Tools assessment and diagnosis to infant colic: a systematic review

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Abstract

Background   Infant colic occurs between 10% and 40% of healthy born children in their first year of life. Its assessment is complex, and there are only a few instruments of appraisement and diagnosis.
Methods   Scientific articles located through a systematic review using the Pubmed, Scopus, Cochrane, PEDro, Dialnet, IME and Dialnet databases. Two researchers obtained data independently from relevant studies previously identified. Risk of bias was assessed according to the methods recommended by the Cochrane Collaboration, with reporting following the preferred reported items for systematic reviews and meta-analyses guidelines and evaluating their methodological quality based on the EMPRO scale.
Results   Four tools were obtained for valuation of infant colic. *Parental diary of infant cry and fuss behaviour*, *Crying Pattern Questionnaire*, *Infant Colic Scale* and, lastly, a validity of the Turkish version of the *Infant Colic Scale*.
Conclusions   Analysis of the existing tools involves the need to design and validate new assessment scales for this clinical frame.

Introduction

Infant colic is a major medical and public health issue, affecting up to 20% of infants younger than 3 months (Lucassen *et al.* 2001). Infant colic, usually, debut in the first 15 days and is a self-limited early childhood condition. It presents a varied clinic with excessive, inconsolable and intense crying, discomfort and pain, bloating, altered pattern of excreta, extensor pattern, redness of the face, altered sleep pattern and regurgitation (Savino 2007). The assessment of colic is complex, and only few instruments of valuation and diagnosis are used for this purpose. This is mainly due to the unclear and poorly description of the concept of colic. The aetiology is multifactorial, and therefore, therapeutic strategies are ineffective. This drives parents and families to live with anxiety and stress during early months of infancy (Cirgin Ellett & Swenson 2005).

There is a significant deficit of tools for colic assessment, and those that exist have limitations to be used as a criterion for diagnosis. Almost all of these tools are only focused on the criterion 'crying', which is important for clinical feature; however, it cannot be used to define 'colic' by itself. The best characterized and known tools that are used in clinical practice are *Crying Diaries* (Barr *et al.* 1982, 1988). Crying diaries value the amount and duration of crying, and the behaviour of the baby for 24 h a day. These tools come from another one such as Crying Pattern Questionnaire (CPQ) (Wolke *et al.* 1994), which is similar to Crying Diary but with a more simple format to be filled out by the families. There are also a very few who validate scales in both valuation and diagnostic. The most known scale, but also less used in the clinical setting, is the Infant Colic Scale (ICS) (Cirgin Ellett *et al.* 2003). ICS consists of five subscales referents to

aetiological hypothesis of infant colic. This scale would allow to assess causal factors of colic, although the diagnostic and valuation scope may be limited. Other scales assess the effectiveness of breastfeeding (Matthews 1988; Shrago & Bocar 1990; Armstrong 1992; Mulford 1992; Jensen *et al.* 1994; Howe *et al.* 2007; Da Costa & van der Schans 2008) that, indirectly, could assess clinical aspects of colic but are not used for this purpose.

The purpose of this study is to identify, describe and evaluate the psychometric properties and quality of the assessment and diagnostic tools existing in the infant colic. To achieve this goal, we will conduct a systematic review by selecting assessment tools that enable a more effective clinical and professional analysis and also disseminate the importance of implementing assessment tools in cases of colic.

Methods

Design

Systematic Review of assessment tools.

Search strategy

We conducted a review of the scientific literature until the month of December 2015 regarding the available approaches for evaluation of infant colic on different databases: Pubmed, Scopus, Cochrane, IME and PEDro.

The search strategy used in the databases was as follows: (validity OR validation OR assessment OR measure OR diary OR scale OR evaluation OR score OR instrument OR diagnostic toll AND infantile colic OR infant colic OR excessively crying OR fuss behaviour OR feeding problems OR sleeping problems) in the databases of Pubmed; (evaluation AND infant* colic*) in the databases PEDro; (infant* colic*) in the databases Dialnet; (evaluación del cólico del lactante) in the databases IME; (evaluation OR validation OR validity AND infant* colic*) in the databases Scopus; (evaluation OR validity AND infant* colic* in the databases of Cochrane (Table 1).

