



## Non-steroidal Anti-inflammatory Drugs Misuse among Newly Diagnosed and Resurged Peptic Ulcer Patients in Maiduguri-City, Nigeria

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### Authors' contributions

This work was carried out in collaboration between the authors JDO and TSJ. Author JDO designed the study, wrote the protocol, performed the data analyses and wrote the first draft of the manuscript. Author TSJ managed the literature searches and data collection. Author TSJ has read and approved the final manuscript.

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### ABSTRACT

**Background:** Many patients are often unaware of the risks posed by indiscriminate use of non-steroidal anti-inflammatory drugs (NSAIDs) in aggravating peptic ulcer disease (PUD) related discomfort or delaying its healing.

**Aim:** The objectives of the study are to investigate the extent of NSAIDs consumption among newly diagnosed and resurged ulcer cases, identify the various types and forms of NSAIDs commonly misuse as well as evaluate their possible potentials risks in patients with fresh and resurged ulcer pains.

**Methods:** NSAIDs use were assessed through prospective study in 237 patients (114 males and 123 females) using questionnaire. All patients were assessed for NSAIDs consumption, duration of use, types of NSAIDs, their combinations and ulcerogenic potentials.

**Results:** The proportions of NSAIDs users were 0.52 (n=123; 95% CI=0.46-0.58) comprising 45.6%

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(proportion=0.47, 95% CI= 0.41-0.53) and 55.1% (proportion= 0.55; 95% CI= 0.49-0.61) of new and resurged PUD respectively. There was no gender variation in NSAIDs consumption in the two groups. However, NSAIDs use was higher in female below 30 years than men though this trend was reversed in those above 50 years. Also, 43.0% (n=104) used NSAIDs containing single agents while 8.0% (n=19) used combinations of NSAIDs. Misused NSAIDs in their various formulated oral dosage forms are ibuprofen (19.0%), piroxicam (3.4%), diclofenac (14.8%), naproxen (1.11%), acetylsalicylic acid (3.0%), and ketoprofen (1.3%). The duration of NSAID used ranged below 1 year (8.9%) to >10years (1.9%) with the result being skewed toward low frequency of higher duration in year.

**Conclusion:** Several PUD patients were using NSAIDs indiscriminately and lacking the knowledge of their ulcerogenic potentials. This underscores the need for patients' drug therapy care, education and counseling, and monitoring in order to limit hospitalization or physician visits, morbidity or mortality and drug therapy problems while adherence with therapeutic guiding principles for NSAIDs use in PUD patients is to be encouraged.

*Keywords: Peptic ulcer disease (PUD); Non-steroidal anti-inflammatory drugs; Fresh and resurged Ulcer; Ibuprofen; NSAIDs users; Ulcerogenic potentials.*

## 1. INTRODUCTION

Peptic Ulcer Disease (PUD) is one of the gastrointestinal tract ailments with considerable morbidity and mortality rates that negatively affect the quality of life of patients. The ailment affect 5%-10% of the general population [1] with approximately 3-9 million diagnosed cases in the United States and a reported new cases of 200,000 to 400,000 each year [2], thereby making the condition a quality public health problems requiring attention in any given society.

Changes involving excessive secretion of acid and pepsin in the stomach, which result to an imbalance between the aggressive and defensive factors have been known as one of the pathophysiological basis for the disease [3]. Other contributing factors like stress, gastrinoma in Zollinger-Ellison syndrome and hereditary induced ulcer [4] are similarly reported. The association between factors like smoking cigarette, ageing, alcoholism, caffeine use and emotional factors and PUD may be significant [5]. There are also factors related to gender and geographic location that have been reported to influence the course of the disease [6]. The disease may be associated with seasonal variations since more PUD cases are observed during autumn and winter than during the summer times [7].

