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Clinical Pharmacist Mediated Pharmaceutical Care On Health Outcomes Of Chronic Disease Patients: A Randomized Control Trial

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ABSTRACT:
Introduction: *The study aimed to assess the impact of clinical pharmacist-mediated care on patients managing chronic conditions like hypertension and type 2 diabetes mellitus. Medication non-adherence remains a major challenge, with the World Health Organization indicating that approximately 50% of patients with chronic illnesses do not adhere to their prescribed treatments.* ***Methodology:*** *The study was conducted at Govt. General Hospital Kadapa over a year. It employed a randomized control trial, a robust method for assessing intervention effectiveness. Patients were randomly divided using a simple randomization method, with odd-numbered patients in the pharmaceutical care group and even-numbered patients in the usual care group. Statistical analysis was performed using descriptive statistics and two-way ANOVA to assess health outcomes.* ***Results:*** *A total of 333 patients participated, with 168 males and 165 females. Significant improvements were observed in the pharmaceutical care group, particularly in reduced blood pressure and blood sugar levels when compared to the usual care group.* ***Conclusion:*** *The study demonstrated that clinical pharmacist intervention positively impacts medication adherence and health outcomes. Personalized medication information, provided directly on packaging, proved effective in improving adherence, emphasizing the importance of clinical pharmacists in managing chronic disease patients' care.*

Keywords: *Clinical pharmacist, pharmaceutical care, health outcomes, chronic diseases, medication adherence.*

INTRODUCTION:

Clinical pharmacist mediated patient care aids in improving quality of life of patients, particularly while managing chronic medical conditions like diabetes and hypertension. The World Health Organization highlights the seriousness of pharmaceutical non-adherence by noting that, despite its relevance, the average non-adherence rate among people with chronic illnesses is 50%.[1] Quality of treatment and patient outcomes depends on the amount of time they spend interacting with health care professionals, the better the interaction better the outcome.[2] Patients drug-taking behaviour is also influenced by multiple factors like patient discordance with physician, literacy level, illness characteristics and social stigmas. Medication non-adherence has several negative effects including medication waste, disease progression, decreased functional abilities, decreased quality of life, and a higher need for medical services like hospital stays, visits, and admissions. Dispensing covers with label instructions play a pivotal role in enhancing patient care, these covers serve as a bridge between healthcare professionals and patients, providing crucial information about medication usage, dosage, and potential side effects and aiding in the proper administration of medications. [3-4]. So, our study aimed to correlate health outcomes with clinical pharmacist-mediated pharmaceutical care.

AIM AND OBJECTIVES:

The main aim of the study was to assess the impact of clinical pharmacist mediated pharmaceutical care on health outcomes of chronic disease patients (like hypertension and type 2 diabetes mellitus).

Main objectives:

The first objective of this study was to develop patient-specific medication labels for effective use of medicines. The second objective of this study was to correlate health outcomes in both pharmaceutical care group and usual care group with clinical pharmacist intervention.

Secondary objectives:

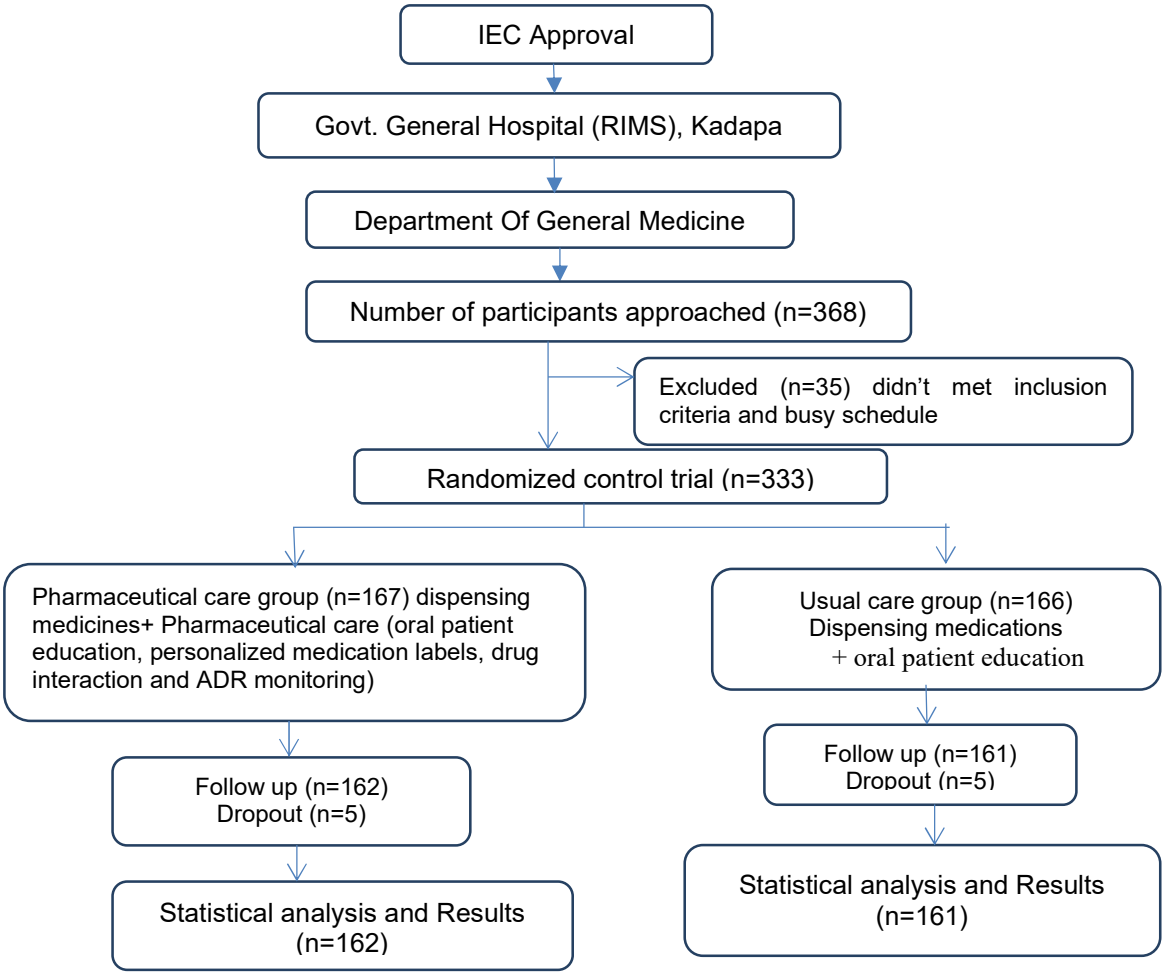
To evaluate potential drug-drug interactions those are observed in prescriptions.

To identify and report any suspected adverse reactions if any.

MATERIALS AND METHODS:

The study was conducted at the Govt. General Hospital Kadapa, for one year. The study design was a randomized control trial which is a robust method for assessing the effectiveness of medical interventions, A simple randomization method was used where an odd number of patients were assigned in the pharmaceutical care group and an even number of patients were assigned in the usual care group.

- The inclusion criteria for this study consists of adult patients of both genders who have been prescribed more than two drugs, with chronic diseases like hypertension and type 2 diabetes mellitus with or without co-morbidities.
- On the other hand, the exclusion criteria comprise patients who are unwilling to provide consent, children, individuals with visual or hearing impairments, and pregnant women or lactating mothers due to the unique considerations of their medical conditions.



To gather comprehensive and accurate information data was collected using reliable data sources like patient medical records, lab records, prescriptions and by asking Open ended questions which were taken from World Health Organization (WHO) five moments for medication safety. The pharmaceutical care and interventions proposed for this study were aimed at optimizing patient outcomes and safety. They include individual patient counseling sessions conducted by clinical pharmacists lasting 15-20 minutes each to ensure proper medication use. Both oral and written patient education approaches will be employed to enhance understanding and adherence to medication regimens. In pharmaceutical care group in order to assist patients with sorting pills, medication labels along with pictorial illustrations that contain information on dosage, purpose, side effects and instructions on how to administer were provided. Collectively these interventions provide complete pharmaceutical care that considers several aspects of medication use and the well-being of patients. Potential drug-drug interactions and adverse drug reactions were identified and reported in this study.

STATISTICAL ANALYSIS:

Patients with prescribed medications were randomly assigned to pharmaceutical care and usual care groups. The intervention involves patient education along with personalized medication labels that provides information on dosage, side effects, purpose and how to administer medications. Data collection included demographics, medical history, and a self-prepared questionnaire. The Morisky scale was used to assess medication adherence. To assess knowledge and medication-taking behaviour patterns both before and after intervention 5 moments for taking medications by WHO was used. All the data of recruited subjects was entered into a Microsoft Excel spread sheet. Graphs are plotted in Microsoft Excel. Descriptive statistics like mean, standard deviation, and sample percentage were used to calculate demographic data of all subjects. Two-way ANOVA was used to find the significant difference pre- and post-intervention i.e., usual care vs pharmaceutical care. Health outcomes were measured by using laboratory parameters. Statistical methods were employed to compare the outcomes between groups. A statistically significant P-value is one that is less than 0.05.

