

**AN OBSERVATIONAL STUDY ON THE AWARENESS OF ADVERSE DRUG REACTIONS DUE TO ANTIDIABETIC DRUGS AMONG COMMUNITY PHARMACISTS IN SOUTHERN PART OF KERALA****Sneha P. S.<sup>\*1</sup>, Renisha R. S.<sup>1</sup>, Soumya R. V.<sup>2</sup>, Pavithra J.<sup>3</sup>, Nithin Manohar R.<sup>4</sup> and Prasobh G. R.<sup>5</sup>**<sup>1</sup>Student, Eighth Semester B. pharm, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.<sup>2</sup>Associate Professor, Department of Pharmacy Practice, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.<sup>3</sup>Lecturer, Department of Pharmacy Practice, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.<sup>4</sup>Professor and HOD, Department of Pharmacy Practice, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.<sup>5</sup>Principal, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.**\*Corresponding Author: Sneha P. S.**

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**ABSTRACT**

Diabetes mellitus (DM) is brought on by a lack of insulin production, injury to pancreatic cells or insulin resistance brought on by inadequate insulin utilization. This is an observational study conducted for community pharmacies at southern part of Kerala. In this study 100 community pharmacies with 156 pharmacists were selected. We observed the awareness of adverse drug reactions due to antidiabetic drugs among community pharmacists and to assess the knowledge, attitude and practice of a newer class of antidiabetic drug (GLP-1 receptor agonists) among the community pharmacists by using suitably designed questionnaire. The study shows that, while community pharmacists possess adequate knowledge and awareness of adverse drug reactions (ADRs) related to antidiabetic drugs, there is a noticeable gap in their understanding of pharmacovigilance and methods for identifying ADRs. Overall, community pharmacists showed good knowledge, attitude, and practice towards antidiabetic drugs, but targeted training programs are recommended to strengthen their expertise in pharmacovigilance and newer drug therapies.

**KEYWORDS:** Diabetes mellitus, Adverse drug reactions, Antidiabetic drugs, Community pharmacists, Questionnaire, Pharmacovigilance.

**INTRODUCTION**

Diabetes mellitus (DM) is a metabolic disease, involving inappropriately elevated blood glucose levels. Diabetes mellitus (DM), a severe public health issue, affects about 400 million people globally.<sup>[1]</sup> Diabetes mellitus (DM) is brought on by a lack of insulin production, injury to pancreatic cells or insulin resistance brought on by inadequate insulin utilization.<sup>[2][3]</sup> Chronic microvascular, macrovascular, and neuropathic life-threatening consequences are caused by this metabolic disease over time.<sup>[4]</sup>

There are two types of diabetes mellitus: Type 1 DM and Type 2 DM. Type 1 diabetes mellitus is an autoimmune disease that damages pancreatic cells and reduces or inhibits insulin production and also known as Insulin Dependent Diabetes Mellitus (IDDM)/ Juvenile diabetes. Type 2 diabetes mellitus is brought on by a lack of beta

cells in the pancreas, which makes it difficult for people to use insulin and also known as Non- Insulin Dependent Diabetes Mellitus (NIDDM)/ Adult or Maturity onset Diabetes Mellitus.<sup>[5]</sup>

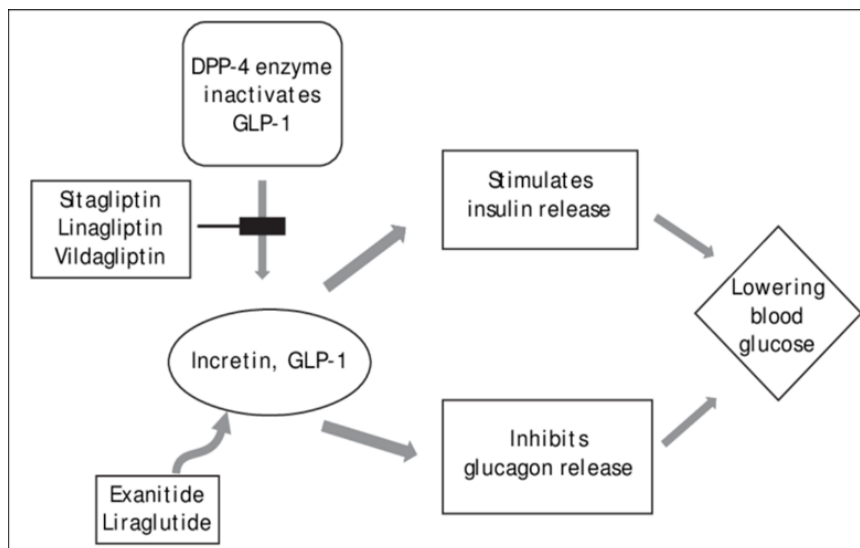
Signs and symptoms of diabetes mellitus are hunger, polyphagia, weight loss, hypotension, vulvitis, polydipsia, polyuria, tachycardia, wasting.