The limits applied to narrow the search were as follows: the Pubmed database, 'human studies', 'validation studies', 'English, Spanish, Italian and French'; the Scopus database, 'type of document', 'subject area', 'English, Spanish, French and Portuguese'; the Dialnet database, 'type of document'.

The names of the authors' articles that we found were used to find other possible manuscripts. We also reviewed the reference list of the selected articles (the names of the authors of this referred articles and the titles) and contacted some of the experts in this field in order to find new papers. Then, the relevant articles were identified on the basis of the analysis of the title and their abstract to then review the full text of the manuscripts.

Table 1. Search strategy

Pubmed	23
#1: 'validity' [Title/Abstract]	
#2: 'validation' [Title/Abstract]	
#3: 'reliability' [Title/Abstract]	
#4: 'assessment' [Title/Abstract]	
#5: 'measure' [Title/Abstract]	
#6: 'diary' [Title/Abstract]	
#7: 'scale' [Title/Abstract]	
#8: 'evaluation' [Title/Abstract]	
#9: 'score' [Title/Abstract]	
#10: 'instrument' [Title/Abstract]	
#11: 'diagnostic tool' [Title/Abstract]	
#12: #1 OR #2 OR #3 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11	
#13: 'infantile colic' [Title/Abstract]	
#14: 'infant colic' [Title/Abstract]	
#15: 'excessively crying' [Title/Abstract]	
#16: 'fuss behaviour' [Title/Abstract]	
#17: 'feeding problems' [Title/Abstract]	
#18: 'sleeping problems' [Title/Abstract]	
#19: #13 OR #14 OR #15 OR #16 OR #17 OR #18	
#20: #12 AND #19	
#21: Limit #20 TO: evaluation studies, validation studies AND Humans AND Languages: English, Italian, Spanish and French.	
Scopus	3
#1: 'evaluation'	
#2: 'validation'	
#3: 'validity'	
#4: #1 OR #2 OR #3	
#5: 'Infant* colic*'	
#6: #4 AND #5	
#7: Limit #6 TO: type of document AND subject area AND Languages: English, Spanish, French and Portuguese.	
Cochrane	137
#1: 'evaluation'	
#2: 'validity'	
#3: #1 OR #2	
#4: 'infant* colic*'	
#5: #3 AND #4	
IME	1
#1: 'evaluación del cólico del lactante'	
PEDro	1
#1: 'evaluation'	
#2: 'infant* colic*'	
#3: #1 AND #2	
Dialnet	22
#1: 'colic* AND infant*'	
#2: Limit #1 TO: type document.	

Study selection

After this search, all papers found were analysed by two unbiased reviewers, and only the ones that met the inclusion criteria (which are shown in the next discussion) were selected.

Inclusion criteria

Instrument validation studies for valuation of infant colic.

Articles published in Spanish, English, French and Italian.

Data extraction

Two researchers obtained data independently from relevant studies previously identified. Acquired data are presented in Table 2, including the following analysis dimensions: population, reliability, internal consistency, responsiveness, floor and ceiling effects, administration burden, administration time, readability, content validity, criterion validity and construct validity (Table 2).

Risk of bias assessment

Risk of bias was assessed according to the methods recommended by the Cochrane Collaboration, with reporting following the preferred reported items for systematic reviews and meta-analyses guidelines and evaluating their methodological quality based on the EMPRO scale (Valderas *et al.* 2008).

In case of discrepancies between these two assessors, we used the intervention of a third reviewer to sort out this discrepancy.

Results

Study selection

The search performed in Pubmed, Scopus, Cochrane, IME and PEDro provided 187 articles, while three more were obtained from an additional search (names of the authors' articles that were found, reference lists from the selected articles and contacted experts). Four (Barr *et al.* 1988; Wolke *et al.* 1994; Cirgin Ellett *et al.* 2003; Cetinkaya & Başbakkal 2007) articles were acquired according to tools that are used for infant colic valuation. Articles that do not include assessment tool of infant colic were the most common exclusion criteria (see flowchart, Fig. 1).

