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Review Article

Consensus of expert through Indian perspective on the fixed-dose combination dapagliflozin and linagliptin combination in type 2 diabetes mellitus: CONSEPDT study

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ABSTRACT

Effective management of type 2 diabetes mellitus (T2DM) increasingly demands a shift from a glucose-centric model to a comorbidity-centric approach, particularly in populations with high cardio-renal risk profiles. The fixed-dose combination (FDC) of dapagliflozin, a sodium-glucose co-transporter-2 inhibitor (SGLT2i), and linagliptin, a dipeptidyl peptidase-4 inhibitor (DPP4i), presents a synergistic, safe, and effective treatment option for patients with complex comorbidities. This combination not only improves glycemic control but also offers pleiotropic benefits, such as weight neutrality and reduced risk of hypoglycemia. Despite robust clinical evidence supporting its efficacy and safety, the absence of standardized, region-specific guidelines has led to inconsistent adoption in clinical practice across India. A consensus tailored to Indian clinical settings is necessary to ensure rational, evidence-based, and uniform use of this FDC. Such a framework will assist healthcare providers in making informed decisions, improving adherence, minimizing complications, and ultimately enhancing patient outcomes. The consensus aims to harmonize diabetes management by incorporating global evidence into local clinical practice.

Keywords: Type 2 diabetes mellitus, Dapagliflozin-linagliptin fixed-dose combination, Cardiorenal protection, Expert consensus (India)

INTRODUCTION

India holds the second highest number of individuals affected by T2DM globally, with an estimated 77 million people diagnosed with the condition. The Indian Council of Medical Research-India Diabetes (ICMR-INDIAB) epidemiological study indicates a growing prevalence of T2DM in both urban and rural regions. The incidence of T2DM is particularly high in the 25 to 34-year age group, indicating a changing age distribution of diabetes in India.[1]

T2DM is a progressive metabolic disorder characterized by chronic hyperglycemia, which, if left uncontrolled, significantly increases the risk of cardiovascular disease (CVD) and chronic kidney disease (CKD). Effective glycemic control is essential, but the presence of comorbid conditions such as heart failure, renal impairment, and other metabolic abnormalities complicates disease management. These overlapping cardio-renal-metabolic (CRM) risks not only elevate morbidity and mortality but also necessitate a comprehensive, patient-centered approach. Modern management strategies emphasize the use of evidence-based therapies SGLT2i and DPP4i addresses both glycemic control and organ protection. Additionally, individualized treatment plans must consider the risk of hypoglycemia, patient comorbidities, and the need for multidisciplinary care to optimize outcomes.

Linagliptin is a highly effective DPP4i that lowers the risk of hypoglycemia by controlling glucagon secretion and enhancing prandial insulin secretion, as demonstrated in studies. SGLT2i like dapagliflozin promote the excretion of glucose through urine by obstructing the renal reabsorption of glucose, which ultimately results in a decrease in plasma glucose levels. The combination therapy with linagliptin and dapagliflozin have demonstrated good efficacy and safety in patients with T2DM who do not achieve adequate glycemic control with metformin alone with better cardiovascular and renal benefits.[2]

Need for consensus

A paradigm shift from a traditional glucose-centric approach to a more comprehensive, "comorbidity-centric" strategy is essential for optimizing glycemic control and ensuring cardio-renal protection in the management of T2DM.[3] The FDC of SGLT2i and DPP4i provides both glycemic and pleiotropic effects including lower risk of hypoglycemia and weight neutral.[4]

The combination of linagliptin and dapagliflozin offers a synergistic, safe, and effective approach to managing T2DM, especially in patients with complex comorbidities. However, the lack of standardized guidelines leads to inconsistent use. A consensus statement is tailored to regional needs and supported by clinical evidence which would help to optimize outcomes, prevent diabetes-related complications, reduce side effects, improve adherence, and ensure rational use of these therapies. Establishing a consensus will aid clinicians in making informed decisions, ensuring standardized care, and improving patient outcomes across diverse clinical settings in India.

