



**St. Paul Hospital Millennium Medical College
Graduate Study Program**

**Tramadol prescription patterns for adult patients in the general surgery department over
one year period: An institutional-based retrospective study**

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Addis Ababa, Ethiopia

January 2023



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To my advisors I would like to thank you.

Abstract

Introduction: Tramadol pain management is widely used in many clinical settings including per-operative, acute and post-surgical pain management and in obstetrics pain management. However, tramadol use is among other opioids leading to drug-induced morbidity and mortality. There is also a concern that tramadol prescription contributes to tramadol misuse and abuse that increase tramadol intoxication and adverse effects.

Objectives: The study aimed to assess tramadol prescription patterns in patients admitted and discharged from the general surgery department of Saint Paul's Hospital Millennium Medical College (SPHMMC) in Addis Ababa, Ethiopia, between (January and December 2021).

Methods: This is an institutional-based a retrospective chart review study over one year period. Retrospective descriptive.

Data collection was done through systematic sampling technique.

Results: A total of 380 patients' charts (224 females) were reviewed. The mean ($\pm$,SD) age is 42.25 ($\pm$,14.023) years.

Tramadol was prescribed to 335 (93.4%) patients, while 25 patients (6.6%) were not prescribed tramadol. Gender is strongly associated with tramadol prescription with a prevalence (OR = 2.52, $p = 0.046$) as female patients are twice likely to have tramadol prescribed compared to male patients. Tramadol prescription pattern in 67 (17.6%) patients was as monotherapy while as part of the combinational medications in 288 (75.8%) patients. Diclofenac sodium was the most frequently prescribed medication (in 262 charts or 68.9%) followed by acetaminophen (in 16 charts or 4.2%). The results also showed that tramadol was indicated for post-operative pain (88.7%), abdominal pain (6.3%), genitourinary (1.8%), and back/neck pain (1.6%).

Conclusion: Overall, the findings indicate that tramadol prescription is high in the general surgical ward, mostly as part of the combinational medications. Female gender has association with tramadol prescription. Female patients are twice likely to have tramadol prescribed compared to male patients. Furthermore, post-operative pain was the most frequent complaint associated with the prescription of tramadol

Keywords: Tramadol, prescription patterns, Ethiopia, general surgery.

Table of Content

Contents

Abstract	4
Table of Content.....	5
Acronyms and Abbreviations	7
1. Introduction	8
1.1 Background	8
1.2 Statement of the problem	8
1.3 Significance of study	9
1.4 Research Questions	9
1.5 Objectives.....	9
General objective.....	9
Specific objectives.....	10
2. Literature Review.....	10
2.1 Global Overview:	10
2.2 Regional Overview:.....	10
2.3Tramadol Prescription in Ethiopia	11
3. Methodology:.....	11
3.1 Study area and study period	11
3.2 Study design	11
3.3 Source and Study Population	11
Source population	11
3.4 Study Population	11
3.5 Defining operational terms:.....	11
3.6 Inclusion and exclusion criteria.....	12
Inclusion criteria	12
Exclusion criteria.....	12
3.7 Variables of the study:.....	13
3.8 Data analysis plan.....	14
3.8.1 Dissemination of study finding	14

4. Results.....	14
4.1 Socio-demographic data.....	14
4.2 Complaints	14
4.4 Gender and tramadol prescription:	18
4.5 Gender Association with the number of tramadol prescription refills:	19
5. Discussion:	22
6. Conclusion:.....	24
7. Recommendation.....	24
8. Limitation of study	24
9. References	25
Assurance of Principal Investigator	27
Approval of the Primary Advisor.....	27
Annexes	28
Table Summary of study	29
Annex I Study Tools: Demographic data, Questionnaire for discharged patients at the department of general surgery.....	30
Work Plan;.....	32
Cost calculation of study:.....	33

Acronyms and Abbreviations

BID	Bis in Die, Twice a day
ED	Emergency Department
GC	Gregorian calendar
GSD	General Surgery Department
GPs	General practitioners
IV	Intravenous
NA	Nucleus accumbens
PO	Per Oral Intake
Pt	Patient
QID	Quarter in Die, Four Times a day
RNs	Registered Nurses
SPHMMC	Saint Paul`s Hospital Millennium Medical College
TID	Ter in Die, Three times daily
WHO	World Health Organization

1. Introduction

1.1 Background

Opioid abuse or misuse and opioid use disorders are increasing dramatically and are a global concern (22, 23, and 24). According to the United Nations Office on Drugs and Crime (UNODC), there are over 35 million opioid users globally, (UNODC, 2017). While opioids are known to have the most severe negative health impacts, cannabis remains the most commonly used illicit substance in the world (135 million users) (United Nations Office on Drugs and Crime, 2017). Opioids account for up to 17 million of the 17 million disability-adjusted life years associated with substance use disorders.

