

Study to Find out the Market Potential of Gliptins as Anti-Diabetic Drugs

By

Abhilasha Pandey

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The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer Airport
Jaipur-302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: www.iihmr.edu.in

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Abhilasha Pandey student of MBA Pharmaceuticals Management (MBAPM) from The IIHMR University, Jaipur has undergone internship training at The IIHMR University, Jaipur , from 04.02.2016 to 02.04.2016.

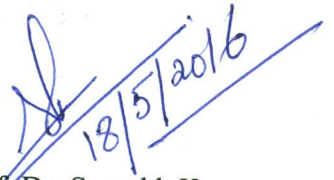
The Candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all her future endeavors.



Col. Dr. Ashok Kaushik
Dean, Academics and Student Affairs
The IIHMR University, Jaipur



Asst Prof. Dr. Saurabh Kumar
The IIHMR University, Jaipur

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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **A study to find out the market potential of Gliptins as Anti-Diabetic drugs** and submitted by **Abhilasha Pandey** under the supervision of **Dr. Saurabh Kumar** for award of MBA in Pharmaceutical Management of the University carried out during the period from 04/02/2016 to 02/04/2016 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.


Signature

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Background for the topic included

It is known that in recent years *the Indian diabetes market is growing exponentially and expects the Indian diabetes market to grow at a CAGR of 29% during 2015-2017 reaching revenues worth INR 6700 Crores.* A growing drug treated population coupled with the launch of several new drugs will drive the Indian diabetes market to INR 6300 Crores by 2015. In 2009, the market for Non-Insulin Anti-diabetics was worth INR 1377 Crores. This represented a highly fragmented market with USV being the leading player. USV's Glycomet GP (Glimepiride+Metformin) was the leading drug in the Non-Insulin Anti-diabetics market. It is expected around 15 new Drugs to be launched in the Non-Insulin Anti-diabetics market in the next five years. Seven of them are expected to be in the DPP-IV Inhibitor and GLP-1 Agonist classes. The Insulin Market was worth INR 527 Crores in 2009 with Abbott being the biggest player in this market. Sanofi Aventi's Lantus (Insulin Glargine) represents one of the fastest growing drugs in the last five years. The total number of diabetes patients in India is expected to reach 87 Million by 2030. Around 56% of these patients will be from the urban regions. Several new drugs have been approved by the US FDA for the treatment of type 2 diabetes mellitus. Each class of drug is known to have its benefits, disadvantages and undesired effects in patients with pre-existing clinical conditions that may preclude its use in these patients. The sulfonylureas are a class of agents that lower blood sugar as a result of increasing release of insulin from the pancreas. The sulfonylureas have been associated with rare cases of idiosyncratic drug induced liver disease with somewhat similar pattern of onset, injury and outcome. While the sulfonylureas are derivatives of sulfonamides, they have no

intrinsic antibacterial activity. They are believed to lower blood glucose levels by stimulating insulin release from pancreatic beta cells. However, their effects on blood glucose with chronic therapy are more complex, and the sulfonylureas may have extra-pancreatic actions that affect blood sugar, reducing hepatic clearance of insulin or increasing insulin sensitivity. They have little effect in type 1 diabetes, in which there is a deficiency in insulin producing pancreatic beta cells. The sulfonylureas (particularly the first generation agents) can also cause alcohol intolerance. India has the largest population of patients with type 2 diabetes mellitus. The conventional agents used to treat type 2 diabetes frequently exhibit reduced efficacy over time leading to inadequate glycaemic control and are also associated with adverse effects. Hence, there is a need for alternative therapies that can overcome the limitations associated with conventional anti-diabetic agents. Gliptins show significant improvements in glycaemic control and are well tolerated, particularly with regard to weight change and hypoglycemia. Hence, gliptins are considered as useful agents for the treatment of type 2 diabetes mellitus. So, there is a need to investigate a new class of Anti-diabetic drugs i.e, Gliptins.

Literature review:

Global Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Industry 2015 Market Research Report:

The Global DPP4 Inhibitor industry 2015 market research report is a professional and in depth study on current state of DPP4 Inhibitor .The report provides a basic overview of the industry including definitions ,classification, application and industry chain structure. The DPP4 Inhibitor s market analysis is provided for the international market including market including development trends, competition

landscape analysis, and key regions development status. Development policies and plans are discussed as well as manufacturing processes and cost structure are analyzed. This report also states import/export consumption, supply and demand figures, cost, price, revenue and gross margins.

The report focuses on global leading industry players providing information such as company profile, product picture and specification, capacity, production, price, cost, revenue and contact information. Upstream raw materials and equipment and downstream demand analysis is also carried out. The DPP4 Inhibitors industry development trends and marketing channels are analyzed. Finally the feasibility of new investment projects are assessed and overall research conclusion offered.

With 172 tables and figures the report provides key statistics on the state of the industry and is a valuable source of guidance and direction for companies and individuals interested in the gliptin market.

DPP4 inhibitor Market: Global Industry Analysis and Forecast 2015 – 2021:

DPP IV inhibitors are a class of hypoglycemic agents that block the enzyme named dipeptidyl peptidase IV. Dipeptidyl peptidase IV enzyme break down the proteins that are responsible for stimulating the insulin producing cells that slows down gastric secretion. Proteins can activate the release of insulin and can control the blood sugar level if DPP IV is inhibited in our body. Moreover, DPP IV inhibitors restrict the formation of glucagon, a hormone that increases blood glucose level and thereby control the glucose levels in the body. DPP IV inhibitors are widely utilized as a treatment for type 2 diabetes. Sitagliptin, vildagliptin, saxagliptin and linagliptin are included in the drug class DPP IV. Nasopharyngitis, headache,

nausea and hypersensitivity are some of the adverse effects due to the utilization of DPP IV.

