

Original Research

Management of musculoskeletal pain in retail drug outlets within a Nigerian community: a descriptive study

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Abstract

Objective: This work aimed to describe attitudes and practices of both community pharmacies and patent and proprietary medicine vendor (PPMV) outlets towards over-the-counter (OTC) analgesic use for musculoskeletal pain states within Zaria, Nigeria.

Methods: The study was carried out in 2 phases from May to August 2016. Phase one was a cross-sectional survey of 40 retail drug outlets (10 community pharmacies and 30 PPMVs). A simulated patient scenario of a young adult male complaining of acute onset back pain was used to collect data on the type and quality of analgesic recommended, duration of consultation, as well as nature of information provided during the drug dispensing process. The second phase involved semi structured interviews with 7 drug vendors (4 pharmacists and 3 patent medicine vendors). The interviewees were asked questions to assess their knowledge of analgesics as well as what type of analgesic they would recommend in three hypothetical patient scenarios.

Results: A wide variety of therapeutic agents were recommended for the simulated patient. Majority of these drugs were oral analgesics and contained NSAIDs either alone or in combination. Less than half of both patent medicine outlets and pharmacies (26.7% and 40% respectively) provided the simulated patient with information on duration of therapy, and asked the patient questions about their past medical and medication history (30% and 33.3% respectively). All analgesics purchased from the pharmacies were registered with the Nigerian drug regulatory agency and had expiry dates compared to only 66.7% and 90% of those bought from patent medicine outlets. Interviewed drug vendors admitted to obtaining a large amount of their knowledge on analgesics from drug information leaflets and prior learning. They also showed some knowledge deficits when questioned on side effects of analgesics and appropriate drug selection in the hypothetical scenarios.

Conclusions: There are problems with both the OTC analgesics recommended, and the counselling provided for these medicines by drug vendors within the Zaria community. While both pharmacies and patent medicine outlets had shortcomings in several of the areas assessed by the simulated patient, the pharmacies performed better.

Keywords

Nonprescription Drugs; Professional Practice; Pharmacies; Pharmacists; Anti-Inflammatory Agents, Non-Steroidal; Patient Simulation; Qualitative Research; Nigeria

INTRODUCTION

Pain is a very common manifestation of various pathological conditions and is one of the main reasons why people seek medical care.¹ While it can manifest in various forms, acute musculoskeletal pain (especially back pain) is a very commonly encountered type.² Thus, it is one of the most commonly encountered complaints in patients assessing care from drug retailing outlets like pharmacies within communities.³ Paracetamol and various Non-Steroidal Anti-inflammatory drugs (NSAIDs) alone or in combination with other agents are commonly used analgesics for this indication.⁴ These drugs are often widely used by patients to self medicate^{5,6}, although actual patient knowledge on their rational use is poor.^{7,8}

In Nigeria, virtually all of these agents can easily be obtained over-the-counter (OTC), both from pharmacies and patent and proprietary medicine vendor (PPMV) outlets. Patent medicine vendors are individuals without

formal medical/pharmaceutical training who sell pharmaceutical products for profit.⁹ They are only legally permitted to sell common OTC medicines. However, due to regulatory lapses they often stock a wide range of both OTC and prescription-only medication. Prach *et al.* (2015) observed drug sales at 250 patent medicine shops in North-central Nigeria. They reported that analgesics were very often sold, with over 1200 customers buying these drugs out of the 2359 purchases they observed.¹⁰ Other cross sectional surveys carried out on consumers all around the country have suggested that analgesic abuse is common¹¹⁻¹⁴, and self-medication the norm amongst members of the community.

Side effects of NSAID usage are many and can include morbidity related to various body systems. However in spite of this, for several years these drugs were largely perceived to be safe. While it is known that NSAID use can elevate blood pressure and cause heart failure, there is new evidence linking them with an increased risk of cardiovascular disease. In 2015, the American Food & Drug Administration (FDA) strengthened its warning that NSAID use increased the chances of developing heart attacks or strokes even following short term use.¹⁵ This is noteworthy especially within the Nigerian setting, where an increasing number of adults have one or more cardiovascular disease (CVD) risk factors.¹⁶⁻¹⁸ A related concern is the renal damage associated with these agents especially when they are used in combination with other nephrotoxic drugs. Kidney disease is on the rise worldwide due to a variety of

