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Original Research Article

## Study on drug utilization pattern in conservative management of patients with pancreatitis in a tertiary care teaching hospital

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### ABSTRACT

**Background:** Drug utilization plays a key role in helping the healthcare system to understand, interpret and improve the prescribing, administration and use of medications. The objective of the study was to assess the drug utilization pattern of drugs prescribed in conservative management of pancreatitis patients in a tertiary care teaching hospital.

**Methods:** This prospective observational study was conducted in department of surgery, Rajah Muthiah Medical College and Hospital, Annamalai University. The study period was six months from November 2019 to April 2020. A total of 115 patients were selected based on inclusion and exclusion criteria.

**Results:** The study population containing of 90% (n=104) males and 10% (n=11) females were included in the study. Most of the patients between age group of 25-44 years (48%). The most common etiology was alcoholic 68% (n=78). 7% of population with comorbidities (5% hypertension, 2% diabetes mellitus). In analgesics, tramadol (28%) and in antibiotics cefotaxime 21% was most prescribed. Lactated ringer solution (36%) was prescribed most as intravenous hydration. 7% (n=8) and 3% (n=4) of patients receiving enteral nutrition and parenteral nutrition. The average number of drugs per prescription was 8.5. Out of 1205 drugs, 61% of drugs prescribed in generic form, 39% were prescribed in brand name. The study analyzed that 69% of drugs were prescribed from essential drugs list (EDL) 2019 and 84% drugs prescribed from national list of essential medicines (NLEM) 2015. Number of prescriptions with injection were 79.07%. The overall antibiotic encounter rate 15%. Prescribed daily dose/defined daily dose (PDD/DDD) ratio of folic acid was 5.

**Conclusions:** Drug utilization study can help in evaluating the quality of care given to the pancreatitis patients and promote rational use of medicines.

**Keywords:** Drug utilization, Defined daily dose, Prescribed daily dose, Prescribing pattern, Pancreatitis

### INTRODUCTION

Drug utilization research is an invaluable tool for all involved in drug and health policies and related decision-making. Drug utilization is defined by World Health Organization (WHO) in 1977 as “marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences”.<sup>1</sup> Research on drug utilization focus on factors related to prescribing, dispensing, administering and taking of medication and its associated events.

The ultimate purpose of drug utilization research is to contribute the optimal quality of drug therapy by Rational use of drug requires that patient receive medication appropriate to their clinical needs, in dose that meet their own individual requirements for the adequate period and the lowest cost to them and their community, identifying, documenting, analyzing problems in drug utilization and monitoring the consequences. The major factors can be patients, prescribers, work place and supply system. Therefore, it is important to recognize negative consequences of inappropriate drug use to promote

rational use of drug.<sup>2</sup> Irrational drug use and polypharmacy are the most common problem in clinical scenario. There is a scope for continuous research to identify more effective and safer drug utilization pattern among pancreatitis patients.

Hence this study was designed to evaluate the drug utilization pattern among pancreatitis patients in a tertiary care teaching hospital.

## METHODS

It was a prospective observational study. The study will be conducted in department of surgery in Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram, Tamil Nadu, a 1250 bed multi-speciality, tertiary care teaching hospital located in South India. The period of the study was 6 months (from November 2019 to April 2020).

### Inclusion criteria

Patients of both genders with age group of 18 to 75 years and who are admitted in the department of surgery were included in the study.

### Exclusion criteria

Patients unable to communicate i.e. patients on ventilation or critically ill (coma) patients requiring intensive care unit (ICU) admission; patients who are unwilling to participate; pregnant and lactating women; and patient with malignant pancreatitis were excluded from the study.

### Sample size

A total of 115 patients in both genders with age group from 18-75 year were included in the study.

Sample size was calculated by using the formula as below.

$$N = \frac{z^2 p (1 - p)}{d^2}$$

### Data analysis

We collected the following data: demographic data of patients, prescription details like date, number of drugs, names of individual drugs (brand/generic), any fixed-dose combination prescribed, Intravenous fluids, whether the prescribed drugs were available from the hospital pharmacy or to be bought by the patient from a private chemist, dose, dosage form, dosing schedule, duration of treatment.

