Drug Utilization And Adverse Effects Profile in A Pain Clinic in A Tertiary Care Hospital

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Abstract
Context: *A Pain clinic is a health care facility which mainly concentrates on the diagnosis and management of chronic pain . pain clinic is taken care by team of Health care professionals. Primary care doctors refer their patients to pain clinic when they exhausted other methods of pain relief therapy.*
Aim: *To study the recent trends in drug utilization pattern in a pain clinic which also includes evaluation of response to pharmacological pain therapy and to assess the adverse effects profile in a pain clinic.*
Study Design: *Observational study*
Methods and Material: *For this study 100 patients attending pain clinic were enrolled in the study for prescheduled two months. Datas of the patients were collected . patients followed up from the first visit at the initiation of therapy , at the end of first month and at the end of second month to access the response of pain therapy and adverse effects which were noted*
Statistical analysis used: *Descriptive statistics*
Results: *Patients attending pain clinic was diagnosed with different painful conditions like chronic knee pain , plantar fasciitis , low back pain, trigeminal neuralgias and neuropathic pain etc..patients were treated with multimodal pharmacotherapy in an integrated multidisciplinary therapeutic approach. commonly prescribed class of drugs were paracetamol, NSAIDS and opioids along with by adjuvant therapies like Anti depressant and Anti epileptics etc..*
Conclusions: *Paracetamol and NSAIDS like aceclofenac, opioids like tramadol were commonly prescribed drugs followed by adjuvant drugs like pregabalin, gabapentin and amitriptyline. Among the combination drugs three drug combinations , paracetamol+tramadol+amitriptyline , paracetamol+aceclofenac+pregabalin and four drug combination paracetamol+ tramadol + pregabalin+amitriptyline shows favourable response in improving pain relief and quality of life .*
Keywords: *NSAIDs, paracetamol and opioids, pain clinic, tertiary care hospital*

I. Introduction

Drug utilization research[1] is defined as the marketing, distribution, prescription, and use of drugs in a society, with emphasis on the resulting medical, social and economic consequences.The main aim of drug utilization research is to facilitate the rational use of drugs. For the individual patient, the rational use of a drug implies the prescription of a well documented drug at an optimal dose and duration of treatment along with the correct information, at an affordable price .A perfect knowledge about drug prescription enables us to improve prescribing habits..This research in itself does not necessarily provide answers, but it contributes to rational drug use in important ways.

Drug utilization and pharmacoepidemiology[1] gives knowledge about pattern , quality, determinants and outcome of drug usage.It also gives estimation of number of patients exposed to specified drugs within a given Period of time. The study of prescribing pattern seeks to monitor rational use and cost effectiveness of drug usage. It also determines the proper usage of drugs whether over used or under used and the extent to which alternative drugs are available to treat particular conditions.This study aims to provide a knowledge about drugs , that were prescribed in a pain clinic and to obtain a pattern of rational drug usage and to monitor the adverse effects profile. International Association for the study of pain define pain [2] as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage' . One in five people of all ages have moderate to severe pain ,one third of individuals of working age who have chronic pain have lost the ability to perform wage earning or other work.

Chronic pain[3] is defined as 'pain without apparent biological value that has persisted beyond the normal tissue healing time usually taken to be 3 months'. Access to timely and appropriate treatment for chronic pain is an international problem. poor access to care can lead deterioration of health ,decreases quality of life. Pain clinic have been designed to help patients suffering from different painful conditions. A multidisciplinary pain clinic[4] is typically started by anesthesiologist, neurologists, physical medicine and rehabilitation doctors ,

oncologist, psychologist, physical therapist and acupuncturist. Achieving effective pain management requires careful assessment and regular review of the patients experience[5] of pain. As pain is a subjective symptom, pain assessment tools are usually based on the patients own perception of his/her pain and its severity[6].National initiative on pain control(NIPC)[7] has 3 diagnostic tools to access pain.
1) 0-10 numeric pain rating scale
2) Wong baker faces pain rating scale
3) Pain quality assessment scale.

This study was done in a pain clinic
❖   To assess the drug utilization pattern in pain clinic ,
❖   To determine the effectiveness of pharmacological pain therapy using pain assessment tool[7] and adverse effect profile monitoring using naranjo adverse drug reaction probability scale[8] .

II. Methods And Material

This study was done by Department of pharmacology, Govt.Stanley Medical College in Department of Anaesthesia, Govt. Stanley Medical College and Hospital, Chennai after getting approval from the Institutional Ethics Committee.

