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Peptic ulcer treatment evaluation in tertiary and secondary hospitals in north central Nigeria

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ABSTRACT

Despite the availability of evidence-based treatment guidelines for treating peptic ulcer disease with the possibility of complete resolution of the disease, the treatment of the ulcer disease is still plagued with sub-optimal outcomes with non-adherence to treatment guidelines being highlighted as part of the reasons for sub-optimal peptic ulcer disease outcomes. This study sought to assess peptic ulcer treatment patterns at one tertiary (Jos University Teaching Hospital) and one secondary (Plateau State Specialist Hospital) healthcare facilities in Jos, Plateau State North-Central Nigeria, and compared their adherence to WHO/local peptic ulcer treatment guidelines. The study employed a retrospective study design utilizing a designed study pro-forma used in extracting data relevant to the study objectives from the patients' medical records. The data were analyzed with the aid of Statistical Package for Social Sciences (SPSS) for windows version 16.0. Descriptive statistics were generated for treatment patterns while Chi-Square test set at 95% confidence interval was run for comparison of patterns between the two healthcare facilities. The results showed that females suffer more from PUD than males in both hospitals (75.8%/ 73.7% tertiary/ secondary healthcare facility respectively). Those 21- 30 years of age had the highest percentage of PUD. Proton pump inhibitors (PPIs) were the most prescribed category of peptic ulcer medications in both facilities (79.2%/ 92.3% tertiary/ secondary healthcare facility respectively). One-quarter of prescriptions compared to one-third of prescriptions in tertiary/secondary healthcare facilities respectively had prescriptions for *H. pylori* eradication. The mean cost per prescription of ulcer drugs in tertiary and secondary was NGN1512±957.035 and NGN2241±1607.789 respectively, and the difference was statistically significantly ($P<0.05$). Peptic ulcer treatment in both health care facilities did not adhere strictly to Standard Treatment Guidelines.

Key words: peptic ulcer, patients, standard treatment guidelines, hospitals, evaluation

INTRODUCTION

Peptic ulcer disease (PUD) is a clinical syndrome of the gastrointestinal tract which arises due to erosion of the gastric or duodenal mucosa by gastric acid and pepsin. Two types of PUD include duodenal and gastric ulcers. Mucosal erosion could be equal to or greater than 0.5 cm. This distinguishes from ordinary mucosal erosions which are superficial [1, 2]. A major causative factor (60% of gastric and up to 90% of duodenal ulcers) is chronic inflammation due to *Helicobacter pylori* that colonizes the antral mucosa [3, 4]. Another major cause is chronic use of non-steroidal anti-inflammatory drugs (NSAIDs). The global prevalence of ulcer is not the same. In the US, PUD causes an estimated 1 million hospitalizations and 6500 deaths per year. Duodenal ulcers dominate in Western populations while gastric ulcers are more frequent in Asia. In Western countries the prevalence of *Helicobacter pylori* infections roughly matches age (i.e., 20% at age 20, 30% at age 30, 80% at age 80 etc.). Prevalence is higher in third world countries where it is estimated at about 70% of the population, whereas developed countries show a maximum of 40% ratio. Overall, *H. pylori* infections show a worldwide decrease, more so in developed countries. Transmission is by food, through human saliva (such as from kissing or sharing food utensils) and contaminated groundwater [5]. In Nigeria, the prevalence of *H. pylori* infection has been put at 70-90% in adults

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and 82% in children within 5-9 years. The incidence of complications secondary to peptic ulcer increases with age and has been attributed to increased risk for bleeding associated with non-steroidal anti-inflammatory drugs (NSAIDs) use [1]. Despite lack of large population-based pediatric studies, the rate of peptic ulcer disease in childhood appear to be low, and is much less common in this age group than adults [6, 7].

There are various drugs for treating PUD with the clinical management of the disease guided by evidence-based treatment guidelines recommendations for optimal attainment of treatment outcomes. Yet PUD treatment is usually plagued with sub-optimal outcomes especially in developing nations. Poor adherence to treatment guidelines recommendation has been highlighted by many authors as a major reason for PUD treatment failure and this PUD treatment pattern might vary between tertiary and secondary healthcare facilities. The objectives of this study were to determine: prescription patterns of PUD, generic prescription of anti-ulcer drugs, and average treatment cost per prescription, and to compare the pattern to local/WHO standard treatment guidelines of peptic ulcer.

