

Research Article

Impact of Clinical Pharmacist-Mediated Pharmaceutical Care Using WHO Medication Safety Programme Through Dispensing Covers and Auxiliary Labeling- A Randomized Control Trial

Giri Raja Sekhar Dornadula¹, S Umadevi^{2*}

¹*Research Scholar, Department of Pharmacy Practice, Vels Institute of Science Technology and Advanced Studies, Chennai, Tamil Nadu, India- 600117.*

²*Professor, Department of Pharmaceutics, Vels Institute of Science Technology and Advanced Studies, Chennai, Tamil Nadu, India- 600117.*

ABSTRACT:

Aim & Objective: The aim of this study was to assess the impact of clinical pharmacist-mediated² care on medication knowledge in Type II Diabetes Mellitus (T2 DM) patients and medication adherence.

Methodology: A forward-looking observational study was undertaken in the General Medicine departments, encompassing both inpatients and outpatients. Departments at GGH, Kadapa. for six months by recruiting 112 subjects and having two follow-up visits. Subjects with Type 2 diabetes who were provided with written informed consent were included and divided into Groups A and B. Subjects in Group B received education using dispensing covers and leaflets at each follow-up, whereas no structured education to subjects in Group A. The questionnaire used was the Morisky Scale (MMAS-8) for Medication Adherence at baseline and the following follow-ups. Data were evaluated using the Graph Pad Prism software. Results: Among 112 subjects who participated in the study, 56 were Grouped as A and the other 56 Group B. Most of the study subjects were males (69%), with the majority between 61 and 65. At baseline, the mean fasting blood sugar (FBS) values of subjects in group A were 151.89 ± 52.751 and 166.60 ± 56.25 in group B. During the most recent follow-up, the blood sugar levels during fasting (FBS) and postprandial (PPBS) in group B subjects were comparatively lower ($p < 0.05$) than those in group A subjects. **Conclusion:** The findings of this study imply that clinical pharmacist-mediated structured education has a beneficial effect on medication knowledge and adherence, which is a key factor in diabetes management.

KEYWORDS: Medication familiarity, Medication conformity, Diabetes type 2, patient education, glycemic control.

**Author for correspondence:* Dr. S Umadevi, *Email:* umadevi.sps@vistas.ac.in

Received: 18/11/2024 *Accepted:* 20/11/2024

DOI: <https://doi.org/10.53555/AJBR.v27i3.3932>

© 2024 The Author(s).

This article has been published under the terms of Creative Commons Attribution-Noncommercial 4.0 International License (CC BY-NC 4.0), which permits noncommercial unrestricted use, distribution, and reproduction in any medium, provided that the following statement is provided. "This article has been published in the African Journal of Biomedical Research"

INTRODUCTION:

Diabetes is a chronic metabolic illness defined by excessive blood glucose levels due to the pancreas failure to produce enough insulin. Whereas diabetes mellitus which causes insulin resistance^{1,2}. Type 1 diabetes, also called Diabetes insipidus or juvenile, is a long-term condition in which trace amount of insulin is produced by the pancreas. Therefore, it is commonly referred to as insulin-dependent diabetes. This is caused by the autoimmune destruction of pancreatic beta

cells³. Although diabetes insipidus usually occurs during childhood or adolescence, it can also be seen in adulthood. Diabetes mellitus causes inadequate insulin utilization (insulin resistance)⁴. Adult-onset diabetes includes risk factors like genetic susceptibility, physical inactivity, and obesity⁵. Most of the individuals with non-insulin-dependent diabetes exhibit abnormal obesity, which causes insulin resistance. The latest estimate by the International Diabetic Federation (IDF), suggests that about 537 million people are living with diabetes

globally and they presume it could increase to 643 million by 2030⁶. International Diabetes Federation predicted that 463 million people globally will have diabetes by 2020, including 88 million people in Southeast Asia region⁷. In India, 77 million individuals suffer from diabetes mellitus. Diabetes prevalence grew from 1980 to 2014, the population increased from 108 million to 422 million.

Diabetes was the tenth biggest cause of death in 2019, accounting for an estimated 1.5 million fatalities caused directly by excessive blood sugar levels⁸.

