

The perceptions and prescribing patterns of complementary medicines for infantile colic by pharmacists in Johannesburg, South Africa

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Background. Complementary medicines (CMs) for infantile colic are widely available on the South African market, in various pharmacies and retail outlets, without the need for a prescription. Pharmacists therefore have an important role to play in educating patients about safe and appropriate use of CM products.

Objectives. To investigate the perceptions and prescribing patterns of CMs for infantile colic by pharmacists and pharmacist assistants employed in the greater Johannesburg area.

Methods. We used a quantitative approach with a descriptive survey design. A total of 100 pharmacists and pharmacist assistants registered with the South African Pharmacy Council completed a pen-and-paper questionnaire.

Results. Many participants reported recommending both conventional and CMs for infantile colic and, overall, positive perceptions of CM were reported. Most participants agreed that they had a responsibility to counsel patients on the use of CM but felt that they needed to expand their own knowledge base.

Conclusions. There appears to be a positive shift towards CM for the treatment of infantile colic; however, improved training is needed to ensure pharmacists and pharmacist assistants are better informed regarding CM products in order to give appropriate advice to patients.

S Afr J Child Health 2024;18(2):e808. <https://doi.org/10.7196/SAJCH.2024.v18i2.808>

Infantile colic (IC) is a common functional gastrointestinal disorder estimated to affect 5 to 40% of infants worldwide. It is characterised by recurrent and prolonged periods of inconsolable crying, fussiness and irritability without an obvious cause, that cannot be resolved by parents or caregivers.^[1] Although colic is considered benign and usually self-resolving, it has a significant negative impact on the quality of life of the infant and their family. The pathophysiology of IC is poorly understood, and as such, there is currently no standardised and proven approach for the management of this condition.^[2] Current treatment options may include pharmacological agents such as simethicone, dicyclomine hydrochloride, cimetropium bromide and proton-pump inhibitors, while dietary interventions, probiotics, manual therapies, complementary medicines and parental behavioural strategies may also be utilised.^[3]

The term 'complementary medicine' (CM) refers to medicines prescribed in aromatherapy, Ayurveda, homeopathy, traditional Chinese medicine, Unani Tibb and Western herbal medicine. These medicines (category D medicines identified as 'complementary medicines') are widely available in the South African (SA) market and regulated by the SA Health Products Regulatory Authority (SAHPRA). The category of complementary medicines also includes modern supplement-type of medicines (such as health supplements, including probiotics).^[4]

CM products for IC remain popular among the general public, despite the limited research available on their effectiveness and safety.^[5,6] A recent survey study conducted in SA showed that parents and caregivers frequently made use of CMs for their infant's colic, with the most popular products being homeopathic remedies and herbal medicines. Most CMs are currently unscheduled, allowing for them to be purchased from pharmacies and other retail outlets without a prescription.^[7]

Pharmacists are in an ideal position to provide patients with evidence-based information to ensure appropriate and safe use of CMs; however, limited integration of CM into pharmacy education curricula has an impact on the level of knowledge many pharmacists have on the health effects of these products.^[8] The present study aimed to explore prescribing patterns and perceptions of CM for IC by pharmacists and pharmacist assistants in Johannesburg, SA, by means of a questionnaire.

Methods

Research sampling

The research sample consisted of pharmacists and pharmacist assistants who were registered with the SA Pharmacy Council and currently employed in a pharmacy in the Johannesburg area. Participants were recruited by means of purposive sampling. According to Moodley and Suleman,^[9] Gauteng Province had the greatest number of registered pharmacies in 2014, with 1 079 active registered pharmacies in the province, followed by KwaZulu-Natal Province with 499 and the Western Cape with 459.^[9] Gauteng is divided into three metropolitan municipalities, the City of Ekurhuleni, City of Johannesburg and City of Tshwane Metropolitan Municipalities. Johannesburg was selected for the study sample as it is the most populous district in SA.^[10] The sample size was calculated based on the estimated population size with a 95% confidence interval and a margin of error of 10%. While a margin of error of 5% would have improved the precision of the data, increasing the sample size may have had a negative impact on the response rate, thus a 10% margin of error was chosen for this exploratory study.^[11] The greater Johannesburg area was divided into 4 regions (North, East, South and West) and the number of survey questionnaires was divided between these areas. All of the pharmacies were randomly selected