2.1 Study Design:

It is an Observational study done in100 patients attending pain clinic. Patients and case records were reviewed in the study and parameters were noted. The inclusion criteria were (1) Age above 18 years of age and below 60 years of age (2) Both males & females.(3) Patients attending pain clinic who are managed conservatively.(4) Patients who are willing to participate in the study. (5) Patients treated with oral formulation. (6) Patients treated with fixed dose combinations. The main exclusion criteria were patients below 18 years of age and above 60 years of age, patients who are not willing to participate in the study, patients who are critically ill attending pain clinic for palliative care, patients with past H/O gastrointestinal diseases, patients with past H/O renal disease, patients with past H/O liver disease.

2.2 Study Procedure:

This study was conducted by Department of pharmacology, Govt. Stanley Medical College in Department of Anaesthesia, Govt. Stanley Hospital,Chennai. This will be a hospital based, observational study reviewing 100 patients attending pain clinic. Patients diagnosed with different painful conditions were enrolled in the study considering the inclusion and exclusion criteria. The following parameters will be recorded.
❖   Age
❖   Gender
❖   Diagnosis
❖   Number of drugs prescribed
❖   Response to pain therapy assessed by pain scale and
❖   Adverse effects profile by using naranjo adverse drug reaction probability scale
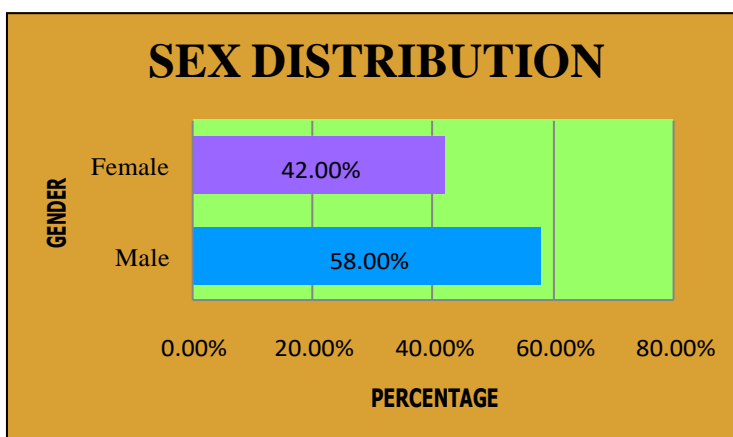
III. RESULTS

3.1 Gender distribution

Fig. 1: Details of Gender distribution of patients.

There was a male preponderance in patients attending pain clinic.
Out of 100 patients, 58 (58 %) patients were males and 42(42 %) patients were females(vide fig no.1).
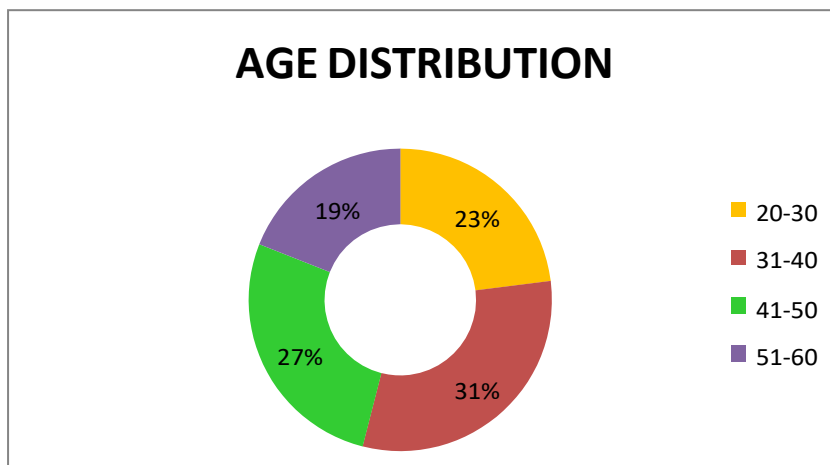
3.2 Age distribution

Fig. 2: Age distribution of patients

The results of this study revealed that patients attending pain clinic in the age group 31-40 was 31%, in the age grp 41-50 was 27%, 20-30 was 23%, 51-60 was 19% as shown in the fig no.2