An estimated 425 million people worldwide (10.2% of total population) are suffering from the disease. The global healthcare expenditure in managing the diseased condition has crossed USD 727 billion. China, India and United States of America were reported to be the top three countries with maximum number of patients between the ages 20 – 79 years.<sup>[6]</sup>

Recent studies suggest that one important target for the

treatment of type 2 diabetes may be the incretin system. The gut mucosa responds to meals by producing hormones called incretins. There are two known incretin hormones: glucagon-like peptide-1 (GLP-1) and glucose-dependent insulintropic polypeptide. A more recent family of drugs known as GLP-1 receptor agonists has been authorised for the treatment of adult type-2 diabetes mellitus. The medications are known to moderately lower blood glucose levels.<sup>[7]</sup> According to the

medication's safety profile, administering GLP-1RA may raise the risk of thyroid C-cell neoplasia, cause pancreatitis, local irritation, and upset stomach. Due to an incomplete safety profile, the medicine is not recommended for use in pregnant or lactating women. Since this group of compounds were recently introduced, thorough information is essential for safe use of medications.



**Fig. 1: Mechanism of action of GLP-1 receptor agonists.**

Exenatide and Liraglutide are the drugs which are belongs to the category of GLP-1 receptor agonists. Tirzepatide is the most recently approved antidiabetic drug which comes under the category of GLP-1 receptor agonists.

Pharmacovigilance is defined as the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems”.

World Health Organization (WHO) defines Adverse drug reaction as “response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function”.

The WHO which is responsible for International Drug Monitoring and its headquarters at Uppsala Monitoring Centre located in Sweden, plays an important role in adverse drug reaction monitoring in India. It is a global hub for collection and analysis of adverse drug reaction reported data from various countries. It provides tools and many resources to India for establishing and maintaining the pharmacovigilance programme which is directly dealing with adverse drug reaction. It promotes the reporting and monitoring of adverse drug reaction in different country across the globe.<sup>[8]</sup> The PvPI is structure by inspiring from WHO UMC guidelines and recommendations as other countries. The processes and

methods used by PvPI is aligned with WHO UMC system. The data collected by PvPI is submitted to WHO UMC. This is allowing the WHO UMC to collect the data from all over the country and globe which provide a clear, confirmed and accurate data collection.<sup>[9][10]</sup>

## METHODOLOGY

### Study setting

The study was conducted among community pharmacists in southern part of Kerala.

### Study Period

The study was conducted for a period of 6 months.

### Study design

An observational study on the awareness of adverse drug reactions due to antidiabetic drugs among community pharmacists in southern part of Kerala

### Sample size

The sample size of the proposed study is calculated by the following formula

$$\text{Sample Size } n = \frac{Z\alpha^2 P(1-P)}{d^2}$$

Where:

Z $\alpha$  - The standard normal variate with  $\alpha$  % level of significance

P- Estimated proportion of the cases

d- Precision or margin of errors of the study

From the previous study, the proportion of awareness of the antidiabetic drug adverse reaction in the community is reported as 20%. The margin of error or precision is assumed to be 8% with a significant level of 5%. The required sample size is estimated as

$$\text{Sample Size } n = \frac{1.96^2 \times 0.20 \times 0.80}{(0.08)^2} = 96 \text{ samples}$$

### Study procedure

- A suitably designed questionnaire were prepared to analyse the awareness of adverse drug reactions due to antidiabetic drug.
- We collected data among the 156 registered pharmacists in community pharmacy
- We ask the following questions to the pharmacists about ADR suspected in antidiabetic therapy.
- They responded to the questions in the form of yes or no.
- To assess the knowledge, attitude and practice about a newer class of antidiabetic drug among the community pharmacists by a suitably designed questionnaire.
- Proper counselling were given to community pharmacists using validated leaflet.
- Finally, the data collected is analysed using suitable statistical method with assistants of qualified statistician.