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factors, however the prognosis of patients with this condition in third world settings like Nigeria is remarkably worse.¹⁸ Other side effects of NSAID misuse can include gastrointestinal (GI) side effects and bleeding. Within the Nigerian setting particularly, GI adverse effects have been demonstrated in several studies.^{19,20} Consequently, describing NSAID use patterns within the community setting is important if rational use of these drugs is to be encouraged. The aim of this work was to describe the management of musculoskeletal pain states by pharmacies and patent medicine outlets within the Zaria community and explore their attitudes and practices towards analgesic use.

METHODS

Study setting

This study was carried out in Zaria, which is a major city in Kaduna state, Northwest Nigeria. Zaria has a population of fewer than 700,000 people according to the 2006 Nigerian national census figures. Agriculture is the main occupation of residents, majority of whom could be said to be low to middle income earners.

Study design

This study used mixed methods and was carried out in two phases from May - August 2016. Phase one was a cross-sectional survey of 40 retail drug outlets (10 community pharmacies and 30 patent medicine outlets) using a single simulated patient scenario. The simulated scenario was a young adult male complaining of acute onset back pain (pain started 3 days ago). The simulated patient visits were all conducted by a single individual, who was a 26 year old male final year pharmacy student. After the exchange of pleasantries, all that was said by the simulated patient in English language was "I have been suffering from lower back pain for at least 3 days". More information was given upon request by the attending personnel (see Table 1), and the analgesic recommended by each vendor purchased in order to obtain further information relevant to the study. Immediately after leaving the surveyed retail outlets, the simulated patient answered a checklist of questions after debriefing the 2 other principal researchers to reduce subjectivity. These questions revolved around the nature of consultation with the drug sales personnel including the type of analgesic recommended, recommended dose and duration, length of consultation, as well as other information provided/not provided during the drug dispensing process. Purchased medication was also visually inspected for signs of quality like presence of expiry dates and Nigerian drug regulatory body registration number. The second phase involved semi structured interviews with 7 drug sellers (4 pharmacists and 3 patent medicine vendors), the aim of which was to qualitatively describe

their perceptions and knowledge of various aspects of analgesic use. The questions explored areas including their knowledge of NSAIDs, pain presentation and patient types in addition to other areas. In addition, they were also asked to talk to the interviewer through their approach towards managing three hypothetical scenarios involving three specific patient types who might require OTC analgesics. All interviews were conducted in English and audiotaped.

Sampling

For the purposes of this work we divided the town into 10 suburbs. The sampling frame used was a list of all registered retail and wholesale pharmacy premises in Zaria (28 outlets in total) as published by the Pharmacists Council of Nigeria (PCN).²¹ Because there is currently no official list of patent medicine outlets located within the state, we then counted the number of patent medicine outlets easily visible from the main roads in the aforementioned suburbs (87 outlets in total). Consequently, one pharmacy and 3 patent medicine outlets were randomly sampled from each suburb.

For the second phase, interview requests were sent out to 5 pharmacies and 15 patent medicine outlets that were sampled during the first phase. Only drug sellers that consented to this invite were included. The sampling was tilted in favor of pharmacists because majority of the invited patent medicine vendors refused to be interviewed.

Ethical Considerations

This study had ethical approval from the research ethics committee of the Faculty of Pharmaceutical Sciences, Ahmadu Bello University, Zaria, Nigeria. Because of the nature of this study, drug vendors were not informed in advance nor asked for consent to participate. Interviewed drug sellers were however asked for their consent before they were interviewed.