Peptic ulcer diseases may relapse. About 50% to 90% of patients with duodenal ulcer (DU) may have relapsed symptoms within one year of diagnosis, while the relapse rate for gastric ulcer is always lower [2]. Other PUD maybe refractory

and failing to heal or re-occur after 8-12 weeks of therapy [8] which is attributed to persistent or resistant *H. pylori* infection and several other risk factors including food, dietary habit, smoking, and alcohol consumptions etcetera [9]. Large ulcers may however cause impairment of healing, acid hyper-secretory states, impaired response to anti-secretory agent, co-morbid disease and emotional stress [10,11]. An unsuccessful treatment of Zollinger-Ellison-syndrome may also result to recurrent ulcers [11,12] which can develop at the same location as the previous one or at different sites [11]. Poor patient's compliance to medication, or resistance to secretory inhibition may account for resurging ulcer in some patients [13]. Some researchers have identified risk factors like smoking, alcoholism, ulcerogenic agents and age as the etiologies of persistent and worsening PUD [13] though revealed that 8 weeks still remains reasonable period to define refractory ulceration [14].

The morbidity and mortality of PUD vary from one region to another but these incidences are higher in gastric ulcer (GU) than in duodenal ulcer (DU) in Japan [15] although the lower morbidity and mortality rates in some quarters are attributed to higher hygiene standard and continued use of antibiotics [16]. An improved understanding of the course of the disease and its associated predisposing factors has led to declining mortality among people in some regions [6]. It is hoped that the application of these therapeutic principles will enhance similar outcomes in other regions with high PUD proportions.

*Helicobacter pylori*, a major etiological factor in the development of PUD which occurs in 90% cases of DU and 70% of GU patients [17,18] is also capable of causing relapse. People who regularly take NSAIDs; such as those with chronic conditions like arthritis, are five times more likely to develop peptic ulcers than people who do not take them [19]. Although NSAIDs occasional users can develop peptic ulcer at any age, the risk increases with the dose, frequency, type and combinations, duration of consumption, and the age of patient (60 and above at greater risk) [20]. Other identified risk factors of people in this category are gender (more women than men), family history of peptic ulcers and behavioral changes such as smoking, alcohol and corticosteroids use [21].

NSAIDs inhibit both COX-1 and COX-2 but it is the inhibition of COX-1 that is related to ulcer development. This is because COX 1 enzyme is involved in producing prostaglandin that protects the stomach lining from stomach acid and helps control bleeding [19]. Other factors that increase the incidence of NSAIDs induced PUD are prior history of abdominal problems (ulcer or bleeding), taking high doses of NSAIDs, using corticosteroids in addition to NSAIDs, having infection with *Helicobacter pylori* (*H. pylori*), using NSAIDs as daily medication or using blood thinners (anticoagulants) such as warfarin or antiplatelet medicines [21].

## 2. AIM AND OBJECTIVES

Many studies have focused on peptic ulcer as a disease but much attention is required on the extent to which patients understand the key risk factors associated with the disease. The objectives of the study are to investigate the extent of NSAIDs consumption among newly diagnosed and resurged ulcer cases, identify the various types and forms of NSAIDs commonly misuse and to evaluate their ulcerogenic potentials by PUD patients.

## 3. MATERIALS AND METHODS

The prospective study was carried out at General Out-Patient Department (GOPD) of University of Maiduguri Teaching Hospital, Maiduguri, Nigeria. Maiduguri-City lies between latitude 11.5° North and 13.5° East in the Sudan Savannah. The

hospital has over 500 bed capacity and runs several clinics including the gastrointestinal units.

A total of 237 patients comprising 114 males and 123 females were recruited to take part in the study. Informed consents were obtained and purposes of the research were clearly stated. Both cases of freshly diagnosed ulcer patients (defined as ulcer cases not exceeding three months of diagnosis) and those with resurged ulcer conditions (defined as ulcer cases that were previously healed over past times as well as chronic cases) were included in the study.

All patients were assessed for NSAIDs consumption, duration of use (in year), types of NSAIDs used, and the combination of NSAIDs in use that may be influencing the course of the disease. The demographic data and other relevant information of patients such as age and gender, occupation, education, family history, smoking and alcohol lifestyle were obtained from each patient's case note while structured questionnaires were used to assess the various risk factors associated with ulcer pains among PUD literate patients. For other categories of patients with low educational status and those with limited proficiency in reading and writing in English or others with language barriers, both oral interview and the services of interpreters were used to clarify and facilitate patient's understanding and responses. The patient's choices of option were based on their perceived condition. Convenient sampling method was used and all PUD related cases who visited the GOPD between the period of 5 months (December, 2010 to April, 2011) and who consented to take part were included. This period corresponded peak PUD episode in the region. Descriptive statistics were performed between two variables for fresh and resurged cases while proportions and odds were performed at 95% confidence interval using statistical package for social sciences (SPSS version 17).

