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(RESEARCH ARTICLE)

Real-world insights on cardiometabolic, glycemic, and safety outcomes of dapagliflozin-based therapy in patients with type 2 diabetes

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder requiring combination therapy for optimal control. Dapagliflozin, a sodium-glucose cotransporter-2 (SGLT2) inhibitor, offers added metabolic and cardiovascular benefits with other oral antidiabetic agents. This study aimed to assess healthcare professionals' (HCPs) real-world experience with dapagliflozin-based regimens in Indian patients with T2DM, focusing on glycaemic outcomes, metabolic benefits, and safety.

Methods: This multicentre, questionnaire-based study was conducted among 104 HCPs, including endocrinologists, diabetologists, and general physicians across India. The structured 17-item questionnaire assessed patient demographics, comorbidities, dietary compliance, glycaemic control, HbA1c reduction with various combination therapies, weight changes, adverse events, and treatment adjustments based on the last 10 patients managed by each HCP. Descriptive analysis was performed, and outcomes were expressed as percentages.

Results: Most HCPs (63.46%) reported that their patients were older than 55 years, and 60.58% had diabetes for more than three years. Chronic kidney disease (40.38%) and dyslipidaemia (31.73%) were the most common comorbidities. Nearly half of the HCPs (48.08%) reported an HbA1c reduction of 1.25%-1.5% with dapagliflozin (10 mg) and vildagliptin (100 mg). The triple combination of dapagliflozin, vildagliptin, and metformin showed similar efficacy. Most HCPs (77.88%) reported no significant side effects, with minimal discontinuations (72.12%) and infrequent hypoglycaemic episodes. Additionally, 66.35% observed weight reduction in 6-10 patients receiving dapagliflozin-based therapy.

Conclusion: Dapagliflozin-based combinations are well tolerated and effective for glycaemic control and metabolic improvement in Indian T2DM patients. Vildagliptin and metformin combinations were preferred for those with high HbA1c and cardiovascular risk. These findings support the safety and utility of dapagliflozin regimens, though larger studies are needed for validation.

Keywords: Type 2 Diabetes Mellitus; Dapagliflozin; Vildagliptin; Combination Therapy; Glycaemic Control; Safety

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1. Introduction

Type 2 diabetes mellitus (T2DM) is a metabolic disorder characterised by chronic hyperglycaemia due to insulin resistance and relative insulin deficiency [1]. It is a major global public health challenge, with prevalence rising rapidly in both developed and developing countries. According to the International Diabetes Federation, an estimated 537 million adults were living with diabetes in 2021, and this number is projected to reach 643 million by 2030 [2]. India contributes substantially to the global diabetes burden, with over 77 million people affected, earning the nation the title of the "diabetes capital of the world" [3]. The increasing prevalence of diabetes in India is driven by urbanisation, sedentary lifestyles, dietary transitions, obesity, and genetic susceptibility [4]. Persistent hyperglycemia contributes to the development of both microvascular (retinopathy, nephropathy, neuropathy) and macrovascular complications (cardiovascular disease, stroke, peripheral arterial disease), which account for significant morbidity, mortality, and healthcare costs [5].

Optimal glycaemic control remains the cornerstone of T2DM management to reduce long-term complications and improve quality of life. While initial therapy emphasises lifestyle modifications, pharmacotherapy becomes essential for most patients. Metformin is the first-line drug followed by sulfonylureas, thiazolidinediones, and insulin as needed [6,7]. Metformin, the mainstay of therapy in T2DM, still leads to the need for additional agents due to progressive beta-cell dysfunction, often requiring combination therapy with drugs of different mechanisms of action [7].

Sodium-glucose cotransporter-2 (SGLT2) inhibitors, such as dapagliflozin, have emerged as a milestone in T2DM treatment. By inhibiting renal glucose reabsorption in the proximal tubules, dapagliflozin lowers plasma glucose independently of insulin secretion, while promoting natriuresis, weight loss, and reduced blood pressure [8,9]. Cardiovascular outcome trials (CVOTs), including DECLARE-TIMI 58, have demonstrated dapagliflozin's efficacy in reducing hospitalisation for heart failure, slowing renal decline, and improving overall cardiovascular outcomes in T2DM patients with or without established atherosclerotic disease [9,10].

