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Research Article

A Prospective Observational Study to Assess Rationality and Drug Characterisation in the Prescription of Opioids in Post-Operative Patients in A Tertiary Care Hospital

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A B S T R A C T

Opioid are the narcotic analgesics which are routinely prescribed for postoperative pain management.The CDC developed guidelines for prescribing opioids to ensure safe, effective care and reduce opioid-related issues in chronic pain management.

This prospective observational study focused on assessment of rationality opioid in the prescription and drug characterization of opioid among post operative patients in a tertiary care hospital for a period of 6 months. The data was collected using information provided by patient medical record, CDC guidelines were used to assess rationality. Rationality in the opioid prescription was assessed using CDC guideline and revealed that majority of the opioid prescription were rational. High degree of irrationality was observed with Inj.Tramadol and long duration opioid prescription, emphasizing the importance of implementation of CDC guidelines.

Opioid drug characterization study revealed that majority of the patients were prescribed with Tab. Tramadol during hospitalization and discharge followed by inj. Tramadol, buprenorphine, morphine. In addition, some of the patients prescribed with buprenorphine at discharge possibly indicating leading to the misuse of the opioid.

Key words: *Opioids, Rationality, CDC guidelines, post operative.*

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INTRODUCTION

Opioid are the narcotic analgesics prescribed to treat persistent and severe pain which binds to opioid receptor leading to the release of endorphins which suppress the perception of pain and boost feelings of pleasure, creating a temporary but powerful sense of well-being leads to the addiction of the drug. India is said to be going through an opioid epidemic.[1] According to data from the International Narcotics and control board (INCB), the global opioid analgesic use more than double.[1] Opioids are routinely prescribed for postoperative pain management with tramadol the most commonly prescribed agent in India. Developed nations are facing opioid misuse crises due to the increasing use of opioid analgesics for non-cancer chronic pain.

WHO acknowledged that tramadol death out number's heroin death. Surgery is among the most common indications for opioid initiation. Excessive prescribing of opioids for pain treatment after surgery has been recognized as an important concern for public health and a potential contributor to patterns of opioid misuse and related harm [3].The Centre for Disease Control and Prevention (CDC) developed the CDC

Guidelines for Prescribing Opioids to treat chronic pain in post-operative patients. The Guideline improves communication between clinicians and patients about the benefits and risks of using prescription opioids for chronic pain, provide safer, more effective care for patients with chronic pain, help reduce opioid use disorder and overdose. [7] The guideline-based prescription of opioid analgesics resulted in decrease opioid supply with no increase in pain score or repeat opioid prescription requirement. [7, 9].It has been demonstrated that combination therapy, which uses a tiny quantity of opioid together with a nonopioid pain medication, is successful in lowering opioid intake.The guideline-based prescription of opioid analgesics resulted in decrease opioid supply with no increase in pain score or repeat opioid prescription requirement. [4]According to 2019 National Survey of India, 2.1% of Indian population use opioids but it was only 0.7% in 2004 though this figure is small, but it indicates that India is thrice the global average prevalence of opiate consumption. [6] CDC reported an average of 128 American' s dies every day from an opioid overdose and drug overdose death involving prescription opioids rose from 3442 to 16416 in 1999-2020. [10]

MATERIALS AND METHOD

STUDY DESIGN:

A Prospective observational study was carried out to assess rationality and drug characterization in the prescription of opioids in post operative patients in a tertiary care hospital.

SAMPLE SIZE: The sample taken for the study was 220 [8]

STUDY CRITERIA:

Inclusion criteria:

- Individuals aged 18 years or above
- Patient admitted to the surgery department prescribed with any class of analgesics.
- Patient prescribed with opioid drugs during discharge.

Exclusion criteria:

- OPD patients
- Severely ill, unconscious and unresponsive patients.

SOURCE OF DATA COLLECTION:

The required information was collected from patient's medical records.

STATISTICAL ANALYSIS:

Statistical analysis involves collecting and scrutinizing every data sample in a set of items from which samples can be drawn and a suitable statistical test was applied to analyse the data. The collected data using Microsoft Excel 2019 and Social Science Statistics.

