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Indian Journal of Pharmacy and Pharmacology

Journal homepage: https://www.ijpp.org.in/

Original Research Article

A Cross-Sectional study on the quality and safety of weak opioid prescriptions in community pharmacies in Kayes, Mali

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Abstract

Background: Pain is one of the most common symptoms encountered in clinical practice and accounts for approximately two-thirds of all medical consultations. Depending on its intensity, pain is managed with analgesics of appropriate potency.

Objective: This study aimed to analyze the prescription patterns of weak opioids in community pharmacies in the city of Kayes.

Materials and Methods: A descriptive cross-sectional study was conducted across 12 community pharmacies over a six-month period from July to December 2024.

Results: A total of 357 medical prescriptions containing weak opioids were included. The over-45 age group was the most frequent, with 105 prescriptions. The average number of drugs per prescription was 3.98. Illegible prescriptions accounted for 13.16% (n=47). With regard to the pharmacography of the drugs prescribed, the dosage was not mentioned on 76.19% (n=272) of the prescriptions. The duration of treatment were not indicated on 98.32% (n=357) of prescriptions. Tramadol was the most prescribed step 2 analgesic at 55.74% (n=199). However, 36.13% (n=129) of prescriptions contained at least one drug interaction, including 12 contraindicated associations. Moreover, 5.32% (n=19) and 2.52% (n=9) of prescriptions contained at least one high-dose drug and one drug not required.

Conclusion: Overall, the average number of medications per prescription was high, and a significant number of prescriptions were illegible. The most frequent and serious prescribing errors were the omission of treatment duration and the use of contraindicated drug combinations.

Keywords: Weak opioid, Tramadol, Medication errors, Prescription, Kayes, Mali

Received: 30-07-2025; **Accepted:** 03-09-2025; **Available Online:** 25-09-2025

1. Introduction

Pain is inseparable from birth, growth, illness and death; it is an inherent part of the human experience. As the most frequently reported symptom, pain accounts for approximately two-thirds of all medical consultations, making analgesics the most commonly prescribed class of medications.[1,2] To facilitate and guide pain treatment, the World Health Organization (WHO) has established a scale for the use of analgesics, based on the intensity of the pain assessed, in three steps. Step 1 or non-opioids, Step 2 or weak opioids, which are used alone or in combination with Step 1 analgesics, and Step 3 include strong opioids.[3]

The use of opioids is undeniably essential in the treatment of pain. However, increased consumption of opioid analgesics can lead to serious complications. From 2000 to 2017, the rate of hospitalization due to the use of opioid analgesics prescribed by doctors increased from 15 to 40 hospitalizations per million inhabitants. Between 2000 and 2015, the mortality rate linked to opioid use rose from 1.3 to 3.2 deaths per million inhabitants, with at least four deaths per week.[4,5,6,7] Research carried out in Africa, such as that by Dodo et al. in 2018 in Benin, showed that the consumption of weak opioids was 2.6 times higher than that of strong opioids. Moreover, research carried out in Mali in 2021 on the distribution of prescription and self-medication analgesics revealed that weak opioids were dispensed 1.27 times more than non-opioid analgesics.[2,8]

A retrospective study conducted from 2011 to 2020, using data from French Pharmacovigilance Centre databases, identified 155 cases of adverse drug reactions associated with weak opioid analgesics. The majority of cases

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https://doi.org/10.18231/j.ijpp.47530.1758803757

involved tramadol (56.1%), followed by codeine (38.7%). Gastrointestinal symptoms were the most frequently reported, occurring in 80% of tramadol-related cases and 65% of codeine-related cases. Codeine was also associated with severe adverse events such as anaphylaxis and acute pancreatitis.[9]

In this context, the present study aimed to analyze the prescribing patterns of weak opioids in community pharmacies in the city of Kayes, with a focus on evaluating the quality of prescriptions and potential medication-related risks.