Increasing prevalence of type 2 diabetes is a major public health concern worldwide. National Centre for Biotechnology Information in 2011 stated that in the U.S. more than 8% of the total population is diagnosed with diabetes. Diabetes is associated with a number of complications that includes cardiovascular disease, nephropathy, retinopathy, and neuropathy. Thus, the above mentioned factors derives the global DPP IV inhibitors market. However, the cost for DPP IV inhibitors is very high that might hinder the global DPP IV inhibitors market.

Geographically, North America and Europe dominates the global market for DPP IV inhibitors due to high prevalence rate and rising awareness among people about the DPP IV inhibitors. Asia – Pacific is considered as a fastest growing market due to increasing obese population.

Various key players contributing to the global DPP IV inhibitors market comprises Arisaph Pharmaceuticals, Inc., Boehringer Ingelheim GmbH, Eli Lilly And Company, Bristol-Myers Squibb, Merck & Co, Inc., AstraZeneca Plc, Mitsubishi Tanabe Pharma Corporation, Takeda Pharmaceutical Company Limited and Novartis AG.

Research questions

What is the market potential of Gliptins?

What are the biggest challenges in Gliptins market?

What is the competitor profile in Gliptins market?

Study Objectives:

The objectives of the proposed study are to:

- a. To find out the market potential of Gliptins as Anti-diabetic drugs.
- b. To identify current gap in Gliptin market.

Research Plan

Study Design: Descriptive study

Methodology

Study Area: South-East Delhi.

Target respondents : Pharmacists ,chemists and drug retailers of South East Delhi.

Sampling and Sample Size:Random sampling with 110 respondents.

[The total number is based on perceived number of the total number of pharmacies/personals working in the hospital and their statistical significant number.Then Data collection for the study has been done.]

The data had been collected from both men and women and in all age groups among the respondents proportionately.

Methods of Data Collection

Primary Data collection through structured semi-structured questionnaire was done. Interview with Pharmacists, chemists and drug retailers: Being an important stakeholder, they had been interviewed to find out the market potential of anti-diabetic drugs as they deal with all type of drugs could provide important information with the issues related to the market potential of anti-diabetic drugs.

Timeline- 4th Feb to 2nd April 2016

Data analysis: data analysis has been done through Microsoft excel

Operational Plan

Step 1: After the proposal got awarded, the proposal had been submitted to the Institutional ethics Review Board for their approval.

Step 2: Followed by the approval the data collection tools had been developed in English and later on translated in to Hindi. A back translation into English had been done for quality check.

Step 3: The tools had been pre-tested in drug retail stores, other than the sampled stores. The final tools had been peer-reviewed.

Step 4: Mentor's permission had been sought for the respective study.

Step 5: First visit had been done on 4th of feb 2016 and initiation of the data collection process. The data collection had been done by interviewing the Pharmacists, chemists and drug retailers by me.

Step 6: The data thus collected had been screened & accumulated by data entry methods. The data cleaning acceptance of only data which is good in quality had been involved in assessment. Partial/incomplete data had been rejected.

Step 7: The analysis of data in the form of frequency table/ charts had been done and forwarded as Draft Report to Institute. After the incorporating suggestion from the reviews by the Institute, a final report had been prepared and forwarded.

Data management

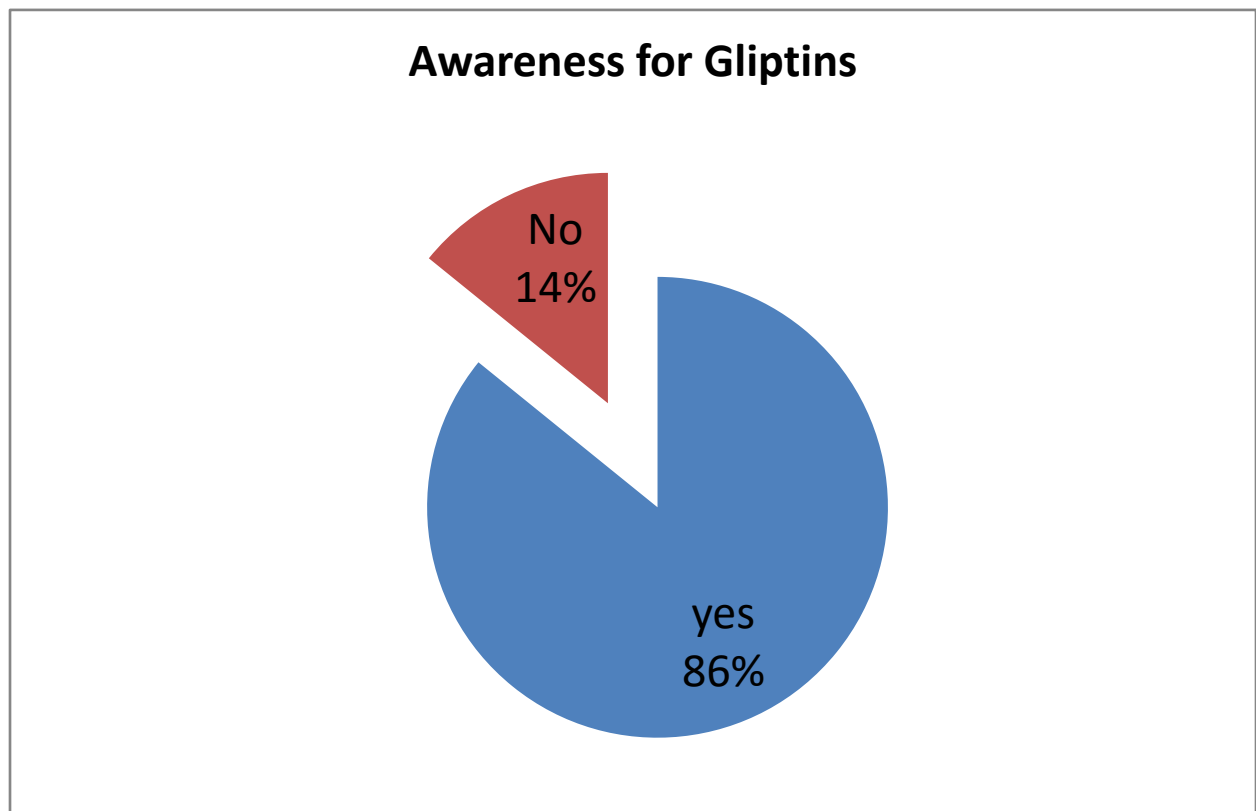
The data once collected had been securely stored. This had been done after the satisfaction with the data quality. All the identifiers had been removed and the transcripts had been coded to ensure the confidentiality of data. Screening of the data had been done to check the data quality. Data entry had been done in MS Excel followed by Cleaning of data. Analysis of the data is to find the variation/ frequencies and variability of the data gathered had been done.

