

Systematic Review and Meta-Analysis: Fussing and Crying Durations and Prevalence of Colic in Infants

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Objective To determine the mean duration of fussing and crying and prevalence of colic using modified Wessel criteria in infants in the first 3 months of life.

Study design A systematic literature search was performed using the databases Medline, PsycINFO, and Embase. The major outcome measure was mean total fuss/cry duration during 24 hours at ages 1-2 weeks (11 samples), 3-4 weeks (6 samples), 5-6 weeks (28 samples), 8-9 weeks (9 samples), and 10-12 weeks (12 samples).

Results Of 5687 articles reviewed, 28 diary studies (33 samples) were suitable for inclusion in meta-analysis; these studies included 8690 infants. No statistical evidence for a universal crying peak at 6 weeks of age across studies was found. Rather, the mean fuss/cry duration across studies was stable at 117-133 minutes (SDs: 66-70) in the first 6 weeks and dropped to a mean of 68 minutes (SD: 46.2) by 10-12 weeks of age. Colic was much more frequent in the first 6 weeks (17%-25%) compared with 11% by 8-9 weeks of age and 0.6% by 10-12 weeks of age, according to modified Wessel criteria and lowest in Denmark and Japan.

Conclusions The duration of fussing/crying drops significantly after 8-9 weeks of age, with colic as defined by modified Wessel criteria being rare in infants older than 9 weeks. Colic or excessive fuss/cry may be more accurately identified by defining fuss/cry above the 90th percentile in the chart provided based on the review. (*J Pediatr* 2017;185:55-61).

olic is a common source of concern for parents, a frequent reason for seeking help and advice from healthcare professionals.^{1,2} It may be a trigger for abusive head trauma.³ However, definitions for colic vary widely ranging from gastrointestinal symptoms^{4,5} to inconsolable crying,⁶ which has resulted in variations of the reported prevalence rate from 1.5% to 11.9%.⁷ Increasingly colic is defined in terms of total daily duration of fussing and crying.⁸⁻¹¹ The most widely used definition for colic is the "Rule of Three's"¹²: an infant is considered to have colic if the infant fusses or cries for >3 hours, >3 days per week, for >3 weeks. However, it is impracticable for parents to assess and document fuss/cry duration for a 3-week period using detailed diaries.¹³ Thus, the "modified Wessel criteria" are most often used, requiring the infant to have fussed/ cried for more than 3 hours a day, on at least 3 days in any 1 week.^{12,14,15}

Although the modified Wessel criteria are widely used, normative studies in the general infant population are lacking.¹⁵ Considerable changes in infant care have occurred since the Wessel criteria were published,^{16,17} thus, the prevalence may be different than that noted in the 1950s. Although modified Wessel criteria have been used in different countries, the impact of cultural variations such as caregiving styles¹⁸⁻²³ and maternal soothing techniques^{23,24} on the duration of infant fussing and crying need to be taken into consideration. Furthermore, the cry/fuss duration may depend on the patterns of feeding (breast vs bottle).²⁵ Finally, several studies have documented a developmental pattern of fuss/cry duration in the first 3 months of life,^{1,26-29} indicating a gradual increase that peaks at 5-6 weeks of age with a decrease to one-half the amount by 3-4 months of age. ^{18,22,27,28,30,31} This "normal crying curve" has been interpreted as universal across cultures, ¹⁸ although some have not found evidence. ^{20,32,33}

We conducted a systematic review and meta-analysis of fuss/cry durations reported in diary studies from around the world. Twenty-four-hour behavior diaries are considered to be the international gold standard for measurement. 14,34-36 We investigated the change in fuss/cry duration over the first 12 weeks of life to determine if there is a universal "crying curve" (5- to 6-week fuss/cry duration peak) and if mean fuss/cry duration varies across studies in different countries, according to feeding type or study quality. We also determined the prevalence of colic according to the modified Wessel criteria at different ages in the first 12 weeks.

Methods

The current meta-analysis was conducted in line with PRISMA guidelines.³⁷ We searched the databases Medline (1964-December 2015), PsycINFO (1964-December 2015), and Embase (1964-December 2015) using the search headings "infant and crying" OR "crying and amount" OR "crying and duration" OR "fussing and infant." In addition, infant cry researchers who had participated in the International Cry Research Workshops were approached concerning unpublished

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data. Finally, we conducted a separate bibliography search and included all new relevant research.

Criteria for inclusion of articles in the analysis were as follows: (1) at least one 24-hour behavior diary to measure fuss/cry duration; (2) unselected sample (ie, no infants had been excluded according to fuss/cry duration [eg, only colic infants or all noncolic infants]); (3) observation study (ie, no intervention trial); (4) infant age between 1 and 13 weeks; and (5) the authors reported (or provided after request) mean fuss/cry duration as well as distribution indices (ie, SD). For the colic prevalence analysis, only the studies that reported at least three 24-hour behavior diaries were included to meet the modified Wessel criteria. Abstracts were screened according to the selection and inclusion criteria explained above by 2 authors, each screening one-half of the abstracts. Study selection and data extraction were performed independently by 2 authors.

