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Original Article

Infantile Colic: A Survey of Physicians in Pakistan

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ABSTRACT

Purpose: Infantile colic diagnostic criteria were established by Rome IV. A universally accepted management remains to be established. We aimed to evaluate diagnostic criteria, management strategies, and perceived regional prevalence of infantile colic in Pakistan, as well as its effect on physicians and parents.
Methods: A questionnaire was distributed amongst 1,256 physicians.
Results: We received 800 replies. Wessel and Rome IV criteria were used by most physicians for diagnosis; however, the response "any infant who cries a lot" was selected by older physicians (48% of those over 60 years), physicians in rural areas (32%), physicians practicing in private clinics (27%), and general physicians (30%). Estimated prevalence of infantile colic ranges from 21–40%. Reassurance was the most widely recommended management strategy followed by herbal teas (51%), switching to a different formula (49%), probiotics (28%) and antibiotics (26%), discontinuation of breastfeeding (14%), elimination of dairy products from the breastfeeding mothers' diet (6%), and the administration of colic drops (1%). Most physicians considered the negative impact of colic on their personal lives and the parents as mild-to-moderate. Notably, 38% of percent of physicians routinely screened for maternal depression, and 45% of physicians were aware of the association between infantile colic and shaken baby syndrome.
Conclusion: Most physicians in Pakistan diagnose and manage infantile colic according to the established guidelines. However, the guidelines pertaining to treatment planning are not followed. Educational efforts directed toward general physicians and doctors practicing in rural areas and clinics must be implemented to avoid unnecessary testing and treatment burden.

Keywords: Functional gastrointestinal disorders; Excessive crying

INTRODUCTION

Infantile colic (IC) and gastroesophageal reflux are the most common functional gastrointestinal disorders (FGID) that occur during the first year of life. IC is defined as "unexplained and inconsolable crying episodes lasting for more than 3 hours per day, for 3 or more days per week, and for 3 or more weeks in an otherwise healthy baby" according to the Wesel criteria [1]. The Rome IV criteria define IC as "a parental report during a telephone or

Conflict of Interest
The authors have no financial conflicts of interest.

face-to-face consult with a researcher or clinician, that their infant had cried or fussed for 3 or more hours per day, during 3 or more days in the preceding week" [2]. Crying episodes are characterized by the presence of facial expressions suggestive of pain, flushing, and flexion of the legs, abdominal distension, and flatulence. The Rome IV criteria specify the diagnostic parameters for defining IC; however, a standard approach for the management of IC that is universally accepted remains to be established. IC can be diagnosed based on the findings of physical examination and history-taking. However, this approach may not be suitable for all cases. IC is a transient, non-serious issue; however, many physicians use less strict diagnostic criteria and intervene, contrary to the recommendations [2].

Physicians may recommend various therapeutic approaches, in addition to parental assurance. Interventions, such as the consumption of a dairy-free diet by lactating women; the administration of partially or extensively hydrolyzed protein formula, low-lactose or lactose-free formula, and probiotics; switching the infant formula; interruption of breastfeeding; massage; the administration of simethicone; manipulative therapy; acupuncture; teas, and the consumption of herbal or other natural products, have been recommended. Some of these interventions are listed in the guidelines, whereas others are not. Evidence supporting the effectiveness of these interventions remains lacking; moreover, some of these interventions have dangerous side effects. However, reassurance alone may not be suitable management strategy for anxious parents who may seek a second opinion from other physicians, family members, or online advice.

No previous study has evaluated the prevalence and management of IC in Pakistan. Therefore, this study aimed to determine (a) the estimated prevalence of IC; (b) the diagnostic criteria, diagnostic tools, and management strategies for IC; (c) the effect of IC on the physicians' and parents' lives; and (d) awareness regarding the associations of IC with maternal depression and shaken baby syndrome among physicians.

