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Assessment of Gastrointestinal and Renal Side Effects Associated with Long-Term Use of Over-the-Counter Painkiller Tablets. A Cross-Sectional Clinical Study

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ABSTRACT

Background: Over-the-counter (OTC) painkiller tablets are commonly used for self-medication without clinical supervision. Long-term or frequent use, particularly of non-steroidal anti-inflammatory drugs (NSAIDs), is associated with gastrointestinal (GI) and renal adverse effects. In populations with high rates of unsupervised medication use, understanding these risks is essential.

Objectives: To assess the prevalence of GI and renal side effects among adults using OTC painkillers for more than three months and to examine the relationship between analgesic use patterns and adverse outcomes.

Methods: A cross-sectional clinical study was conducted among 100 adults with OTC painkiller use exceeding three months. Structured interviews documented the type, duration, and frequency of analgesic intake. Clinical and laboratory assessments, including serum creatinine, blood urea nitrogen (BUN), estimated glomerular filtration rate (eGFR), urinalysis, and stool occult blood testing, were performed to detect adverse effects. Statistical analyses evaluated associations between analgesic use patterns and complications.

Results: Participants had a mean age of 38.6 ± 12.4 years, and 57% were female. Paracetamol was the most frequently used analgesic (62%), followed by ibuprofen (48%) and diclofenac (31%). GI symptoms occurred in 68% of users, with dyspepsia (42%) and abdominal pain (36%) being the most common. Renal abnormalities were observed in 34% of participants, including elevated serum creatinine (19%) and reduced eGFR (17%). Longer duration and higher frequency of use were significantly associated with both GI and renal complications ($p < 0.05$).

Conclusion: Long-term OTC painkiller use, especially NSAIDs, is strongly associated with gastrointestinal and renal adverse effects. Public education, responsible self-medication, and periodic clinical monitoring are essential to minimize preventable harm.

Keywords: Analgesics, NSAIDs, Gastrointestinal, Renal, Toxicity, Self-medication, Overuse, Nephropathy, Ulceration, Screening

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INTRODUCTION

OTC analgesic pills continue to be one of the most frequently used drugs in all parts of the world to manage the symptomatic treatment of headaches, musculoskeletal pain, fever, menstrual pain, and minor injuries. Their easy availability, low cost, and perceived safety have greatly led to an increase in self-medication behavior amongst different age groups worldwide [1]. In most places, particularly the low and middle-income countries, the drugs are readily available without professional advice and are overused, overconsumed, or misused. Popular OTC analgesics include paracetamol (acetaminophen), ibuprofen, diclofenac, aspirin, and other non-steroidal anti-inflammatory drugs (NSAIDs), and they are available over the counter to ordinary people [2].

Although these medications have therapeutic effects and abilities to relieve common symptoms within a short period, rising scientific evidence suggests that chronic,

unmonitored, or excessive use of these drugs is associated with pronounced adverse health effects. Among the most common agents of drug-related gastrointestinal (GI) complications, NSAIDs deserve mentioning since their inhibitory activity against cyclooxygenase (COX-1 and COX-2) enzymes leads to reduced production of protective prostaglandins in the gastric mucosa [3]. The decrease in mucosal defense predisposes users to dyspepsia, gastritis, gastric erosions, peptic ulcer disease, gastrointestinal bleeding, and NSAID-induced enteropathy. These GI toxicities become more frequent and severe with increased dosage, prolonged use, and polypharmacy with the use of other analgesics [4].

The other effect of long-term exposure to NSAIDs or mixed analgesics has been renal adverse effects that are well known. Given that the condition is medically recognized as nephrotoxicity triggered by NSAIDs, it is mainly associated with hindering the effect of prostaglandins on vasodilation of the afferent arteriole and consequently leading to lowering the glomerular filtration rate (GFR), acute kidney injury (AKI), electrolyte imbalances, chronic interstitial nephritis, and in severe instances, leading to analgesic nephropathy [5]. Even drugs that are typically believed to be safer, like paracetamol, have renal and hepatic risks (which most people would think to be not only real but also incurable) when taken regularly, in large amounts, or when used by people with underlying comorbid factors like diabetes, high blood pressure, or pre-existing renal disease [6].

Analgesic-related toxicity is an even greater burden in low- and middle-income countries like Pakistan, where self-medication is common, regulatory controls are minimal, and understanding of the correct dosage and contraindication, and toxicity profiles is not always sufficient [7]. The belief that OTC drugs are harmless due to cultural factors, as well as the limited access to medical specialists, additional promotes abuse. Co-morbidities, chronic pain syndromes, and a combination of multiple analgesics increase the vulnerability to adverse events and physical complications in particularly gastrointestinal and renal complications [8].