Tramadol, an opioid analgesic, is typically used to relieve moderate to severe pain (Miotto et al., 2017; United Nations Office on Drugs and Crime, 2013). It has a strong likelihood of being abused (Almér Herrnsdorf et al., 2022; Dart et al., 2011; Kertesz, 2017; World Health Organization, 2014). Tramadol, which has two distinctive mechanisms of action, which are weak opioid agonist, and inhibition of Monoamine neurotransmitter reuptake.

Tramadol misuse and abuse has been a global concern, although some studies noted that tramadol has an equal or lower abuse potential compared to other opioids, moreover they stated the highest risk for tramadol abuse is when administered orally and the risk reduces upon dose increment (6).

Predictors of tramadol abuse from previous studies typically include male gender, being separated from parents, living in an institutional setting, polygamous family background, low socioeconomic status, and parental marital status (Abdul Malik et al., 2009; Duru et al, 2017). Although prescription patterns were not stated as a factor in those studies it was stated as of importance when abusers are shifting to synthetic opioids. A study in the USA reported that tramadol prescription pattern increased by 22.8% between 2012 and 2015 (3).

1.2 Statement of the problem

Opioid misuse is on the rise globally, with a prevalence of 5% in Europe (United Nations Office on Drugs and Crime, 2017). Tramadol was one of the prescription medications that UK university students used the most frequently, according to an online poll (Holloway, Bennett, Parry, & Gordon, 2014). Additionally, this pattern is prevalent in many regions of Asia and Africa. According to a study from Egypt, tramadol is the most often used opioid (Mohamed, El Hamrawy, Shalaby, El Bahy, & Allah, 2015), whereas a study from Iran found that the lifetime prevalence of tramadol misuse was 4.8% (male 7.6%, women 1.8%). (Nazarzadeh, Bidel & Carson, 2014). The opioid issue in Africa and its non-medical usage are discussed in a recent global Lancet report (Salm-Reifferscheidt, 2018).

Abuse of tramadol, a synthetic opioid, which is not subject international control, has become a serious problem in Number of African countries, especially in North Africa. Trafficking in tramadol to Africa appears to be increasing as well as confirmed by a series of large attacks of Tramadol appeared in West Africa in 2012 with a total of over more than 132 tons of tramadol-

containing preparations from India intercepted in Benin, Ghana, Senegal and Togo (International Narcotics Control Board, 2012).

In sub-Saharan Africa, recently the prescription trends in less developed African nations became an increasing concern outside of South Africa. The other countries have less capacity and training to respond to the needs of prescription of medication including Tramadol for pain management which need informed practitioners to do it (9).

There is a growing concern that misuse of Tramadol prescription may lead to toxicity related to the irrational use of this medication in many parts of world including Europe, Middle East and Western Africa (10). Tramadol is generally well tolerated in clinical trials. The most common side effects (incidence 1.6-6.1%) were nausea, dizziness, drowsiness, and sweating, vomiting, and dry mouth. Importantly, unlike other opioids, tramadol has no clinically relevant effects on respiratory or cardiovascular parameters at recommended doses in adults or children (2).

There is a higher risk for opioid use in patients one year after their treatment with tramadol as per a Colombian study & recommended educating prescribers about the risk of tramadol and other opioids (11).

From our observation, we came across patients diagnosed with opioid use disorder that stated their use of tramadol started after they were prescribed it postoperatively and they continued using due to its availability and access to it without the need for prescription.

1.3 Significance of the study

Unregulated prescription of tramadol could risk the users to develop misuse, dependency and overdose; however, there are no published studies in Ethiopia about tramadol prescription patterns or opioids misuse nor dependency.

This study is the first of its nature in Ethiopia to assess the prescription patterns of tramadol for patients admitted in the surgical department at SPHMMC, Addis Ababa, Ethiopia and its associated factors. As well, this study provides grounds for further studies in the use of tramadol and avail data for the relevant authorities for needed intervention to avoid harmful use of this medication.

1.4 Research Questions

What are the patterns of tramadol prescription at the general surgery department at St. Paul's Hospital Millennium Medical College?

1.5 Objectives

General objective

- To assess the pattern of tramadol prescription at the department of general surgery at Saint Paul's Hospital Millennium Medical College.

Specific objectives

- To describe the patterns of prescribing tramadol at the general surgery department at St. Paul Hospital over One year span (January 2021-December 2021).
- To identify the factors that affect the prescription of tramadol.

