

Prevalence of Drug Related Problems in Patients with Chronic Diseases - A Community Based Study in Dakshina Kannada

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ABSTRACT

Drug related problem (DRP) can be defined as an event which involves drug therapy that may actually or sometimes potentially interfere the desired health outcomes. DRPs in patients with chronic diseases are more common due to the longer duration of therapy as well as altered physiology in such patients. In addition to this, patients suffering from chronic illnesses usually have multiple diseases and take more number of medicines including over the counter medications in community settings. There is a relative lack of information and inadequate documentation about DRPs in the community setting which may be because of gaps in the continuity of medical and pharmaceutical care. So a community based observational study was conducted in different places of Dakshina Kannada district of Karnataka to identify and assess the prevalence of drug related problems in patients with chronic diseases using Hepler - Strand classification for duration of 6 months from October 2019 to March 2020 by enrolment of 150 patients diagnosed with any chronic disease. Patients diagnosed with psychiatric illnesses, patients aged below 18 years old, pregnant and lactating women were excluded from the study. Medical information was collected using structured patient interview form and data were analysed and interpreted using Microsoft Excel 2010. From this study, it was found that the prevalence of patients identified for the presence of DRPs was 54.67% and was more in female gender, age above 60 years, patients with multiple co-morbidities and patients on poly-pharmacy. Thus the study concluded that pharmacist interventions play a major role in identifying and assessing prevalence of DRPs and their risk factors.

Key words: Drug Related Problem, Chronic diseases, Community setting, Prevalence, Risk factors

INTRODUCTION

Drug related problems (DRPs) are events or circumstances involving drug therapy that interfere with desired therapeutic outcome and can become actually or potentially harmful to a patient's health or which prevent patients from optimally benefiting from the treatment^{1,2}. DRPs can occur in any stages of the medication process starting from prescription to follow-up of treatment. A DRP develops when a patient experiences or is likely to experience either a symptom, disease or an event which has an actual or suspected relationship with given drug therapy. The term DRPs comprises medication error, adverse event and adverse drug reactions³. Inappropriate medication prescribing, discrepancies between actual and prescribed regimens, incomplete or improper patient's history collection, self-medication, poor medication adherence, drug interaction, inappropriate use of medication, inadequate monitoring of patient's condition, lack of patient's follow up and surveillance for adverse drug reactions etc. can be the reasons for such problems associated with drug therapy^{3,4,5}. They often constitute safety issue related to patient's health leading to patient harm, reduced quality of life, increased hospital stay and increased health care costs^{6,7}. They act as a major problem associated with

drug therapy and are main cause of morbidity and mortality⁸.

As the number of available drugs increases, drug use and prescribing becomes more complex, leading to variety of DRPs⁹. Patients suffering from multiple chronic conditions are mainly vulnerable to a sense of burden with their treatment regimen because they are often required to engage in a complex array of self-care activities in order to maintain health along with their long term treatment¹⁰. In addition to this, patients suffering from chronic diseases usually have multiple diseases and take more number of medications including over the counter medications in a community setting¹.

DRPs are common in patients with chronic diseases as they have altered physiology and require long term treatment. Not only this, they are more frequent among patients who are discharged from hospital which may be due to gaps in the continuity of medical and pharmaceutical care¹¹. But there is a relative lack of information about Adverse Drug Events (ADEs) in the community setting. In contrast to inpatients, outpatients are responsible for both acquiring and administering their own medications. Therefore, the process of drug therapy in outpatients is much less

controlled than the process in an inpatient setting. In addition to this, physicians do not have regular contact with outpatients and are hence less likely to come to know about their problems associated with drug therapy if any. Medication chart review in this setting also has limitations related to inadequate documentation and high costs¹².

A recent statistical study from NHS (National Health Service) England suggests that more than 237 million medication errors occur in England in one year¹³. Another statistical report from Delhi found that out of 1000 prescription, 82 are likely to result in adverse events approximately¹⁴. These statistical studies suggest that there is a need of more studies to identify and assess magnitude of drug related problems across India.

Drug related problem can be classified by various classification systems. These include American Society of Hospital Pharmacists (ASHP) Systems, Cipolle et al., Granada consensus, Hepler/Strand, Pharmaceutical Care Network Europe (PCNE) classification, Problem-Intervention Documentation (PI-Doc) and Westerlund classification⁵.