The quality of studies was evaluated according to 8 criteria: (1) subject selection (whole vs convenience population), (2) recruitment rate (\geq 50% vs <50%), (3) participation rate (\geq 75% vs <75%), (4) sample size (\geq 101 vs <101), (5) whether the following 4-sample characteristics were reported: socioeconomic status, parity, infant sex, and maternal age (3 of 4 reported vs <3 reported), (6) feeding type (reported vs not reported), (7) resolution time for the diary (5 vs 15 minutes), (8) number of days requested for diary (\geq 4 vs <4 days), and (9) whether modified Wessel criteria were employed. Each sample, at each measurement age, received a score of 0 or 1 for each of the criteria. A score of 0 was also given in cases where the information for the criterion was not reported. The individual scores were summed to give a total quality score that could range from 0 to 8 (**Table I**; available at www.jpeds.com).

The major outcome measure was mean total fuss/cry duration during 24 hours. The studies were grouped according to age at assessment: 1-2 weeks (11 samples), 3-4 weeks (6 samples); 5-6 weeks (28 samples), 8-9 weeks (9 samples), and 10-12 weeks (12 samples). Furthermore, information regarding the sample size and feeding type (bottle-fed, breastfed, mixed) was extracted from the articles.

To test fuss/cry peak duration, we calculated a weighted mean and the pooled weighted SD for each period. To test for mean differences, ANOVA was performed between individual weighted means. To evaluate the prevalence of colic, 3 samples which used the diaries for less than 3 days were removed from the 8- to 9-week analysis. The prevalence of colic for each study at each assessment point was computed according to the modified-Wessel criteria, and overall prevalence rates are reported as weighted mean and pooled weighted SD.

Meta-analysis was conducted with the comprehensive meta-analysis software. Effect sizes are reported as standardized mean difference with 95% CIs for each study. The mean difference (Cohen d) compares the individual study's mean with the overall weighted mean across studies at each assessment time. A d of .20 is a small, .50 medium, and .80 or more a large effect. Effect sizes were analyzed using the random effects model, in which the error term is composed of variation originating from both within-study variability and between-study differences. Heading the standardized mean differences are reported as standardized mean difference as standardized mean diff

The distribution of effect sizes was examined using tests of heterogeneity. Significant heterogeneity indicates that differences across effect sizes are likely due to sources other than sampling error, such as different study characteristics. Categorical moderator tests were applied to test for within groups $Q\left(Q_{w}\right)$ and between groups $Q\left(Q_{b}\right)$. A significant value for Q_{w} indicates that the effect sizes within a category of the moderator variable are heterogeneous, whereas a significant value for Q_{b} indicates that the effect sizes are significantly different across different categories of the moderator variable. Meta-regression analyses were performed to test quality of assessment as a continuous moderator.

We examined the potential for publication bias by using 2 methods suggested for observational studies. First, biases according to study size were assessed with use of the Begg and Mazumdar⁴² rank correlation test (Kendall tau b). Second, the Duval and Tweedie^{43,44} "trim and fill" method was applied.

Results

The online search yielded 5680 articles. An additional seven potential studies were identified through searches of bibliographies and from the Infant Cry Research Workshops (Figure 1; available at www.jpeds.com). After removing the duplicates, the overall systematic literature search included 4109 articles. We reviewed the titles and abstracts of all articles found (N = 4109), resulting in 227 abstracts for joint review. After excluding 138 articles based on their abstract, a total of 89 fulltext articles were independently reviewed by 2 authors. Based on the inclusion criteria, 43 articles were further excluded. Among the remaining 46 articles, there were 18 studies with missing data, which required their authors to be contacted to obtain further information about the fuss/cry duration or moderator variables. However, some authors were not able to provide missing data (eg, means, SD etc)8,14,15,22,45-49 or could not be reached⁵⁰⁻⁵⁴; and some studies did not meet the inclusion criteria (eg, selected population, no fuss/cry duration data etc.).⁵⁵⁻⁵⁸ These studies were, therefore, not included in the metaanalysis. Five study reports^{20,21,59-61} reported on more than one sample, resulting in a total of 28 articles with 33 samples being included in the meta-analysis (Table I). The majority of the studies used at least 3 days diary except 3 samples from 2 study reports. 60,62 The studies included in the analysis with their quality rating scores and descriptions of each study are shown in Table I.

The overall agreement in the selection of articles according to the predefined criteria was Cohen k = 0.89 at the full-text retrieval stage. The discrepancies in articles were discussed and mutually resolved by the coders.

Fuss/Cry Duration across 1-12 Weeks of Age

Mean Fuss/Cry Duration. The weighted mean average for each period was computed (Figure 2, A). As shown, mean fuss/cry durations were 117-133 minutes (SDs: 66-70) in the first 6 weeks and then dropped to 68 minutes (SD: 46) by 10-12 weeks of age. Post-hoc comparisons showed that fuss/cry duration did not significantly differ from each other across the

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