2. Literature Review

2.1 Global Overview:

Evidence shows that tramadol prescription has increased worldwide, in a USA, prescription patterns of tramadol increased by 22.8% between 2012 and 2015 relative to other opioids. Family physicians prescribed highest followed by internal medicine (Luisa M. Bigal, 2015). As well the in the USA, IMS Health National Prescription Audit revealed 65% increment in tramadol prescription in 2007, 2011, 2017 and tramadol is ranked second in the total US opioid market sales At 14.7%, prescribers' impression that tramadol has low addiction liability and a favorable safety profile was among the factors contributing to that rise (Karen Miotto 2017).

Tramadol prescriptions first capped in France, and then they were increased and dropped globally in Germany. Women had higher receipts. In France and Germany, delayed release formulations of tramadol (SR-TRAM) and tramadol in conjunction with paracetamol (COMB) were the most often prescribed drugs. The largest average doses and durations were found with SR-TRAM, followed by COMB and immediate release Tramadol (IR-TRAM). Long-term treatment was brought on by the average ambient tramadol intake of 1.5% in France and 8.2% in Germany. (Karin Hedenmalm & Jim Slattery 2018). Another study in Germany showed that there is higher rates of tramadol prescription among elderly patients. The study further showed that around 20% of one of five patients are prescribed tramadol in combination therapy. Tramadol prescription patterns in Asia is of concern too, In Korea a study of ten years noted an increment on tramadol prescription from 19% in 2003 to 33% in 2013 (Kyubeom Kim, Hyesung Lee & Ju-Young Shin, 2019).

As well, postsurgical prescriptions for opioid is found to be associated with overdose and high risk of developing opioid use disorder (Li S, Perry, 2000). Compared to receiving oxycodone and receiving tramadol, tramadol has twice the risk of overdose. An increased risk of opioid overdose was linked to a history of a mental disorder and the amount of tramadol pills prescribed (Groenewald, 2019).

In Asia, Iran has reported significant rises in Tramadol related deaths that occurred between 2005 and 2008 in Tehran (32.5 times more in 2008), (Iravani 2010). In Northern Ireland it is reported a 10% increase in tramadol related death from 1996 to 2012 and 47% were prescribed by medical practitioners, they identified depression, seizures and addiction as risk factors (Randall 2014).

2.2 Regional Overview:

In South Africa Tramadol, an atypical opioid, in combination with paracetamol accounted for 71.90% of products, followed by tramadol alone (22.74% of products) (18). In Egypt, for instance, the misuse of Tramadol prescription also includes using falsified medication which claim to be Tramadol for pain control and which may put patients at risk too which has a criminal implications at the same time (15).

2.3 Tramadol Prescription in Ethiopia

There has not been a study in Ethiopia that describe the prescription patterns of tramadol or any other opioid for that matter and in many cases tramadol tablets are available over the counter. This study is looking into and analyzing the prescription patterns of Tramadol in St. Paul Hospital and gives its results and recommendations.

3. Methodology:

3.1 Study area and study period

This study review patient's charts at the general surgery department in St. Paul Hospital admitted (January 2021-December 2021). The study is duration is over the period of 6 months from April 1 to September 30/2022.

3.2 Study design

A retrospective chart review study implementation to determine the patterns of tramadol prescription and its associated factors.

3.3 Source and Study Population

Source population

All adult patients admitted in St. Paul Hospital's General Surgery ward between (January 1st 2021 to December 31st 2021).

3.4 Study Population

Available General Surgery patient's records kept in the span of one year (2021-2021).

3.5 Defining operational terms:

Dependence potential:

Drug dependence is a chronic, progressive disease characterized by significant impairment that is directly associated with persistent and excessive use of a psychoactive substance.

Abuse Potential:

Functional magnetic resonance imaging (fMRI) used to study the effects of tramadol on the reward system in humans to assess drug abuse has shown several brain regions including nucleus accumbens (NAc) were activated during gain anticipation in the MID task under both tramadol and placebo. It concluded that tramadol enhances the reward system and has the potential to precipitate drug abuse in humans

Prescription is an instruction written by a medical practitioner that authorizes a patient to receive medicine or treatment.

Tramadol: A weak opioid analgesic which has both opioid and monoamine properties that is mainly prescribed to manage acute and chronic pain.

Prescription Patterns: The extent and profile of drug use, trends, quality of drugs, and compliance with regional, state or national guidelines like standard treatment guidelines, usage of drugs from essential medicine list and use of generic drugs.

3.6 Inclusion and exclusion criteria

Inclusion criteria

Adult patients admitted at the general Surgery ward between (January 1/ 2021- December 31/2021) GC.

Exclusion criteria

Patients younger than 18 years of age (16).

Patients diagnosed or treated for opioid use disorder.

Sample Size determination:

From the registry records & clinical audits at the department of surgery showed the number of patients admitted in the ward is approximately 3,348 last year, using single population proportion formula at 95% confidence interval (CI).

