Survey Report

Perception Mapping of Indian Physicians on Efficacy and Safety of Sitagliptin + Glimepiride + Metformin in T2DM Management

Version No.: 1.1

The study was conducted according to the approved protocol and in compliance with the protocol, Good Clinical Practice (GCP), and other applicable local regulatory requirements.

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1. INTRODUCTION

Diabetes mellitus, affecting 415 million people globally in 2015, is a growing concern, particularly in India, where cases are projected to rise from 69.2 million in 2015 to 123.5 million by 2040 [1]. For managing type 2 diabetes mellitus (T2DM), combination therapies that target both insulin resistance and beta-cell dysfunction are crucial [2]. Metformin is the first-line treatment, but when it is insufficient, sulfonylureas like glimepiride are commonly added, especially in India [3]. Glimepiride, preferred over older sulfonylureas, is approved for use alone or with metformin or insulin due to its benefits like optimal insulin secretion, weight neutrality, and lower hypoglycemia risk [4]. It also has anti-inflammatory and cardioprotective effects, making it a safer option for patients with cardiovascular disease [5].

Perception mapping of Indian physicians on the use of sitagliptin + glimepiride + metformin in managing T2DM focuses on balancing efficacy and safety while optimizing patient outcomes. The combination of glimepiride and metformin has shown a significant reduction in glycemic parameters compared to the sitagliptin and metformin combination. Glimepiride, a sulfonylurea, stimulates insulin secretion, leading to greater reductions in blood sugar levels. When combined with metformin, a first-line insulin sensitizer, this combination has a potent effect on lowering HbA1c levels. However, sitagliptin, a DPP-4 inhibitor, offers a more moderate reduction in glycemic levels but with fewer side effects like hypoglycemia. This balance of effects is often seen as an advantage when combining all three medications [6]. Sitagliptin have a better safety profile, particularly due to its lower association with hypoglycemia and weight gain, which are common concerns with glimepiride while glimepiride is associated with hypoglycemia risks, it remains a powerful agent in glycemic control, especially when patients fail to reach targets on metformin alone. Combining it with sitagliptin helps mitigate some of the risks, making this triple combination valuable in high-risk patients [7]. Indian physicians also factor in patient adherence when prescribing combination therapies. The triple combination offers convenience and effective control, which could improve patient adherence to therapy. As discussed in various studies, simplifying regimens and achieving stable

glycemic control encourages better patient satisfaction and long-term compliance [8]. A combination like sitagliptin, glimepiride, and metformin allows tailoring treatment to the patient's specific needs, particularly in those with poor glycemic control on dual therapy [9].

Indian physicians see the sitagliptin + glimepiride + metformin combination as a versatile and effective regimen for achieving glycemic targets while balancing safety, particularly by mitigating the risks associated with glimepiride through the use of sitagliptin. This combination allows for personalized treatment, optimizing both efficacy and patient satisfaction.

2. RATIONALE OF THE STUDY

The rationale for utilizing a combination therapy of sitagliptin, glimepiride, and metformin in managing T2DM stems from the complementary mechanisms of action these drugs provide. Metformin is widely used as the first-line treatment for T2DM due to its role in improving insulin sensitivity and reducing hepatic glucose production. Adding sitagliptin, a DPP-4 inhibitor, helps enhance insulin secretion and reduces glucagon levels without a significant risk of hypoglycemia. Glimepiride, a sulfonylurea, further stimulates insulin release, offering robust glycemic control. The combination of these agents, often delivered in a fixed-dose combination (FDC), not only enhances glycemic management but also improves patient adherence, reduces treatment costs, and minimizes long-term complications by providing a simplified therapy. Moreover, studies show that such combinations offer effective glycemic control, with Metformin/Glimepiride being potent but carrying a higher risk of hypoglycemia compared to sitagliptin/metformin, which is often favored for safety.

This survey was designed to explore and map physicians' perceptions on efficacy and safety of sitagliptin + glimepiride + metformin in T2DM management. By assessing physician perspectives, the survey aimed to identify the efficacy and safety of sitagliptin + glimepiride + metformin in T2DM management, as well as any barriers that may hinder its wider application in clinical practice. This survey provided

valuable insights into optimizing acromegaly management and improving patient outcomes.

3. OBJECTIVES

The primary objective of this study was to assess the perception of Indian physicians regarding the efficacy and safety of sitagliptin + glimepiride + metformin in T2DM management.

METHODS

This study was a cross-sectional, questionnaire-based survey designed to assess the perceptions, practices, and clinical experiences of Indian physicians regarding the use of the combination therapy sitagliptin + glimepiride + metformin in the management of T2DM. The survey comprised 11 questions aimed at capturing data on treatment protocols, efficacy, safety perceptions, and prescribing trends for this combination therapy.

Physicians practicing in India and involved in T2DM management were invited to participate through professional networks and medical associations. Participants were informed about the study objectives and provided with consent before participation. The survey was administered electronically, ensuring convenience and efficiency in data collection.

The study targeted a sample size of 100 Indian physicians to ensure a representative distribution across different regions and practice settings. Data was securely collected and analyzed statistically to identify key trends and insights. Findings were compiled into a report to be shared through scientific publications and medical conference presentations, as appropriate.