There are eight categories of DRPs according to Hepler and Strand classification, which are tabulated below¹⁵.

DRPs	DESCRIPTION
Untreated Indication	The patient has a medical indication that calls for drug therapy but is not receiving a drug for the same.
Improper Drug Selection	The patient has an indication for a particular drug but is taking the wrong drug for it.
Sub-therapeutic Dosage	The patient has a medical condition that is being treated with the correct drug but with too little of it.
Failure to Receive Drugs	The patient has a condition by virtue of his or her not receiving a drug for pharmaceutical, psychological, sociological or economic reasons.
Over-dosage	The patient has a medical problem that is being treated with the correct drug but with too much of it (may lead to toxicity).
Adverse Drug Reactions	The patient has a medical problem due to an Adverse Drug Reaction or adverse effect.
Drug Interactions	The patient has a medical problem that caused by a drug-drug, drug-food or drug-laboratory interaction.
Drug Use Without Indication	The patient is taking a drug for no medically valid indication.

Objectives: Drug related problems are serious issue in patients with chronic diseases especially in outpatients. The objective of this study was to identify and assess the prevalence of drug related problems and to ascertain the risk factors contributing towards drug related problems in patients with chronic diseases in community setting of Dakshina Kannada.

METHODOLOGY

Study site: A community based observational study was carried out in different places of Dakshina Kannada district of Karnataka state (India).

Study design: A community based observational study

Study period: The study was conducted for duration of 6 months from October 2019 to March 2020

Study sample size: 150 Patients

Ethical clearance: The study protocol was approved by the Institutional Ethics Committee (IEC) of Srinivas Institute of Medical Science and Research Centre (SIMS&RC), Mukka, Mangaluru.

Study criteria:

Inclusion criteria:

- Patients aged 18 years and above.
- Patients diagnosed with any chronic diseases.
- Patients who are willing to participate in the study.
- Patients who are not pregnant or lactating.

Exclusion criteria:

- Patients aged below 18 years.
- Patients diagnosed with acute illnesses
- Patients with psychiatric illnesses.
- Pregnant and lactating women.
- Patients who are not willing to participate in the study.

Source of data: The data for study was taken by reviewing prescription, physician notes of patients with chronic diseases and medical information provided by the patients. Data collected included patient's demographic data, personal history, medical and medication history, current diagnosis and drug therapy details, and any problems observed by the patient during the course of treatment.

Sampling method: Medical information of patients (male and female) diagnosed with any chronic diseases and participated in this community based study from October 2019 to March 2020 was obtained from different places of Dakshina Kannada. A total of 150 patients met the selection criteria.

Materials used: Data were collected using a structured patient interview form to document demographic details, medical and medication history, personal history, allergic history, diagnosis, treatment including dose, frequency, route of administration and problems with associated therapy.

Study method: Ethical committee approval was obtained before starting of this study. Patient interview form was designed as per need of the study. The data were collected from the homes of patients via interview and patient interview forms. The data included patient demographic data, personal history, medical and medication history, current diagnosis and drug therapy details, and any problems observed by the patient during the course of treatment were collected. Drug Related Problems were identified by investigators and were analyzed. All the data were kept confidential.

Data analysis: Data were collected and analyzed using Microsoft Excel 2010.

RESULTS

a) Demographic details:

A total of 150 patients diagnosed with chronic diseases were included in the study. Medical information was collected from each patient with the help of patient interview form. Out of 150 patients, 73 were male and 77 were female. Out of this, 74 patients were of above 60 years old and rest of them i.e. 76 population belonged below 60 years category. Among the 150 patients who participated in the study, 18 were alcoholic, 16 were smokers and 9 were both alcoholic and smokers. 48 patients who participated in this study had more than 3 co-morbidities and 51 patients were prescribed with more than 4 drugs. The detailed demographic features of patients participated in this study is given in Table 1.