The sample size calculation using the following single population proportion formula

$n = N * X / (X + N - 1)$ Where;

$X = Z_{\alpha/2}^2 * p * (1-p) / MOE^2$

N= the population size

$Z_{\alpha/2}$ is the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96).

P is the sample proportion= 0.05

MOE is the margin of error = is the margin of error to be tolerated (5%).

Using this formula our sample size was 345 then we added 10% non-response 34.5 to that resulting in 379.5 and we rounded the number to **380**.

Sampling Procedure

The sample is selection by a single formula technique.

Patients admitted in the general surgery ward in the span and their charts are kept is sorted then the sample size is divided quarterly (every three months) allocating 93 charts per each quarter.

By choosing a chart in every nine charts using the single formula is our method to avoid bias, in any case of default the next in line would be chosen for the study.

3.7 Variables of the study:

Dependent variables:

Tramadol Prescription

Independent variables:

Socio-demographic variable- Age, Sex, Complaints, Diagnosis, Combination with other medications, chronic use of tramadol.

Data Collection tool:

A questionnaire's guide was designed and tested for validity to assess the patterns of prescription and the charts were sorted by a trained assistant, supervised, revised and analyzed by the investigator. An orientation was provided to the data collectors on the study and the use of the study tool, the principle investigator supervised the data collection process to avail accuracy and avoid bias.

Ethical Consideration:

Ethical approval was obtained from the Institutional Review Board of Saint Paul's Hospital Millennium Medical College. Only data relevant to the study as mentioned in the questionnaire was collected.

3.8 Data analysis plan

Collected data was entered, cleaned and analyzed using SPSS version -25. Results are presented in descriptive statistics (frequency, mean, range etc.) tables and graphs. Associations checked using chi-square, logistic regressions, and p value of ≤ 0.05 used to test significant associations.

3.8.1 Dissemination of study finding

The results of the study project will be shared be in the fulfillment of psychiatry training at Saint Paul's Hospital Millennium Medical College and with the possibility of publishing it as a journal article.

4. Results

4.1 Socio-demographic data

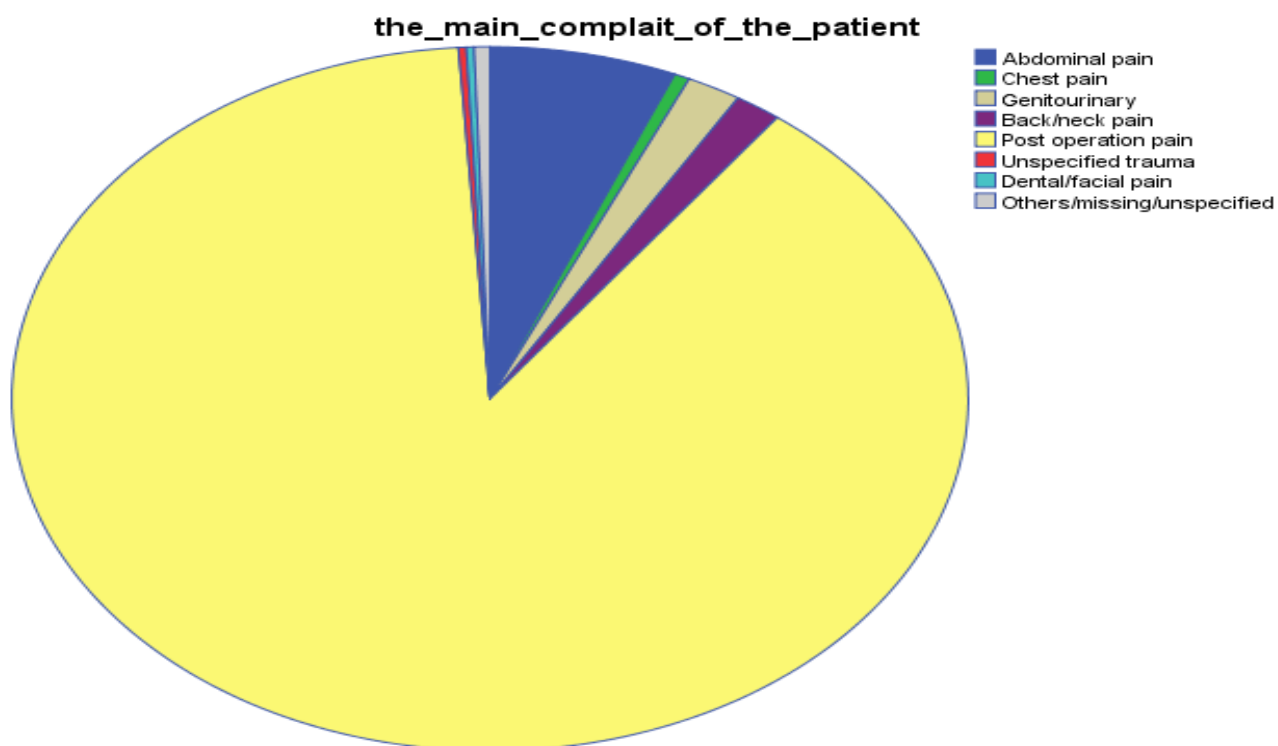
After securing access to the database and record room with the ethical approval, 420 charts were initially collected, after applying the inclusion & exclusion criteria 380 charts were collected and organized by a trained & supervised research assistant. Females were 224 patients (58.9%), 156 were males counting for (41.1%). The mean age is 42.25 years with standard deviation (14.023).