### Analysis of drug

Data were analysed for who prescribing Indicators like average number of drugs per prescription, percentage of

drugs prescribed in generic name, number of drugs prescribed from national list of essential medicines (NLEM) 2015, number of drugs prescribed from essential drugs list (EDL) 2019 and percentage of prescriptions with injections.<sup>3</sup>

The prescribed drugs were classified according to the anatomical therapeutic chemical (ATC) classification and defined daily dose (DDD), prescribed daily dose (PDD), and PDD/DDD ratio was calculated.<sup>4</sup>

The DDD of these drugs was calculated according to the WHO ATC/DDD system based on DDD's/1000 inhabitants per day.

### Utilization in DDD

$$= \text{No. of packages used} \\ \times \text{No. of DDD in a package}$$

$$\frac{\text{DDDs}}{1000} \text{inhabitants} \\ \text{day} \\ = \frac{\text{Utilization in DDDs}}{\text{No. of inhabitants}} \times 1000 \\ \times (\text{no. of days in the period of data collection})$$

To overcome the inherent limitations of the DDD, the PDD has been used alongside the DDD. PDD gives the average daily amount of the drug which is actually prescribed.<sup>5</sup>

$$PDD = \frac{\text{Total amount of drug (mg)}}{\text{Duration of hospital stay}}$$

### Ethical consideration

The study was conducted after obtaining permission from the institutional ethics committee (IEC). All the data collected as a part of this study was kept strictly confidential and used for the purpose of this study only.

### Statistical analysis

Data was entered and analysed with Microsoft excel 2016. We used descriptive statistics to analyze the results. Percentage and averages of the variable were also calculated to compare the data with other findings.

## RESULTS

Out of 115 patients receiving conservative management for pancreatitis during the study period, most of the patients are males; 90% (n=104) and 10% (n=11) were females. The mean age was 38.2 years, and the range was 20–75 years.

We observed that the most common etiology of pancreatitis was seen in alcoholic patients 68% (n=78) followed by gallstones 15% (n=17), hyperlipidemic 8% (n=10), idiopathic 7% (n=8) then drug induced 2% (n=2).

Overall etiology wise distribution of patients according to age are summarized in Table 1.

In our study most of the patients with risk factors of alcoholic consumption (n=90) followed by smoking (n=30), both (n=70) and obesity (n=5). 11% (n=13) of patients are literate, other 89% (n=102) are illiterate in our study. 92% (n=106) living with family, only 8% (n=9) of patients are alone in our study.

In our study two comorbidities were found. They are hypertension 5% (n=6) and diabetes mellitus 2.5% (n=2).

Antiulcer agents 21% (n=153) are most frequently prescribed drugs among patients, followed by analgesics 18% (n=132), antibiotics 18% (n=136). Detailed therapeutic class-wise distribution of drugs prescribed is shown in Table 2.

91% (n=104) of prescriptions prescribed with 3 large volume parenteral (LVP), followed by 6% (n=7) of prescriptions with 2 LVP and 3% (n=4) of prescriptions with 1 LVP. 61% (n=70) of prescriptions prescribed with 4 SVP, followed by 18% (n=21) of prescriptions prescribed with 3 SVP, 15% (n=17) of prescriptions prescribed with 5 SVP and 6% (n=15) of prescriptions prescribed with 2 SVP.

In intravenous hydration Ringer lactate 36% (n=110) is the most prescribed followed by normal saline 32% (n=98), dextrose in normal saline 32% (n=20). In present study 90% (n=103) of patients who receiving intravenous hydration within 48 hours of symptoms. 10% of patients receiving intravenous hydration after 48 hours of symptoms onset. In our study 7% (n=8) of patients receiving enteral nutrition, 3% (n=4) of patients receiving parenteral nutrition.

WHO prescribing indicators like average number of drugs per prescription (8.5), percentage of drugs prescribed in generic name 61%, and number of drugs prescribed from NLEM – 2015 (84%), number of drugs prescribed from WHO essential drug list 2019 were 69% and percentage of prescriptions with injection 79.07% were shown in Table 3.<sup>6-8</sup>

The number of prescriptions with an injection were 79.07%. The overall Antibiotic encounter rate as per our study was 15%. Third generation cephalosporins was the highly used antibiotics category 77% (n=105) followed by penicillin's 15% (n=21) and fluoroquinolones 8% (n=10). Most commonly prescribed antibiotics among the antibiotics was cefotaxime (72%) followed by cefixime, ceftriaxone, piperacillin- tazobactam, ciprofloxacin (2%). In analgesics opioids 55% (n=98) are most commonly prescribed analgesics, followed by non-opioids 29% (n=52) and non-steroidal anti-inflammatory drugs (NSAID's) 16% (n=29). Most commonly prescribed drugs in analgesics are tramadol (58%), paracetamol (33%), diclofenac (7%), and aceclofenac (2%).

