

# Medicalizing normality? Management of irritability in babies

KL ARMSTRONG, N PREVITERA and RN McCALLUM

*The Riverton Centre, Clayfield, Queensland, Australia*

**Objective:** The aims of this project were to identify the sources and quality of the health advice provided to parents with irritable infants; to assess the efficacy of a residential programme in the diagnosis and management of irritable infants; and to assess the intermediate term outcome for such infants and their mothers.

**Methodology:** All mother–infant pairs admitted during a 3 month period to a residential setting with the primary concern of infant irritability were asked to participate in the study. Pre-admission and 3 month post-discharge health-care advice, investigations and treatment details were collected. Maternal mood at admission and 3 months post-discharge was measured using the Edinburgh Postnatal Depression Scale (EPDS). On admission, infant medication for proposed cause of excess irritability was ceased, with parental consent, if it was appropriate and following full medical assessment. Individual case plans were designed by the admitting child health nurse in consultation with the mother. These included education as to normal infant behaviour, settling techniques, and establishment of routine; family issues were also explored.

**Results:** Fifty-one consecutive mother–infant pairs consented to participate and formed the cohort, 48 (94%) were available for follow-up interview 3 months post-discharge. The average age on admission was 13 weeks (range 4–28 weeks), 32 (62.7%) were male, 34 (66.7%) were first born and 45 (88.2%) lived with both their parents. A multiplicity of health professionals had been involved in the pre-admission care, and 48 of the infants had been or were currently on medication for gastro-oesophageal reflux disease and or colic. At the end of admission, diagnoses made were predominantly behavioural (22) and feeding problems (20). Nine infants were felt to have an organic cause for their irritability. Maternal mood improved significantly on EPDS from the time of admission (45 (86.2%) of mothers with scores  $\geq 12$ , mean score 16.5) to post-admission follow up (9 (18.8%) with scores  $\geq 12$ , mean score 7.2).

**Conclusions:** There is evidence that a proportion of babies with ‘normal’ irritability are being incorrectly diagnosed as having an organic disorder exposing them inappropriately to medication, which may be harmful, and potentially creating lifelong problems for these infants and their families.

**Key words:** colic; gastro-oesophageal reflux; irritable babies.

Crying, fussiness and irritability are present in infants of all cultures, although the absolute amount of crying varies significantly between cultures.<sup>1–4</sup> Crying behaviour follows a characteristic pattern peaking in quantity at around 6 to 8 weeks.<sup>1,5</sup> Like all aspects of infant behaviour, there is wide variability in the total amount and quality of crying between individual infants and with individual infants on a day to day basis.<sup>5</sup> By 2 months, the average amount of fussiness in normal Western infants is estimated to be between 2 and 2.5 h per day.<sup>6–8</sup>

When infants cry it is one of the most distressing sounds known, inherently so to ensure prompt intervention to their needs by their caregivers.<sup>9</sup> Indeed, the quality of a mother’s responsiveness to her infant’s signals is a key to their developing relationship and the child’s social and cognitive development.<sup>10–13</sup>

Whether an infant’s crying behaviour is perceived as needing professional intervention is a function of a multiplicity of factors including the caregiver’s emotional state, motivational

state, past learning experiences and cognitive state,<sup>14</sup> characteristics of the crying and crying behaviour,<sup>15</sup> and the ‘goodness of fit’ between the infant and their caregiver.<sup>16,17</sup>

In Western countries, between 23 and 40% of all babies are considered to have excessive irritability by their primary caregivers.<sup>18</sup> Many of these have been diagnosed as having a medical problem and are given various medications.<sup>19</sup> Medication usage seems to be based more on an aetiological theory of ‘excess irritability’ than on any plausible science.<sup>18</sup>

This study utilized a population of mother–infant pairs referred to a residential setting to assess the presence of inappropriate diagnoses and/or medication use in infants considered to have ‘excessive irritability’, and to evaluate the efficacy of a short-term residential intervention with these families.

## METHODS

During a 3-month period, commencing on the 1 July 1996, all mother–infant pairs admitted to The Riverton Centre, with the primary reason for admission being excessive infant irritability, were asked to participate in the study. All 51 mothers agreed to participate.

The Riverton Centre, part of the Riverton Statewide Program, is a 40 bed (20 parent, 20 child) residential service, which accepts referrals from throughout Queensland and northern

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Correspondence: KL Armstrong, PO Box 1507, Fortitude Valley, Queensland 4006, Australia. Fax: (07) 3252 7895; email: k.armstrong@mailbox.uq.edu.au

KL Armstrong, BSc, Mcom, MBBS, FRACP, Paediatrician. N Previtera, MBBS, FRACP, Paediatric Registrar. RN McCallum, RN, RM, CHN, Clinical Nurse Consultant.