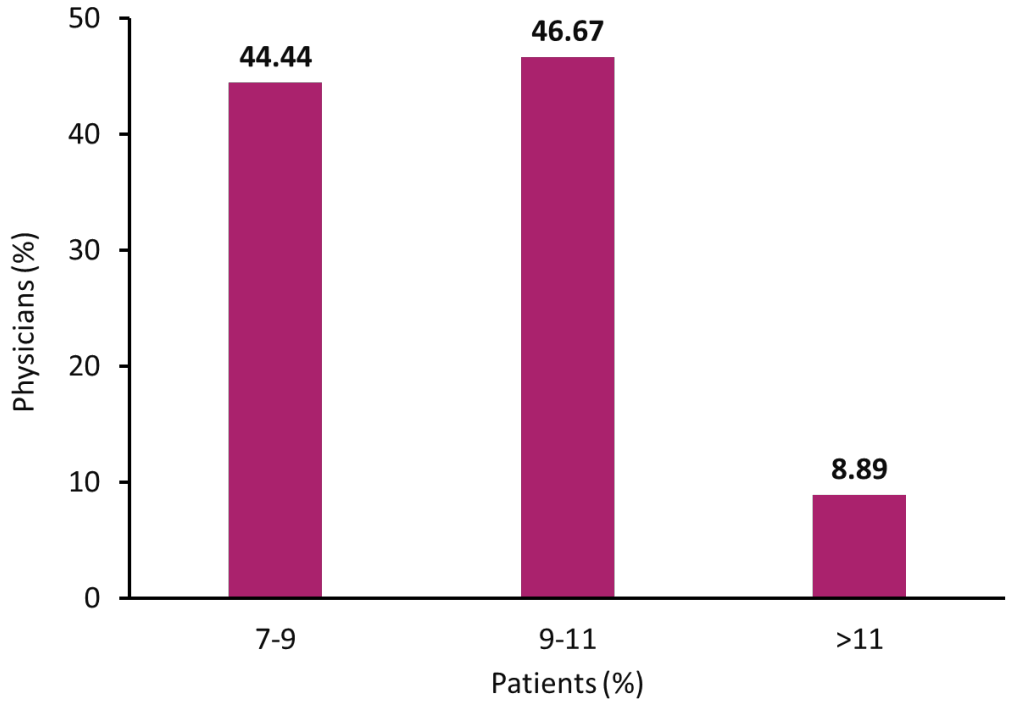
The study adhered to ethical guidelines as outlined in the Declaration of Helsinki, and participants were assured of confidentiality and the right to withdraw at any time. Ethical approval was obtained from an independent committee before the study commenced.

4. RESULTS

A total of 90 HCPs participated in the survey. Below is the summary of the responses.

[1] What is usual HbA1c at which patients present with T2DM in your clinical practice?

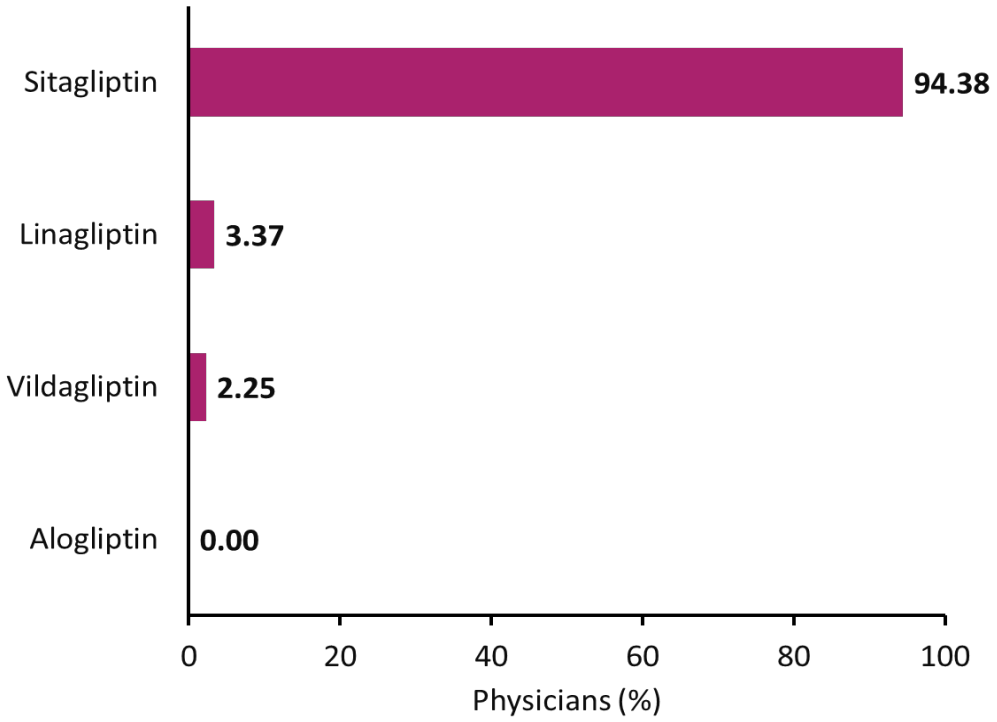
a. 7-9%
b. 9-11%
c. >11%



- The majority (46.67%) of physicians reported that patients with T2DM typically present with an HbA1c in the range of 9-11%.
- Around 44.44% of physicians reported that patients usually present with an HbA1c in the range of 7-9%.
- A small portion (8.89%) of physicians reported that patients typically present with an HbA1c >11%.

[2] In your clinical practice, which is the preferred DPP4i?

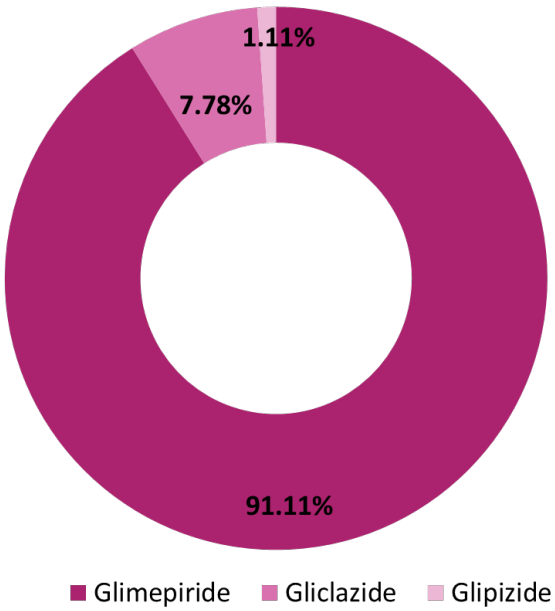
a. Sitagliptin
b. Linagliptin
c. Vildagliptin
d. Alogliptin



- The majority (94.38%) of physicians preferred sitagliptin as the DPP-4 inhibitor of choice in clinical practice.
- Around (3.37%) of physicians prescribed linagliptin as the DPP-4 inhibitor of choice in clinical practice.
- A smaller portion (2.25%) of physicians preferred vildagliptin as the DPP-4 inhibitor of choice in clinical practice.
- None of the physicians prescribed alogliptin.