Study characteristics (Table 2 summarizes the characteristics of the four included tools and the risk of bias).

Clinimetric properties of each of the tools selected and included in Table 2 are described in the next discussion.

First, 'Parental diary of infant cry and fuss behaviour' by Barr *et al.* (1988) focuses on evaluating sleep and crying baby during 24 h a day by a parent daily. This diary was validated in two studies (Barr *et al.* 1982, 1988). On the first one (Barr *et al.* 1988), construct validity was compared with audio recordings of 24 h of baby vocalizations. In order to do this, a system of active voice that had freedom of movement and an active circuit was used allowing 24 h of analysed continuous recordings. In these recordings, crying is interpreted as an expression of negative emotion designated as a negative vocalization compared with neutral sounds (such as grunting) and positive sounds (like lullabies). For analysis of construct validity, 10 mothers of 6.3 weeks – average age of children – at the time of data recollecting were selected. Five of the kids were boys while the other half were girls. Categorizing the sounds of the tape as 'negative vocalizations', 'no negative vocalizations', 'vocalizations parents and other sounds' and transcribing the tapes' only negative and the one observer vocalizations, it was concluded that the correlation between the frequency of crying and combinations of discomfort or complaints and episodes of negative vocalizations on the tape was moderately strong (Table 2). In the second validation (Barr *et al.* 1982), the validity of this diary was analysed by comparing it directly with recordings of crying episodes for 24 h).

In this validation studies, the content validity, factor analysis, discriminant validity, internal consistency by Cronbach's alpha value or test–retest reliability are not performed.

Second, referencing the diary questionnaire crying pattern was performed using the CPQ by Wolke *et al.* (1994). It consists of eight items about crying and fussing, and it is divided into four periods: morning (06.00 am to midday), afternoon (midday to 06.00 pm), evening (06.00 pm to midnight) and night (midnight to 06.00 am). The CPQ was compared with a daily record of 24 h during 7 days (parental diaries), for the evaluation of the duration and episodes of crying and complaints in infants. Regarding the length of crying and fussing was found moderate to good convergence between maternal reports in the CPQ and daily records (Rho of Spearman 0.51–0.68 $P < 0.001$). Convergences were lower but significantly higher in the reports of the number of crying in 24 h (r of Pearson 0.27–0.51 $P < 0.001$). That is, the

Table 2. Summary of the characteristics of the four included tools and the risk of bias

	Parental diary	CPQ	ICS	Turkish version ICS
Population	10 mothers of children with an average age of 6.3 weeks (5 girls and 5 boys)	237 mothers of children with an average age of 8 months (134 boys and 103 girls)	14 children with colic in the first phase (96.1% girls), 160 children with colic in the second phase (94.4% girls) and 254 children with colic in the third phase (94.5% girls). Age in the 3 phases ranged from 5 to 8 weeks.	110 mothers of 132 children
Reliability	Untested	Untested	Untested	Pearson correlation coefficient of 0.65.
Internal consistency	Untested	Untested	Cronbach's alpha coefficient was 0.73 for the total scale. Cronbach's alpha were 0.45 to 0.91 for the subscales.	Cronbach's alpha coefficient was 0.73 for the total scale. Cronbach's alpha were 0.55 to 0.89 for the subscales.
Responsiveness	Untested	Untested	Untested	Untested
Floor and ceiling effects	Untested	Untested	Untested	Untested
Administration burden	Untested	Untested	The Infant Colic Scale items are evaluated on a 6-point Likert-type scale. The responses range from 1 (strongly disagree) to 6 (strongly agree). A low total score from the tool is positive for showing colic, and a high score indicates a negative state.	The Infant Colic Scale items are evaluated on a 6-point Likert-type scale. The responses range from 1 (strongly disagree) and 6 (strongly agree). A low total score from the tool is positive for showing colic, and a high score indicates a negative state
Administration time	24 h a day for, approximately, 7 days	–	–	About 15 min
Readability	Untested	Untested	A pilot study with five mothers was conducted to test readability and clarity.	The scale was translated from English to Turkish by three experts and, later, from Turkish to English by two experts. It was tested by nine experts who evaluated the tool and made the necessary changes. Factor analysis was conducted too.
Content validity	Untested	Untested	Experts conducted the initial reduction of left the ítems. Later, it is used in patients for the final reduction of the items. Besides, factor analysis was conducted.	
Criterion validity	Untested	Untested	Untested	Untested
Construct validity	Daily compared with audio recordings 24 h (convergent validity). $r = +0.64$ $P = 0.03$	CPQ compared with diary 24 h for 7 days (adequate convergent validity) For the duration of fuss and cry: r of Spearman: 0.51–0.68 ($P < 0.001$) For the number of episodes of fuss and cry: r of Pearson: 0.27–0.51 ($P < 0.001$)	'Difficult infant temperament' measurement of the ICS Scale compared with ICQ; correlation coefficient of Spearman: 0.72.	Untested