RESULTS:

This study had 333 patients in total; effectiveness of pharmaceutical care versus usual care was investigated among recruited patients. The characteristics of the patients were assessed across various variables, including age, residence, and education. Among them 168 (50.45%) were males while 165 (50.55%) were female. The average age of the patients in the pharmaceutical care group was 45.8 years with a standard deviation of 12.76, while the usual care group had an average age of 43.2 years with a standard deviation of 11.5. Although there was a numerical difference, the p-value of 0.092 indicated no statistically significant difference in age between the two groups. Residence distribution showed that approximately half of the patients in both groups resided in urban areas, with no significant difference ($p = 0.634$).44.5% of patients in the pharmaceutical care group were educated, compared to 48.5% in the usual care group. A slightly higher percentage of uneducated patients were present in the pharmaceutical care group (55.5%) compared to the usual care group (51.5%). Education status did not significantly differ between the pharmaceutical care and usual care groups ($p = 0.965$). These findings are depicted in Table 1, Figure 1.

Table 1: Demographic and Background Characteristics of Patients:

Variable			Pharmaceutical Care(n=162)	Usual Care (161)	P value
Age	Years 18-28 29-38 39-48	45.8(±12.76) 25 25 40	43.2(±11.5) 24 23 45	*0.092*	

	49-58 59-68 >68	45 25 2	50 19 0	
Residence	Urban 18-28 29-38 39-48 49-58 59-68 >68	76(46.9%) 13 12 19 23 8 1	81(50.6%) 13 11 22 27 8 0	*0.634*
	Rural 18-28 29-38 39-48 49-58 59-68 >68	86(53.1%) 12 13 21 22 17 1	80(49.4%) 11 12 23 23 11 0	
Education	Educated 18-28 29-38 39-48 49-58 59-68 >68	117(72.2%) 23 21 32 29 12 0	110(67.9%) 21 20 36 24 9 0	*0.965*
	Uneducated 18-28 29-38 39-48 49-58 59-68 >68	45(27.8%) 2 4 8 16 23 2	51(32.1%) 3 3 9 26 10 0	