[3] In your clinical practice, which is the preferred SU?

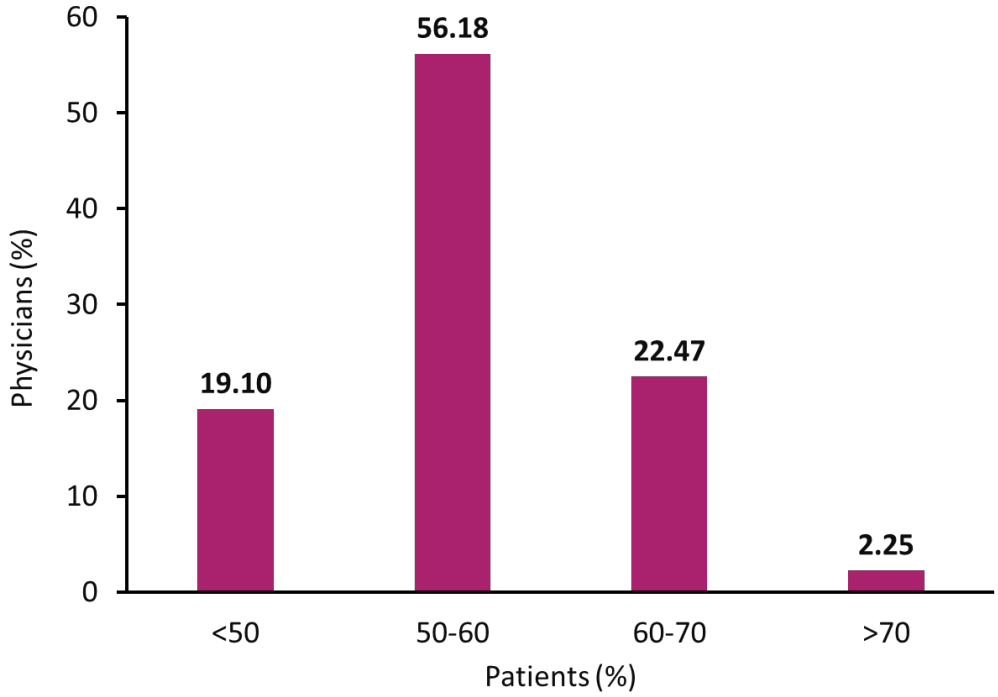
a. Glimepiride
b. Gliclazide
c. Glipizide



- The majority (91.11%) of physicians prescribed glimepiride as the sulfonylurea of choice in clinical practice.
- A smaller portion (7.78%) of physicians preferred gliclazide as the sulfonylurea of choice in clinical practice.
- Only a very small portion (1.11%) of physicians preferred glipizide as the sulfonylurea of choice in clinical practice.

[4] What percent of T2DM patients are uncontrolled on dual therapy?

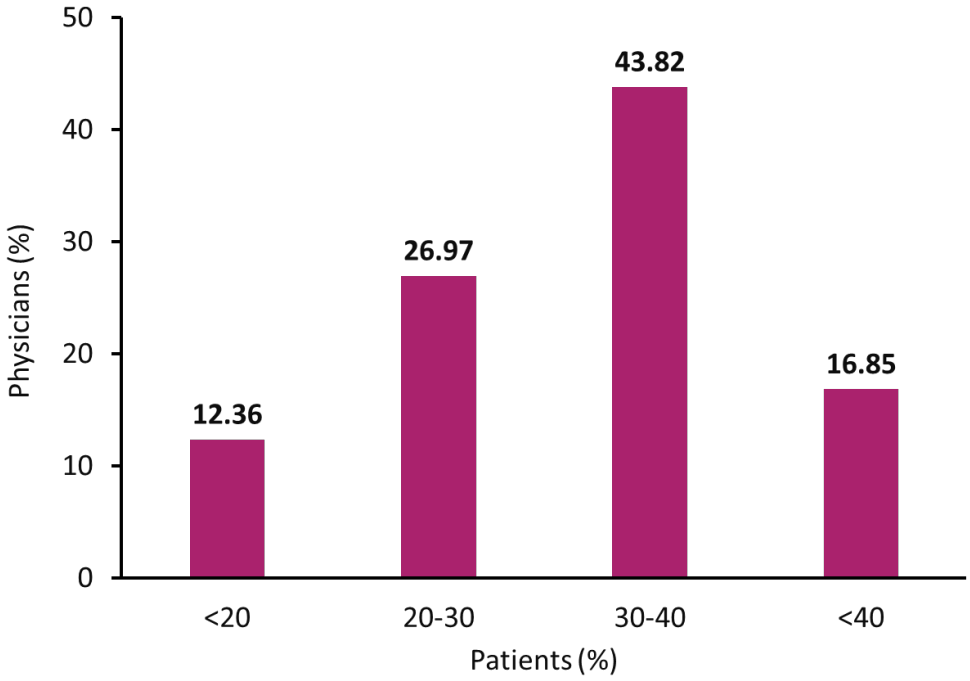
a. <50%
b. 50-60%
c. 60-70%
d. >70%



- The majority (56.18%) of physicians observed that 50-60% of T2DM patients are uncontrolled on dual therapy.
- Around 22.47% of physicians reported that 60-70% of patients are uncontrolled on dual therapy.
- A smaller portion (19.10%) of physicians estimated that less than 50% of patients are uncontrolled on dual therapy.
- Only a very small portion (2.25%) of physicians reported that more than 70% of patients are uncontrolled on dual therapy.