CPQ, Crying Pattern Questionnaire; ICS, Infant Colic Scale; ICQ, Infants Characteristics Questionnaire.
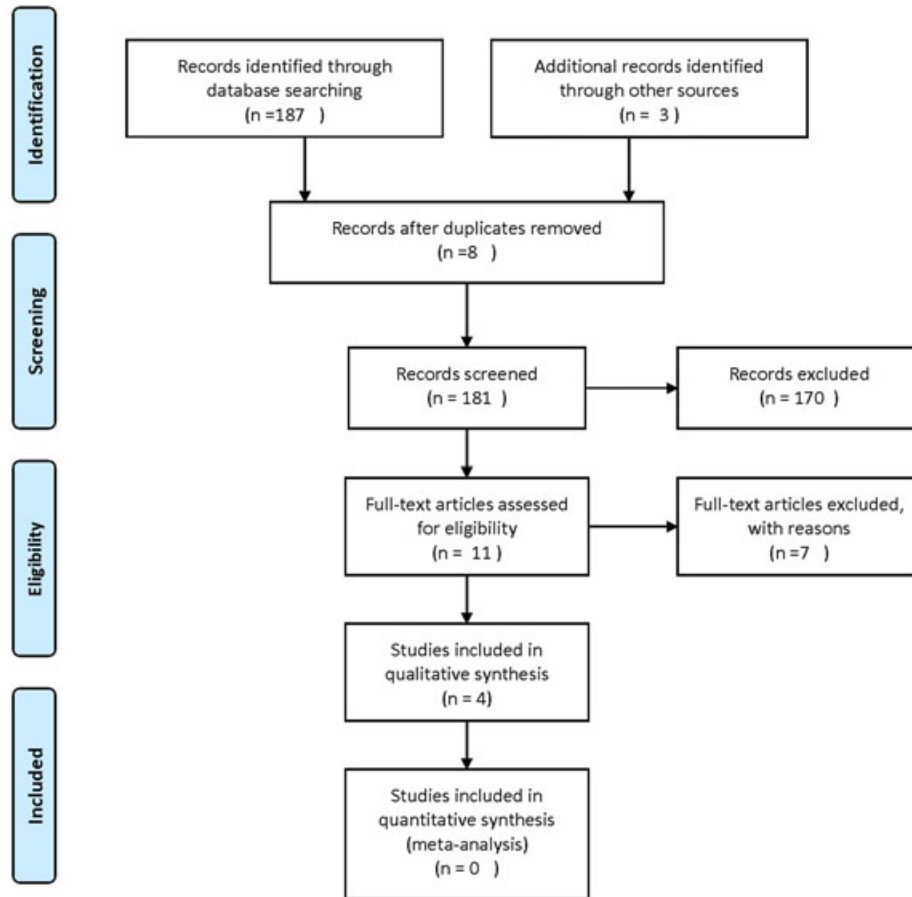
Figure 1. Flowchart.

convergent validity is tested (within the construct validity) showing appropriate values, finding that tool is valid. The total amount of crying and fussing was overestimated by mothers when they used the CPQ against the diary by 13%. The data that support the CPQ can be a useful instrument to carry out large-scale studies on the prevalence of excessive crying.

