A
Dissertation Project
On
ANALYSING MARKET POTENTIAL OF GLIPTINS

Submitted By:
Avani V. Chauhan
Pharmaceutical MBA
IIHMR University,
Jaipur

Under guidance of:
Dr. Sandeep Narula,
Associate Professor,
IIHMR University,
Jaipur

Introduction

- **T2DM**

✓ Metabolic discomfort of carbohydrate, fat & protein into body, a chronic condition characterized by the presence of abnormally high blood glucose levels

- **Reasons for T2DM**

1. Insulin deficiency & resistance
2. Beta cells dysfunction
3. Hepatic glucose over production

List of gliptins

- Sitagliptin (Merck Sharp and Dohme Corp, approved as Januvia by US FDA in year 2006)
- Vidagliptin (Novartis, approved as Galvus by EU in year 2007)
- Saxagliptin (Bristol-Myers Squibb, approved as Onglyza by US FDA in 2010)
- Linagliptin (Boerhinger Ingelheim, approved as Tradjenta by US FDA in year 2011)
- Alogliptin (developed by Takeda Pharmaceutical Company Limited, approved for use in Japan)
- Dutogliptin (being developed by Phenomix Corporation)
- Gemiglaptin (being developed by LG Life Sciences)
- Teneligliptin (Mitshubishi-Japan, India, Argentina, Korea)

Add on Therapies

- With metformin
- With insulin
- With sulfonylurea
- With thiazolidinedione

Need for Study

- Useful information to company prior launching an oral anti-hyperglycemic (OAH) molecule (gliptin).
- Market scenario
- Indication for usage
- Most commonly prescribed gliptin for T2DM with efficacy, safety & durability parameters.
- Most prescribed combination therapy with gliptin
- Identification of highest stock & sale of gliptin
- Most prescribed brands
- Major competitors
- Unmet Medical Need in case of T2DM with future scopes of gliptin

Research Question

- What is the market potential of gliptins in patients with type 2 diabetes in Mumbai city?

Objectives

- To identify the market scenario of gliptins in type 2 diabetes mellitus
- To analyze the prescription pattern of gliptins in type 2 diabetes mellitus
- To determine highest sales volume & stock of gliptins
- To identify the unmet needs of gliptins in in type 2 diabetes mellitus

Methodology

Sample design

Descriptive (Cross-sectional)

Sampling method

Non-Probability (Purposive) sampling

Study Area

Mumbai city.

Sample population

Doctors (general physician, consultant physician, dialectologist, cardiologist, and endocrinologist), chemists & stockiest

Sample size:

184

Doctors: 67

Chemist: 75

Stockiest: 42

Data collection:

Primary data- The primary data for this project was gathered through survey using questionnaire, face to face interview.

Secondary data- The secondary data for this project was gathered through different dependable articles and research reports.

Research Instrument (tools and techniques)

- Both open and close ended questions.
- The information was collected by interviewing with doctors, chemist & stockiest. All the questions could not find included in the questionnaire as it would have resulted in to a lengthy format which results into negative response of the sample population. Hence some data was collected with the help of informal talk with the doctors, chemist & stockiest.

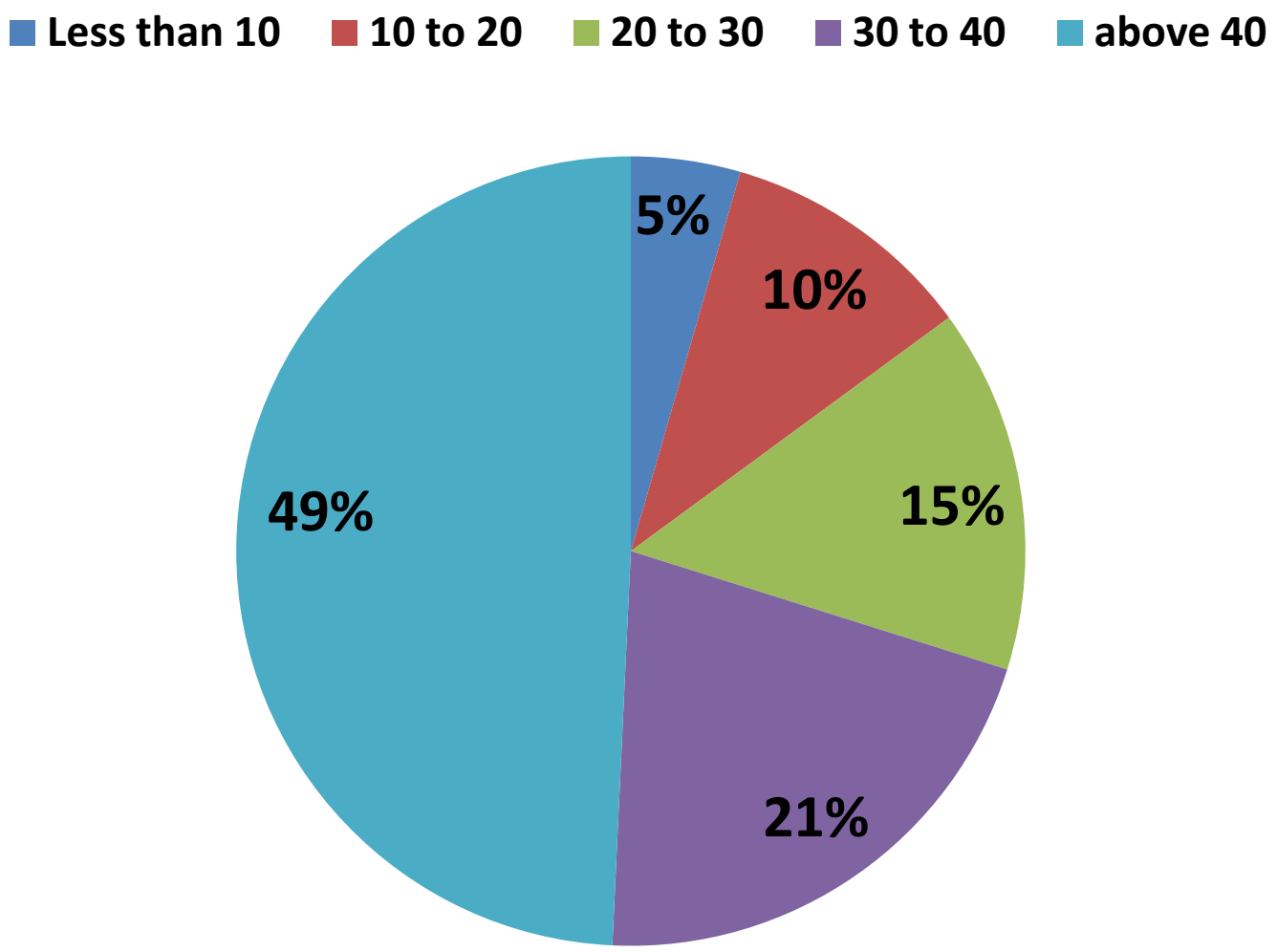
Study duration

3 months (1st February to 5th May)