STUDY DESIGN

The expert opinion for this study was obtained through a modified Delphi process. The process began with the development of a structured questionnaire by the steering committee, which was formed based on members' clinical experience and research expertise. The committee conducted extensive literature research on dapagliflozin and linagliptin to formulate 26 key statements for expert evaluation. This questionnaire was then distributed to a multidisciplinary panel of 93 experts, comprising 59 endocrinologists, 17 nephrologists, 12 cardiologists, 3 diabetologists, and 1 consultant physician. Each expert was asked to rate the statements using a 5-point Likert scale: strongly agree, agree, neutral, disagree, or strongly disagree. Following the survey, 7 advisory board meetings were held with the steering committee to discuss the results and finalize the consensus statements. A statement was considered to have reached consensus if over 70% of the panelists either agreed or strongly agreed with it. Ethics approval was obtained for the same from ACEA, an independent ethics committee based in Ahmedabad under project number LU/02/240525.

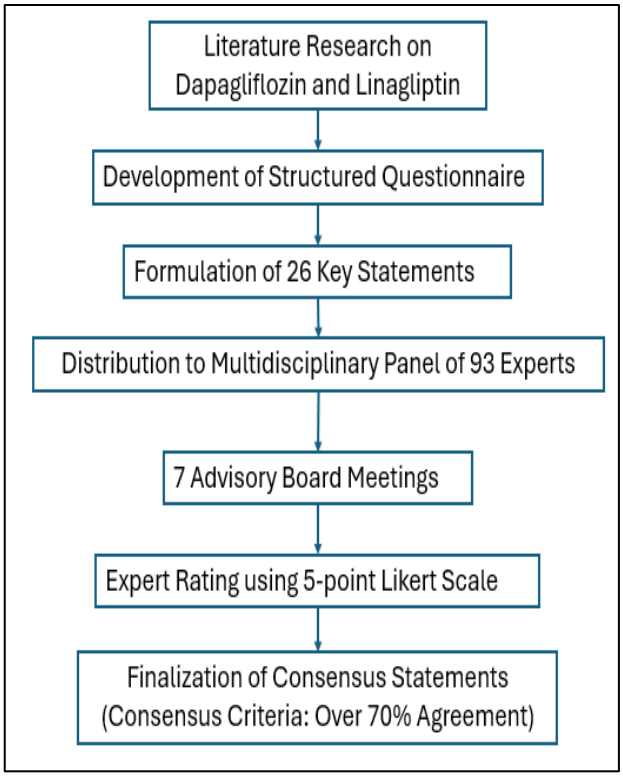

Figure 1: Methodology flowchart.

The questionnaire addressed specific issues, such as: Addressing the burden of T2DM in India and screening strategies for T2DM. Early intervention with combination therapy of dapagliflozin/linagliptin FDC.

Dapagliflozin/linagliptin in cardiovascular outcomes and hospitalization rates. Dapagliflozin/linagliptin in renal and metabolic benefits. Dapagliflozin/linagliptin in special populations and considerations and benefits of triple combination of Dapagliflozin and linagliptin as an add on to metformin

BURDEN OF T2DM AND SCREENING STRATEGIES OF T2DM

Expert opinion: burden, screening and need for early intervention

Rising T2DM prevalence

Experts (78.26%) concur on the escalating T2DM burden in India, particularly among individuals over 30, necessitating urgent public health strategies.

Routine screening advocacy

A significant majority (86.95%) of expert's advocate for routine screening of T2DM in adults aged 30 and above, emphasizing early detection to facilitate timely interventions.

Comprehensive screening approach

Experts recommend a multifaceted screening strategy that combines clinical assessments with biochemical parameters to ensure early diagnosis and effective management of T2DM.

HbA1c and complication risks

Elevated HbA1c levels are linked to increased risks of vascular complications; each 1% rise in HbA1c is associated with a 38% higher risk of macrovascular events, 40% higher risk of microvascular events, and 38% higher risk of death.

Increased cardiovascular risk

Individuals with T2DM have a 2-4 times higher risk of CVD, which account for about half of all deaths globally.

Early intervention and combination therapy

Initiating early and effective combination therapies is crucial to mitigate disease progression and reduce the risk of comorbidities. Economic considerations, including the cost and availability of pharmacological interventions, significantly influence therapeutic decisions. A balanced approach that optimizes clinical outcomes while ensuring affordability is essential.

