 to 12 months) in independent infants vs. the non-independent infants (daytime sleep:  $\beta = -0.12, p < 0.05$ ; total sleep time:  $\beta = -0.21, p < 0.01$ ). Although nighttime sleep duration increased over time for all infants, the independent

ones tended to increase less in nighttime sleep ( $\beta = -0.25, p < 0.05$ ) than non-independent infants.

### Parent-Reported Sleep Problems

About 10% of the infants were reported by parents as having a problematic sleep, with a different distribution at the various assessments: parents reported a low level of problems at 3 months that increased at 9 months (1 month: 10.4%; 3 months: 4%; 6 months: 9.5%; 9 months: 12.6%; 12 months: 10.4%). Parental perception of an overall sleep problem at all ages significantly correlated with different sleep variables. Medium ( $r = 0.30$ ) to large ( $r = 0.50$ ) effects were observed for nocturnal awakenings and difficulties falling asleep (Table 6), while null effects were found for sleep latency and duration, number of naps, bedtime, and rise time.

**Table 4**—Sleep duration in independent and non-independent infants.

	Independent		Non-independent		p
	Mean	SD	Mean	SD	
<b>3 months</b>					
Nighttime sleep	579.2	72.07	561.8	77.78	< 0.01
Daytime sleep	228.9	141.26	191.6	124.32	< 0.001
Total sleep time	808.1	154.70	753.4	143.59	< 0.001
<b>6 months</b>					
Nighttime sleep	592.1	60.80	589.5	61.98	NS
Daytime sleep	155.7	80.31	133.2	72.44	0.001
Total sleep time	747.7	104.93	722.7	100.53	0.01
<b>9 months</b>					
Nighttime sleep	595.1	59.22	590.9	58.34	NS
Daytime sleep	134.9	63.76	124.9	63.07	NS
Total sleep time	730.0	87.48	715.8	88.56	NS
<b>12 months</b>					
Nighttime sleep	588.3	57.47	589.5	53.74	NS
Daytime sleep	132.1	60.95	117.2	54.74	0.01
Total sleep time	720.4	84.11	706.8	76.34	NS

## DISCUSSION

### Sleep Duration and Sleep Schedule

Our study represents the first longitudinal analysis of sleep patterns during the first year of life in the Italian population. To our knowledge, most of the data on the sleep pattern development in the previous reports were derived from longitudinal studies designed to collect different information but not exclusively intended to assess sleep structure and ecology; our study is one of the very few longitudinal survey specifically designed to evaluate the infant sleep development.

We found that total and night sleep duration were somewhat stable at 6, 9, and 12 months, while daytime sleep significantly decreased from 3 to 12 months, and the number of daytime naps declined. Accordingly, Sadeh et al.<sup>2</sup> reported that in their sample, the age groups between 6 and 17 months showed no significant changes in total and nighttime sleep duration indicating, the stability of sleep length during that period. A recent actigraphic study corroborated our findings of stability of sleep schedule and duration in the first year, showing continuity and nonsignificant changes from 8 to 14 months.<sup>23</sup> This pattern

**Table 5**—Growth curve models: goodness-of-fit indices.

Model	$\chi^2$	df	CFI	TLI	RMSEA	RMSEA 90% CI	p	MC	$\Delta\chi^2$	$\Delta df$	p
<b>Nighttime sleep</b>											
Model 1	103.623***	8	0.73	0.80	0.13	0.11–0.15	0.001				
Model 2	66.534***	5	0.83	0.79	0.13	0.11–0.16	0.001	1 vs. 2	37.089	3	0.001
Model 3	18.957***	4	0.96	0.94	0.07	0.04–0.10	0.10	2 vs. 3	47.577	1	0.001
<b>Daytime sleep</b>											
Model 1	294.706***	8	0.23	0.42	0.23	0.20–0.25	0.001				
Model 2	109.240***	5	0.72	0.66	0.17	0.15–0.20	0.001	1 vs. 2	185.466	3	0.001
Model 3	13.264**	3	0.97	0.94	0.07	0.03–0.11	0.16	2 vs. 3	95.976	2	0.001
<b>Total sleep time</b>											
Model 1	149.578***	8	0.70	0.77	0.16	0.14–0.18	0.001				
Model 2	34.589***	5	0.94	0.92	0.09	0.06–0.12	0.01	1 vs. 2	114.989	3	0.001
Model 3	23.734***	3	0.96	0.91	0.09	0.06–0.13	0.01	2 vs. 3	10.855	2	0.01