### Data collection tool

A questionnaire were prepared to analyse the awareness

of adverse drug reactions due to antidiabetic drug in community pharmacists and to assess the knowledge, attitude and practice about a newer class of antidiabetic drug among the community pharmacists in southern parts of Kerala was used as a tool for data collection.

### Data analysis

After collecting the data, was analysed using suitable statistical method.

## RESULTS AND DISCUSSIONS

In this study the data on demographic characteristics, awareness of adverse drug reactions due to antidiabetic drugs and Knowledge, Attitude and Practice score were collected from 100 community pharmacies with 156 pharmacists. The collected data were subjected to statistical analysis. All the analysis were carried out with help of statistical software.

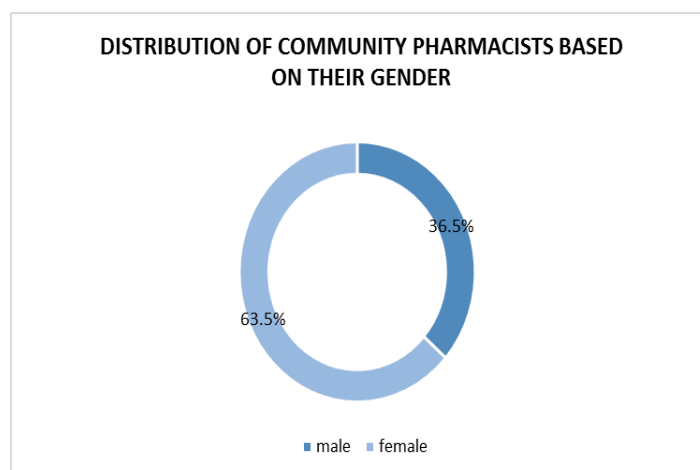
### DEMOGRAPHIC CHARACTERISTICS OF COMMUNITY PHARMACISTS

In this section demographic characteristic of community pharmacist were collected represented as bar graph or pie chart.

#### Distribution of community pharmacists based on their gender

**Table 1: Distribution of community pharmacists based on their gender.**

Sl no	Gender	Frequency	Percentage
1	Male	57	36.5%
2	Female	99	63.5%



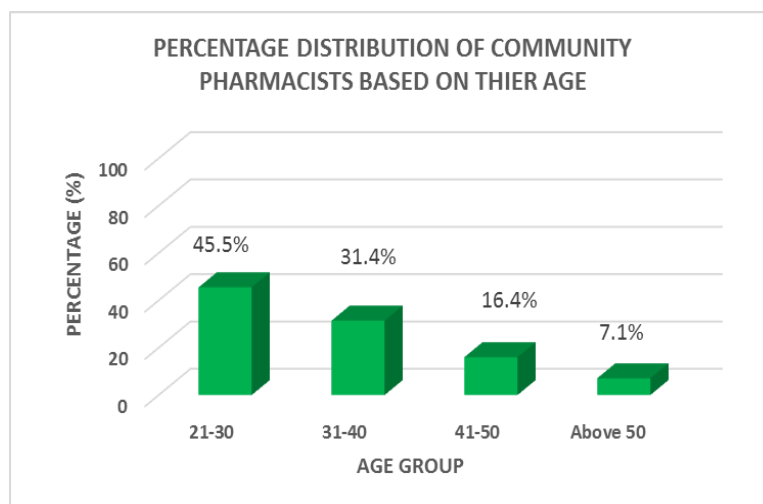
**Graph 1: Diagrammatic representation of distribution of community pharmacists based on their gender.**

In this study 100 community pharmacies with 156 pharmacists were selected. In case of gender, female community pharmacists is higher than male community pharmacists. It was found that 63.5% of community pharmacists were females & 36.5% males.