Gender	Frequency	Percent	Valid Percent	Cumulative Percent
Male	156	41.1	41.1	41.1
Female	224	58.9	58.9	100.0
Total	380	100.0	100.0	

4.2 Complaints

After analyzing the data, we found post-operative (88.7%) followed by abdominal pain (6.3%), Genitourinary (1.8%), Back/neck pain (1.6%).

Complaint	Frequency	Percent	Valid Percent	Cumulative Percent
Abdominal pain	24	6.3	6.3	6.3
Chest pain	2	.5	.5	6.8
Genitourinary	7	1.8	1.8	8.7
Back/neck pain	6	1.6	1.6	10.3
Post operation pain	337	88.7	88.7	98.9
Unspecified trauma	1	.3	.3	99.2
Dental/facial pain	1	.3	.3	99.5
Others/missing/unspecified	2	.5	.5	100.0
Total	380	100.0	100.0	



Tramadol prescription: (93.4%) of patients were prescribed tramadol while 25 (6.6%) of patients were not prescribed.

Tramadol prescribed	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	355	93.4	93.4	93.4
No	25	6.6	6.6	100.0
Total	380	100.0	100.0	

Tramadol prescription as monotherapy is 67 (17.6%) patients, while it's combination with other medications in 288 patients representing 75.8% of the total sample size.

Tramadol Monotherapy/combination frequency :

	Frequency	Percent	Valid Percent	Cumulative Percent
Not prescribed	25	6.6	6.6	6.6
Monotherapy	67	17.6	17.6	24.2
Combined	288	75.8	75.8	100.0
Total	380	100.0	100.0	

As well, 25 patients did not receive tramadol prescription counting for 6.6% from the total sample size.

Frequency of prescribing other drugs:

	Frequency	Percent	Valid Percent	Cumulative Percent
Missing/not prescribed	92	24.2	24.2	24.2
Acetaminophen	16	4.2	4.2	28.4
Diclofenac Na	262	68.9	68.9	97.4
Antidepressant	1	.3	.3	97.6
Other opioids/opiates	9	2.4	2.4	100.0
Total	380	100.0	100.0	

The assessment results in diclofenac Sodium was the most frequently prescribed medication in 262 charts (68.9%) followed by acetaminophen prescribed for 16 patients (4.2%), The findings also showed 92 (24.2%) charts had missing information or no prescription of any medication documented.

Associated Factors

We also looked if there was association between different variables and if any was significant statistically.

The following variables did not have any correlation with our outcome variable: patient residence, patient age, diagnosis and duration of the duration of admission.

However, there are important correlations:

- Gender is strongly associated with tramadol prescription with a prevalence ($P = 0.046$) with an odds ratio of (2.524).
- Pain complaint has a significant in distribution with tramadol prescription with ($P = 0.000$) with an odds ratio (0.000).

4.4 Gender and tramadol prescription:

Gender			Tramadol prescribed		Total
			Yes	No	
Male	Count		141	15	156
	Expected Count		145.7	10.3	156.0
	% within gender of patients		90.4%	9.6%	100.0%
	% within tramadol given or not		39.7%	60.0%	41.1%
	% of Total		37.1%	3.9%	41.1%
	Count		214	10	224
	Expected Count		209.3	14.7	224.0
	% within gender of patients		95.5%	4.5%	100.0%
	% within tramadol given or not		60.3%	40.0%	58.9%
	% of Total		56.3%	2.6%	58.9%
Total	Count		355	25	380
	Expected Count		355.0	25.0	380.0
	% within gender of patients		93.4%	6.6%	100.0%
	% within tramadol given or not		100.0%	100.0%	100.0%
	% of Total		93.4%	6.6%	100.0%

For the male patients 141 were counted represented 39.7% had tramadol prescribed in their charts and 15 patients did not receive tramadol prescription.

Female patients who received tramadol prescription were 214 (60.3%) patients while only 10 patients did not have tramadol prescribed for them.