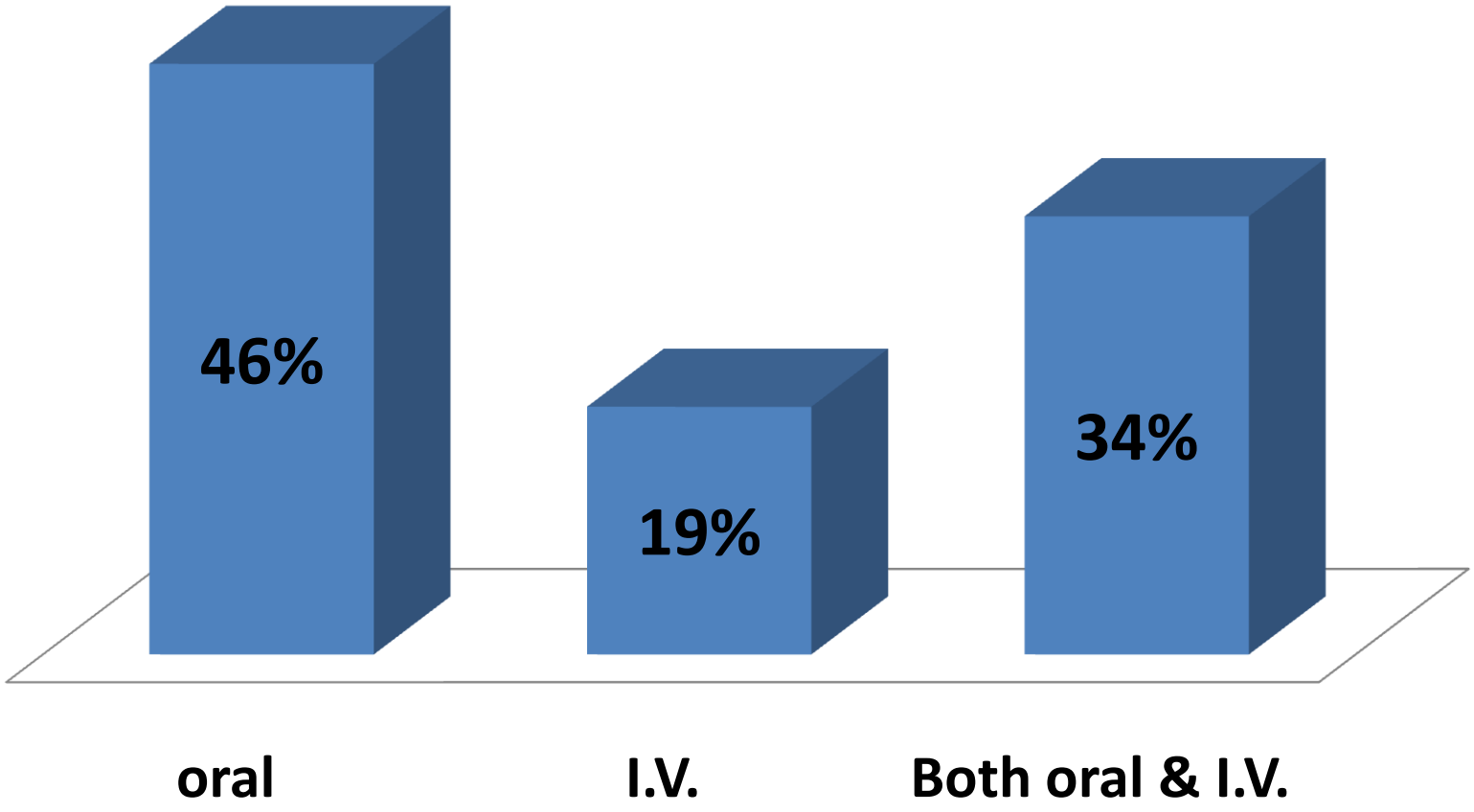
Data Analysis

For Doctors

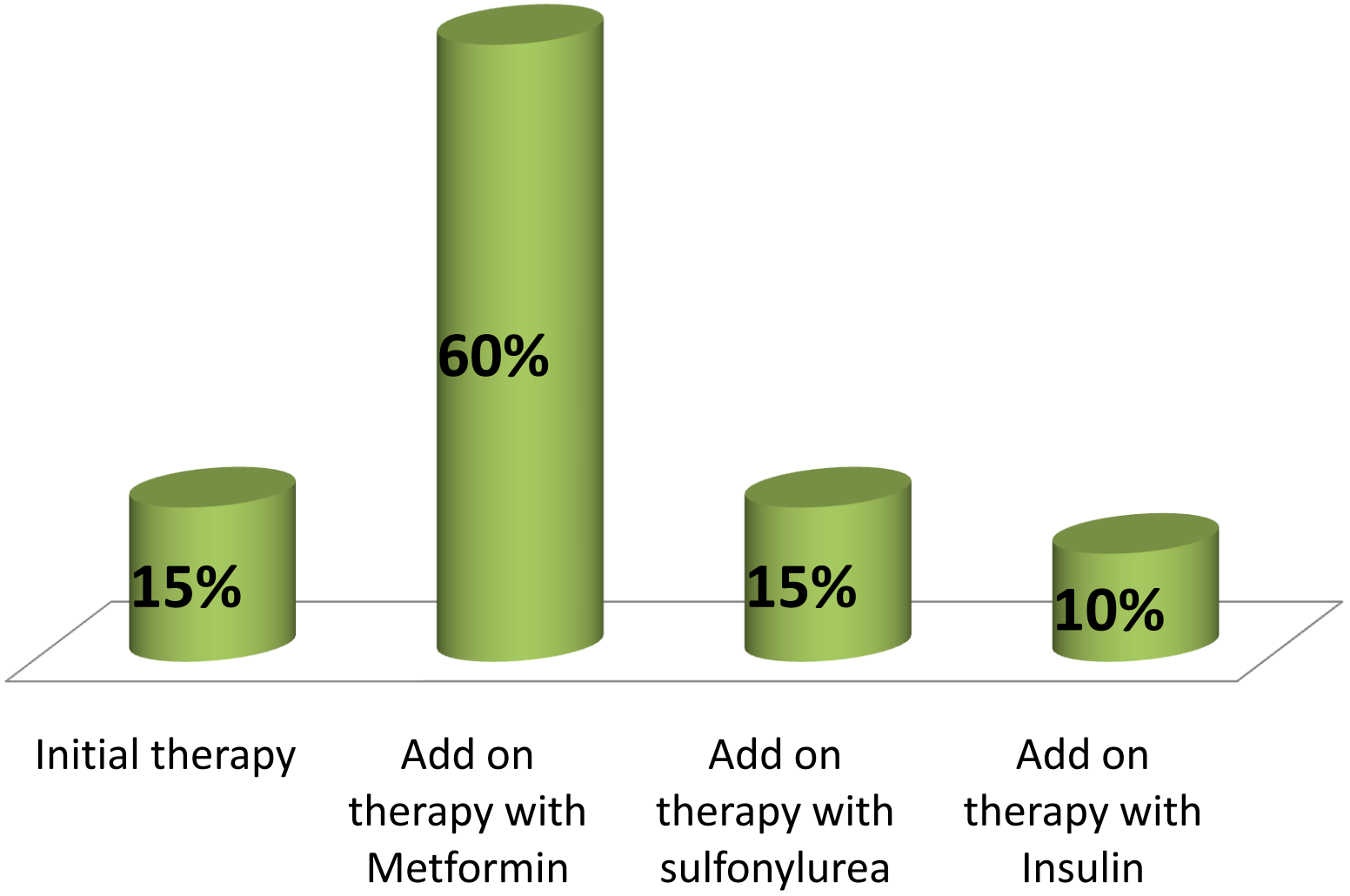
% Number T2DM patents examine per week



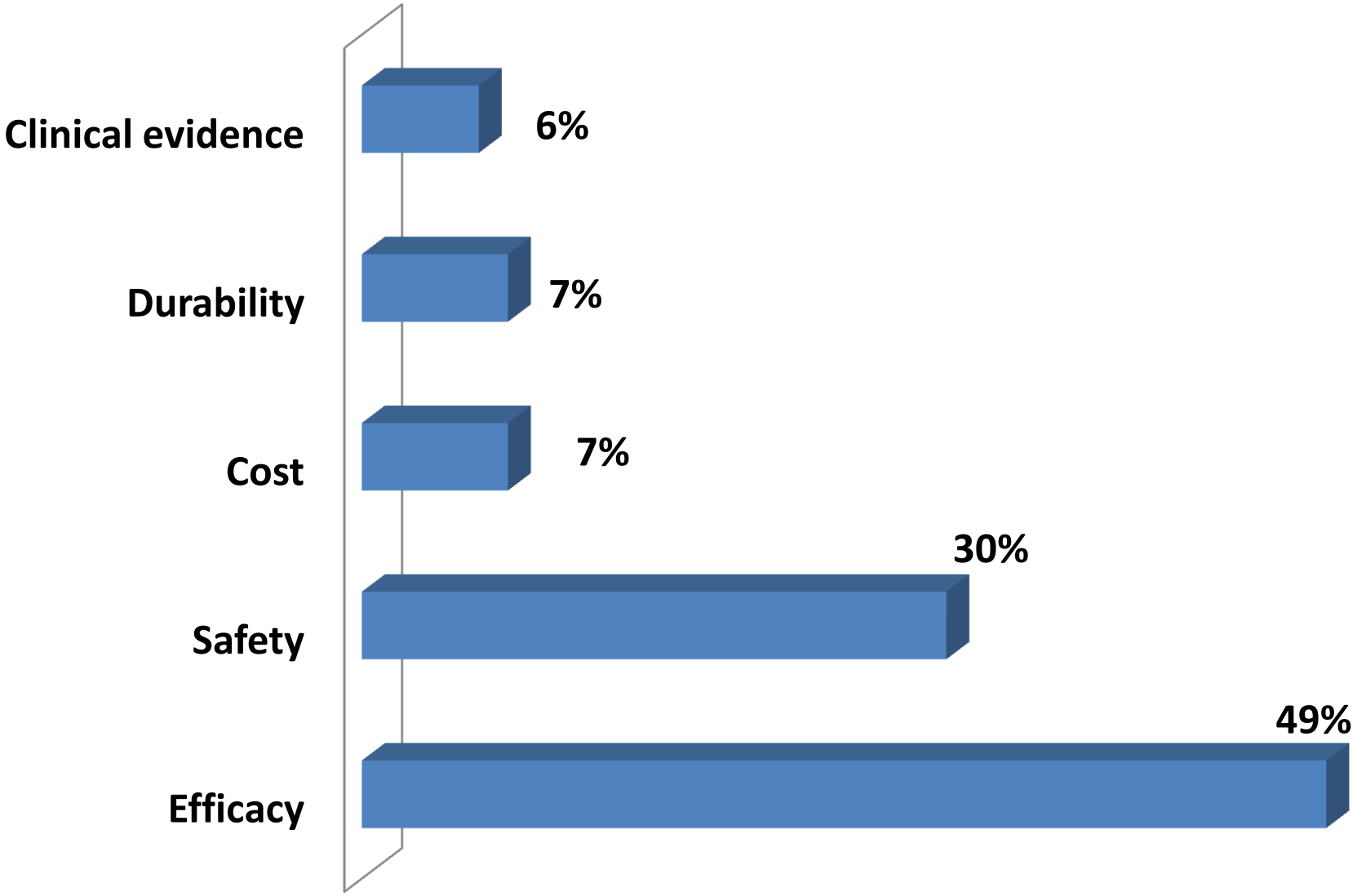
% of treatments used for T2DM



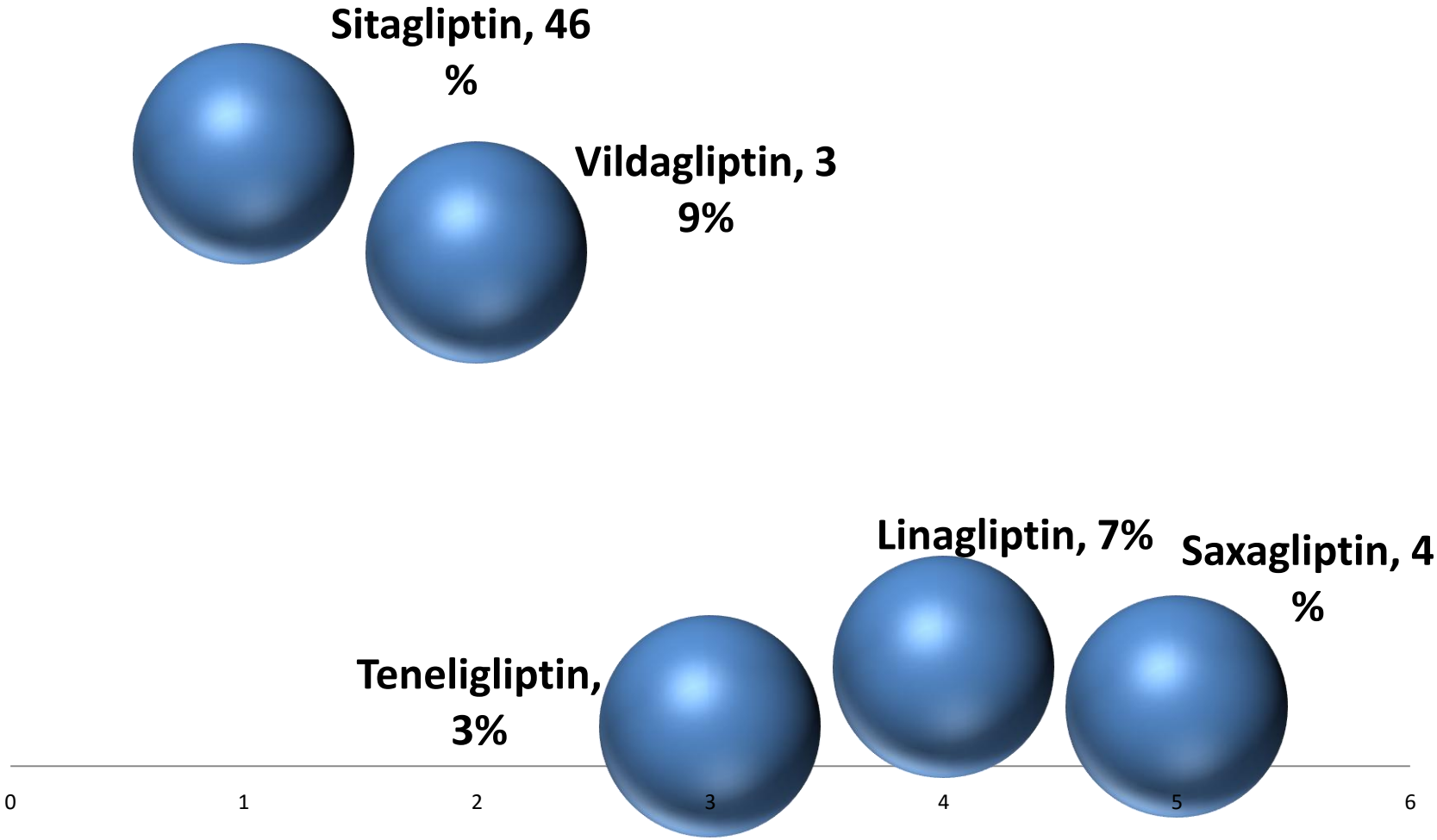
% of indication for usage of gliptins