3.3 Disease distribution

As Shown in fig no.3, the percentage distribution of chronic knee pain was 21%, plantar fascitis was 16%,low back pain was 13%, chronic fibromyalgia was 11 %, post herpetic myalgia was 11% ,pudendal neuritis was 7%, migraine was 3%, Undiagnosed was 2% .
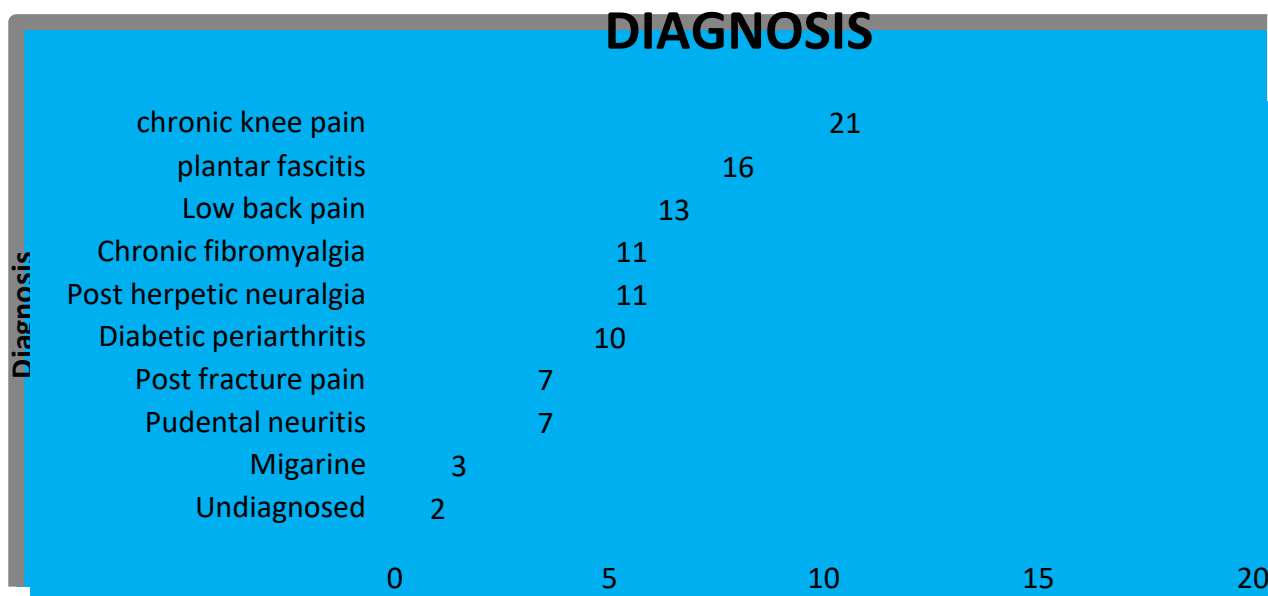

Fig. No 3. Details of Disease distribution.

3.4 Drugs prescribed

Table 1: Details of drugs prescribed

S.NO	Name of drugs used in pain clinic with dose	No of prescription	Percentage%
1.	Aceclofenac(100mg)	38	38%
2.	Tramadol(50mg)	62	62%
3.	Paracetomol(500mg)	99	99%
4.	Pregabalin(75mg)	32	32%
5.	Gabapentin(300mg)	14	14%

6.	Amitriptyline(25mg)	47	47%
7.	Ranitidine(150mg)	29	29%
8.	Omeprazole(20mg)	58	58%
9.	ondansetron(4mg)	16	16%
10.	Bisacodyl (5mg)	26	26%
11.	Cefixime (400mg)	32	32%
12.	Antacid	51	51%
13.	Multi vitamin tab	49	49%

Results of table 1 reveals that Paracetamol (99%) was the commonly prescribed drug, followed by tramadol (62%). Aceclofenac was prescribed less commonly accounts for 38%. Other drugs apart from analgesics in decreasing order of frequency are omeprazole(58%), antacid(51%), multivitamin(49%), ranitidine(29%), bisacodyl (26%) and ondansetron(16%). Drugs prescribed for neuralgic pain were pregabalin(32%) followed by gabapentin (14%).

