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QUALITY ASSESSMENT OF PRAZIQUANTEL TABLETS SOLD IN MEDICINE STORES IN KANO METROPOLIS

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ABSTRACT
The efficacy, availability, tolerable side effects and relative affordability of praziquantel makes it the drug of choice in the treatment and various control programmes of schistosomiasis in the endemic areas with excellent outcomes. However, there are reports of low cure rate with praziquantel observed by clinicians with various speculations on the likely causes. This study explored poor drug quality as a possible cause of praziquantel treatment failure in schistosomiasis. On the spot sampling of twelve different samples of praziquantel tablets from various patent medicine shops in Kano metropolis were assayed for active ingredient using British Pharmacopeia methods. Only 6 out of 12 (50%) of the praziquantel tablets studied were found to be acceptable of quality. Cost and number of months before expiry date were not found to be significantly associated with the quality of the drug. Poor quality praziquantel currently in the market may possibly explain failure of standard dose of the drug in the treatment of schistosomiasis. Therefore, it is recommended that additional vigilance by regulatory agencies is required to ensure quality drugs in the market.
Key words: Efficacy, Kano, praziquantel, quality, schistosomiasis.

INTRODUCTION

Schistosomiasis has been a disease of public health importance in many African, Asian, Middle East and South American countries. This is more so with respect to recent concern over the efficacy of praziquantel, the drug of choice for the treatment of various forms of schistosomiasis. (Donato & Pica 2003) There are rising concerns about the quality of the available praziquantel in the drug stores which may possibly explain schistosomiasis treatment failure with the drug. (Doenhoff *et al*, 2009). This may cause a great setback to the various helminth control programmes especially in developing countries where such efforts are mainly via mass use of the drug. (Gryseels *et al,* 2002)

Poor quality drugs do not meet official standards for strength, quality, purity, packaging and/or labelling (NAFDAC 2008). They may be legally registered innovator or generic products, or they could be counterfeits (i.e. deliberately mislabelled for identity, strength, or source). Whether counterfeit or unintentionally substandard, poor quality drugs result in serious health implications including treatment failure, adverse effects, increased morbidity, and mortality, development of resistance and wastage of resources (NAFDAC 2008). Recent reports have indicated that the proportion of substandard and counterfeit drugs has reached a disturbing proportion in many low-income countries (NAFDAC 2008).

The quality of praziquantel in terms of amount of active ingredient in various drug formulations from different manufacturers matters a lot in its efficacy in the treatment of schistosomiasis. Compositional variation between manufacturers, which is caused by variation in excipients, along with some batch-to-batch variation in the tablets from a single manufacturer has been reported from drug samples in the market; Low quality praziquantel may result in apparent low cure rate of the standard dose of the drug (Jial *et al*. 2007).

Aim and objectives

The aim of the study is to determine the quality of praziquantel tablets sold in patent medicine shops in Kano metropolis, with a view to determining the incidence of substandard formulations among them. The objectives of this research are

- To collect samples of praziquantel tablets sold in patent medicine shops of Kano metropolis by "on the spot sampling procedure " (Kolawole *et al*, 2002)
- To carry out quality assessment of the sample obtained using The British Pharmacopeia (1980) methods.

MATERIALS AND METHODS

The praziquantel tablets were obtained by on-the-spot sampling procedure as any other purchaser (Kolawole *et al*, 2002). Sample collection was done within Kano metropolis patent medicine shops. Twelve praziquantel cards were randomly purchased from randomly selected patent medicine shops in four of the eight local governments within the Kano metropolis. Out of the twelve cards of praziquantel tablets, ten were of different manufactures and two were from the same company, but were of different batch number.

All the samples were stored in the condition specified by their manufactures, and were assayed before their expiry dates.

Twenty tablets of praziquantel were grounded to powder and a quantity of the powder equivalent to 0.15g of praziquantel was added to 50ml of 0.1M sodium hydroxide. It was diluted with 100ml of distilled water and shaken for fifteen minutes, and sufficient distilled water was added to produce 200ml. It was mixed and filtered, and 10ml of the filtrate was diluted with distilled water to 100ml. Then 10ml of the resultant solution was added to 10ml of 0.1m sodium hydroxide, and diluted to 100ml with distilled water. The absorbance of the resulting solution was measured at the maximum of about 257nm. (British Pharmacopeia 1980)

RESULTS

The British pharmacopeia 1980 specification of active ingredient for praziquantel tablets is 95.0-105.0%. (British pharmacopeia, 1980)

TABLE 1: Quality assessment of praziquantel tablets sold in patent medicine shops in Kano metropolis.

