Indian Journal of Pharmacy Practice., 2024; 17(4):317-324.
https://www.ijopp.org

Original Article

A Dashboard for Monitoring Opioids: Initiating and Assessing the Impact of Opioid Stewardship Programme in the Pain Management at Multispeciality Hospital in India

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ABSTRACT

Introduction: Pain affects 20% of adults globally and has an effect on their quality of life. Since 1999, the number of opioid overdose deaths has increased, leading to an opioid crisis. India's opioid prevalence is three times the global average, with 2.1% of the population using opioids. The opioid stewardship programme consists of a variety of harmful lowering interventions or methods that are widely used to steer clear of the effects of prescription opioids, including abuse, improper use, addiction, and opioid disorders. **Materials and Methods:** This was a single-centre prospective interventional study conducted at Kovai Medical Centre and Hospital (a 1000-bed hospital with 18 operating theatres and 135 ICU beds) in the state of Tamil Nadu from April 2023 to September 2023 to analyse the impact of OSP. **Results:** A total of 471 patients were included in the analysis. The mean age of the study population was 53.71 years (SD: 14.40), and statistical significance was observed (p-value = 0.53). The average numerical pain rating scale was measured by ANOVA, and the difference was significant between different opioids. Statistically, no association was observed between opioids and side effects (p-value > 0.05). The prevalence rate of sleeping disturbances and drowsiness was higher with the use of both benzodiazepines and opioids. No significant difference was observed in the average morphine milligramme equivalent across departments, p-value>0.05. **Conclusion:** We conclude that a comprehensive opioid stewardship programme offers a rational enhancement of the use of opioids and helps recognise the risks associated with opioid use.

Keywords: Opioid, Opioid crisis, Opioid stewardship programme, Pain, Morphine.

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Received: 12-06-2024;
Revised: 29-06-2024;
Accepted: 24-07-2024.

INTRODUCTION

Pain affects 20% of adults globally and has an effect on their quality of life. Untreated chronic pain has physical, psychological, social, and economic consequences. Opioids, considered essential for pain management by the World Health Organization since 1986, treat moderate to severe pain.[1] Since 1999, the number of drug overdose deaths has increased fourfold, making the opioid crisis a far greater threat to society than the COVID pandemic. Over 6% more people died from opioids in 2018-2019, and over 15% more people died from synthetic opioids.[2] Opioid prescriptions have skyrocketed over the previous 20 years, reaching a peak of 255,000,000 in 2012, or 81.3 opioid prescriptions per 100 people. Between 1999 and 2017, there were approximately 4 lakh opioid overdose fatalities (including those from illicitly authorised prescriptions).[3] India's opioid prevalence is three times the global average, with 2.1% of the population using it. Despite lower figures than in the USA, UK, and Canada, the future may see a shift towards a prescription-opioid epidemic.[4] Almost all of the 60-lakh estimated opioid use disorders in India originate primarily from the following states: Panjab, Haryana, Uttar Pradesh, Rajasthan, Gujarat, Maharashtra, Andhra Pradesh, and Delhi.[5] According to reports from developed countries, Opioid-Related Adverse Events (ORAEs) and deaths are very common, and an international catastrophe seems to be brewing. Prescription opioids seem to be the main factor contributing to overdose, which mostly happens inadvertently in patients.[6] The opioid crisis, which was declared a national emergency in 2017 by the US Department of Health and Human Services, has prompted hospitals and health care systems to develop strategies for addressing the opioid crisis. The Institute of Safe Medication Practices Canada defines opioid stewardship as coordinated interventions to improve, monitor, and evaluate opioid use, modelled after previous antimicrobial stewardship efforts. The term stewardship is defined as the task of taking

DOI: 10.5530/ijopp.17.4.51

care of something. Similar to antibiotic stewardship, the Opioid Stewardship Programme (OSP) consists of a variety of harmful lowering interventions or methods that are widely used to steer clear of the effects of prescription opioids, including abuse, improper use, addiction, and opioid disorders.[7]

Domains of the Opioid Stewardship Programme

According to the American Hospital Association (AHA), the Opioid Stewardship Measures Advisory Group, and the Centres for Medicare and Medicaid Services (CMS), certain domains will help to control the opioid crisis in several ways.[8]

Average total MME per prescription: This statistic shows the average daily number of Morphine Milligramme Equivalents (MME) provided per opioid prescription.

Number of opioid prescriptions per prescriber at discharge: This helps to control unwanted opioid prescriptions at discharge.