Ethical Concerns

Informed consent form was attached with the questionnaire. Voluntary participation of the stakeholders is must to be included in the study. Privacy confidentiality has been maintained for the sake of keeping anonymity and safeguard the right of each respondent; only initials had been taken of each respondent instead of the full detail of the stakeholders. Risk involved in the study is the privacy of the organization and its working culture along with stakeholders. Benefits involved in the study are the assessment of the quality of the reporting system included in the facility.

Data interpretation:

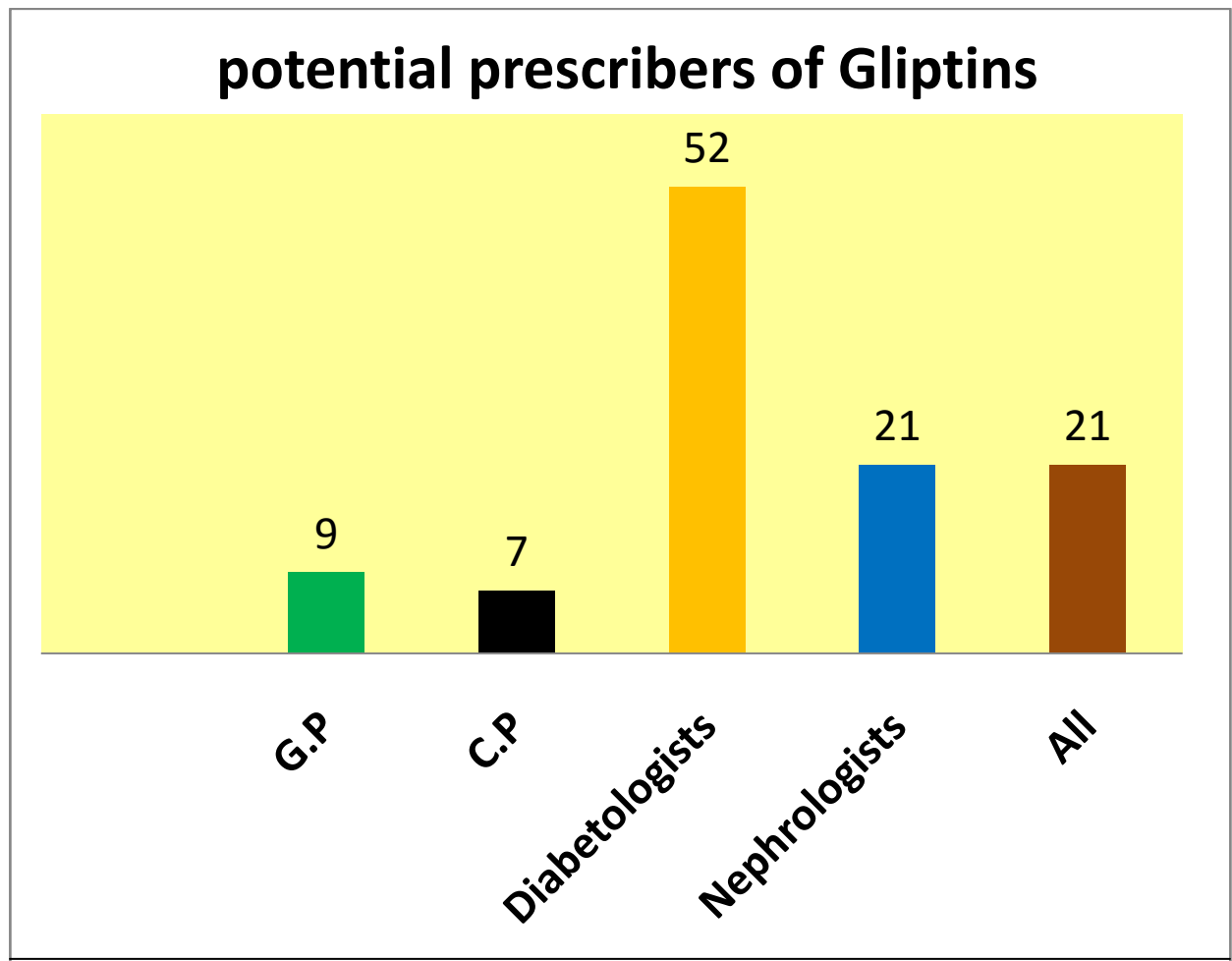
Are you aware about gliptis?