MATERIALS AND METHODS

Survey design

A questionnaire comprising 27 items was developed based on existing data and common practices followed by Pakistani physicians [3,4]. The first 10 items pertained to the demographic characteristics, such as the respondents' age, place of practice (urban or suburban practice), type of practice (hospital, government/military, university, and clinic), number of weekly clinics, and patient characteristics, such as the estimated percentage of patients under 17 years and under 5 months of age visiting their practice, prevalence of infants who were exclusively breastfed until 6 months of age, and FGID in infants aged ≤5 months. The remaining items pertained to the perceived prevalence of IC, characteristics of the affected infants, parental behaviors, diagnostic and management approaches used in their practice, and the perceived effect of IC on their practice and parents.

The last two items were similar to the last two of the first ten items; however, these items were phrased differently. These items were used to determine the reliability of the responses. Question 7 was, "What is the average number of pediatric outpatients you see in a day?" In contrast, question 27 was "What is the average number of children below the age of 17 years that you see in a normal work week?" Question 10 was "What is the percentage of infants aged 0–5 months with functional gastrointestinal complaints in your practice?" In contrast,

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question 26 was "If you had to estimate the percentage of your patients under 5 months of age suffering from colic, which of the following answers would you chose?" We arbitrarily determined that whether the answers to the these pairs of questions differed from each other by ≥20%; the survey was discarded in such cases. In addition, any respondents who stated that they had <7 half-day clinic sessions per week were excluded, as this was not representative of the workload of most general physicians (GP) and pediatricians (P) in Pakistan.

IC we gave three options were provided for the definition of IC: (a) Rome IV criteria, (b) Wessel criteria, and (c) a less strict definition: "Whenever the parents tell me that the baby cries a lot or that they are at their wits end."

This questionnaire was validated by several authors. The survey link was distributed amongst 1,256 GP and pediatricians listed in the Medical Association of Pakistan via email and WhatsApp. Two reminders were sent several weeks later. The physicians completed the survey anonymously.

The survey was approved by the Ethics Committee of Baqai Medical University on July 8th, 2021 (BMU-EC04-2021).

Statistical analysis

Convenience sampling was used to collect data. The blinded data were entered into a Google Drive database by two different researchers and analyzed using STATA MP11 statistical software (StataCorp). The results are presented as percentages with 95% confidence intervals (CIs), and significant differences were calculated for certain questions. Each variable (place of practice, sex of the respondent, and specialty) was considered a categorical variable to determine the differences between the responses (another categorical variable). The chi-square test was used to examine significant differences, associations, linkages, impacts, and effects of the base variables with other categorical variables in the same population. Statistical significance was set at $p<0.05$.

RESULTS

Among the 1,256 physicians who received the survey link, 800 participated in the study (63.7%). Thirty-four of the completed questionnaires exhibited a difference of ≥20% in terms of reliability; therefore, these questionnaires were excluded from the final analysis. Thus, 766 questionnaires were analyzed in this study. None of the doctors worked less than seven half-days per week.

Characteristics of the respondents and patient population

Approximately 78% of the respondents practiced in an urban setting (population of ≥100,000). Physicians and general practitioners accounted for 67% and 32% of the study population, respectively. The remaining respondents were pediatric gastroenterologists. The age distribution of the respondents was as follows: <40 years of age, 64%; 41–50 years, 21%; 51–60 years, 9%; and >60 years, 4%. Notably, 59% of the respondents were males. Most female respondents were aged <41 years of age (83%), and the proportion of women in the 41–50, 51–60, and >60 age groups was 13%, 3%, and 1%, respectively. The distribution of the respondents in terms the type of practice was as follows: government facilities, 52%; private practice, 34.9%; and universities and clinics, 13.1%.

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The prevalence of FGID was estimated to range from 21% and 40% by most physicians, which is consistent with that of IC (**Supplementary Table 1**).

