Title: Functional Gastrointestinal disorders in infants: practice, knowledge and needs of Australian pharmacists.

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Key words: Pharmacists, colic, constipation, gastro-oesophageal reflux, infants

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Abstract

Aim: To determine the nature and extent of interactions between retail pharmacists and families of infants concerned about Functional Gastrointestinal Disorders (FGIDs).

Methods: A 15 question online survey was developed that could be completed by retail pharmacists in approximately 5 minutes. This survey aimed to obtain information relating to the frequency of interactions with parents of infants seeking advice and/or information about colic, gastro-oesophageal reflux (GOR) or constipation in pharmacies; what recommendations and/or advice was given by the pharmacists; from where the pharmacists obtained their information, and what guidelines/recommendations they would value, and demographic information.

Results: A total of 362 pharmacists from every State and Territory within Australia completed the survey. Conversations with parents/carers about constipation at least once a week were reported by 85% of pharmacists, with the equivalent percentages for GOR and colic both being 76%. In the case of constipation medication was recommended in 70% of cases and a nutritional approach recommended in 67% of cases. Medication was recommended in 81% of cases of suspected colic, significantly greater than nutritional advice at 50%. For possible GOR, recommendations were similar with medication being suggested in 66%, and nutritional advice in 68%. GOR guidelines were the most sought after with 42% of pharmacists placing such guidelines as their number one need.

Conclusions:

This survey indicates the need for greater emphasis being given to reassurance by health care professionals involved in management of FGIDs in infancy as well as consideration of the construction of easily accessible evidence-based national guidelines.

Brief Points: Authors are to provide up to 3 separate points for each Brief Point: 'What is already known on this topic' and 'What this paper adds'.

What is already known on this topic

- 1) FGIDs are commonly seen affecting up to 30% of infants.
- 2) Published treatment algorithms focus on nutritional advice and parental reassurance and support to a large extent.
- 3) Medication is often prescribed to such infants by a cross section of health care professionals.

What this paper adds

- 1) Parents and carers of infants with potential FGIDs interact with retail pharmacists on a very regular basis seeking advice and guidance.
- 2) Medication rather than nutritional advice is provided in many cases of possible FGIDs as has been reported in previous studies of other health care professionals.
- 3) Pharmacists reported that guidelines relating to the treatment of GOR were most sought after.

Introduction

It is well recognised that functional gastrointestinal disorders (FGIDs), namely regurgitation, colic and functional constipation are seen in up to 30% of all infants (1). Furthermore, this study concluded on a review of 30 publications, the likely prevalence of colic, regurgitation and functional constipation was about 20%, 30% and 15% respectively, although it should be noted that the prevalence varied between studies. Reflux and regurgitation are frequently used interchangeably in the literature (2) and from here on will be referred to as of gastro-oesophageal reflux (GOR). A 2017 study in the USA used the relatively recent Rome IV criteria (3) for FGIDs and found similar results in that 24.7% of infants and toddlers fulfilled these symptom-based criteria (4). Moreover, it has been recently reported that a significant number of infants have multiple FGIDs. In a recent survey of over two thousand infants in France some 63% of the infants had two FGIDs and a further 15% had three or more disorders (5).

There are considerable economic costs associated with FGIDs with a recent study from England showing that the total cost of treating FGIDs in 2014/15 was at least £72.3 million. This figure consisted of £49.1 million spent on National Health Service prescriptions, community care and hospital treatment as well as a further £23.2 million spent by parents and/or carers on over the counter products (6). In addition, the authors noted that these costs were likely to be a significant underestimate because of the conservative nature of their estimates.

Algorithms for health care professionals have been developed for the practical management of FGIDs. These algorithms focus on nutritional advice, parental support and parental

reassurance to a large extent (7,8) and a recent review confirmed the validity of this approach to dealing with FGIDs (9).

There have been a number of recent reports that suggest in many cases primary management of some FGIDs by health care professionals in Australia frequently does not use these algorithms. For example, Bell and colleagues (10) evaluated the diagnosis and management of gastro-oesophageal reflux (GOR) between 2006 and 2016 from about 1000 general practitioners each year in Australia. Counselling in cases of GOR occurred in 38.5% of GP visits, however, the prescribing of acid suppressants (proton pump inhibitors and H₂-receptor antagonist combined) occurred in 43.5% of visits. Moreover, the prescribing of proton pump inhibitors in cases of GOR increased significantly over the study period, from 12.2% of visits in 2006-08 to 28.3% in 2016-18 ($p=0.043$). These data are concerning as the literature shows that acid suppressants in infants perform no better than placebo (11) and recent studies reports that their use in infants may be associated with an increased risk of all allergic diseases and obesity in childhood (12,13).

Of importance, also, is the work of McGann and colleagues (14) that aimed to determine the barriers and enablers influencing the use of recommendations relating to infant colic by maternal and child nurses and emergency department doctors. They concluded that there was a lack of knowledge in diagnosing colic by the maternal and child health nurses. Also, emergency medical staff were reluctant to change treatments and potentially disrupt the family's relationship with their primary care practitioner.

Finally, a recent study investigated knowledge, practice and attitudes of Australian paediatricians in relation to FGIDs in children and adolescents. Specifically, 327 paediatricians provided comment on two clinical vignettes concerning functional abdominal pain and irritable bowel syndrome (15). These authors concluded that there was a lack of awareness of evidence-based therapies for these two FGID's in the population studied, and only 37% of respondents were aware of the international diagnostic criteria relating to FGIDs (16).