Out of 110 respondents, most of the respondents were aware of Gliptins only 14% respondents were unaware.

Who are the potential prescribers of Gliptins?

G.P.....9
C.P.....7
Diabetologists.....52
Nephrologists.....21
All.....21

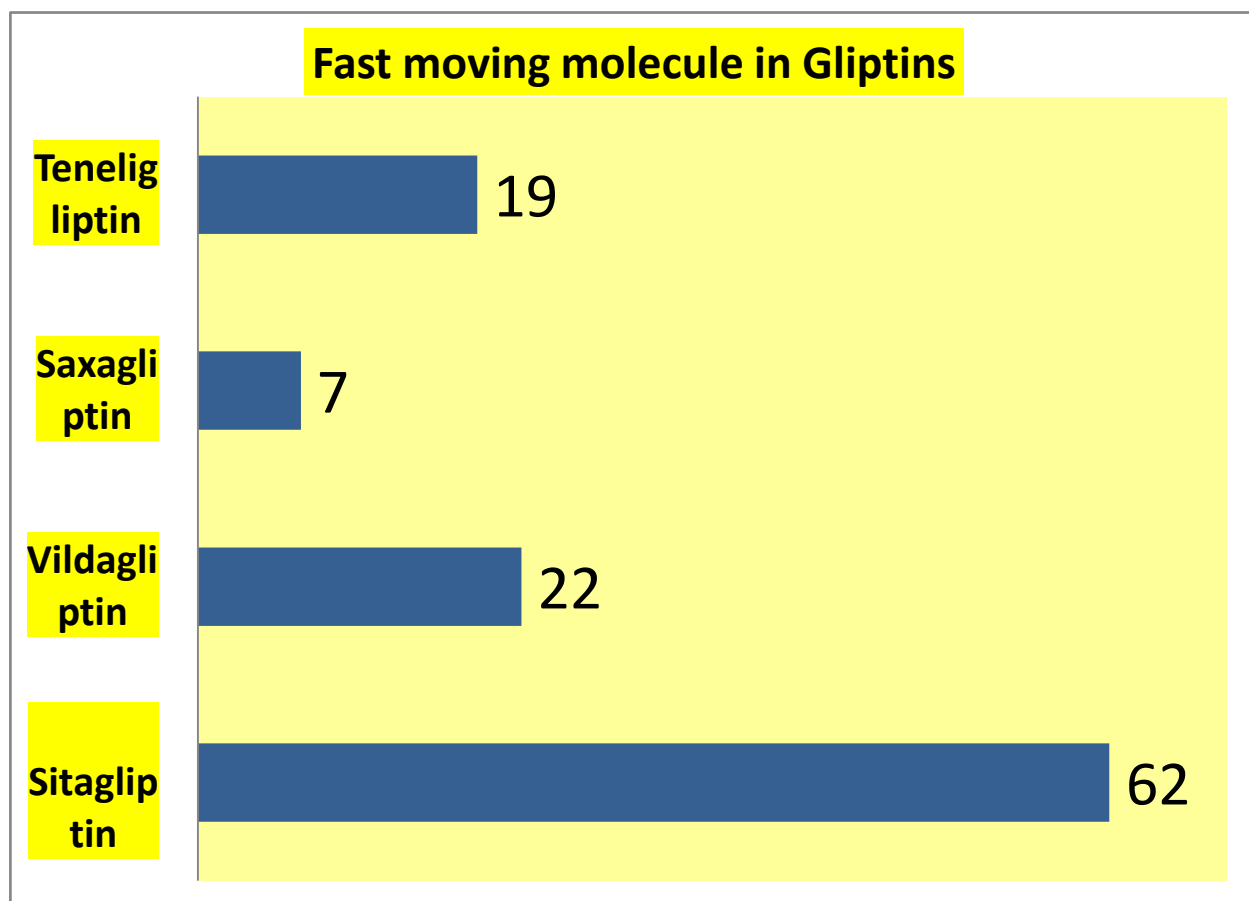


Out of 110 respondents, 52 response came in favor of Diabetologist followed by 21 response for Nephrologist followed by 21 response for all.

There is very less no. of responses came in favor of G.P and C.P i.e. 9 and 7 respectively.

Which are the fast moving molecule in the Gliptin class?