Table 1. Demographic features and clinical characteristics of the patients

Variable	Category	Frequency N=150	Percentage
Age	< 40 years old	19	12.67%
	40 ≤ x < 60 years old	57	38.0%
	≥ 60 years old	74	49.33%
Gender	Male	73	48.67%
	Female	77	51.33%
Social habits	Alcoholic	18	12.0%
	Smoking	16	10.67%
	Both	9	6.0%
	None	107	71.33%
Number of chronic diseases	1	61	40.67%
	2	41	27.33%
	≥ 3	48	32.0%
Number of drugs prescribed	1-4	99	66.0%
	≥5	51	34.0%

b) Chronic diseases included:

The chronic diseases included in this study were categorized as cardiovascular diseases, endocrine disorders, respiratory disorders, kidney disorders, neurological disorders, blood disorders, hepatic disorders and others. Hypertension, diabetes mellitus and their co-morbidities were the most commonly observed chronic diseases. The details of chronic diseases involved in this study are given in the Table 2.

Table 2: Chronic diseases involved in this study

Organ system	Diseases and co-morbidities	No. of patients	Percentage
Cardiovascular	HTN	25	16.67%
	HTN &DM	14	9.33%
	HTN & Co-morbidities	30	20.0%
Endocrine	DM	10	6.67%
	DM & Co-morbidities	9	6.0%
	Hypothyroidism	6	4.0%
	Hypothyroidism & others	6	4.0%
Neurological	PD	2	1.33%
	PD &Co-morbidities	2	1.33%
	Others	3	2.0%
Respiratory	Asthma	3	2.0%
	Asthma & Co-morbidities	4	2.67%
	COPD & Co-morbidities	5	3.33%
Nephrology	CKD & Co-morbidities	10	6.67%
Blood	Anemia	5	3.33%
	Anemia & Co-morbidities	2	1.33%
Hepatic	CLD	1	0.67%
	CLD & Co-morbidities	3	2.0%
	Hepatocellular carcinoma	2	1.33%
Others	Others	8	5.33%

c) Prevalence of drug related problems:

Out of 150 patients who participated in this study, 82 patients were found to have DRPs. A total of 121 DRPs were identified in 82 patients. The identified DRPs were classified according to Hepler-Strand Classification. The prevalence of patients with DRPs among patients with chronic diseases can be calculated by using the following formula¹⁶:

Prevalence of patients with DRPs among patients with chronic diseases = (Number of patients with DRPs in chronic diseases / Total number of patients with chronic diseases considered under study)* 100

The prevalence of patients with DRPs among patients with chronic diseases was found to be 54.67% in this study. Figure 1 shows the number of patients identified for the presence of DRPs.