RESULT

DEMOGRAPHIC OF THE PATIENT:

The research included 338 participants in total, the mean age was 57.35 years (minimum 18 and maximum 85), and the sex ratio (male/female) was 1.28. The majority of participants were between 41-50 (25.73%) year old followed by 51-60 (24.55%), 31-40 (23.96%), above 60 years (13.60%) and 18-30 (12.13%). The majority of patients 65.08% were prescribed opioid analgesics.57.98% were prescribed opioids during discharge. 44.08% of patients were prescribed a combination of opioid and non-opioid medications, i.e., either in one form or in separate forms. In addition, 53.25% of patients were considered for the interviews. The prevalence and demographics of the patients are shown in Table 1.

Table 1: Age wise Distribution of patient

Category	Variables	No. of subjects (n=338)	%
Gender	Male Female	190 148	56.21 43.79
Age (years)	18-30 31-40 41-50 51-60 > 60	41 81 87 83 46	12.13 23.96 25.73 24.55 13.60
No. of patients prescribed with opioids during post-operative hospitalisation		220	65.08
No. of patients prescribed with combination of opioid and non-opioid analgesics		149	44.08
No. of patients prescribed with opioids during discharge		196	57.98

Table 2: Characteristic of opioid prescribed to post-surgical hospitalized patients

Opioid	Total no. Of patients (n=220)	Gender		Age (years)			Mean dose prescribed	Mean MME/day prescribed
		Male (n=126)	Female (n=94)	18-30	31-60	>60		
T.Tramadol	133	133	73	60	12	89	29.04	3.8
Inj. tramadol	68	68	40	28	4	59	50	7.4
Inj morphine	5	5	4	1	1	4	10	10
Inj fentanyl	3	3	2	1	1	2	0.1	12
Buprenorphine patch	8	8	4	4	2	5	0.25	9
Inj butorphanol	3	3	3	0	0	3	1	5

TO DETERMINE CHARACTERISTICS OF POST-SURGERY PRESCRIPTION OF OPIOID ANALGESICS

Opioid characterization of post-surgical opioid prescription:

Analysis of opioid use in 220 patients revealed significant insights. Tramadol in tablet form is the most commonly prescribed opioid, 60.44% (133), with 73 men and 60 women. The mean dose for tramadol was 29.04 mg and the mean MME was 3.8, followed by tramadol in injection form, which was prescribed to 68 (30.9%) patients with a mean dose of 50 mg and a mean MME of 7.4. Injection morphine, butorphanol, and fentanyl were used in a limited number of cases, namely 5, 3, and 3 patients, respectively.

Notably, buprenorphine patches were administered in 8 patients. Mean morphine equivalence was determined by dividing the product of the strength of the opioid per unit and the number of units administered per day by the standard MME conversion factor for each opioid, and it was found that no drug was prescribed for more than 50 MME, which may be one of the factors leading to rational prescribing of opioids (Table No. 2)

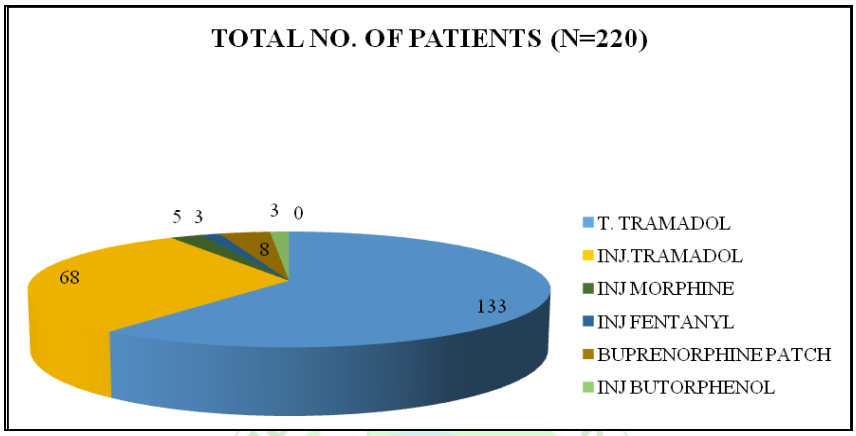

Figure 1: Characteristic of opioid prescribed to post-surgical hospitalized patients

Characteristic of opioid prescribed to discharge patients:

Among patients discharged from the hospital, there was a notable pattern in opioid medication prescribing. The most frequently prescribed opioid was Tab. Ultracet was given to the majority of 71.4% of the 140 patients, suggesting that it is the preferred choice for pain management amongdischarge medications in a substantial proportion of patients, followed by Tab. Semi-Ultracet was prescribed to 44 (22.42%) patients, Tab. Tramadol was given to 9 patients, suggesting that it is important in a smaller subset of cases. In addition, 3 patients were prescribed buprenorphine at discharge, possibly indicating its use in the treatment of opioid dependence or addiction.