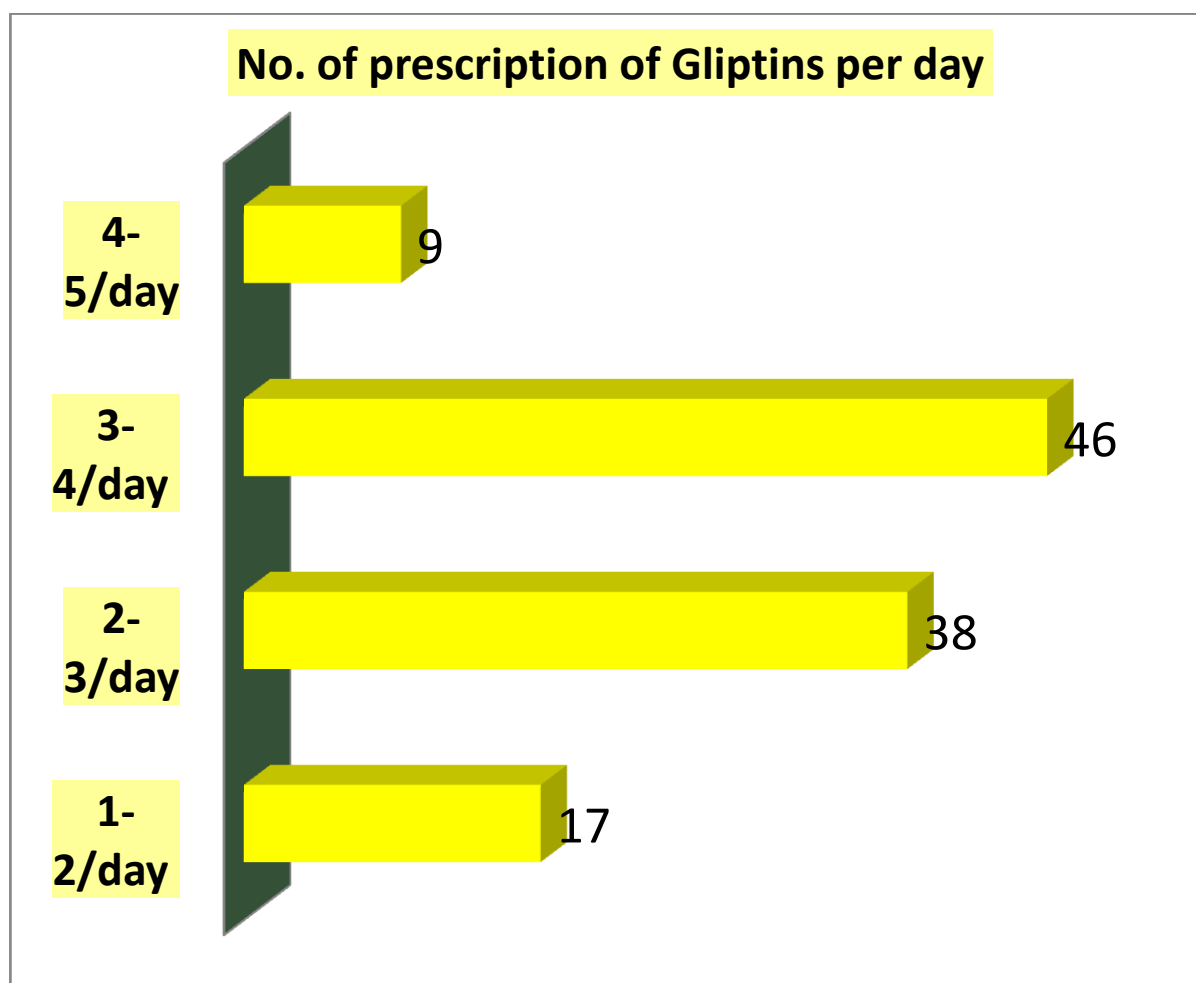
Teneligliptin19
Sitagliptin62
Vildagliptin.....22
Saxagliptins.....07



Out of 110 respondents, 62 response came in favor of sitagliptin followed by 22 response for vildagliptin followed by 19 response for teneligliptin. There is very less no. of responses came in favor of saxagliptin

No. of prescriptions of Gliptins per day?

1-2/day17
2-3/day.....38
3-4/day.....46
4-5/day.....09



Out of 110 respondents, 46 response came in favor of 3-4 prescription of Gliptin per day followed by 38 response for 2-3 prescription per day followed by 17 response for 1-2 prescription per day. There is very less no. of responses came in favor of G.P and C.P i.e. 9 and 7 respectively.