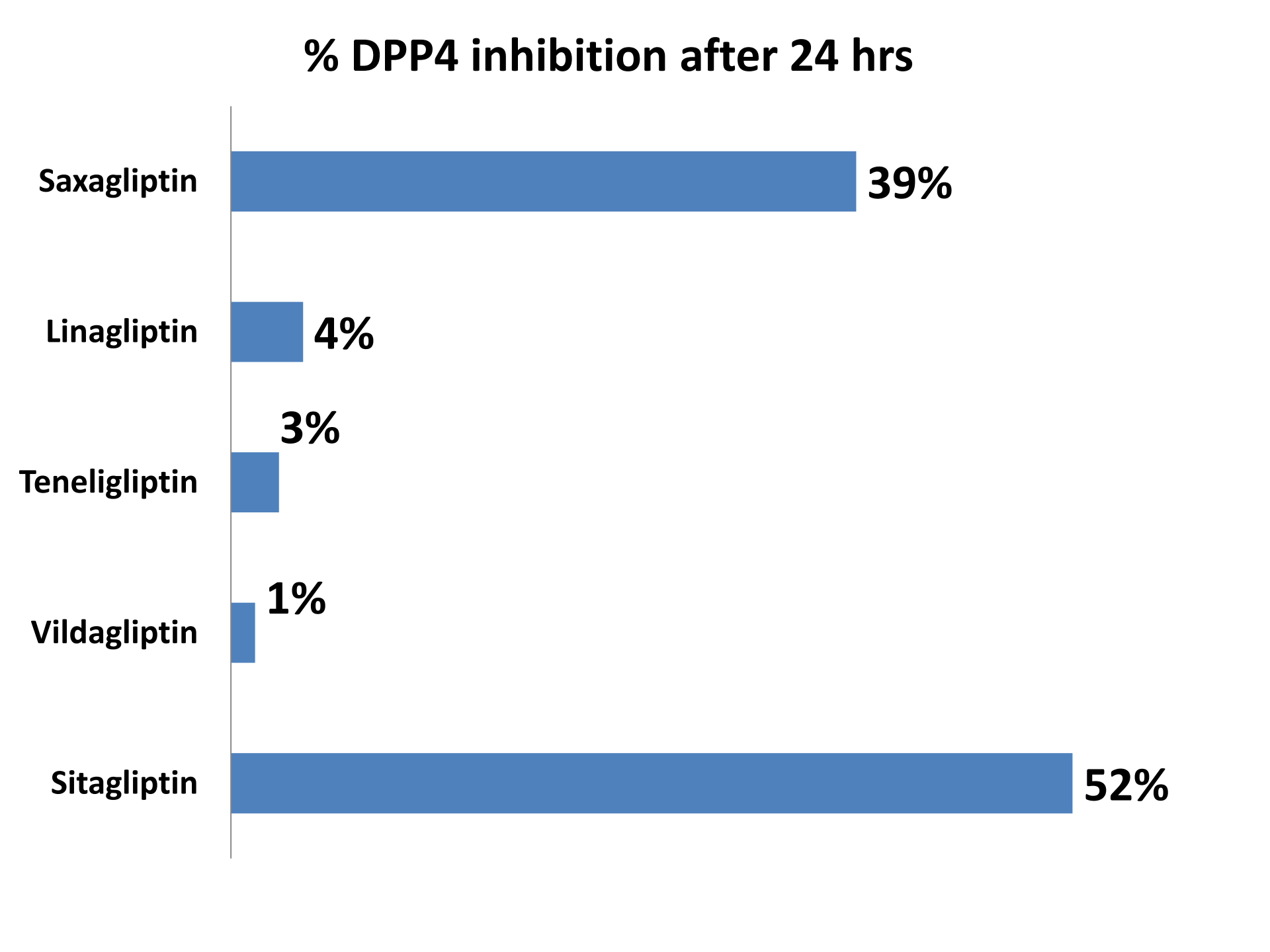


% of factors influence to Rx any gliptin

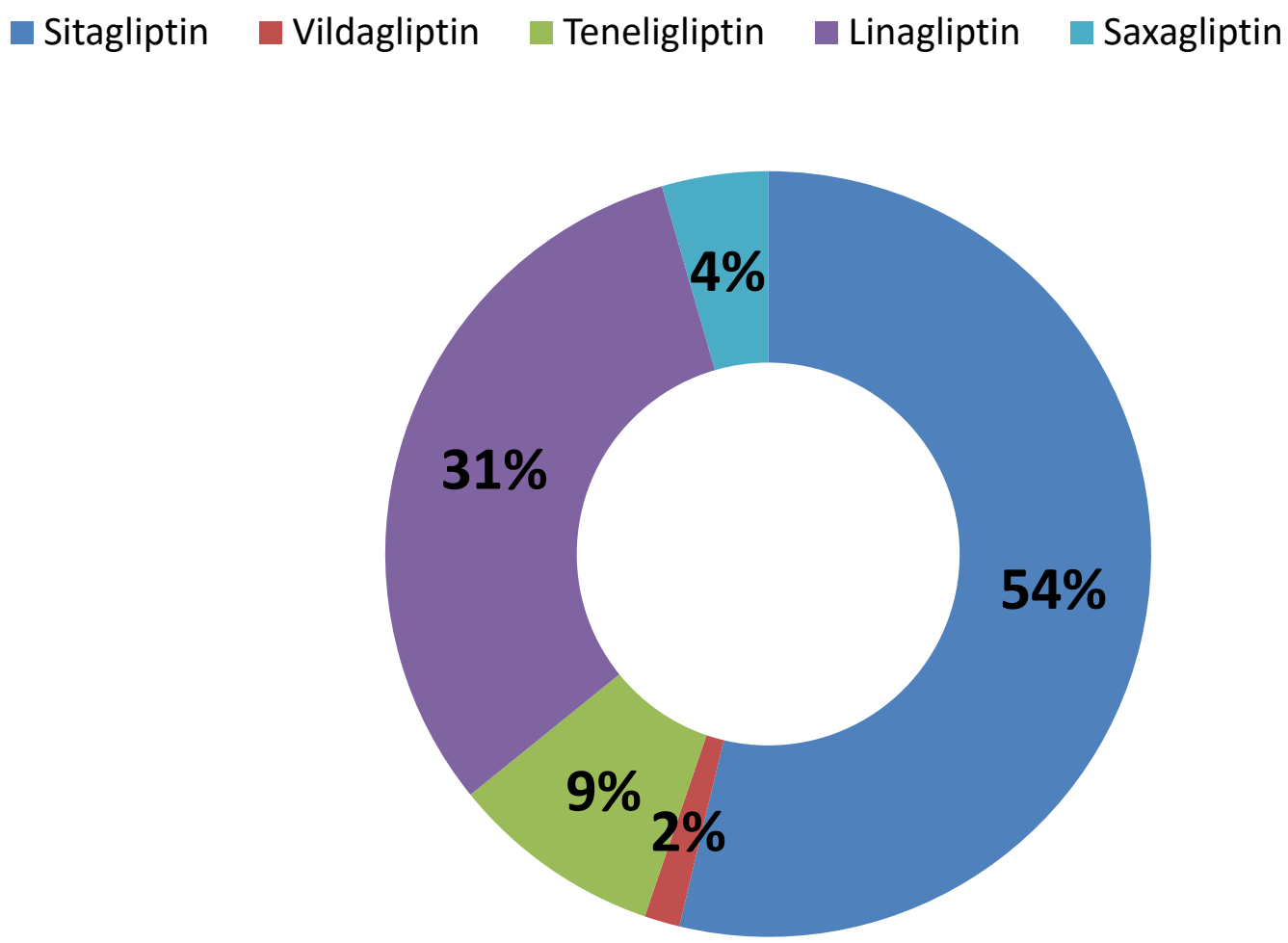


% onset of action of gliptins(selectivity)

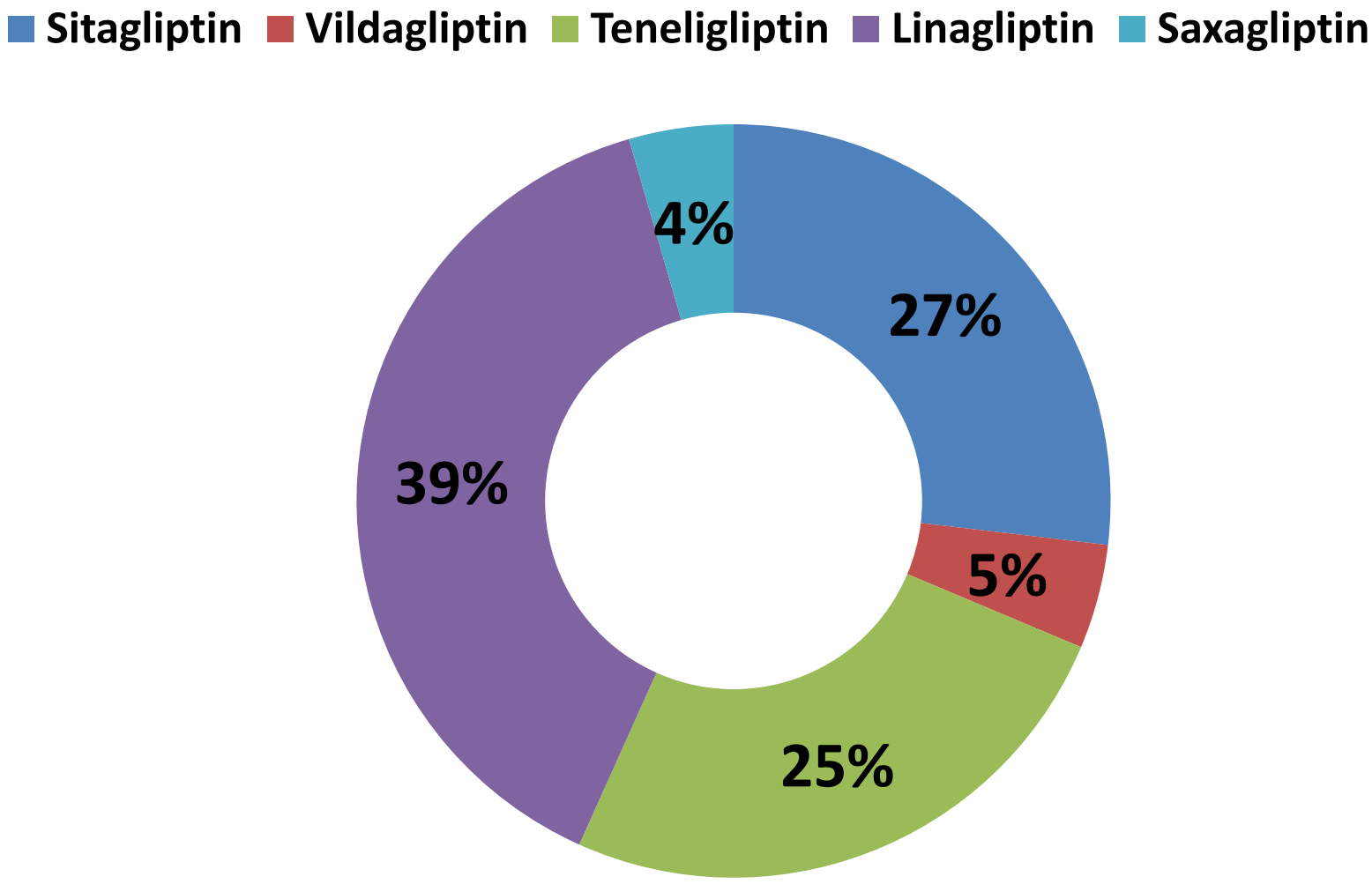



% DPP4 inhibition after 24 hrs
Saxagliptin
39%
Linagliptin
4%
Teneligliptin
3%
Vildagliptin
1%
Sitagliptin
52%