Table 3: Highly prescribed opioid drugs during discharge

Sl.no.	Opioid medication	No. Of patient prescribed with opioid	%
1	Tab. Ultracet	140	71.4%
2	Tab. Semi ultracet	44	22.42%
3	Tramadol	9	4.59%
4	Buprenorphine patch	3	1.53%

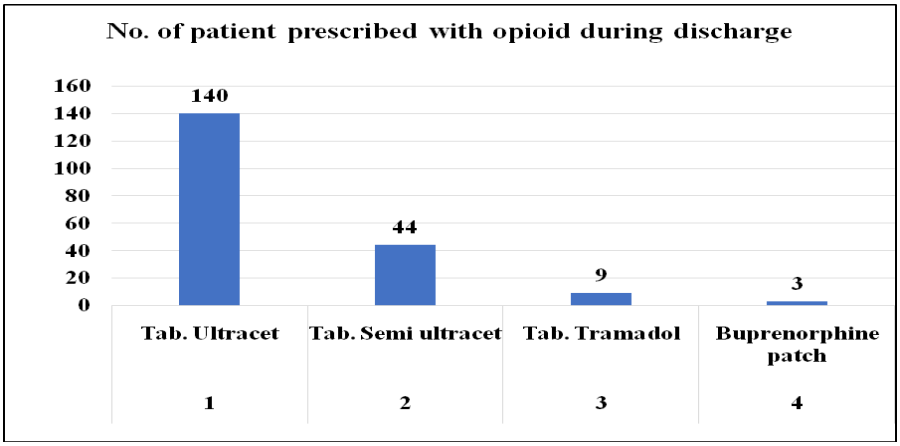

Figure 2: Highly prescribed opioid drugs during discharge

Duration of opioid prescription:

A large proportion of patients required a prescription for opioids, and these prescriptions were distributed over different time periods. Specifically, 131 (59.54%) postoperative patients admitted to the hospital and 81 (41.32%) discharged patients were prescribed opioids for a short duration of 1 to 5 days, indicating acute pain management. sixty-seven hospitalized patients and 59 discharged patients received opioid prescriptions for a duration of 6 to 15 days, indicating a need for intermediate pain relief and treatment. Additionally, 8 hospitalized and 31 discharged patients were prescribed opioids for a longer period of time, ranging from 16 to 29 days, which may indicate a longer treatment schedule and thus an increased risk of addiction.

Table 4: Duration of opioid prescription

Sl No.	Duration of prescription(days)	During post-operative hospitalization		During discharge	
		No. of patients(n=220)	%	No. of patients(n=196)	%
1	1-5	131	59.54	81	41.32
2	6-10	67	30.45	59	30.5
3	11-15	14	6.36	25	12.75
4	16-30	8	3.63	22	11.22
5	>30	0	0	9	4.59