Chi Square Test;

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.970 ^a	1	.046		
Continuity Correction	3.176	1	.075		
Likelihood Ratio	3.891	1	.049		
Fisher's Exact Test				.058	.038
N of Valid Cases	380				

The data in Table tested with Chi-square goodness of fit to determine if gender significantly differed among the patient. The study tested the subsidiary hypothesis that:

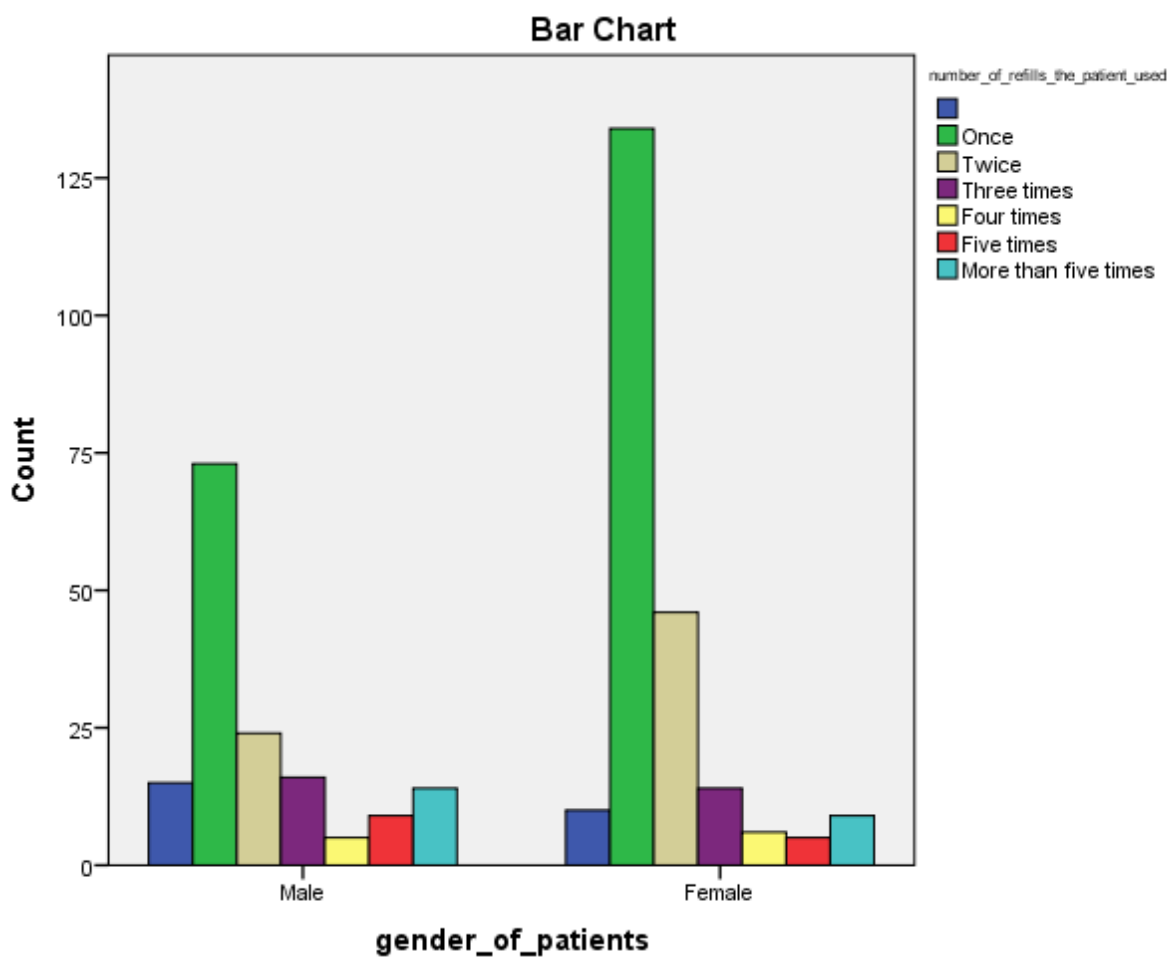
There is significant association between the gender of patients and the pattern of tramadol prescription.

4.5 Gender Association with the number of tramadol prescription refill:

Female patients (134) were more in having one refill than male patients (73). Male patients (9, 14) have five or more refills than female's patients (5, 9).

Gender of a patient	Number of refills the patient used					
	Not Rx	Once	Twice	Three times	Four times	Five times
Male	15	73	24	16	5	9
Female	10	134	46	14	6	5
Total	25	207	70	30	11	14

Gender of the patient	Number of refills the patient used	Total
	More than five times	
Male	14	156
Female	9	224
Total	23	380



The data in Table tested with Chi-square goodness of fit to determine if gender significantly associated the refill frequency. The study tested the subsidiary hypothesis that:

There is no significant association between the gender of patients and the pattern of tramadol prescription refill.