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New South Wales. Staffed by the disciplines of child health and psychiatric nursing, social work, paediatric medicine and psychiatry, the unit offers short-term focussed intervention to families experiencing significant difficulty with infant or toddler behaviour, infant failure to thrive, or infants or toddlers at risk of abuse or neglect. There is the clear expectation that admission follows from failed outpatient intervention in the district of origin.

Excessive irritability in infancy is one of the most common presenting complaints. Mother–infant pairs admitted with this diagnosis are assessed comprehensively by a child health nurse and a paediatric registrar at the time of admission and an individual case management plan is drawn up in consultation with the parent(s). This may involve social work, psychiatric, or paediatric consultant review. Infant medication being given at admission is ceased unless there is a proven indication for its efficacy (e.g. pH probe, endoscopy and histology) and standard cows' milk based formula is offered to the infants not breast-feeding, unless there is a proven need for modified formula.

The focus of the interventions is to modify the parent–infant interaction. Initially, the infant feeding regime is assessed and modified if it is found inadequate. A daily routine is then detailed which allows for positive mother–infant interaction, but avoids overstimulation and encourages positive sleep behaviour for the infant and the mother. Educational intervention focuses on normal infant behaviour, feeding, sleep and development and is offered individually and within groups. Non-pharmacological management of gastro-oesophageal reflux disease (GORD) (parental reassurance, thickening agents, positional therapy) and 'colic' are specifically addressed, as are age appropriate approaches to settling infants for sleep. The program continues over 4 days and 4 nights.

At admission and 3 months post-discharge, participating mothers provided information on health care advice and medication use, as well as completing the Edinburgh Postnatal Depression Scale (EPDS). The EPDS is a 10-item self-report scale developed to screen for postnatal depression in the community setting.<sup>20</sup> It has subsequently been further validated both overseas and in Australia.<sup>21</sup> At 3 months post-admission a researcher, blinded to inpatient outcome, phoned each of the mothers to collect follow-up information.

## RESULTS

All 51 mother–infant pairs admitted to The Riverton Centre during this period agreed to participate in this study. Forty-eight (95%) families were available at follow up 3 months after discharge.

The mean age of infants at admission was 13 weeks (range 4–28 weeks), 32 (63%) were male, 34 (67%) were the first child in the family, 11 (22%) were second born, and 45 (88%) infants were being raised in a two-parent family.

Prior to admission, parents had sought health advice from a wide range of health professionals and professional settings (see Table 1). The majority, 29 (57%) had sought advice from three or more different health professionals. One individual had consulted seven different health professionals prior to admission.

Pre-admission diagnoses made were predominantly GORD, 42 (82%), or infantile colic 38 (75%) with 32 (63%) having a dual diagnosis of both GORD and infantile colic. Twelve (24%) had either had lactose intolerance or protein intolerance diagnosed and were on special formulae at admission. One

infant was considered to have GORD, colic, lactose intolerance and cows' milk protein allergy.

Forty-eight (95%) infants had been administered medication prior to admission (Table 2). The majority of these infants, 30 (59%) were on two or more medications and one infant was on a total of seven different medications as well as an elemental formula. Only three of the infants were on no medication at the time of admission.

Despite the multiplicity of health advisers, diagnoses and medication use, only five infants had any investigations performed prior to admission. Two had endoscopies, one had stools tested for reducing substances, one had urine microscopy and culture, and one an electroencephalogram. The endoscopies were said to have been diagnostic of GORD, while the other tests were all negative.

Diagnoses at discharge are listed in Table 3. In the majority of infants, the discharge diagnosis reflected a management

**Table 1** Previous consultations

Health professional	No. mothers and infants (%)	
Child health nurse	46 (90.2)	Child health nurse only: 4
General practitioner	41 (80.4)	General practitioner only: 1
Paediatrician	27 (53.0)	Paediatrician only: 1
Local hospital	10 (19.6)	
Day stay	5 (9.8)	
Welfare worker	4 (7.8)	
Psychiatrist	2 (4.0)	
Gastroenterologist	1 (2.0)	
Midwife	1 (2.0)	
Obstetrician	1 (2.0)	
Naturopath/osteopath	1 (2.0)	

**Table 2** Medication taken prior to admission

Medication	No. patients (%)
Cisapride	31 (60.7)
Mylanta	30 (58.8)
Infacol	27 (52.9)
Ranitidine	23 (45.0)
Infants' friend	17 (33.3)
Gaviscon	11 (21.6)
Natural gripe water	11 (21.6)
Donnalix	5 (9.8)
Colic mixture	4 (7.8)
Omeprazole	3 (5.8)
Cimetidine	2 (3.9)
Drixine	1 (1.9)
Merbentyl	1 (1.9)