Percentage of patients receiving multimodal pain management: Patients with at least one opioid analgesic dose and at least one non-opioid analgesic. increase in patients receiving multimodal pain management.

Patient pain management planning and education: Is a set of organised exercises intended to enhance a patient's health state, health-related behaviours, or a combination of both. These activities promote the patient's knowledge base to understand and effectively manage pain. management.

Pain reassessment within 60 min of administration of pain medication: After the administration of analgesics, a reevaluation was performed to determine whether the intervention was effective. Reassessment will occur within 60 min after drug administration. If the pain score remains above 5, the patient will be offered additional interventions, including alternative therapies.

Percentage of patients with opioids and benzodiazepines co-prescribed: Co-prescription of benzo and opioid may increase the risk of morbidity.

Naloxone is prescribed for opioid overdose patients: Healthcare providers should consider providing naloxone to patients who are at a greater risk of overdosing on opioids.

Number of adverse safety events due to opioids: Balance of the harms and benefits of opioid events

Number of urine and blood drug screens: To screen the toxicity of opioids

Opioid/controlled substance agreement signed: The policy paper and controlled substance agreement are given to the patient by a doctor or medical assistant for perusal and signature.

Opioid tapering plan documented: Opioid tapering is a gradual decrease in opioid dosage. Tapering can be performed in inpatient or outpatient settings under physician supervision.

MATERIALS AND METHODS

Study Design and Setting

This was a single-centre prospective interventional study conducted at Kovai Medical Centre and Hospital (a 1000-bed hospital with 18 operating theatres and 135 ICU beds) in the state of Tamil Nadu from April 2023 to September 2023 to analyse the impact of OSP. This study was conducted after obtaining the approval of the institutional ethics committee and written informed consent from the patient.

Study Populations

The patient's medical records were reviewed prospectively to collect the data, and the data were entered in the data collection form. Patients are mostly covered by the following departments: surgical, orthopaedics, oncology, gastroenterology, and general medicine. The inclusion criteria were patients who were newly started on opioid analgesics, patients whose therapeutic goals had not been achieved with their current pain medication regimen, and patients who required long-term opioid therapy. The exclusion criteria were allergic reactions to morphine, hydrocodone, tramadol, and/or anaesthesia. The Numerical Pain Rating Scale (NPRS) 0-10 scale for assessing pain scores, with 0 representing no pain and 10 representing the most severe pain, was analysed in all patients before and after administering opioid medications. The use of Morphine Milligramme Equivalent (MME) allowed for the quantification of opioid use in terms of drug, dosage, frequency, and duration of use.

Study plan

Primary and Secondary Objectives

Primary objectives include assessing the health status of patients during opioid therapy and determining whether the prescribed opioids optimally meet the patient's needs and goals of care.

Secondary objectives include recognising Opioid Related Adverse Drug Effects (ORADE's), Analysing the daily dose of opioids using Morphine Milligramme Equivalents (MME), and examining the effects of co-prescribing opioids and benzodiazepines.

Statistical Analysis

All categorical variables were expressed using frequency and percentages. Continuous variables that did not follow a normal distribution were summarised using the median with quartiles (Q1, Q3); otherwise, the mean/SD was used. The Kolmogorov-Smirnov test was used to test normality. The median age across males and females was compared using the Mann-Whitney u test. The comparison of average morphine milligramme equivalents across

different departments was performed using the Kruskal-Walli test. A two-way repeated measure mixed ANOVA was performed to analyse whether the change in the average Numerical Pain Rating Scale (NPRS) over a period was significant between different opioids and departments. The association between opioids and side effects was assessed using Fisher's exact test. All statistical analyses were performed using SPSS, and a *p*-value less than 0.05 was considered statistically significant.