The use of OTC analgesics is incredibly popular in Pakistan, but the relative lack of research conducted on a local level to assess the long-term consequences of the use of these drugs on gastrointestinal and renal well-being is quite apparent. A majority of the existing research concentrates on short-term use or in certain clinical populations instead of habitual self-medication at the community level. Consequently, it is critical to comprehend the prevalence, nature, and level of these complications among chronic users to inform policy, educate society, and enhance clinical practice [9].

The current research paper will seek to evaluate the prevalence and trend of gastrointestinal and renal adverse effects with long-term use of OTC analgesics in adults. The study aims to give evidence-based information to clinicians, public-health authorities, pharmacists, and policymakers to ensure safer analgesic use and avoid preventable drug-related morbidity by identifying risk factors concerning duration, dosage, and type of analgesic used.

MATERIALS AND METHODS

The study was a cross-sectional clinical study that was carried out during the outpatient departments of the Itefaq Trust Hospital, Lahore, and the Urology department of the Dr. Faisal Masood Teaching Hospital, Sargodha, located in Pakistan, during a period of sixteen months between November 2023 and February 2025. One hundred respondents to the study were sampled through a non-probability consecutive sampling method, where all eligible patients who came forward within the study period and met the study inclusion criteria were invited to participate until the required sample size was reached. They included adults between the ages of 18 years and above who had been taking the over-the-counter (OTC) painkiller tablets for a period of three months or more. Analgesics that were tested in the current study included readily available preparations like paracetamol, ibuprofen, diclofenac, naproxen, and aspirin.

To reduce confounding factors, people were excluded in case they had known gastrointestinal diseases (including peptic ulcer disease, gastritis, or inflammatory bowel disease), chronic kidney disease, liver cirrhosis, had undergone additional surgery of the gastrointestinal tract in the past, or were taking other nephrotoxics. The information about the demographics, type of administered analgesic, period and frequency of consumption, pain indicators, related symptoms, and medical history was collected using a structured interviewer-administered questionnaire. Period of analgesic use was classified into 36 months, 72 months, and above, and intake frequency was classified as occasional (1-2 times per week), moderate (3-5 times per week), and frequent (daily use). The size of 100 participants was taken as sufficient due to the feasibility and because it is a common margin in cross-sectional clinical studies, and because it was backed by an a priori power calculation: with a prevalence of the gastrointestinal or renal side effect of analgesic use estimated at 60, the desired confidence level set at 95, a margin of error of 10, and the statistical power set at 80, the size of the necessary sample was estimated to be about 92, and thus the size of the final sample of 10.

All of the participants were specifically subjected to a thorough clinical assessment with laboratory studies of complete blood count (CBC), serum creatinine, blood urea nitrogen (BUN), estimated glomerular filtration rate (eGFR), serum electrolytes, and a urinalysis to determine the existence of renal abnormalities like proteinuria or hematuria. The evaluation of the gastrointestinal symptoms consisted of the following: abdominal pain, bloating, nausea, vomiting, dyspepsia, heartburn, constipation, diarrhea, melena, and hematemesis. The occult blood testing in stool was done to identify the subclinical bleeding in the gastrointestinal tract, and a selective abdominal ultrasound was done when there was suspicion of abnormal

results. The institutional review board of Dr. Faisal Masood Teaching Hospital gave ethical approval of the study under approval number DFMT-IRB/2023/24, and informed consent in writing was signed by all the participants before their enrolment. In the study, data confidentiality and anonymity were examined to a considerable extent. The statistical software was used to analyze all data, and descriptive statistics, including means, standard deviations, frequencies, and percentages, were estimated. Chi-square tests were used to assess associations between patterns of analgesic use and gastrointestinal or renal side effects in categorical variables, and independent t-tests were used to assess the same in continuous variables, with a p-value less than 0.05 being considered statistically significant.

RESULTS

The researchers investigated 100 adults who took the painkiller tablets over the counter for more than three months. The average age of the participants was 38.6/12.4 years, and females constituted a slightly greater percentage (57) than males (43). According to Table 1, paracetamol was the most prevalent analgesic (62%), then ibuprofen (48%), diclofenac (31%), and aspirin (19%). The 20% who had taken analgesics over 3-6 months, 33% over 7-12 months, and 27% over 12 months were the participants of the same duration of use. The frequency of consumption revealed that 38 percent used painkillers once a week, 33 percent once 2 to 5 times a week, whilst 29 percent consumed them daily. All these findings indicate a large percentage of continuous and prolonged OTC analgesic use, which puts the users at risk of related complications.

The gastrointestinal symptoms were frequent, with 68% of the participants reporting at least one of them. Table 2 indicates that dyspepsia (42%), abdominal pain (36%), bloating (28%), nausea (24%), and heartburn (21%) were the most prevalent symptoms. In 17 percent and 14 percent of participants, constipation and diarrhea were reported, respectively, and 6 percent of participants had more severe symptoms, including melena or hematemesis, which suggests the possibility of upper gastrointestinal bleeding. These findings indicate a high prevalence of GIT issues in long-term users of analgesics, which is in line with known mucosal injury with NSAIDs.