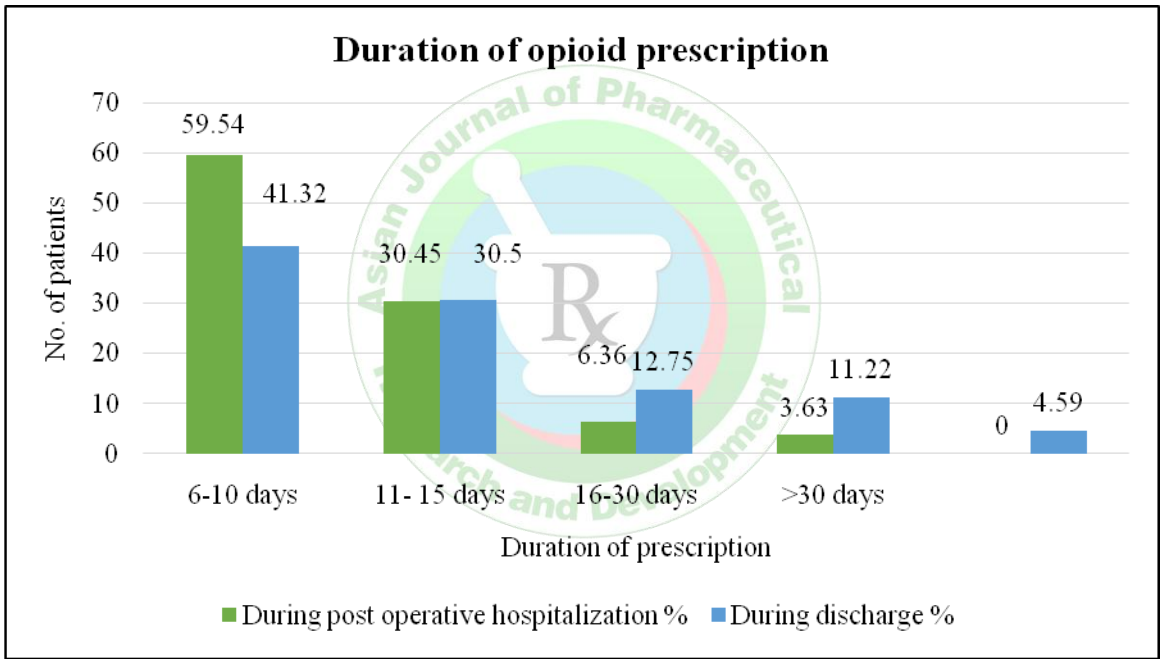

Figure 3: Duration of opioid prescription

To Assess The Rationality of Opioid Prescription Using Cdc (Centre For Disease Control And Prevention) Guidelines

Assessment of rationality in the opioid prescription using CDC guideline:

Analysis of rationality in the opioid prescription was done using CDC guidelines which has provided 12 criteria to be considered before and during prescribing opioid to any patients. Those 12 criteria were analysed for each opioid prescription and if it met 6 or more criteria it is considered as rational prescription or else it was considered as irrational prescription. Out of the 220 prescriptions studied, 129 (58.63%) were classified as rational and 91 (41.37%) as irrational. Rational prescriptions were more likely to adhere to safer opioid use practices. Thus, only 32 (24.80%) of rational prescriptions used opioids as first line therapy, while 99 (75.82 %) were in the irrational category.

Regarding the consideration of risk factors for opioid use and addiction, this was considered in majority 77 (59.68%) rational prescriptions, compared to limited 15 (11.62%) irrational ones. Importantly, only 69 (53.48%) rational prescriptions of opioids were prescribed to treat mild to moderate pain while 82 (90.10%) irrational prescriptions did. None of the rational prescriptions had blood or urine tests to detect controlled/illegal drugs, while 4.39% of the opioid prescribed irrationally along with benzodiazepines.

In addition, 93 (72.09%) rational prescriptions were reviewed using PDMP data, compared with 69 (53.48%) in the irrational category. These findings underscore the importance of adhering to rational prescribing practices to ensure patient safety and mitigate the opioid crisis. Efforts to improve prescribing practices, such as limiting opioid as first line

analgesic agent, discussing risks and benefits with patients, avoiding opioids to treat mild to moderate postoperative pain, are critical steps toward safer opioid use and better patient care.

Table 5: Assessment of rationality in the opioid prescription using CDC guideline

Sl. No	CDC criteria	Rational prescription (n=129)		Irrational prescription (N= 91)	
		No. Of prescription	%	No. Of prescription	%
1	Opioid used as first line therapy	32	24.80	69	75.82
2	Discussed of risk and benefits of opioid with patient.	82	63.56	9	9.89
3	Therapy is started with immediate- release opioid	44	57.36	12	9.30
4	Lowest effective dose was prescribed	98	75.96	63	48.83
5	Prescribed short duration opioid for acute pain.	129	100	83	91.20
6	Evaluation of benefits and harm frequently with patient.	85	65.89	23	25.27
7	Consideration of risk factor for opioid use in patient	77	59.68	15	11.62
8	Prescription of higher opioid doses i.e., ≥ 50mme per day	0	0	0	0
9	Prescription of opioid for mild- moderate pain	69	53.48	82	90.10
10	Blood/urine test to detect controlled/ illicit drugs	0	0	0	0
11	Prescription of opioid along with BZD	0	0	4	4.39
12	PDMP data were reviewed	93	72.09	69	53.48

Association between Opioidal drug characteristic and rationality:

The Data presented are in terms of the number of irrational and rational prescriptions, along with the corresponding percentages and P values to indicate significance. It was observed that T. Tramadol (n=133) had 42 cases (31.57%) of irrational prescription and 91 cases (68.43%) of rational prescription, with a highly significant P value of <0.0001, Inj. Tramadol (n=68) had 43 cases (63.23%) of irrational prescriptions, while 25 cases (36.77%) were rational. Followed by Inj. Morphine sulfate (n=5) had no cases of irrational prescription; all 5 cases (100%) were rational. Buprenorphine patch (n=8) had 5 cases (62.5%) of irrational prescription and 3 cases (37.5%) of rational prescription. Inj. Fentanyl citrate (n=3) had 1 case (33.3%) of irrational prescription and 2 cases (66.7%) of rational prescription. Inj. Butorphanol (n=3) had no cases of irrational prescription; all 3 cases (100%) were rational. Association between opioid drug characteristics and rationality determined in terms of a duration which showed 1-5 days (n=131) had 49 cases (37.40%) of irrational prescription and 82 cases (62.59%) of rational prescription, with a P value of <0.05. In the 6–10 day duration group (n=67), 28 cases (41.79%) were irrational prescriptions, while 39 cases (58.20%) were rational. In the 15–29 day duration group (n=14), 8 cases (57.14%) were categorized as irrational, and 6 cases (42.85%) were rational. In the group with a duration of ≥ 30 days (n=8), there were 5 cases (62.5%) of irrational prescription and 3 cases (37.5%) of rational prescription.

The data reveals several important findings: The type of opioid drug used significantly influences the rationality of prescription. T. Tramadol had the highest number of rational prescriptions, while Inj. Tramadol had the highest number of irrational prescriptions. The duration of opioid use also has a significant impact on prescription rationality. Shorter durations (1-5 days) had a higher proportion of rational prescriptions, while longer durations (≥ 30 days) had a higher proportion of irrational prescriptions. These findings are significant for healthcare professionals to underscore the importance of tailoring opioid prescriptions to the specific drug and the expected duration of use. It also highlights the need for vigilance when prescribing opioids like Inj. Tramadol, especially for longer durations. It shows that the choice of opioid drug and the duration of use are crucial factors in determining the rationality of opioid prescriptions in post-operative patients. These findings can guide healthcare providers in making more informed and appropriate prescription decisions.

Table 6: Association between opioid drug characteristics and rationality

Category		Irrationality		Rationality		P Value
		No. of irrational prescription (n= 91)	%	No. of irrational prescription (n= 91)	%	
Opioid drug	T. Tramadol (n=133)	42	31.57	91	68.43	<0.0001
	Inj. Tramadol (n=68)	43	63.23	25	36.77	
	Inj. Morphine sulphate (n=5)	0	0	5	100	
	Buprenorphine patch (n=8)	5	62.5	3	37.5	
	Inj. Fentanyl citrate (n=3)	1	33.3	2	66.7	
	Inj. Butorphanol (n=3)	0	0	3	100	
Duration (days)	1-5 (n=131)	49	37.40	82	62.59	<0.05
	6-10 (n=67)	28	41.79	39	58.20	
	15-29 (n=14)	8	57.14	6	42.85	
	≥ 30 (n=8)	5	62.5	3	37.5	