[5] What percent of your T2DM patients are on Triple Therapy?

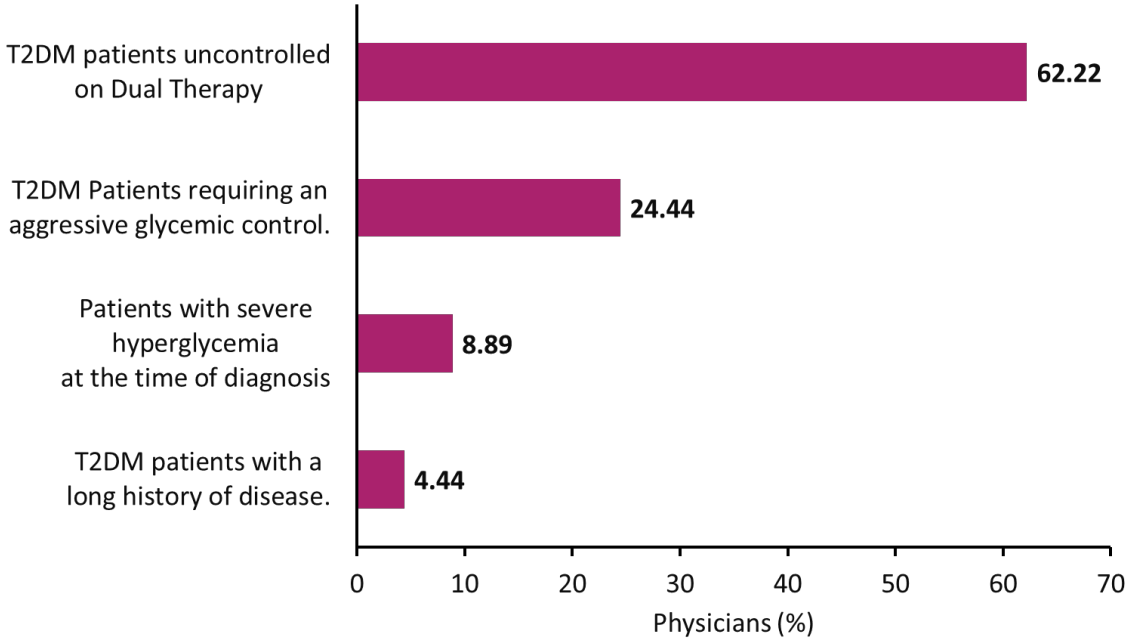
a. <20%
b. 20-30%
c. 30-40%
d. >40%



- The majority (43.82%) of physicians reported that 30-40% of their T2DM patients are on triple therapy.
- A significant portion (26.97%) of physicians stated that 20-30% of their T2DM patients are on triple therapy.
- Around (16.85%) of physicians observed that more than 40% of their T2DM patients are on triple therapy.
- Only a small portion (12.36%) of physicians reported that less than 20% of their T2DM patients are on triple therapy.

[6] In which patient profile would combination of Sitagliptin + Glimepiride + Metformin be preferred? (Can mark more than 1, if necessary)

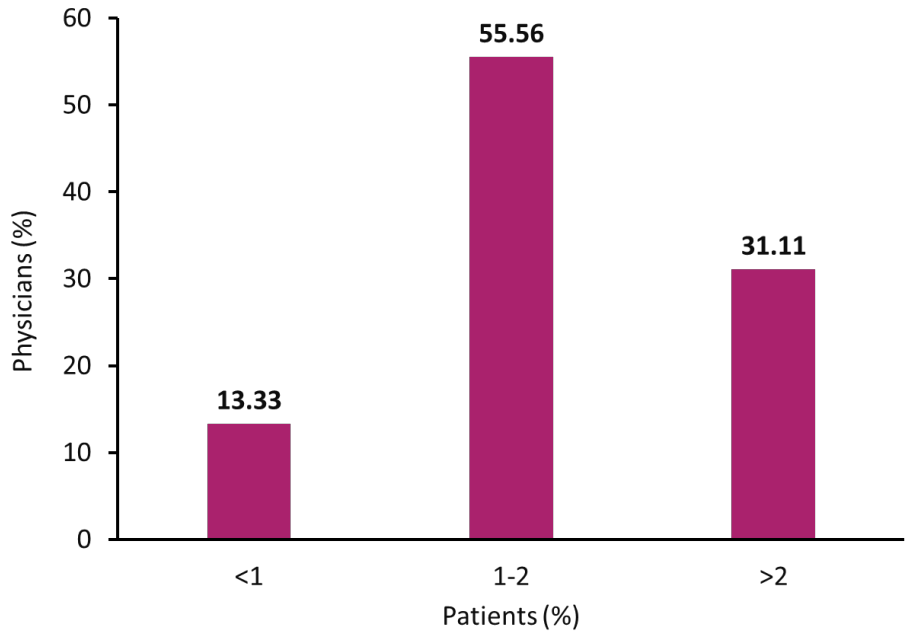
a. T2DM patients uncontrolled on Dual Therapy
b. Patients with severe hyperglycemia at the time of diagnosis
c. T2DM Patients requiring an aggressive glycemic control.
d. T2DM patients with a long history of disease.



- The majority (62.22%) of physicians preferred sitagliptin + glimepiride + metformin combination for T2DM patients who are uncontrolled on dual therapy.
- Around (24.44%) of physicians preferred sitagliptin + glimepiride + metformin combination for T2DM patients requiring aggressive glycemic control.
- A smaller portion (8.89%) of physicians chose this combination for patients with severe hyperglycemia at the time of diagnosis.
- Only a very small portion (4.44%) of physicians preferred it for T2DM patients with a long history of the disease.