2. Materials and Methods

2.1. Description of the study area

The Kayes region is Mali's first administrative region, and has been since 1960. Situated in the west of the country, in 2023, when the new regions are established, its surface area will be reduced from 260545 km² to 63210 km² in favour of the regions of Nioro du Sahel and Kita. The Kayes region is bordered to the south by Guinea, to the east by the Nioro and Kita regions, to the north by Mauritania and to the west by Senegal. The location of the Kayes region can be seen on the map **(Figure 1)**. The capital is the town of Kayes. It covers an area of 22190 km² and has a population of 513362. There are 27 community pharmacies in Kayes.[10,11,12]

Figure 1: Map of Mali with the Kayes region on the left

2.2. Type, choice of location and study period

This was a descriptive cross-sectional study conductedin 12 community pharmacies chosen by lot from the 27 community pharmacies, randomly selected from the 27 community pharmacies located in the town of Kayes. The study was carried out over a six-month period, from July to December 2024, with a two-week data collection period in each pharmacy. The sample size was determined based on the total number of eligible cases according to predefined inclusion and exclusion criteria. All prescriptions containing at least one weak opioid were included in the analysis. Data collected from the prescriptions included information on the patient, prescriber, and dispenser, as well as the drug type, dosage, duration of treatment, and pharmaceutical form. This information was used to identify potential prescribing or dispensing errors.

2.3. Data processing and analysis

The information collected using KoboCollect was transferred to Microsoft Excel. Data analysis was then performed using GraphPad Prism, version 5.0.4. Descriptive statistics were applied to determine the frequency and percentage distributions of the study variables.

3. Results

Three hundred and fifty-seven medical prescriptions were included in this study during the 6-month survey period in the 12 community pharmacies selected.

3.1. Socio-demographic profile of patients

In this study, the over-45 age group was the most common, with 105 patients. Age was not mentioned on 35.57% (n=127) of prescriptions. Patients under 16 years of age were the least frequent with 1.68% (n=6) **(Table 1)**.

Table 1: Characteristics of patients.

Variables	Categories	Effective	Percentage (%)
Gender	Female	178	49.86
	Male	179	50.14
Age group	0 to 15 years	6	1.68
	16 to 30 years	43	12.05
	31 to 45 years	76	21.29
	Over 45 years	105	29.41
	NS	127	35.57
	Total	357	100.0

NS: Not specified

3.2. Prescription elements

The patient's first name and surname were not mentioned on 0.84% (n=3) of prescriptions. The prescription date and signature were not mentioned on 0.56% (n=2) and 2.52% (n=9) of prescriptions respectively. Illegible prescriptions accounted for 13.16% (n=47). With regard to the pharmacography of the drugs prescribed, the dosage was not mentioned on 76.19% (n=272) of the prescriptions. The posology and route of administration were missing from 2.24% (n=8) and 0.56% (n=2) of prescriptions respectively. The duration of treatment was not mentioned on 98.32% (n=357) **(Figure 2)**.