by using an internet search engine to locate them. For this pilot study, a minimum of 89 completed questionnaires were required for analysis (Survey Monkey sample size calculator (<https://www.surveymonkey.com/mp/sample-size-calculator/>))

Questionnaire development and data collection

We used a quantitative exploratory approach with a prospective, descriptive survey design. Pharmacies in Johannesburg were randomly selected using an internet search of the area. An information letter detailing the study was emailed to the responsible pharmacist at each pharmacy, and permission was obtained to conduct the study at these premises. Once eligible participants gave informed consent, they completed a hard copy of the questionnaire in a private setting, which took ~15 to 20 minutes of their time.

The questionnaire consisted of 17 questions pertaining to demographic information (including age, gender, highest level of education, and number of years qualified), prescribing patterns, as well as perceptions of CMs for IC. The pen-and-paper questionnaire was compiled by the researchers, using validated surveys utilised in other similar studies.^[7,12] Participants were asked about their prescribing patterns for both conventional and CMs, their responsibilities regarding counselling of patients, as well as referral of patients to healthcare providers. They were also asked to rate various statements pertaining to perceptions of CM products on a 5-point Likert scale; Cronbach's alpha value (0.795) for this construct was above the acceptable threshold value of 0.7. A pilot study was conducted prior to commencement of the research to validate the reliability of the questionnaire.

Data analysis

Data were analysed using frequencies and custom tables and are presented graphically (Fig. 1).

Ethics

Participation was voluntary and participants could withdraw from the study at any point up until the questionnaire was completed and sealed in an envelope. Participants were provided with an information letter explaining the purpose and procedures of the study and were asked to sign a consent form prior to questionnaire completion. Participants had the right to anonymity and no identifiable data were requested. Participants completed the questionnaire independently in a private setting. All records were only viewed by the researchers and all captured information was stored on a password-protected computer. There were no anticipated risks to being involved in this study. Permission to conduct the survey was obtained from the University of Johannesburg's Faculty of Health Sciences Research Ethics Committee (ref. no. REC-01-141-2016).

Results

A total of 250 questionnaires were distributed to various pharmacies in Johannesburg; 110 questionnaires were returned and 100 were completed correctly and subsequently analysed.

Demographics

Of the 100 participants, 47 (47%) were qualified pharmacists and 53 (53%) were pharmacist assistants. A large portion of the sample were female ($n=68$; 68%) and qualified within the previous 5 years ($n=49$; 49%) (Table 1).

Knowledge of complementary medicine and counselling role

Most participants rated their knowledge of IC and the treatments

available as good ($n=38$; 38%) or reasonable ($n=46$; 46%) and obtained their information largely from pharmaceutical representatives ($n=75$; 75%) and information leaflets ($n=59$; 59%). While 86% ($n=86$) of participants felt they had a professional responsibility to counsel patients about CM, the large majority ($n=84$; 84%) felt that patients expect more information from them regarding CM than they did 5 years ago (Table 1).

Prescribing patterns

Most participants ($n=76$; 76%) reported recommending both complementary and conventional treatment options for IC. Regarding CMs, products containing simethicone were most favoured, but were only recommended by 20% of the sample. CMs most recommended by participants included probiotics ($n=64$; 64%) and this was followed by various herbal (five products) and homeopathic medicines (five products) (Table 2).

Referral of patients

Participants were also asked about referral of patients with IC to healthcare providers. Most of the participants referred patients to general practitioners for further treatment ($n=81$; 81%), while some also referred to homeopaths ($n=41$; 41%), chiropractors ($n=17$; 17%), reflexologists ($n=6$; 6%), massage therapists ($n=5$; 5%), or phytotherapists ($n=4$; 4%).