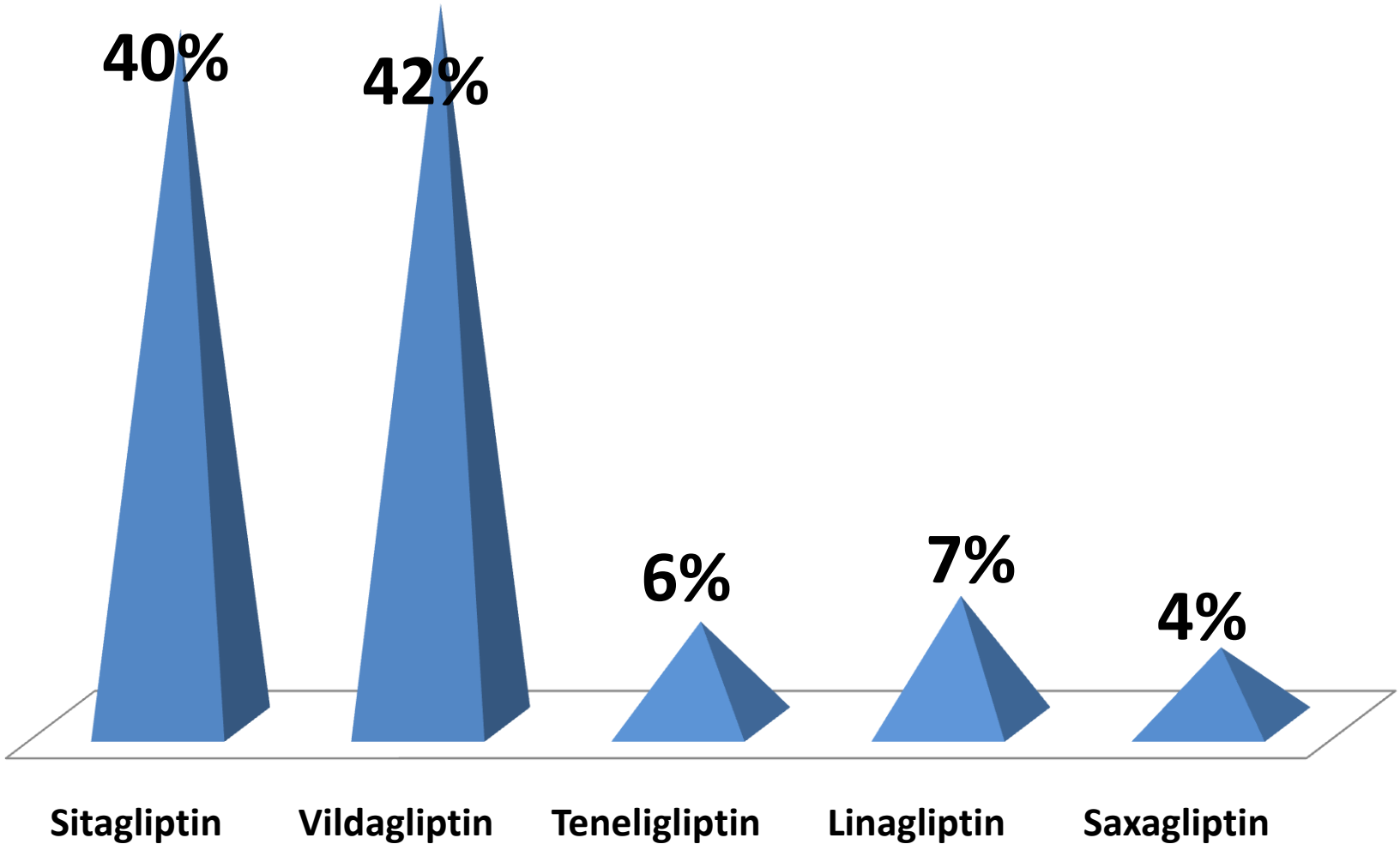
% of CV safety with gliptins

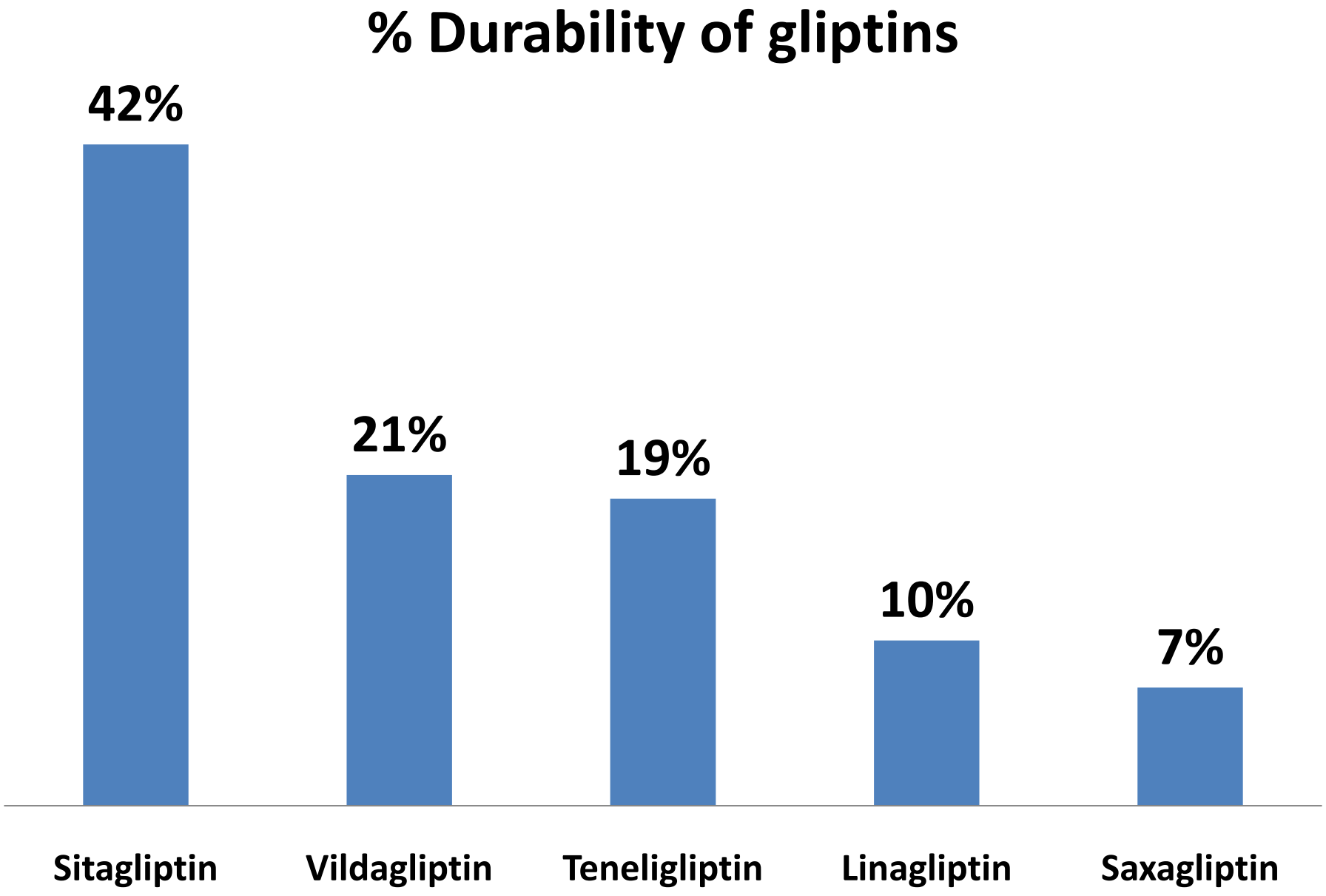


% of hepatic & renal safety with gliptins

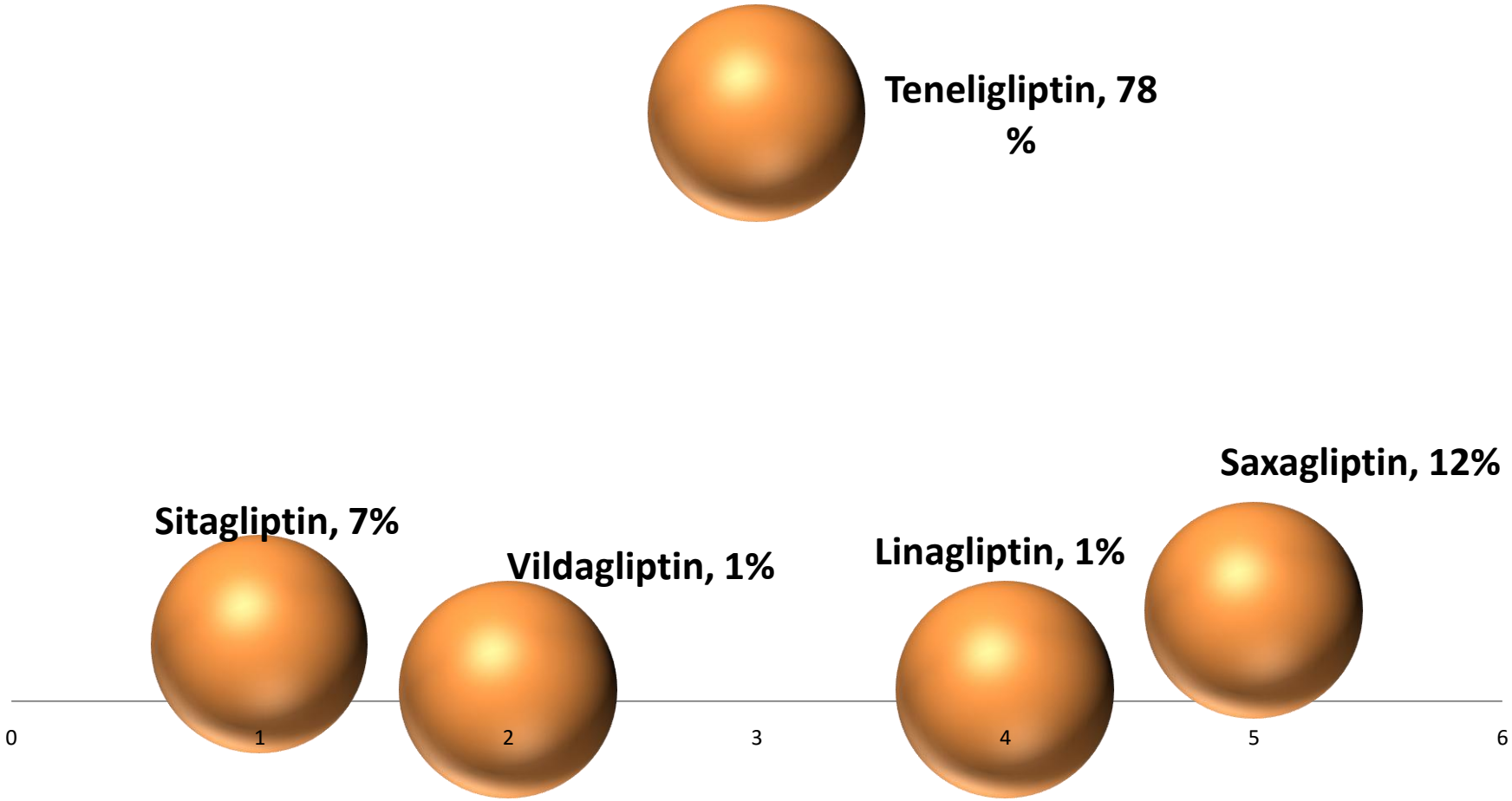


% efficacy with gliptins

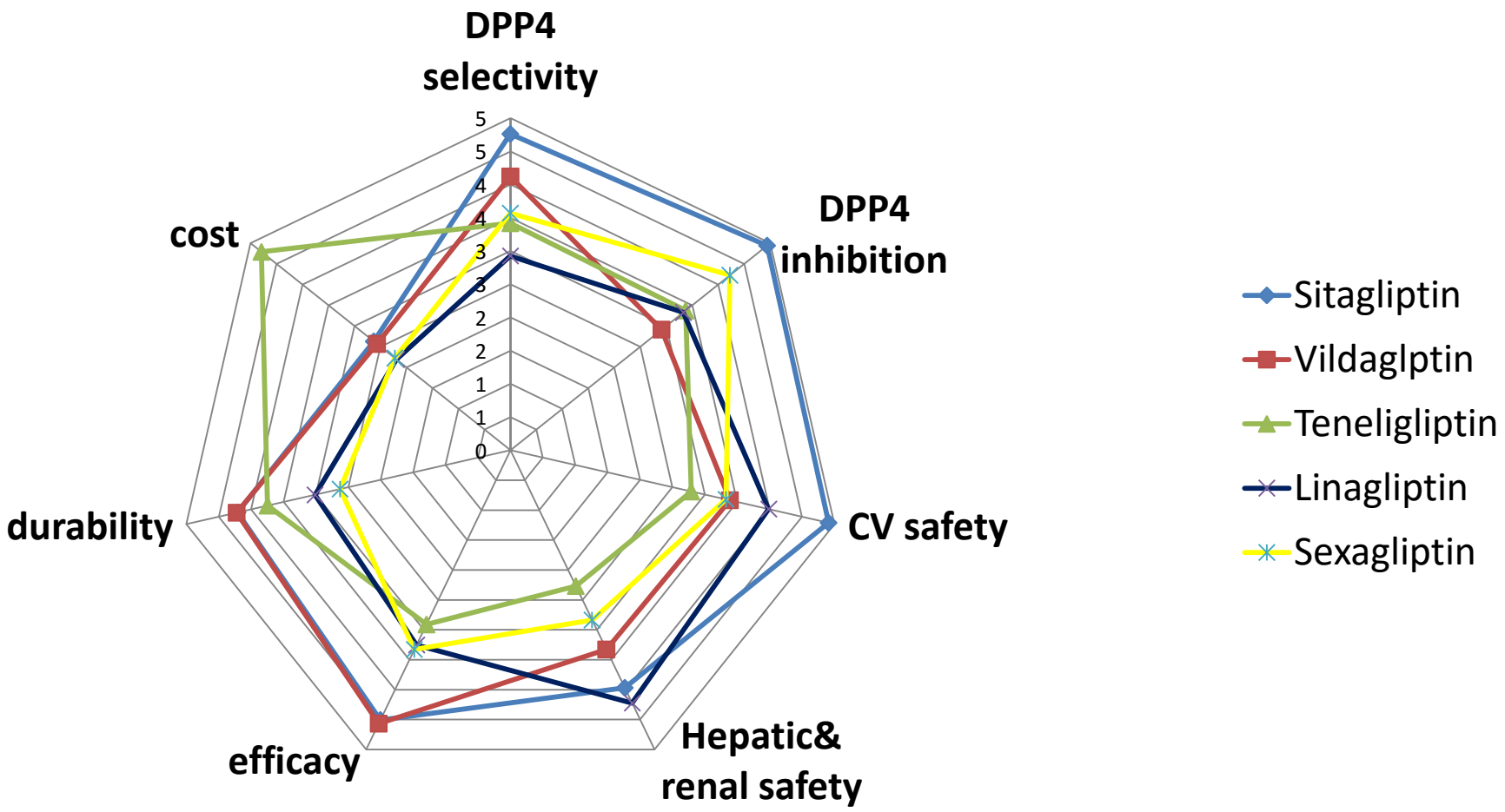



% Durability of gliptins
42%
21%
19%
10%
7%
Sitagliptin
Vildagliptin
Teneligliptin
Linagliptin
Saxagliptin

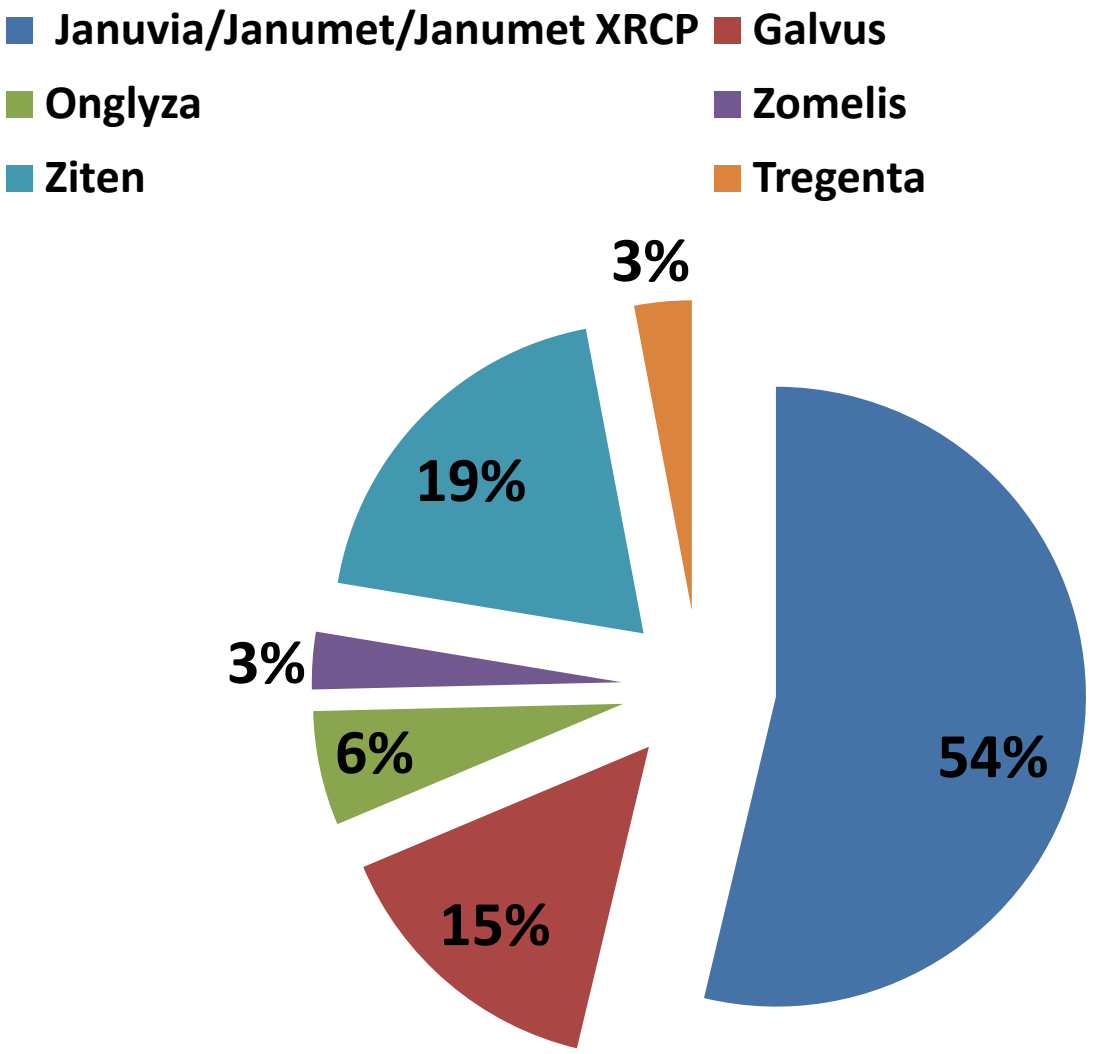
% cost effectiveness with gliptins



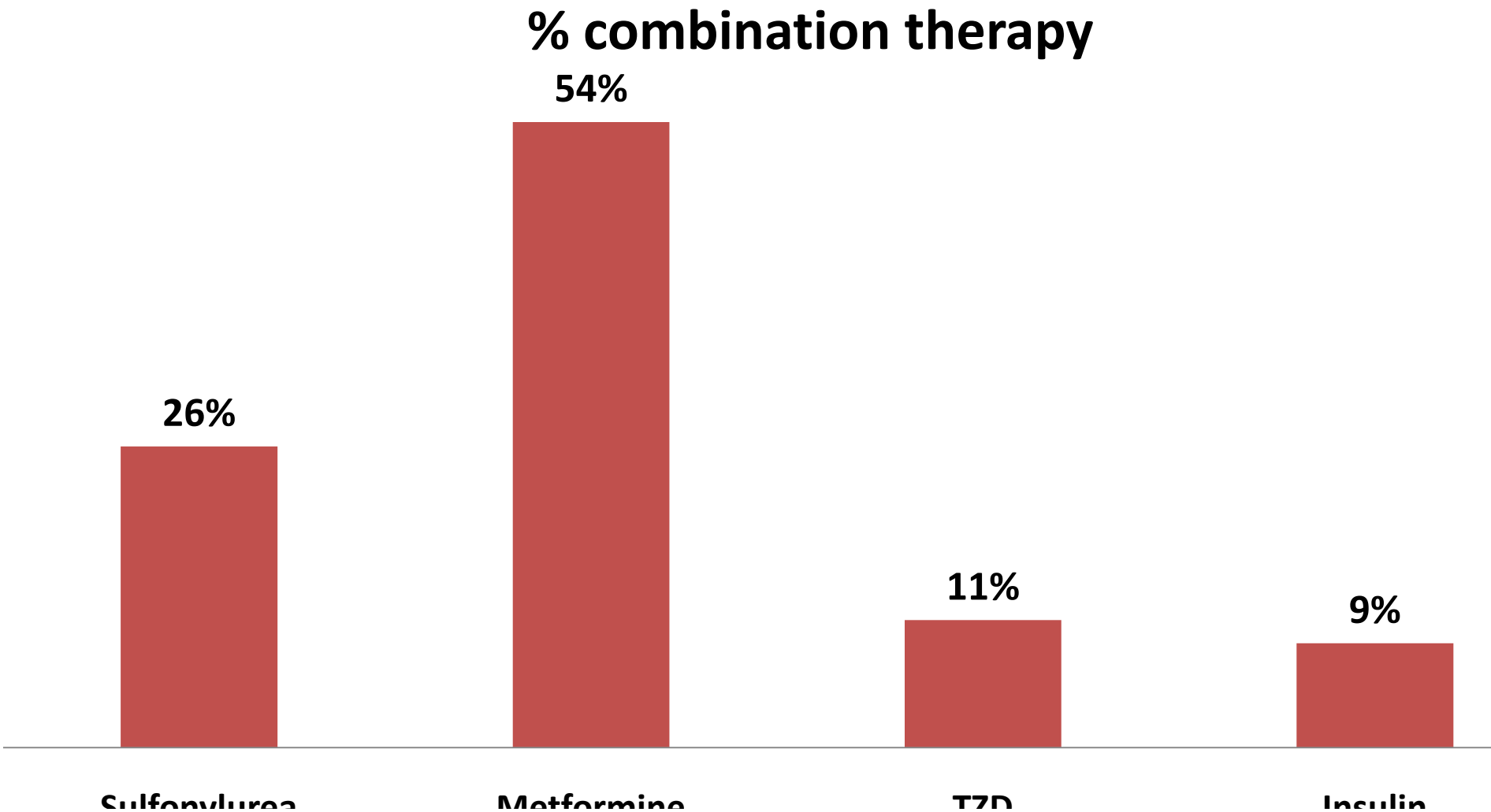
Comparison of all gliptins



% of most preffered brands



Combination therapy	Preferred combination therapy	% of combination therapy
No	16	24%
Yes	51	76%