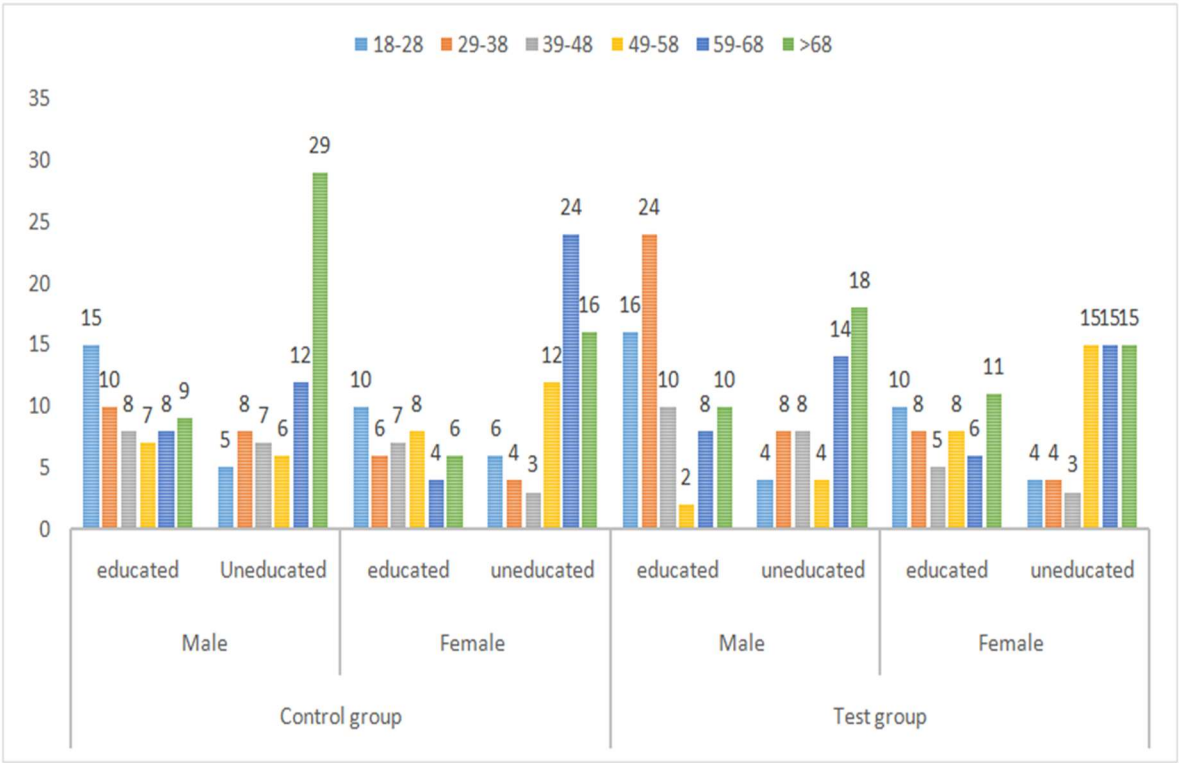


Figure 1: Categorization of patients based on education

Patients were asked some open-ended questions to assess their knowledge and medication adherence patterns both before and after intervention the responses were listed in table 2. Before intervention, a significant proportion of patients from both groups lacked knowledge about the names and purposes of their medications with 37.03% in pharmaceutical care and 55.6% in usual care. Similarly, awareness of risks and possible side effects was limited with 33.33% and 64.5% in pharmaceutical and usual care respectively. The study revealed substantial improvements in pharmaceutical care post-intervention, notably in understanding medication names 62.96%, risks and side effects 66.67%, and proper dosages and timing 34.57%. Notably, pharmaceutical care had a positive impact on patients' comprehension of how to manage side effects 68.52% and the duration of medication use 26%. Moreover, a higher percentage of patients receiving pharmaceutical care recognized the necessity of their medications compared to those in usual care. These findings demonstrate the effectiveness of pharmaceutical care in improving patients' overall knowledge and understanding of their medications. Pharmaceutical care has positive impact on patient's health outcomes.

Before the intervention, 62 patients in the pharmaceutical care group had low adherence compared to the usual care group with 65 patients. On the other hand, 79 patients in the usual care group have medium adherence compared to the pharmaceutical care group 83 patients. When it comes to high adherence, both groups have the same number of patients before the intervention (17 in pharmaceutical care and 17 in usual care). After the intervention, there was a noticeable improvement in adherence in the pharmaceutical care group. Number of patients with low adherence decreased from 62 to 35, and those with medium adherence increased from 83 to 63. Interestingly, number of patients with high adherence significantly increased from 17 to 64 in the pharmaceutical care group. In usual care group, the numbers also shifted, with a decrease in low adherence from 65 to 56, an increase in medium adherence from 79 to 85, and a slight increase in high adherence from 17 to 20.

These findings are shown in figure 2 and suggest that pharmaceutical care had a positive impact on medication adherence, with more patients showing higher adherence levels after the intervention.

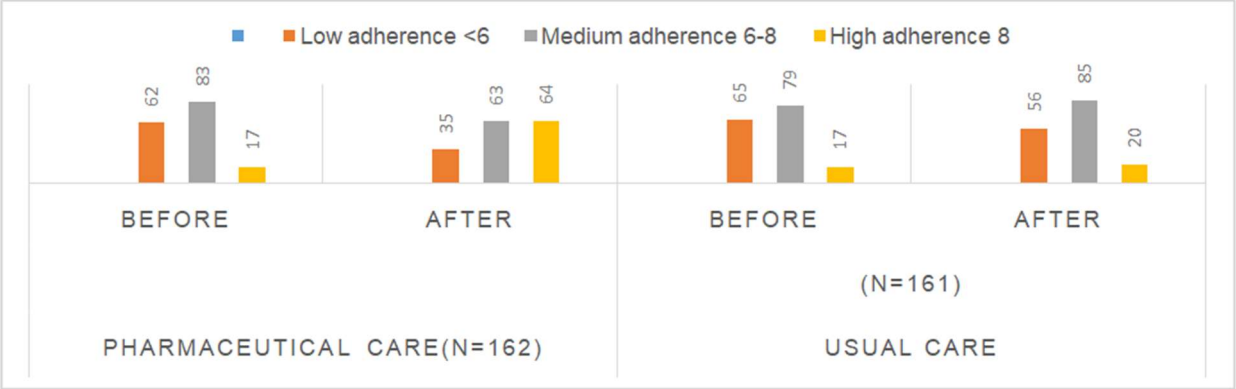
Table 2: Comparison of Medication Understanding between Pharmaceutical Care and Usual Care Group:

Open-ended questions	Pharmaceutical Care (n=162)				Usual Care (n=161)			
	Before		After		Before		After	
	Know	Do not know	Know	Do not know	Know	Do not know	Know	Do not know
What is the name of the medication and what is it for?	37.03% (n= 60)	62.96% (n=102)	55.6% (n= 90)	44.4% (n=72)	30.2% (n=49)	69.8% (n= 112)	36.64% (n=59)	63.36% (n= 102)
What are the risks and possible side-effects?	33.33% (n=54)	66.67% (n=108)	64.5% (n=104)	35.5% (n=58)	25% (n=40)	75% (n=121)	31.7% (n=51)	68.3% (n=110)
When should I take this medication and how much should I take each time?	65.43% (n=106)	34.57% (n=56)	84% (n=136)	16% (n=26)	29% (n=47)	71% (n=114)	42.2% (n=68)	57.8% (n=93)
What should I do if I have side-effects?	31.48% (n=51)	68.52% (n=111)	81% (n=131)	19% (n=31)	8% (n=13)	92% (n=148)	27.3% (n=44)	72.7% (n=117)
How long should I take each medication?	74% (n=120)	26% (n=42)	80% (n=130)	20% (n=32)	45% (n=72)	55% (n=89)	52.2% (n=84)	47.8% (n=77)
Am I taking any medication I no longer need?	29% (n=47)	71% (n=115)	71% (n=115)	29% (n=47)	19% (n=31)	81% (n=130)	32.9% (n=53)	67.1% (n=108)
When should I stop each medication?	25.9% (n=42)	74.1% (n=120)	73.913% (n=120)	26.087% (n=42)	23.92% (n=36)	76.08% (n=125)	39.1% (n=63)	60.9% (n=98)

If I have to stop my medication due to an unwanted effect, where should I report this?	54.3% (n=88)	45.7% (n=74)	73.04% (n=118)	26.96% (n=44)	10.87% (n=17)	89.13% (n=144)	14.3% (n=23)	85.7% (n=138)

Figure 2: Level of Medication Adherence Before and After Pharmaceutical Care Intervention

There is a significant reduction in systolic BP in the usual care group but not in the pharmaceutical care group



with a very small P value of 0.00048 indicating that the changes observed were statistically significant, the same pattern is observed for diastolic BP with significant differences in BP reduction between the groups (P value = 0.01228). Random blood sugar levels decreased slightly in the usual care group but increased in the pharmaceutical care group. The statistical significance of this change is confirmed by a P value of 0.008. In both groups, there is a slight decrease in HbA1C but the changes were more pronounced in the pharmaceutical care group compared to the usual care group (P value = 0.00093). These findings are shown in Table 3.