#### Distribution of community pharmacists based on their age

**Table 2: Distribution of community pharmacists based on their age.**

Sl no	Age	Frequency	Percentage
1	21-30	71	45.5%
2	31-40	49	31.4%
3	41-50	25	16.0%
4	Above 50	11	7.1%



**Graph 2: Diagrammatic representation of distribution of community pharmacists based on their age.**

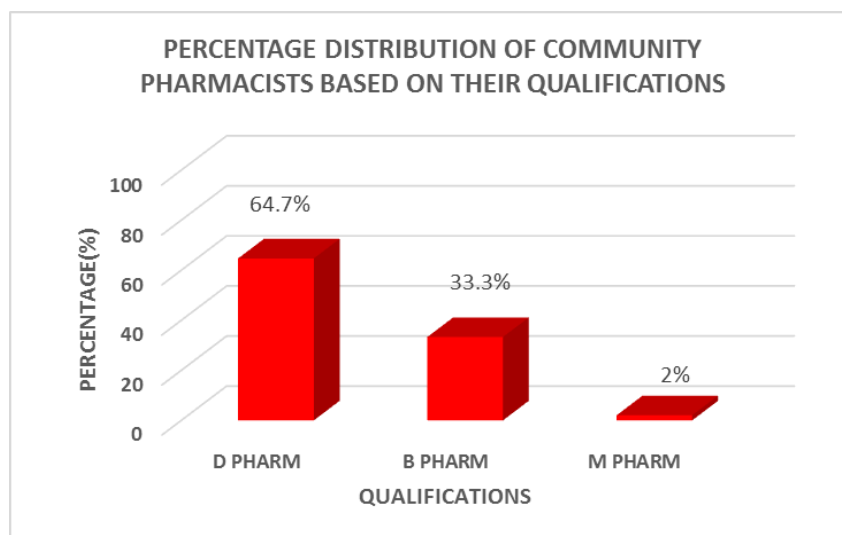
In this study 100 community pharmacies with 156 pharmacists were selected. From the table, it shows the community pharmacists having age group between 21-30 were more in number, i.e., 45.5%. About 31.4% of

community pharmacists were from the age group 31-40. About 16.4% of community pharmacists were from the age group from 41-50. About 7.1% of community pharmacists were from the age group above 50.

#### **Distribution of community pharmacists based on their qualification**

**Table 3: Distribution of community pharmacists based on their qualification.**

Sl no	Qualification	Frequency	Percentage
1	D Pharm	101	64.7%
2	B Pharm	52	33.3%
3	M Pharm	3	2%



**Graph 3: Diagrammatic representation of distribution of community pharmacists based on their qualification.**

In this study 100 community pharmacies with 156 pharmacists were selected. From the study it was understood that most of the community pharmacists were qualified with D. Pharm. About 64.7% of community pharmacists were qualified with D. Pharm. About 33.3% of the community pharmacists were qualified with B. Pharm and only 2% of community pharmacists were qualified with M. Pharm.

#### **AWARENESS OF ABOUT ADVERSE DRUG REACTIONS OF ANTIDIABETIC DRUGS AMONG COMMUNITY PHARMACISTS IN THE SOUTHERN PARTS OF KERALA**

This study is to evaluate the awareness of about ADR of antidiabetic drugs among community pharmacists in the southern parts of Kerala. We conducted a survey of pharmacists in the southern parts of Kerala, about ADR reporting and some questions regarding ADR of antidiabetic drugs.

The questions asked to the pharmacist of southern parts of Kerala were from question set 1 and 2 and the

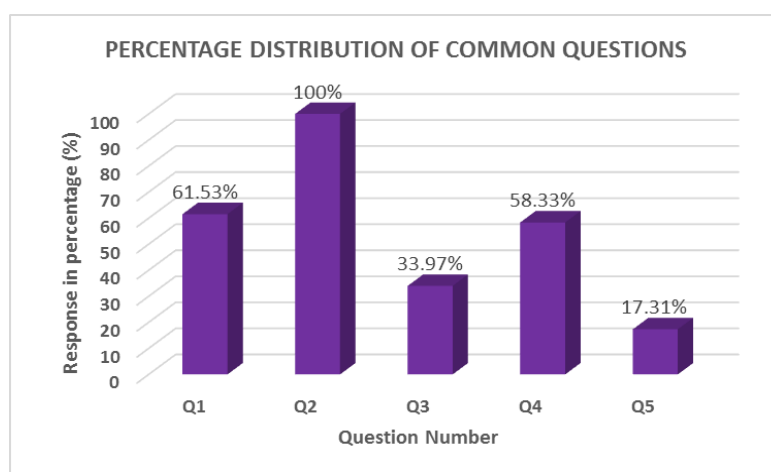
response is represented graphically in graphs 4 and 5, respectively.