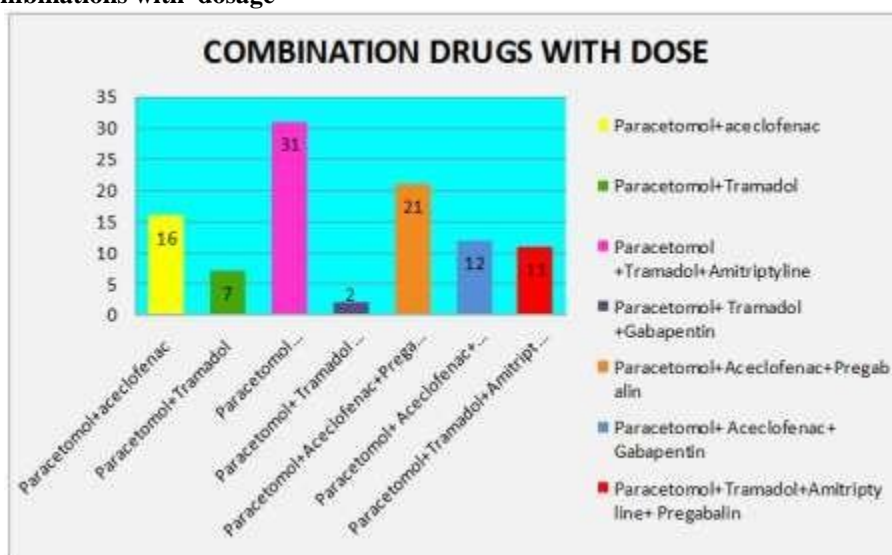### 3. 5 Drug combinations with dosage

Fig 4: Details of combination drugs with dose

Of the combination therapy, the commonly prescribed combination was paracetamol+ tramadol + amitryptyline (31%). Paracetamol was present in all the combinations. Of the 7 combination therapies, two were dual drugs, four were triple therapies and one was quadruple therapy as shown in fig no. 4

3.6 Response to pain therapy

The response to combination therapies according to universal pain scale shows good response to combination drugs like paracetamol + tramadol + amitriptyline , paracetamol + tramadol + amitriptyline + pregabalin, paracetamol + aceclofenac + pregabalin. as shown in fig no 5.
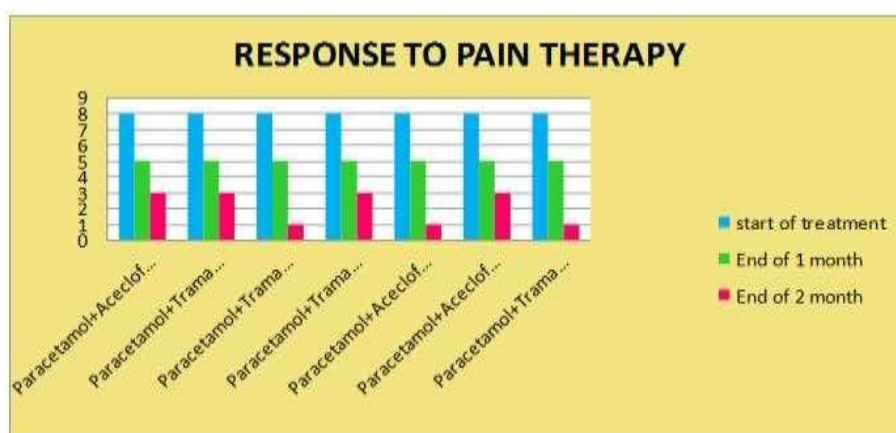

Fig 5: Response to pain therapy

3.7 Adverse effects

The Adverse effects noted in the study were heartburn, nausea, epigastric pain, headache, dizziness. Heartburn (31%) was the commonly encountered adverse effect and it occurred due to NSAIDS and tramadol followed by nausea (24%) predominantly produced by tramadol. Epigastric pain accounts for 19% was due to aceclofenac and pregabalin.as shown in fig no. 6
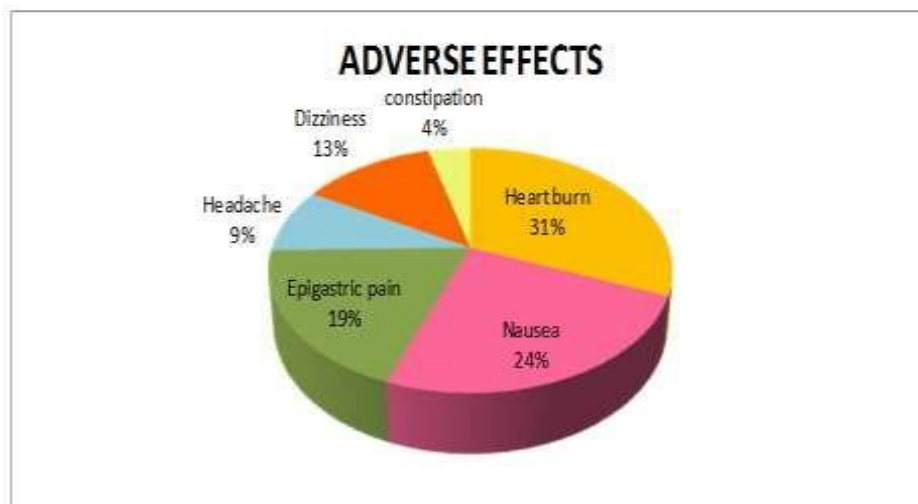