Knowledge of adult-onset diabetes is associated with improved medication adherence and glycemic control⁹. Poor understanding and habits among diabetics are some of the characteristics impacting the disease's progression and problems, which are mostly preventable by imparting knowledge about medication use, which reduces long-term complications. 'Adherence' is defined by WHO as "how closely a person's actions, such as medication intake, dietary adherence, and lifestyle adjustments, align with the guidance provided by healthcare professionals". Medication adherence is a significant universal factor impacting subject health outcomes, particularly in enduring illnesses such as diabetes.

Inadequate compliance with anti-diabetic medication can result in treatment failure, resulting in diabetes-related complications such as microvascular and macrovascular changes in the retina, neurons, and nephrons, which reduce quality of life and increase medical care costs. These elements are signs of medication nonadherence and should be carefully evaluated and managed accordingly^{10,11}. Patient education is giving physical, psychological, and social information on treatment results in health care¹². The goal of this study was to assess people's diabetes knowledge as well as their medication adherence and the association between a person's diabetic knowledge, its impact on medication adherence, and blood glucose levels.

AIM AND OBJECTIVES:

This study evaluates the influence of clinical pharmacists on medication awareness and adherence among patients with Type II diabetes.

OBJECTIVES:

The key objectives of the study include:

- To separate diabetic subjects based on their demographic parameters.
- To assess the patient's knowledge about medication usage among diabetic subjects.
- To achieve optimum medication adherence through patient education.
- To compare the knowledge before and medication adherence pre-and post-educational intervention.
- To develop dispensing covers as an aid to enhance patient adherence.

METHODOLOGIES:

Study design and duration:

A forward-looking observational study was undertaken in the General medicine department, encompassing both inpatients and outpatients departments at GGH, Kadapa. The trial

spanned six months, from December 2021 to May 2022.

Source of data:

Case sheets, interviews, and questionnaire forms were used to collect information from research participants. Sample size: A sample of 112 subjects were recruited.

Inclusion criteria:

All subjects of either gender with Diabetes mellitus for at least one year of disease history.

Subjects with poor glycemic control or poor medication adherence.

Subjects with other co-morbidities.

Exclusion criteria:

Women with Gestational diabetes mellitus, lactating women, and pediatrics.

Subjects with end-organ failure.

Subjects unwilling to participate in the study.

Method of data collection:

The Research study was conducted in the Department of General Medicine, Government General Hospital, Kadapa. Following an explanation of the study methodology, the study participants submitted informed consent.

Study Tools:

The Morisky Medication Adherence Scale with 8-Item:

The 8-item Morisky Medication Adherence Scale was used to assess adherence. Adherence was categorized into three categories based on the scores obtained by individual Subjects:

- Low adherence <6
- Moderate adherence 6-8
- High adherence >8

1. American Public Health Association (APHA) Foundation Knowledge questionnaire:

Knowledge was assessed by using the American Public Health Association (APHA) Foundation questionnaire and the knowledge was categorized into three categories based on the scores obtained by individual subjects:

- Beginner <25
- Proficient 25-31
- Advanced 32-36

Study tools like dispensing covers and leaflets were used to obtain optimum medication adherence.

2. Dispensing covers, and leaflets:

Self-prepared dispensing covers and leaflets prepared in the local language were distributed to the Subjects which were used as an aid in patient education.

Statistical Analysis:

- Data was collected from recruited subjects and entered into a Microsoft Excel sheet.
- Graphs were plotted using Microsoft Excel.
- Descriptive statistical analysis like mean, standard deviation, and sample percentage were used to calculate

Impact of Clinical Pharmacist-Mediated Pharmaceutical Care Using Who Medication Safety Programme Through Dispensing Covers and Auxiliary Labeling- A Randomized Control Trial

the demographic data of all subjects.

- TWO-WAY ANOVA (Analysis of Variance) was used to determine statistically significant variation between groups A and B.

RESULTS:

We included 112 patients based on inclusion criteria and were

followed up for 2 visits. Our study sample size was 112. Subjects were randomized into Group A (Medications) and Group B (Medication+ Patient education). Out of them (56 from Group A and 56 from Group B) completed all follow-ups of the study. All the study subjects were classified based on gender which is shown in figure 1 with male predominance of 69%.