Evidence

The international diabetes federation (IDF) estimates that 589 million adults (20-79 years) were living with diabetes globally in 2024, representing 1 in 9 adults. This number is projected to rise to 853 million by 2050, according to the IDF diabetes Atlas. Additionally, an estimated 252 million people worldwide are unaware they have diabetes.[5] India is home to approximately 89.8 million adults living with diabetes, making it the country with the second-highest number of diabetes cases globally, with projections indicating a rise to 156.7 million by 2050. Diabetes mellitus is an iceberg disease in India with nearly 57% of adults (43.9 million) undiagnosed.[6]

EARLY INTERVENTION WITH COMBINATION THERAPY OF DAPAGLIFLOZIN/LINAGLIPTIN FDC

Expert opinion: combination therapy with dapagliflozin and linagliptin

The 84.78% agreed on initiating newer generation SGLT2i along with DPP4i in a fixed dose combination based on the patient's individual glycemic control.

The 86.95% agreed on value of Dapagliflozin/Linagliptin FDC as an early treatment option for managing treatment-naïve type 2 diabetes patients with HbA1c >8.5%, where metformin is contraindicated or intolerant.

Experts agreed on the complementary action of Dapagliflozin and Linagliptin, offering superior glycemic control with added metabolic and cardiovascular benefits.

Experts highlighted that Linagliptin is preferred among DPP4 inhibitors for its once-daily dosing, no dose adjustments in renal/ hepatic impairment and sustained efficacy.

Experts noted that linagliptin-monotherapy can achieve HbA1c reductions of 0.7% to 0.9%.

The 82.60% agreed on initiating Dapagliflozin/Linagliptin FDC early, in addition to metformin, for managing type 2 diabetes in patients with HbA1c >8.5%.

Evidence

Early adoption of combination therapy must be initiated as a strategic approach to mitigate the onset of complications in T2DM patients.[7] Multiple studies including UKPDS, ADVANCE, diabetes and aging study highlight the importance of early and intensive treatment in newly diagnosed patients with T2DM to maximize long-term protection, known as "legacy effect".[4] Hong et al in a clinical study showed that the combination resulted in significant reductions in HbA1c levels.[8] The American diabetes association (ADA) 2025, American association of clinical endocrinology (AACE) 2023, European society of cardiology (ESC) 2023 and research society for study of diabetes in India (RSSDI) guidelines recommend early combination therapy for CV and renal protection in patients with T2DM.[3,9,10]

RSSDI 2022 GUIDELINES

In some cases, dual therapy may be indicated initially if it is considered unlikely that single agent therapy will achieve glucose targets/to extend time to treatment failure.

Dual therapy: Patient-centric approach - If glucose control targets are not achieved: Add SGLT2i or DPP4i or SU or TZDs or SGLT2i, AGI or oral GLP1-RA. Individualize patient care based on comorbidities. Triple/Quadruple therapy: Patient-centric approach.[11]

Table 1: Overview of clinical efficacy of dapagliflozin/linagliptin.