Drug use evaluation, sometimes referred to as drug utilization review, is a system of continuous, systematic, criteria-based drug evaluation that ensures the appropriate use of drugs. It is a method of obtaining information to identify problems related to drug use and if properly developed, it also provides a means of correcting the problem and thereby contributes to rational drug therapy. Drug use evaluation can assess the actual process of administration or dispensing of a medication (including appropriate indications, drug selection, dose, route of administration, duration of treatment and drug interactions) and also the outcomes of treatment (e.g. cured disease conditions or decreased levels of a clinical parameter).The objectives of drug use evaluation include ensuring that drug therapy meets current standards of care, controlling drug cost, preventing problems related to medication, evaluating the effectiveness of drug therapy, identification of areas of practice that require further education of practitioners. Retrospective studies include evaluation of indications, monitoring use of high-cost medicines, comparison of prescribing between physicians, cost to patient, adverse drug reactions, and drug interactions [8, 9].

MATERIALS AND METHODS

***Setting/ Study Design*:** The design employed for this study was a retrospective study that utilized a designed study pro-forma used to extract data from the patients' records relevant to study objectives. The two healthcare facilities – Jos University Teaching Hospital (Tertiary) and Plateau State Specialist Hospital(Secondary) used for this study are located in Jos metropolis, the capital of Plateau State. Plateau state is one of the 36 states in Nigeria. It is located in the North-Central geo-political region of Nigeria. There are three Tertiary and --- secondary healthcare facilities in Jos metropolis. The study sites randomly selected for this study are: ---- (tertiary facility) and --- (secondary facility).

***Inclusion and Exclusion Criteria*:** Relevant medical records of all patients treated for PUD disease at the two healthcare facilities from January 2010 to December 2012 were used for data extraction. However, pregnant patients and children below – of age were excluded from study.

Sample Size: There were 522 and 845 PUD-related cases from the Medical Records departments of tertiary and secondary hospitals respectively. Using Krejcie and Morgan, (1970) sample size determination Table, 219 and 266 PUD medication cards were randomly selected from tertiary and secondary hospitals respectively for the study.

Data collection: Random sampling was utilized to obtain required sample size in each hospital. Relevant patient/treatment data were extracted from patients' records using a study pro-forma consisting of patients' demography, prescription pattern, and cost of medications. Patients' demography extracted included age, gender, occupation, and diagnosis. Prescription pattern information extracted included: number of drugs prescribed, drug doses, generic prescription, route of administration, fixed dose combinations of drugs, and duration of drug medication per encounter.

***Ethical Clearance*:** The study was conducted after obtaining permission from the Institutional Ethics Committee of the two hospitals, and from the departments where the research was carried out. All Ethical issues pertaining to the study was taken into consideration.

Data Analysis: Data analysis was done using Statistical Package for Social Sciences (SPSS) for windows version 16.0 (SPSS Inc, Chicago IL) Descriptive statistics (frequency, percentage, means) were generated for treatment patterns and cost of medications per prescription. Chi-Square test set at 95% confidence interval was run to compare these measures between the two facilities. Guidelines criteria related to indication, dosage,

and combination were used to determine if prescription comply with treatment guidelines or not. The results of the study were in tables and text.

RESULTS

Demographics of patients: Demographic characteristics of study participants are shown in Table 1. Three-quarters of patients with PUD in both healthcare facilities were females (75.8% and 73.7%, tertiary and secondary healthcare facility respectively). About one-third of patients with PUD in both hospitals were housewives which was the highest frequency compared to other occupational subgroups (28.3% and 33.8%, tertiary and secondary healthcare facility respectively). More than half of the patients with PUD in both study sites were within 20 – 40 years of age (58.5% and 55.6%, tertiary and secondary healthcare facility respectively). About 4 out of every 10 patients with PUD had other co-morbid conditions in the study sites (35.2% and 38.7%, tertiary and secondary healthcare facility respectively).