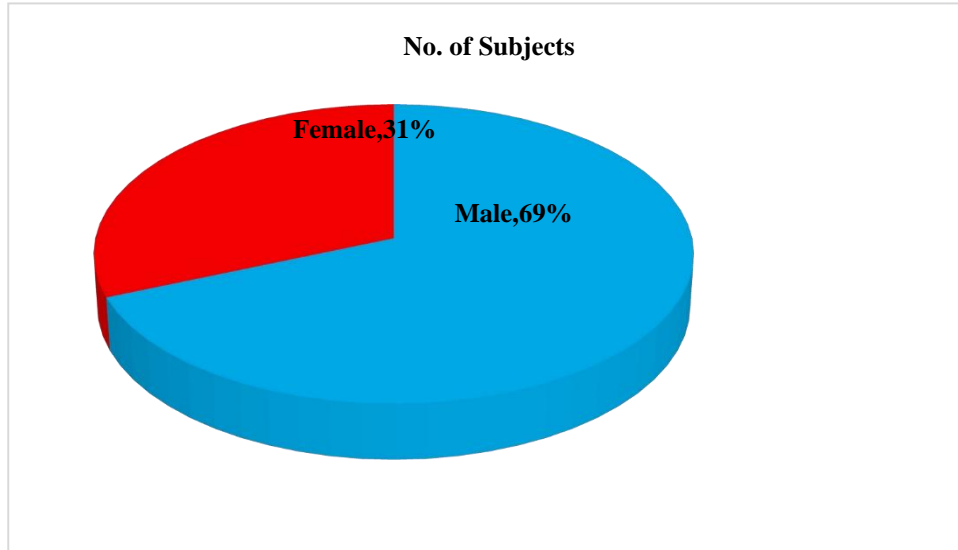


Fig:1 Graphical Representation of Percentage Distribution based on Gender

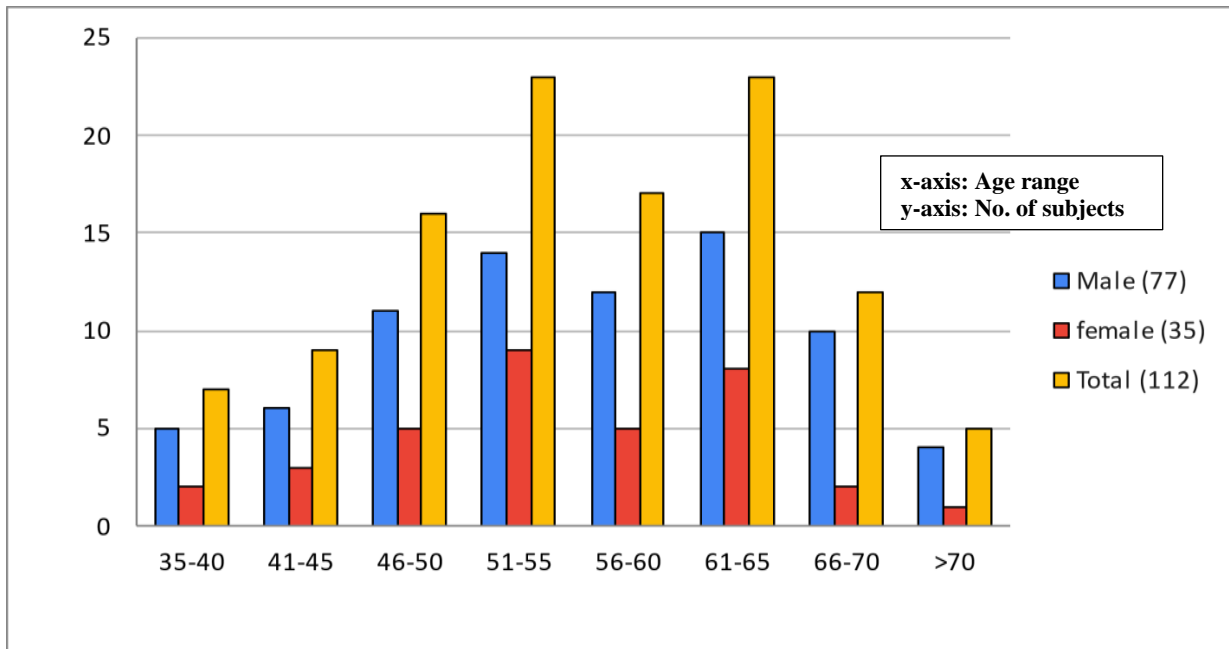


Fig:2 Distribution of samples based on age groups

Subjects were classified into age groups as shown in figure 2 and the subjects were in the age group of 60-65 years.