[7] What is the expected HbA1c reduction with a combination of Sitagliptin + Glimepiride + Metformin?

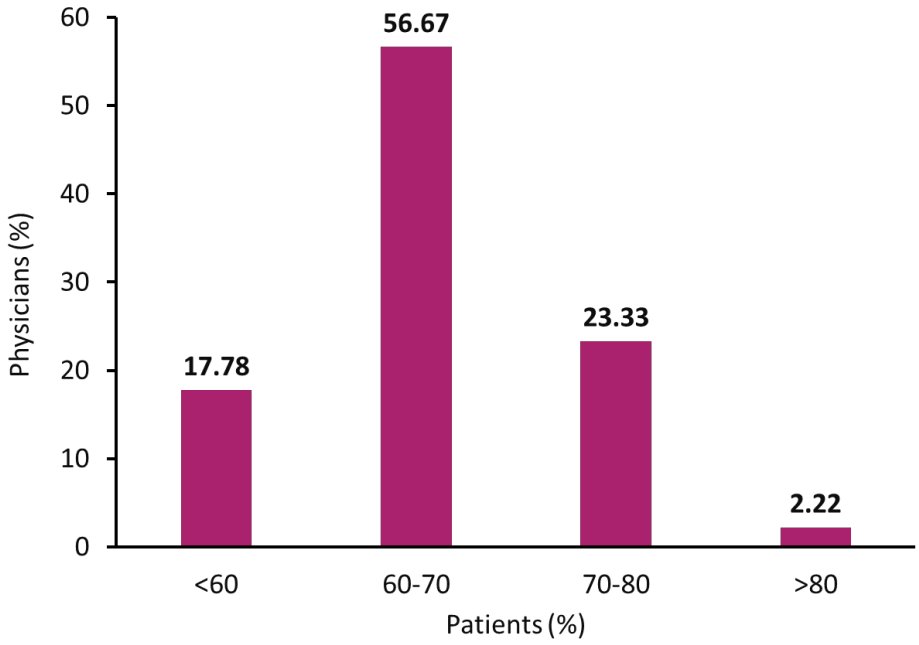
a. <1%
b. 1-2%
c. >2%



- The majority (55.56%) of physicians expected an HbA1c reduction of 1-2% with sitagliptin + glimepiride + metformin combination.
- A significant portion (31.11%) of physicians reported an HbA1c reduction of >2% with sitagliptin + glimepiride + metformin combination.
- A smaller portion (13.33%) of physicians expected an HbA1c reduction of <1% with sitagliptin + glimepiride + metformin combination.

[8] What percentage of patients achieve HbA1c reduction of <7% with a combination of Sitagliptin + Glimepiride + Metformin?

a. <60%
b. 60-70%
c. 70-80%
d. >80%



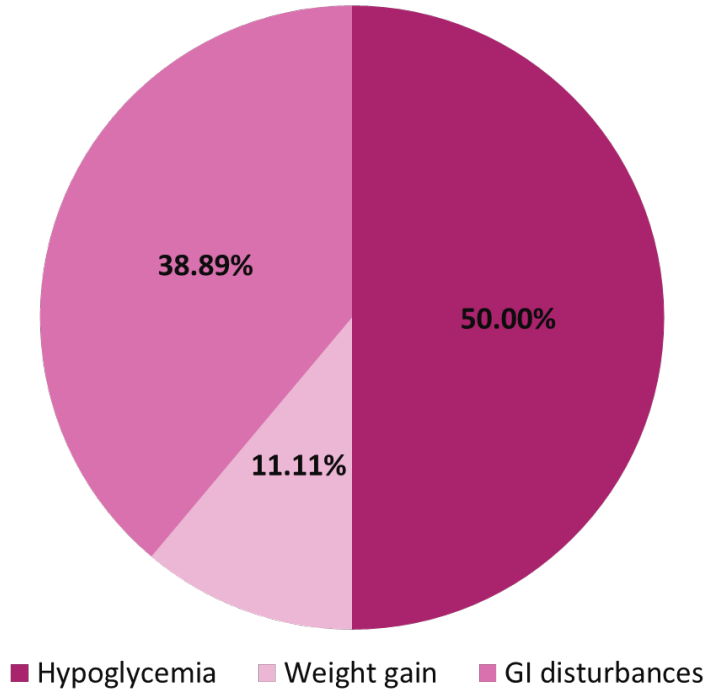
- The majority (56.67%) of physicians reported that 60-70% of patients achieve an HbA1c reduction of <7% with a combination of sitagliptin + glimepiride + metformin.
- A significant portion (23.33%) of physicians observed that 70-80% of patients achieve this HbA1c reduction with a combination of sitagliptin + glimepiride + metformin.
- Around (17.78%) of physicians noted that less than 60% of patients achieve an HbA1c reduction of <7% with a combination of sitagliptin + glimepiride + metformin.
- Only a very small portion (2.22%) of physicians indicated that more than 80% of patients achieve this HbA1c reduction.

[9] What are the side effects associated with the combination of Sitagliptin + Glimepiride + Metformin? (Mark more than 1, if necessary)

a. Hypoglycemia

b. Weight gain

c. GI Disturbances



- The majority (50%) of physicians reported that hypoglycemia is a common side effect associated with a combination of sitagliptin + glimepiride + metformin.
- Around (38.89%) of physicians noted gastrointestinal disturbances as a frequent side effect of the combination of sitagliptin + glimepiride + metformin.
- A smaller portion (11.11%) of physicians observed that weight gain is a side effect of this combination.