#### Question set 1: Common questions

**Table 4: Percentage distribution of common questions.**

Sl no	Questions	Response		Response (Yes) in percentage (%)	P value
		Yes	No		
1	Are you aware about Pharmacovigilance?	96	60	61.53%	0.02*
2	Are you aware of adverse drug reactions?	156	-	100%	0.001*
3	Do you know how to report adverse drug reactions to an authorised person or office?	53	103	33.97%	0.03*
4	Do you know how to find out the adverse drug reactions?	91	65	58.33%	0.02*
5	Do you know the procedure used in identifying the adverse drug reactions?	27	129	17.31%	0.078

\*significant



**Graph 4: Response (yes/positive) in percentage for the question set 1.**

In this study 100 community pharmacies with 156 pharmacists were selected. When we asked about pharmacovigilance, 61.53% of pharmacists were aware about it but the remaining 38.47% did not have an idea about it. 100% of pharmacists were aware about the adverse drug reactions. Only 33.97% of pharmacists knew how to report ADR to an authorized person or office and 66.03% of pharmacists did not know about the method to report ADR. About 58.33% of pharmacists were able to identify the ADR but 41.67% of

pharmacists were not able to identify the ADR. Finding out that so few of them i.e., 17.31% are familiar with the methods for identifying ADR, while 82.9% of the pharmacists do not know about the techniques to identify ADR.

The study was correlated with the study of Sagar N Ande et al conducted a study on "Awareness survey for antidiabetic drug adverse reaction in community pharmacists (Amravati)".<sup>[11]</sup>

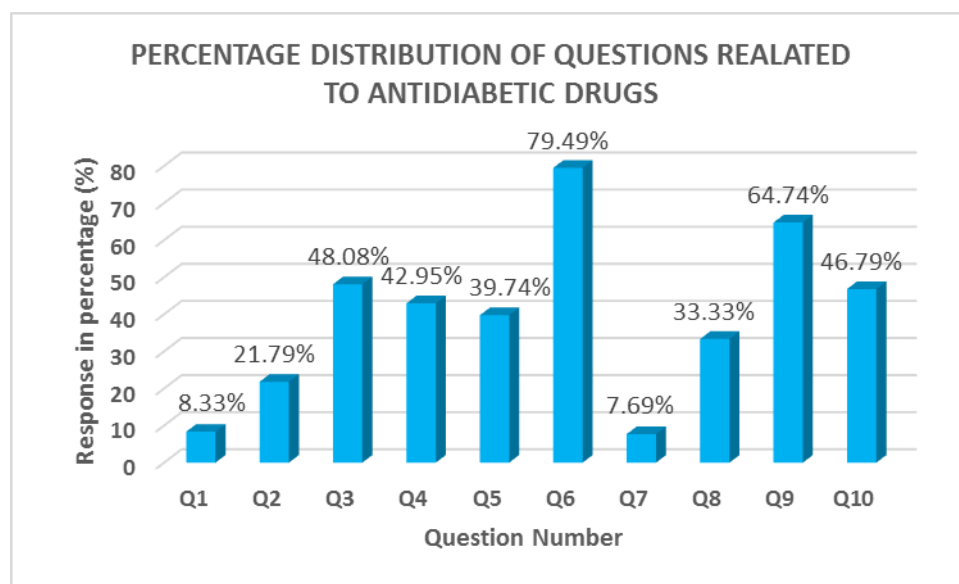
#### Question set 2: Questions related to antidiabetic drugs

**Table 5: Percentage distribution of questions related to antidiabetic drugs.**

Sl no	Questions	Response		Response (Yes) in percentage (%)	P value
		Yes	No		
1	Are you aware of the new antidiabetic drugs that have been introduced recently?	13	143	8.33%	0.308
2	Do you offer patient counselling regarding the ADR of antidiabetic drugs?	34	122	21.79%	0.064
3	Does a patient's age have any impact on antidiabetic medication?	75	81	48.08%	0.01*
4	Are you aware of the most prevalent antidiabetic medication toxicity?	67	89	42.95%	0.01*
5	Do the patients report any ADR to you?	62	94	39.74%	0.03*
6	Do the patients take their medications as	124	32	79.49%	0.001*

	directed?				
7	Are you involved in the treatment decisions?	12	144	7.69%	0.481
8	Do you think that genetics is the primary cause of diabetes?	52	104	33.3%	0.03*
9	Do you think that people with diabetes need to change their lifestyle?	101	55	64.74%	0.001*
10	In your opinion, Is insulin is more preferable over the oral antidiabetic drugs?	73	83	46.79%	0.02*