## 4. RESULTS

The results of newly diagnosed and resurged ulcer cases assessed for age distribution, duration of diagnosis, NSAIDs users and non-users, NSAIDs types and distribution, age characteristics, duration of use and ulcerogenic potentials are presented in Tables 1-7.

**Table (1a): Showing the frequency distribution of age and gender of patients and (1b): Showing the frequency distribution of duration of diagnosis of PUD**

1a. Age and gender distribution of patients				1b. Duration of PUD diagnosis		
Age range (Years)	Male (%)	Female (%)	Male/Female (%)	Age (Years)	Frequency	Percentage (%)
0-10	0(0)	0(0)	0(0)	<1	111	46.8
11-20	1(0.9)	8(6.5)	9(7.3)	1-2	30	12.7
21-30	64(56.1)	75 (61)	139(58.6)	3-5	54	22.8
31-40	33(28.9)	20(16.3)	53(22.4)	6-10	30	12.7
41-50	9(7.9)	13(10.6)	22(9.3)	11-20	10	4.2
51-60	4(3.5)	5 (4.1)	9(7.3)	>20	2	0.8
61-70	1(0.9)	1(0.8)	2(0.8)	Total	237	100
>70	2(1.8)	1(0.8)	3(1.3)			
Total (%)	114(48.1)	123(51.9)	237(100)			

**Table 2. Frequency distributions of fresh and resurged PUD with respect to age**

Sex of patients	Ulcer cases	Rank of age (Yr)							
		11-20	21-30	31-40	41-50	51-60	61-70	71-80	Total
Male	Fresh	1	24	7	5	0	0	0	37
	resurged	0	40	26	4	4	1	2	77
	Total	1 (0.9)	64(56.1)	33(28.9)	9 (7.9)	4 (3.5)	1 (0.9)	2(1.8)	114 (100)
Female	Fresh	4	34	7	4	2	1	0	52
	resurged	4	41	13	9	3	0	1	71
	Total	8 (6.5)	75(61)	20(16.2)	13(10.6)	5(4.1)	1(0.8)	1(0.8)	123 (100)
Group total		9(3.8)	139(58.6)	53(22.4)	22(9.3)	9(3.8)	2(0.8)	3(1.3)	237(100)

**Table 3. Distribution of NSAIDs users and nonusers among PUD patients**

Patient's habit	Fresh cases	Resurged cases	Total	Percentage
NSAIDs users	42	81	123	51.9%
NSAIDs nonusers	48	66	114	48.1%
Total	90	147	237	100%
Odds (users)	0.88	1.23	1.08	-
Proportion (users)	0.47	0.55	0.52	-
Percentage users (%)	47.0%	55.0%	52.0%	-

**Table 4. Types of NSAIDs used**

NSAIDs types	No. of users	% among NSAIDs users (n=123)	% among study population (n=237)
Diclofenac Na or K	35	28.5	14.8
Piroxicam	8	6.5	3.4
Ibuprofen	45	36.6	19.0
Ketoprofen	3	2.4	1.3
Naproxen	4	3.3	1.7
acetyl salicylic acid	7	5.7	3.0
Ibuprofen/diclofenac	8	6.5	3.4
Ibuprofen/piroxicam	4	3.3	1.7
others	9	7.3	3.8
Total	123	100%	52%

**Table 5. NSAIDs users among resurged and new ulcer cases with respect to age**

Age class	No. of users with fresh PUD	No. of users with resurged PUD	Total	% users in the population
<20 years	2	1	3	1.3
20-40 years	34	65	99	41.8
40-60 years	6	12	18	7.6
60-80 years	0	3	3	1.3
>80 years	0	0	0	0
Total	42	81	123	51.9%