We calculated DDD for the drugs, which prescribed to study participants. We have calculated DDD separately for each category of drugs (obtained from the WHO ATC/DDD website).<sup>9</sup> Based on DDD the most frequently prescribed drugs were pantoprazole, tramadol, ondansetron, octreotide followed by cefotaxime, metronidazole, paracetamol, drotaverine, sucralfate and piperacillin-tazobactam and the drugs were given ATC codes were shown in Table 4.

In present study highest ratio of PDD/DDD seen in folic acid which was 5, and the other drug PDD/DDD ratio ranges from 0.002-0.4 (Table 4).

**Table 1: Indicates etiology wise distribution according to age and gender.**

Etiology	Alcoholic		Gallstones		Hyperlipidemic		Drug induced		Idiopathic	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Age										
25-44	50	-	1	3	2	1	-	-	3	-
45-64	24	1	-	3	1	1	2	-	-	2
>65	3	-	5	5	3	2	-	-	3	-
Percentage	68		15		8		2		7	

**Table 2: Indicates therapeutic class of prescribed drugs.**

S. no	Category	Frequency	Percentage
1	Antiulcer agents	153	21
2	Analgesics	132	18
3	Antiemetics	94	13
4	Somatostatin analogues	91	12
5	Antibiotics	136	18
6	Amebicides	56	8
7	Vitamin supplements	42	6
8	Anticonvulsants	8	1
9	Antianxiety agents	8	1

Continued.

S. no	Category	Frequency	Percentage
10	Diuretics	7	1
11	Insulin analogues	7	1
12	Prokinetics	8	1

**Table 3: Indicates WHO prescribing indicators.**

S. no	Prescribing indicator	Values obtained	WHO standards
1	Average number of drugs per patient encounter	8.5	1.6-1.8
2	Percentage of drugs prescribed by generic name	61	100
3	Percentage of drugs prescribed from NLEM	84	100
4	Percentage of drugs prescribed from WHO EML	69	100
5	Percentage of prescriptions with injection	79.07	13.4-24.1
6	Percentage of drugs prescribed with one or more antibiotics	15	20.0-26.8

**Table 4: Indicates DDD, PDD and PDD/DDD ratio of most commonly prescribed drugs.**

S. no	Drug	ATC code	WHO DDD measure (mg)	DDD/1000 inhabitants/day (mg)	PDD (mg)	PDD/DDD
1	Pantoprazole	A02BC02	40	100	80	2
2	Tramadol	N02AX02	300	14.8	100	0.3
3	Ondansetron	A04AA01	16	22.2	8	0.5
4	Octreotide	H01CB02	0.7	12.7	0.2	0.2
5	Cefotaxime	J01DD01	4000	26.7	8	0.002
6	Metronidazole	J01XD01	1500	14.8	1000	0.6
7	Paracetamol	N02BE01	3000	11.1	1500	0.5
8	Drotaverine	A03AD02	100	8.8	40	0.4
9	Sucralfate	A02BX02	4000	7.2	1500	0.3
10	Piperacillin + tazobactam	J01CR05	14000	0.02	3000	0.6
11	Cefixime	J01DD08	400	0.1	400	1
12	Diclofenac	M02AA15	100	24.4	100	1
13	B. complex	A11EA	1	46.7	2	2
14	Ranitidine	A02BA02	300	20	300	1
15	Folic acid	B03BB01	0.4	94.4	2	5

## DISCUSSION

Limited data are available in general, particular in India on drug utilization on pancreatitis patients. We undertook this study in order to understand the pattern of drug use and drug related issues in pancreatitis patients.