Prescription pattern: Results for prescription pattern for PUD management in the study sites are shown in Table 2. Proton pump inhibitors were the most prescribed ulcer healing drugs category with the utilization frequency more in tertiary compared to secondary healthcare facilities (91.3% and 74.8%, tertiary and secondary healthcare facility respectively). The utilization prevalence of ulcer healing medications varied in the two healthcare facilities with statistical significance ($P = 0.000$). In both centers omeprazole was most utilized proton pump inhibitor (65.95 and 62.7%, tertiary and secondary healthcare facility respectively). The use of injectable anti-ulcers was less than 1 out of every 100 encounters (0.25% and 0.8%, tertiary and secondary healthcare facility respectively). Generic prescription was high in tertiary healthcare facility compared to secondary healthcare facility and the difference was statistically significant ($P = 0.000$). For example, more than 6 out of every 10 (64.8%) anti-ulcer prescriptions in tertiary healthcare facility utilized generic names (64.8%) while about 6 out of every 10 prescriptions for anti-ulcers utilized proprietary names (57.9%). Antacid utilization in both study centers was high as about 7 out of every 10 encounters had antacid prescription (67.1% and 68.4%, tertiary and secondary healthcare facility respectively). The average number of anti-ulcer medications per prescription in both centers was 2 (2.25 and 2.22, tertiary and secondary healthcare facility respectively).

Adherence to PUD treatment guidelines: Using guidelines criteria for anti-ulcer prescription there were a number of inappropriate prescriptions (Table 3). Dosage regiment for PUD appropriateness was poor in secondary healthcare facility compared to tertiary healthcare facility; as more than half of PUD dosage regiment in secondary healthcare facility was adjudged inappropriate and this was statistically significant compared to tertiary healthcare dosage regiment appropriateness ($P = 0.000$). However, appropriateness of regiment for eradication of *H pylori* was higher in secondary healthcare facility compared to tertiary healthcare facility ($P = 0.003$).

DISCUSSION

Medicines are essential tools in the management of diseases and ailments. They are cost-effective tools in health care delivery and crucial elements of health systems. For the medicines to be useful to the patients, it must be safe, efficacious and affordable, and the user must adhere to the dosage regimen [10, 11]. This study was undertaken at two major health care facilities providing health care needs to the generality of persons in the study area.

The demographic characteristics of the patients revealed that females suffer more from peptic ulcer disease (PUD) than males in both hospitals. This is different from what some researchers got as their male to female ratio: Dong *et al* [12], 3.95:1, Rosenstock and Jorgensen [13], 2.2:1, and Kurata *et al*, [14] 1:1. Peptic ulcer disease is a worldwide common disease, but the incidence of peptic ulcer disease in different countries and regions is obviously different. This may be the reason for variation in the ratio. The group of patients that suffered most from PUD in both health care facilities was house wives. This has contributed to high female ratio in PUD because a lot of them are not educated, not empowered economically and may suffer from lack of proper sanitation, of safe drinking water, and of basic hygiene, as well as poor diets and overcrowding, all play a role in determining the overall prevalence of PUD [5,12].

The age groups between 21- 40 years had the highest percentage of PUD patients in both hospitals. This could be attributed to the hyperactivity and exposure to stress of this age group. Sharma *et al* [15] found out that peptic ulcer disease is a significant cause of morbidity in urban population of Nepal with more prevalent of erosive diseases in productive age group (20-49 years). Also, Dong *et al* [12] reported that peptic ulcer disease in Hunan and Guangdong provinces in China occurred most in patients between 20 and 50 years old, which was similar to the results of the reports from India. Ramakrishnan and Salinas [16] reported that 70 per cent of PUD patients in United States are between the ages of 25 and 64 years. The above findings agree with the results.