Subjects were classified depending on their co-morbidities. Hypertension is the most prevalent comorbidity among

patients with type 2 diabetes mellitus. Other comorbidities are shown in figure 3.

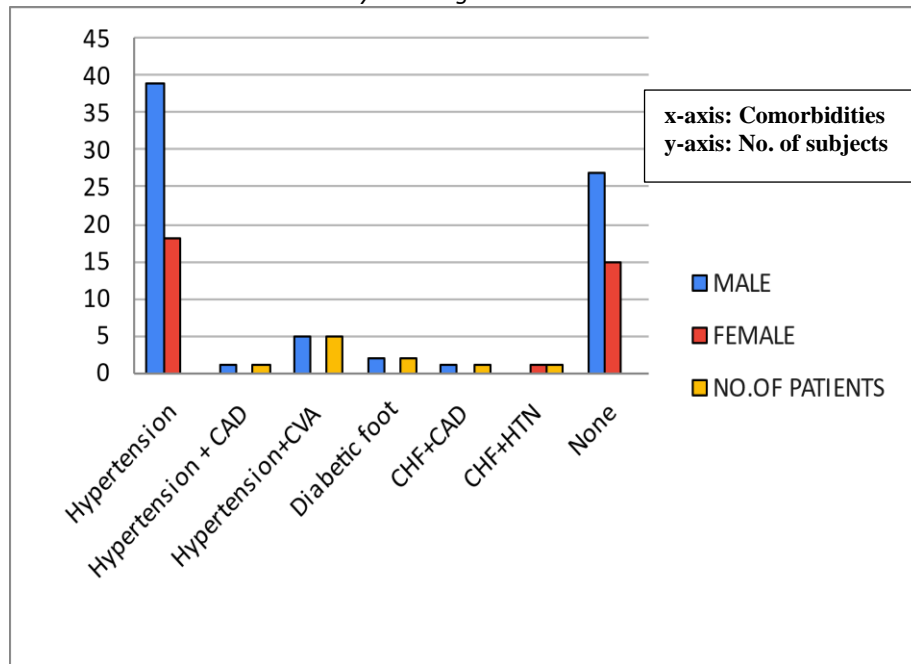


Fig 3: Co-morbidity-based sample distribution

- Fig. 4 shows that patients in group B (Medication + Patient Education) had higher baseline knowledge at final follow-up than group A (Medications).
- Adherence was categorized as low, medium, or high based on scores.
- Compared to Group A, Group B subjects had higher adherence from baseline to final follow-up.