CFI, comparative fit index; TLI, Tucker-Lewis index; RMSEA, root mean square error of approximation; RMSEA 90% CI, confidence interval; Model 1, strict stability; Model 2, linear growth; Model 3, nonlinear growth. \*\*p < 0.01. \*\*\*p < 0.001.

supports previous findings that nocturnal sleep schedules are relatively consistent in the second half of the first year of life.<sup>11,24</sup>

Our results confirm the developmental trend of some sleep characteristics, and as already pointed out in the 1996 study,<sup>6</sup> comparison with other studies shows that our infants sleep less than infants of the same age living in other countries.<sup>13,14,25</sup> With respect to our previous 1996 Italian study,<sup>6</sup> we found similar data for total sleep duration (approximately 720 min) but shorter daytime sleep (150 vs. 210 min) in the first year. Sleep duration in Italian infants is approximately 1 hour shorter than the reference values at all ages tested. This is confirmed also by the comparison of our data with those of a recent longitudinal English study<sup>16</sup> showing reduced total and nighttime sleep duration but similar daytime sleep duration.

A strong cultural influence on sleep duration has been demonstrated in infants from predominantly Asian countries that had significantly shorter sleep (1 h less over the 0-12 year range) compared to infants from Caucasian/non-Asian countries.<sup>4</sup> It is interesting to note that, paradoxically, Italian infants seem to have sleep duration more similar to that of infants from Asian countries, rather than from other Caucasian groups. Mindell et al.<sup>4</sup> reported that these differences were related to later bedtimes rather than daytime sleep, suggesting a strong culturally based influence to nighttime sleep behaviors. The dissimilarities found may be due to the sociocultural and climate differences and may reflect certain social habits of Italian families, such as allowing their children to participate to the family evening life, including a late dinner and consequently a late bedtime, in comparison to other European countries, such as France,<sup>15</sup> Switzerland,<sup>1</sup> and England.<sup>16</sup>

The decrease in sleep duration that we observed in the cohort during early childhood might represent a generational change<sup>26</sup>; data from a Swiss study<sup>1</sup> clearly showed a reduction in sleep duration among the younger children over 2 decades, suggesting that younger children in the 1990s were getting less sleep than did those in the 1970s.

Another interesting finding is that bedtime at 6, 9, and 12 months remained stable at around 10:00 PM with a progressive but not statistically significant delay in the waking up hour in the morning; it is likely that the continuity in sleep start time partially reflects parental caregiving schedules and bedtime routines that tend to remain relatively constant during that period.<sup>2</sup>

### Sleep Latency, Nighttime Awakenings, and Daytime Naps

Sleep latency was estimated to be stable across 0-6 years of age in different studies and was, on average, 19 min in children aged 0-2 years.<sup>25</sup> We found the same trend in our sample with very few variations in sleep latency from 3 to 12 months. In respect to our previous study, sleep latency was slightly reduced in the present study (15 vs. 20 min), while bedtime was similar at around 10:00 PM, being probably culturally influenced; rise time was later (around 7:40 vs. 6:30).

It is well known from systematic reviews that nighttime awakenings tend to remain stable during the first year of life, ranging from 0 to 3.4 episodes per night for very young infants (0-2 months) to 0-2.5 per night (1-2 year olds).<sup>25</sup> In our sample we observed the same trend and similar values, with mean number of nighttime awakenings of 1.1 at 3 months and 1.4 at 12 months.

**Table 6**—Association between parental perception of an overall sleep problem and sleep variables.

	3 months	6 months	9 months	12 months
Sleep latency	0.08	0.16	0.12	0.17
Night time sleep	0.04	-0.06	-0.10	-0.15
Daytime sleep	-0.07	-0.08	-0.13	-0.12
Total sleep time	-0.04	-0.09	-0.16	-0.19
Number of naps	-0.01	-0.04	-0.06	-0.01
Bedtime	-0.08	0.00	0.01	0.06
Rise time	-0.03	-0.06	-0.09	-0.10
Nighttime awakenings	0.35*	0.41*	0.45*	0.46*
Falling asleep difficulties	0.35*	0.42*	0.37*	0.40*

\*p < 0.01.