Third, the ICS by Cirgin Ellet *et al.* (2003) arises from the five theoretical explanations for colic: allergy/intolerance protein cow's milk or soy, immaturity of the gastrointestinal system, immaturity of the central nervous system, difficult infant temperament and problems in the parent–child interaction. These five explanations provided the organizational framework for the development of this multidimensional Likert scale with 22 items. The response options were 'strongly agree', 'moderate disagree', 'slightly agree', 'slightly disagree', 'moderately disagree' and 'strongly disagree'.

In the ICS, we also analysed the construct validity by comparing the dimension '"difficult infant temperament' of this scale with the questionnaire 'Infants Characteristics Questionnaire', a questionnaire commonly used to measure the infant temperament. It contains 28 items rated on a 7-point scale, 1 being described as the best feature of temperament and 7 as difficult temperament trait. The sample consists of 254 parents; 235 were mothers, 5 grandmothers and 14 parents. The dimension of difficult infant temperament indicated a correlation of 0.72 with the total scale Infants Characteristics Questionnaire, indicating adequate construct validity. It was held, also, the factor analysis of this tool, using the five theoretical explanations, and calculated the value of Cronbach's alpha coefficient for each dimension, which reached values ranged from 0.45 to 0.91 for each of the five dimensions. The internal consistency of the scale was also established globally considered obtaining a value of Cronbach alpha coefficient of 0.73 and is therefore suitable. In this validation by Cirgin Ellet *et al.* (2003), we did not find any additional analysis of validity and reliability and sensitivity to change.

Later, a transcultural adaptation of this scale to Turkish was performed (Cetinkaya & Başbakkal 2007). The translation and back-translation was carried out from English to Turkish. Content validity of the ICS in its Turkish version was tested by sending the scale to nine experts who evaluated the tool and made the necessary changes. It is correlating each of the 22 items with the total scale eliminating three initial 22 items studied. The internal consistency of the final Turkish version of the ICS, which included 19 items, was established calculating the value of Cronbach's alpha coefficient which was 0.73. This coefficient was 0.55 to 0.89 for each of the five dimensions. It has been made a factor analysis on 19 items, by the method of main components being, as in the English version, five dimensions, which accounted for 57.63% of the total variance. The analysis placed two items in different subscales from the original English version, but as these elements were shown to have a significant correlation with its original subscale were returned to it. The test–retest reliability, with 2 weeks of separation between measurements, was studied only by 30 of the 110 mothers included in the study. It was found that the correlation r of Pearson showed a value of 0.65 ($P < 0.01$).

Discussion

There is a lack of assessment tools for colic, and those that exist have limitations to be used as appraisement and diagnostic. Existing tools are, preferably, focus on the variables 'crying and irritability'. This tools focused on determining quantity and type of crying as key to describe the effect of therapeutic approaches to symptoms of colic aspects. However, symptomatology of colic is very diverse, and other factors can cause this 'crying and irritability' (problems on the suction, latch on difficulties, unsatisfactory breastfeeding, craniofacial alterations, changes in sleep patterns, vomiting and reflux, alteration in the pattern of excreta and constipation, among others) (Aguayo Maldonado 2004; Aguilar Cordero 2005; Asociación Española de pediatría 2008); and we believe that, until now, it has not been assessed, completely, as colic; because the variety of aetiological hypotheses and clinical features are not considered.

On the basis of the identification and description of tools on this review, the most known and used in clinical practice is daily crying. These daily measure the amount and duration of crying and the baby's behaviour during 24 h a day (Barr *et al.* 1982, 1988). However, analysing the construct validity of *Parental diary of infant cry and fuss behaviour,* we find certain biases in their use that we must discuss. First, although this shows a strong correlation ($r = +0.64$, $P = 0.003$), 1 diary, of the 10 analysed, was much less precise than the other nine because three episodes of negative vocalizations that had been omitted in the diaries and three other negative episodes on the tape had been merged in only one episode in the diary; so in this diary, there were inaccuracies. In addition, the sample to analyse the construct validity was insufficient. Parents were not told how often they had to fill out the diary, but most parents said that they had filled out the diary every 3 or 4 h; therefore, this can give enough variability between responses to complete the diary. Other than this, we observed that the correlation between daily and audio recordings is considered strong by being greater than or equal to 0.5. However, the total average duration and combinations of crying and discomfort or complaints registered daily (125 min in 24 h) was much greater than the total length of the negative vocalizations in the tape (29 min in 24 h). This may be because the crying records by parents may have been biased by the presence of the recorder. Also, the lack of a formal practice session and instructions may result in less optimal records. There were also large differences between parents based on the use of the symbol 'discomfort or complaints' and the symbol 'fuss'; so much so that, one parent did not use the symbol 'disturbance' at any time, so this suggests that there was a wide range of styles in the daily registration by parents.