Data collection and analysis

The data collection checklist the simulated patient completed after exiting the study sites had 2 responses (yes or no) to 6 questions evaluating the practices of the drug vendors when dispensing analgesics. Quality of medicines was evaluated by the presence or absence of expiry dates and Nigerian Agency for Food and Drug Administration and Control (NAFDAC) registration number. The doses and dosing frequencies of recommended drugs at the surveyed outlets were compared to those for usual use in the drugs monograph within the British National Formulary (BNF 68).²² Several of the combined analgesics did not have monographs in the BNF and in that case, the monograph for the analgesic closest to normal recommended doses was checked. If the recommended dose and frequency fell within the BNF specified range, then it was classed as appropriate, any deviation from this standard was classed

Age	26 years
Sex	Male
Symptoms	<ul style="list-style-type: none"> • Lower back pain, which is interfering with his daily activities and sleep. • Ordinary pain, no nerve/"electric shock-like" pain
Symptom Duration	For the last three days (Started after some heavy lifting of furniture)
Any other medical conditions	No
Any medications taken for the pain	No

Drug composition and strength	Patent medicine outlets n (%)	Pharmacies n (%)
1. Tabs ibuprofen 400mg	6 (20)	3 (30)
2. Tabs diclofenac 50mg	5 (16.7)	0 (0)
3. Tabs diclofenac 100mg	2 (6.7)	0 (0)
4. Caps piroxicam 20mg	4 (13.3)	0 (0)
5. Methylsalicylate ointment	0 (0)	1 (10)
6. Tabs aceclofenac 100mg+paracetamol 500mg	0 (0)	2 (20)
7. Tabs chlorzoxazone 250mg + paracetamol 500mg	0 (0)	1 (10)
8. Tabs diclofenac 100mg + B vitamins	7 (23.3)	1 (10)
9. Tabs diclofenac 50mg + paracetamol 325mg + caffeine 30mg	4 (13.3)	1 (10)
10. Tabs ibuprofen 200mg+paracetamol 325mg + caffeine 30mg	2 (6.7)	1 (10)

as inappropriate. All of this data was then coded and entered into a Microsoft Excel 2013 sheet, and descriptive statistics used to present the data thus obtained.

Qualitative data obtained from the interviews was transcribed. The manifest content of the transcribed interviews was analyzed using qualitative content analysis.

RESULTS

Analgesics recommended by drug outlets

A wide variety of therapeutic agents were recommended for the simulated patient at the surveyed drug outlets as seen in Table 2, ranging in price from around 100 Nigerian Naira (NGN) to around 250 NGN. Majority of the drugs were oral analgesics and contained NSAIDS either alone or

in combination with other agents, the only exception was chlorzoxazone which is a skeletal muscle relaxant although it was combined with paracetamol. Diclofenac (alone or in combination) was the most often recommended analgesic in patent medicine stores (59.8%) compared to Ibuprofen in 40% of pharmacies.

Other aspects assessed by the simulated patient

Other information assessed by the simulated patient is presented in Table 3. Only about 30% of doses from both types of outlets were appropriate. Under dosing was more common with all of the analgesics, especially those containing other drugs in combination. Over dosing was mainly a problem with piroxicam 20mg capsules, as all of the vendors recommended it be taken twice daily.

Less than half of both patent medicine outlets and

	Patent medicine outlets n (%)	Pharmacies n (%)
Adequacy of dose recommended		
Appropriate	10(33.3)	7(70)
Inappropriate	20(66.7)	3(30)
Instruction given on how to take NSAID containing drugs		
None	24(80)	4(50)
Take after meals	6(20)	4(50)
Provided simulated patient with information on duration of therapy		
Yes	8(26.7)	4(40)
No	22(73.3)	6(60)
Asked simulated patient questions about past medical and medication history		
Yes	10(33.3)	3(30)
No	20(66.7)	7(70)
Non-pharmacological intervention suggested		
Yes	0(0)	1(10)
No	30(100)	9(90)
Suggested additional drug therapy		
Yes	1(3.3)	0(0)
No	29(96.7)	10(100)
Recommended patient seek medical opinion if pain persists		
Yes	0(0)	0(0)
No	30(100)	10(100)
Consultation times		
1 minute	14(46.7)	4(40)
2 minutes	13(43.3)	3(30)
3 minutes	3(10)	2(20)
4 minutes	0(0)	1(10)
mean	1.30	2.00
Presence of NAFDAC Registration number on purchased medicines		
Present	20(66.7)	10(100)
Absent	10(33.3)	0(0)
Presence of Expiry dates on purchased medicines		
Present	27(90)	10(100)
Absent	3(10)	0(0)