4. Which is the leading brand of Gliptins?

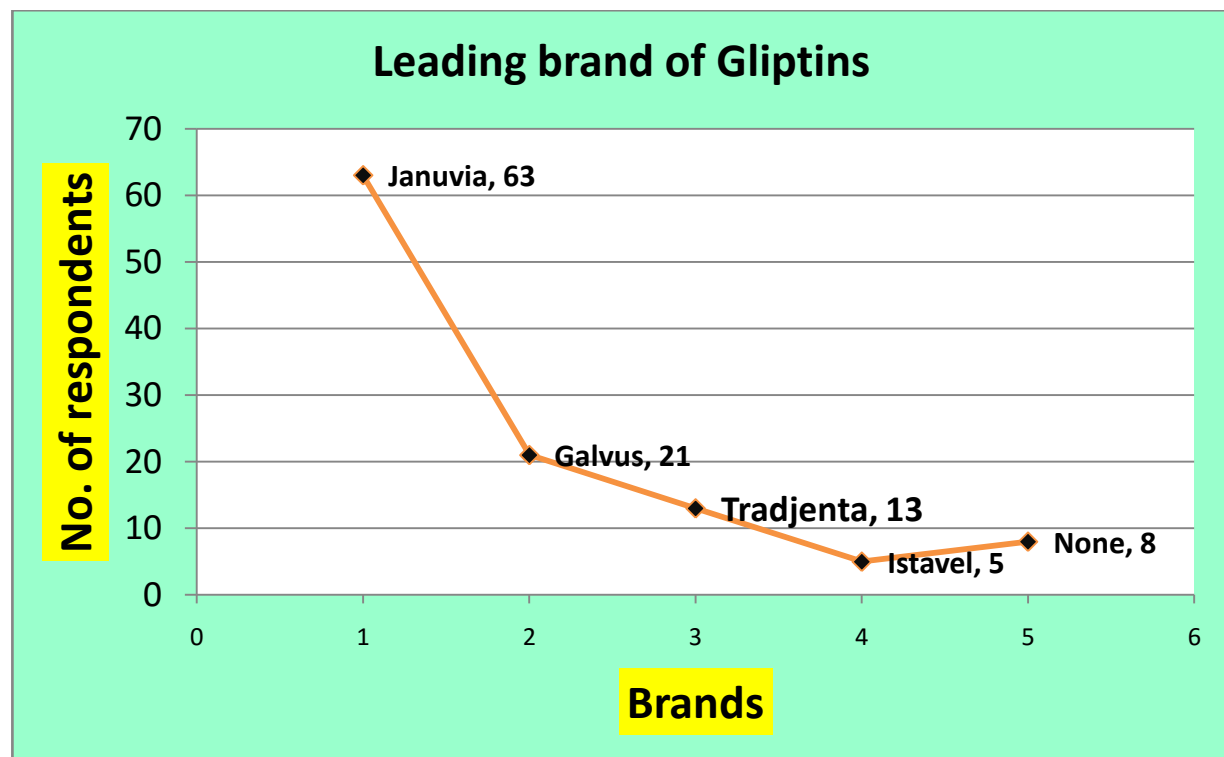
Januvia.....63

Galvus.....21

Tradjenta...13

Istavel.....05

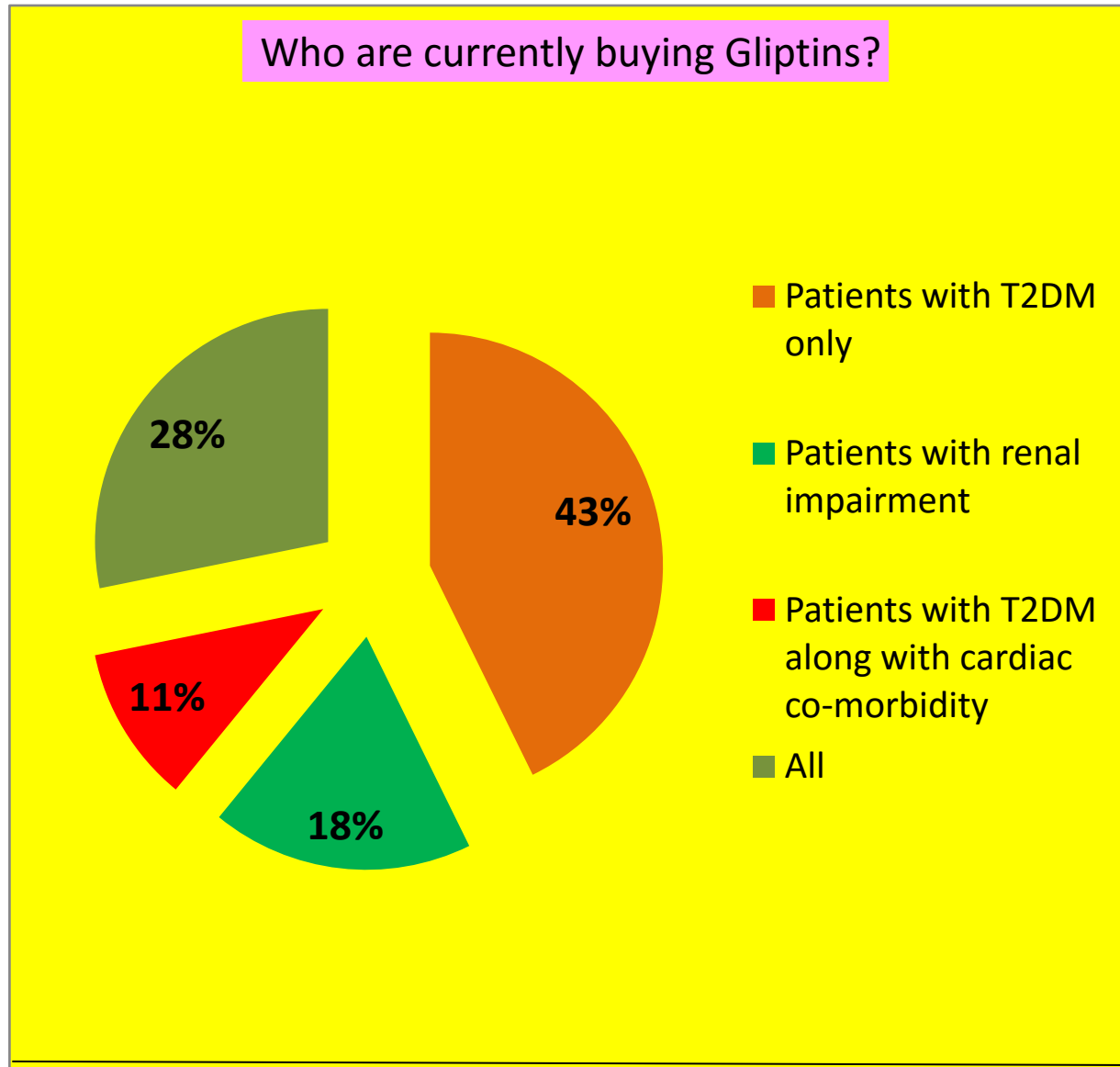
Misllaneous.08



Out of 110 respondents, 63 response came in favor of Januvia followed by 21 response for Galvus followed by 13 response for Tradjenta. For others 8 response came. There is very less no. of responses came in favor of Istavel i.e. 05 only