### Disease condition

Alcoholic 68% (n=78) was the most common etiology of pancreatitis followed by gallstones 15% (n=17). Study conducted by AGA reported gallstones (40-70%) are the first most common cause of acute pancreatitis.<sup>10</sup> Unlike in our study alcohol consumption (68%) is the first most common and gallstones (15%) are second most common whereas in AGA study alcoholic was the second most common (30%). Variability in these results may be due to higher incidence alcoholic consumption in patients who visiting the study site. Incidence of gallstone pancreatitis was higher in female patients (15%) in our study due to higher prevalence in women.<sup>11</sup>

In our study most of the patients with risk factors of alcoholic consumption (n=90) followed by smoking (n=30), both (n=70) and obesity (n=5). Ammann et al stated that some patients (not all) with alcohol use disorder may have nonprogressive acute alcohol induced pancreatitis.<sup>12</sup> Studies suggest that tobacco smoking have higher risk of pancreatitis and dose response relationship between increasing number of cigarettes use.<sup>13</sup>

In fluid resuscitation aggressive intravenous (IV) hydration with ringer lactate solution is mostly used (n=110). Current guidelines recommends Ringer lactate is a preferential isotonic crystalloid replacement fluid among normal saline. Ringer lactate reduce the incidence of systemic inflammatory response syndrome as compared to normal saline.<sup>14</sup>

Most of the patients (90%) with IV hydration within 48 hours of symptoms resume to their oral intake within a week in our study. It reflects the effectiveness of IV hydration. Our study complies with international consensus guidelines.<sup>15</sup>

Only 2% probiotics are prescribed. Study conducted by Gou et al concluded that probiotics do not appear effective in patients with pancreatitis.<sup>16</sup> But in our study lower rate of probiotics are prescribed for diarrhoea associated with antibiotics therapy.

### *Analysis of WHO prescribing indicators*

#### *Average number of drugs per prescription*

The average number of drugs per prescription was  $\pm 8.5$ . Which is slightly higher than the WHO standards. This deviates from the WHO standards of 1.6-1.8. Minimum number of drugs per prescription was 6 and maximum number of drugs per prescription was 15. The highest number of drugs per prescription was seen in patient with comorbidities ( $10 \pm 2.23$ ) patients. Also, highest number of drugs per prescription was increasing in number of hospital stay days.

Out of 115 patients, 15 (13.04%) patients were taking less than five medicines per day and 100 (96.96%) of patients were taking more than five medicines per day. This indicates the majority of patients in our study were having polypharmacy. Polypharmacy unfortunately is very common in India and some other countries. Considering the adverse outcomes associated with polypharmacy, including adverse drug reactions (ADR), drug-drug interactions (often very complex), increased cost of medications and/or treatment, increased risk of hospitalization, patient non-adherence with treatment (which increases with complex regimens), and various medication errors, we need to take appropriate measures for minimizing the extent of polypharmacy.

Out of 1205 drug formulations, 915 (75.93%) contained only one active ingredient, while 290 (24.07%) were FDCs. FDCs increase the risk of drug interactions and ADRs. However, the use of FDCs can improve compliance with therapy by decreasing the number of formulations to be taken. The risk/benefit ratio should be assessed before prescribing FDCs. It is not possible to increase or decrease the dose of an individual ingredient alone. However, considering that the number of FDCs in India, which is around 60% of all available formulations.<sup>17</sup> The use of FDCs in our institution is relatively low, reflecting rational use of medicines.

#### *Number of drugs prescribed with generic name*

Out of 1205 drugs prescribed, 61% (n=735) of drugs were prescribed in generic form, 39% (n=400) were prescribed in brand name. It still falls short of the WHO recommendation of 100%. However, still there is a need to encourage prescribing by generic names. Prescribing drugs by generic name led to decrease in irrational prescribing and increase in availability of essential drugs, thus ultimately promoting rational use of drugs at cheaper cost. NLEM India, promotes prescription by generic

names.

#### *Number of drugs prescribed from EDL and NLEM*

We analyzed that 69% of drugs prescribed were from EDL 2019 and 84% of drugs prescribed from NLEM 2015, which is the reason why there was a very good positive outcome in patients during the treatment period.

#### *Number of prescriptions with an injection*

The number of prescriptions with an injection were 79.07%, which is not appropriate with WHO recommended range of 13.4%-24.1%. Advantage of parenteral drugs is their ability to enhance drug adherence.

#### *Number of prescriptions with antibiotic*

The overall antibiotic encounter rate as per our study was 15% that fall below the WHO recommended range of 20-26%. This reflects avoiding bacterial resistance. American college of gastroenterology (ACG) recommends use of antibiotics in extra pancreatic infections only not for prophylactic or routine use.<sup>18</sup> Our study concordance with the current recommendations of ACG guidelines.