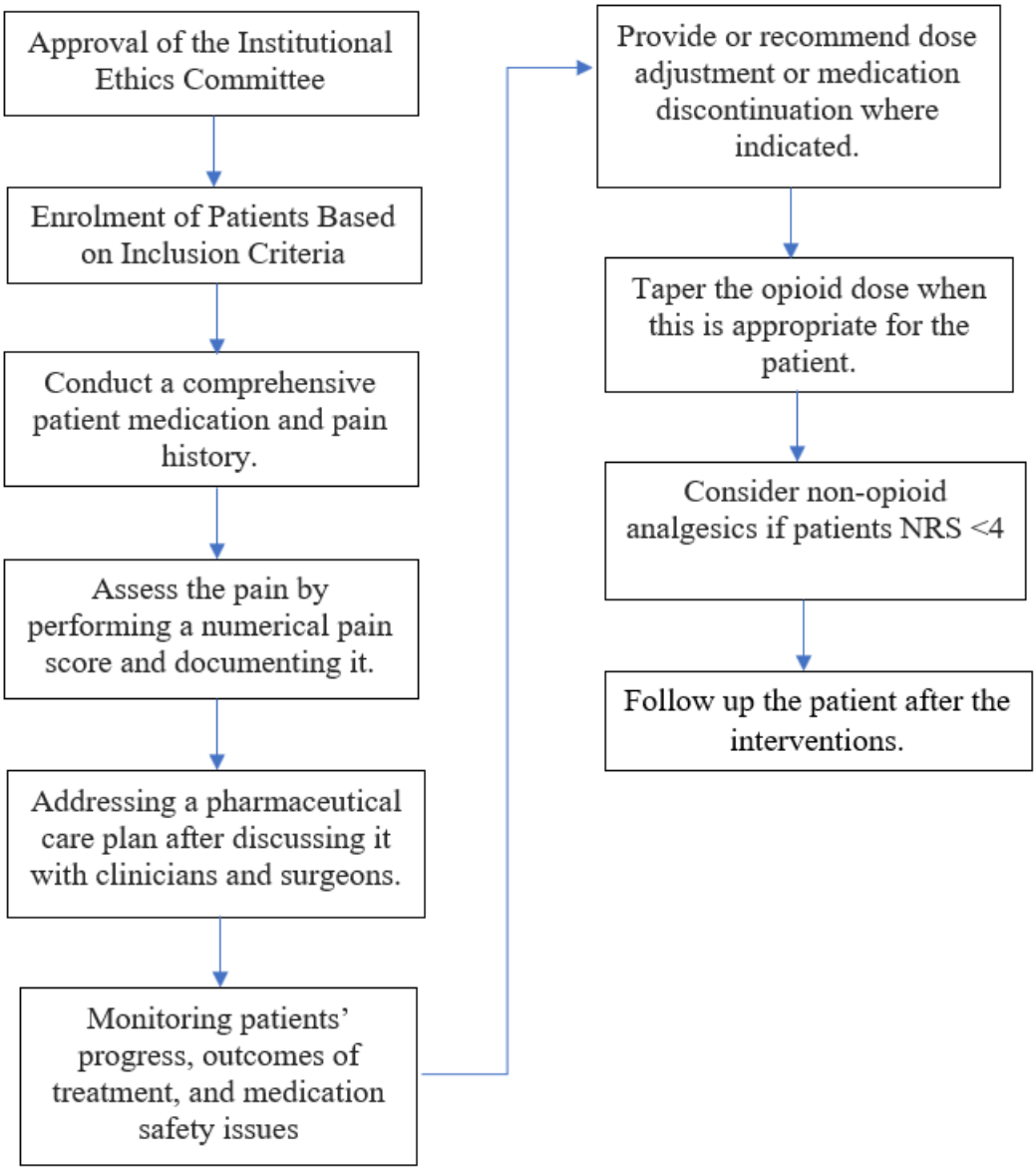
RESULTS

A total of 471 patients were included in the analysis: 204 patients from surgery (43.3%), 85 from oncology (18%), 54 from orthopaedics (11.4%), 27 from gastroenterology (5.7%), and 101 from other departments (21.4%). As Table 1 shows, the mean age of the four seventy-one (n = 471) patients was 53.71 years (SD: 14.40). Statistically, no significance was observed in the median age between males and females (p-value = 0.53).

Among the 471 participants, tramadol was the most used drug (n =275), followed by fentanyl (n=38) and buprenorphine patch (n=18). Tapentadol is the least commonly used opioid in our hospital settings; Morphine only suggested in cases of chronic pain. Certain patients were prescribed a combination drug (n=123). Combination therapy was applied if the patient's therapy goal was not met.