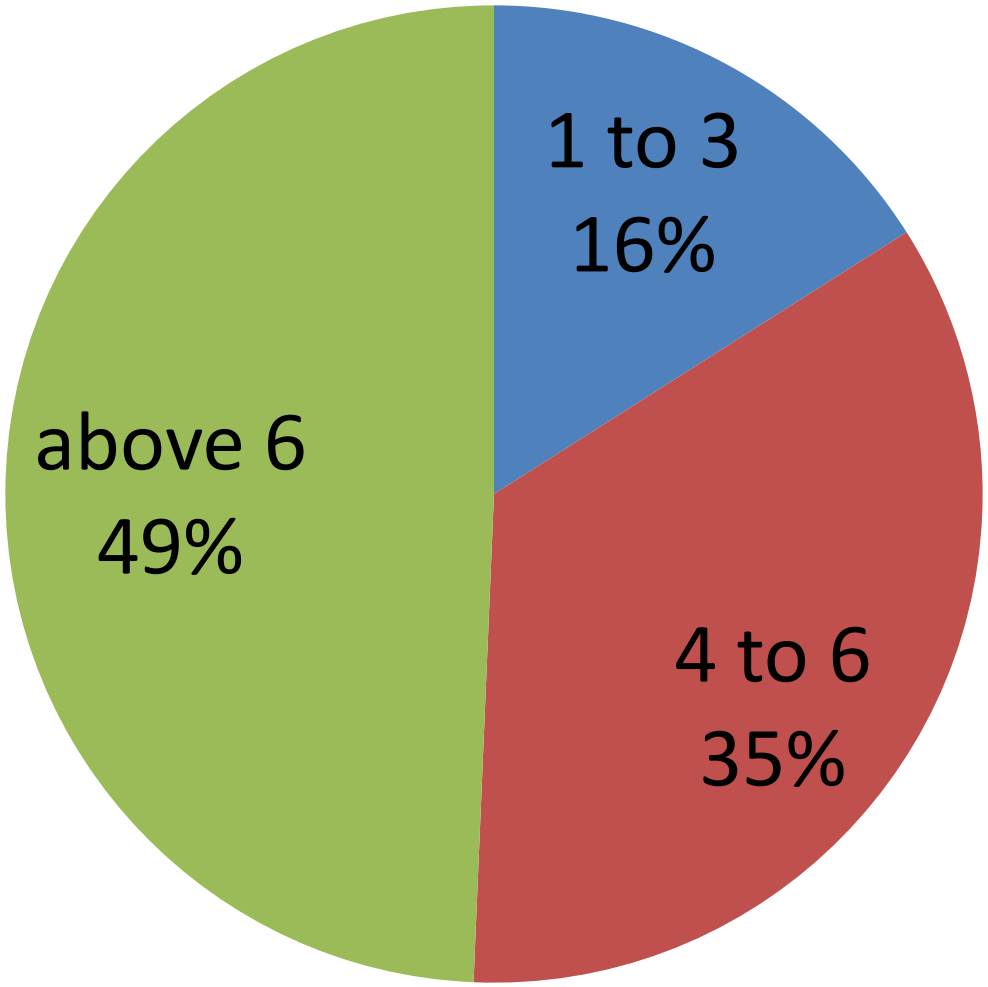
Unmet needs of gliptins in patients with T2DM

- Molecules with minimum side effects with cost effectiveness are need for market

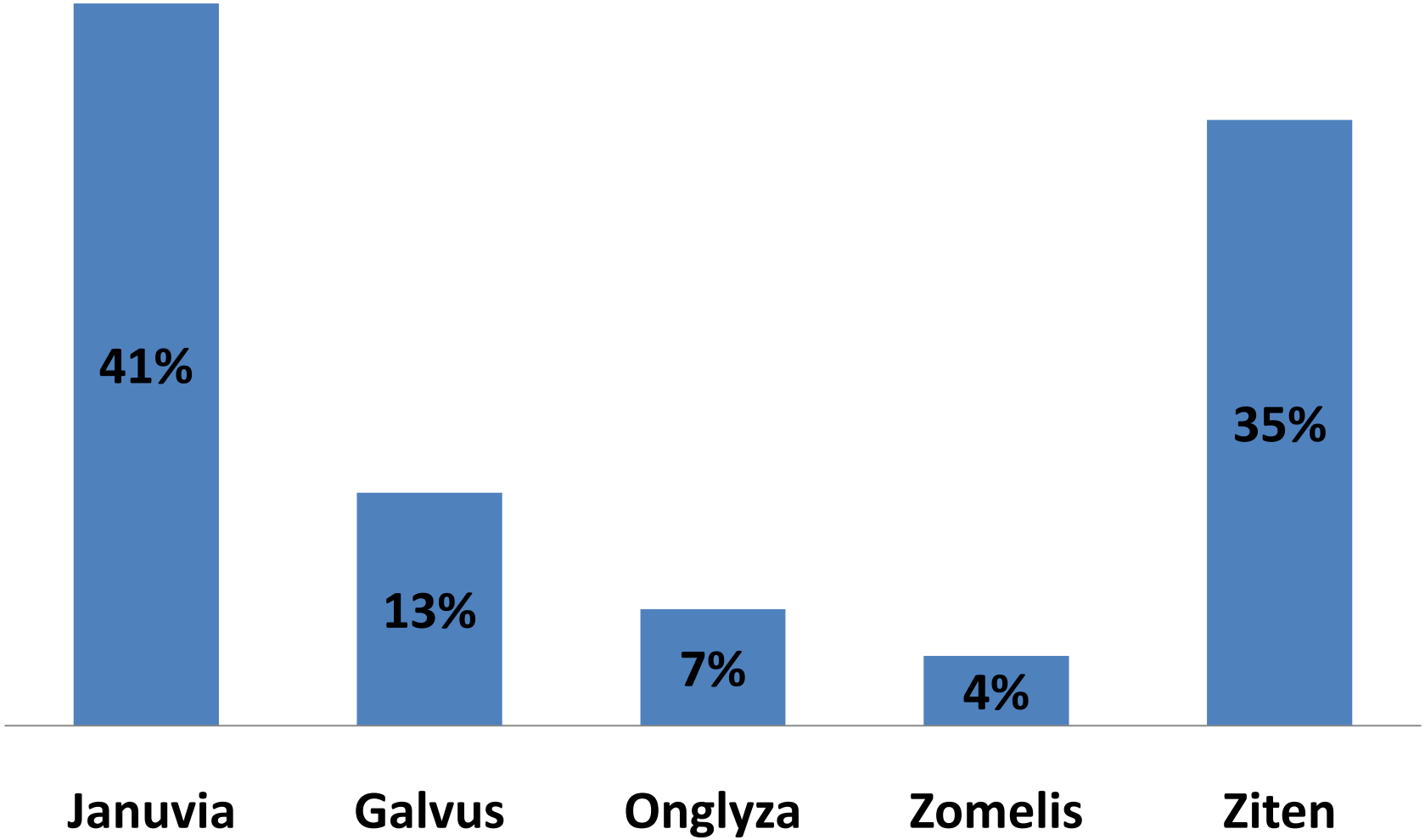
- Combination therapy could be better than single molecule