Fig 6: Details of Adverse effects

IV. Discussion

For this study, 100 patients attending pain clinic were enrolled in the study for prescheduled two months. Datas of the patients were collected . patients followed up from the first visit at the initiation of therapy , at the end of first month and at the end of second month to access the response of pain therapy and adverse effects which were noted. The results of the study revealed that out of 100 patients , 58(58%)patients were males and 42(42%) patients were females .According to similar Indian study done by Debjyoti dutta[9] et al , results shows that female outnumbers males but in our study, there was a male preponderance in patients attending pain clinic as shown in figure 1. 31% of the study population belongs to the age group of 31-40 years of age. Patients attending pain clinic were maximum at the age group of 31-40 years of age which was similar to the results of Debjyoti dutta et al.The provisional diagnosis was made at the first visit for 98 patients ,remaining 2 was undiagnosed.

Among 98 patients attending pain clinic , chronic knee pain(21%) was the most common cause for pain which was similar to previous Dejyoti dutta et al drug utilization study , other causes were plantar fascitis (16%), low back pain(13%), fibromyalgia(11%),post herpetic neuralgia(11%). Neuropathic pain like diabetic periarthritis accounts for 10% and pudendal neuritis accounts for 7%. Migraine accounts about 3%. The most commonly prescribed drugs were analgesics that is paracetamol, NSAIDS and opioids along with adjuvant drugs amitriptyline , Pregabalin and gabapentin where as in the previous study by Debjyoti dutta et al carbamazepine, flunarizine, valprote were other adjuvants additionaly given . gabapentin and pregabalin was given for neuropathic pain. Gastro protective agents like antacid, ranitidine,omeprazole were prescribed for adverse effects like heartburn and epigastric pain. But in the previous study by Debjyoti dutta et al shows that rabeprazole and famotidine were commonly prescribed gastroprotective agents. Bisacodyl was given for patients complaining of constipation. Cefixime was the commonly preferred antibiotic for patients associated with bacterial infections.

Almost all patients in this study were prescribed with combination drugs as shown in figure 4. Of these combination drugs, paracetamol+ tramadol +amitriptyline(31%) were given to maximum number of patients and interestingly paracetamol(99%) was present in all the combination drugs, there were no fixed dose combinations given in the pain clinic.

Of the seven combination drugs , the response to pain therapy according to universal pain scale shows that greatest improvement in pain relief was found in patients receiving three drug combinations Paracetamol+tramadol+amitriptyline, Paracetamol+aceclofenac+pregabalin and in patients receiving four drug combinations Paracetamol+tramadol+amitriptyline+pregabalin .In this the pain scale shows at the initiation of therapy it was 7-8 , at the end of first month 5-6 and at the end of second month 1-2.In patients receiving two drug combinations like paracetamol +aceclofenac , paracetamol+tramadol, the pain scale at the end of second month was only 3-4, in patients receiving 3 drug combination drugs that is paracetamol+tramadol+gabapentin

and paracetamol+aceclofenac+gabapentin the pain scale reduce to 3-4only. Addition of gabapentin to paracetamol+tramadol and paracetamol+aceclofenac did not siginifically alter the pain scale, where as addition of amitriptyline and pregabalin to paracetamol and tramadol reduced the pain scale from 5-6 at the end of second month to 1-2 at the end of second month.

The adverse effects noted in this study were heart burn, nausea , epigastric pain, headache , dizziness and constipation . Heart burn (31%) was the commonly encountered adverse effect and it was occurred due to NSAIDS and tramadol followed by nausea (24%) predominantly produced by tramadol. Epigastric pain (19%) was mainly due to NSAIDS. 13% of patients had dizziness on using tramadol and pregabalin . Though constipation is the main side effect of tramadol, 9 out of 62 patients receiving tramadol (4%) patients only had complaints of constipation.

So this pattern of drug usage implies that inspite of various combination drugs , compliance were good in combination drugs mainly due to patient's improvement in pain relief and quality of life .

V. Conclusion

In this observational study , we found that paracetamol, NSAIDS like aceclofenac, opioids like tramadol were commonly prescribed drugs followed by adjuvant drugs like pregabalin, gabapentin and amitriptyline. Among the combination drugs three drug combinations , paracetamol + tramadol + amitriptyline , paracetamol+aceclofenac+pregabalin and four drug combination paracetamol+ tramadol +amitriptyline + pregabalin shows favourable response in improving pain relief and quality of life . we need to gain more knowledge about drug utilization study and study to be conducted in more number of patients.

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