Clearly there are many different health care professionals that come into regular contact with infants and their families with FGIDs and treatment and care is not consistent between HCP's or, in many cases, with recommended treatment algorithms. Another group of HCP's that are frequently involved in FGIDs are retail pharmacists, with much of the reported cost of over the counter medicines being purchased through pharmacies (6). Nevertheless, we have been unable to locate data relating to the knowledge base, recommendations and/or practice of this important group of HCPs in Australia, which we consider is a significant gap in our knowledge. The aim of this study was therefore to evaluate the nature and extent of interactions between retail pharmacists and families of infants concerned about FGIDs.

Methods

A 15 question survey was developed which could be completed on line by retail pharmacists in around 5 minutes. The participants were asked to select their responses from options chosen by the researchers.

The survey aimed to provide information relating to:

- 1) The frequency of interactions with parents of infants seeking advice and/or information about colic, GOR or constipation in pharmacies
- 2) What recommendations and/or advice was given by the pharmacist and why
- 3) From where the pharmacists obtained their information
- 4) What further information around guidelines/recommendations they would value
- 5) Demographic information

The aim was to acquire a minimum of 300 responses from retail pharmacists across Australia. A sample size of 300 would ensure that in the maximum 95% Confidence Interval of any reported percentage would be +/- 5.7% (when reported percentage is 50%) which was deemed acceptable. An online marketing research company (Research Now SSI, Sydney, Australia) was utilised to contact and engage with retail pharmacists whose details were held on their database of specialist healthcare professionals. The research was conducted in line with the Australian Market and Social Research Code of Conduct.

The data were analysed using SPSS version 21.0 for Windows (SPSS Inc. Chicago, IL).

Results

The desired sample size was exceeded, with a total of 362 pharmacists responding to the survey with the distribution of responding pharmacists broadly in line with the distribution of the population. Some basic demographic data relating to the gender, location and state/territory of the pharmacists as well as their years of experience, are shown in Figure 1. The frequency of conversations with parents of infants experiencing symptoms of constipation, colic or reflux who have not seen a general practitioner are shown in Figure 2. These data show that 85% of pharmacists have conversations relating to constipation at least once a week, with the equivalent percentages for GOR and colic both being 76%. Results pertaining to the percentage responses to the question, "what do you typically recommend for infants with constipation, reflux and colic" are shown in Figure 3. In the case of constipation, if the detailed results shown in Figure 3 are condensed into broader

categories then the percentages of pharmacists recommending medication or nutrition as an approach to treatment were similar with medication being 70% (95% CI 65% - 67%) and nutrition being 67% (95% CI 62% - 72%). The percentage of pharmacists that recommended a GP visit for an infant with constipation was significantly less, at 43% (95% CI 38% - 48%).

Medication was recommended in 81% (95% CI 77% to 85%) of cases of suspected colic, significantly greater than both a nutritional solution 50% (95% CI 45% - 55%), and a recommendation to visit a GP, 44% (95%CI 39% - 49%), $p<0.001$.

Recommendations given to parents or carers of infants with possible GOR were similar in number across medication, 66% (95%CI 61% - 71%), a nutritional solution, 68% (95% CI 63% - 73%) and a solution involving physical movement (i.e. hold upright for 30 mins after feeding and/or raising the head of the infant's crib/bassinet) also 68% (95%CI 63% - 73%)

Figure 4 shows the most common sources of information on which the surveyed pharmacists base their recommendations. The most common explanation given at 84% was the pharmacist's own knowledge, experience and training.

Guidelines relating to reflux were the most sought after with 42% of pharmacists placing such guidelines as their number one need

Discussion

This study includes pharmacists from every State and Territory within Australia. Approximately 80% of the pharmacists recruited lived in New South Wales, Victoria or Queensland; these three states contain around 77% of the national population. The responding pharmacists had good variation in their experience with 79% having more than 5 years in clinical practice.

The survey has revealed a number of important findings in respect of the interaction of families of infants with possible functional gastrointestinal disorders and pharmacists. Firstly, such interactions are common with more than 20% of pharmacists having 2 to 3 conversations per week with parents about FGIDs (Figure 2). Secondly, despite the publication of treatment algorithms that focus on nutritional advice, parental support and parental reassurance (7,8) medication was a common recommendation in all three of the FGIDs considered here. Previous similar studies of Australian GPs' and paediatricians' management of infantile GOR have also shown the frequency with which parents consult health care providers as well as the common use of prescribed medicines (17,18). For constipation recommended medications included over the counter laxative powders, liquids or capsules. For colic, medications that were recommended included over the counter gripe

water and/ or “gas drops”. However clinical studies and reviews have largely considered these as placebos (19). Perhaps most concerning was the high rate of recommended medication for infants with possible GOR, which included acid suppressants, proton pump inhibitors and H2-receptor antagonist, with around a quarter of pharmacists surveyed stating that such medications were typically recommended despite their efficacy having been shown to be poor (11) and that they may be associated with the development of allergy and obesity (12,13). It is both interesting and noteworthy therefore, that reflux was the most sought-after condition for which guidelines were requested by the pharmacists surveyed.

This survey provides a useful snapshot of Australian pharmacists’ current management recommendations for FGID in infants. It further enhances our understanding of this group of disorders that are common in infancy and impact not only on the patients and their families but also cause significant health care expenditure. Furthermore, the survey would suggest the need for much greater emphasis being given to reassurance in the education of health care professionals involved in the management of FGIDs as well as the consideration of the construction of easily accessible evidence-based national guidelines, or care pathways such as those that exist for general practitioners for other common conditions. Further research could involve looking at the impact of these interventions on advice given by pharmacists for FGIDs.

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Gender

State or Territory

Location

Years of Experience

JPC_14536_Figure 1 Surveyed pharmacists demographic data.tif

JPC_14536_Figure 2 Frequency of pharmacist conversations with parents of infants with FGIDs.tif

Reason for Recommendations

JPC_14536_Figure 4 Source and or basis of the pharmacists recommendations.tif

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