In the paediatrics, Guariso and Gasparetto, [17] reported that PUD in children is worldwide with an estimated frequency of 8.1 and 17.4% in Europe and US respectively. The result from the two health care facilities showed that 1.6 (16 -17 years) and 5% (12 -17 years) respectively in secondary and tertiary were children. Some workers have reported the low prevalence of PUD in children [2, 7]. Kato *et al* reported that gastric and duodenal ulcers in children (10 -16 years) were linked to *H. pylori* infection while those of 9 years and below were not [18]. Because of the different factors surrounding the cause of PUD one cannot categorically say that PUD is more prevalent in the elderly than children or vice versa. In the elderly, however, it is likely infection can disappear as the stomach's mucosa becomes increasingly atrophic and inhospitable to colonization. The proportion of acute infections that persist is not known, but several studies that followed the natural history in populations have reported apparent spontaneous elimination. This is apparent from the results obtained from the two hospitals on the percentage of elderly persons with PUD. It is also very important to state here that apart from the house wives the other groups that also suffered more from PUD were students, self-employed, civil servants and the clergy in descending order. This may be as a result of emotional and psychological reaction to stress. Although the above groups are prone to stress, which can lead to stress ulcer, the emotional reaction of the clergies to stress may be far less than the other groups [19, 20]. Also, most of the clergies are males and they suffer less from PUD than the females in accordance with the result. Peptic ulcer disease, from the results, was co-morbid with other diseases. PUD may be the primary disease or secondary to the primary disease. In the two hospitals, 61.3% and 64.8% of the patients from secondary and tertiary respectively, were not associated with other co-morbid disease. Co-morbidity of PUD with other diseases such as hypertension, hepatitis, arthritis and other infections ultimately leads to polypharmacy. This affects the prognosis of the disease because lack of compliance and adherence may set in [21].

Most of the drugs prescribed for PUD belong to the class of proton pump inhibitors (PPIs) while the H_2 receptor antagonists (H_2 RAs) had the least. This shows that there is a tremendous shift from prescribing H_2RAs to PPIs and this is commendable. The reasons for this trend may not be farfetched, and it has to do with tradition, superiority, and cost: The PPIs are more superior to the H_2 RAs, and omeprazole is the traditional PPI and is more available and cheaper than the other PPIs [1, 21, 23]. These reasons made omeprazole to be the most prescribed drug in the management of PUD in the two health care facilities. None of the hospitals prescribed lansoprazole or bismuth which may be as a result of lack of awareness or non-availability. Standard treatment guidelines (STGs) for PUD are available from World Health Organization (WHO), Nigeria, Ghana, World Gastroenterology Organization (WGO), etc. The Federal Ministry of Health in Nigeria (2008) in collaboration with WHO came up with STGs for PUD. The guidelines specify that PUD with *H. pylori* involvement would require the following drug treatment: triple therapy with metronidazole 400 mg orally every 8 hours for 7 days, amoxicillin 500 mg orally every 8 hours for 7 days, and omeprazole 20 mg orally every 12 hours for 7 days. Or clarithromycin 500 mg orally every 12 hours for 7 days, amoxicillin 1 g orally every 12 hours for 7 days, and omeprazole 20 mg orally every 12 hours for 7 days.

The Republic of Ghana, Ministry of Health in 2010 came up with the sixth edition of her STGs and gave a STGs for PUD with H. pylori involvement as follows: triple therapy with clarithromycin 500 mg orally every 12 hours for 7 days, amoxicillin 1 g orally every 12 hours for 7 days (or clarithromycin 500 mg orally every 12 hours for 7 days and metronidazole 400 mg every 12 hours for 7 days), and esomeprazole 20 mg orally every 12 hours for 7 days. Or clarithromycin 500 mg orally every 12 hours for 7 days, amoxicillin 1 g orally every 12 hours for 7 days (or amoxicillin 500 mg orally every 8 hours for 7 days and metronidazole 400 mg every 8 hours for 7 days), and omeprazole 20 mg orally every 12 hours for 7 days. Or clarithromycin 500 mg orally every 12 hours for 7 days, amoxicillin 1 g orally every 12 hours for 7 days (or clarithromycin 500 mg orally every 12 hours for 7 days and metronidazole 400 mg every 12 hours for 7 days), and rabeprazole 20 mg orally every 12 hours for 7 days [25].