Perceptions of complementary medicine

Participants rated their level of agreement with statements related to their perception of CM in the treatment of colic on a 5-point scale (Fig. 1). Overall, positive perceptions were obtained, with most participants agreeing or strongly agreeing that CM is effective in treating colic ($n=78$; 78%); that it works well in combination with conventional treatment ($n=79$; 79%); that it works well for children ($n=74$; 74%) and produces fewer side-effects than conventional pharmaceuticals ($n=65$; 65%). Furthermore, 79% ($n=79$) of participants reporting feeling confident in recommending CM products for colic; however, 74% ($n=74$) also felt that they needed to expand their knowledge base.

Discussion

The results of this study show that most participants recommended both complementary and conventional treatment options for IC, with only a small number of them preferring one modality over the other. Participants recommended a variety of different CM products for IC, including probiotics ($n=64$; 64%), herbal medicines (specific products ranging from 25% to 53%) and homeopathic medicines (4% to 31%).

Probiotics are beneficial live organisms such as *Lactobacillus* and *Bifidobacterium* that have potential beneficial effects on gut health. Prebiotics are non-digestible food ingredients that promote the growth of beneficial probiotic bacteria, while synbiotics are products containing both probiotics and prebiotics. There are a wide variety of probiotic-related products on the market; however, the research related to their use for IC is limited to certain microbial strains.^[13]

In recent years, lactobacilli have received attention owing to their potential involvement in the spread of antibiotic resistance. Intrinsic resistance has minimal potential for horizontal spread; however, acquired resistance to tetracycline, erythromycin, chloramphenicol, and clindamycin has been detected in lactobacilli isolated from various sources.^[14] Anisimova *et al.*^[14] raised concerns about the safety of the investigated probiotic products in terms of antibiotic resistance spread. The data provided evidence for extensive revision