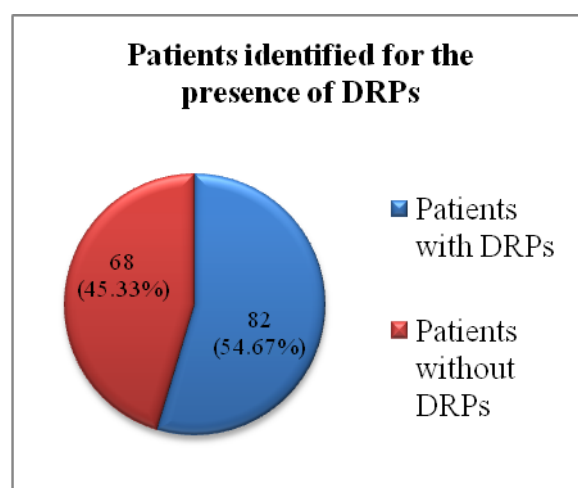


Figure 1: Patients identified with the presence of DRPs

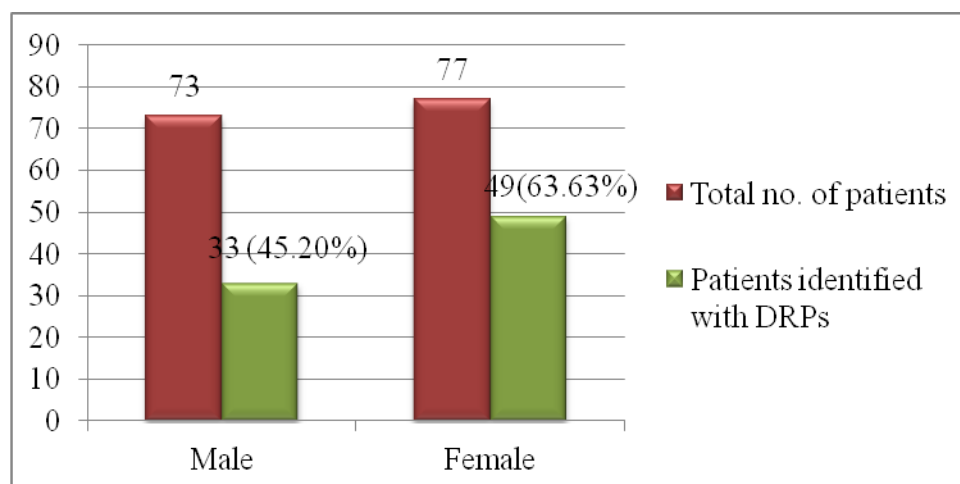


Figure 2: Prevalence of DRPs among male and female patients.

Among 150 patients, 33 male patients (45.20%) out of 73 and 49 female patients (63.63%) out of 77 had DRPs which indicates that the prevalence of DRPs in female patients is more than male patients. This is because female patients are generally lighter in weight and smaller in build than male patients but usually receive the same drug doses resulting in exposure to higher dose per body weight for the females than males^{16,17}. Figure 2 shows the prevalence of DRPs among male and female population.

In the case of age group, prevalence of DRPs was found to be increased with

increase in age. 8 out of 19 patients (42.10%) with age less than 40 years, 29 out of 57 patients (50.88%) with age 40 to 60 years and 45 out of 74 patients (60.81%) with age more than 60 years were identified to have DRPs. This is mainly because medicines and doses are often similarly prescribed in older and young patients and pharmacological studies have shown for decades that many medications act differently in older and younger people due to the physiological and pathological changes that accompany ageing¹⁸. Figure 3 shows the presence of DRPs with increasing age group.