Regarding safety, dapagliflozin is generally well tolerated, with the most common adverse effects reported as genital mycotic infections and rare cases of diabetic ketoacidosis [11]. Meta-analyses confirm its favourable risk-benefit ratio, particularly when used in combination regimens to achieve better glycaemic control and reduce glucose variability [12,13]. Real-world studies support the combination of dapagliflozin with other agents like dipeptidyl peptidase-4 inhibitors (e.g., vildagliptin) or sulfonylureas to augment reductions in glycated haemoglobin (HbA1c) and improve metabolic parameters with an acceptable safety profile [13]. The present study provides insights from healthcare professionals (HCPs) on the use of dapagliflozin-based regimens for Indian patients with T2DM, evaluating glycaemic outcomes, metabolic benefits, safety, and treatment decisions in a real-world clinical setting.

2. Methods

2.1. Study design

This questionnaire-based, multicenter study was designed to evaluate the real-world use of dapagliflozin-based regimens in the management of T2DM in Indian patients. All study-related findings and data presented in this report were based on HCPs' expert opinions, focusing on glycaemic outcomes, metabolic benefits, safety, and treatment decisions.

2.2. Study questionnaire

The study questionnaire was designed based on clinical guidelines, existing literature, and experts' opinions. It included 17 questions focusing on glycaemic, metabolic, and safety outcomes in patients with T2DM treated with dapagliflozin-based regimens. Areas covered included patient demographics, duration of diabetes, comorbidities, dietary compliance, glycaemic control, HbA1c reduction with various combination therapies, occurrence of hypoglycaemia, weight changes, side effects, and treatment adjustments. The questionnaire focused on the last 10 patients treated by HCPs. The study protocol was approved by the independent ethics committee (ACEAS - Independent Ethics Committee, Ahmedabad, India; Date of approval: 06 November 2024).

2.3. Data collection method

The HCPs, mainly including endocrinologists, diabetologists and general physicians, participating in the study were provided with a concise overview of the study's nature and the process for completing the questionnaire. The questionnaire was given to HCPs either in person or through online platforms, as per the HCP's convenience.

2.4. Data analysis

Responses to questions were entered into Microsoft Excel. Descriptive analysis was performed, and the outcome was presented as percentages.

3. Result

3.1. Demographic and baseline glycaemic characteristics

A total of 104 HCPs were included in this study. The majority of HCPs (63.46%) reported that most patients belonged to the age group greater than 55 years, followed by 45-55 years (22.12%). Most of the HCPs (60.58%) observed that patients had diabetes for more than 3 years. Among the common comorbid disorders, chronic kidney disease (CKD) (40.38%) and dyslipidaemia (31.73%) were reported as the most frequent comorbidities. The majority of HCPs (62.50%) indicated that 6-10 patients were diet non-compliant, with likely less time in range on continuous glucose monitoring (CGM) (Table 1).