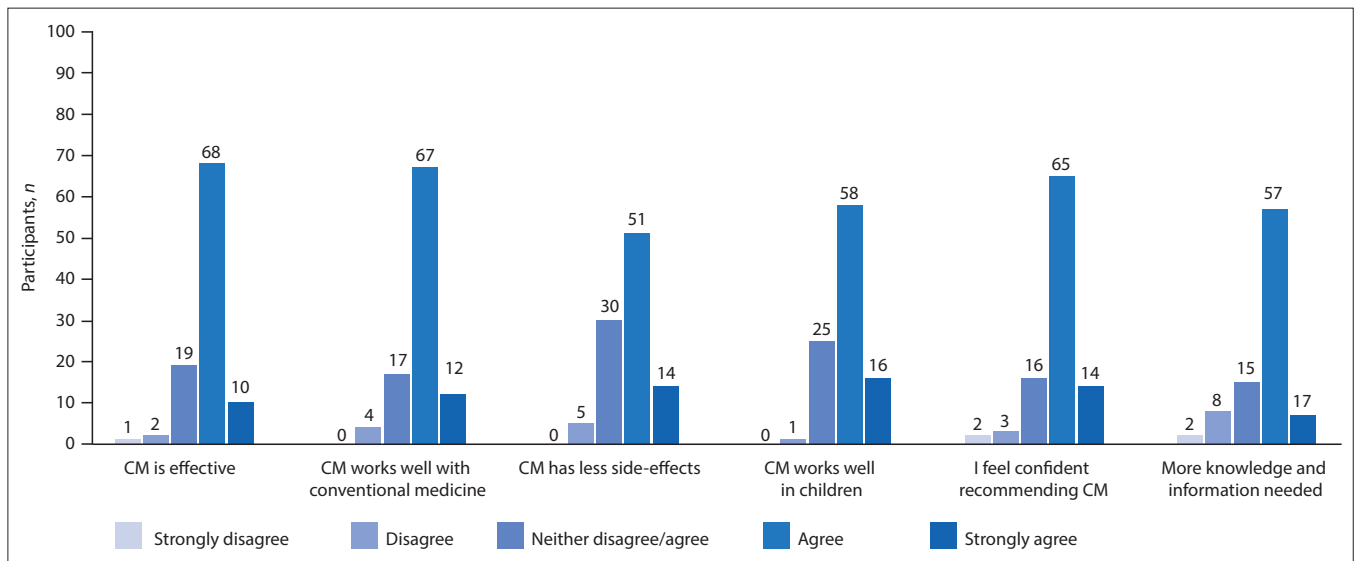


Fig. 1. Perceptions of complementary medicine (CM) for infantile colic.

of the regulation of microorganisms for human consumption as probiotic preparations and dietary supplements.^[14]

In response, Pang *et al.*^[15] more recently concluded that *Lactobacillus reuteri* extracellular membrane vesicles (MVs) reproduce the mechanistic actions by which strain DSM 17938 is thought to ameliorate IC. Bacterial extracellular MVs are potent mediators of microbe-host signals, important in host-pathogen interactions and for the interactions between mutualistic bacteria and their hosts.^[15] Furthermore, a systematic review by Simonson *et al.*^[16] showed that the oral administration of probiotics to breastfed infants with colic reduced crying time by 50% compared with placebo; however, its efficacy in formula-fed infants needs further investigation. The authors of the review similarly concluded that certain probiotic strains, and in particular *Lactobacillus reuteri* DSM 17938, could provide a safe treatment option for infants with colic.^[16]

Although there is currently little research on the effectiveness and safety of specific herbal and homeopathic medicine products for IC, there is some growing evidence to support its use and safety. A randomised, double-blinded, placebo-controlled trial investigated the effectiveness of a standardised extract of fennel (*Foeniculum vulgare*), chamomile (*Matricariae recutita*) and lemon balm (*Melissa officinalis*). The results showed that the herbal extract significantly reduced crying time in infants within one week.^[17] Another randomised controlled trial showed that fennel seed oil emulsion significantly reduced colic symptoms in infants.^[18] An observational, retrospective case-control study evaluated parents' perception of the effectiveness of a proprietary herbal treatment, containing fennel (*Foeniculum vulgare*), anise (*Pimpinella anisum*), and mint (*Mentha piperita*) for IC. Of the 1218 participants surveyed, 771 utilising the treatment reported significantly fewer colic symptoms. The treatment was perceived to effectively reduce colic symptoms in a short period of time and was perceived as successful in 65% of the cases.^[19] A clinical trial by Evans and Lorentz^[20] evaluated the effectiveness and safety of a proprietary homeopathic complex on 30 infants aged 3 to 16 weeks. The product contained vegetable charcoal (*Carbo vegetabilis*), blackthorn (*Prunus spinosa*), caraway (*Carum carvi*), chamomile (*Matricaria chamomilla*), fennel (*Foeniculum vulgare*), ginger (*Zingiber officinale*), lemon balm (*Melissa officinalis*), and peppermint (*Mentha piperita*). Their results showed that this intervention produced a significant reduction in abdominal

distension and pain and decreased daily crying time in infants.^[20] A prospective, multicentred, randomised, clinical trial by Raak *et al.*^[21] compared the effectiveness of simethicone to a homeopathic complex containing *Chamomilla* D6, *Cina* D6, *Colocynthis* D6, *Lac defloratum* D6 and *Magnesium chloratum* D6. The homeopathic complex was significantly more effective than simethicone in reducing IC symptoms.^[21] In light of these findings, and to promote treatment efficacy, it is recommended that herbal and homeopathic medicines should be recommended under the guidance of suitably qualified practitioners, especially when prescribing herbal medicines as they need greater care with regards to dosage. It was therefore reassuring that 41% of the sample in our study referred patients to homeopaths, and albeit a lesser degree, to phytotherapists.