Definition and prevalence IC

The diagnostic criteria used most commonly for diagnosing IC varied significantly across the groups (**Table 1**). The less strict option "Whenever the parents told me that the baby cries a lot…," was selected by 24% and 17% of the male and female respondents, respectively. The prevalence of this response exhibited a increasing trend: <40 years, 16%; 41–50 years, 27%; 51–60 years, 32%; >60 years, 48%. A significant difference between the estimated prevalence of IC reported by GP and pediatricians (**Fig. 1**). The estimated prevalence of IC among the patient population reported by urban (33%) and rural (35%) physicians was equal (21–40%). However, the proportion of physicians practicing in urban areas (26%) who estimated the prevalence of IC as 12–40% was significantly greater higher than that of the physicians practicing in rural areas (15%) (p=0.043).

Most respondents (66%), comprising male and female physicians, reported that the prevalence of IC was equal in both sexes, regardless of their age group. However, 6% could

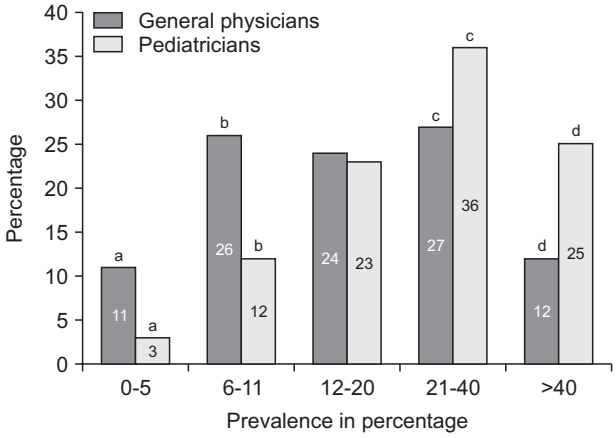

Fig. 1. Estimated prevalence of infant colic reported by general practitioners compared with that reported by pediatricians. The values with the same letters exhibited statistically significant differences (p<0.001).

Table 1. Diagnostic criteria for infant colic according to the place of practice, specialty, and age of the responders

	Wessel	Rome IV	Excessive crying
Area of practice			
Urban	36	46	18[a]
Rural	28	40	32[a]
Specialty			
General physician	36	33[b]	31[c]
Pediatrician	32	51[b]	17[c]
Place of practice			
Government	34	48	18
Private	36	44	20
University	42	43	15
Clinic	27	46	27
Age of the physician (yr)			
<40	37.6	45.8[d]	16.6[g]
41–50	28.1	46.2[e]	25.7[h]
60	26.4	41.2[f]	32.4[i]
>60	31	20.7[d,e,f]	48.3[g,h,i]

Values are presented as percentage of physicians who responded.
Numbers with the same letters exhibited statistically significant differences (p<0.001).

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not make an estimation. Approximately 30% of the respondents reported that the prevalence of IC was higher among formula fed infants, whereas 24% estimated that the prevalence was similar in infants who were formula-fed and those who were exclusively breastfed. Notably, ≤5% of the respondents reported that IC more prevalent among exclusively breastfed infants.

Diagnostic and management approaches

The majority of physicians in all facilities diagnosed IC based in the finding clinical examinations only (93%). However, some physicians requested laboratory testing (**Table 2**, **Fig. 2**).

Reassurance was the most widely implemented measure (**Table 2**), various measures, such as such as colic drops (70%), herbal teas (51%), formula changes (49%), probiotics (28%), antibiotics (26%), discontinuation of breastfeeding (14%), and elimination of dairy products from the breastfeeding mothers' diet (6%), have been recommended for the management of IC. Among the infants who were not breastfed, 51% switched to a formula containing probiotics, 27% switched to formula containing a partially hydrolyzed or a lactose-free formula, 11% switched to an antiregurgitation formula, 9% switched to an extensively hydrolyzed formula, and 1% switched to goat milk. Notably, 21% did not change formula, mainly in clinics; infants who were treated at private offices recommended switching to partially or extensively hydrolyzed protein formula more frequently. When responders were asked about if they felt less comfortable with patients diagnosed with IC, 54% replied that they felt the same as for any other diagnosis, 26% were somewhat bothered, 14% were bothered considerably, and 6% answered that if they could avoid such patients, they would.