Authors and years	Design	Inclusion criteria	Intervention	Results
Dharmalingam et al, 2024[12]	Multicenter, randomized, double-blind, active-controlled, parallel-group, phase III clinical study 18 weeks	-Age ≥18 to ≤65 years -Diagnosis of T2DM -BMI≥45.0 kg/m^2	Treatment A: Dapagliflozin 10 mg + Linagliptin 5 mg Treatment B: Dapagliflozin 10 mg + Vildagliptin SR 100 mg	HbA1c reduction: Dapagliflozin/linagliptin: -1.59%, Dapagliflozin/vildagliptin: -1.25% (p<0.0001) PPBG reduction: Dapagliflozin/linagliptin: -59.99 mg/dL, Dapagliflozin/vildagliptin: -55.34 mg/dL FPG reduction: Dapagliflozin/linagliptin: -32.91 mg/dL, Dapagliflozin/vildagliptin: -26.78 mg/dL Compared to dapagliflozin and vildagliptin combination therapy, dapagliflozin and linagliptin FDC significantly improved glycemic control.
Hong et al, 2024[8]	Multicenter, randomized, double-blind, parallel-group, placebo-controlled phase III study	7% ≤HbA1c ≤10.5%	Dapagliflozin +linagliptin 10/5 mg/day (n=117) Linagliptin 5 mg + placebo (n=118)	- HbA1c reduction: Dapagliflozin+linagliptin: 7.93%±0.82% to 7.11%±0.61%. Control: 7.80%±0.71% to 7.87%±0.94%. Difference: -0.88% (95% CI: -1.07 to -0.68; p<0.0001) Patients achieving HbA1c <7.0%. Dapagliflozin +linagliptin: 44.8%. Control: 18.6% (p<0.001) Dapagliflozin and linagliptin FDC showed potent glucose-lowering effects
Ahmad et al, 2024 [13]	Randomized double-blind study	T2DM patients on stable dose of metformin	Group 1: Dapagliflozin 10 mg+Linagliptin 5 mg Group 2: Linagliptin	-Dapagliflozin+ Linagliptin group experienced a mean decrease of 1.36% of HbA1c (±0.05%). -There was a reduction of 25.90 (±1.23) % in FPG from baseline. -A decrease of 52.41 (±2.29) % in PPG was observed -A modest weight loss was noted, with least squares mean decrease of 1.34 kg (±0.07 kg). Dapagliflozin-Linagliptin combination provided superior glycemic control with good tolerability
Kumthekar et al, 2025[14]	Phase 3, prospective, randomized, double-blind, multicenter study	-Patients with T2DM -Stable dose of metformin ≥1000 mg/day as monotherapy	Arm A: Dapagliflozin 10 mg + Linagliptin 5 mg Arm B: Linagliptin 5 mg	HbA1c reduction: -1.28% (combination) vs. -0.83% (linagliptin); p=0.0003 FPG reduction: -26.94 mg/dL (combination) vs. -21.59 mg/dL (linagliptin); p=0.0003 PPG reduction: -49.16 mg/dL (combination) vs. -29.14 mg/dL (linagliptin); p=0.0022 Body wt reduction: -1.06 kg (combination) vs. -0.54 kg (linagliptin); p=0.0253 FDC of dapagliflozin 10+linagliptin 5 mg was superior to linagliptin 5 mg in terms of efficacy
Jain et al, 2024[2]	Double-blind, randomized, multicentric, parallel-group phase III trial	-Patients with T2DM -Age 18-65 years -HbA1c 7.5-10.5% -On ≥1000 mg/day of metformin monotherapy	Dapagliflozin 10 mg+ linagliptin 5 mg (Test group, n=115) Linagliptin 5 mg (Reference group, n=110)	Greater decrease in HbA1c with dapagliflozin/linagliptin (-1.28%) vs linagliptin (-0.83%) (p=0.0003, p<0.0001 respectively). FPG and PPG showed significant reductions in the test group compared to reference group. Greater reduction in test group vs reference group FDC of dapagliflozin/linagliptin demonstrated superior glycemic control, weight reduction, and tolerability compared to linagliptin alone.

*BMI: Body mass index; FDC: Fixed-dose combination; FPG: Fasting plasma glucose; HbA1c: Glycated hemoglobin; OCP: Oral contraceptive pill; PPBG: Postprandial blood glucose; PPG: Postprandial glucose; SR: Sustained release; T2DM: Type 2 diabetes mellitus

CARDIOVASCULAR (CV) BENEFITS AND RENAL IMPAIRMENT

Expert opinion on cardiovascular benefits and renal impairment

The 90.21% agreed on Dapagliflozin/Linagliptin FDC reducing the risk of MACE and/or HF hospitalization in T2DM patients with ASCVD risk, especially those with established CKD.

The 86.95% agreed on dual therapy with Dapagliflozin and Linagliptin reducing UACR in obese and non-obese T2DM patients with microalbuminuria, particularly when ASCVD or CKD is present.

The 72.00% agreed on the FDC of Dapagliflozin/Linagliptin (SGLT2i/DPP-4i) effectively lowering SBP in T2DM patients on other antihypertensives, especially in ASCVD/CKD, while also improving lipid parameters in those at risk of DLP.

The 86.95% agreed on Dapagliflozin and Linagliptin dual therapy reducing MACE and/or HF hospitalization rates in T2DM patients with established ASCVD, as part of CKD prevention.

The 91.30% agreed on Dapagliflozin/Linagliptin FDC reducing CKD progression and cardiovascular events in T2DM patients with an eGFR ≥20 mL/min/1.73 m² and urinary albumin ≥200 mg/g creatinine, without requiring dose adjustment.

In patients with nephropathy, experts preferred a stepwise approach with dapagliflozin/Linagliptin, prioritizing safety over rapid intensification.

Evidence

Heart failure is a common initial manifestation of CVD and stroke is the second most frequent cause of death in T2DM patients. [16] The management of T2DM is shifting from a pure glucocentric view into the present CRM outcome-oriented approach. The different interventions for cardio-renal protection should be carefully selecting the best regimen for the patient with T2DM.

ADA 2025[15]

"SGLT2i show CVD benefit in patients with T2DM and established ASCVD or indicators of high CV risk, established kidney disease, or HF".