\*significant



**Graph 5: Response (yes/positive) in percentage for the question set 2.**

In this study 100 community pharmacies with 156 pharmacists were selected. Latest antidiabetic drugs were known to 8.33% pharmacists only. 21.79% of pharmacists counsel the patients about ADR, while dispensing the drugs. About 48.08% know that patient's age have impact on antidiabetic medication. About 42.95% of pharmacists know about the major toxicity of anti-diabetic drugs. About 39.74% of patients report ADR to the pharmacist. Approximately 79.49% of pharmacists reported that patients have followed their diabetes medication regimens. Only 7.69% of pharmacists are involved in treatment decisions in case of diabetes. About 33.3% of a pharmacists are of the opinion that the major cause of diabetes is heredity. According to 64.74% of pharmacists, diabetic patients should modify their lifestyle in order to quickly and successfully adjust to therapy. About 46.79% of pharmacists think that insulin therapy is better the oral anti-diabetic agents while 53.21% said that patients are not comfortable with insulin therapy, they prefer oral anti-diabetics in treatment.

The study was correlated with the study of Sagar N Ande et al conducted a study on "Awareness survey for antidiabetic drug adverse reaction in community pharmacists (Amravati)".<sup>[11]</sup>

#### **KNOWLEDGE, ATTITUDE AND PRACTICE OF A NEWER CLASS OF ANTIDIABETIC DRUG (GLP-1 RECEPTOR AGONISTS) AMONG THE COMMUNITY PHARMACISTS**

The Knowledge, Attitude and Practice of a newer class of antidiabetic drug (GLP-1 RA) in community pharmacists were assessed by using the suitably designed questions.

In this section scores on KAP obtained from community pharmacists were selected and converted into percentage (%).

In this study the scoring is represented as:

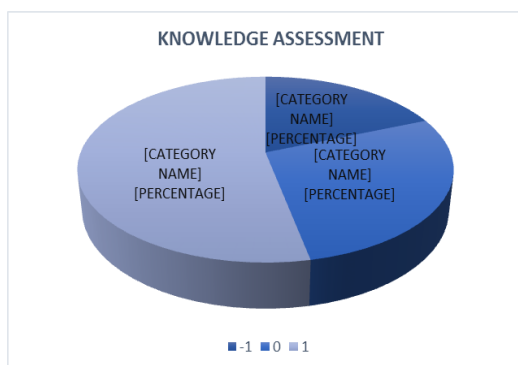
- -1 =Poor
- 0 =Fair
- +1 =Good



**Knowledge assessment****Table 6: Knowledge assessment.**

Sl no	Questions	Scoring			P-value
		-1	0	+1	
1	Do you know about Glucagon like peptide-1 receptor agonists?	0	35	121	
2	Are you aware that Glucagon like peptide-1 receptor agonists are the latest addition in the management of type-2 diabetes mellitus?	29	64	63	
3	Does giving Glucagon like peptide-1 receptor agonists to people with type-2 diabetes not result in hypoglycaemia?	35	61	60	
4	Is it accurate to say that using Glucagon like peptide-1 receptor agonists can lower blood pressure?	49	34	73	
5	Do you know that Glucagon like peptide-1 receptor agonists therapy can cause pancreatitis in diabetic patients?	34	24	98	
TOTAL (%)		18.85%	27.95%	53.20%	0.001*

\*significant

**Graph 6: Knowledge assessment.**

good knowledge. The p-value is found to be .001 and is significant and conclude that the overall knowledge of community pharmacists is very good.

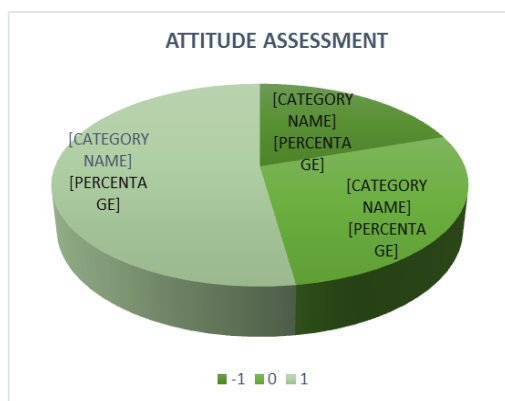
The study was correlated with the study of Syed Imam Rabbani et al conducted a study on “Knowledge, Attitude and Practice about a Newer Class of Antidiabetic Drug (Glucagon-like peptide-1 receptor agonist) Among the Health Care Professionals of Qassim University, Saudi Arabia”.<sup>[12]</sup>