Impact of OSP on the Goal of Therapy

The primary objective of the study was to analyze whether the prescribed opioids optimally met the patient's goal of care. A two-way repeated measure mixed ANOVA was conducted to analyze the significance of the change in the average

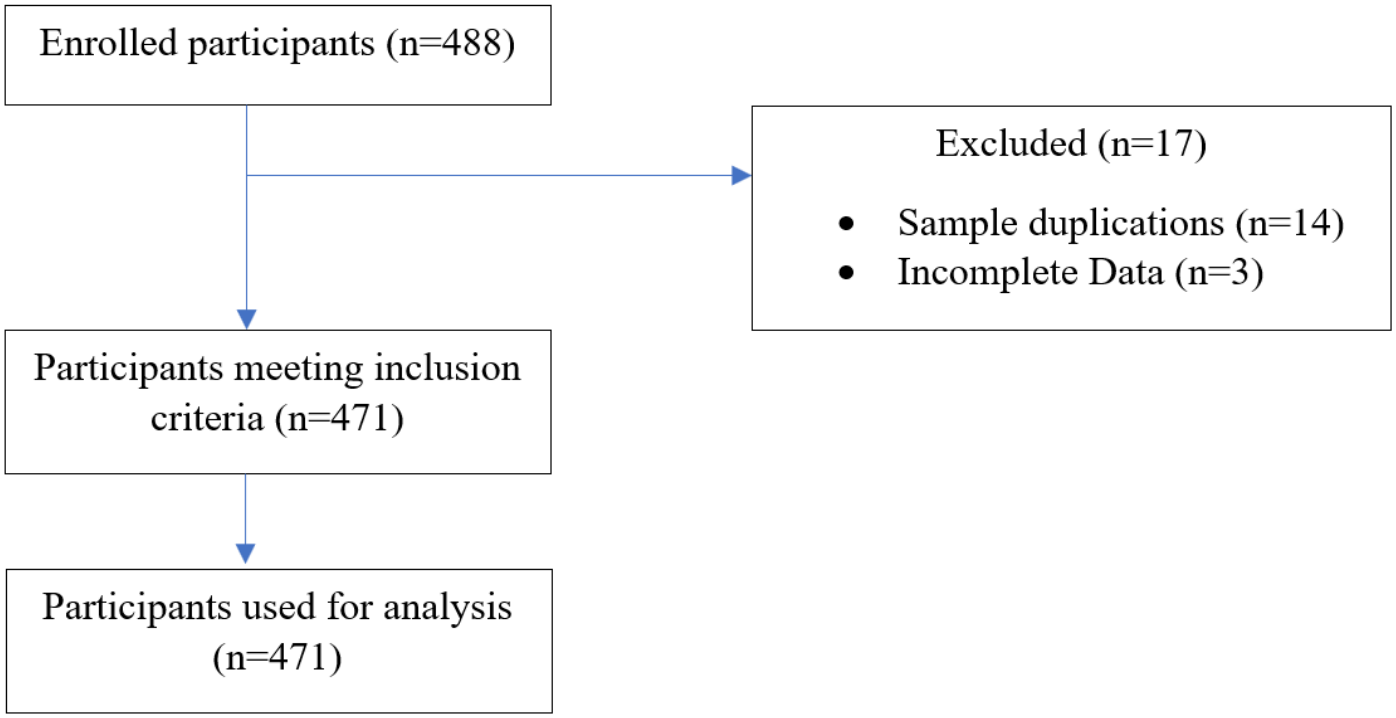


Flow of the study plan as per the study protocol.

numerical pain rating scale over time among different opioids. The interaction between group and time points proved to be statistically significant, with an F statistic of 9.75 and a *p*-value of 0.001 (Table 2). The average numerical pain rating scale was higher across all opioid groups at baseline compared to after the treatments. Pain scores were highest among those administered morphine, followed by combination therapy, buprenorphine, fentanyl, tramadol, and tapentadol. The mean numerical pain rating scale was higher in the morphine arm (7.00±2.28) and lower in the tapentadol arm (4.17±1.60) before intervention.

Impact of OSP on Side-Effects

As Table 3 shows, while no statistical association was observed between opioids and side effects (*p*-value>0.05), clinical difference was observed in the proportion of side effects between groups administered with different opioids. OSP helps to monitor the major side effects caused by opioids, which could be missed out during opioid therapy. A total of 259 side effects were encountered. Among the side effects, constipation (21.65%) was the most common, followed by nausea (12.1%), vomiting (4.2%), dry mouth (5.30%), sleeping problems (7.21%), drowsiness (3.82%), and itching (0.63%). Opioid-induced constipation is a common complication in patients who use opioid medications because of a



Flow of Participants as per the study protocol.

Table 1: Demographic characteristics of the study population.