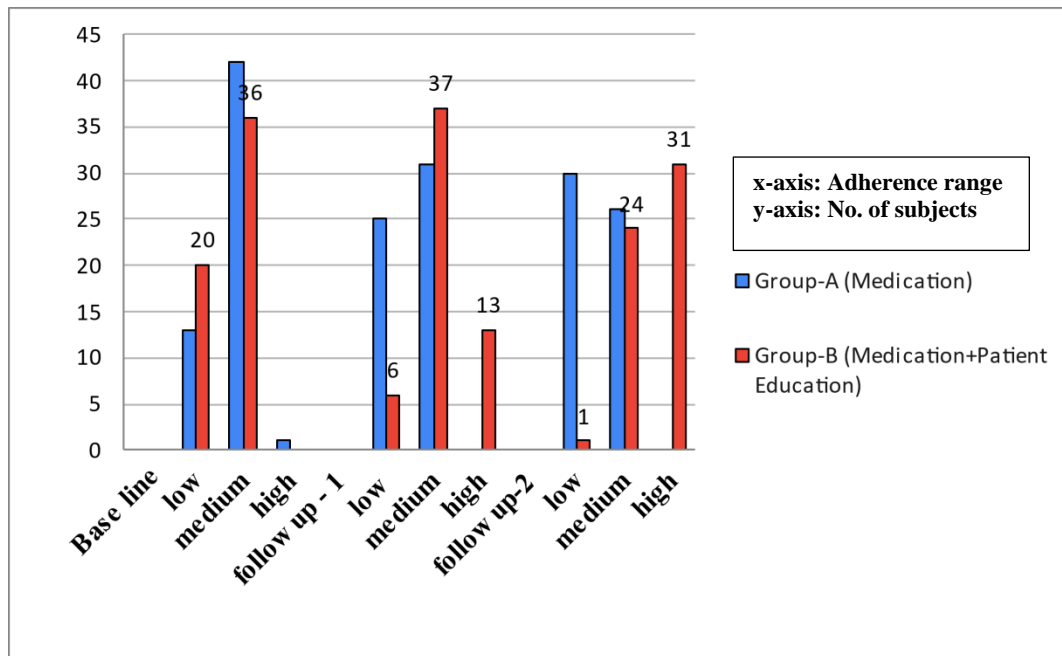


Fig:4 Comparison of Adherence in Group A and Group B

- Group B (Medications + Patient Education) had lower glycemic control than Group A (Medications), as shown in Figure 5.
- Group A had an average fasting blood sugar level of 151.89 ± 52.751 at baseline and 180.73 ± 55.83 at final follow-up. Post-prandial blood sugar readings were 217.94 ± 74.58 and 245.32 ± 56.87 .
- In group B FBS levels at baseline and final follow-up were 166.60 ± 56.25 and 135.57 ± 32.60 and PPBS levels were 240.16 ± 79.99 and 195.51 ± 52.51 respectively.
- The p-value of FBS (<0.0001) and PPBS (0.0002) was found statistically significant by using TWO-WAY ANOVA