Chi Square Test:

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	16.711 ^a	6	.010
Likelihood Ratio	16.530	6	.011
N of Valid Cases	380		

The result showed there is a prevalence of ($P=0.010$) is depose the null hypothesis and proves a strong association of gender and the refill frequency.

Complaint:

Postoperative pain was the most frequent complaint associated with prescription of tramadol of 315 patients (88.7%) followed by abdominal pain 23 patients (4.2%).

Complaint	Tramadol Prescribed		Total
	Yes	No	
Abdominal pain	23	1	24
Chest pain	2	0	2
Genitourinary	7	0	7
Back/neck pain	6	0	6
Post operation pain	315	22	337
Unspecified trauma	1	0	1
Dental/facial pain	1	0	1
Others/missing/unspecified	0	2	2
Total	355	25	380

Chi Square Test:

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	29.826 ^a	7	.000
Likelihood Ratio	13.460	7	.062
N of Valid Cases	380		

Table shows the results of chi-square test of Pain complaint and tramadol prescription association. It shows that (N=380) = 29.826. , $p= 0.000$ which led to rejection of the null hypothesis. The hypothesis that there is no association between pain complaint & tramadol prescription. Therefore, there is strong association between the pain complaint & tramadol prescription.

5. Discussion:

Our study assess the pattern f tramadol prescription and its associated factors and it gave significant results of which we are going to discuss here and compare our findings with other literature. Africa being on the alert for it as well as on the forefront of tramadol high prescription as stated by the WHO studies, it reasoned its prescription due to affordability & availability of tramadol across Africa and the lack of other opioids/opiates and variation of analgesics in the medical centers across the continent[1,2,8,9].

This is the first study of its kind in Ethiopia that focuses on the prescription of tramadol with the intention of finding a baseline information to assess the pattern and the associated factors that may or may not affect the prescription of tramadol.

Tramadol prescription has increased in recent years with special emphasis on the study in USA that inclined an increase in tramadol prescription [3], this study affirms that as well with frequency in prescription (93%) of the patients.

We found that Age, residence and diagnosis of the patient had no significant association with tramadol prescription.

Gender has significant association with prescription with females being two times more likely to have tramadol prescribed to them than males. However, since it is a retrospective study we could not relate this outcome to the over representation of female patients in the overall sample or its due to other factors thus further studies are needed in this area.

As well female patients (5-9) had more frequent refill compared to male patients, however male patients (9-14) were more frequent to have five times or more tramadol prescription refills. For postsurgical patients a single refill increased the potential of misuse by more than 40% [19] and compared with some of these patients having more than five refills of tramadol it increases the risk of misuse significantly.

This should be a focal point of examination for upcoming investigators as we have noted the high frequency of refills, the duration of each prescription is also an important predictor for misuse [19].

We also found that postoperative pain was the most frequent complaint associated with tramadol prescription for 337 (88.7%) patients, followed by abdominal pain 24(6.3%) patients but these complaints were less likely to affect the prescription pattern of tramadol. These results show difference from the outcome of the study that had abdominal pain as the most frequently associated complaint tramadol prescription in ER [16].

Tramadol was prescribed as monotherapy for 67 patients (17.6) compared to the study in South Africa that found tramadol alone (22.74% of products), while we found tramadol combination in 288 patients (75.8%) compared to the same study (71.90%)that combined tramadol with acetaminophen, our study showed only (4.2%) had acetaminophen combination with tramadol [9,18].

The results are also comparable to the study published in Germany, which concluded approximately one of five tramadol patients were prescribed tramadol in combination therapy [4].

One of the hardships we faced while conducting this study is the absence of pain management guideline that can regulate the prescription of tramadol as well as other types of analgesics [7, 11] and the poor documentation that made the harnessing of data more difficult.

We also had difficulties tracking other types of opioids/analgesics to assess the levels of prescriptions, a hurdle we hope future studies can address.

6. Conclusion:

Over all demographic factors in the study are comparable to most studies 224 patients 58.9% were females, while only 156 were males counting for 41.1%. In addition, the mean age is 42 years.

From the total sample of 380, as frequent as 355 patients (93%) had tramadol prescription, female patients were more frequent to have tramadol prescription than male patients were. As well female patients (5-9) had more frequent refill compared to male patients, however male patients (9-14) were more frequent to have five times or more tramadol prescription refills.

Postoperative pain was the most frequent indication for tramadol prescription followed by abdominal pain.

Tramadol was prescribed as monotherapy for 67 (17.6%) and 75% had a combination with other medications and analgesics.