In 34 percent of the participants, renal abnormality was seen. High serum creatinine was identified in 19%, decreased eGFR in 17, and increased BUN in 15% as shown in Table 3. Urinalysis revealed a proteinuria (12%), hematuria (10%), and such symptoms as flank pain (14%), decreased urine outflow (9%), etc. These results indicate that a large percentage of persistent analgesic users had biochemical or symptomatic indications of hindrance in the kidney, especially those who consumed NSAIDs.

There was a strong correlation between the number of adverse effects and the length of the analgesic application. Gastrointestinal symptoms, as exemplified in Table 4, rose with 3-6 months of use to 76% in individuals who used analgesics for 7-12 months, and 93% in those individuals who had used analgesics for over 12 months. On the same note, renal abnormalities increased, 15% in the 36-month group, to 33% in the 712-month group, and 63% in the permanent users who had used the drug for more than one year. This shows a distinct dose duration effect, which proves that long-term use was significant in increasing the risk of both GI and renal complications ($p < 0.05$). There was a higher percentage of high creatinine and low eGFR among the users of NSAIDs, i.e., diclofenac and ibuprofen, than among the heavy users of paracetamol. In general, the gastrointestinal symptoms prevailed over the renal abnormalities, and both types of complications escalated significantly as the duration and frequency of analgesic use increased.

The data of the current research prove that the use of long-term over-the-counter analgesics is highly correlated with the occurrence of both gastrointestinal and renal complications. A high percentage of users complained of gastrointestinal complaints, and dyspepsia, abdominal pain, and bloating were the most common, although a smaller but clinically significant percentage had gastrointestinal bleeding. There was also a significant renal impairment in chronic users, and this was revealed by increased serum creatinine, lower eGFR, and abnormal urinalysis results. The findings also indicated that there is an apparent dose-duration effect, with those who took analgesics over a period of over one year showing significantly higher incidences of gastrointestinal as well as renal abnormalities than those who took analgesics over a period of less than one year. The burden of biochemical renal deterioration in NSAID users (especially those taking diclofenac and ibuprofen) than paracetamol users, underscoring the increased nephrotoxic and gastrotoxic potential of these agents. In general, the findings indicate that the regular and extended use of analgesics without supervision is a significant health risk, which merits the population to be aware of, dispensing to be controlled, and clinical monitoring performed regularly to avoid the unnecessary complications related to drugs.

Table 1: Baseline Characteristics of Study Participants (N = 100)

Variable	Frequency (n)	Percentage (%)
Age (Mean ± SD)	38.6 ± 12.4 years	
Gender		
Male	43	43%
Female	57	57%
Most Common Painkillers Used		
Paracetamol	62	62%
Ibuprofen	48	48%

Diclofenac	31	31%
Aspirin	19	19%
Duration of Use		
3–6 months	40	40%
7–12 months	33	33%
>12 months	27	27%
Frequency of Use		
1–2 times/week	38	38%
3–5 times/week	33	33%
Daily use	29	29%

Table 2: Gastrointestinal Side Effects Among Users

GI Side Effect	Frequency (n)	Percentage (%)
Dyspepsia	42	42%
Abdominal pain	36	36%
Bloating	28	28%
Nausea	24	24%
Heartburn	21	21%
Constipation	17	17%
Diarrhea	14	14%
Melena / Hematemesis	6	6%
Any GI symptom	**68**	**68%**

Table 3: Renal Function Abnormalities

Renal Parameter / Symptom	Frequency (n)	Percentage (%)
Elevated serum creatinine	19	19%
Increased BUN	15	15%
Reduced eGFR	17	17%
Proteinuria	12	12%
Hematuria	10	10%
Flank pain	14	14%
Reduced urine output	9	9%
Any renal abnormality	**34**	**34%**

Table 4: Relationship of Duration of Painkiller Use with Side Effects

Duration of Use	GI Side Effects (n, %)	Renal Side Effects (n, %)
3–6 months	18 (45%)	6 (15%)
7–12 months	25 (76%)	11 (33%)
>12 months	25 (93%)	17 (63%)

DISCUSSION

The results of the current paper indicate a significant number of gastrointestinal and renal complications among the long-term users of over-the-counter (OTC) analgesic pills, which is a worldwide trend since the self-medication process is steadily increasing, especially in areas with poor access to healthcare infrastructures and without regulations of the sale of these over-the-counter medicines [1,2]. The prevalence of analgesic use in this population fits the international statistics that have reported massive dependence on the readily available pain drugs based on a perceived safety, cheapness, and a cultural view that self-medication is acceptable [3]. Here, the gastrointestinal (68%) and renal (34) complications, which were common in the current study, are clinically relevant, as well as aligned with the risks of chronic exposure to the NSAIDs reported in other communities [4].