A Swiss longitudinal study reported that the percentage of infants with nighttime awakenings decreased during the first 3 months of life and remained stable (approximately 33% to 35%) during the first year. In the longitudinal study of Blair et al.<sup>16</sup> at 6 months, approximately 13% of infants had 1-2 awakenings/night and 10% had 3 or more; in our sample at 6 months the prevalence was higher, with 46% of infants who woke 1-2 times per night and 21% who woke 3 or more times per night. The percentage of infants with more than 2 awakenings per night was lower in the present sample (20% to 25% vs. 35%) than in the 1996 study.<sup>6</sup>

The literature reports that the number of naps decreases gradually in the first year of life between 1 and 6 months at a rate of 0.28/month, between 7 and 12 months at a rate of 0.1/month, with a mean of 1.7 naps/day in 0- to 2-year-old children.<sup>25</sup> In our sample, the number of daytime naps decreased significantly from a mean of 3.4 at 3 months to 1.9 at 12 months.

### Sleeping Arrangements

Only few subjects reported solitary sleeping in the first 3 months of life, while most of the infants slept in a crib/bed in the parent room at 3 months. Our data are similar to those by Hauck et al.<sup>27</sup> who reported that 85% of their infants slept in the same room as their mother, but at 12 months the rate was 29%; in our study it remained high, at around 54%. We found that co-sleeping was present in approximately 10% of infants at 3-6 months with a gradual increase to 18% at 9 and 12 months. These results suggest that Italian parents find co-sleeping acceptable and might be unaware of the risk for sudden infant death or for the development of later sleep onset association insomnia.<sup>28</sup> Co-sleeping was surprisingly high in this study, with more than 10% of infants that shared a bed with parents increasing to 18% at 12 months, compared to only 2% in the previous 1996 survey.

It should also be considered that sleep location might be more relevant in the context of specific sleep symptoms/behaviors. In our study we found that sleeping in the parent bed was associated with a higher number of nighttime awakenings that may be considered more problematic by parents if they co-sleep with their child. In fact, different studies have shown that parents of infants who bed-share reported an increased number of awakenings when compared with solitary-sleeping infants.<sup>29-31</sup>

## Developmental Trajectory of Nighttime Sleep, Daytime Sleep, and Total Sleep Time

The analysis of trajectories of sleep duration during the first 12 months showed that sleep duration followed a nonlinear trend with an increase from 3 to 12 months of nighttime sleep and a nonlinear decrease of daytime and total sleep time. Furthermore, our analysis allowed us to affirm that the changes in sleep duration followed different nonlinear trajectories, suggesting a high interindividual variability, in agreement with previous studies.<sup>32,33</sup> We found that, beside the different predictors analyzed (i.e. socioeconomic status, feeding method, sleeping arrangements, gender, sleep initiation method), parental involvement in settling behaviors was the only predictive variable influencing sleep duration with independent infants who have normally longer sustained sleep periods than non-independent ones.<sup>34</sup>

An interesting finding, not reported before, is that the independent infants in the first year of life tended to decrease more in daytime sleep and total sleep time and to increase less in nighttime sleep than non-independent infants. These trajectories could be linked either to environmental factors (parental bedtime practices) or to genetic factors. It is known that daytime sleep duration is strongly influenced by shared environmental factors and that consolidated nighttime sleep duration is largely influenced by genetic factors.<sup>32-35</sup>

Corroborating this, we did not find differences in the nighttime sleep duration between independent and non-independent infants, while daytime sleep duration continued to show differences in almost all the time points considered. This indirectly confirms that environmental factors acting since the first months continued to influence daytime sleep over the first year of life.

Furthermore, active parental settling behaviors have been frequently reported as the cause of sleeping disturbances in early ages since they reduce the opportunity for the infant to learn to self-settle. Consistent with this view, parental presence or active involvement in settling the child to sleep has been found to be a correlate of poorer sleep quality in the first years of life in cross-sectional and longitudinal studies.<sup>34,36</sup>

Although it is known that breastfeeding was associated with nighttime awakenings,<sup>2,4</sup> few studies have analyzed the differences in sleep duration. In our study, type of feeding was not predictive of sleep duration, in agreement with another study showing no significant differences on nighttime sleep duration between infants who were exclusively breastfed and infants receiving either exclusive formula or a combination between formula and breast feeding.<sup>37</sup>

### Parent-Reported Sleep Problems

Our results showed that 10% of parents perceived their infants as problematic for sleep during the first year of life, with a mild increase at 9 months. These findings are similar to the rate of prevalence of studies based on parental reports<sup>9,38</sup> and confirm that this is a common complaint that remains stable throughout the first year of life and begins in early life. In fact, many parents consider their child's sleep as problematic at ages as young as 2-4 months, with approximately 15% of parents of 3-month-old infants reporting their infant sleep as problematic.<sup>19</sup> We found also that the parental perception of an overall sleep problem at all ages significantly correlates with nocturnal

awakenings and difficulties falling asleep, while sleep latency, sleep duration, daytime naps, bedtime, and rise time showed no correlation. According to our findings, other studies have shown that the frequency of nighttime awakenings is one of the main factors by which parents judge the quality of their child sleep.<sup>16,39</sup>

Therefore, in order to screen for infants with sleep problems, key questions should be focused mainly on the number of night awakenings and the presence of trouble falling asleep, since these were the parameters associated with parental perception of a sleep problem in the infant at all time points considered.