7. Recommendation

- We recommend larger multicenter prospective study with longer duration of follow up to determine possible predictive factors of tramadol misuse and use disorder.
- Useful method of keeping track of such patients is setting up of an institutional registry.
- We also recommend using the WHO pain ladder or developing pain management guidelines and prescribing tramadol for short duration to avert the risk of dependency.

8. Limitation of the study

- As a retrospective study, many data were not properly filled
- It is institution based study, so it may not be applicable to the general public

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Assurance of Principal Investigator

I the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project. I will provide timely progress report to my advisor and seek the necessary advice and approval from my primary advisors in the course of the research. I will communicate timely to my advisors all stakeholders involved in the study including any source of funding for this research.

Name of the student: _____

Signature: _____

Date: _____

Approval of the Primary Advisor

Name of the primary advisor: _____

Signature: _____

Date: _____

Approval of the Second Advisor

Name: _____

Signature: _____

Date: _____

Annexes

1. Table summary of the study.
2. Data collection tool
3. Work Plan
4. Cost of the study.
5. Acknowledgment

Table Summary of the study

Name of investigator	Garang Akuot, MD
Full title of the research project	Prescription patterns of Tramadol in the general surgery department at Saint Paul's Hospital Millennium Medical College in Addis Ababa Ethiopia: One year institutional based retrospective study
Duration of the project	6 months
Study Area	St. Paul Hospital, Addis Ababa, Ethiopia
Total Cost of the project	25,000 birr only
Source(s) of Funding	St. Paul Hospital Millennium Medical College
Address of investigator	Tel: 0973083836
	Cell phone: 0947647317
	Fax: NIL
	Email: garangapiu@gmail.com
Name of Advisor(s)	Dr. Solomon Dabi, Psychiatrist, Assistant Professor of Psychiatry. Faiz Kassim, PHD

Annex I Study Tools: Demographic data, Questionnaire for discharged patients at department of general surgery

Note: Circle the appropriate answer

Demographic Data

1. Date of Admission (____/____/____)(DD/MM/Y)
2. Date of Discharge (____/____/____)
3. Date of Prescription ____/____/____
4. Medical Record Number (MRN) _____
5. Age ()
6. Gender
 - A. Male
 - B. Female
7. Residence: _____
8. Diagnosis _____
9. Complaint:
 - 1- Abdominal pain.
 - 2- Non-fracture extremity pain.
 - 3- Headache.
 - 4- Chest pain.
 - 5- Genitourinary.
 - 6- Back/neck pain.
 - 7- Post Operation Pain.
 - 8- Unspecified trauma,
 - 9- Dental/facial pain.
 - 10- Others/missing/unspecified.
10. Tramadol Prescribed:
 - 0- Yes
 - 1- No
11. If Yes,
 - A. Monotherapy
 - B. Combined
12. Monotherapy:
 - A. Dosage Forms of Tramadol:
 - 1- Tablets
 - B. Dosage in mg:
 - 1) 50
 - 2) 100
 - 3) 150
 - 4) 200
 - 5) 300
 - 2- Capsule:
 - 1) 50
 - 2) 100
 - 3) 150
 - 4) 200
 - 5) 300
 - 3- IV Solution:
 - 1) 50
 - 2) 100
 - 3) 150
 - 4) 200
 - 5) 300
 - C. Rout:
 - 0) PO
 - 1) IM
 - 2) IV

D. Frequency:

- 0) Once Daily 1) BID 2) TID 3) QID
4) Additional Per Need Use

E. Duration:

- 1- < Month
- 2- One month
- 3- Two months
- 4- Three months
- 5- > Three Months

13. Number of Refills:

- 1- Once
- 2- Twice
- 3- Three times
- 4- Four times
- 5- Five Times
- 6- More than Five Times

14. If Combined:

- 1- Acetaminophen
- 2- Diclofenac Na
- 3- NSAID
- 4- Antidepressant
- 5- Other Opioids/Opiates
- 6- Other Medications.

Work Plan;

N O	Task	Jan- Feb	March	Apr	May	June	July	Aug	Sep	Oct	Nov
1	Topic selection & approval										
2	Proposal Submission										
3	Oral defense/ Obtaining ethical clearance										
5	Pre Test & evaluation of questionnaire										
6	Data Collection										
7	Data Analysis										
8	Report writing & submission										

Cost calculation of the study:

S/N	ITEMS	MEASUREMENT	QUANTITY	UNIT PRICE	TOTAL
1.	Pen	Pieces	10	10	100
2.	Notebook	Pieces	5	25	125
3.	Marker	Pieces	5	25	125
4.	Photocopy costs	Pieces	370*3	2	2,220
5.	2 Data Collectors/ Runner	Per diem	2*30	200	12, 000
6.	Supervisor fee	Per diem	1*30	250	7, 500
7.	Refreshment				300
8.	Contingency 5%				3,650
9.	Total				25, 920