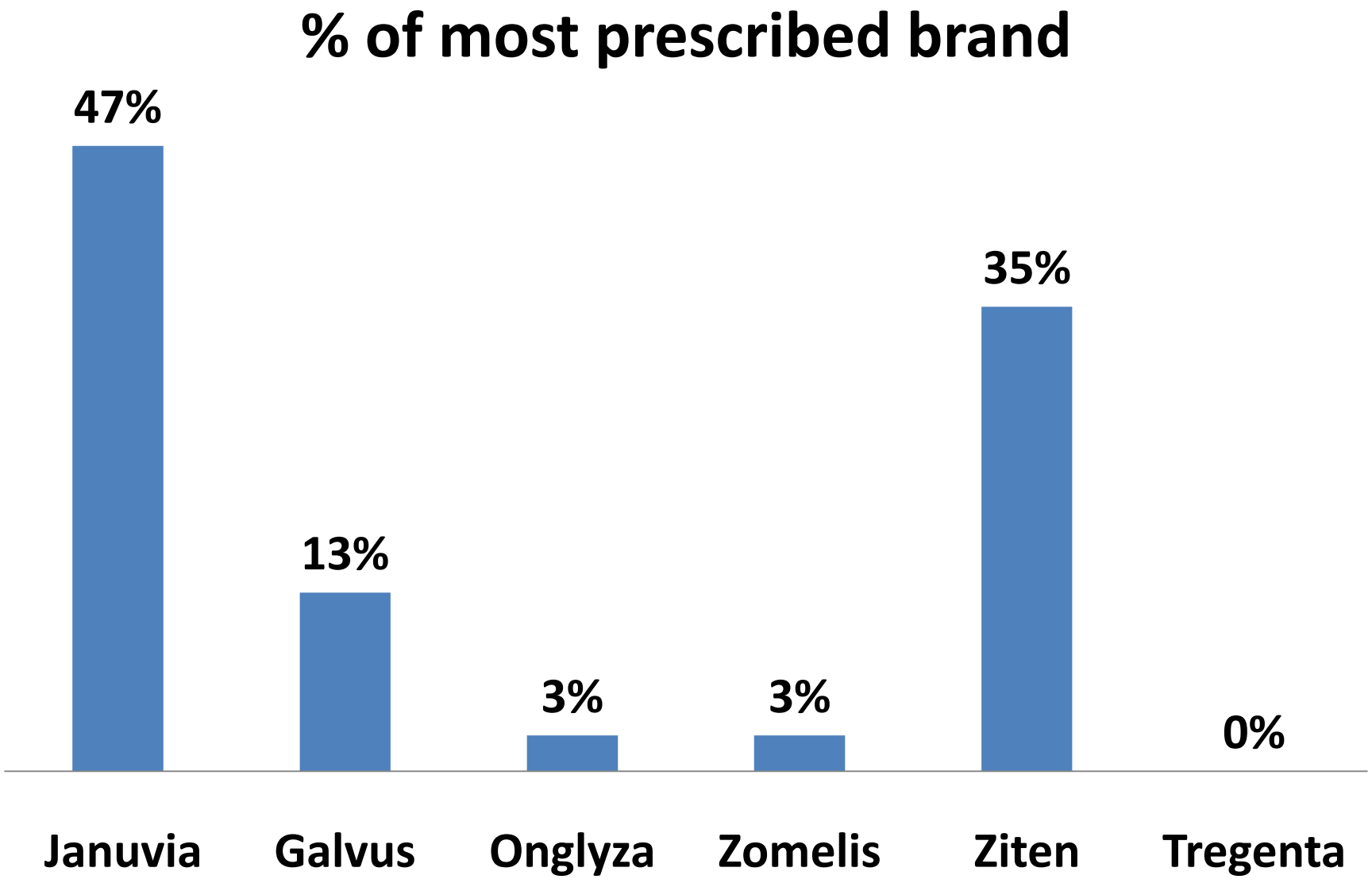
Analysis of Chemists

% no of gliptins brands

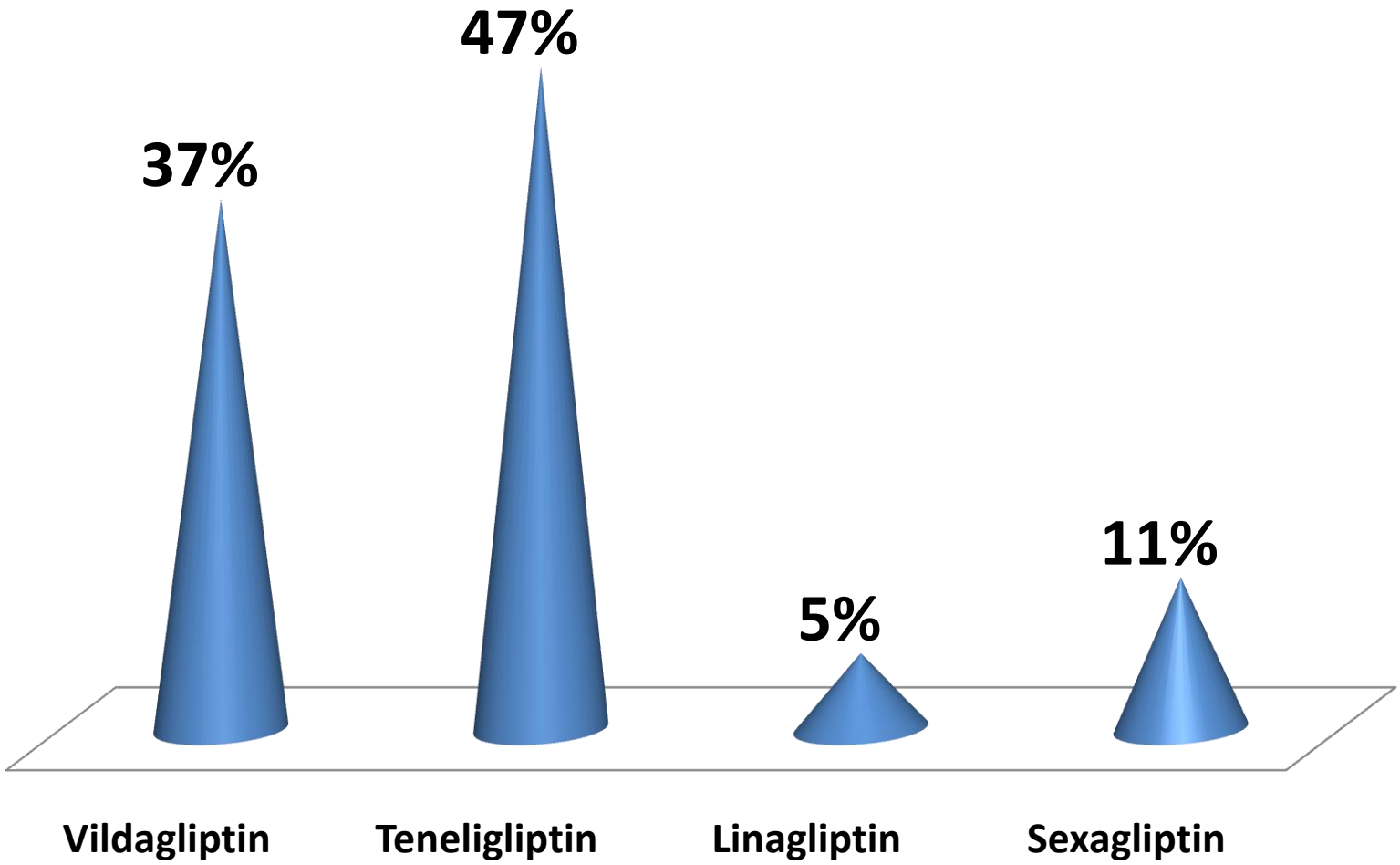


% of brands in stock

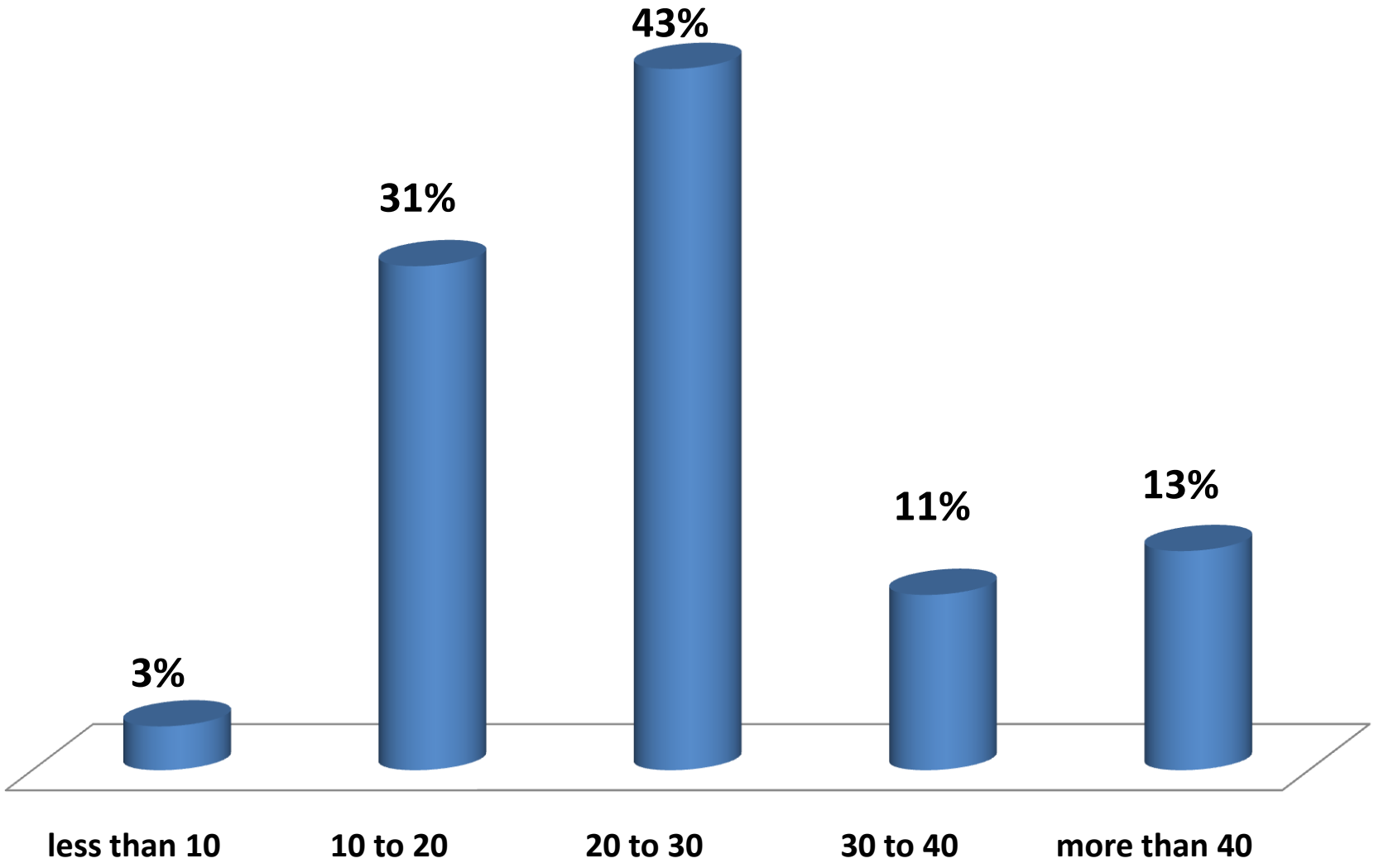



% of most prescribed brand
47%
13%
3%
3%
35%
0%
Januvia
Galvus
Onglyza
Zomelis
Ziten
Tregenta

