

Survey to assess management of abdominal pain and cramping in South African pharmacy chains

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Background: Most consumers with abdominal cramps and pain choose to treat them with over-the-counter (OTC) medication. Currently there are no data evaluating the approach of South African pharmacy staff to abdominal cramps and pain. The purpose of this survey was to evaluate the approach of pharmacy healthcare providers (HCPs) to abdominal pain and cramping and attitudes towards Buscopan (hyoscine butyl bromide) for treatment of abdominal cramps.

Method: An online and face-to-face survey was conducted with 142 pharmacists and 82 pharmacist's assistants from two major retail pharmacy chains. The study was commissioned by an independent research company.

Results: Pharmacists and pharmacist's assistants reported providing advice to an average of 13 patients with abdominal cramps weekly. The majority of HCPs recommended treatment based on symptoms, potential for drug interactions and safety. Only approximately half of consumers always followed the advice of the HCP. HCPs commonly saw patients who had taken inappropriate medication for their abdominal pain and cramping, including nonsteroidal anti-inflammatory drugs (NSAIDs), paracetamol and codeine-containing preparations. Overall, 85% of pharmacists recommended Buscopan for the treatment of abdominal pain and cramping, based on perceptions of efficacy, tolerability and improvement in quality of life.

Conclusions: Consumers don't always select an appropriate medication for abdominal pain and cramping, and require advice from a pharmacy HCP. Fostering trust and confidence is essential to ensure that the patient follows the advice given. Most South African pharmacy HCPs within these two major retail chain pharmacies recommend Buscopan as first line for treatment of abdominal cramps.

Background

Abdominal pain and cramping are extremely common. The prevalence in the general population has been estimated at between 10–46%, with women reporting symptoms more commonly than men.¹ These nonspecific symptoms may be associated with a wide spectrum of gastrointestinal (GI), urological and gynaecological disorders and, even in a hospital setting and despite use of imaging modalities, abdominal pain presents a major diagnostic challenge.²⁻⁴

Although most abdominal pain is benign and not life-threatening, it can nevertheless have a substantial impact on quality of life.^{5,6} Functional GI disorders (FGID) are a common cause of painful abdominal cramps, and are characterised by GI symptoms related to a combination of motility disturbance, visceral hypersensitivity, altered mucosal and immune function, altered gut microbiota, and altered central nervous system (CNS) processing.^{1,3} Up to 50% of these symptoms can be attributed to irritable bowel syndrome (IBS), an FGID symptom complex of abdominal pain and cramping, with other digestive symptoms including constipation, diarrhoea, bloating and flatulence.¹ IBS significantly impacts work and social life. One study indicated that reduction in quality of life is severe enough that, on average, patients would sacrifice between 10 and 15 years of their remaining life expectancy for an immediate cure.⁶ The current standard treatment recommendations for abdominal pain and discomfort are to use a symptom-directed approach

with medication aimed at alleviating pain, constipation and/or diarrhoea. Antimuscarinic agents are recommended first line for symptomatic management of abdominal cramps.²

A substantial proportion of people with GI symptoms never consult a doctor and remain without a specific diagnosis.² Multinational surveys have shown that the majority of people with intermittent cramping and pain use OTC medication, keep stock at home and rarely use medication for prevention, but rather on demand when pain occurs.^{1,7} Consequently, when asked what they expect from their medication, consumers consistently rate fast onset of action, long-lasting action, highly effective and good tolerability as most important.^{2,7} Antispasmodics are the most common class of therapeutic agents used by consumers.^{1,7}

Buscopan (hyoscine butylbromide, HBB) is an anticholinergic antispasmodic medication indicated for the treatment of abdominal pain associated with cramps induced by GI spasms. It has been available both on prescription and OTC for almost 70 years.⁸ The muscle relaxing/antispasmodic effect of HBB is due to its high affinity for muscarinic receptors located on the smooth muscles of the GI tract. It also binds to nicotinic receptors, inducing a ganglion-blocking effect. Numerous clinical trials have demonstrated its efficacy in abdominal pain associated with cramping. Because it is barely absorbed after oral administration and does not penetrate the blood-brain barrier it is generally well tolerated and few adverse events (in

particular no significant increase in anticholinergic side-effects) have been reported.⁸

Currently there are no data evaluating the approach of South African pharmacy staff to abdominal cramps. Consequently, we conducted a survey to investigate the experience of pharmacy HCPs in two leading pharmacy retailers and their treatment recommendations for abdominal cramps, with a particular emphasis on attitudes towards Buscopan. The main objectives were to evaluate reasons for recommending Buscopan, to assess the level of knowledge about its efficacy, tolerability and perceived impact on quality of life, and to investigate other factors that might influence recommendations for management of abdominal pain and cramps.