### Study Limitations

There are several limitations of this study that should be taken into account. All sleep measures were based on parent reports, and the bias of subjective evaluation cannot be ruled out. Thus, the findings of this study may reflect more precisely parental perceptions of sleep than sleep of the individual child per se. In order to collect specific data for our purposes, we needed to pool data from different sleep questionnaires. As reported in other studies, we ensured comparability of data in our statistical analyses using the same wording and the same trained interviewer that performed the questions. Nevertheless, measurement imprecision could have been introduced by the lack of parallel measures for some questions at different assessment points. Moreover, the potential impact of cultural differences in defining sleep problems was minimized because only a negligible percentage of the subjects were not Caucasian and not have Italian nationality. Future analysis of our data will focus on determinants and correlates of sleep problems during the first year of life.

## CONCLUSION

Our study is the first attempt to longitudinally evaluate sleep patterns of Italian infants in the first year of life and confirms the importance of focused screening for sleep during infancy. These normative data might be used to reassure parents about their infant's sleep, to evaluate if their sleep pattern is adequate and normal, and might help in counseling families about what to expect from their babies' sleep. Finally, they can help pediatricians and parents to identify incorrect parental behaviors and might allow a specific intervention to prevent the development of sleep disorders.

## REFERENCES

1. Iglowstein I, Jenni OG, Molinari L, Largo RH. Sleep duration from infancy to adolescence: reference values and generational trends. *Pediatrics* 2003;111:302-7.
2. Sadeh A, Mindell JA, Luedtke K, Wiegand B. Sleep and sleep ecology in the first 3 years: a web-based study. *J Sleep Res* 2009;18:60-73.
3. Mindell JA, Kuhn BR, Lewin DS, Meltzer LJ, Sadeh A, Owens JA. Behavioral treatment of bedtime problems and night wakings in infants and young children. *Sleep* 2006;29:1263-76.
4. Mindell JA, Sadeh A, Wiegand B, How TH, Goh DY. Cross-cultural differences in infant and toddler sleep. *Sleep Med* 2010;11:274-80.
5. Johnson CM. Infant and toddler sleep: a telephone survey of parents in one community. *J Dev Behav Pediatr* 1991;12:108-14.
6. Ottaviano S, Giannotti F, Cortesi F, Bruni O, Ottaviano C. Sleep characteristics in healthy children from birth to 6 years of age in the urban area of Rome. *Sleep* 1996;19:1-3.