The most frequent adverse effects were gastrointestinal side effects, which supports the well-proven correlation of NSAID therapy and upper gastrointestinal mucosal injury [5]. The adverse effects of NSAIDs include inhibition of the cyclooxygenase (COX-1 and COX-2) enzymes, which leads to the inhibition of the production of prostaglandin, weakening of the mucosa, exposure to gastritis, dyspepsia, peptic ulceration, and gastrointestinal bleeding [6]. The prevalence of dyspepsia, abdominal pain, bloating, and nausea in this study is in line with the local and international reports of the same, which indicate that they exhibit such symptom patterns among regular NSAID users [7,8]. The incidence of melena and hematemesis in 6% of participants supports clinically significant mucosal injury, and is consistent with the findings of population-based research indicating that chronic use of NSAIDs can raise the risk of gastrointestinal bleeding many times [9,10]. Additionally, these findings indicate that the dose-duration correlation was high in the reported range, where 45 percent of short-term users would develop negative GI effects, and 93 percent of those who would have intake of analgesics for over one year were known to have cumulative mucosal toxicity [11].

Renal problems were also prominent, as evidenced by high serum creatinine, low eGFR, and abnormal urinalysis results on a significant number of participants, according to the evidence that the chronic use of NSAIDs impairs renal

perfusion by blocking prostaglandin-mediated afferent arteriolar vasodilation [12]. The mechanism predisposes vulnerable individuals to acute kidney injury, electrolyte imbalance, and chronic interstitial nephritis, especially when dehydration, hypertension, or diabetes exist [13]. The result of the present study is similar to other studies carried out in the global arena that have noted similar renal impairment effects on regular users of NSAIDs, including proteinuria, hematuria, and worsening renal filtration capacity [14,15]. Even though paracetamol is considered safer than NSAIDs, in some situations, chronic or high-dose use has been associated with nephrotoxicity, arguing against the mild renal stress in some paracetamol-taking subjects in this study [16]. Notably, the renal abnormalities of those taking diclofenac and ibuprofen were much higher, which is in line with the previous evidence that posits the two as the highest-renal-risk agents in the NSAIDs group [17].

The general tendency of negative impact within this population is especially alarming since the plethora of OTC painkillers is still present, and the general population is unaware of the necessary dose and possible poisoning. Other studies on low- and middle-income countries also found that there was a lack of awareness of NSAID risks, high cultural acceptability of unsupervised analgesic therapy, and inadequate pharmacist-led counselling, which also leads to the high morbidity of drug-related events [18]. These results highlight the importance of specific public health interventions, such as educational activities on safe analgesic practices, better labelling of over-the-counter products, and regulated dispensing guidelines. Clinicians must also be proactive as they ought to screen analgesic overuse, especially when dealing with patients with comorbidities like diabetes or hypertension who are prone to drug-induced renal and gastrointestinal toxicity [19]. At the policy level, the routine adoption of national policies of structured guidelines on rational analgesic use and promotion of periodic renal and gastrointestinal surveillance to users of chronically prescribed OTC analgesics can go a long way in reducing morbidity that can be prevented with long-term use of the drugs [20].

The study has weaknesses, even though it has strengths. The study with a cross-sectional design limits the causal inferences; self-reported analgesic use can be biased in the recall, and neither endoscopy nor renal imaging could be given to all involved, since the study was limited by resources. However, the research provides valuable localized data on the necessity of regulatory change and patient-specific education to decrease the increasing load on analgesic-related complications [13,17].

CONCLUSION

NSAIDs as pain relievers in the pill form constitute some of the most drastic gastrointestinal and renal adverse side effects, with greater effect when the pill is taken over a long time and repeatedly. Among chronic users, gastrointestinal symptoms and, specifically, dyspepsia and lower abdominal pain were also prominent, whereas renal impairment was also prominent. Having the results described, the increased awareness of people regarding the risks of using analgesics without supervision, a stricter control over the distribution of OTC pain medications, and periodic clinical control of individuals who have to be under continuous analgesic therapy should be raised. The problem of GI and renal complications related to drugs also demands the introduction of responsible self-medication and enhancing the education of patients, which can reduce the GI and renal burden of the community to a considerable extent.

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Authors' contributions:

- **MLM**: Concept, study design, data collection.
- **HI**: Clinical assessment, urology-related evaluation, data interpretation.
- **MH**: Orthopedic assessment, data support, manuscript drafting.

All authors read and approved the final manuscript.

Data Availability Statement: The data used in this study are available upon reasonable request from the corresponding author, subject to ethical and institutional guidelines.

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