**Table 6. Duration of use of NSAIDs among ulcer patients**

NSAIDs agents	Duration of use of agents by patients						Total
	<1 Yr	1-3 yrs	4-6 yrs	7-10 yrs	>10 yrs	Unknown duration	
Diclofenac	6	7	6	1	1	14	35
Piroxicam	-	-	2	1	-	5	8
Ibuprofen	8	10	4	6	2	15	45
Ketoprofen	1	2	-	-	-	0	3
Naproxen	-	1	-	-	-	3	4
Acetyl salicylic acid	-	1	1	2	-	3	7
Ibuprofen/diclofenac	2	1	-	1	-	4	8
Ibuprofen/piroxicam	-	-	-	1	1	2	4
Others	4	-	1	-	-	4	9
Total (%)	21(8.9)	22 (9.3)	14 (5.9)	12 (5.1)	4(1.9)	51(21.5)	123 (51.9)

**Table 7. Ulcerogenic potentials of NSAIDs used by patients**

Ulcerogenic potentials	NSAID agents	Nos & % of users
Low ulcerogenic risk	Ibuprofen	45 (19.0)
Intermediate ulcerogenic risk	Piroxicam, naproxen, ketoprofen and diclofenac	50 (21.1)
Severe ulcerogenic risk	ASA, combined low/intermediate risk and 2 agents with intermediate risk	28 (11.8)

**4.1 Age and Gender Characteristic of Patients**

The age distribution of PUD patients (Table 1a) is skewed toward low frequency of higher age, with the mean and standard deviation of 31.50±10.20 years for all subjects. The age range for female and male patients ranges from 18-80 years and 20-73 years respectively. The highest incidence occurred in young male and female adults (Table 1a). Ulcer cases decline in those above 50 years. However, both genders showed similar distribution pattern but the mean and standard deviation for the female was 30.7±10.8 years while that of the male was 32.4±9.4 years. The ages of PUD onset among subjects are 20 and 18 years for male and female respectively.

PUD cases were observed higher in female of all demographic age strata than male of similar

pairs except in those who are between 31-40 years (Table 1a). However, the variations were not found to be significant (P>0.05).

The frequency distribution of the diagnoses of ulcer pains (Table 1b) showed that 46.8% cases of new and resurged ulcer pains occurred within one year of diagnosis and decreases thereafter. The least occurred in those who has had ulcer above 20 years.

**4.2 Ulcer Characteristics and Age Distribution**

The peak PUD incidences in both fresh and resurged ulcer cases for both genders occurred within 20-40 years. This accounted for 81% of the population. Beyond this age, the distribution decreased significantly (Table 2). Above 50 years, no fresh cases of PUD pains were observed among male subjects. In contrast to

this, newly diagnosed ulcer cases were observed to decrease among female subjects after 30 years of age. The distribution patterns for resurged ulcer in both genders are similar to the pattern observed in newly diagnosed cases. However, resurged PUD cases were higher in both genders than new cases.

### 4.3 NSAIDs Users and Nonusers

The NSAIDs users and nonusers in both cases of ulcer accounted for 51.2% and 48.1% respectively (Table 3). Among the population of patients with fresh ulcer cases (n=90), 42.7% are NSAIDs users giving rise to 0.88 odds value. The corresponding values for resurged cases (n=147) was 55.0% giving rise to 1.08 odds value. The proportion of NSAIDs users who experiences discomfort/pains were found to be 0.52 (95% CI=0.46-0.58).

### 4.4 NSAIDs Types

When the various NSAIDs types were assessed among the NSAIDs users (Table 4), the result indicated that ibuprofen was the commonly used singly formulated NSAIDs accounting for about 37% of the users' population (19.0% of the entire population) and ketoprofen use (2.4%) was the least. Among the combined NSAIDs, ibuprofen with diclofenac accounted for 6.5% among users, which is equivalent to 3.4% of the entire population. Ibuprofen/piroxicam combinations are used in 3.3% proportion of NSAIDs users' population (equivalent to 1.7% of the entire population). In general, 43.0% (n=104) used NSAIDs containing single agents while 8.0% (n=19) used combinations of NSAIDs (Table 4).

### 4.5 NSAIDs Use and Age of Patients

The results of NSAIDs use with respect to age of patients (Table 5) showed peak users to correspond to young adults in their third to fourth decades of life (20-40 years) accounting for 41.8% (99/237; 95% CI: 0.36-0.48) of the entire population. NSAIDs use in those normally considered at high risk for developing PUD (above 65 years) were in minor proportion (1.3%; n=3). However, above 40 years the proportion of NSAIDs users accounted for 2.5% and 6.3% in those with new and resurged PUD cases respectively.