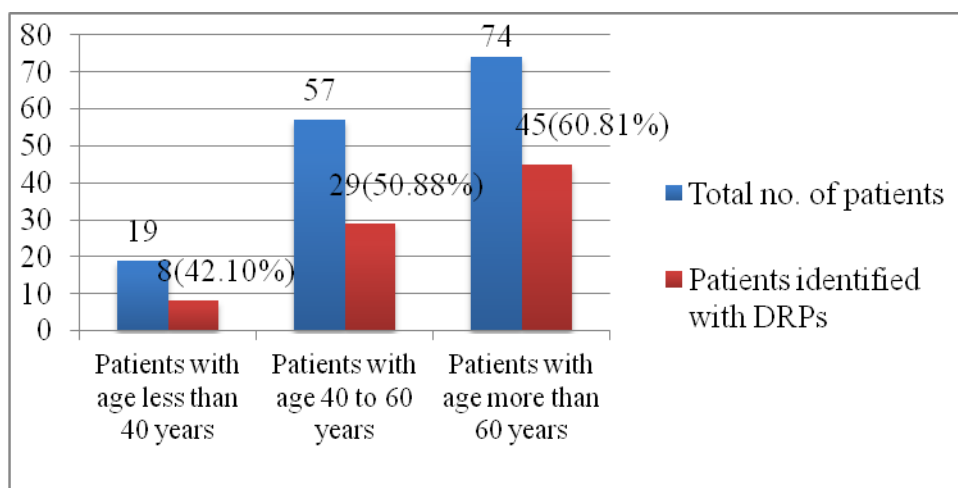


Figure 3: Prevalence of DRPs across age groups

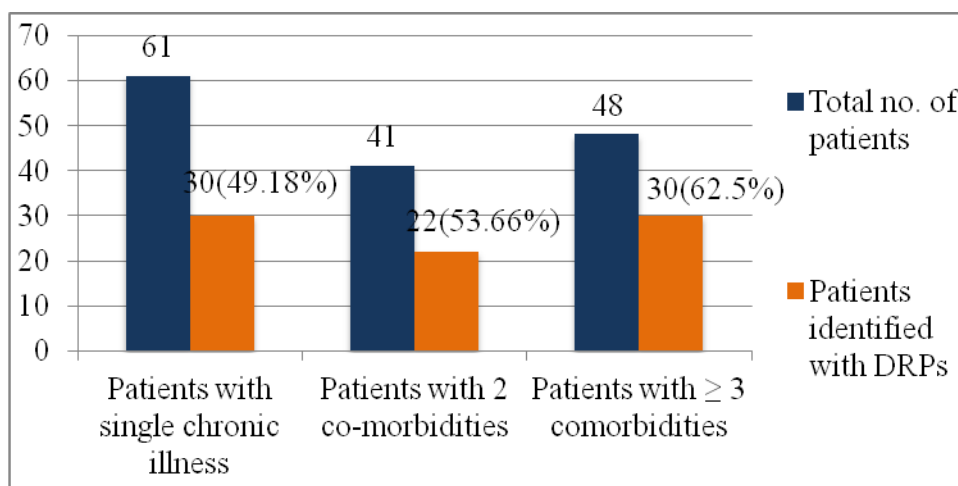


Figure 4: Prevalence of DRPs with increasing number of co-morbidities

From this study, it was found that the prevalence of DRPs was more with increasing number of co-morbidities. In this study, 30 out of 61 patients (49.18%) who were diagnosed with one chronic illness, 22

out of 41 patients (53.66%) who had 2 chronic illnesses and 30 out of 48 patients (62.50%) who had more than 3 co-morbidities were found with DRPs. Figure 4

shows the prevalence of DRPs with increasing number of co-morbidities.

While considering the number of drugs prescribed, it was observed that 50 out of 99 patients (50.50%) prescribed with 1-4 drugs and 32 out of 51 patients (62.74%) prescribed with more than 4 drugs were

identified to have DRPs. A cross sectional observational study by Krahenbuhl-Melcher A and colleagues found patients with poly-pharmacy were associated with increased risk of DRPs¹⁹. Figure 5 shows the prevalence of DRPs with increase in number of drugs prescribed.

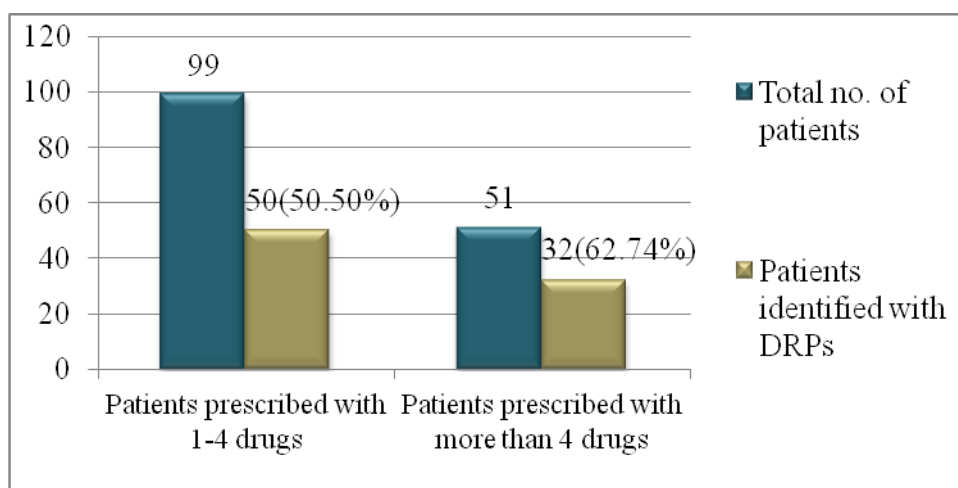


Figure 5: Prevalence of DRPs against number of drugs prescribed

d) Prevalence of DRPS among study subjects:

Out of 150 patients, 82 patients were found to have DRPs. Among them, a total of

121 DRPs were identified. The identified DRPs were classified based on Hepler-Strand Classification as shown in Table 4.

Table 4: Prevalence of DRPs among study population using Hepler-Strand classification