We would like to mention that, this tool does not value other dimensions such as stools, gas, burp and vomiting/regurgitation. The 'sleep' can be assessed through subdimensions as hours of sleep or type of sleep; however, this tool only values sleep hours, but still, this assessment is not valid, because Kirjavainen *et al.* (2004) think that parents are partial to assess sleep in infants. On sleep polygraph study performed for 24 h in 24 children with excessive crying and 23 control infants 6 weeks old, keeping diaries of parents for 4 days, determined that the parents of the control group were more likely to overestimate the hours of sleep of the baby.

It is important to mention that in this diary certain baby behaviours are measured when babies are awake, for example, if they are happy, crying, eating or sucking. However, they do not evaluate whether the crying is conceivable or inconsolable, what kind of movements and gestures performed while babies are crying or whether there are differences depending on the type of nursing. Understanding this, these factors

could justify the 'irritability' infant and crying crises characterizing of colic.

Although it is commonly used to assess colic, completing a 24-h diary becomes very difficult for some parents. Also, this parental diary was not designed to evaluate colic but to describe patterns of childhood behaviour in a general area. In addition, analysing the clinometric properties, we note that the only analysis that was made was the construct validity and insufficient sample, so we believe that there is insufficient evidence to consider it valid and reliable.

For all these reasons and according to our review, diaries of parents are not recommended to assess or diagnose colic. Furthermore, given the biases and limitations of this tool, we do not consider appropriate to use CPQ (Wolke *et al.* 1994), because this tool is similar to daily crying but easier to be filled out by families.

In this review, we have identified and described the most known scale in the field of infant colic called Infant Colic Scale (Cirgin Ellett *et al.* 2003). This scale seems limited for a complete assessment of colic, but it is used for diagnosis trying to establish the possible aetiologic hypothesis that causes colic. This scale consists of five subscales concerning aetiological hypotheses of infant colic but has limitations and biases closely related to the validation process: no inclusion criteria for the study participants were established; there were children between 5 and 8 months old (age where colic is not contextualized); the children were diagnosed with colic by their own parents after reading the definition of colic provided by the researchers and, finally, statistical bias.

Other tools assess the effectiveness of breastfeeding and, indirectly, could appreciate certain initial clinical aspects of colic; however, they are not used for this purpose. Some of these tools are *Infant Breastfeeding Assessment Tool* by Matthews (1988), *Systematic Assessment of the Infant Breast* by Shrago and Bocar (1990), *Mother–baby Assessment* by Mulford (1992), *A New Breastfeeding Assessment Tool* by Jensen *et al.* (1994), *Breastfeeding Observation Form* (Armstrong 1992) and *Neonatal Oral-Motor Assessment Scale* by Da Costa and van der Schans (2008) and Howe *et al.* (2007).

Conclusion

The analysis of existing tools entails the need to design and validate new assessment scales for this clinical picture, given its importance in early childhood.

Key messages

- Infant colic occurs between 10% and 40% of healthy born children in their first year of life.
- Presents a varied clinic with excessive, inconsolable and intense crying, discomfort and pain, bloating, altered pattern of excreta, extensor pattern, redness of the face, altered sleep pattern and regurgitation
- The assessment of colic is complex, and only few instruments of valuation and diagnosis are used for this purpose.
- Existing tools are, preferably, focus on the variables 'crying and irritability'.
- The analysis of existing tools entails the need to design and validate new assessment scales for this clinical picture, given its importance in early childhood.