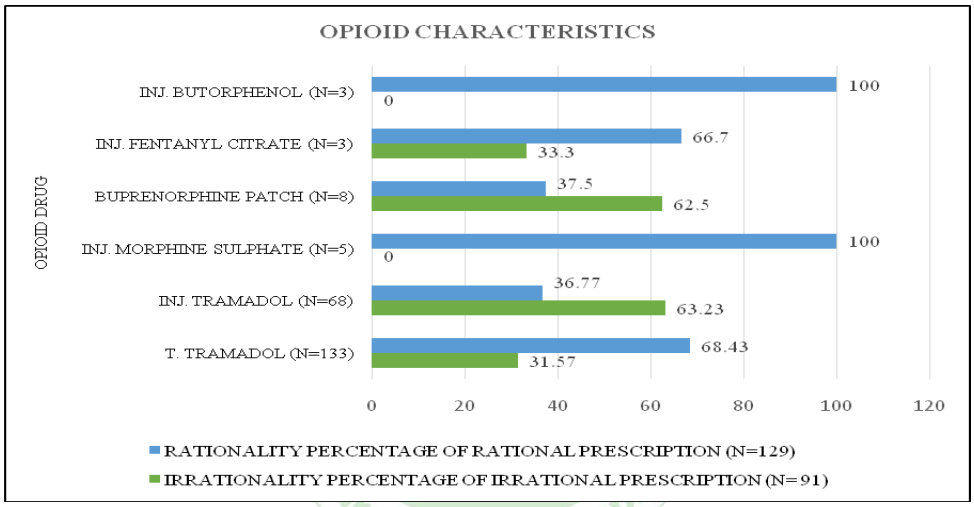

Figure 4: Type of opioid and rationality

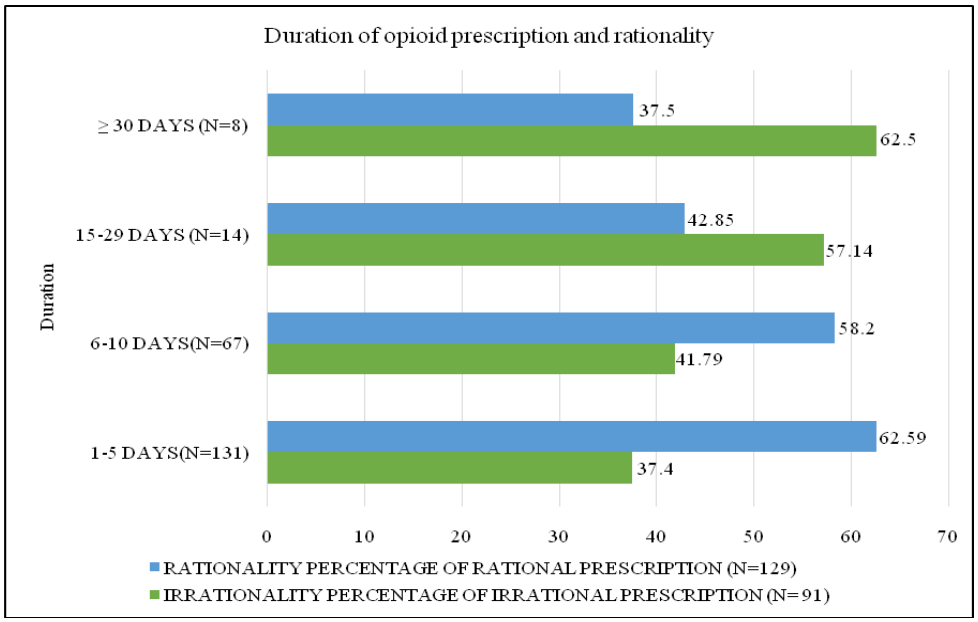

Figure 5: Duration of opioid prescription and rationality

Surgical Procedures and Opioid Prescription:

The Surgical procedure profile of current study population revealed there were 69 patients who underwent cardiac surgery, and 40 of them (18.18%) were prescribed opioids. Among these, 8 (8.79%) were identified as having irrational prescriptions. Out of 82 patients undergoing general surgery, 59 (26.81%) were prescribed opioids. Among those, a significant proportion, 47 (51.64%), were identified as having irrational prescriptions. Among 28 patients who had OBG surgery, 11 (5%) received opioid prescriptions, and 3 (3.29%) of these prescriptions were deemed irrational. There were 95 patients who underwent orthopaedic surgery, and a substantial number, 84 (38.18%), received opioid prescriptions. Of these, 26 (28.57%) were considered irrational. In case of uro-surgery, 31 patients had procedures, and 9 (4.09%) of them were prescribed opioids. Among these, 3 (3.29%) were categorized as having irrational prescriptions. Among, 33 patients who underwent neuro-surgery, 17 (7.72%) received opioid prescriptions, and 4 (4.39%) were found to have irrational prescriptions. This data lies in assessing the rationality of opioid prescription in different surgical categories and substantial variation in the prescription rates of opioids across different surgical procedures. The data indicates that there is a higher prevalence of irrational opioid prescriptions in the context of general surgery (51.64%) compared to other surgical categories, with orthopaedic surgery (28.57%) following closely behind. This finding underscores the need for improvements in prescription practices in these surgical specialties. While the data focuses primarily on prescription rationality, it also sets the stage for evaluating the effectiveness of patient education programs. Future analysis could determine if patient education has an impact on reducing the irrational use of opioids and improving their safe usage, handling, storage, and disposal. This data can serve as a starting point for further investigation into the rationality of opioid prescription practices in post-operative patients, with a specific focus on different surgical categories, and to assess the effectiveness of patient education in promoting safe opioid use.