Types of DRPs	Description	Frequency N=121	Prevalence in terms of ratio	Prevalence in terms of Percentage
Untreated Indication	The patient has a medical indication that calls for drug therapy but is not receiving a drug for the same.	7	0.0578	5.78%
Improper Drug Selection	The patient has an indication for a particular drug but is taking the wrong drug for it.	6	0.0496	4.96%
Sub therapeutic Dosage	The patient has a medical condition that is being treated with the correct drug but with too little of it.	3	0.0248	2.48%
Failure to Receive Drugs	The patient has a condition by virtue of his or her not receiving a drug for pharmaceutical, psychological, sociological or economic reasons.	11	0.091	9.09%
Over dosage	The patient has a medical problem that is being treated with the correct drug but with too much of it (may lead to toxicity).	5	0.0414	4.13%
Adverse Drug Reactions	The patient has a medical problem due to an Adverse Drug Reaction or adverse effect.	57	0.4711	47.11%
Drug Interactions	The patient has a medical problem that caused by a drug-drug, drug-food or drug-laboratory interaction.	29	0.2397	23.97%
Drug Use Without Indication	The patient is taking a drug for no medically valid indication.	3	0.0248	2.48%

In the present study, Adverse Drug Reactions (47.11%) were most commonly identified DRPs followed by drug interactions (23.97%), failure to receive drugs (9.09%), untreated indications (5.78%), improper drug selection (4.96%),

over dosage (4.13%), sub therapeutic dose (2.48%) and drug use without use (2.48%).

e) Risk factors contributing towards drug related problems

In this study, several factors such as female gender (63.63%), age above 60 years

(60.81%), poly-pharmacy (62.74%) and multiple co-morbidities (62.5%) were found to be associated with increased number of

DRPs. Table 3 shows the association between several variables and DRPs.

Table 3: Association between risk factors and prevalence of DRPs

Variables	Category	Total population N=150	Patients identified with DRPs	Prevalence of DRPs in terms of ratio	Prevalence in terms of percentage
Age	< 40 years old	19	8	0.4210	42.10%
	40 – 60 years old	57	29	0.5087	50.87%
	≥ 60 years old	74	45	0.6081	60.81%
Gender	Male	73	33	0.4520	45.20%
	Female	77	49	0.6363	63.63%
Number of chronic diseases	1	61	30	0.4918	49.18%
	2	41	22	0.5365	53.65%
	≥ 3	48	30	0.625	62.5%
Number of drugs prescribed	1-4	99	50	0.5050	50.50%
	≥5	51	32	0.6274	62.74%

e) Distribution of identified DRPs across chronic diseases

In the present study, it was found that DRPs were more commonly seen in

chronic diseases such as hypertension and diabetes mellitus. The distribution of identified DRPs across chronic diseases is given in Table 5.

Table 5: The distribution of identified DRPs across chronic diseases

Types of DRPs	Diagnosed chronic diseases	Number of cases
Untreated Indication	Filariasis	1
	Inflammatory Bowel Disease	1
	Anemia	3
	Psoriasis	1
	Sick Sinus Syndrome	1
Improper Drug Selection	HTN+DM+CKD	1
	Portal hypertension	1
	Filariasis	1
	Migraine	1
	CAD & Hyperlipidaemia	1
Sub therapeutic Dosage	HTN & COPD	1
	Arthritis	1
	Alcoholic liver Cirrhosis	1
Failure to Receive Drugs	DM	2
	HTN	3
	HTN & DM	1
	HTN, DM & Stroke	1
	HTN & Epilepsy	2
	HTN & Stroke	1
	DM, HTN & Renal artery stenosis	1
Over dosage	Gastritis	1
	HTN	1
	Arthritis	2
	HTN, DM & Hypothyroidism	1
Adverse Drug Reactions	DM	10
	HTN	15
	Hepatocellular carcinoma	1
	CLD, ALD & Portal hypertension	1
	Hypothyroidism	8
	HTN, CAD & LVD	4
	Filariasis	1
	Gastritis	1
	Dermographism	1
	Anemia	3
	Coccyx edema	1
	Migraine & vertigo	1
	Migraine	3
	Parkinsonism	1
	Hyperlipidaemia	2
	Evan's syndrome	1
	Gout	1
Adenomyosis	1	
HTN & COPD	1	

Table 5 Continued

Drug Interactions	Vertigo &Parasthesia	2
	HTN & Parkinsonism	1
	IHD, LVD & DM	2
	HTN, Epilepsy & Hypothyroidism	1
	HTN, DM & Hypothyroidism	2
	DM	2
	Bronchial Asthma	2
	CAD, HTN &LVD	6
	HTN, DM &Renal artery stenosis	1
	Migraine & Vertigo	4
Hypothyroidism & MI	1	
Hyperlipidaemia & CAD	5	
Drug Use Without Indication	HTN&DM	1
	IHD	1
	Arthritis	1

DISCUSSION

In the present study, 150 patients diagnosed with one or more chronic diseases have participated. Among them, 82 (54.67%) patients are identified with 121 DRPs.