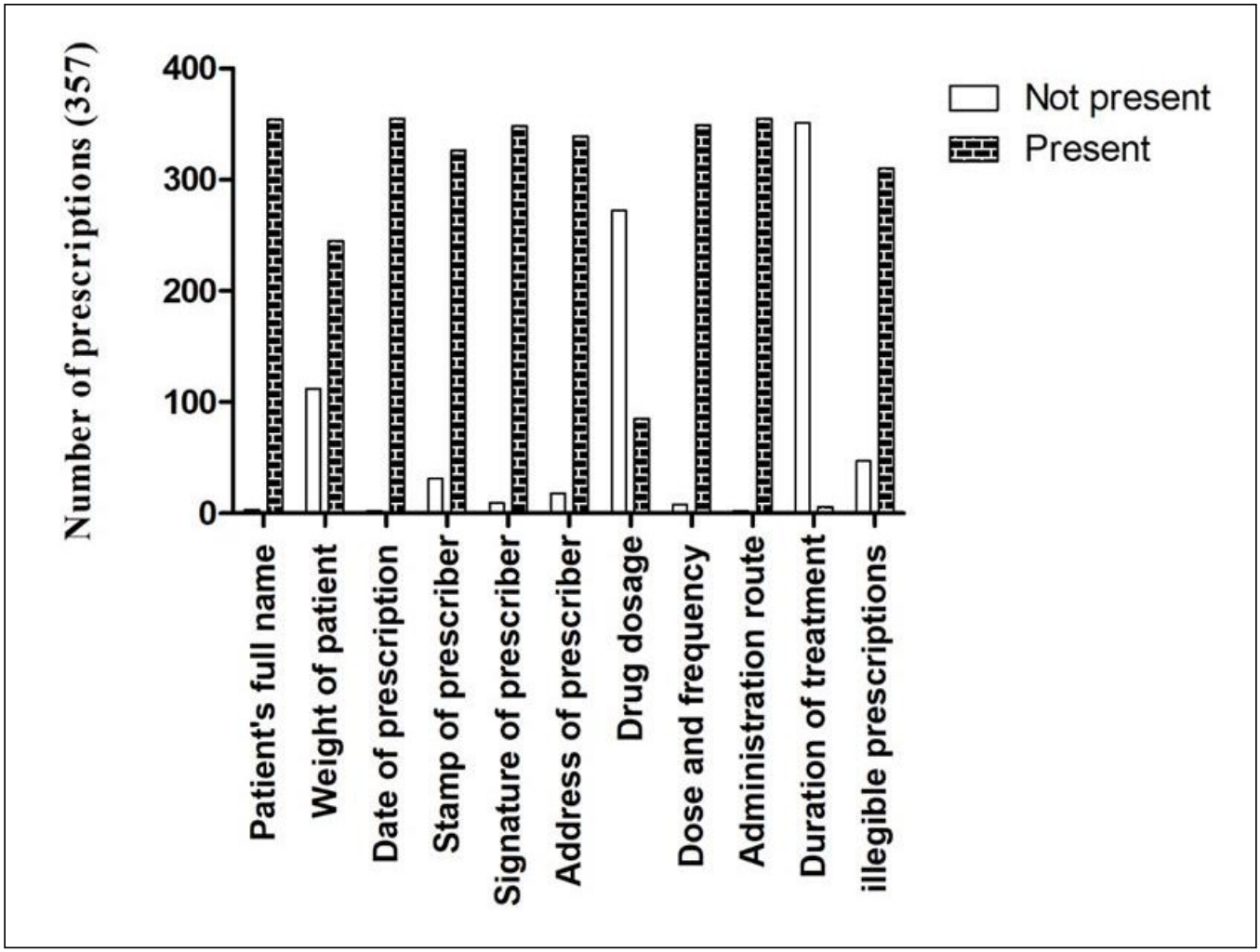

Figure 2: Prescription elements

(Table 2) shows that 1420 drugs were prescribed out of the 357 prescriptions included in this study. The average number of drugs per prescription was 3.98. In addition, 367 prescriptions for weak opioids were recorded. Tramadol, codeine and opium powder were prescribed by 54.22% (n=199), 43.60% (n=160) and 2.18% (n=8) respectively. Except for 16.08% (n=59) of tramadol alone, all the rest were fixed combinations and most often with paracetamol **(Table 2)**.