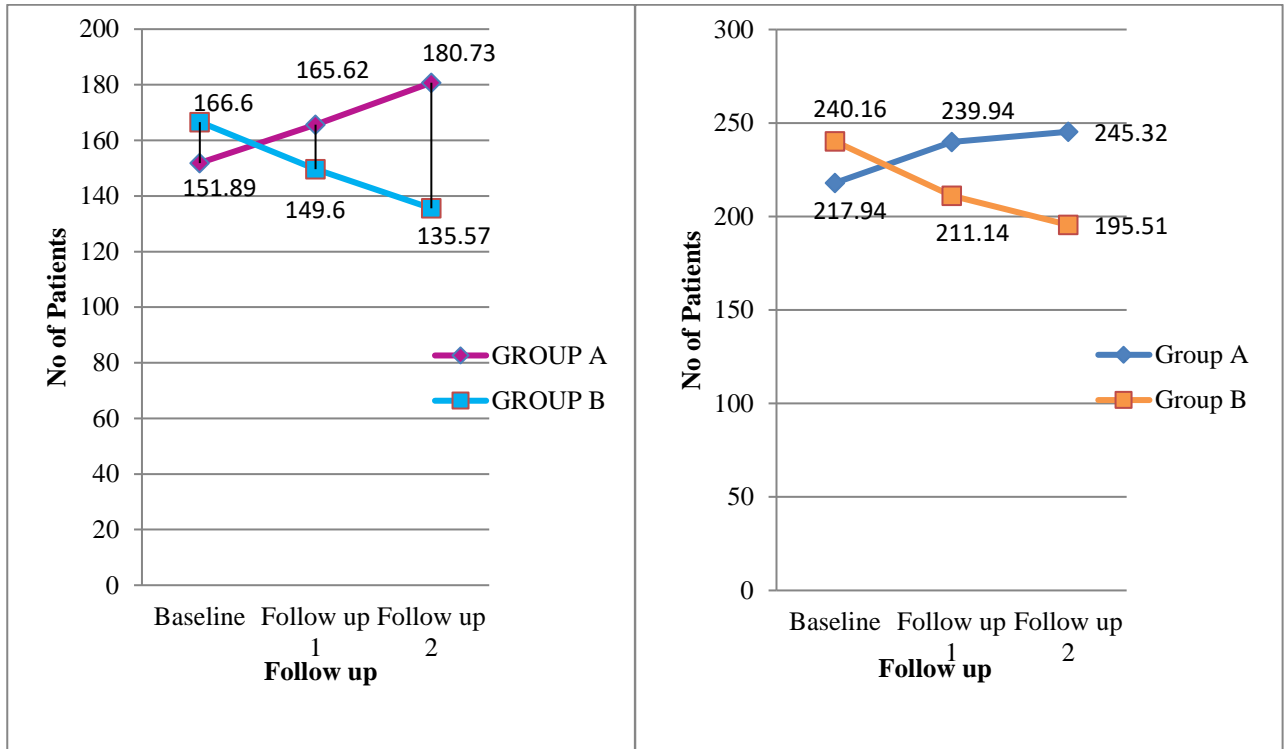


Fig:5 Comparison of Group A and Group B based on glycaemic control

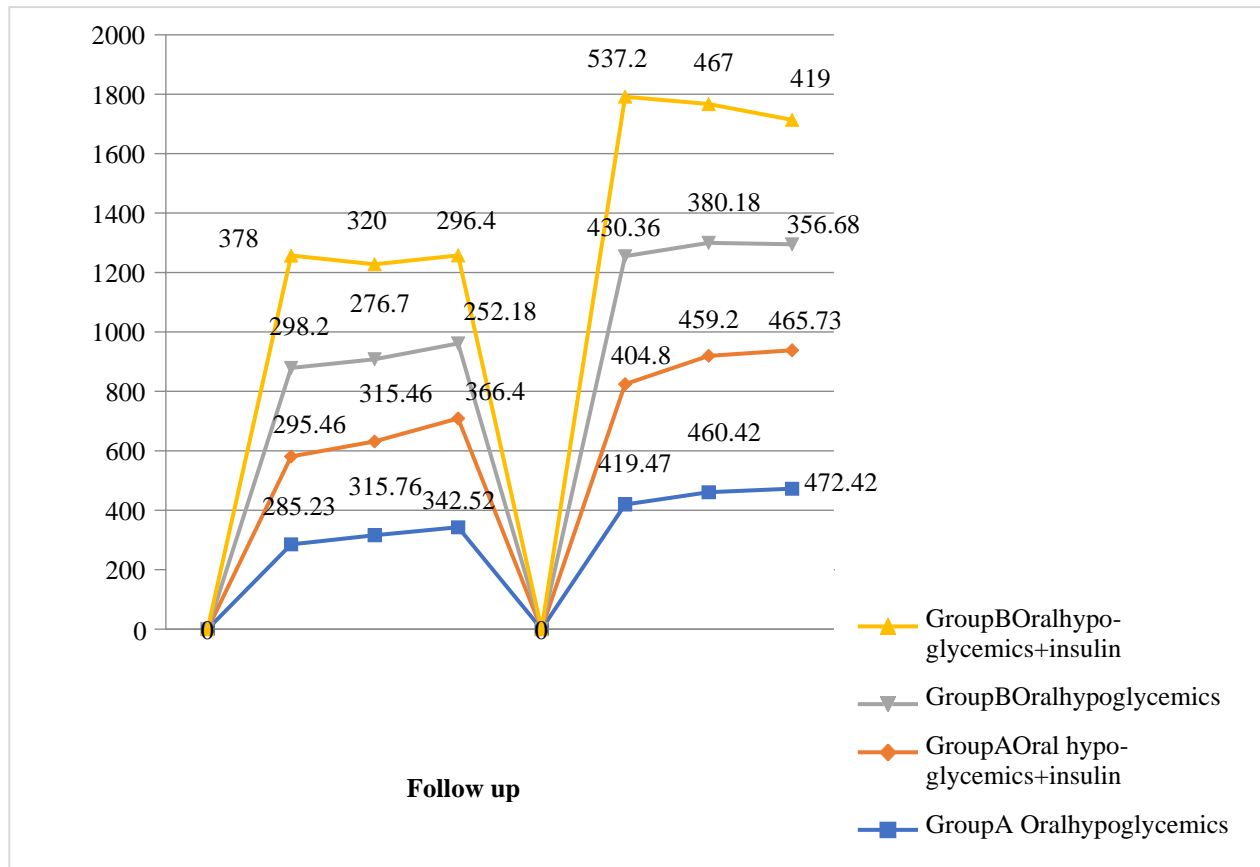


Fig:6 Comparison of Group A and Group B based on treatment

In Fig. 6, we categorized the patients into Group A (Medications) and Group B (Medications+ Patient education)

based on treatment. The glycaemic levels of Group B have decreased compared to Group A. The P-value (<0.0001) was found statistically significant using two-way ANOVA

DISCUSSION:

FBS and PPBS levels reduction can be seen from baseline to follow-up, similar to the study conducted by Krishnaveni Kanda Samy et.al., Pharmacist involvement had an important impact on disease severity, knowledge, and drug adherence. A significant decrease in FBS level was found from baseline to final follow-up, indicating a positive influence of ongoing Patient Education in diabetes treatment¹³.

The present study showed that males were slightly higher than females in the age group between 61-65.