"Patients with T2DM and established ASCVD, multiple ASCVD risk factors, or diabetic kidney disease (DKD), an SGLT2i with demonstrated CV benefit is recommended to reduce the risk of MACE and/or HF hospitalization".[17]

AACE 2023 guidelines: "In established or high risk for ASCVD, heart failure [HF], and/ or CKD, clinicians should prescribe a SGLT2i or GLP1-RA with proven efficacy for the specific condition(s)" independent of glycemic control".[3]

RSSDI 2022

"For patients with established or having high risk for ASCVD, heart failure, diabetic kidney disease (DKD) or in need of weight reduction consider using SGLT2i. In elderly patients with increased risk of hypoglycemia, use a DPP-4 inhibitor as an alternative to sulfonylureas. In patients with renal impairment, preference of therapy would be SGLT2i or DPP4i as add on therapy with metformin.[18]

The 2023 Focused Update of the 2021 ESC Guidelines recommend "SGLT2 inhibitors (Dapagliflozin or Empagliflozin) to reduce the risk of HF hospitalization or CV death in patients with HFpEF or HFmrEF.[10]

The renal benefits of SGLT2i therapy include the alleviation of albuminuria and the mitigation of the deterioration of kidney function.[4] In the dapagliflozin and prevention of adverse outcomes in DAPA-CKD trial, Dapagliflozin significantly reduced the risk of decline in the estimated GFR of at least 50%, end-stage kidney disease, or death from renal causes (HR=0.56, p<0.001); CV death or hospitalization for HF (HR=0.71, p=0.009); and all-cause mortality (HR=0.69, p=0.004) in patients with CKD, irrespective of T2DM.[19]

DPP-4i have been shown to be associated with no further decline in estimated glomerular filtration rate (eGFR) in patients with CKD.[4] The CARMELINA trial showed that linagliptin did not lead to increased risk of progression to end-stage kidney disease or death due to kidney disease. The kidney outcome (time to first occurrence of adjudicated death due to renal failure, ESRD, or sustained 40% or higher decrease in eGFR from baseline) were similar in linagliptin and placebo group (HR, 1.04; 95% CI, 0.89-1.22; p=0.62).[20]

In the DAPA-advKD trial, patients with advanced CKD (eGFR 10-30 mL/min/1.73 m²) and evidence of rapid progression were randomized to receive dapagliflozin (5-10 mg daily) plus integrated CKD care or CKD care alone. Over a median follow-up of 1.62 years, dapagliflozin significantly slowed the rate of eGFR decline and reduced the risk of key renal outcomes, including renal replacement therapy, substantial eGFR decline, and renal or cardiovascular death. The combination of renal and cardiovascular composite outcome was also significantly lower in the dapagliflozin group. While a transient eGFR dip was more common with dapagliflozin, the incidence of acute kidney injury and heart failure was higher in the control group. There were no significant differences in major cardiovascular events or electrolyte disturbances. These findings support the use of dapagliflozin in patients with stage 4-5 CKD, even when initiated at lower eGFR levels.[21]

HEPATIC IMPAIRMENT

Expert opinion: patients with renal or hepatic impairment

The 90.21% agreed on the safe use of Dapagliflozin/Linagliptin FDC in T2DM patients with mild-to-moderate hepatic impairment, without any dose adjustment.

SAFETY

Expert opinion on safety

The 77.18% agreed that the dual combination of Dapagliflozin and Linagliptin lowers the risk of genitomycotic infection in patients with T2DM.

The 91.30% agreed that the combination of Dapagliflozin and Linagliptin can be used in obese patients with diabetes without an increased risk of hypoglycemia.

The 70.65% agreed that dual therapy with Dapagliflozin and linagliptin decreased the risk of AF/AFL events in high-risk patients with T2DM.

The 75.00% agreed that dual therapy with Dapagliflozin and linagliptin decreased the risk of recurrent PCI followed by acute events in post-PCI patients with T2DM, and this combination can be used as secondary prevention.