	Gender								*p*-value
	Female				Male				
	Median	n	Percentile 25 (Q1)	Percentile 75 (Q3)	Median	n	Percentile 25 (Q1)	Percentile 75 (Q3)	
Age	55	168	45	65	55	303	43	63	0.53
Age (Mean age = 53.7)									
18-20					2				
20-29					25				
30-39					50				
40-49					85				
50-59					131				
60-69					118				
>70					60				

Table 2: Comparison of the numerical pain rating scale before and after the study population was administered with different opioids.

Parameter	Group	Sample size (*n*)	Before Mean±SD	After Mean±SD	Interaction F value (*p* value)
Numerical pain rating scale	Tramadol	275	4.61±0.94	1.60±1.43	9.75 (<0.001*)
	Buprenorphine Patch	18	5.50+1.04	1.94±1.06	
	Fentanyl Patch	38	5.11±0.83	1.18±1.23	
	Morphine	11	7.00±2.28	4.09±3.24	
	Tapentadol	6	4.17±1.60	2.00±1.41	
	Combination	123	5.65±1.18	1.63±1.35	

*Statistically significant.

Table 3: Opioid associated side effects among the study populations.

Side Effects		Opioids												Fishers exact test *p*-value
		a		b		c		d		e		f		
		n= 275	%	*n*= 18	%	*n*= 38	%	*n*= 11	%	*n*= 6	%	*n*= 123	%	
Constipation	No	228	82.9	16	88.9	29	76.3	5	45.5	5	83.3	86	69.9	0.005*
	Yes	47	17.1	2	11.1	9	23.7	6	54.5	1	16.7	37	30.1	
Nausea	No	243	88.4	15	83.3	34	89.5	10	90.9	4	66.7	108	87.8	0.61
	Yes	32	11.6	3	16.7	4	10.5	1	9.1	2	33.3	15	12.2	
Vomiting	No	266	96.7	17	94.4	35	92.1	11	100.0	6	100.0	116	94.3	0.52
	Yes	9	3.3	1	5.6	3	7.9	0	0.0	0	0.0	7	5.7	
Sleeping Disturbance	No	230	96.2	14	93.3	27	96.4	9	100.0	5	100.0	79	77.5	0.001*
	Yes	9	3.8	1	6.7	1	3.6	0	0.0	0	0.0	23	22.5	
Drowsiness	No	236	98.7	15	100.0	27	96.4	8	88.9	4	80.0	90	88.2	0.001*
	Yes	3	1.3	0	0.0	1	3.6	1	11.1	1	20.0	12	11.8	
Dry Mouth	No	258	93.8	16	88.9	38	100.0	11	100.0	6	100.0	117	95.1	0.47
	Yes	17	6.2	2	11.1	0	0.0	0	0.0	0	0.0	6	4.9	
Itching	No	273	99.3	17	94.4	38	100.0	11	100.0	6	100.0	123	100.0	0.26
	Yes	2	0.7	1	5.6	0	0.0	0	0.0	0	0.0	0	0.0	

a-Tramadol, b-Buprenorphine patch, c-Fentanyl patch, d-Morphine, e-Tapentadol, f-Combination therapy.*Statistically significant.

reduction in GI motility. Opioids can cause unwanted side effects for short-course periods; they may worsen during long-course periods. Itching is the least and rare side effect caused by opioids due to pseudoallergic immune reactions.

Impact of OSP on Daily Dose (Morphine Milligramme Equivalents)

This result suggests that no significant difference was observed in the average morphine milligramme equivalents across departments, *p*-value>0.05. The median range of MME in all departments was 15 with different quartile ranges. OSP helps to maintain the normal opioid daily dose window in each individual. As Table 4 demonstrates, daily doses of opioids are normal (<90MME).

Impact of OSP on the Concurrent Use of Benzodiazepines

Of the 471 patients, 72 were prescribed both opioids and benzodiazepines. As many studies have shown, benzodiazepines may increase the risk of a patient's morbidity conditions when used with opioids. Figure 1 illustrates the prevalence rates of sleep disturbances and drowsiness among patients undergoing opioid therapy, comparing those with and without benzodiazepines.