#### *DDD*

DDD is the criteria used to compare utilization of drugs at international level. We used this parameter to study drug use based on dose. We calculated DDD for the drugs that were prescribed to study participants. Importance given for ten most prescribed drugs.

Based on ATC, DDD is calculated for antibiotics, analgesics (A), blood disorders and blood forming agents (B), gastrointestinal drugs and genitourinary drug (G), enzyme drugs (E), hormonal preparation drugs (H), and musculo skeleton drugs (M). Based on DDD pantoprazole (A02BC02), tramadol (N02AX02), ondansetron (A04AA01), octreotide (H01CB02), cefotaxime (J01DD01), metronidazole (J01XD01), paracetamol (N02BE01), drotaverine (A03AD02), sucralfate (A02BX02), and piperacillin-tazobactam (J01CR05).

Pantoprazole (A02BX02), sucralfate (A02BX02) comes under gastrointestinal drugs is being prescribed for gastric hypersecretion and gastric ulcer. Cefixime (J01DD08), cefotaxime (J01DD01), metronidazole (J01XD01) and piperacillin-tazobactam (J01CR05) comes under antibiotics is being prescribed for infected necrosis and extra pancreatic infections. Metronidazole penetrate pancreatic necrosis tissue and delay or avoid surgical intervention and to decrease morbidity and mortality.<sup>18</sup> Tramadol (N02AX02) an opioid analgesic comes under analgesics mainly for moderate to severe pain and paracetamol (N02B01), diclofenac (M02AA15) are NSAID's comes under analgesics mainly for mild to moderate pain. Basurto et al study suggested opioids are the safe and effective in pancreatitis.<sup>19</sup> Compared to

other opioids tramadol was acting at both the opioid receptors as well as serotonin–norepinephrine reuptake inhibition and lesser abuse potential and cost effective in management of pancreatic pain.<sup>20</sup>

Octreotide (H01CB02) comes under hormonal preparations is prescribed for suppressing pancreatic secretions. It reduce mortality in patients with acute severe pancreatitis.<sup>21</sup>

### **PDD/DDD ratio**

Cefixime, diclofenac, ranitidine had PDD/DDD ratios equal to 1. Most of the drugs had the PDD/DDD ratio below 1 and the drugs pantoprazole, paracetamol, thiamine, B-complex and folic acid (highest PDD/DDD ratio) had their ratios above 1.

Drugs with PDD/DDD ratio lesser or greater than 1 are either under or over utilized. Often PDD can vary due to factors like illness treated, and national therapeutic procedures. For example, PDDs are often lower in Asian than in Caucasian populations. It does not mean there is underutilization of drug. Also WHO ATC/DDD for management of moderate intensity hence the WHO encourages countries to have their own DDD list based on local data.<sup>22</sup>

### **Limitations**

Sample size of our study is small and study period is 6 months. We could not compare the effectiveness and adverse effect profile of various analgesics. At the same time our study has numerous strengths. Ours was the first study done in this area regarding utilization of drugs in conservative management of pancreatitis. We have used various drug utilization metrics like ATC/DDD classification, PDD, PDD/DDD ratios to present our data in a scientific manner to enable comparison with other studies.

### **CONCLUSION**

This study provides a baseline data regarding the prescribing pattern of drugs used in conservative management of patients with pancreatitis. Drug utilization studies are need of the hour for rational prescription of drugs.

Our findings shown that majority of patients were on polypharmacy. Polypharmacy is reduced by reviewing previous medication history, monitor for adverse drug withdrawal events, assess for drug-drug interactions and also use tools such as beers criteria, START/STOPP criteria, deprescribing, medication appropriateness index and ARMOR protocols. Pharmacists' especially clinical pharmacist, doctor of pharmacy (Pharm D) who intervene drug therapy and drug related problems in clinical scenario play a vital role in reducing polypharmacy. The prescription of drugs in brand name could be changed to

generic name. The use of drugs from national and WHO essential medicine list needs to be increased in order to have more rational drug prescribing.

There is always scope for improvement of rational prescribing by introducing appropriate educational interventions, which may be considered as an effort to improve quality of health care. This study provided a scope for further research in this area.

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