Evidence

Role in GTI (genital tract infections)

The relative risk of GTI is lower with SGLT2i and DPP4i combination compared to only SGLT2i regimen.[4] Although the mechanisms whereby DPP4i might reduce this SGLT2i-associated risk are still highly speculative, the additional benefit of DPP4i reducing the risk of genital infections in fact strengthens the rationale for SGLT2i/DPP4i combination therapy.[22] Patient counselling has an important impact on medication adherence and quality of life (QOL) in patients with recurrent UTI. Early reporting of UTI symptoms leads to early treatment, reduced burden of infection, lower morbidity and mortality.[4]

Role in PCI (Percutaneous coronary intervention)

A single-centre retrospective analysis study (n=786) in patients with AMI undergoing PCI showed that Dapagliflozin reduced MACE in patients with AMI, particularly in patients with advanced age and hypertension and in those who did not receive ARNI. Moreover, the study revealed that DAPA administration significantly decreased AIP and the TyG index 12 months after discharge. Thus, Dapagliflozin is an independent protective factor against MACE and may provide incremental prognostic information in patients with AMI undergoing PCI.[23]

Role in adverse events

A phase III study included patients with inadequate response to metformin (≥1000 mg/day) plus linagliptin (5 mg/day) were randomized to receive either FDC (dapagliflozin/linagliptin 10/5 mg/day, n=117) or linagliptin 5 mg plus placebo (n=118) for 24 weeks. Among the 234 patients in the safety set, treatment-emergent adverse events (TEAEs) occurred in 20.5% of the FDC group and 21.2% of the linagliptin plus placebo group, with no significant difference (p=0.8989). The incidence of adverse drug reactions, serious adverse events, and trial discontinuations was comparable. Gastrointestinal and nervous system disorders were the most common TEAEs in the FDC group, while hyperglycemia was most frequent in the control group. No symptomatic hypoglycemia was reported. Discontinuation due to AEs occurred in two FDC patients (dyspepsia, hyperhidrosis) and one control patient (cardiac failure).[17]

TRIPLE COMBINATION

Expert opinion on triple combination

The 86.95% agreed that in drug-naïve patients with ASCVD risk, Metformin/Dapagliflozin/Linagliptin FDC is a valuable early treatment option for managing type 2 diabetes with HbA1c >8.5%.

The 84.78% agreed that triple drug therapy of Metformin/Dapagliflozin and linagliptin reduces the risk of MACE and/or HF hospitalization rates in T2DM patients with left ventricular ejection fraction less than 40% (HFrEF).

The 90.21% agreed that triple drug therapy of Metformin/Dapagliflozin and linagliptin reduces the risk of MACE and/or HF hospitalization rates in T2DM patients with left ventricular ejection fraction more than 40% (HFmrEF).

The 92.40% agreed that triple drug therapy of Metformin/Dapagliflozin and linagliptin reduces the risk of MACE and/or HF hospitalization rates in T2DM patients with left ventricular ejection fraction more than 50% (HFpEF).

The 85.87% agreed that Metformin/Dapagliflozin/Linagliptin FDC can be initiated in patients with T2DM and CKD (eGFR >45 mL/min/1.73 m2) without any dose adjustment.

Evidence

The FDC of dapagliflozin 10 mg and linagliptin 5 mg was added to patients with T2DM who were inadequately controlled on a stable dose of metformin. Metformin

therapy continued throughout the study. After 16 weeks, the addition of the FDC resulted in significantly greater reductions in HbA1c (-1.35% vs. -0.92%; p≤0.0001), fasting plasma glucose (-26.13 mg/dL vs. -22.59 mg/dL; p=0.0492), 2-hour postprandial plasma glucose (-52.29 mg/dL vs. -30.35 mg/dL; p≤0.0001), and body weight (-1.32 kg vs. -0.42 kg; p≤0.0001) compared to linagliptin monotherapy. The FDC group also had a higher proportion of patients achieving HbA1c <7.0% (42.24% vs. 22.41%; p=0.0012).[24]

Table 2: Expert consensus statements.