Table 2: Step 2 analgesic prescribed alone or in a fixed combination

Variables	Effective	Percentage (%)
Number of prescriptions	357	
Number of drugs prescribed	1420	
Average number of drugs per prescription	3.98	
Step 2 analgesic prescribed	n=367	
Tramadol	59	16.08
Tramadol + paracetamol	140	38.15
Codeine + paracetamol	133	36.24
Codeine + paracetamol + caffeine	19	5.18
Codeine + aspirin + caffeine	08	2.18
Opium powder + colchicine + tiemonium	02	0.54
Opium powder + paracetamol + caffeine	5	1.36
Opium powder + paracetamol	01	0.27

+ : fixed combination

Table 3: Medication errors and dispenser profile

Characteristic	Effective	Percentage (%)
Number of prescriptions with drug interactions	129	36.13
Number of prescriptions with high doses	19	5.32
Number of prescriptions with drugs not required	09	2.52
Number of prescriptions dispensed by the pharmacist	25	7.00
Number of prescriptions dispensed by the pharmacy student	136	38.1
Number of prescriptions dispensed by pharmacy auxiliaries	196	54.9

Table 4: Drug interactions

Type of interaction	Molecules	Effective	Risks
To be taken into account		50	
Precaution for use		53	
Inadvisable	Codeine + Quinine	01	Decreased efficacy of the opioid
	Lumefantrine + Clarithromycin	01	Increased risk of ventricular rhythm disorders
	Diclofenac + Niflumic acid	01	Increased ulcerogenic and digestive hemorrhagic risk Increased ulcerogenic and digestive hemorrhagic risk Increased ulcerogenic and digestive hemorrhagic risk
	Diclofenac + Etoricoxib	02	
	Diclofenac + Aceclofenac	02	
	Rivaroxaban + Etoricoxib	03	Increased risk of haemorrhage
	Vildagliptin + Perindopril	01	Increased risk of angioedema
	Sitagliptin + Losartan	01	Increased risk of angioedema
Contraindicated	Tramadol + Amitriptyline	02	Risk of seizures and serotonin syndrome
	Domperidone + Lumefantrine	5	Risk of torsades de pointes
	Domperidone + Piperaquine	3	Risk of torsades de pointes
	Ciprofloxacin + Lumefantrine	2	QTc prolongations and torsades de pointes
	Piperaquine + Ofloxacin	2	QTc prolongations and torsades de pointes

3.3. Medication errors

One hundred and twenty-nine prescriptions, or 36.13% of prescriptions, contained at least one drug interaction. The percentage of prescriptions containing a high-dose drug and a drug not required were 5.32% (n=19) and 2.52% (n=9) respectively. Pharmacy auxiliaries dispensed 54.9% (n=196) of these prescriptions **(Table 3)**. Of the one hundred and nineteen prescriptions containing at least one drug interaction, the associations to be taken into account and precautions for use were found on 50 and 53 prescriptions respectively. In addition, 14 inadvisable associations and 12 contraindicated associations were identified. The risks likely to occur with the inadvisable combinations were mainly ulcerogenic, haemorrhagic and angioedematous risks. Risk of prolongation of the QTc interval and torsades de pointes were the risks likely with contraindicated associations. An antimalarial drug was involved in all cases of contraindicated combination. On the other hand, the combinations that were inadvisable were mainly between NSAIDs **(Table 4)**.

4. Discussion

The results of this study were used to evaluate prescriptions dispensed in community pharmacies in the town of Kayes. Overall, the indicators showed more favourable results. The completeness of the prescriber, patient and date information was very high. However, some quality problems were observed. Of the 357 medical prescriptions in this study, 1420 drugs were prescribed. The average number of drugs per prescription in this study was 3.8, with a standard deviation of 1.5, which is higher than the WHO ideal standard (1.6 - 1.8)[3]. This result is slightly higher than that of Sangho et al. with 3.4 drugs per prescription.[13] However, our result is in disagreement with those reported by Bilal et al. in Ethiopia and Ofori-Adjei et al. in Ghana, with 2.2 and a standard deviation of 0.8 and 4.4 drugs per prescription respectively.[14,15] Furthermore, illegible prescriptions continue to be issued, despite their obvious incompatibility with appropriate delivery and use. Ensuring the clarity of medical prescriptions is essential to prevent errors in the delivery and administration of drugs. On several prescriptions, information relating to dosage and duration of treatment was missing. The authors mentioned that this information is crucial for prescriptions to provide essential information about the treatment, facilitating appropriate delivery and better adherence to treatment.[16,17] Indeed, in this study, the most frequent type of prescription error was omission of treatment duration 100% (n=357) and dosage 76.19% (n=272), while illegible writing accounted for 13.16% (n=47). Suclupe et al. found that illegible handwriting accounted for 28.8% and omission of dosage form accounted for 36.3%.[18] With regard to step 2 analgesics, tramadol was