Batch Number	No. of Months Before Expiry	Cost per card (₦)	Percentage content %	Remark
YOOO1533	4	300	86.40	Fail
340667	10	200	109.50	Fail
20161109	15	300	104.47	Pass
6178876	12	200	89.10	Fail
5526874	12	300	100.74	Pass
20170107	9	200	93.84	Fail
6178876	7	300	91.60	Fail
20161107	5	350	94.77	Fail
6278879	16	300	102.61	pass
YOOO1533	10	400	95.89	pass
20081109	7	400	99.41	Pass
5526874	13	300	96.80	pass

Number of months before expiry date and cost per card were not statistically significantly related to the quality of the praziquantel tablets ($p < 0.05$)

TABLE 2: Percentage of Praziquantel tablets that passed and failed the assay of active content.

NAME OF DRUG	PASS NUMBER (%)	FAIL NUMBER (%)	TOTAL
PRAZIQUANTEL TABLETS	6(50%)	6(50%)	12(100%)

Half (50%) of the praziquantel tablets have failed the quality assessment tests sig the British Pharmacopeia method

DISCUSSION

Praziquantel tablets were readily available in all the patent shops involved in the study. This shows that they are in high demand as patent medicine vendors commonly stock drugs that are regularly purchased.

Of the twelve various samples of praziquantel studied, only 6(50%) were found to be within acceptable limits of their specifications. This is comparable with similar finding in Lagos and Abuja, Nigeria; where only 48% of drugs samples were found to be within acceptable limits (Akunyili 2005). The result obtained for praziquantel tablets is slightly lower than that obtained for promethazine injection and tablets in the same Kano metropolis in which 54.5% of the injection and 62.5% of the tablets were found to be within acceptable limits of their specification (Wudil, 2005). This slight difference may be accounted for by the difference in stability of the two drugs under adverse storage conditions. Akunyuli (2005) also reported that about half (54%) of the drugs on sale at major outlets in Lagos are fake. This is in keeping with this study's finding on praziquantel.

Even though there was an observed percentage difference between quality of praziquantel and its cost, it was expected that there will be a statistically significant difference between the two groups of praziquantel, with more expensive praziquantel having better quality as a result of extra care put by their manufactures. However, this was not established by the study ($p > 0.05$). This may be because that irrespective of their quality at production, praziquantel tablets are exposed to the same adverse transportation, storage and marketing conditions in our hot and sunny environment.

The chi – square test showed no statistically significant difference in quality of praziquantel between those having eight month or less before expiry, and those having more than eight months before expiry date. This is possibly because effect on quality occurs early during shelving of drugs and when they are transported.

CONCLUSION

In conclusion, it has been found out by this study that only half (50%) of praziquantel tablets sold in patent medicine shops of Kano metropolis were of acceptable quality, having satisfied the quality specification.

This has attendant consequences on our health care system, and patients. It can also be concluded that the quality of the drugs assayed was independent of the cost of the drugs, and the number of month before expiry date. The poor quality of praziquantel tablets revealed by this study is mostly in keeping with previous studies conducted on drugs quality.

RECOMMENDATIONS

In view of the finding of this study, the following are recommended:-

- There is need for periodic sampling of drugs on sale at various outlets to determine the quality and factors that may account for poor quality.
- The patent medicine vendors need to be properly enlightened and educated about recommended storage conditions for various drugs.
- There should be emphasis on the need to test for compliance with established specifications of identify, potency, efficacy, purity, uniformity stability and safety at the various stages of design, development, research, manufacture, distribution and presentation of pharmaceutical products. And tests are to be performed by well-trained and experienced staff using well-maintained and validated analytical equipment.

Conflict of Interest

There are no conflicts of interest

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Authors' contribution

Gadanya M.A and Ahmad K.A contributed equally to the conception, data acquisition, analysis and report writing for this research.

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