S. no.	Statements
1.	The choice of initiating newer generation dapagliflozin along with linagliptin in a fixed dose combination should be based on the patient's individual glycemic control.
2.	Dapagliflozin/Linagliptin FDC in should be initiated early in addition to metformin for managing type 2 diabetes in patients with HbA1c >8.5%.
3.	Dapagliflozin/Linagliptin FDC is a valuable early treatment option for managing treatment-naïve type 2 diabetes patients with HbA1c >8.5%, where metformin is contraindicated or intolerant.
4.	Dapagliflozin/Linagliptin FDC reduces the risk of MACE and/or HF hospitalization rates in T2DM patients with a risk of ASCVD, especially those with established CKD.
5.	Dual therapy with Dapagliflozin and linagliptin reduces UACR in both obese and non-obese patients with T2DM and microalbuminuria, especially when ASCVD/CKD is present.
6.	The FDC of Dapagliflozin/Linagliptin (SGLT2i/DPP-4i) effectively lowers SBP in T2DM patients with HTN on other AHTs, particularly in ASCVD/CKD, while also improving TC, HDL, and apo-A in those at risk of DLP.
7.	Dual combination of Dapagliflozin and Linagliptin lowers the risk of Genito -Mycotic infection in patients with T2DM.
8.	Dual therapy of Dapagliflozin and linagliptin decreased the risk of AF/AFL events in high-risk patients with T2DM.
9.	Dual therapy of Dapagliflozin and linagliptin decreased the risk of recurrent PCI followed by acute events in post-PCI patients with T2DM and the combination can be used as secondary prevention.
10.	In drug-naïve patients with ASCVD risk, Metformin / Dapagliflozin/Linagliptin FDC is a valuable early treatment option for managing type 2 diabetes with HbA1c >9 %.
11.	Triple drug therapy of Metformin/Dapagliflozin and linagliptin reduces the risk of MACE and/or HF hospitalization rates in T2DM patients across varying degrees of reduced and preserved left ventricular ejection fraction (less than 40% HFrEF, more than 40% HFmrEF, and more than 50% HFpEF respectively)
12.	Metformin/Dapagliflozin/Linagliptin FDC can be initiated in patients with T2DM and CKD (eGFR>45 mL/min/1.73 m^2) without any dose adjustment.

CONCLUSION

The CONSensus of Expert through Indian Perspective on the FDC Dapagliflozin and Linagliptin combination in T2DM: CONSEPDT study consensus brings together expert opinions from across India to assess the use of the FDC of dapagliflozin and linagliptin in managing type 2 diabetes. Based on clinical experience and current evidence, the experts agree that this combination offers a practical and effective treatment choice for a wide range of patients. Its ability to lower blood sugar without causing weight gain or hypoglycemia, along with added cardiorenal benefits, makes it especially valuable in the Indian setting, where patients often face early disease onset and multiple risk factors. Initiating early linagliptin and linagliptin based combination therapies is pivotal in attenuating the progression of T2DM and in reducing the burden of associated comorbidities. This therapeutic approach is suitable for a wide spectrum of all T2DM patients. The panel also highlights how linagliptin based combinations can help reduce pill burden, improve adherence, and support timely treatment intensification. Overall, the consensus encourages clinicians to consider this combination as part of a personalized, goal-oriented approach to diabetes care in India.

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REFERENCES

1. Expert Opinion: Optimum Clinical Approach to Combination-Use of SGLT2i + DPP4i in the Indian Diabetes Setting | Diabetes Therapy. Available at: https://link.springer.com/article/10.1007/s13300-022-01219-x. Accessed on 15 March 2025.
2. Jain A, Vispute A, Dange A, Naskar A, Mondal A, Vivekanand B, et al. A Randomized, Double-Blind, Parallel-Group Phase III Trial Investigating the Glycemic Efficacy and Safety Profile of Fixed-Dose Combination Dapagliflozin and Linagliptin Over Linagliptin Monotherapy in Patients with Inadequately Controlled Type 2 Diabetes with Metformin. Diabetes Ther. 2024;15(1):215-27.