There is a paucity of evidence relating to the effectiveness of both complementary and conventional medicines for the treatment of IC. According to a Cochrane systematic review by Biagioli *et al.*^[22] the available evidence for both complementary and conventional treatment options consist of small-scale studies with various limitations and biases. This review found no evidence to support the use of simethicone as a pain-relieving agent for IC and did not find sufficient evidence to recommend the use of herbal agents, sugar, dicyclomine and cimetropium bromide.^[22] Our study found that only 20% of the sample recommended simethicone, and an even smaller percentage recommended cimetropium bromide, supporting the previous Cochrane finding.

Salman Popattia *et al.*^[23] developed a bioethical framework pertaining the pharmacists' responsibilities when selling traditional and CMs, which proposes that pharmacists should be able to provide evidence-based information and recommendations for these products to assist people to make informed decisions about their use. Pharmacists and pharmacist assistants are often the primary source of information when it comes to the choice of medication to use for certain conditions, and therefore need to be well trained to give the best advice possible to the patient. In our study, while most participants felt they had reasonable or good knowledge about IC and the various treatment options available, many reported relying largely on information given by pharmaceutical representatives; therefore, limited training or information on certain CM products could affect the confidence of pharmacy staff when advising patients. Participants largely agreed that

Table 1. Demographics and background information (N=100), n (%)

Occupation	
Pharmacist	47 (47)
Pharmacist assistant	53 (53)
Gender	
Female	68 (68)
Male	32 (32)
Highest qualification	
Diploma	37 (37)
Bachelor's degree	31 (31)
Honours degree	13 (13)
Master's degree	3 (3)
Doctorate	1 (1)
Other	15 (15)
Years since qualification	
0 - 5	49 (49)
6 - 10	17 (17)
11 - 15	14 (14)
16 - 20	5 (5)
≥21	15 (15)
Knowledge of complementary medicine for infantile colic	
Excellent	5 (5)
Good	38 (38)
Reasonable	46 (46)
Average	9 (9)
Poor	2 (2)
Sources of complementary medicine information	
Pharmaceutical representatives	75 (75)
Information leaflets	59 (59)
Courses and the internet	29 (29)
Lectures	28 (28)
Books/magazines	22 (22)
Complementary medicine practitioners	21 (21)
Family and friends	15 (15)
Patients expect more information	
Yes	84 (84)
No	16 (16)
Responsibility to counsel patients about complementary medicine	
Yes	86 (86)
No	14 (14)

they require more knowledge and information about CM for IC; these results strongly support the need for additional training which could be included in pharmacy programmes, or as postgraduate courses or continuous professional development (CPD) training. The findings also concur with the study conclusion by Koh *et al.*^[24] on pharmacists' patterns of use, knowledge, and attitudes toward complementary and alternative medicine, encouraging further training and education.

Thandar *et al.*^[25] conducted a study evaluating the knowledge, attitude and practices of Durban-based pharmacists regarding CMs for atopic dermatitis. Their results showed that despite most pharmacists not being familiar with CMs, many recommended them to patients. Around 92% of participants reported never having or having had only minimal CM training at undergraduate and/or postgraduate level and felt their lack of knowledge affected their confidence when advising patients. Most were interested in broadening their knowledge and felt it would prepare them adequately to counsel their patients.^[25] Similarly,

Table 2. Prescribing patterns (N=100), n (%)