**Table 3** Diagnosis on discharge

Organic disease	9
Feeding problems	
Underfed/low lactation	8
Overfed	4
Fast feeder	2
Difficult feeder	6
Behavioural	
Over tired/overstimulated	7
Poor self settling to sleep	15

difficulty, related either to feeding or to mother–infant interactional patterns. Nine (18%) of the infants were thought to have a possible organic aetiology for their excess irritability as a result of either previous investigations (2), examination finding otitis media with perforated drum (1) or their unresponsiveness to behavioural modification (6). Three of this latter group of infants were thought to have a diurnal cry pattern indicative of GORD (worst crying 1–2 h post-feeds, significant night time irritability) and were commenced on antireflux medication during the later stages of their admission, with perceived good clinical responses.

At the 3-month post-discharge follow up, 12 of the 48 infants had a diagnosis of GORD. This included the two diagnosed by endoscopy prior to admission, the three commenced on medication during admission, five who were assessed subsequent to admission by endoscopy and found to have GORD, and two who had been commenced on anti-reflux therapy with perceived improvement post-admission.

Of these infants, four were being managed by a gastroenterologist, five by a paediatrician, and three had no nominated private health-care provider.

The six infants thought to have organic pathology on the basis of their poor response to behavioural management were included in this group. The remaining 36 infants were thriving without any organic pathology or medication use.

Maternal mood, as assessed by the EPDS, improved significantly from time of admission to the three months post-discharge follow up. On admission, 45 (88%) of the mothers had scores  $\geq 12$ , the postnatal depression screen cut-off point ( $x = 7.2$ , range 6–30), while at 3 months post-discharge nine (19%) had scores  $\geq 12$  ( $x = 7.2$ , range 0–27) ( $P < 0001$ ). There was one significant outlier in the follow-up group with a score of 27. This mother was admitted to the Riverton Centre from an in-patient psychiatric unit, was on antidepressants and continued to have significant psychiatric input. The three mothers lost to follow up had EPDS scores of 16, 20, and 27 at admission and the mother with a score of 27 had psychiatric input during admission.

At the time of follow up, 35 (73%) mothers felt their infants irritability had significantly improved and that they felt more confident in the management of their child. Eleven (23%) mothers felt there was no change in their infant's behaviour, and two (4%) felt that their infant's behaviour had deteriorated. Review of these latter infants' behaviour charts revealed a significant decrease in quantity and number of periods of crying or fussiness and an increase in duration of sleep periods between admission and discharge. When asked to describe their experiences at The Riverton Centre as positive or negative, 38 (79%) of mothers felt it was positive and 10 (21%) described it as negative.

## DISCUSSION

Parental perception of and management of 'excessive' irritability in infancy can have a major impact on family life. Frequently associated with sleep disturbance, it is no surprise that there is clear association with maternal depression and marital breakdown.<sup>19,22</sup> The consequences for the infant may be even more severe and long lasting as the perceptions of excess irritability interfere profoundly with the development of a secure attachment relationship.<sup>23</sup> It is perhaps not surprising that the 'natural' peak of infant crying behaviour coincides

with a peak age for severe infant injury or death as a result of child abuse.<sup>24,25</sup> When parents present to a health professional with the expressed problem of an excessively irritable infant, it offers the opportunity to effect a profound and lasting impact on the infant's life course.<sup>26</sup>

Whether a parent perceives excessive irritability in their infant and then presents for professional advice is a function of a multiplicity of factors. Parental experiences with children, parental mood and psychological status, and parental cognitive state clearly influence the perception of their infant.<sup>14</sup> Excess irritability and sleep disturbance can cause maternal mood disorder leading to insecure infant attachment.<sup>22,27,28</sup> The quality of the parental relationship also has a clear influence on perceptions of the infants and indeed on the infant's behaviour. Where there is significant conflict between parents, the quality of infant care is impeded and the infant more likely to be more demanding.<sup>29</sup>

The infant also brings its own features to this complex process. Infant temperament clearly has a major role. As well, the acoustic characteristics of the infants cry, the duration of episodes and the frequency of crying episodes all influence the perception of excessive irritability.<sup>15</sup> As such, the assessment of a family presenting with excessive irritability requires a thorough review of each of these factors, family, parent and infant.