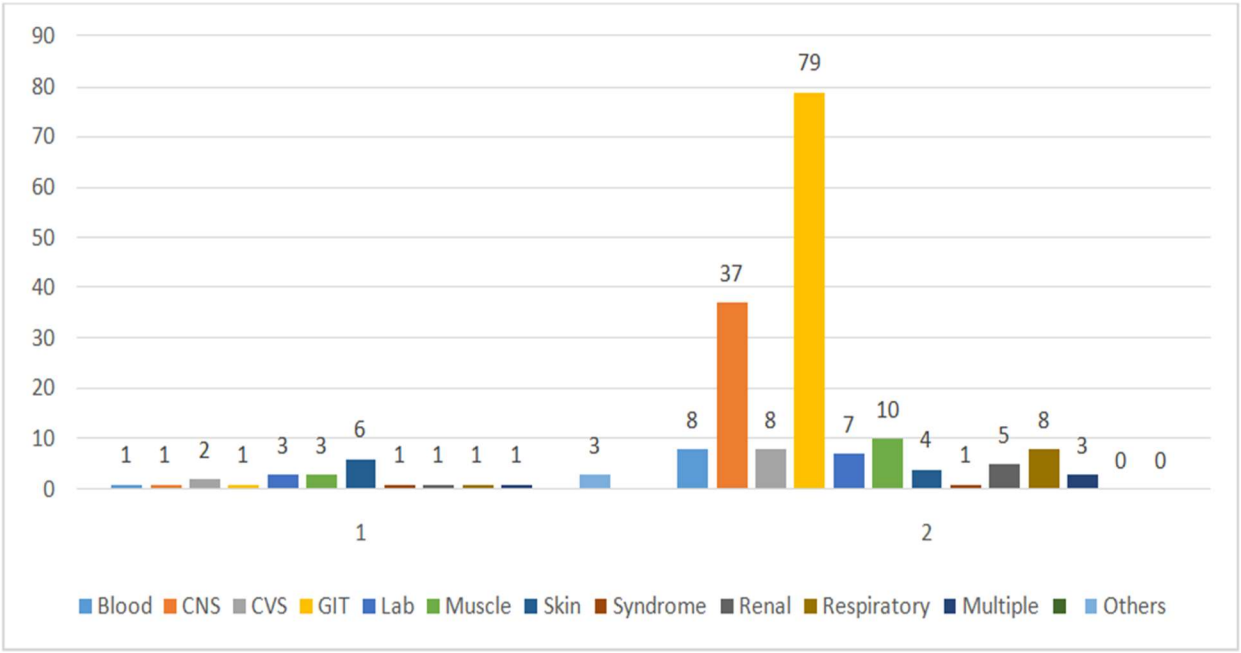
Table 3: Comparison of Outcome Parameters between Pharmaceutical Care and Usual Care Groups Before and After Intervention:

Outcome Parameter	Pharmaceutical Care				Usual Care				**P-value**
	Before		**After**		**Before**		**After**		
	Male	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	
Systolic BP(mm/Hg)	131.4(±13.6)	136.3(±14.09)	127.1(±13.75)	126.98(±10.2)	134.6(±13.75)	138.09(±11.91)	138.4(±9.8)	140.33(±9.14)	*0.00048**
Diastolic BP(mm/Hg)	91.1(±6.64)	91.85(±6.3)	84.14(±6.7)	84.53(±6.67)	90.25(±6.22)	90.31(±6.30)	88.71(±6.08)	89.16(±5.99)	*0.01228**
Random blood sugar (mg/dl)	185.2(±12.6)	187.5(±13.7)	175(±11.58)	174.3(±13.2)	184.3(±11.9)	182.4(±9.6)	181.3(±9.41)	180.8(±9.5)	*0.008**
HbA1C	7.14(±0.74)	7.08(±0.73)	6.52(±0.60)	6.46(±0.63)	7.048(±0.73)	7.12(±0.76)	7.11(±0.72)	7.00(±0.73)	*0.00093**

Adverse drug reactions (ADRs) were reported to the ADR monitoring center. From the above figure 3, it is

evident that these reactions can impact different parts of the body and the most commonly affected areas are the gastrointestinal tract (23.7%), the central nervous system (11.1%), and the skin (1.8%). Some reactions also occurred in the cardiovascular system (2.4%), respiratory system (2.4%), and renal system (1.5%). This information sheds light on the diverse ways medications can affect various anatomical sites in the body.

Fig 3: Anatomical site affected due to adverse drug reaction



The presented drug-drug interactions in the above data outline various classifications of drug interactions like major, moderate, and minor. Object-precipitant drug combinations, mechanisms, and corresponding pharmacist interventions. For significant interactions like amiodarone with Digoxin, adjustments in Digoxin dosage as amiodarone can increase serum digoxin levels. The pairing of Ciprofloxacin and ondansetron, on the other hand, is cautioned against as it may lead to congenital long QT Syndrome. Additionally, combinations like Carbamazepine with Hydrochlorothiazide could result in hyponatremia so there is need for ongoing monitoring of electrolyte levels. The details stress the importance of avoiding certain combinations, such as Chloroquine with Amlodipine, where co-administration is discouraged as chloroquine increases serum Amlodipine levels. In cases like Azithromycin with Digoxin, a careful administration schedule with a 2 to 4-hour gap is recommended to prevent increase in Digoxin levels. Moderate interactions, like amiodarone with phenytoin, call for diligent monitoring of elevated drug levels. It is important to avoid combining drugs like spironolactone with aspirin and hydrochlorothiazide with furosemide and to keep monitoring your electrolyte levels. Minor interactions such as phenytoin with furosemide and amiodarone with diclofenac show either decreased drug absorption or synergistic effects guiding pharmacists in their interventions. This data was shown in Table 4, and it underscores the crucial role of pharmacists in assessing and managing these interactions to ensure patient safety and optimal therapeutic outcomes.