Conflict of interests

The authors have no financial relationships relevant to this article to disclose.

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References

AEP Asociación Española de Pediatría. (2008) Manual de lactancia materna. De la teoría a la práctica.

Aguayo Maldonado, J. (2004) La lactancia materna (ed.). Sevilla: Universidad de Sevilla.

Aguilar Cordero, M.J. (2005) Lactancia materna (ed.). Madrid [etc.]: Elsevier.

Armstrong, H. C. (1992) *Training Guide in Lactation Management.* IBFAN y UNICEF, New York.

Barr, R. G., Kramer, M. S., Boisjoly, C., McVey-White, L. & Pless, I. B. (1988) Parental diary of infant cry and fuss behaviour. *Archives of Disease in Childhood*, **63**, 380–387.

Barr, R.G., Kramer, M.S., Leduc, D.G. (1982) Validation of a parental diary of infant cry/fuss behaviour by a 24-hour voice-activated infant recording (VAR) system. *Program Ambulatory Pediatric Association.* p. 69.

Cetinkaya, B. & Başbakkal, Z. (2007) A validity and reliability study investigating the Turkish version of the Infant Colic Scale. *Gastroenterology Nursing*, **30**, 84–90 .discussion 90

Cirgin Ellett, M. L. & Swenson, M. (2005) Living with a colicky infant. *Gastroenterology Nursing*, **28**, 19–25 .quiz 26–7

Cirgin Ellett, M. L., Murphy, D., Stroud, L., Shelton, R. A., Sullivan, A., Ellett, S. G., & Ellet, L. D. (2003) Development and psychometric testing of the infant colic scale. *Gastroenterology Nursing*, **26**, 96–103.

Da Costa, S. P. & van der Schans, C. P. (2008) The reliability of the Neonatal Oral-Motor Assessment Scale. *Acta Paediatrica*, **97**, 21–26.

Howe, T.-H., Sheu, C.-F., Hsieh, Y.-W. & Hsieh, C.-L. (2007) Psychometric characteristics of the Neonatal Oral-Motor Assessment Scale in healthy preterm infants. *Developmental Medicine and Child Neurology*, **49**, 915–919.

Jensen, D., Wallace, S. & Kelsay, P. (1994) A new breastfeeding assessment tool. *Journal of Human Lactation*, **10**, 9–10.

Kirjavainen, J., Lehtonen, L., Kirjavainen, T. & Kerom, P. (2004) Sleep of excessively crying infants: a 24-hour ambulatory sleep polygraphy study. *Pediatrics*, **114**, 592–600.

Lucassen, P. L., Assendelft, W. J., van Eijk, J. T., Gubbels, J. W., Douwes, A. C. & van Geldrop, W. J. (2001) Systematic review of the occurrence of infantile colic in the community. *Archives of Disease in Childhood*, **84**, 398–403.

Matthews, M. K. (1988) Developing an instrument to assess infant breastfeeding behaviour in the early neonatal period. *Midwifery*, **4**, 154–156.

Mulford, C. (1992) The Mother–Baby Assessment (MBA): an "Apgar score" for breastfeeding. *Journal of Human Lactation*, **8**, 79–82.

Savino, F. (2007) Focus on infantile colic. *Acta Paediatrica*, **96**, 1259–1264.

Shrago, L. & Bocar, D. (1990) The infant's contribution to breastfeeding. *Journal of Obstetric, Gynecologic, and Neonatal Nursing*, **19**, 209–215.

Valderas, J. M., Ferrer, M., Mendívil, J., Garin, O., Rajmil, L., Herdman, M. & Alonso, J. (2008) Scientific committee on "Patient-Reported Outcomes" of the IRYSS Network. Development of EMPRO: a tool for the standardized assessment of patient-reported outcome measures. *Value in Health*, **11**, 700–708.

Wolke, D., Meyer, R. & Gray, P. (1994) Validity of the crying pattern questionnaire in a sample of excessively crying babies. *Journal of Reproductive and Infant Psychology. Taylor & Francis Group*, **12**, 105–114.