In this study, most of the subjects had high adherence (31) moderate adherence (24), and low adherence (1) on follow-up after providing patient education which was similar to the study conducted by Olufunsho et al, in which overall improvement in adherence rate of 86.8% was observed with a decline of non-adherence rate after interventions were made¹⁴.

In the current study, the majority of the subjects were at an advanced stage (31), proficient (25), and beginner (0) after the final follow-up of providing patient education, conducted by Chethana Rame Gowda et al, and was a significant improvement in knowledge after health education¹⁵.

CONCLUSION:

We conclude effective medications that meet individual subjects' needs with proper health education can improve diabetic subjects' knowledge with increased awareness. Health education is appropriate for people of all ages, genders, and educational levels. The implementation of a standard strategy inpatient education using dispensing covers, pamphlets, or booklets had an impact on diabetes subject's health education. Education can be considered as an integral part of the treatment which helps to make treatment Plans for each patient for his/her education accessibility of clinical pharmacists or health care professionals to diabetic patients should be made easy which helps to raise awareness about diabetes and prevent further difficulties.

DECLARATION:

Regarding this work, the authors have no conflicts of interest.

PATIENT CONSENT: Yes

ACKNOWLEDGMENTS:

We sincerely thank Superintendent Govt. General Hospital, and all the study participants for taking part in this study as well as duty nurses of General Medicine for helping in data acquisition.

REFERENCES:

World Health Organization. Definition of diabetes mellitus [Internet]. Available from: <https://www.who.int/news-room/fact-sheets/detail/diabetes>. [Accessed 2021 Nov 10].
Pulipaka S, Suttee A, Kumar MR, Sriram P. Effective use of phytotherapy in the management of diabetes by plant-based medicine: A review. *International Journal of Pharmaceutical Quality Assurance*. 2022;13:337-46. Available from:

<https://doi.org/10.25258/ijpqa.13.3.20>

More RK, Pingale PL, Upasani CD. Promising antidiabetic effects of pomegranate fruit parts. *International Journal of Drug Delivery Technology*. 2024;14:609-14. Available from: <https://doi.org/10.25258/ijddt.14.1.82>

Elias NG, Al-Shammaa NMJ. Evaluation of fetuin-A and insulin resistance among Iraqi type 2 diabetic patients with and without ischemic heart disease. *International Journal of Drug Delivery Technology*. 2022;12:738-42. Available from: <https://doi.org/10.25258/ijddt.12.2.48>

Attia ZM, Hammood HJ, Assi MA. Assessment of oxidative stress biomarker (8-OHdG) and paraoxonase 1 in type II diabetic mellitus. *International Journal of Drug Delivery Technology*. 2021;11:1389-93. Available from: <https://doi.org/10.25258/ijddt.11.4.45>

International Diabetes Federation. World Diabetes Day Campaign [Internet]. Available from: <http://idf.org>. Updated 2014 Nov 14; cited 2015 May 11.

Epidemiology of diabetes [Internet]. Available from: https://en.m.wikipedia.org/wiki/Epidemiology_of_diabetes. [Accessed 2021 Jul 5].

World Health Organization. Diabetes epidemiology [Internet]. Available from: <https://www.who.int/news-room/fact-sheets/detail/diabetes>. [Accessed 2021 Nov 10].

Al-Qazaz H, Sulaiman SA, Hassali MA, Shafie AA, Sundram S, Al-Nuri R, Saleem F. Diabetes knowledge, medication adherence, and glycemic control among patients with type 2 diabetes. *International Journal of Clinical Pharmacy*. 2011;33:1028-35.

Fadheel QJ. Prevalence of diabetes mellitus and its complications in Iraq. *International Journal of Pharmaceutical Quality Assurance*. 2018;9:109-16. Available from: <https://doi.org/10.25258/ijpqa.v9i2.13631>

Jackson IL, Adibe MO, Okonta MJ, Ukwe CV. Medication adherence in type 2 diabetes patients in Nigeria. *Diabetes Technology & Therapeutics*. 2015;17:398-404.

Bhandari S, Garg V, Dwivedi S. Impact of counseling on patient education and dietary quality of lifestyle and nutritional anemia in diabetes mellitus patients: A case-control study. *International Journal of Pharmaceutical Quality Assurance*. 2023;14:1312-4. Available from: <https://doi.org/10.25258/ijpqa.14.4.75>

Kandasamy K, Sundaram S. Impact of a pharmacist intervention on improving medication adherence and knowledge towards diabetes mellitus: A randomized controlled study. *International Journal of Research*. 2019;11:416-20.