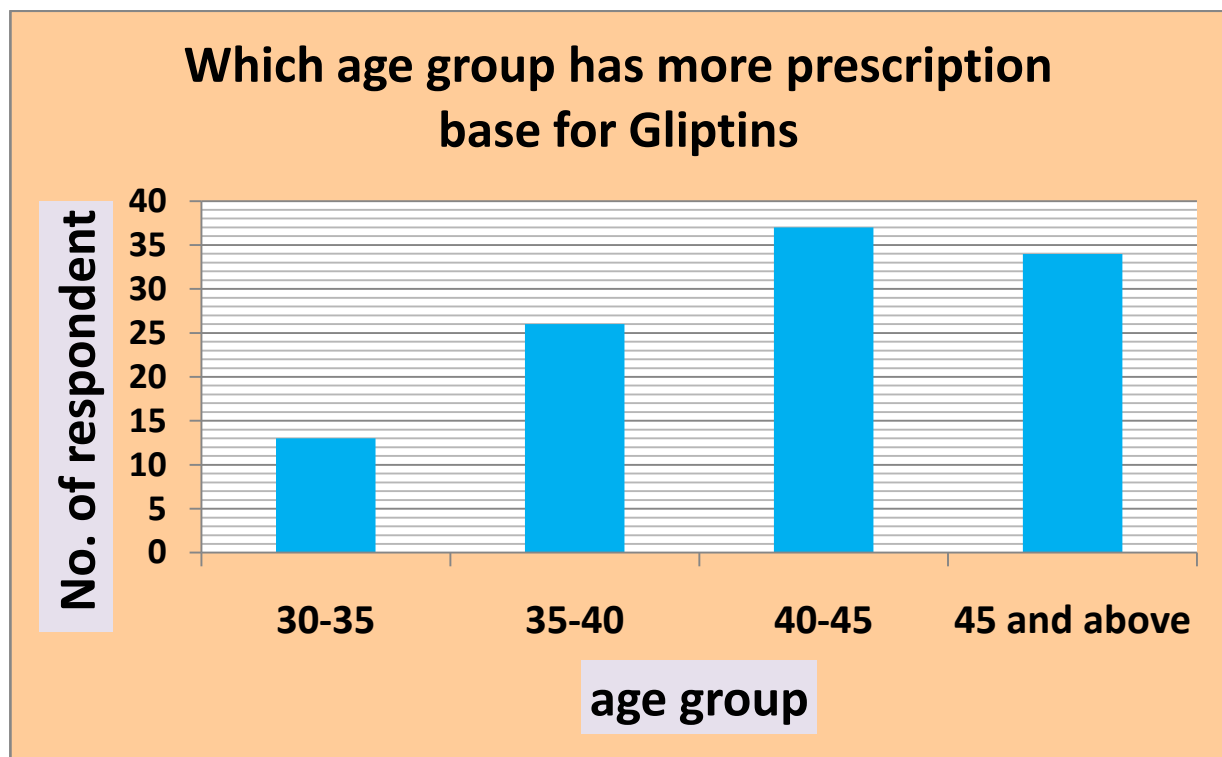
What class of patients are on Gliptins therapy?

Patients with T2DM only.....	47
Patients with renal impairment.....	20
Patients with T2DM along with cardiac co-morbidity.....	12
All	3



Which age group has more prescription base for Gliptins ?

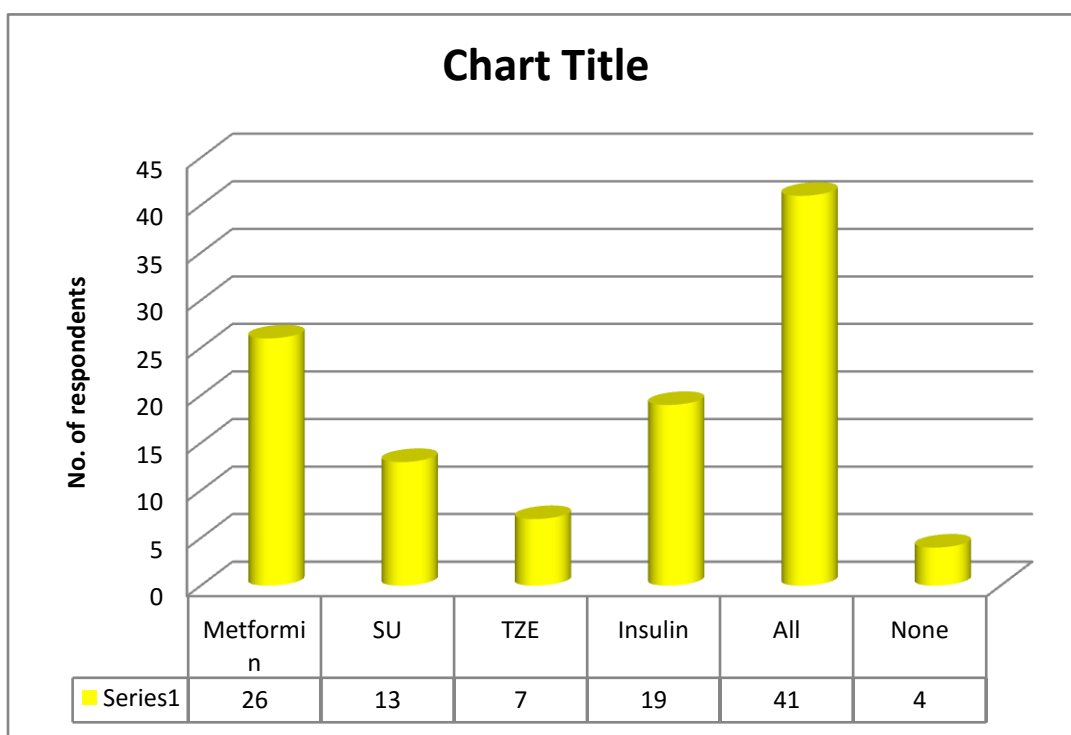
30-35.....13
35-40.....26
40-45.....37
45 and above....34



With the investigation it clearly reflects that population under age of 40-45 is most vulnerable to diabetic condition and population of 34-40 is also very prone towards Diabetes and the co-morbid conditions.

Gliptins are given as an add-on therapy with.....???