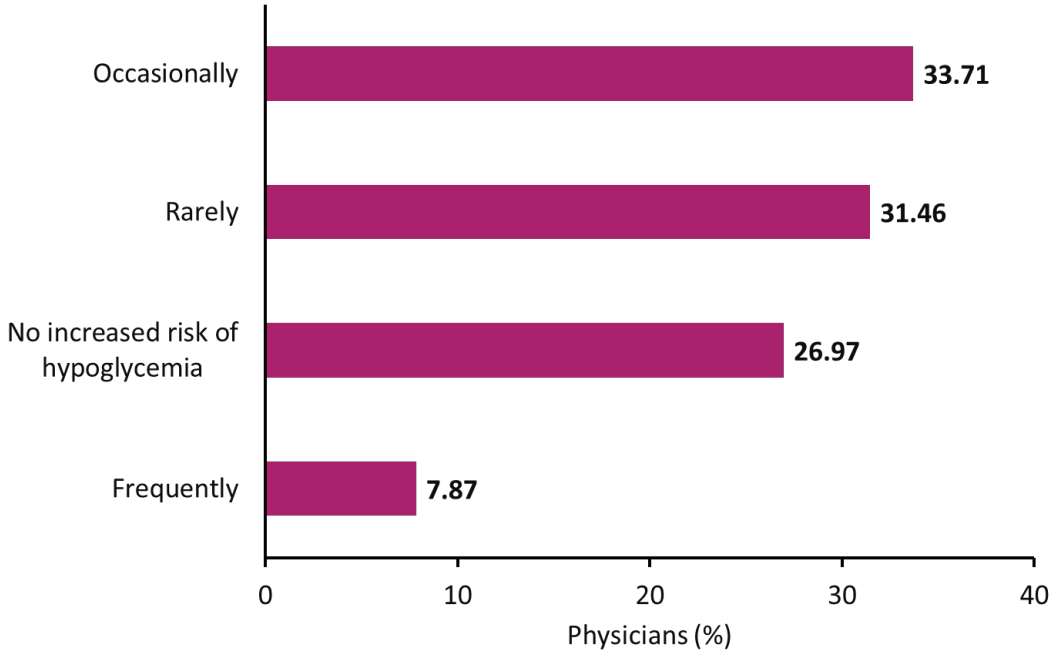
[10] In your experience, how does adding Sitagliptin to a treatment regimen already containing Glimepiride and Metformin affect the risk of hypoglycemia?

a. No increased risk of hypoglycemia

b. Rarely

c. Occasionally

d. Frequently



- Around (33.71%) of physicians reported that adding sitagliptin to a treatment regimen already containing glimepiride and metformin occasionally increases the risk of hypoglycaemia
- A significant portion (31.46%) of physicians stated that the risk of hypoglycemia is rarely increased by adding sitagliptin to a treatment regimen already containing glimepiride and metformin.
- Approximately (26.97%) of physicians noted that there is no increased risk of hypoglycaemia by adding sitagliptin to a treatment regimen already containing glimepiride and metformin.
- Only a very small portion (7.87%) of physicians indicated that the risk of hypoglycemia is frequently increased.

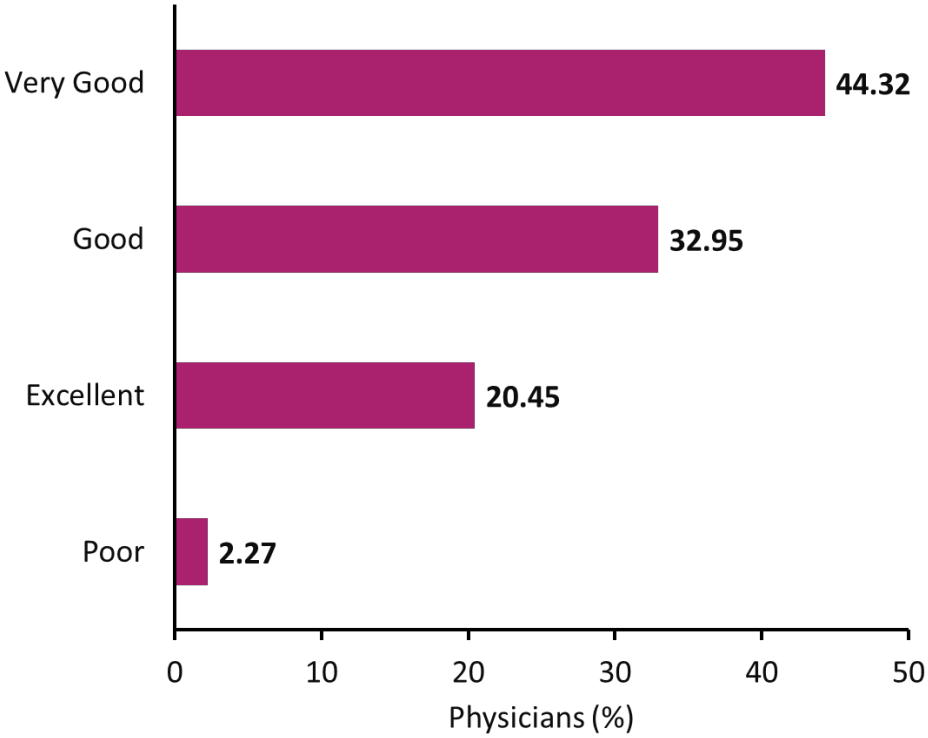
[11] In your opinion, how is the long-term safety profile of Sitagliptin + Glimepiride + Metformin?

a. Excellent

b. Very Good

c. Good

d. Poor



- The majority (44.32%) of physicians reported the long-term safety profile of sitagliptin + glimepiride + metformin combination as very good.
- A significant portion (32.95%) of physicians rated the long-term safety profile of sitagliptin + glimepiride + metformin combination as good.
- A smaller portion (20.45%) of physicians noted the long-term safety profile of sitagliptin + glimepiride + metformin combination as excellent.
- Only a very small portion (2.27%) of physicians rated it as poor.