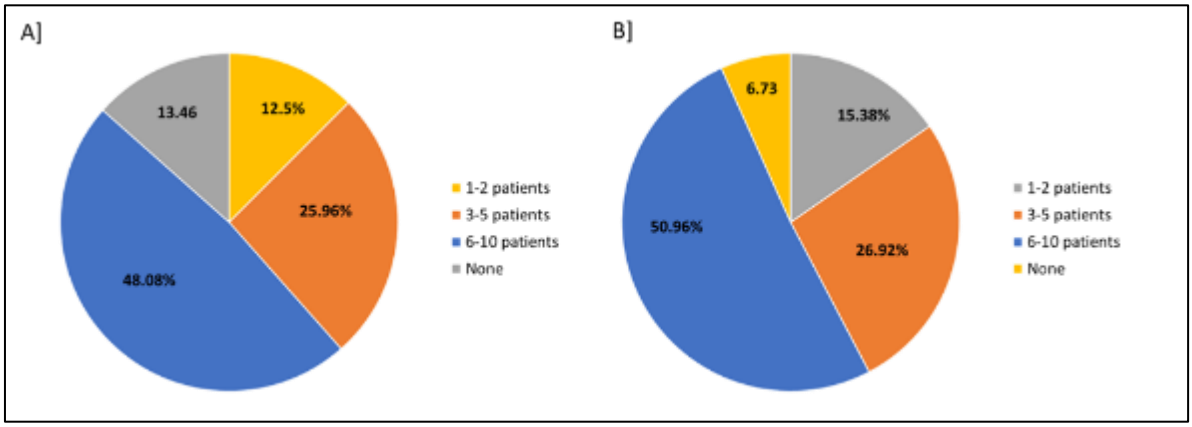
Table 1 Demographic and baseline glycaemic characteristics of patients with T2DM

Parameters	**Response of HCPs (N=104)**
Common age group	
25-35 years	6 (5.77)
35-45 years	9 (8.65)
45-55 years	23 (22.12)
Greater than 55 years	66 (63.46)
Common duration of diabetes	
Newly diagnosed T2DM	5 (4.81)
Less than 1 year	7 (6.73)
1-3 years	29 (27.88)
Greater than 3 years	63 (60.58)
Common comorbid disorders	
IH	11 (10.58)
NAFL	18 (17.31)
Dyslipidaemia	33 (31.73)
CKD	42 (40.38)

Data represented as n (%).: CKD, chronic kidney disease; dyslipidaemia, abnormal lipid metabolism; HCPs, health care providers; IH, ischemic heart disease; NAFL, non-alcoholic fatty liver; T2DM, type 2 diabetes mellitus.

In terms of glycaemic control, nearly half of the HCPs (48.08%) reported that 6-10 patients failed to achieve an HbA1c level below 7.0% despite diet and metformin therapy, whereas only 13.46% reported no such patients (Figure 1A). Similarly, 50.96% of HCPs observed that 6-10 patients had HbA1c levels exceeding 8.5% (Figure 1B).

A] not achieving HbA1c < 7.0% after diet + Metformin B] Patients with HbA1c > 8.5%



HbA1c, glycated hemoglobin; T2DM, type 2 diabetes mellitus.

Figure 1 Distribution of HbA1c categories among patients with T2DM

3.2. Treatment patterns and combination choices in patients with T2DM

Physicians shared their clinical experience with 10 patients regarding treatment decisions and combination choices in T2DM. According to 37.5% of HCPs, all clinical parameters, including HbA1c levels, duration of diabetes, age, cardiovascular (CV) complications, and comorbid conditions, were considered while selecting combination therapy. In patients with HbA1c levels greater than 8.5%, more than half of the HCPs (53.85%) prescribed the triple combination of dapagliflozin (10 mg), metformin (500 mg), and vildagliptin (100 mg). For patients with mean amplitude of glycaemic excursions (MAGE) and glycaemic variability, 59.62% of HCPs preferred the combination of dapagliflozin (10 mg), metformin (500 mg), and vildagliptin (100 mg) for cardiovascular disease (CVD) prevention (Table 2).