### 4.6 Duration of NSAIDs Used by Patients

Patients have used NSAIDs at varying durations (Table 6). The longest duration of use are found

in about 1.9% (n=4) patients who have used NSAIDs for more than 10 years. About 8.9%, 9.3%, 5.9% and 5.1% of the patients reported that they have been regular users of NSAIDs for below 1 year, 1-3 years, 4-6 years and 7-10 years respectively.

### 4.7 Ulcerative Potential of NSAIDs

The evaluation of NSAIDs used by patients with their ulcerative potentials (Table 7) showed that agents classified as low ulcerative agents were used in 19.0% proportion. Intermediate and severe ulcerogenic agents occurred in 21.1 and 11.8% proportion respectively.

## 5. DISCUSSION

Peptic ulcer disease affects all people of various age strata in any given society. In this study the onsets of the disease are nearly at equal ages for male and female. Many authors have reported similar age range as people with high risk of developing PUD [22,23]. However, no case of ulcer was recorded in children below 10 years which is also consistent with the finding of other researchers [24]. In contrast to this, ulcer incidences were reported in those below 19 years in the magnitude of 8.1% in Europe and 17.4% in US [25] which has been attributed to *H. pylori* infection and NSAIDs use as well as eating food that stimulate the production of gastric acid, pepsin and severe underlying illness. The older people are naturally prone to ulcer due to increased usage of non-steroidal anti-inflammatory drugs and changes in stomach lining that turns fragile with increasing age [26].

The observed PUD onset age of 20 and 18 years for male and female respectively are lower than the 30-50 years commonly reported though lower age of this have been reported in other regions [27]. However, wide age range among female population with PUD or PUD related ailments (18-80 years) may be suggestive of the existence of the two forms of the disease as well as variation in other predisposing factors contributing to the course of the disease in the region.

The higher incidences of PUD in female of all age strata than men have similarly been demonstrated in many studies [16,23,28] and consistent with the previous report in the region [29]. However, the results of some authors are not in agreement with this finding [30] but recent trends in USA and UK indicated equal

proportions among the two genders [31]. Ohieku and Bashir [29] previously reported that there is socio-economic factors that favor the early health intervention seeking behavior of women in public hospital compare to men. Most men may prefer visiting the community health centers in a bit to avoid prime time wastage or lost in vital wage hours. The decline in ulcer cases in those above 50 years is in contrast to peak ulcer incidence of between 50-70 years reported in some regions [2,32].

Resurged PUD cases were higher in both genders than new cases indicating that there may be both health and patient related factors associated with management failure influencing this observed pattern. Other workers have similarly reported patterns that are consistent with this study [33].

Majority of ulcer diagnosis or hospital visits occurred within one year which possibly suggested that ulcer cases may be on the increase in the last few years in the region. Although the reason for this observed pattern is unknown and requires further investigation, but most patients with long standing ulcer may have declined in their hospital visits due to an improved knowledge of the disease and self-care.

Resurged ulcer was higher than fresh cases in both gender (Table 2) because most PUD can resurged. In our study, we found interplay of several factors including NSAID use, long duration of fast, smoking, stress, alcohol intake, and poor nutritional habits as the cause of this observed pattern. There are also cases of non-compliance to medication, continued and unnecessary use of NSAID and possibly resistant *H. Pylori* infection eradication or incomplete *H. pylori* medication as reasons for higher resurged cases than fresh ones. These factors have similarly been identified by other researchers as capable of impairing ulcer healing and causing resurgence [33]. Additionally, most PUD cases are known to occur and resurge during autumn and winter than during summer [23]. These seasons corresponded with the coldest and warmest periods in the tropical area and falls within this study periods (i.e. December to April) although 8-12 weeks after therapy may remain a reasonable period for an ulcer to resurge [14].