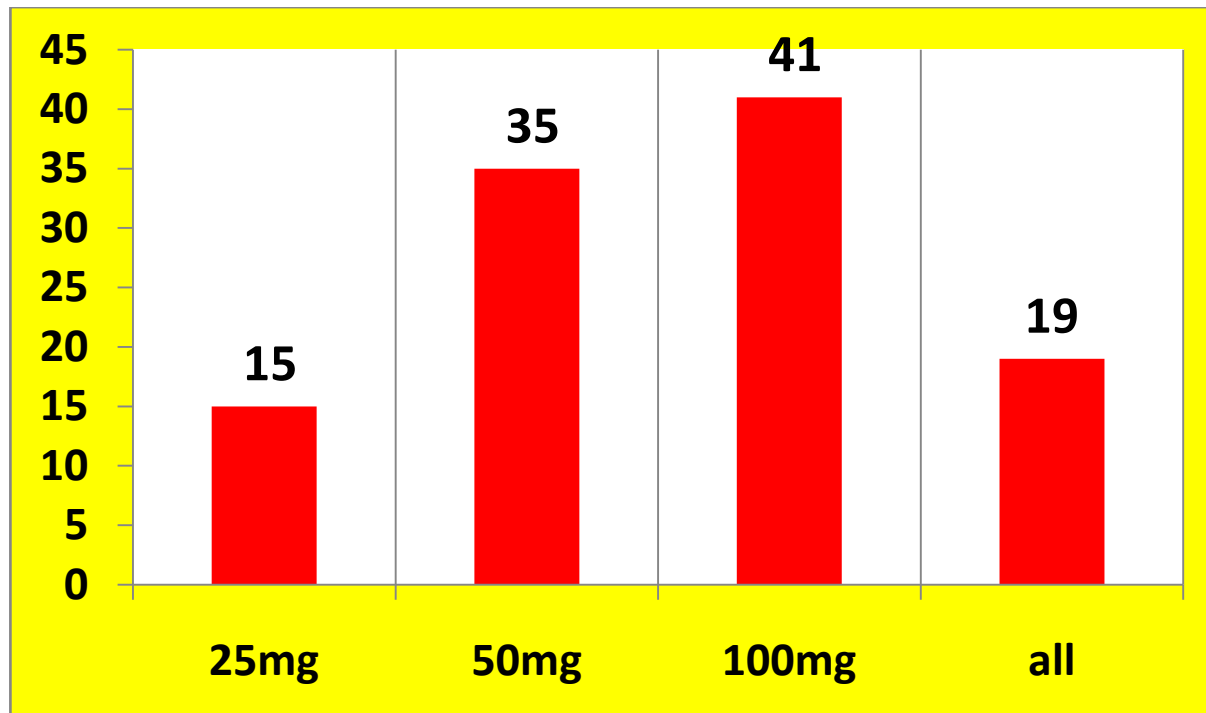
Metformin.....26
SU.....13
TZE.....07
Insulin.....19
All.....41
None.....04



Out of 110 response, Gliptins was found as safest class of molecule and can be given as an add on to several conventional molecules like Metformin, SU and TZE

Which strength of the Gliptins has more prescription inflow?

25mg
50mg
100mg
All



out of 110 response, the more response came in favor of 100 mg of Gliptin i.e.41 followed by 35 response for 50 mg followed by 19 for all strength and 15 for 25mg.

Important findings of the study:

The largest no. of potential prescribers of Gliptins were Diabetologist.

The potential Gliptin molecule found in my study was found out to be sitagliptin followed by Vildagliptin.

The leading brand is Januvia 100 mg in Gliptins class followed by Galvus 100 and Tradjenta.

The study reflects that Metformin is the major class of the drug which is given as an add on therapy with Gliptins.

Limitations of the study:

This is a pilot study and this study had conducted only in South-East Delhi with limited sample size. The study has been done only to access the Gliptin class. This study doesn't include other major anti-diabetic drug like Metformin, SU, SGLT2 inhibitors.

Suggestion:

The branded Gliptins are facing stiff competition from the generic market. Hence, future market strategy should come up to address this problem

Conclusion:

The market is growing exponentially in terms of Gliptins class. And in this study, Sitagliptin was observed as potential molecule for further study investigations.

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3. Walsh J. The Incretins: GLP-1 Agonists and DPP-4 Inhibitors. Available from: http://www.diabetesnet.com/diabetes_treatments/incretins.php. [cited on 2008 Sep 2]
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Annexure :

QUESTIONNAIRE:

Market assessment of Gliptins

1. Are you aware about Gliptis?

- ☐ YES
- ☐ NO

2. Who are the potential prescribers of gliptins?

- ☐ G.P
- ☐ C.P
- ☐ Diabetologists
- ☐ Nephrologists
- ☐ All

3. Which are the fast moving molecule in the Gliptin class?

- ☒ Sitagliptin
- ☐ Vildagliptin
- ☐ Saxagliptin
- ☐ Teneligliptin,

4. Which is the leading brand of gliptins?

- ☐ Januvia
- ☐ Galvus
- ☐ Tradjenta
- ☐ Istavel

5. No. of prescriptions of Gliptins per day?

- ☐ 1-2/day
- ☐ 2-3/day

- ☐ 3-4/day
- ☐ 4-5/day

6. What class of patients are on Gliptins therapy?

- ☒ Patients with T2DM only
- ☐ Patients with renal impairment
- ☐ Patients with T2DM along with cardiac co-morbidity
- ☐ All

7. Which age group has more prescription base for Gliptins

30-35

35-40

40-45

45 and above

8. Gliptins are given as an add-on therapy with.....???

- ☐ Metformin
- ☐ SU
- ☐ TZE
- ☐ Insulin
- ☐ All
- ☐ None

9. Which strength of the Sitagliptins has more prescription inflow ?

- ☐ 25mg
- ☐ 50mg
- ☐ 100mg
- ☐ All