5. SUMMARY

This survey explored the experiences of 90 physicians regarding the use of sitagliptin + glimepiride + metformin in managing T2DM. The findings revealed that most physicians reported T2DM patients typically present with an HbA1c in the range of 9-11% (46.67%) or 7-9% (44.44%). The combination therapy was most commonly prescribed for uncontrolled T2DM patients on dual therapy (62.22%) and those requiring aggressive glycemic control (24.44%). Physicians commonly expect an HbA1c reduction of 1-2% (55.56%) with this regimen, with 56.67% of patients achieving an HbA1c reduction of <7%. The safety profile of the combination was rated as very good by 44.32% of physicians, with hypoglycemia identified as a common side effect (50%), followed by gastrointestinal disturbances (38.89%) and weight gain (11.11%). A smaller portion (20.45%) rated its long-term safety as excellent, while only 2.27% rated it as poor. Regarding dual therapy, 56.18% of physicians reported 50-60% of patients remain uncontrolled, and about 30-40% of T2DM patients were on triple therapy. Adding sitagliptin to a regimen of glimepiride + metformin occasionally increases the risk of hypoglycemia (33.71%), but a significant portion (31.46%) said it rarely increases this risk. Overall, physicians expressed a favorable view of sitagliptin + glimepiride + metformin, highlighting its effectiveness in controlling blood glucose with manageable side effects, although concerns about hypoglycemia and the need for more aggressive control in certain cases remain.

6. DISCUSSION

The results of this survey provide valuable insights into the prescribing patterns and clinical perceptions of physicians regarding the use of sitagliptin + glimepiride + metformin for managing T2DM. The findings reveal that T2DM patients commonly present with HbA1c levels in the range of 9-11% or 7-9%, which is consistent with the clinical challenge of managing patients who are not well controlled on monotherapy or dual therapy. The majority of physicians report preferring the combination therapy of sitagliptin + glimepiride + metformin for patients who are uncontrolled on dual therapy (62.22%), highlighting its role in managing more complex cases of T2DM. Additionally, the combination is often selected for aggressive glycemic control, particularly in patients who require more intensive treatment, with 24.44% of physicians choosing this regimen for such cases.

The expectation of an HbA1c reduction of 1-2% with this combination reflects the therapeutic efficacy of the regimen, with 56.67% of patients achieving an HbA1c reduction of <7%. This aligns with existing evidence supporting the effectiveness of these agents in controlling blood glucose levels. In terms of safety, the combination was generally well-regarded, with a majority of physicians rating its long-term safety as either very good or good (44.32% and 32.95%, respectively). Hypoglycemia was identified as the most common side effect (50%), followed by gastrointestinal disturbances (38.89%) and weight gain (11.11%). These findings underscore the need for careful monitoring of blood glucose levels, particularly when combining agents like Glimepiride with other drugs that can increase the risk of hypoglycemia.

The survey also indicates that the combination therapy is often used in conjunction with triple therapy for a significant portion of T2DM patients, with 43.82% of physicians reporting that 30-40% of their patients are on triple therapy. Despite its benefits, the data reveal that sitagliptin + glimepiride + metformin is perceived as occasionally increasing the risk of hypoglycemia, but it is rarely considered to pose a significant risk, which highlights the careful balance physicians must strike between efficacy and safety in diabetes management.

Overall, the survey results suggest that sitagliptin + glimepiride + metformin remains a preferred and effective treatment option for many T2DM patients, particularly those who are uncontrolled on dual therapy. Physicians appreciate the combination's efficacy in lowering HbA1c, though concerns about hypoglycemia and gastrointestinal side effects remain important considerations. The safety profile is viewed as generally favorable, but ongoing physician education on managing side effects is crucial for optimizing patient outcomes and adherence.

7. CLINICAL RECOMMENDATIONS

Based on the findings of this survey, several clinical recommendations can be made regarding the use of sitagliptin + glimepiride + metformin in managing T2DM in the Indian healthcare context. The data show that this combination therapy is primarily prescribed for patients who are uncontrolled on dual therapy, with 62.22% of physicians opting for this regimen in such cases. As dual therapy is commonly used in T2DM management when patients fail to achieve adequate glycemic control, sitagliptin + glimepiride + metformin should be considered as a second-line or third-line option for patients who have not responded to initial treatment with either monotherapy or dual therapy.

In terms of efficacy, 55.56% of physicians expect an HbA1c reduction of 1-2% with this combination. Additionally, 56.67% of respondents reported that 60-70% of patients achieve an HbA1c reduction of <7%, suggesting that this combination can be effective for a significant proportion of patients, particularly for those requiring more intensive glycemic control. These results support the clinical utility of the combination as a potent regimen for improving blood sugar levels in patients with inadequately controlled T2DM. However, physicians should be mindful of potential side effects, particularly hypoglycemia, which was reported as a common occurrence by 50% of respondents.

Hypoglycemia remains a significant risk, especially when glimepiride, a sulfonylurea, is combined with Metformin and sitagliptin. It is therefore essential for clinicians to

monitor blood glucose levels closely, particularly in patients who may be at greater risk for hypoglycemic episodes, such as the elderly or those with renal impairment. Patient education should be a priority, ensuring patients are aware of the symptoms of hypoglycemia and how to prevent or manage it. Physicians should also monitor for other potential side effects, including gastrointestinal disturbances (38.89%) and weight gain (11.11%), which were noted by respondents, especially in patients on Metformin.

The long-term safety of the combination was rated as very good or good by the majority of respondents (76.27%), indicating that it is generally well-tolerated when appropriately prescribed. Clinicians should take a holistic approach to patient management, considering factors such as the duration of T2DM, renal function, and comorbid conditions, when prescribing this regimen. For patients with a long-standing history of diabetes or those with more severe disease, this combination may be particularly beneficial.

Additionally, sitagliptin + glimepiride + metformin was frequently recommended for triple therapy in 30-40% of patients. This suggests its use in patients who are struggling to control their blood sugar with two agents, providing an effective and well-tolerated option for more intensive therapy.