The proportion of NSAIDs users was higher in the resurged group than the fresh group. This is

contrary to expectation since it implies that the duration of the disease does not significantly impact knowledge to patient regarding risk factors of the disease. The high rate of NSAIDs use may have contributed along with other factors to the course of the disease in both conditions, since their continued use is associated with reduction of mucosal prostaglandin and subsequent gastric mucosa damage [34]. Many authors have similarly reported the influence of ulcer pains/discomfort arising from NSAIDs use [32,33,35]. This present study found patient's poor knowledge of effects of NSAIDs on PUD and their lack of disclosure of their NSAIDs consumption habits as responsible for continued use of these ulcerogenic drugs.

In this study, majority of patients used single agent containing NSAIDs and nearly one-tenth of the population used more than one agent. Many NSAIDs when used alone have the potential for negatively impacting the course of ulcer cases. Ibuprofen for example was the commonly used agent accounting for nearly one-fifth cases because the agent is widely available and cheap. It is also an agent associated with low ulcerogenic potentials which possibly account for its wide range of utilization by many ulcer patients. However, the combination of two or more NSAIDs or when ibuprofen is combined with other agents can lead to an increased risk.

The reasons for the high rates of NSAIDs use among PUD patients may be attributable to the fact that the products are over-the-counter and are hawked by several unskilled people. Many patients also consult multiple physicians thereby increasing the chances for poly-pharmacy. Other reasons include the unavailability of patients' medication records or their poor retrieval systems, poor counseling, co-morbid diseases and the lack of knowledge by patients of impact of NSAIDs use in influencing the course of their disease conditions.

The few proportion (n=3) of the geriatric population that consume NSAIDs in this study may be at increased risk of ulcer related discomfort. This is because advancement in age is considered as risk factor for ulcer development in adults, as well as being prone to NSAIDs gastrointestinal damages. Some guidelines have recommended the use of COX agents rather than NSAIDs in patients at high risk for a serious GI complication from NSAID therapy. COX agents are also recommended for those with advanced age (> 65-70 years) or those with

previous clinical history (within 5 years) of a gastro-duodenal ulcer or perforation or GI bleed. Similarly, PUD patient with current diagnosis of Barrett's esophagus and long-term treatment of chronic inflammatory conditions such as rheumatoid or severe, persistent, inflammatory osteoarthritis also require COX agents. It is hoped that when both practitioners and patients observed these guidelines, incidences of ulcer related discomfort will decrease in the region.

Although this present study did not find significant correlation in NSAIDs use with age, these results however, may have indicated that the combined risk of NSAIDs use and ageing are potential risks for increase in PUD pains.

NSAIDs use ranges from less than one year to more than ten years. Majority of patients in this study have used NSAIDs for less than one year. Some authors reported that NSAIDs use is capable of causing gastric and duodenal lesions in patients who took NSAIDs for less than 3 months, whereas patients with a longer duration of therapy tend to have more lesions in the small bowel and colon [35]. This underscore the need for all PUD patients to be educated on various risk factors associated with the ailment.

### 5.1 Classification of NSAIDs Ulcerogenic Potentials

The NSAIDs ulcerogenic potentials are classified as either low, intermediate and severe. In this present study, agents with low ulcerogenic potentials were used by 19.0% of NSAIDs users while those with intermediate and severe ulcerogenic potentials comprise of about 21.1% and 11.8% respectively (Table 7). These results indicated that about 63.5% of NSAIDs users who complained of ulcer related pains may be having NSAIDs use contributing to such pains.

## 6. CONCLUSION

NSAIDs use may constitute one of the prime risk factors associated with new and resurged cases of PUD. The use of various NSAIDs in addition to other major factors like *Helicobacter pylori* may be influencing the high incidence of new cases of PUD as well as resurged cases in the region. Patient education on ulcer triggers especially as related to medication use is required to ameliorate the poor understanding and NSAIDs use behaviors of many patients.

## 7. RECOMMENDATIONS

It is recommended that all PUD patients be educated on risk factors associated with the disease particularly as it relate to NSAIDs consumption. Patients should be counseled on effect of continued NSAIDs consumptions and be encouraged to seek medical assistance from qualified pharmacists as well as other health personnel. Guidelines relating to NSAIDs use among PUD patients should be followed.

## CONSENT

Informed consent was obtained from the participants.

## ETHICAL APPROVAL

Ethical approval was sought and obtained from the research and ethics committee of the University of Maiduguri Teaching Hospital.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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