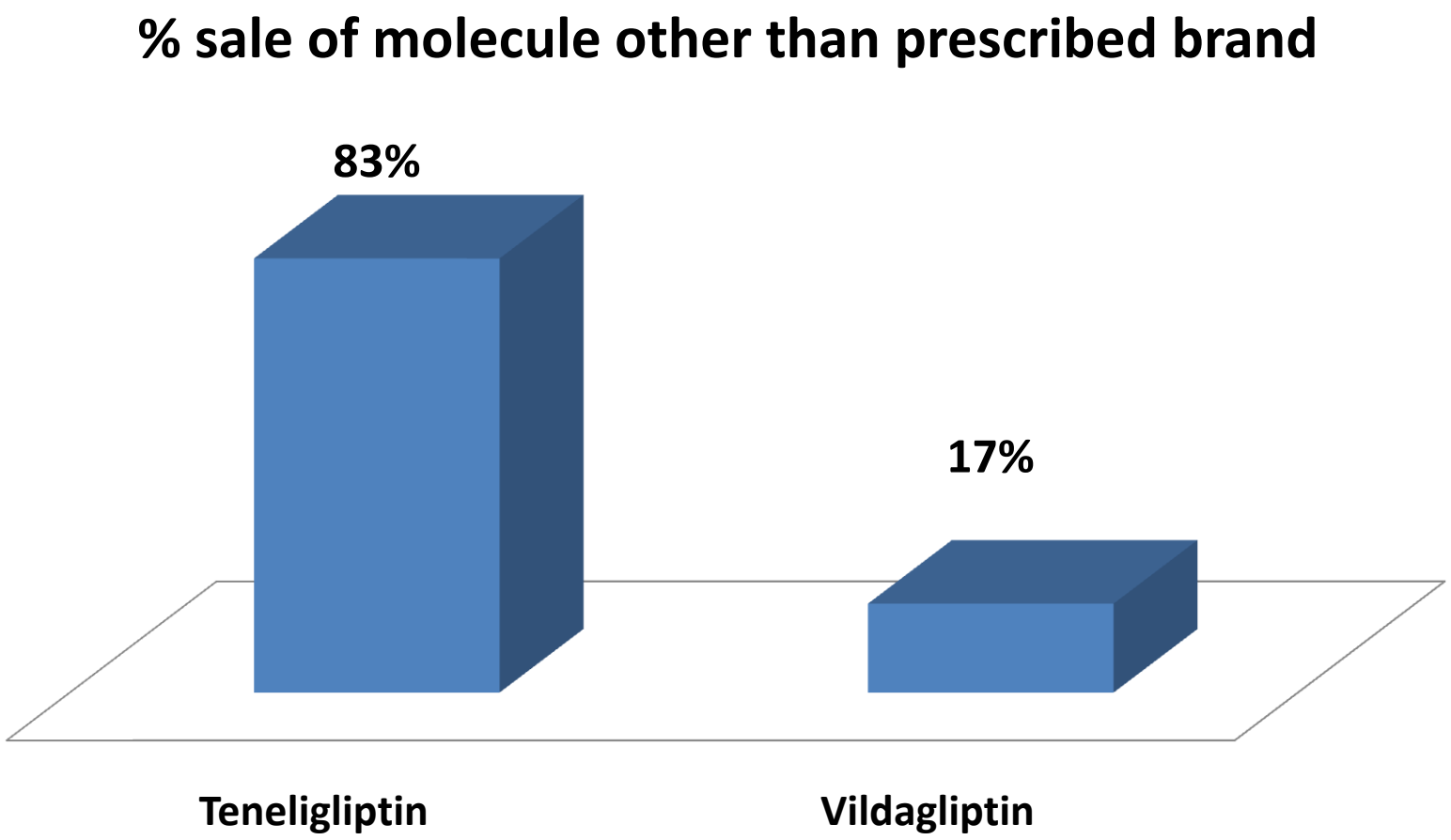
% Competitors of sitagliptin



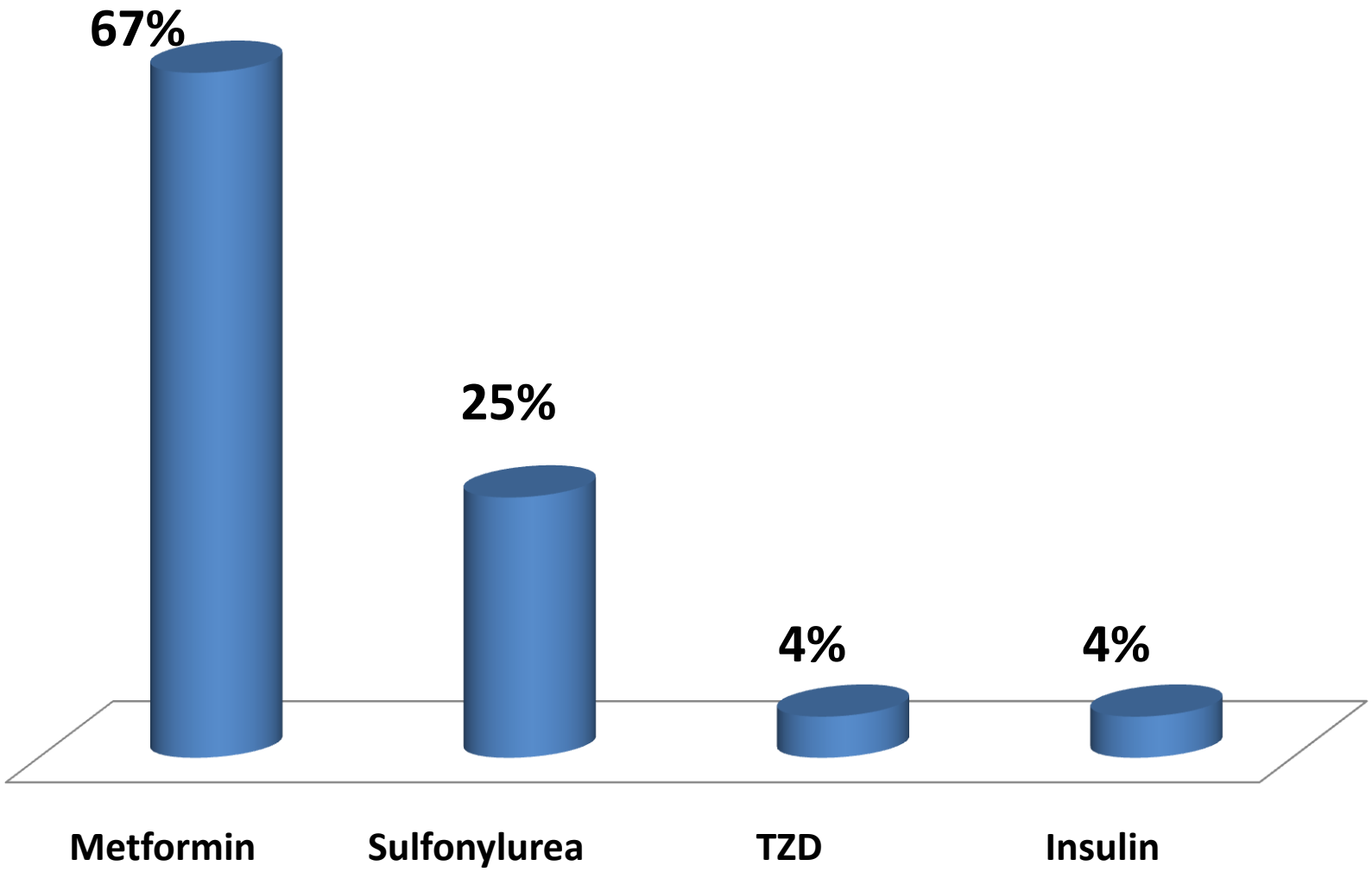
% Januvia sold per week



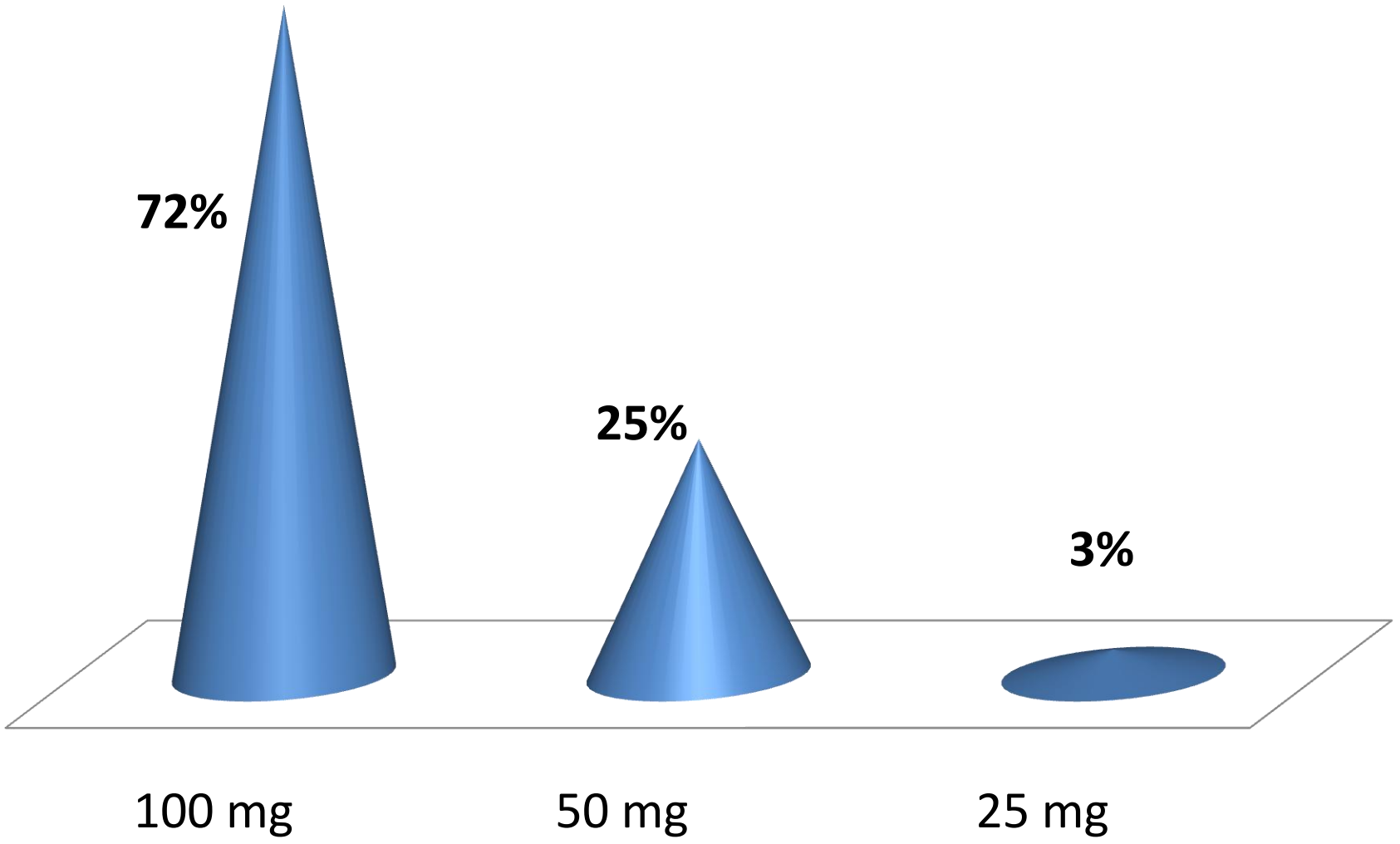
sale of other brand than Rx	Response	% Response
No	65	87%
Yes	10	13%



% of combination therapy with sitagliptin

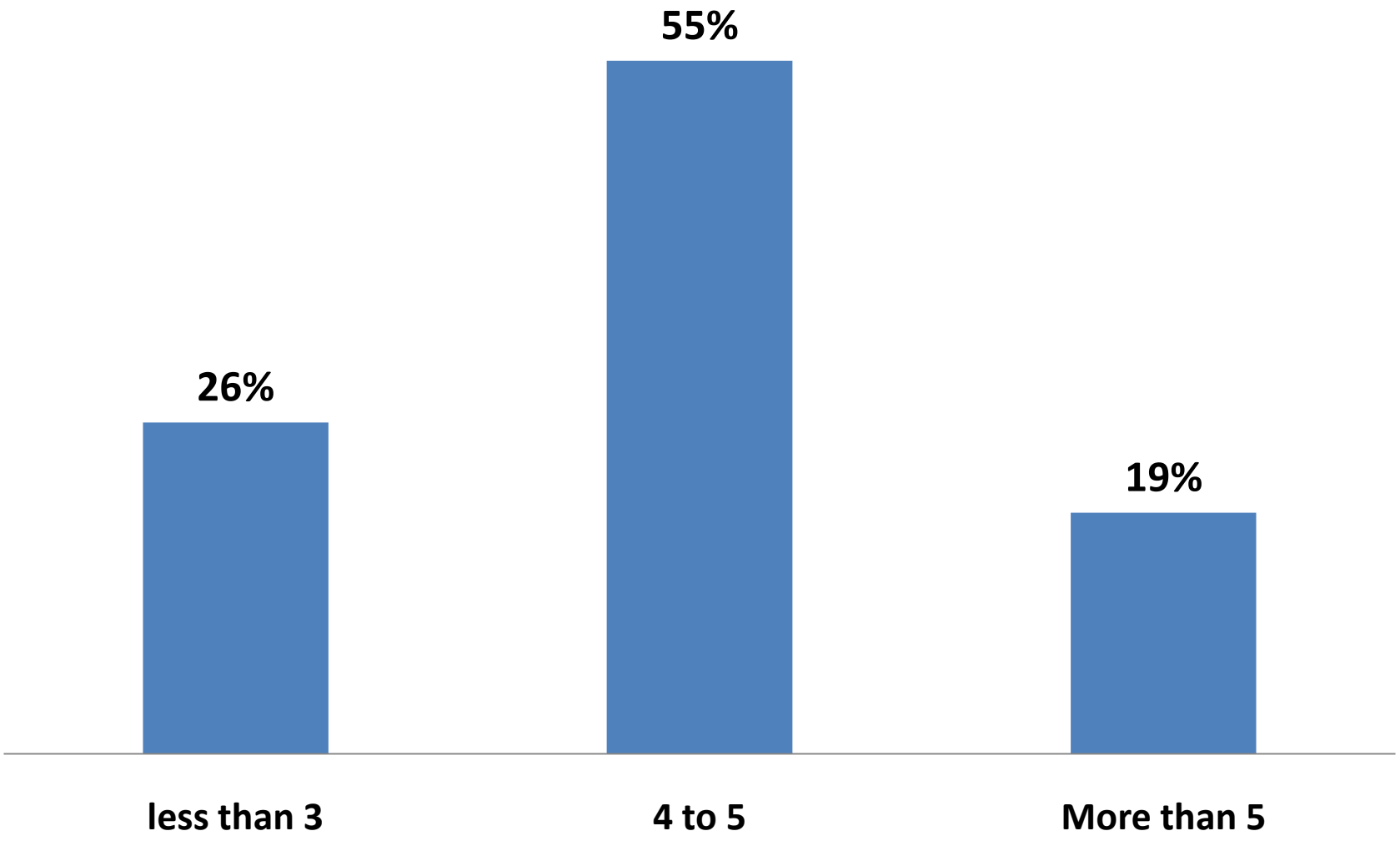


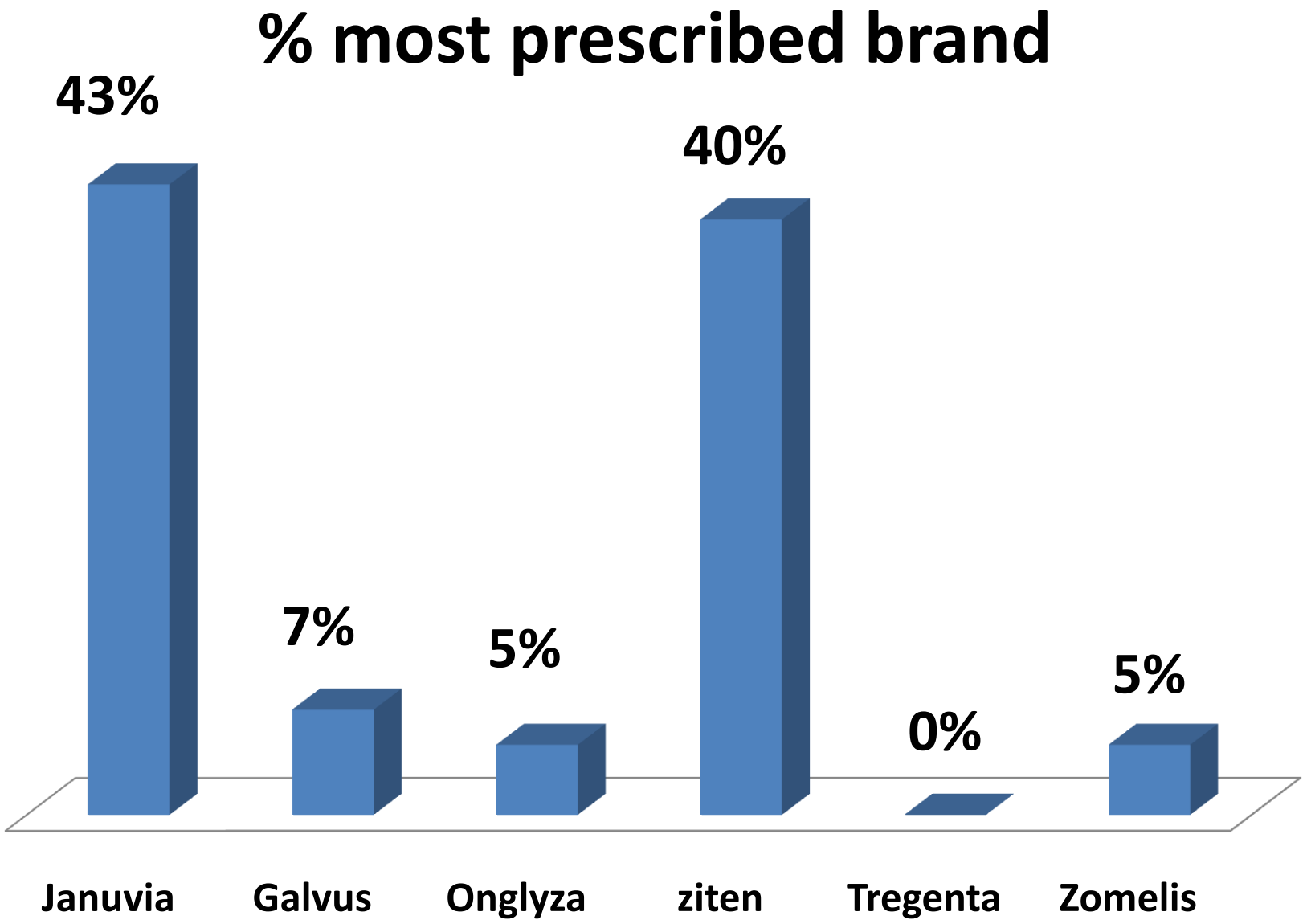
% of most prescribed dose of sitagliptin