NAFDAC: National Agency for Food & Drug Administration and Control

pharmacies provided the simulated patient with information on duration of therapy, and asked the patient questions about their past medical and medication history. It should be noted that past medical and medication history were combined in Table 3 because all the vendors that asked about one aspect, asked about the other. Regarding non-pharmacological interventions, the vendor at one pharmacy recommended that the patient massaged his back using some mentholatum ointment in addition to the oral NSAID he recommended. Additional drug therapy (Aside from the analgesic) was only recommended by one patent medicine vendor, who sold 10 capsules of Ampicillin 250mg to the simulated patient. She/he recommended that one capsule be taken twice daily to treat any "infection" that may have caused the back pain. Generally consultation times with the drug sellers took only about 1-2 minutes. Consultation times at pharmacies were however longer (2 minutes on the average) when compared with the 1.30 minutes average of the patent medicine outlets.

The National Agency for Food & Drug Administration and Control (NAFDAC) is the Nigerian equivalent of the American Food & Drug Administration (FDA). NAFDAC is responsible for ensuring the quality and safety of all drugs that are marketed within the country, and it is a legal requirement that all drugs used within the country should have a NAFDAC registration number. All the recommended drugs from the pharmacies had NAFDAC registration numbers, compared with only 66.7% of drugs from the patent medicine outlets. A similar trend was seen with expiry dates; all the drugs from pharmacies had expiry dates compared to 90% of drugs from patent medicine outlets.

Qualitative data obtained from the semi-structured interviews

Interviewed drug sellers included 4 pharmacists and 3 patent medicine vendors within the age range 27-55 years, who had been selling/dispensing drugs for between 4 months - 27 years. They all agreed that they very often sold analgesics to patients of all ages, and estimated that between 50-70% of these purchases were customer initiated requests (i.e. not recommended by them).

Gastrointestinal side effects were the major adverse effects they identified as associated with NSAID use, although 2 of the pharmacists were also aware of others. With regards to their sources of knowledge on NSAIDs, they all admitted to getting a lot of information from drug leaflets and 'on the job' learning. The pharmacists also agreed that a lot of their information came from their university days

Hypothetical patient scenarios

1. Woman with a 2 month old pregnancy complaining of pain in her leg: All but one of the drug sellers claimed that referral to a doctor would be best in this case. Some agreed that paracetamol could be an option but only if the patient insisted.
2. Elderly lady with chronic back pain: A wide variety of NSAIDs alone or in combination were recommended for this hypothetical scenario. The major concern of the drug sellers here was the possibility of developing gastric ulcers, leading to some suggesting NSAIDs with

some COX-2 selectivity/ combined with gastro protective agents

3. Four year old child who injured himself while playing: Their focus in this case was the need for appropriate wound care (dressing and anti-tetanus shots). Most of the drug sellers however felt that paracetamol would be adequate, although ibuprofen was also suggested as a close substitute, both drugs were recommended for a few days.

DISCUSSION

Globally, demand for healthcare services (especially to manage minor ailments) within the community setting continues to rise.²³ Simulated patient visits can be used to assess the quality of care obtained from retail drug outlets located within communities. When combined with feedback, they can also be a useful means of promoting rational utilization of OTC medicines.²⁴

The NSAIDs (Diclofenac and Ibuprofen alone or in combination) were the most commonly recommended drugs. Other studies both within¹¹ and outside^{5,6,25} the country have reported similar results indicating the widespread use of these drugs. These drugs were mostly in combination with other ingredients, including paracetamol, caffeine and B-group vitamins. The Diclofenac plus B vitamin combination is usually indicated for neuropathic pain²⁶, which was not the case for the simulated patient, raising questions on the rationality of the use of this combination in this scenario. Interestingly also all of the recommended NSAIDs were via the oral route, even though there is good quality evidence showing that topical NSAIDs can provide similar levels of pain relief in acute conditions²⁷, with the added benefit of minimal side effects.