3. Samson SL, Vellanki P, Blonde L, Christofides EA, Galindo RJ, Hirsch IB, et al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm-2023 Update. Endocr Pract. 2023;29(5):305-40.
4. Chadha M, Das AK, Deb P, Gangopadhyay KK, Joshi S, Kesavadev J, et al. Expert Opinion: Optimum Clinical Approach to Combination-Use of SGLT2i + DPP4i in the Indian Diabetes Setting. Diabetes Ther. 2022;13(5):1097-114.
5. IDF Diabetes Atlas 2025. Diabetes Atlas. Available at: https://diabetesatlas.org/resources/idf-diabetes-atlas-2025/. Accessed on 27 March 2025.
6. Pradeepa R, Mohan V. Epidemiology of type 2 diabetes in India. Indian J Ophthalmol. 2021;69(11):2932-8.
7. Khunti K, Aroda VR. Coming Full Circle: Prioritizing Early Glycemic Control to Reduce Microvascular and Macrovascular Complications in People With Type 2 Diabetes. Diabetes Care. 2022;45(4):766-8.
8. Hong JH, Kim MJ, Min KW, Won JC, Kim TN, Lee BW, et al. Efficacy and safety of a fixed-dose combination of dapagliflozin and linagliptin (AJU-A51) in patients with type 2 diabetes mellitus: A multicentre, randomized, double-blind, parallel-group, placebo-controlled phase III study. Diabetes Obes Metab. 2025;27(1):81-91.
9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2025 | Diabetes Care | American Diabetes Association. Available at: https://diabetesjournals.org/care/article/48/Supplement_1/S181/157569/9-Pharmacologic-Approaches-to-Glycemic-Treatment. Accessed on 06 May 2025.
10. McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Böhm M, et al. 2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) With the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J. 2023;44(37):3627-39.
11. Chawla R, Madhu SV, Makkar BM, Ghosh S, Saboo B, Kalra S, et al. RSSDI-ESI Clinical Practice Recommendations for the Management of Type 2 Diabetes Mellitus 2020. Int J Diabetes Dev Ctries. 2020;40(S1):1-122.
12. Dharmalingam M, Kumar Sharma S, Prakash V, Maiti A, Kumar R, Murthy LSS, et al. Evaluating the Efficacy, Safety, and Tolerability of Combination Therapy of Dapagliflozin and Linagliptin Over Dapagliflozin and Vildagliptin in Patients With Type 2 Diabetes Mellitus Inadequately Controlled With Metformin. Cureus. 2024;16(4):e58115.
13. Ahmad J, Ghosh S, Kumthekar PP, Upadhyay MR, Sonawane KR, Khalse M, et al. 932-P: Clinical Efficacy, Safety, and Tolerability of Single-Pill Combination of Dapagliflozin and Linagliptin in Uncontrolled Indian Type 2 Diabetes Mellitus Patients-A Randomized Double-Blind Study. Diabetes. 2024;73(1):932-P.
14. Kumthekar P, Upadhyay MR, Tamma RR, Kranti V, Bhattacharya R, Sharma PK, et al. Fixed-dose Combination of Dapagliflozin and Linagliptin in Individuals with Type 2 Diabetes Mellitus Inadequately Controlled on Metformin: A Randomized Double-blind Multicenter Trial. J Diabetol. 2025;16(1):50.
15. American Diabetes Association. Standards of Care in Diabetes-2025.Diabetes Care. 2025;48(1).
16. Dal Canto E, Ceriello A, Rydén L, Ferrini M, Hansen TB, Schnell O, et al. Diabetes as a cardiovascular risk factor: An overview of global trends of macro and micro vascular complications. Eur J Prev Cardiol. 2019;26(2):25-32.
17. Hong JH, Kim MJ, Min KW, Won JC, Kim TN, Lee B, et al. Efficacy and safety of a fixed-dose combination of dapagliflozin and linagliptin (AJU-A51) in patients with type 2 diabetes mellitus: A multicentre, randomized, double-blind, parallel-group, placebo-controlled phase III study. Diabetes Obes Metab. 2025;27(1):81-91.
18. RSSDI Clinical Practice Recommendations for the Management of Type 2 Diabetes Mellitus 2022. Int J Diabetes Dev Ctries. 2022;42(S1):1-143.
19. Heerspink HJL, Stefánsson BV, Correa-Rotter R, Chertow GM, Greene T, Hou FF, et al. Dapagliflozin in Patients with Chronic Kidney Disease. N Engl J Med. 2020;383(15):1436-46.
20. Rosenstock J, Kahn SE, Johansen OE, Zinman B, Espeland MA, Woerle HJ, et al. Effect of Linagliptin vs Glimepiride on Major Adverse Cardiovascular Outcomes in Patients With Type 2 Diabetes. JAMA. 2019;322(12):1-12.
21. Nesbitt H. American Society of Nephrology | Kidney Week-Abstract Details. 2024. Available at: https://www.asn-online.org/education/kidneyweek/2024/program-abstract.aspx?controlId=4176408. Accessed on 06 May 2025.
22. Cho YK, Kang YM, Lee SE, Lee J, Park JY, Lee WJ, et al. Efficacy and safety of combination therapy with SGLT2 and DPP4 inhibitors in the treatment of type 2 diabetes: A systematic review and meta-analysis. Diabetes Metab. 2018;44(5):393-401.
23. Zhu Y, Zhang J li, Yan X jiao, Sun L, Ji Y, Wang F fang. Effect of dapagliflozin on the prognosis of patients with acute myocardial infarction undergoing percutaneous coronary intervention. Cardiovasc Diabetol. 2022;21:186.

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