Methods

The study recruited 142 pharmacists and 82 pharmacy assistants from two large retail pharmacy chains, who each completed a survey questionnaire either online ($n = 74$) or in a face-to-face interview ($n = 150$). Approximately 60% of respondents were female. The majority (> 30%) had more than four years' experience working in the pharmacy, whereas 47% of pharmacists and 28% of pharmacist's assistants had more than eight years' experience. As different pharmacies and retail groups have various recommendation algorithms and standard operating procedures (SOPs), these two chains were chosen to enable consistency in process and compliance programmes.

Results

Both pharmacists and pharmacist's assistants reported providing advice to an average of 13 people with abdominal cramps per week. Almost half of the pharmacists (47%) and 44% of pharmacist's assistants reported seeing more than 20 patients with cramps per week. The most common causes of cramps (60–70%) or associated symptoms were related to diarrhoea/upset tummy, IBS and menstruation-related cramps. Approximately

half of the pharmacy HCPs reported providing advice to people with gastroenteritis or food poisoning, 40% to those with cramps attributed to gastrointestinal ulcers and 30% to those with cramps attributed to side-effects of antibiotics or other medications. With few exceptions, both pharmacists (96%) and pharmacist's assistants (100%) recommended a specific treatment to patients with abdominal cramps. Their primary considerations when recommending a treatment were cause of symptoms (pharmacists 69%, pharmacist's assistants 61%), potential for drug interactions (61%; 60%), price (56%; 51%) and safety profile (53%; 45%). Only approximately one in five pharmacy HCPs considered comorbidities as important when recommending treatment. Whereas 56% of pharmacists reported that patients followed their advice all of the time, fewer interactions with pharmacist's assistants led to patients always following the advice (41%). The majority of pharmacy HCPs reported seeing a large number of patients (> 6 patients per week) who had treated their abdominal cramps with nonsteroidal anti-inflammatory drugs (NSAIDs). Approximately half said the average dose was 3–4 NSAID tablets per day, whereas one out of four had provided advice to patients taking 5–6 tablets or more per day. While menstruation-related cramps were a common reason for NSAID use, these medicines were also being used for cramps associated with IBS, diarrhoea, nausea/upset stomach and gastroenteritis. Almost half of the pharmacists had encountered patients who were taking NSAID medication for cramps attributed to stomach ulcers. Eighty-five per cent of pharmacy HCPs said they reminded all patients of the risks associated with NSAID use and maximum recommended doses. Similar observations were made for paracetamol and codeine-containing combination medications. However, only 75% of pharmacists and 67–70% of pharmacist's assistants reminded all of the patients about paracetamol- or codeine-associated risks and maximum doses.

More than 90% of these pharmacy HCPs were aware of Buscopan. Approximately 70–80% were aware of generic preparations