Impact of OSP on Pharmaceutical Care

As illustrated in Figure 2, significant advancements in pharmaceutical care were achieved for a group of 471 patients. The programme addressed 259 opioid-related side effects,

employing targeted interventions to ensure patient well-being and adherence. Adequate therapy for side effects was provided to 128 individuals, contributing to a comprehensive approach. Continuous monitoring of the Numerical Pain Rating Scale facilitated prompt adjustments to individualized opioid regimens, optimizing pain control for all 471 individuals. Commitment to patient-centered care was evident through personalized opioid regimens, emphasizing dose tapering when necessary. Patient education initiatives empowered all 459 individuals to actively engage in their treatment plans, resulting in improved adherence and positive outcomes. The switch to non-opioid analgesics for 389 patients occurred upon symptomatic improvement, demonstrating a dedication to diversified pain management strategies. Successful management of morphine milligram equivalents for all 471 patients further contributed to enhanced safety, allowing for the monitoring of daily doses. Additionally, successful benzodiazepine dose management, including tapering or discontinuation when appropriate, contributed to enhanced patient safety for 34 individuals. Overall, this comprehensive approach has demonstrated improvements in patient outcomes, safety, and the responsible use of opioid medications across the entire group.

DISCUSSION

This study provides insight into opioid stewardship and further strong evidence for the need for opioid stewardship and the current role and impact of OSP. We measured major outcomes after the implementation of the opioid stewardship programme based on its domain. A total of 471 patients were analysed with opioid medications over a period of 6 months. We were able to analyse the patient's numerical pain rating scale and calculate the daily dose of opioids administered to each individual patient in a day. These findings collectively imply that this stewardship programme may lower opioid prescription harm and misuse without affecting pain management. During the study period, it was observed that opioid usage during the post-operative surgical period was higher than that in other conditions.

The primary goal of this study was to analyse the goal of therapy for patients with opioids. Opioid medication is only required in cases of moderate to severe pain, the numerical pain rating scale is a unidimensional measure of pain intensity among the study population, ranking from 0 to 10. where zero indicates no pain, whereas increasing the number indicates increasing pain intensity. According to the findings of our study, administering opioid medication to patients with moderate to severe pain aids in pain management and significantly reduces pain scores.

Table 4: **Average morphine milligramme equivalents across different departments.**

Department	Morphine Milligramme Equivalent				Test statistic (*p*-value)
	Median	Q1	Q3	n	
Surgery	15	10	20	204	9.07 (0.06)
Orthopeadics	15	10	60	54	
Gastroenterology	15	11	60	27	
Oncology	15	10	60	85	
others	15	10	60	101	

Normal range < 90MME.

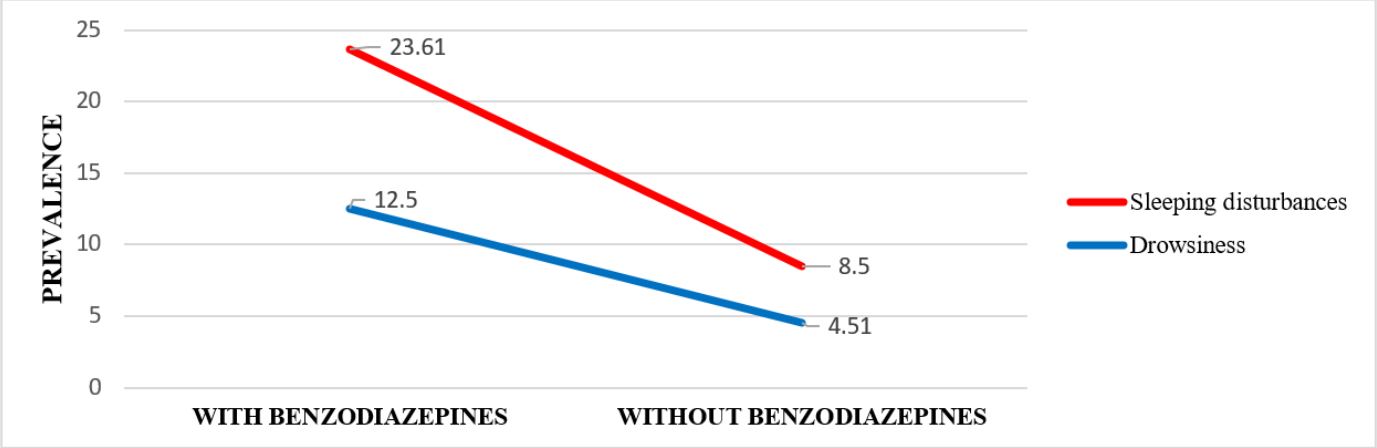


Figure 1: Prevalence of sleeping disturbances and drowsiness.