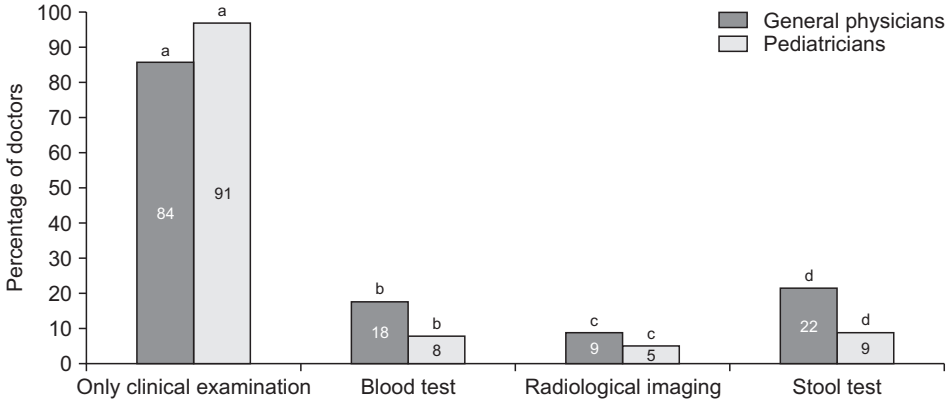

Fig. 2. Diagnostic tools for the diagnosis of infant colic (general practitioners vs. pediatricians). The values with the same letters exhibited statistically significant differences (p<0.001).

Table 2. Diagnostic tools for infant colic according to place of practice, specialty, and age of the responders

	Mainly clinical examination	Blood tests	Radiology	Stool test
Area of practice				
Urban	93	10	6	13
Rural	95	18	6	12
Place of work				
Government	96	7[e]	6[i]	9
Private	94	12[f]	6[j]	18[g]
University	88	21[e,f,g,h]	13[i,j,k]	25
Clinic	97	13[h]	4[k]	6

Values are presented as percentage of physicians who responded.
The values with the same letters exhibited statistically significant differences (p<0.001).

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Before seeking professional advice from the respondents, 51% of parents had used herbal teas, 49% had switched changed formulas, 40% had consulted different physicians, 31% had applied a warm cloth to the abdomen and massaged it, 28% had administered probiotics, 26% had administered antibiotics, and 14% had discontinued breastfeeding. Notably, and only 11% of parents had taken no measures. A significantly higher proportion of parents who visited a GP had not taken any measures to cure IC (18%) before seeking advice. In contrast, those who visited a pediatricians took some measures (92%), such as the administration of herbal teas (52%) and consulting different physicians (42%) (p=0.009).

Among the therapeutic interventions recommended for non-breast-fed infants, 51% of physicians recommended administering a formula containing probiotics, 27% recommended administering a "comfort" formula containing partially hydrolyzed protein and/or low lactose/lactose-free formula, 11% recommended administering a formula containing anti-reflux, 9% recommended administering a formula containing an extensively hydrolyzed protein formula, and 1% recommended administering goat's milk. Notably, 21% of physicians did not recommend switching to a different formula. For non-breastfed infants, 36% and 22% of GP and pediatricians, respectively, recommended administering lactose-free formulas; 3% and 1% of GP and pediatricians, respectively, recommended administering goat milk; and 12% and 27% of GP and pediatricians, respectively, recommended no formula change (p<0.001).

The influence of parental pressure on the diagnostic/therapeutic decision was reported as follows: sometimes, 34%; rarely, 27%; never, 22%; frequently, 15%; and always, 2%.

Impact on family and doctors

Fifty-seven percent of doctors estimated that The burden of IC on parents was reported as moderate, very high, minimal to none, and did not consider by 57%, 26%, 10%, and 7%, respectively. The confidence of the physicians regarding the accuracy of the patients' diagnosis of IC, same as for any other diagnosis, somewhat bothered, and considerably bothered, in 54%, 26%, and 14% of cases, respectively. Notably, 6% of physicians responded that they would avoid such patients.