Treatment type recommended to patients			
Conventional medicine only			13 (13)
Complementary medicine only			11 (11)
Both			76 (76)
Preferred active ingredient/conventional medicine			
Simethicone			20 (20)
Cimetropium bromide			2 (2)
Other			3 (3)
Preferred type of complementary medicine			
Probiotics			64 (64)
Herbal medicine	Herbal product 1		53 (53)
	Herbal product 2		50 (50)
	Herbal product 3		41 (41)
	Herbal product 4		34 (34)
	Herbal product 5		25 (25)
Homeopathy	Homeopathic product 1		31 (31)
	Homeopathic product 2		18 (18)
	Homeopathic product 3		13 (13)
	Homeopathic product 4		12 (12)
	Homeopathic product 5		4 (4)
Other combination complementary medicines			12 (12)

most participants in our study (79%) reported feeling confident in recommending CM products for colic; however, 74% also felt that they needed to expand their knowledge base. This finding provides evidence to concerned stakeholders in pharmacy education to reflect on this identified gap and implement suitable curriculum content to promote the role of pharmacists in ensuring the safe and effective use of CM by patients.

The use of CMs in paediatric patients has gained popularity in many countries, and when given a choice, some parents prefer these alternative options as they are perceived to have a good safety profile.^[26,27] However, many of these products have not been clinically tested for their intended use, and their concomitant use with certain pharmaceutical medicines may result in adverse effects and/or herb-drug interactions. Pharmacists therefore have a key role to play in educating patients about the safe and appropriate use of CM products.^[27] A systematic review by Thin *et al.*^[28] reviewed 23 articles related to the knowledge, attitude, and practices of community pharmacists towards CMs. The results showed that although a large number of community pharmacists recommend CMs to their patients, in some studies, less than half of them engaged or counselled patients about their use and reporting of adverse effects was low. A lack of reliable information was cited as a barrier. In contrast, pharmacists who received education or training about CMs were more likely to provide counselling and recommendations about these products.^[28] Improving education and training and providing access to evidence-based information is necessary so that pharmacists can provide counselling on the appropriate and safe use of CMs to their patients.

Overall, CMs were perceived by pharmacists and pharmacist assistants to be associated with fewer adverse effects than conventional options; however, a relatively high percentage (30%) of the participants did not agree nor disagree that CMs were safe. Homeopathic and herbal medicines are generally considered safe when used appropriately and under the supervision of a healthcare provider; however, research regarding their safety for IC is limited and their use is not without risks.^[20,29] This further emphasises the need for more formalised training of pharmacists in the field of CM.

Overall, positive perceptions of CM were obtained, with most participants agreeing that CMs are effective for IC. There is a growing trend globally towards using traditional and CMs as a treatment option.^[30] According to a systematic review by Tangkiatunjai *et al.*^[31] on the factors that influence CM use, the main reasons include its perceived benefits and safety, as well as dissatisfaction with conventional medicine. In addition, affordability, easy access and traditional use were found to be significant factors among African populations. Despite their widespread use, further research regarding the efficacy and safety of CM products is of vital importance to ensure better treatment outcomes for patients with IC.

Study limitations

A limitation identified in this study is the relatively small sample size and limited geographical area sampled. Some of the pharmacy personnel were not willing to take part in the research study owing to personal time constraints. Also, participants felt that their level of knowledge on CMs for IC was not sufficient, therefore they were not all completely confident in their answers on the various product recommendations. Lastly, no correlation statistics were performed, which would have strengthened the analysis of the data, and it remains a limitation of the present study.

Conclusion

Our exploratory study highlights the overall favourable view of CMs for colic by pharmacists and pharmacy assistants in Johannesburg. There appears to be a positive shift towards CM for the treatment of IC; however, improved training is needed to ensure pharmacists and pharmacist assistants are better informed regarding CMs to give appropriate advice to patients. Further research on the effectiveness and safety of CMs is required which can add to the evidence-base and assist in the development of recommendations for their use.

Declaration. None.

Acknowledgements. The authors would like to thank Mr Anesu Kuhudzai from UJ STATKON for his assistance with the statistical analysis of the study.

Author contributions. Study conception and design: RR, MF; data collection: MF; analysis and interpretation of results: MF, RR, JP; draft manuscript preparation JP, RR, MF. All authors reviewed the results and approved the final version of the manuscript.

Funding. This work was financed by the University of Johannesburg.

Conflicts of interest. None

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Accepted 8 January 2024.