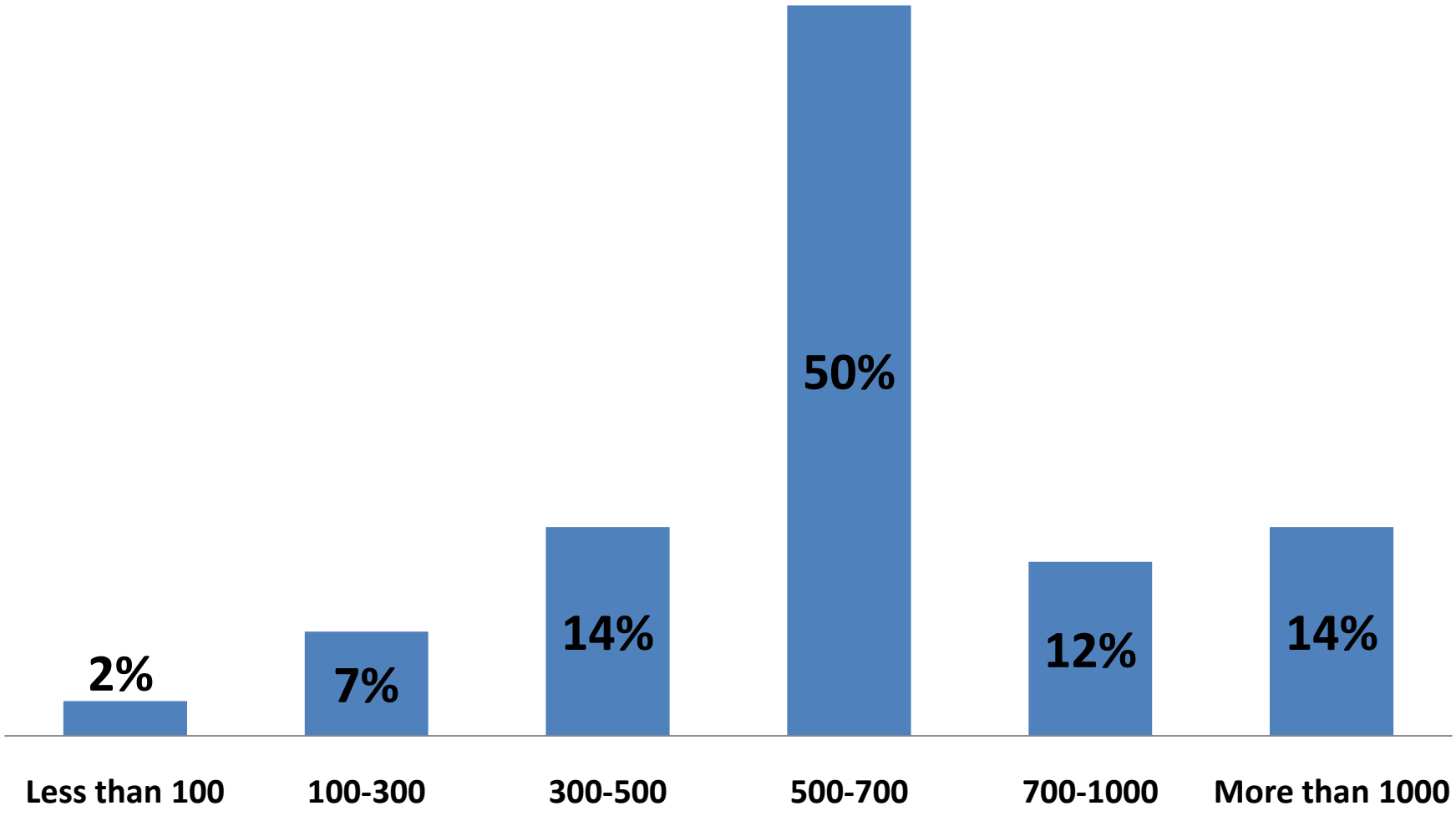
Analysis of stockiest

% no.of brands in stock

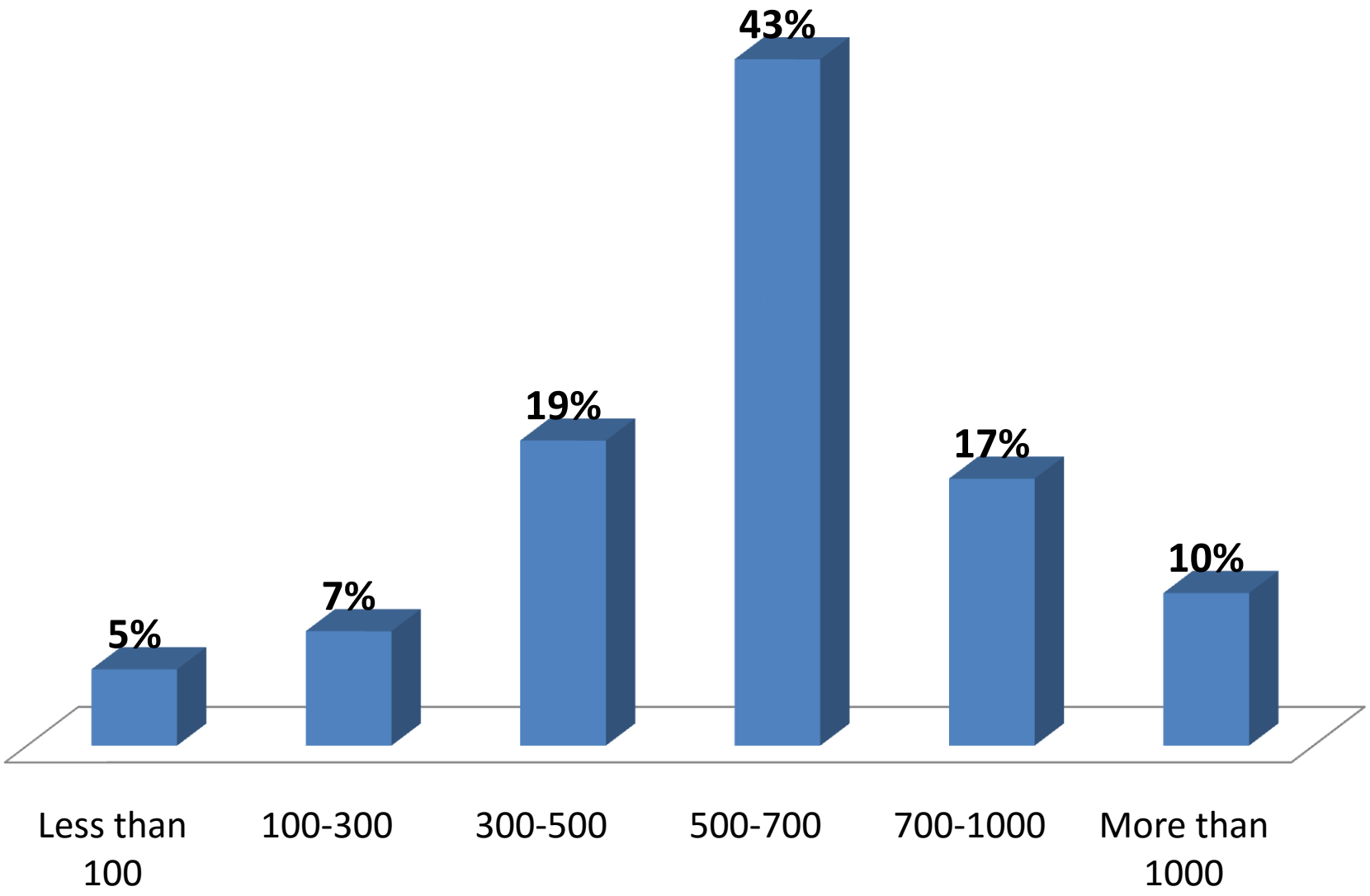



% most prescribed brand
43%
7%
5%
40%
0%
5%
Januvia
Galvus
Onglyza
ziten
Tregenta
Zomelis

% Stock of sitagliptin



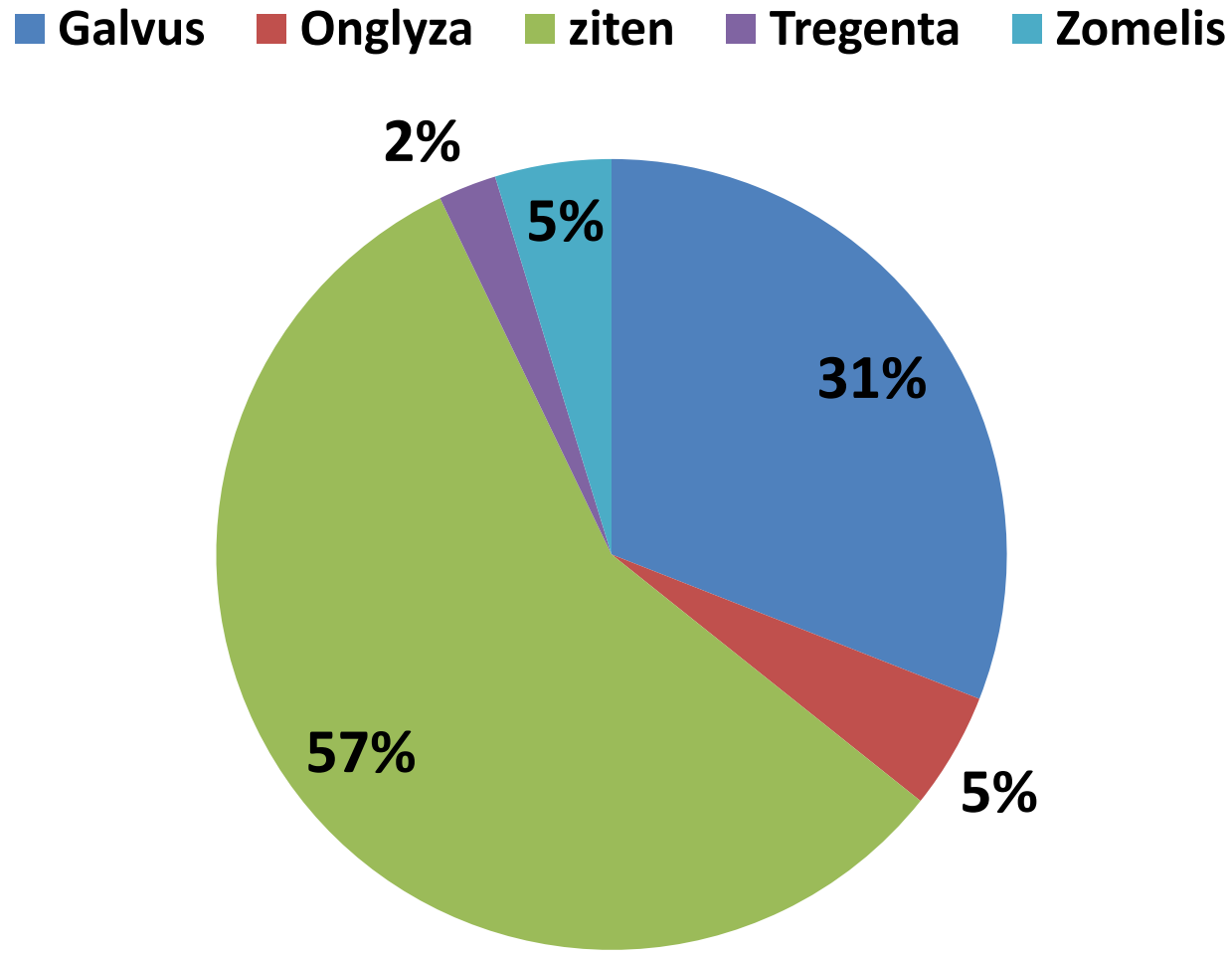
% Sale of sitagliptin



Scheme for brands	% Response
No	67%
Yes	33%

Scheme	% Response
Discount	47%
Free strips	53%

% Competitor of januvia



Findings based on Observation

- Number of patients with diabetes therapy is increasing exponentially.
- Prescription pattern follows efficacy, safety & durability.
- Prescription pattern follows minimum side effects of the molecule
- Prescription pattern follows economy status of the patients.
- According to some doctors prescription trend never remains same, it keeps on changing.
- Many doctors prefer USFDA approved products.

Suggestions

- As India is developing country, with a large population not being financially strong, Teneligliptin is choice of drug because of cost-effectiveness in majority of the clinics, but teneligliptin is having certain side effects. While prescribing any product complication cost can be taken in consideration rather than therapy cost.

- Sitagliptin is the best choice in all gliptins among doctors in termes of onset of action, DPP4 inhibition, CV safety, hepatic & renal safety, efficacy & durability.

- Sitagliptin with Add on therapy with Insulin could be future market driver as it is having good efficacy.

- Cost effectiveness of sitagliptin could help a molecule to become market leader according to some doctors.

- During the study it was found that language is a major constraint. For awareness of a particular product among doctors, company's representatives should know the local languages.

- Stockiest and chemist could give more schemes to attract customers

Limitations

- Sample unit are limited for survey, it affect the accuracy of outcomes.
- Survey was carried out in one region only (Mumbai).
- Time duration of the survey did not allow collecting more data.
- The respondents were very busy and could not afford more time to answer.

References

1. Weir GC, Bonner-Weir S. Five stages of evolving [beta]-cell dysfunction during progression to diabetes. Diabetes. 2004;53(Suppl 3):S16–21. [PubMe
2. Defronzo RA. Banting Lecture.From the triumvirate to the ominous octet: a new paradigm for the treatment of type 2 diabetes mellitus. Diabetes. 2009;58:773–95. [PMC free article] [PubMed]
3. Turner RC, Cull CA, Frighi V, Holman RR. Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus: Progressive requirement for multiple therapies (UKPDS 49).UK Prospective Diabetes Study (UKPDS) Group. JAMA. 1999;281:2005–12. [PubMed]
4. Bell DS. A Comparison of agents used to manage type 2 diabetes mellitus: Need for reappraisal of traditional approaches. Treat Endocrinol. 2004;3:67–76. [PubMed]
5. Nathan DM, Buse JB, Davidson MB, Heine RJ, Holman RR, Sherwin R, et al. Management of hyperglycemia in type 2 diabetes: A consensus algorithm for the initiation and adjustment of therapy: A consensus statement from the American Diabetes Association and the European Association for the Study of Diabetes. Diabetes Care. 2006;29:1963–72. [PubMed]
6. DeFronzo RA, Goodman AM. Efficacy of metformin in patients with non-insulin-dependent diabetes mellitus.The Multicenter Metformin Study Group. N Engl J Med. 1995;333:541–9. [PubMed]
7. UKPDS 28: A randomized trial of efficacy of early addition of metformin in sulfonylurea-treated type 2 diabetes. U.K. Prospective Diabetes Diabetes Study Group. Diabetes Care. 1998;21:87–92. [PubMed]
8. Koro CE, Bowlin SJ, Bourgeois N, Fedder DO. Glycemic control from 1988 to 2000 among U.S. adults diagnosed with type 2 diabetes: A preliminary report. Diabetes Care. 2004;27:17–20. [PubMed]
9. DeFronzo RA. Lilly Lecture 1987. The triumvirate: beta cell, muscle, liver. A collusion responsible for NIDDM. Diabetes. 1988;37:667–87. [PubMed]
10. DeFronzo RA, Gunnarsson R, Bjorkman O, Olsson M, Wahren J. Effects of insulin on peripheral and splanchnic glucose metabolism in non-insulin dependent diabetes mellitus. J Clin Invest. 1985;76:149–55. [PMC free article] [PubMed]
11. DeFronzo RA, Ferrannini E. Regulation of hepatic glucose metabolism in humans. Diabetes Metab Rev. 1987;3:415–9. [PubMed]
12. Unger RH. Lipotoxicity in the pathogenesis of obesity-dependent NIDDM.Genetic and clinical implications. Diabetes. 1995;44:863–70. [PubMed]
13. . Randle PJ, Garland PB, Hales CN, Newsholme EA. The glucose fatty-acid cycle.Its role in insulin sensitivity and the metabolic disturbances of diabetes mellitus. Lancet. 1963;1:785–9. [PubMed]
14. Drucker DJ. The biology of incretin hormones. Cell Metab. 2006;3:153–65. [PubMed]
15. Drucker DJ, Nauck MA. The incretin system: Glucagon-like peptide-1 receptor agonists and dipeptidyl peptidase-4 inhibitors in type 2 diabetes. Lancet. 2006;368:1696–705. [PubMed]

Thank you