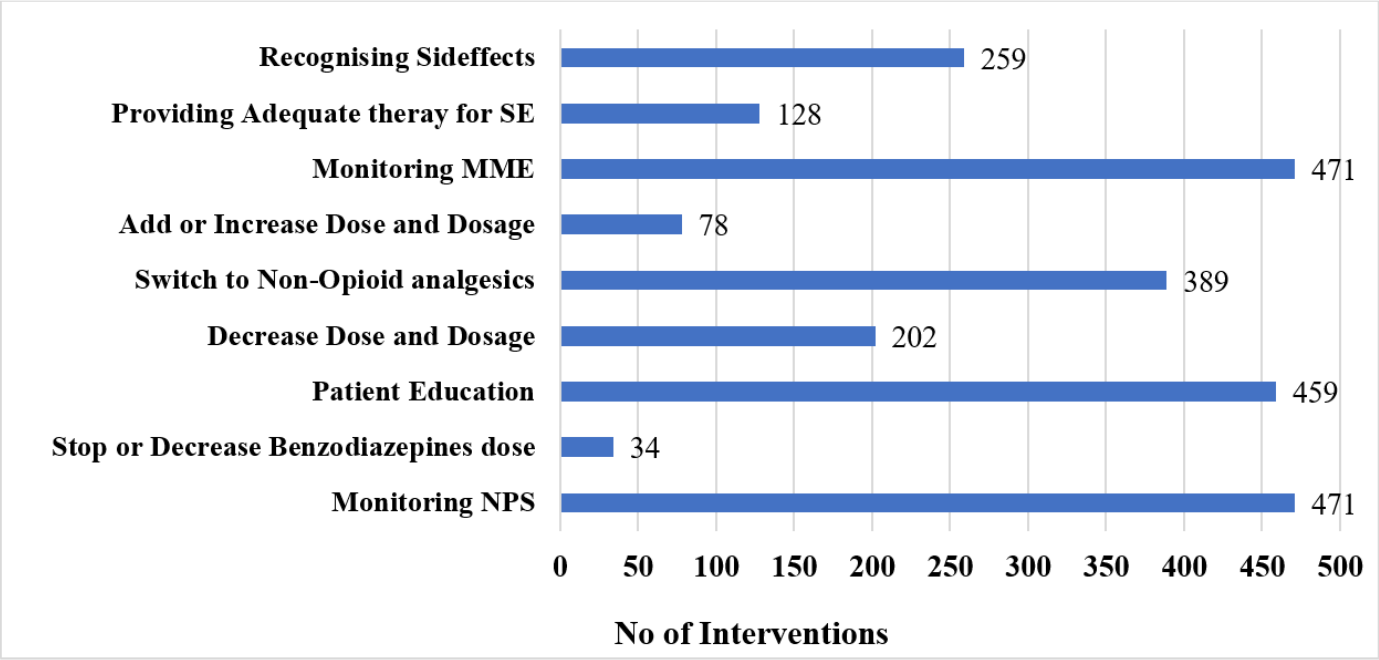


Figure 2: Pharmaceutical Care Through Opioid Stewardship Programme.

This result further strengthened the importance of pain score assessment in pain management.

Side effects associated with opioid therapy are more frequent; 21.6% of patients experience constipation, followed by nausea, vomiting, and itching. Opioid medications offer crucial pain relief for numerous older adults, the emergence of troublesome side effects like constipation, nausea, and itching can profoundly affect their quality of life.[9] Among the 471 patients who received opioids without benzodiazepines, 34 manifested sleeping disturbances, while 18 reported drowsiness. However, it is very difficult to provide an intervention for sleeping disturbances due to the varying types of sleeping disturbances. These findings exhibit parallels with the research indicating that depending on whether opioids are utilized for short-term, long-term, or during tapering, they can elicit varied impacts on sleep architecture.[10] Patients who take opioids may have no side effects or experience minor side effects, which could be missed during opioid therapy unless they are severe. This underscores the importance of the opioid stewardship programme in monitoring each patient's side effects and providing suitable interventions.

The daily dose of opioids is calculated using the Morphine Milligram Equivalent (MME) rather than the Defined Daily Dose (DDD). The defined daily dose for opioids did not correspond to actual opioid dosages.[11] This research may be the first study in India to determine the Morphine Milligram Equivalent (MME) among individual patients receiving opioid medications. The results suggest that the median MME range is under 90, indicating a very low risk of opioid overdose in our multispecialty hospital and positive prescriber attitudes toward opioid use. Moreover, individual patient monitoring, an integral component of our opioid stewardship programme, ensures that each patient's opioid therapy is optimized. Calculating the daily MME for each individual will assist healthcare professionals in tailoring opioid dosing and reducing the risk of opioid overdose and Opioid Use Disorder (OUD).