Thirty-eight percent of doctors frequently assessed for The association between maternal depression and IC was assessed frequently, rarely, always, and never by 38%, 31%, 14%, and 8% of physicians, respectively.

Lastly, when asked whether they were aware that IC could be a risk factor for "shaken baby syndrome," 45% of physicians had never treated a case wherein that IC was a risk factor for "shaken baby syndrome," 36% were not aware of the association, 17% were aware of the association but had only treated a few cases, and 2% had treated several cases. The proportion of GPs (48%) were unaware of this association was significantly higher; in contrast, the majority of pediatricians (70%) were aware of the association (p<0.001).

DISCUSSION

This is the first study to survey physicians in Pakistan to evaluate IC. The response rate was 61%. This compares very favorably with those of other surveys, such as the previous survey on the management of acute gastroenteritis involving European physicians, which had a response rate of 34.5% [5]. Two previous studies have addressed this question. Indrio

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et al. [3] surveyed physicians from the Kingdom of Saudi Arabia, Kuwait, Morocco, Lebanon, and Iraq. The response rate was approximately 75% among pediatricians and 25% among general practitioners, a distribution similar to observed in the present study. Although the authors did not clarify the method of distributing the surveys, 1,628 responses were obtained. Hizili et al. [6] conducted another study in Turkey targeting only pediatricians. Their study received 375 responses. Indrio et al. [3] reported that 92% of respondents diagnosed colic predominantly via clinical examination. Furthermore, most respondents (73%) preferred to reassure parents rather than prescribing therapeutic agents. Hizli et al. [6] reported that the majority of pediatricians used their clinical experience alone to diagnose IC and preferred prescribing probiotic supplements and simethicone as the only medical treatment for IC. They also reported that these pediatricians observed clinical benefits from following the administration of these supplements. The findings of the present study indicate that most physicians in Pakistan diagnose and manage IC according to the recommendations; however, treatment guidelines are not followed in all cases.

Although most surveyed doctors utilized the Wessel and Rome IV criteria to define IC, some used a far less strict definition. The less strict definition was selected more frequently by older doctors, suggesting that these physicians do not keep up with the current literature and guidelines or that experience has told them that it is more practical to consider the diagnostic criteria stringently. In addition, a tendency to use this less strict definition was observed more frequently in certain types of medical institutions and rural areas, which may indicate that parental pressure or other factors may influence the treatment of crying infants.

A systematic review reported that the prevalence rates of IC ranges from 2–73%, with a median rate of 17.7% [7]. The prevalence of IC varied widely in the present study, unlike other estimates. The prevalence of IC is generally considered to be 20%. A similar prevalence rate (21.7%) was reported by Fazil in the district of Mansehra, Pakistan [8]. The upper end of the percentage of infants with IC estimated by doctors in the present survey (40%) was close to that reported in the MENA region (Middle East and North Africa) [3].

Approximately 30% of the respondents considered that IC was more prevalent among formula-fed infants in the present study. This finding is similar to those reported in the MENA region (37%) [3] and by Steutel et al. [9] in Europe.

The findings of the present study indicate that younger doctors (mainly <40 years of age), those between 41 and 50 years of age, those practicing in urban areas, and those practicing in public facilities are more likely to follow the Rome IV criteria for the diagnosis and treatment of IC than older physicians, those practicing in rural areas, and those in private practice. This finding contradicts the assumption that the management of IC is mostly driven by experience rather than evidence [2].

IC is considered a self-limiting problem if it is not associated with signs or other symptoms that could indicate a health compromise. It can be easily treated via reassuring the parents and patiently listening to them. However, this is not always true. As observed in the present and other studies, a multitude of unproven approaches were often recommended in the present study, mostly by rural doctors and those practicing in private clinics, even when physicians were aware of the published management options. A Pakistani website titled ‘How to Cope with Colic’ [10] lists a series of recommendations for the management of IC; however, not all of these recommendations adhere to the guidelines. For example, in the

case of breastfed infants with IC, it is recommended that the mother pay attention to her diet as the infant can be affected when she consumes a particular type of food. Similarly, it was recommended to perform a gentle tummy massage with castor or mustard oil as it can decrease the intensity of gas in the infant's stomach.