Out of 150 patients, 73 (48.67%) were male and 77 (51.33%) were female. Among them, it was found that 33 male patients (45.20%) out of 73 and 49 female patients (63.63%) out of 77 were identified for the presence of DRPs which indicates that the prevalence of DRPs in female patients is more than male patients. This observation is supported with the study conducted by R. Adepu and P.K. Adusumilli¹⁶. This is probably attributable to the exposure to higher dose per body weight for the females than males as female patients being generally lighter in weight and smaller in build than male patients but usually receiving the same drug doses^{16,17}. However there is a lack of evidence to suggest that biological factors associated with gender may affect the pharmacological treatment²⁰.

In this study, it was observed that the prevalence of DRPs was found to be more as age increases. Among study participants, 8 out of 19 patients (42.10%) with age less than 40 years, 29 out of 57 patients (50.88%) with age 40 to 60 years and 45 out of 74 patients (60.81%) with age more than 60 years were identified for the presence of DRPs. This is mainly because medicines and doses are often similarly prescribed in older and young patients and pharmacological studies have shown for

decades that many medications act differently in older and younger people due to the physiological and pathological changes that accompany ageing¹⁸. According to American Geriatrics Society (AGS), many medications have different efficacy and safety profiles in younger and older age groups²¹. In addition to this, elderly patients are more susceptible and vulnerable to drug interaction and therapeutic dissatisfaction which might be due to age-related changes, changes in physiological, biological, physical and social functions²⁰. So the selection of medication, dosing schedules, and combined drug regimens, as well as appropriate follow-up and management of medication treatment, should always be age-specific and highly individualized among geriatric population. Unfortunately, this is not a common clinical practice that makes the geriatric population more prone to DRPs²².

From this study, it was found that the prevalence of DRPs was more with increasing number of co-morbidities. In this study, 30 out of 61 patients (49.18%) with one chronic illness, 22 out of 41 patients (53.66%) with 2 chronic illnesses and 30 out of 48 patients (62.50%) with more than 3 co-morbidities were identified for the presence of DRPs. This may be because as the number of diseases increase the numbers of drugs used by the patient also increase simultaneously. According to a study by Viktil KK et al., the presence of DRPs increased approximately linearly with the number of drugs used²³. Similarly in the present study also, it was found that the

prevalence of DRPs was increased with increase in number of drugs used i.e. 50 out of 99 patients (50.50%) prescribed with 1-4 drugs and 32 out of 51 patients (62.74%) prescribed with more than 4 drugs were identified for the presence of DRPs. A cross sectional observational study by Krahenbuhl-Melcher A et al., also found that patients with polypharmacy (Polypharmacy refers to patients taking four or more medications) were associated with increased risk of DRPs^{19,24}.

In the present study, it was found that several risk factors such as female gender (63.63%), age above 60 years (60.81%), polypharmacy (62.74%) and multiple co-morbidities (62.5%) were found to be associated with increased number of DRPs. Not only this, in this study it was found that diseases such as hypertension and diabetes mellitus were associated with more number of DRPs. Studies conducted by the World Health Organization and Central Disease Control and Prevention in India showed a similar conclusion that the statistical prevalence of cardiovascular diseases and diabetes is the highest²⁵.

CONCLUSION

Prevalence of DRPs in patients with chronic diseases was calculated and it was found to be 54.67%. The risk factors responsible for DRPs in patients with chronic diseases were also assessed and the main risk factors found from this study were female gender, poly-pharmacy, age over 65 years and multiple co-morbidities. However study must be conducted in large sample size to get more significant results.

Limitation of study:

- Small sample size
- There is a chance of bias in the information provided by patients.

Future prospective

This study can be more effectively carried out in a larger population for better outcomes and more statistically significant data generation.

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How to cite this article: Shwetha N, Pradhan A, Ambika V et.al. Prevalence of drug related problems in patients with chronic diseases- a community based study in Dakshina Kannada. *International Journal of Research and Review*. 2021; 8(2): 520-529.