Other researchers such as Harmon and Peura came up with other regimens in 2010: first line treatment involving triple therapy with a PPI, amoxicillin 1 g BID, and clarithromycin 500 mg BID for 10 -14 days. Or sequential therapy which can serve as first line treatment where macrolide resistance is common: a PPI and amoxicillin 1 g BID for 5 days followed by PPI and clarithromycin 500 mg BID, tinidazole 500 mg BID for 5 days. Or where there is treatment failure, a quadruple therapy of a PPI, bismuth 525 mg QID, metronidazole 500 mg QID, tetracycline 500 mg QID for 14 days [3].

The drug treatment showed that per cent individual drugs prescribed from the two health care facilities: omeprazole (tertiary, 65.9% and secondary,

62.7%), esomeprazole (tertiary, 12.3% and secondary, 6%), rabeprazole (tertiary, 7.7% and secondary, 7.9%), pantoprazole (tertiary, 6.4% and secondary, 2.6%), ranitidine (tertiary, 1.4% and secondary, 1.5%), and cimetidine (tertiary, 2.3% and secondary, 3.4%). Among the prescribed PPIs, omeprazole had the highest percentage. When one considers therapeutic efficacy, the evidence suggests that all PPIs have comparable efficacy in treatment of peptic ulcer disease using standard doses and are superior to H_2-receptor antagonists. PPIs have their greatest effect when given before a meal [6].

Peptic ulcer disease treatment evaluation involves drug utilization review in peptic ulcer disease. Drug utilization is defined by the World Health Organization (WHO) as the marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social, and economic consequences. The ultimate purposes of drug utilization studies are to contribute to the optimal quality of drug therapy by identifying, documenting and analyzing problems in drug utilization and monitoring the consequences of interventions [8, 9]. Drug utilization studies are continuing programs that review, analyze and interpret the pattern of drug use against pre-determined standards [26]. The pre-determined standard may include adherence to essential drug list or local formulary, adherence to standard treatment guidelines and cost-effective prescribing. We can say that drug utilization in PUD involves evaluation of rational prescribing and monitoring of drug use outcomes in peptic ulcer disease treatment. The mean value of cost per prescription of ulcer drugs in secondary was significantly higher ($P<0.05$) than that of tertiary. This is because prescribers in tertiary prescribed more generic than those of PSSH. From these results, affordability is a serious concern here because the students, house wives, and other low income earners might not be able to pay for the treatment of PUD. This situation could cause lack of adherence and tolerance leading to complication and poor prognosis in the management of PUD. If developed countries are increasingly advocating for maximum return in health through economic evaluation of therapy, developing countries should do more because of our limited resources and high poverty level [27]. In the management of PUD, analgesics/anti-inflammatory drugs are sometime co-prescribed with PPIs, H_2RAs and antacids in co-morbid situations. Majority of the prescribers in both health care facilities did not prescribe analgesics/anti-inflammatory drugs (tertiary, 85.4% and secondary, 76.7%). This shows that there was rational prescription of analgesics/anti-inflammatory drugs in both health care facilities. The use of selective COX-2 inhibitors seems to have decreased after the cardiac adverse effects which were observed with these drugs [26]. The antacid was either co-prescribed with the other class of drugs or used for symptomatic treatment prior to confirming the diagnosis of PUD (Nigeria STGs, 2008). The Standard Treatment Guidelines of Nigeria, (2008) in collaboration with World Health Organization (WHO), and Ghana Standard Treatment Guidelines ,(2010) specify that antacid suspensions especially mist magnesium trisilicate be given 15 ml every eight hours for the management of dyspepsia associated with PUD [8, 24, 25]. Majority of the prescribers in both health care facilities did not follow these guidelines.

Limitation of the Study

There was no systematic monitoring of treatment outcomes because it is not a prospective study. Incomplete dosage regimen and information from patients' treatment cards unlike from their prescription sheets or folders. Nonetheless, this is first work in this local setting to investigate PUD prescription pattern and thus, results gotten can serve as reference point for more detailed research activity on this topic.