the most prescribed molecule with 54.22% (n=199), followed by codeine with 43.60% (n=160). This trend was observed in a previous study carried out in Bamako, which reported a percentage of 27.81 for tramadol and 26.49 for codeine.[2] This finding indicates that tramadol has become the first prescribed weak opioid analgesic, supporting the results of other studies.[2,19] However, other authors have found that compared with codeine, tramadol was significantly associated with a higher risk of mortality (13.00 vs. 5.61 per 1000 person-years) and cardiovascular events (10.03 vs. 8.67 per 1000 person-years). The use of tramadol as a performance-enhancing drug is thought to increase these risks.[9,20] Among the one hundred and nineteen prescriptions containing at least one drug interaction, 12 were contraindicated. These contraindications each involved an antimalarial with an antiemetic (domperidone) or a fluoroquinolone (ciprofloxacin or ofloxacin). Many authors have reported the risk of prolongation of the QT interval and torsades de pointes with these drugs.[21,22] Evidence of co-prescription of domperidone and other QT-prolonging drugs has been associated with cases of sudden death. The authors state that in the interests of patient safety, these drugs should not be prescribed in association.[22,23] Furthermore, in this study, more than half of the prescriptions were not analysed by a pharmacist or pharmacy student. Pharmaceutical intervention makes it possible to detect and prevent contraindications and other problems associated with drug therapy.[24] Pharmaceutical activity is centred on the validation of prescriptions before drugs are dispensed, with appropriate information for the patient and monitoring of the effects of their use. The absence of the pharmacist, who must play a leading role in community pharmacy in terms of time and capacity, would expose the patient to the consequences of inappropriate treatment.

5. Conclusion

At the end of our study, we conclude that several prescription-related errors were observed, including illegible handwriting, omission of dosage and treatment duration, and the prescribing of unnecessary medications. Some prescriptions with contraindicated interactions were dispensed in the absence of the pharmacist and could lead to serious adverse effects. These results highlight the urgent need to ensure the safety of medicine dispensing in community pharmacies.

6. Approval Statement

Our study protocol has been approved by the dean of the Faculty of Pharmacy at the University of Sciences, Techniques and Technologies in Bamako under the approval number #Reg. No.2024/068/FAPH - Deanship.

7. Authors Contributions

1. **Mahamadou Ballo:** Wrote the protocol, analysed the data and drafted the manuscript. KT: contributed to the drafting of the protocol and manuscript. MFD: contributed to the drafting of the protocol, conducted the survey and contributed to the data analysis.
2. **Moussa Lougue and Sékou Bah:** Verified the accuracy of the results. All authors participated in proofreading the manuscript and approved the final version.

8. Source of Funding

None

9. Conflict of Interest

The author declares that they have no conflicts of interest related to this study

10. Acknowledgement

The authors would like to thank the Faculty of Pharmacy of the University of Sciences, Techniques and Technologies of Bamako and the Order of Pharmacists of Mali for for providing community pharmacies.

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Cite this article: Ballo M, Traore K, Diefaga MDF, Lougue M, Bah S. A Cross-Sectional study on the quality and safety of weak opioid prescriptions in community pharmacies in Kayes, Mali. *Indian J Pharma Pharmacol.* 2025;12(3)*:*176–181