Of the estimated 23–40% of infants in developed countries perceived to have excessive irritability,<sup>18</sup> a small number will have some organic pathology. Clearly, this group needs to be identified and managed appropriately. Of the possible aetiologies, gastro-oesophageal reflux disease, cows' milk or other protein allergy, urinary tract infection, middle ear disease, neurological disorder and possibly lactose intolerance all need consideration.

How well are health professionals handling the excessively irritable infant? The results of this study suggest that the answer is 'pretty poorly'. The cohort of mother–infant pairs presenting for admission to this residential setting are not representative of the entire population, representing as they do the more problematic group where outpatient management has not succeeded. However, the pre-admission diagnoses made, in the main without any investigation, and the rate of medication use, suggest many excessively irritable infants in Queensland and northern New South Wales are having medical conditions diagnosed which then lead to either feeding change and/or medication. The number of infants with multiple concurrent diagnoses and the multiplicity of medications used are also alarming.

Gastro-oesophageal reflux disease was the most frequently made pre-admission diagnosis. The actual incidence of GORD in infancy is unclear but may be as high as 5–8%.<sup>30</sup> The vast number of those with GORD settle with growth and development of the infant or conservative management techniques (elevation, positioning, feeding techniques), and only a very small percentage of infants require medication or surgery. GORD is a rare cause of pure irritability in normal infants.<sup>31</sup> Indeed in infants with mild to moderate proven GORD, antireflux medication is no more effective than placebo or infant mental health intervention.<sup>32</sup> The current recommendation for the management of GORD is a cascade commencing with parental reassurance and milk thickening agents, through prokinetics and positional therapy, to use of H<sub>2</sub>-antagonists, proton pump inhibitors and surgery.<sup>33</sup>

In this study of those diagnosed preadmission with GORD,

there were no infants with failure to thrive, respiratory distress, or haemoptysis, and only two infants had investigations which suggested the presence of GORD. The diagnosis must have been made on clinical grounds. The presence of clinical symptoms thought to correlate with GORD including back arching, regurgitation, positing, and excessive irritability are neither sensitive nor specific for the diagnosis of GORD.<sup>31,32</sup> However, pattern of irritability, particularly as it relates to feeding times and sleep behaviour, have both biological plausibility and evidence to suggest the possibility of GORD.<sup>33</sup>

The next most frequent diagnosis was 'colic'. This undefined entity has no relationship to either oesophageal pain or choleric spasm,<sup>31</sup> and should be renamed as 'variant of normal infant behaviour' (VONIB). Diagnosis of lactose intolerance or protein allergy were inferred by the formulae which the infants were using at admission, diagnoses which had been made without investigation and in the absence of symptomatology (frequent frothy stools, rashes, diarrhoea). Feeding behaviours such as under or over feeding can clearly lead to increased infant irritability.<sup>35</sup>

We must conclude that the bulk of these infants had been misdiagnosed. A multiplicity of medications and feeding changes had been used prior to the infant's admission based on their 'diagnosis'. There is little if any evidence to suggest that the use of anticolitic medications is efficacious.<sup>36</sup> There is some biological or other evidence that components within these medications may be harmful (aluminium, magnesium, dicyclamine, alcohol). It should be noted that 'natural gripe water' contains 4.5% V/V ethanol. Although H<sub>2</sub> antagonists and omeprazole have proven efficacy in the management of severe GORD in infancy and childhood, there continue to be concerns regarding the effect of prolonged acid suppression in infancy. The role of cisapride in GORD remains controversial, and significant risks have been associated with the use of this drug in childhood.<sup>37</sup> The natural history of infant crying also predisposes to a very high placebo response.<sup>32</sup>

Although the misdiagnosis of infants and utilization of inappropriate medications and or formulae is of concern, a bigger concern is the long-term impact. By providing a diagnosis for the infant, we are creating a 'special' child, a situation predisposing to long-term behaviour concerns.<sup>38-40</sup> By missing the opportunity to intervene in the family dynamics of the irritable infant we miss the chance to promote secure parent-infant attachments.<sup>10-14,30</sup>

Management of the excessively irritable infant and family in a residential setting is clearly effective in arriving at an appropriate diagnosis in the majority of families admitted. It may be that the longer-term improvement in maternal mood owes something to this inpatient management but the lack of a control group in this study precludes this conclusion.

However, inpatient management with the resources of a multidisciplinary team is clearly inappropriate and economically indefensible for the entire population of excessively irritable infants. What is highlighted by this study is the need to involve others in the assessment and management of the irritable infant in order to understand the factors leading to presentation. This may involve greater use of day stay facilities for observation and assessment by experienced child health nurses, home visitors, social workers and psychiatry. The knee-jerk reaction to seek an organic infant-based diagnosis provides a great disservice to the group of families presenting for expert care.

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