The concurrent use of benzodiazepines and opioids can result in an overdose, and both drugs can cause sedation and sleep disturbances in patients. One of the main domains of OSP is monitoring the concurrent use of opioids and benzodiazepines. The risk of an opioid overdose can increase when benzodiazepines and opioids are used together.[12] Opioids should be administered carefully, even if the patient is on a short course of benzodiazepines. As per the study results, the prevalence of sleeping disturbances and drowsiness was higher in patients receiving both opioid and benzodiazepines than in those receiving opioid medication. According to the OSP principle, it provides specific health care to patients who are on concurrent use of benzodiazepines and opioids and provides individual interventions based on their condition, such as dose titration and stopping medication.

The outcomes presented in Figure 2 underscore the efficacy of our opioid stewardship programme for 471 patients. Targeted interventions successfully addressed 259 opioid-related side effects, reflecting the program's adaptability to individual patient needs. The utilization of the Numerical Pain Rating Scale allowed for continuous monitoring and timely adjustments to optimize pain control. Patient-centered care was evident through personalized opioid regimens and educational initiatives, fostering active engagement from 459 individuals in their treatment plans.

Diversified pain management strategies, including the switch to non-opioid analgesics for 389 patients upon symptomatic improvement, align with contemporary recommendations and showcase a commitment to tailored care. Successful management of morphine milligram equivalents and benzodiazepine doses contributed to enhanced safety and responsible medication use.

LIMITATIONS

This study has certain limitations. The single-center design over 6 months may limit the generalizability of findings. Additionally, the study's inability to determine the percentage reduction in opioid usage before and after the intervention presents a limitation. Furthermore, the exclusion of pediatric opioid usage analysis, due to age limitations of the numerical pain rating scale, restricts the comprehensiveness of the study. Future research will address these limitations to enhance the programme's effectiveness and applicability across diverse healthcare settings.

CONCLUSION

The implementation of an opioid stewardship programme demonstrates promise in effectively addressing the impending opioid crisis, as evidenced by the findings of this study. Within our multispecialty hospital, the interventions employed have shown tangible benefits in optimizing opioid utilization. Therefore, it is concluded that a comprehensive opioid stewardship programme serves as a rational approach to enhancing opioid use and effectively mitigating associated risks.

ACKNOWLEDGEMENT

We would like to express our sincere gratitude to all the doctors and medical staff at Kovai Medical Centre and Hospitals for their invaluable support and assistance throughout the course of this research. Their expertise, guidance, and dedication have been instrumental in the completion of this study. This work would not have been possible without the collaborative efforts and shared knowledge of the entire team at Kovai Medical Centre and Hospitals. Their professionalism and dedication to advancing medical science are deeply appreciated.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

OSP: Opioid Stewardship Programme; **ORAE:** Opioid-Related Adverse Events; **MME:** Morphine Milligramme Equivalent; **WHO:** World Health Organization; **AHA:** American Hospital Association; **DDD:** Defined Daily Dose; **OUD:** Opioid Use Disorder; **NPRS:** Numerical Pain Rating Scale.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was reviewed and approved by the Institutional Ethics Committee (IEC) of Kovai Medical Centre and Hospitals (KMCH) with the reference number EC/AP/1040/04/2023. Informed consent was obtained from all individual participants included in the study.

SUMMARY

The prospective study was conducted at Kovai Medical Centre from April to September 2023, analyzing 471 patients to evaluate the impact of an Opioid Stewardship Programme. Significant variations in pain scores were noted among different opioids, with benzodiazepines and opioids correlating with increased sleeping disturbances. Side effects associated with opioids and their milligram equivalent were also evaluated. The study underscores the programme's role in optimizing opioid use and mitigating associated risks, demonstrating its promise in effectively addressing the opioid crisis in hospital settings.

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Cite this article: Dhandapani C, Rajkumar KS, Lokesh P, Madhumitha L, Aravinth C, Sharif MS. A Dashboard for Monitoring Opioids: Initiating and Assessing the Impact of Opioid Stewardship Programme in the Pain Management at Multispeciality Hospital in India. Indian J Pharmacy Practice. 2024;17(4):317-24.