In conclusion, sitagliptin + glimepiride + metformin is an effective and safe combination for managing uncontrolled T2DM, but it requires careful monitoring and individualized treatment plans. Physicians should assess the risks of hypoglycemia and other side effects, educate patients on potential issues, and regularly review patient responses to therapy to ensure optimal outcomes.

8. CONSULTING OPINION

The survey findings provide valuable insights into the use sitagliptin + glimepiride + metformin in managing T2DM in India, highlighting several opportunities for growth in the market. A significant portion of physicians (62.22%) prefer this combination for patients uncontrolled on dual therapy, indicating its importance as a treatment option for those needing more intensive glycemic control. Additionally, the combination's

ability to reduce HbA1c by 1-2% (reported by 55.56% of physicians) and achieve an HbA1c <7% in 56.67% of cases underscores its efficacy.

However, hypoglycemia (reported by 50% of physicians) remains a common concern, suggesting a need for education campaigns that focus on managing this risk. Pharmaceutical companies could also explore patient support tools—such as mobile apps for monitoring blood glucose—to help prevent hypoglycemic episodes and improve treatment adherence.

Side effects such as gastrointestinal disturbances (38.89%) and weight gain (11.11%) were also noted, presenting an opportunity for further research into more tolerable formulations or combination therapies. Developing solutions to mitigate these side effects could enhance patient satisfaction and adherence. Moreover, the fact that 43.82% of physicians report 30-40% of their T2DM patients are on triple therapy suggests significant potential for expanding the use of this combination. Companies could leverage the existing familiarity and trust in Glimepiride and Metformin to promote this combination more widely.

Overall, the findings suggest that sitagliptin + glimepiride + metformin has strong potential for broader adoption. Focused education for healthcare providers, patient support programs, and formulation innovations to address side effects will be key strategies for expanding its use in India's T2DM management landscape.

9. MARKET OPPORTUNITIES

The rising prevalence of T2DM in India, coupled with the growing need for effective and well-tolerated treatment options, presents significant market opportunities for the combination of sitagliptin + glimepiride + metformin. As T2DM continues to affect an increasing number of individuals in India, particularly in urban populations, the demand for effective therapeutic regimens to control blood glucose and prevent complications is higher than ever. The survey findings indicate that sitagliptin + glimepiride + metformin is favored by a significant number of physicians, with 62.22% preferring it for patients uncontrolled on dual therapy and 43.82% using it in

30-40% of their T2DM patient population. This preference underscores the growing confidence in this combination's ability to provide comprehensive glycemic control.

Additionally, the combination's potential to reduce HbA1c by 1-2% (reported by 55.56% of physicians) and achieve an HbA1c <7% in 56.67% of patients makes it a strong contender in the Indian market, where achieving optimal glycemic control is a key treatment goal. Furthermore, the high usage of glimepiride (91.11%) and metformin (the foundation of this combination) across the surveyed population suggests that physicians are already familiar and comfortable with these drugs, facilitating the integration of sitagliptin as a complementary addition to treatment regimens.

The survey also revealed concerns about hypoglycemia, a common side effect reported by 50% of physicians. This presents an opportunity for pharmaceutical companies to develop educational campaigns addressing how to manage and mitigate these risks, ensuring physicians feel more confident when prescribing the combination. The market opportunity extends beyond just the prescription of sitagliptin + glimepiride + metformin. With 56.18% of physicians indicating that 50-60% of T2DM patients remain uncontrolled on dual therapy, there is a clear need for more triple therapy options. As sitagliptin + glimepiride + metformin is positioned as a preferred choice for triple therapy, it is well-placed to meet this demand.

To capitalize on these trends, stakeholders in the pharmaceutical industry should focus on expanding physician education, patient adherence programs, and innovative formulations that address side effects like gastrointestinal disturbances and weight gain. By leveraging the growing need for more effective, personalized treatment solutions for T2DM, the combination of sitagliptin + glimepiride + metformin has the potential to become a cornerstone of diabetes management in India, improving patient outcomes and quality of life.

10. MARKET POSITIONING

The combination of sitagliptin + glimepiride + metformin is strategically positioned to address the growing demand for effective, comprehensive treatment options for T2DM in India. As the country faces a rising burden of diabetes, particularly in urban populations, this combination offers a balanced approach to managing the condition, targeting multiple pathways of glucose regulation. Metformin, a cornerstone in diabetes therapy, combined with sitagliptin, a DPP-4 inhibitor, and Glimepiride, a sulfonylurea, provides a synergistic effect in improving glycemic control for patients who are not adequately managed on dual therapy.

The survey results reflect a strong preference for this combination, with 62.22% of Indian physicians choosing it for T2DM patients uncontrolled on dual therapy. This highlights its role as a key solution for patients who have not achieved adequate glycemic control with metformin and other oral agents. Additionally, 43.82% of physicians report using it for 30-40% of their T2DM patient population, suggesting its wide application in clinical practice for patients requiring more intensive glucose-lowering strategies.

Sitagliptin + glimepiride + metformin stands out for its ability to reduce HbA1c levels by 1-2% (reported by 55.56% of physicians) and achieve HbA1c <7% in 56.67% of patients, making it an effective option in achieving tight glycemic control, a critical goal in preventing the long-term complications of diabetes. Moreover, the combination's well-established safety profile and its ability to be used across diverse patient populations, including those at risk for hypoglycemia and weight gain, give it a distinct advantage in the market.

The increasing preference for triple therapy (with 43.82% of physicians using it in their practices) further bolsters its positioning as a go-to solution for T2DM patients who require more aggressive treatment. However, the potential for managing hypoglycemia and gastrointestinal disturbances- common concerns with this

combination- presents an opportunity for pharmaceutical companies to focus on education and patient management strategies.

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