From the above table it is clear that 19% have poor knowledge, 28% have fair knowledge and 53% have

**Attitude assessment****Table 7: Attitude assessment.**

Sl no	Questions	Scoring			P-value
		-1	0	+1	
1	Do you believe GLP-1 receptor agonists therapy is better than other antidiabetic drugs?	69	45	42	
2	Do you feel a moral obligation to discuss the benefits and risk factors associated with Glucagon like peptide-1 receptor agonists therapy?	-	49	107	
3	Do you make any efforts to collect ADR of Glucagon like peptide-1 receptor agonists from patients?	77	54	25	
4	Do you recommend patients on Glucagon like peptide-1 receptor agonists therapy to eat small portions of meals and then wait 30 minutes before eating more?	9	34	113	
5	Do you prefer to encourage patients to self-monitor blood glucose a few times daily for a week or two after initiating the Glucagon like peptide-1 receptor agonists therapy?	-	35	121	
TOTAL (%)		19.87%	27.82%	52.31%	0.0013*

\*significant



Graph 7: Attitude assessment.

From the above table it is clear that 20% have poor attitude, 28% have fair attitude and 52% have positive attitude. The p-value is found to be .001 and is significant and conclude that the overall attitude of community pharmacists is very positive.

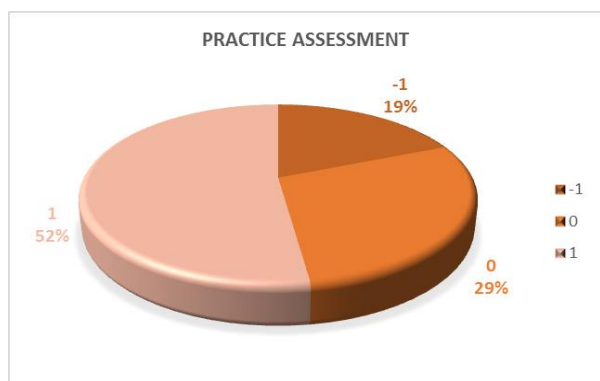
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### Practice assessment

Table 8: Practice assessment.

Sl no	Questions	Scoring			P-value
		-1	0	+1	
1	Do you devote time to read literature for recent additions to the Glucagon like peptide-1 receptor agonists class of anti-diabetic drugs.?	66	67	23	
2	Do you provide drug information about Glucagon like peptide-1 receptor agonists to patients?	3	48	105	
3	Do you inform patients taking Glucagon like peptide-1 receptor agonists medication about the possible side effects such as transient nausea?	6	33	117	
4	Do you advise patients on Glucagon like peptide-1 receptor agonists therapy the possibility of localized irritation?	72	78	6	
5	Do you avoid dispensing Glucagon like peptide-1 agonists without prescription?	-	-	156	
TOTAL (%)		18.84%	28.97%	52.19%	0.001*

\*significant



Graph 8: Practice assessment.

From the above table it is clear that 19% have poor practice, 29% have fair practice and 52% have good practice. The p-value is found to be .001 and is significant and conclude that the overall practice of community pharmacists is very good.

The study was correlated with the study of Syed Imam Rabbani et al conducted a study on "Knowledge, Attitude and Practice about a Newer Class of

Antidiabetic Drug (Glucagon-like peptide-1 receptor agonist) Among the Health Care Professionals of Qassim University, Saudi Arabia".<sup>[12]</sup>

### CONCLUSION

The study shows that, while community pharmacists possess adequate knowledge and awareness of adverse drug reactions (ADRs) related to antidiabetic drugs, there is a noticeable gap in their understanding of pharmacovigilance and methods for identifying ADRs. Overall, community pharmacists showed good knowledge, attitude, and practice towards antidiabetic drugs, but targeted training programs are recommended to strengthen their expertise in pharmacovigilance and newer drug therapies.

As a role of pharmacists, we provided the awareness of adverse drug reactions due to antidiabetic drug to those with poor knowledge using leaflets.

### ACKNOWLEDGEMENT

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