Various management options have been proposed for IC, and some of these options have been evaluated by previous randomized controlled trials (RCTs). However, most of these studies were associated with methodological limitations [3] and may not reflect real-life scenarios. Furthermore, these studies did not consider the individual needs of the family, which made treatment a difficult task. Most of the surveyed physicians provided support and counseling as the main treatment for IC. Studies addressing the value of providing support/counseling to caregivers for the management of IC reported that this approach was beneficial [11]; however, supporting data are limited [12]. Notably, caregiver counseling was more effective than eliminating dairy and soy proteins from the diet in a previous RCT [13].

The administration of probiotics is one of the most frequently prescribed intervention in Pakistan. Although the present study did not evaluate the most frequently recommended probiotics, RCTs have indicated that treatment with *L. reuteri* DSM 17938 results in a decrease in crying time in breastfed babies [14]. A systematic review of five RCTs (271 infants) evaluating the effect of probiotics (various strains) on crying revealed inconsistent results depending on the probiotic species and feeding method [15,16]. Another systematic review and meta-analysis pooling results from eight RCTs concluded that the administration of *L. reuteri* DSM 17938 can be considered for IC [17]. Few physicians discontinued breastfeeding to resolve IC. A systematic review conducted in 2012 concluded that eliminating cow milk protein from the maternal diet is a common strategy for the management of IC [18].

Switching to formulas containing partially hydrolyzed lactose or low/no lactose formulas (comfort) was also recommended by the surveyed physicians. A Cochrane systematic review concluded that the reported benefits of administering hydrolyzed formulations were inconsistent [19].

IC affects infants and their parents. The parents who become exhausted and concerned as they try to comfort their child [20]. The findings of our survey revealed that most physicians did not feel particularly stressed by patients with IC. Although physicians agree that IC induces stress in parents, they do not consider it to be extreme. This finding is in contrast with the results of a survey wherein most pediatricians in Germany and Poland rated the parental burden caused by IC as high or very high [21]. Despite the impression of the physicians in Pakistan that parents are not very affected by IC, parents reported that they attempted consulting other physicians before consulting the respondents. Even when the physicians are not excessively stressed by treating infants with FGID and IC, they frequently order tests and prescribe medications beyond that recommended by the guidelines, probably owing to parental pressure. Mahon et al. [22] estimated that the total cost of treating FGID in infants in England was at least £72.3 million (118M USD) per year in 2014–2015, of which £49.1 million (80.5M USD) was the National Health Service expenditure on prescriptions, community care, and hospital treatment. Furthermore, parents incurred £23.2 million (38M USD) in costs through the purchase of over-the-counter remedies.

The physicians surveyed in the present study conform to what the observation by Vandenplas et al. [23]: "FGID are a frequent cause of parental concern, impairment in quality of life of

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infants and relatives, and impose a financial burden to families, health care, and insurance. Therefore, the primary management of FGID should focus on improving infants' symptoms and the quality of life of the family. If more than parental reassurance is needed, the available evidence recommends nutritional advice, as it is an effective strategy and devoid of adverse effects. The role of healthcare providers in reassuring parents and proposing correct behavior and nutritional intervention by avoiding the inappropriate use of medication is essential in the management of FGID".

Similar to other surveys, the present study relied on the responses of the physicians who returned the questionnaire and the reliability of their responses.

In conclusion, the present study indicated that most physicians in Pakistan, particularly younger pediatricians practicing in the public sector at urban sites, comply with the recommendations for the diagnosis and management of IC. Thus, emphasis should be placed on educating physicians, especially GP, rural doctors, and those practicing in private facilities, regarding the management of IC to avoid unnecessary tests and treatment costs.

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SUPPLEMENTARY MATERIAL

Supplementary Table 1
Infantile Colic Survey: Pakistan

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