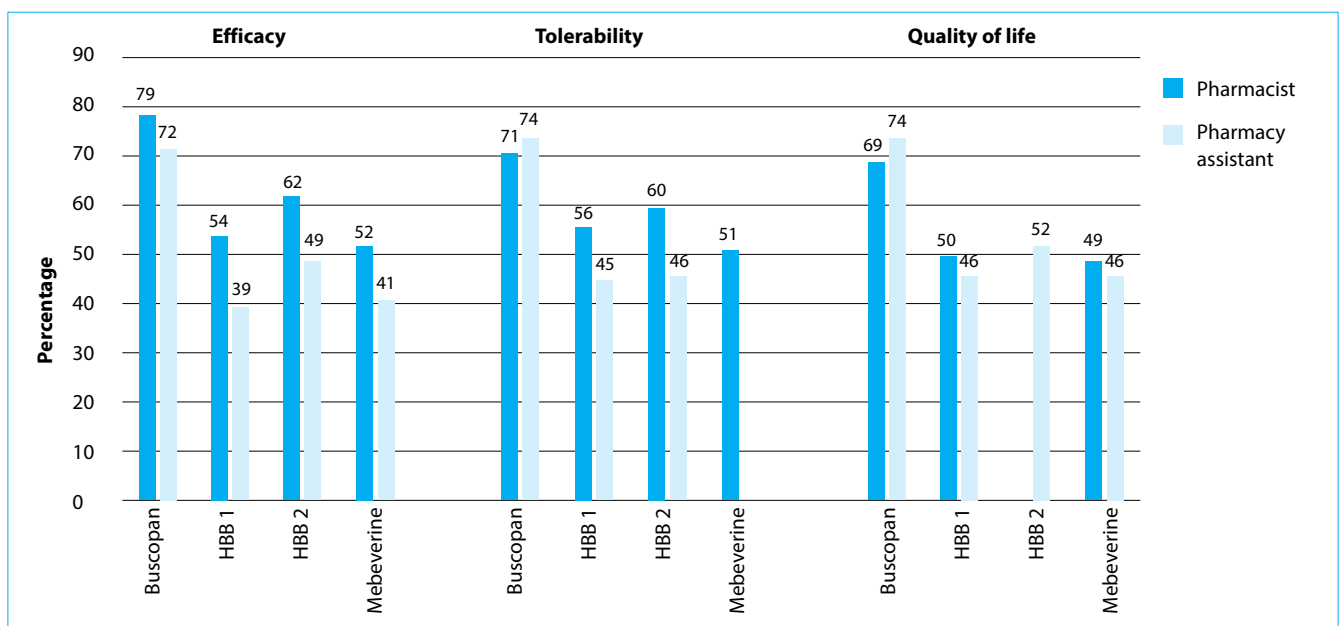


Figure 1: Recommendation practices for treatment of abdominal pain and cramps

HBB – hyoscine butylbromide generic formulations

of HBB, mebeverine and a herbal preparation for treatment of abdominal cramps. Overall, 85% of pharmacists and 85% of pharmacist's assistants said that Buscopan was the most frequently recommended treatment for abdominal pain and cramps. The next most commonly recommended treatments were generic HBB (pharmacists 72%; pharmacist's assistants 55%), mebeverine (66% and 46%, respectively) and a herbal combination preparation (61% and 41%, respectively). While all of the options were considered effective and tolerable for abdominal pain and cramps, when it came to recommendation practices, Buscopan was recommended most frequently, based on perceptions of efficacy, tolerability and improvement in quality of life (Figure 1). Pharmacist's assistants were also inclined to recommend a herbal product based on tolerability.

When asked what product attributes were most important to them when considering Buscopan, the majority of pharmacists (61%) drew attention to the spasmolytic effect consequent to high affinity of HBB for muscarinic receptors on the smooth muscle cells of the GI tract. More than half (56%) rated good tolerability as an important consideration.

Conclusions

This survey demonstrates that, as in other parts of the world, South African pharmacy HCPs are commonly called upon to advise consumers about management of abdominal cramps. In line with treatment recommendations, as far as possible they take a symptom-based/diagnostic approach and the majority also consider the possibility of drug interactions before recommending treatment. However, comorbidities were less commonly considered. An alarming finding of the survey was that a substantial proportion of consumers do not always follow treatment recommendations and use of NSAIDs and other analgesic preparations appears to be common. While a NSAID might be an appropriate choice for patients with dysmenorrhoea, analgesics are not recommended as a general treatment for abdominal cramps.² In particular the elderly and those with a history of peptic ulcer disease are at high risk of NSAID-associated complications and bleeding.⁹ Pharmacy HCPs did not always warn consumers of the risks associated with these medications.

Based on efficacy, tolerability and its perceived effect on quality of life, Buscopan was a leading recommended treatment for abdominal cramps in two major South African pharmacy retail

chains. This is consistent with international guidelines that recommend an antispasmodic treatment as first-line therapy.²

In conclusion, it is common for patients to seek OTC treatment for abdominal cramps without a formal diagnosis. Consumers do not always select an appropriate medication and they require advice from a pharmacy HCP who can assist them with careful questioning about symptoms, other medications and comorbidities. Fostering trust and confidence is essential to ensure that the patient follows the advice given to them.

Funding and conflicts of interest

The survey was commissioned by Sanofi and conducted by Ipsos, an independent global market research agency which subscribes to the professional market research codes of conduct as set out by SAMRA and ESOMAR. Study design, collection, analysis and interpretation of data were independent of the sponsor. Ms Lara Jagwanth is the Medical Head for Africa for Sanofi CHC. Dr David Webb is a professional medical writer and was paid by Sanofi to write the report.

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References: **1.** BUSCOPAN® 10 mg tablets package insert, 13 April 2003. **2.** Lacy BE, Wang F, Bhowal S, Schaefer E; study group. On-demand hyoscine butylbromide for the treatment of self-reported functional cramping abdominal pain. *Scand J Gastroenterol* 2013 Aug; **48**(8):926-935.

[S] BUSCOPAN® 10 mg tablets. Each tablet contains hyoscine butylbromide 10 mg, Reg. No. E 501 (Act 101/1965).

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