Awodele O, Osuolale J. Medication adherence in type 2 diabetes patients: Study of patients in Alimosho General Hospital, Igando, Lagos, Nigeria. *African Health Sciences*. 2015;15:513-22.

Ramegowda C, Hulugappa L. Assessment of health education on knowledge regarding oral antidiabetic drug adherence in an urban area, Bengaluru. *International Journal of Community Medicine and Public Health*. 2020;7:232-3.

Devhare LD, Gokhale N. Antioxidant and antiulcer property of different solvent extracts of Cassia Tora Linn. *Research Journal of Pharmacy and Technology*. 2022;15:1109-13.

Tiwari R, Mishra J, Devhare LD, Tiwari G. An updated

review on recent developments and applications of fish collagen. *Pharma Times*. 2023;55:28–36.

Adimulapu AK, Devhare LD, Patil AA, Chachda NO, Dharmamoorthy G. Design and development of novel mini tablet cap technology for the treatment of cardiovascular diseases. *International Journal of Drug Delivery Technology*. 2023;13:801–6.

Chawla A, Devhare LD, Dharmamoorthy G, Tyagi S. Synthesis and in-vivo anticancer evaluation of N-(4-oxo-2-(4-((5-aryl-1,3,4-thiadiazole-2yl)amino)phenylthiazolidine-3-yl)benzamide derivative *International Journal of Pharmaceutical Quality Assurance*. 2023;14:470–4. Available from: <https://doi.org/10.25258/ijpqa.14.3.47>

Gnana RPM, Devhare LD, Dharmamoorthy G, Khairnar MV, Prasadha R. Synthesis, characterization, molecular docking studies, and biological evaluation of novel benzothiazole derivatives as EGFR inhibitors for anti-breast cancer agents. *International Journal of Pharmaceutical Quality Assurance*. 2023;14:475–80. Available from: <https://doi.org/10.25258/ijpqa.14.3.48>

Sonule M, Devhare LD, Babu MN, Gunjal SD, Varalaxmi S. Microemulgel-based hydrogel of diclofenac sodium using Lipidium sativum as a gelling agent. *International Journal of Drug Delivery Technology*. 2023;13(4):1235–9. Available from: <https://doi.org/10.25258/ijddt.13.4.49>

Shriram BK, Devhare LD, Mehrotra A, Deokar SS, Singh SP. Formulation and evaluation of mosquito repellent stick. *International Journal of Drug Delivery Technology*. 2023;13:1283–6. Available from: <https://doi.org/10.25258/ijddt.13.4.50>

Choudhary RK, Beeraka S, Sarkar BK, Dharmamoorthy G, Devhare L. Optimizing verapamil hydrochloride in-situ delivery: A strategic formulation approach using Box-Behnken design for enhanced performance and comprehensive evaluation of formulation parameters. *International Journal of Drug Delivery Technology*. 2024;14:61–70. Available from: <https://doi.org/10.25258/ijddt.14.1.51>

Kumar KK, Kiran V, Choudhary RK, Devhare LD, Gunjal SD. Design, development, and characterization of nicardipine solid lipid nanoparticles. *International Journal of Drug Delivery Technology*. 2024;14:71–8. Available from: <https://doi.org/10.25258/ijddt.14.1.52>

Priya MGR, Prasanth LML, Devhare LD, Yazdan SK, Gunjal S. Synthesis, DNA binding, molecular docking, and anticancer studies of copper (II), nickel (II), and zinc (II) complexes of primaquine-based ligand. *International Journal of Pharmaceutical Quality Assurance*. 2024;15:69–75. Available from: <https://doi.org/10.25258/ijpqa.15.1.53>

Uplanchiwar VP, Raut SY, Devhare LD, et al. Pharmacological assessment of antiulcer activity of *Gloriosa Superba* Linn tubers in experimentally induced gastric ulcers. *Journal of Medical Pharmaceutical and Allied Science*. 2021;10:2852–6. Available from: <https://doi.org/10.25258/jmpas.10.3.54>

Tiwari G, Gupta M, Devhare LD, Tiwari R. Therapeutic and phytochemical properties of thymoquinone derived from *Nigella sativa*. *Current Drug Research Reviews*. 2024;16:145–56. Available from: <https://doi.org/10.25258/cdrr.16.2.55>