CONCLUSION

Peptic ulcer disease treatment prescribing patterns were found not be satisfactory in both health care facilities. Majority of the prescribers did not prescribe in accordance with Standard Treatment Guidelines. Generic prescribing was not adequate. The average number of drugs per prescription was satisfactory. The cost per prescription of peptic ulcer drugs was moderately satisfactory. There is need for continuous training of clinicians so that benefits from evidence-based treatment guidelines on treating PUD can be translated to patients with PUD in the local setting.

RECOMMENDATION

On the basis of the findings, there is the need to create awareness among health care providers on the importance of using Standard Treatment Guidelines and rational prescribing in the management of peptic ulcer disease. It is imperative to create public awareness on causes and dangers of peptic ulcer disease because most of the PUD patients were low class people, and those that are prone to stress. It is very important to follow and monitor the prescribing patterns of health care providers after presenting the findings to them and to evaluate drug utilization and treatment outcomes thereafter.

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Table 1: Demography of study participants

Variable	Tertiary (n=219)	Secondary (n=266)
Sex		
Male	53 (24.2)	70 (26.3)
Female	166 (75.8)	196 (73.7)
Age category (in years)		
<11 -20	29 (13.2)	19 (7.1)
21-30	84 (38.4)	93 (35)
31-40	44 (20.1)	55 (20.6)
41-50	35 (16.0)	44 (16.6)
51-60	20 (9.2)	28 (10.6)
≥60	7 (3.3)	27 (10.1)
Employment status		
Civil servant	23 (10.5)	41 (15.4)
House wife	62 (28.3)	90 (33.8)
Student	53 (24.2)	51 (19.2)
Self-employed	57 (26.0)	53 (19.9)
Applicant	6 (2.7)	7 (2.6)
Clergy	2 (0.9)	1 (0.4)
Public servant	4 (1.8)	4 (1.5)
Farmers	6 (2.7)	12 (4.5)
Retiree	0(0)	4 (1.5)
Not indicated	6 (2.7)	3 (1.1)
Co-morbidity status		
Without co-morbid condition	142 (64.8)	163 (61.3)
With co-morbid condition	77 (35.2)	103 (38.7)

Table 2: Drug utilization review parameters

Parameters	Tertiary Percentage	Secondary Percentage	Chi-square value	*P* Value
Prescribed PUD drugs				
Proton pump inhibitors (PPIs)	200 (91.3)	199 (74.8)	25.664	0.000
H2 receptor antagonists (H2RAs)	8 (3.7)	13 (4.9)		
Fixed dose combinations	10 (4.6)	52 (19.5)		
Injections	1 (0.5)	2 (0.8)		
Drug name				
Generic	142 (64.8)	112 (42.1)	24.889	0.000
Propriety	77 (35.2)	154 (57.9)		
Antacid				
Appropriate	147 (67.1)	182 (68.4)	0.093	0.761
Not prescribed	72 (32.9)	84 (31.6)		
Analgesic/anti-inflammatory drugs				
Analgesics	21 (9.6)	55 (20.3)	11.798	0.003
Analgesics/anti-inflammatory	11 (5)	8 (3)		
Not prescribed	187 (85.4)	204 (76.7)		
Mean number of drugs on prescription				
Mean number of anti-ulcer drugs	2.247±0.858	2.218±0.977		
Mean number of non-ulcer drugs	1.89±1.038	1.97±1.038		

Table 3: Adherence to treatment guidelines

Parameters	Tertiary Percentage	Secondary Percentage	Chi-square value	*P* Value
Antacid				
Appropriate	13 (5.9)	13 (4.9)	0.415	0.813
Inappropriate	134 (61.2)	169 (63.5)		
Not prescribed	72 (32.9)	84 (31.6)		
Dosage regimen of PUD treatment				
Appropriate	183 **(83.4)**	119 (44.7)	77.06	0.000
Inappropriate	36(16.6)	147 (55.3)		
***H. pylori* treatment regimen**				
Appropriate	64 (29.1)	**108 (40.6)**	11.925	0.003
Inappropriate	30 (13.8)	48 (18)		
Not treated	125 (57.1)	110 (41.4)		

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