Table 7: Surgical Procedures and Opioid Prescription

Surgical procedure	No. of patients prescribed with opioids (n=220) (%)	No. of irrational prescription (n=91) (%)
Cardiac surgery (n=69)	40 (18.18%)	8(8.79%)
General surgery (n=82)	59(26.81%)	47(51.64%)
OBG surgery (n=28)	11(5%)	3(3.29%)
Orthopedic surgery (n=95)	84(38.18%)	26(28.57%)
Uro-surgery(n=31)	9(4.09%)	3(3.29%)
Neuro-surgery (n=33)	17(7.72%)	4(4.39%)

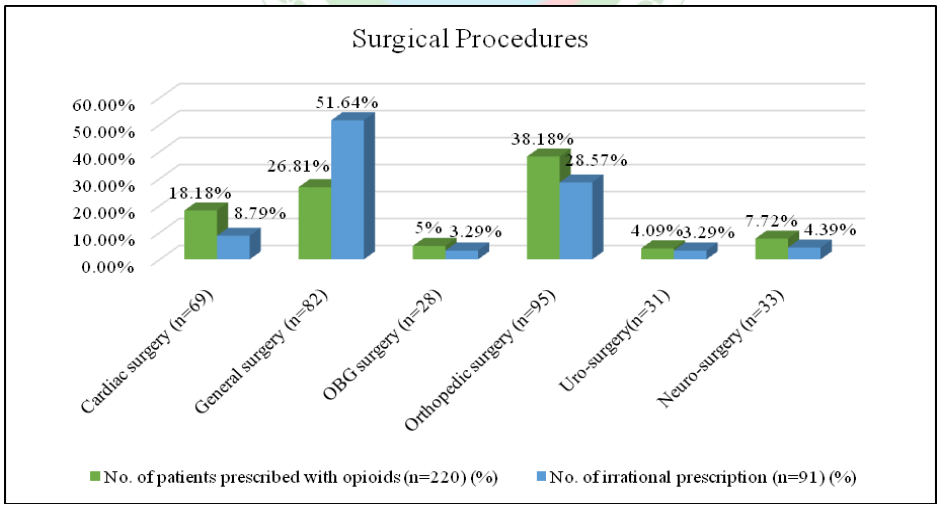

Figure 6: Surgical procedures and rationality

DISCUSSION

The current study revealed that the majority of the opioid prescription 57% (n=127) was found to be rational according to CDC guidelines. The study's findings are alarming, indicating that a considerable proportion (43%) of opioid prescriptions are deemed irrational. This is due to factors such as using opioids for mild to moderate pain, neglecting patient involvement in treatment decisions, and utilization opioids as a first-line treatment for post-operative pain management. Addressing these issues is essential for ensuring responsible opioid use and patient safety.

The study reveals that Tab. Ultracet, Semi-Ultracet, Tramadol, and Morphine are the most commonly received opioid medications in the post-operative patients,

highlighting the crucial role of pain management in patient care, tailored to the severity of pain. The inclusion of Buprenorphine prescriptions suggests potential opioid addiction or dependence in some patients, emphasizing the necessity for specialized care and medication plans in these cases. Furthermore, the study reveals that most patients are prescribed opioids for a short duration but some receive opioids for longer periods. Similar study conducted by Ladha K S et al demonstrates that codeine and tramadol account for a much larger proportion of postoperative opioid prescriptions in Canada, Sweden and United States indicating significant variations in the types of opioids prescribed after surgery across different countries. [2]

The excessive prescription of opioids, while possibly increasing patient satisfaction, also contributes to issues such as excess opioid consumption and a higher risk of opioid diversion. Similar results were obtained by Sabatino J M et al highlighting an excess of opioid pills were prescribed in orthopaedic surgery, contributing the significant contribution of this medical field to the ongoing opioid abuse and diversion epidemic. [5]

CONCLUSION

The finding shows majority of prescription were considered rational with adherence to established guidelines. Clinical practice guidelines, including those for which compliance is voluntary, may be able to change clinician behaviour. Our findings demonstrated that the rationality in the prescription can decreases in key metrics of inappropriate opioid prescribing patterns.

Drug characterization in opioid prescription shows that Tab. Tramadol was highly prescribed drug among opioids. Understanding the characteristic opioid prescribing after surgery and pre disposing factor can help health care provider identify at risk patients and adapt their pain management strategies.

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CONFLICT OF INTERESET

There is no conflict of interest.

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