Table 4: Common drug interactions-drug interactions observed in prescriptions:

CLASSIFICATION	OBJECT – PRECIPITANT DRUG	MECHANISM	PHARMACIST INTERVENTION
Major Drug-Drug Interaction	Amiodarone + Digoxin	Amiodarone increases blood levels of Digoxin	Digoxin dose adjustment
	Ciprofloxacin + Ondansetron	Capable of causing Congenital long QT Syndrome	Combination should be avoided
	Carbamazepine +Hydrochlorothiazide	Hyponatremia	Monitor electrolyte levels
	Chloroquine + Amlodipine	Amlodipine blood levels are elevated	Co-administration should be avoided
	Digoxin + Azithromycin	Azithromycin will increase digoxin leaves by suppressing bacteria that assist drug absorption	Azithromycin should be administered with gap of 2 to 4 hours
Moderate Drug-Drug Interaction	Amiodarone + Phenytoin	Phenytoin levels are elevated	Monitor Phenytoin levels
	Metformin + Digoxin	Digoxin levels are elevated	Mointor Digoxin levels
	Phenytoin + Chloroquine	Chloroquine Metabolism is increased and will be eliminated fast	Oral administration of phenytoin should be avoided
	Digoxin + Furosemide	Furosemide effects are increased, Hypokalemia may occur	Monitor electrolyte levels
	Metoprolol + Prednisolone	Hypokalemia may occur	Monitor electrolyte levels
	Spironolactone +Aspirin	Both increase potassium levels in blood	Combination should be avoided
	Hydrochlorothiazide +Furosemide	Hypokalemia may occur	Monitor electrolyte levels
	Ciprofloxacin +Phenytoin	Ciprofloxacin decreases levels of Phenytoin	Oral administration of Phenytoin should be avoided
	Ciprofloxacin +Carbamazepine	Serum Carbamazepine levels are elevated	Monitor Carbamazepine levels
	Aspirin +Diclofenac	Increase risk of bleeding (mechanism unknown)	Co-administration should be avoided
Minor Drug-Drug Interaction	Amiodarone +Diclofenac	Increase Diclofenac effects	Synergistic effect
	Phenytoin +Furosemide	Furosemide drug absorption is decreased	Co-administration should be avoided
	Prednisolone +Aspirin	Aspirin elimination rate is enhanced	Monitor electrolyte levels
	Ciprofloxacin +Digoxin	Digoxin toxicity can occur	Monitor electrolyte levels

	Diclofenac +Furosemide	Diclofenac decreases Furosemide levels	Co-administration should be avoided

DISCUSSION:

The mean age of the subjects was 45.8 and most of them were males (SD=12.76; range 18 to 80 years) which is similar to the study conducted by Michael S. Wolf. [6] Higher the literacy more will be chances for understanding and adhering to auxiliary labels this study is similar to the study conducted by Davis TC. [7] Use of pictorial illustrations on dispensing cover labels helps in better understanding of instructions and these results are similar to the study conducted by Stephen W Hwang.[8] Subjects level of education is positively associated with self-management of diabetes mellitus and achieving good glycemic control these results are similar to the study conducted by Niknami M.[9] Improvement in patients' blood pressure was after effective pharmacist intervention like counselling, providing educational materials and auxiliary labels and these results are similar to the study conducted by Robinson JD.[10] Incidence of medication errors and adverse events were slightly decreased due to pharmacist intervention, which is contrary to the study conducted by Gurwitz JH.[11]

CONCLUSION:

This study shows that clinical pharmacist intervention has a positive influence on patient medication adherence and health outcomes in pharmaceutical care group. The personalized medication information delivered directly on medication packaging proves effective in increasing medication adherence. The observed improvements in patient understanding, as well as notable enhancements in medication adherence and decrease chance for occurrence of adverse drug reactions underscore the transformative impact of pharmaceutical care on the overall well-being of patients. By tailoring information to individual needs and preferences, this approach not only bridges gaps in comprehension but also empowers patients to actively participate in their healthcare journey.

CONFLICT OF INTEREST

The authors declare that they have no potential conflicts of interest.

PATIENT CONSENT: Yes

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