7. Petit D, Touchette E, Tremblay RE, Boivin M., Montplaisir J. Dysomnias and parasomnias in early childhood. *Pediatrics* 2007;119:e1016-e25.
8. Sadeh A. A brief screening questionnaire for infant sleep problems: validation and findings for an Internet sample. *Pediatrics* 2004;113:e570-7.
9. Wake M, Morton-Allen E, Poulakis Z, Hiscock H, Gallagher S, Oberklaid F. Prevalence, stability, and outcomes of cry-fuss and sleep problems in the first 2 years of life: prospective community-based study. *Pediatrics* 2006;117:836-42.
10. Acebo C, Sadeh A, Seifer R, Tzischinsky O, Hafer A, Carskadon MA. Sleep/wake patterns derived from activity monitoring and maternal report for healthy 1-to-5-year-old children. *Sleep* 2005;28:1568-77.
11. Burnham MM, Goodlin-Jones BL, Gaylor EE, Anders TF. Nighttime sleep-wake patterns and self-soothing from birth to one year of age: a longitudinal intervention study. *J Child Psychol Psychiatry* 2002;43:713-25.
12. Weissbluth, M. Naps in children: 6 months–7 years. *Sleep* 1995;18:82-7.
13. Klackenbergh G. Sleep behaviour studied longitudinally. *Acta Paediatr Scand* 1982;71:501-6.
14. Richman N. Surveys of sleep disorders in children in a general population. In: Guilleminault C, ed. *Sleep and Its Disorders in Children*. New York: Raven Press, 1987:115-28.
15. Mantz J, Muzet A. Le sommeil de l'enfant de trois ans. Enquête en milieu scolaire. *Arch Fr Pediatr* 1991;48:19-24.
16. Blair PS, Humphreys JS, Gringras P, et al. Childhood sleep duration and associated demographic characteristics in an English cohort. *Sleep* 2012;35:353-60.
17. Barr RG. Changing our understanding of infant colic. *Arch Pediatr Adolesc Med* 2002;156:1172-4.
18. Hollingshead AA, ed. Four-Factor Index of Social Status. Unpublished manuscript. New Haven, CT: Yale University, 1975.
19. Byars KC, Yolton K, Rausch J, Lanphear B, Beebe DW. Prevalence, patterns, and persistence of sleep problems in the first 3 years of life. *Pediatrics* 2012;129:e276-84.
20. Muthén LK, Muthén BO. Mplus User Guide. 5th ed. Los Angeles, CA: Muthén & Muthén, 1998-2007.
21. Browne MW, Cudeck R. Alternative ways to assess model fit. In: Bollen KA, Long JS, eds. *Testing Structural Equation Models*. Newbury Park, CA: Sage, 1993:136-62.
22. Hu L, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Struct Equ Modeling* 1999;6:1-55.
23. Scher A. Continuity and change in infants sleep from 8 to 14 months: a longitudinal actigraphy study. *Infant Behav Dev* 2012;35:870-5.
24. Tikotzky L, Sadeh A. Maternal sleep-related cognitions and infant sleep: a longitudinal study from pregnancy through the 1st year. *Child Dev* 2009;80:860-74.
25. Galland BC, Taylor BJ, Elder DE, Herbison P. Normal sleep patterns in infants and children: a systematic review of observational studies. *Sleep Med Rev* 2012;16:213-22.
26. Matricciani L, Olds T, Petkov J. In search of lost sleep: secular trends in the sleep time of school-aged children and adolescents. *Sleep Med Rev* 2011;16:203-11.
27. Hauck FR, Signore C, Fein SB, Raju TN. Infant sleeping arrangements and practices during the first year of life. *Pediatrics* 2008;122:S113-20.
28. Horsley T, Clifford T, Barrowman N, et al. Benefits and harms associated with the practice of bed sharing: a systematic review. *Arch Pediatr Adolesc Med* 2007;161:237-45.
29. Baddock SA, Galland BC, Beckers MG, Taylor BJ, Bolton DP. Bed-sharing and the infant thermal environment in the home setting. *Arch Dis Child* 2004; 89:1111-16.
30. Lozoff B, Askew GL, Wolf AW. Cosleeping and early childhood sleep problems: effects of ethnicity and socioeconomic status. *J Dev Behav Pediatr* 1996;17:9-15.
31. Mao A, Burnham MM, Goodlin-Jones BL, Gaylor EE, Anders TF. A comparison of the sleep-wake patterns of cosleeping and solitary-sleeping infants. *Child Psychiatry Hum Dev* 2004;35:95-105.
32. Touchette E, Côté SM, Petit D, et al. Short nighttime sleep-duration and hyperactivity trajectories in early childhood. *Pediatrics* 2009;124:e985-93.
33. Touchette E, Dionne G, Forget-Dubois N, et al. Genetic and environmental influences on daytime and nighttime sleep duration in early childhood. *Pediatrics* 2013;131:e1874-80.
34. Adair R, Bauchner H, Philipp B, Levenson S, Zuckerman B. Night waking during infancy: role of parental presence at bedtime. *Pediatrics* 1991;87:500-4.
35. Brescianini S, Volzone A, Fagnani C, et al. Genetic and environmental factors shape infant sleep patterns: a study of 18-month-old twins. *Pediatrics* 2011;127:e1296-1302.
36. Sadeh A, Tikotzky L, Scher A. Parenting and infant sleep. *Sleep Med Rev* 2010;14:89-96.
37. Tikotzky L, De Marcos G, Har-Toov J, Dollberg S, Bar-Haim Y, Sadeh A. Sleep and physical growth in infants during the first six months. *J Sleep Res* 2010;19:103-10.
38. Meltzer LJ, Johnson C, Crosette J, Ramos M, Mindell JA. Prevalence of diagnosed sleep disorders in pediatric primary care practices. *Pediatrics* 2010;125:e1410-18.
39. Palmstierna P, Sepa A, Ludvigsson J. Parent perceptions of child sleep: a study of 10,000 Swedish children. *Acta Paediatr* 2008;97:1631-39.

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