Use of analgesic combinations seems to be particularly prevalent within the Nigerian setting¹²⁻¹⁴, raising several safety concerns. Caffeine is a common ingredient found in many analgesic combinations, and is believed to act mainly by lowering gastric PH and improving absorption of the main analgesic.²⁸ A meta-analysis by Derry *et al.* found that the addition of caffeine in doses of 100 mg or over to a standard dose of several commonly used analgesics provided a small increase in the proportion of participants who experienced a good level of analgesia.²⁸ Lower doses of caffeine were found in the products purchased in this study (around 60mg), although the products contained 2 analgesics (Paracetamol and an NSAID). Further research needs to be carried out into the rationality of these products, especially to ascertain a positive benefit-risk profile. Caffeine has some unpleasant side effects, and it would be interesting to investigate if the advantages of the sub-therapeutic caffeine dose outweigh its risks. Similarly while combining paracetamol with various NSAIDs has been shown to produce better pain relief²⁹, a major concern with these combinations are inadvertent paracetamol overdoses by patients, leading to potentially serious adverse effects.³⁰ None of the vendors in this study who dispensed paracetamol containing combinations provided the simulated patient with this information and/

warned him not to take other analgesics (especially paracetamol) simultaneously.

Several shortcomings that could affect rational analgesic use were noted both in the pharmacies and patent medicine stores surveyed in this work. These lapses ranged from inappropriate dosing and provision of inadequate information to issues around the quality of the recommended drugs. Pharmacies generally performed better than patent medicine outlets in most of these areas. While this is to be expected since as earlier mentioned, these outlets are often staffed by individuals with no formal medical training. It is also worrisome because of how easily accessible these outlets are as well as the high patronage they receive from members of the public.³¹ Other studies carried out within Nigeria have shown that patent medicine vendors contribute to irrational drug use for several common conditions including malaria, diarrhea and respiratory infections.^{31,32} They do this in several ways including increasing treatment costs, stocking sub-standard/fake drugs and poor dispensing practices.

The role of proper patient counselling in optimizing safe and effective drug use is well known. A study by Abdel Shaheed et al (2016), which also used simulated patient scenarios, had somewhat similar results to this study on inadequate counselling for OTC analgesics recommended by pharmacists for back pain states.²⁵ They surveyed 534 pharmacies all over Australia, and reported that incomplete information was provided by the pharmacists in several of the encounters they recorded. Omitted information included advice on possible side effects, dosing instructions and maximum dose of medicine(s) to be taken daily. To further compound the problem, about 80% of all the medicines purchased during this study were only in blister packs, and did not come with any information leaflets. This is common with OTC medicines sold in developing countries, as a cost cutting measure on the part of manufacturers. It can thus be inferred that consumers are often left with information deficits on how to use these drugs properly, which could potentially contribute to their abuse/misuse.

Areas where knowledge gaps on NSAIDs could be seen were in vendor knowledge of adverse effects of NSAID use and in the hypothetical scenarios. Drug vendors seemed aware of the dangers of NSAID usage in pregnancy, as all of them claimed that the pregnant woman in the hypothetical scenario should be referred to a doctor. They however seemed to be less cautious on recommending NSAIDs for the elderly patient and young child. Their only concern with the elderly patient was the development of a gastric ulcer. However, several other problems exist with the use

of NSAIDs in this patient population, due to several physical and biological changes that can occur in the course of normal ageing.³³

Limitations

1. Sampling: for the simulated patient scenarios, patent medicine outlets sampled might not have been a true representation of all of patent medicine outlets actually present within the study area. This is because only stores that were easily accessible by major access roads were sampled. For the interviews as earlier stated, most of the invited patent medicine vendors declined to be interviewed, which affected the qualitative data collected.
2. Because the aim of the study was to explore the type of medication related information delivered/not delivered by personnel at the surveyed outlets, this work did not assess the quality of interaction or the influences demographic characteristics of vendors (or the simulated patient) could have had on the patient counselling process
3. Hypothetical patient scenarios, while a valid method of data collection, may not actually reflect the true practices of the interviewees. This is because there is often disparity between what people say they do, and what they really do.

CONCLUSIONS

Results obtained from this study suggest that there are problems both with the OTC analgesics recommended, and the counselling provided for these medicines by drug vendors for musculoskeletal pain within the Zaria community. While both pharmacies and patent medicine outlets had shortcomings in several of the areas assessed by the simulated patient, patent medicine outlets were noticeably worse. There is a need for public enlightenment campaigns targeted at drug vendors on the appropriate use of analgesics to mitigate against their abuse in addition to better monitoring and/ stricter regulation of the activities of patent medicine vendors.

CONFLICT OF INTEREST

The authors have no funding or conflict of interest to report.

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