Table 2 Treatment patterns and combination choices in patients with T2DM

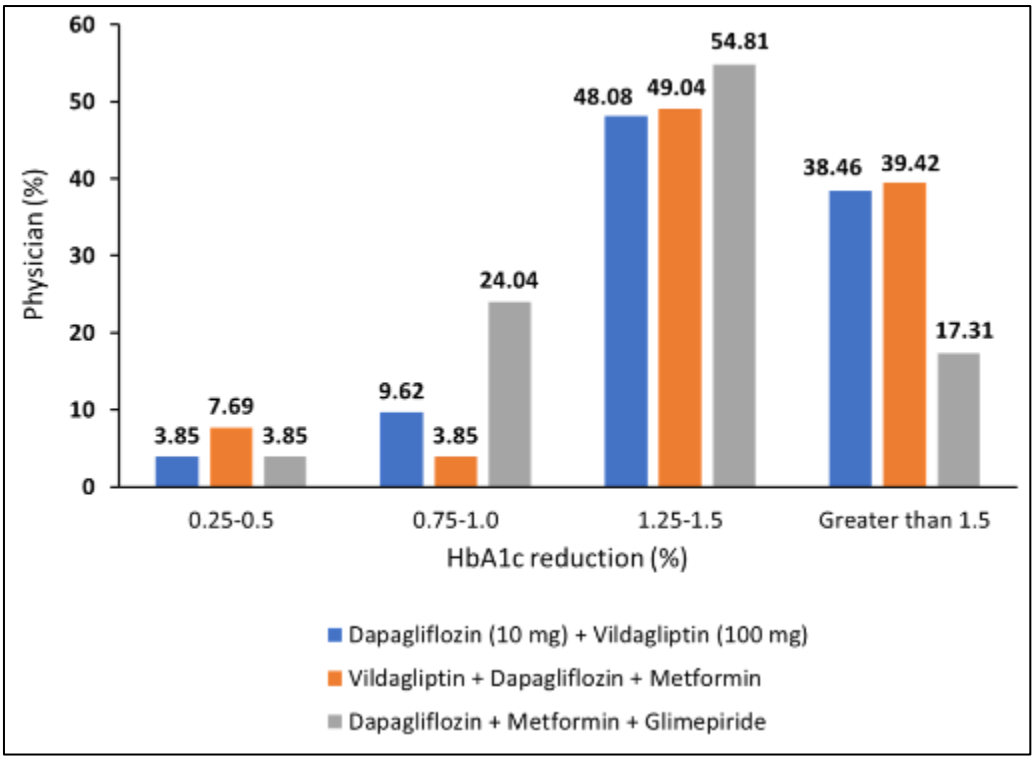
Parameters	**Response of HCPs (N=104)**
Factors considered while choosing combination therapy	
HbA1c	6 (5.77)
Duration of diabetes	11 (10.58)
Age of the patients	17 (16.35)
CV complications	16 (15.38)
Other complications of diabetes	7 (6.73)
Comorbid diseases	8 (7.69)
All of the above	39 (37.50)
Prescribed combinations in patients with HbA1c > 8.5%	
Dapagliflozin (10 mg) + Vildagliptin (100 mg)	16 (15.38)
Dapagliflozin (10 mg), Metformin (500 mg) and Vildagliptin (100 mg)	56 (53.85)
Dapagliflozin (10 mg) and Metformin (1000 mg)	5 (4.81)
Dapagliflozin (10 mg) and Metformin (500 mg)	12 (11.54)
Dapagliflozin (10 mg), Metformin (1000 mg) and Glimepiride 1 mg/2 mg	15 (14.42)
Preferred combination in patients with MAGE and glycaemic variability for preventing CVD	
Dapagliflozin (10 mg) + Vildagliptin (100 mg)	10 (9.62)

Dapagliflozin (10 mg), Metformin (500 mg) and Vildagliptin (100 mg)	62 (59.62)
Dapagliflozin (10 mg) and Metformin (1000 mg)	13 (12.50)
Dapagliflozin (10 mg) and Metformin (500 mg)	9 (8.65)
Dapagliflozin (10 mg), Metformin (1000 mg) and Glimepiride 1 mg/2 mg	10 (9.62)

Data represented as n (%).: CV, cardiovascular; CVD, cardiovascular disease; HbA1c, glycated haemoglobin; HCPs, healthcare professionals; MAGE, mean amplitude of glycaemic excursions.

3.3. Glycaemic efficacy and metabolic benefits of dapagliflozin-based combinations

According to HCPs, dapagliflozin-based combinations demonstrated glycaemic efficacy among patients with T2DM. Nearly half of the HCPs (48.08%) reported an HbA1c reduction of 1.25%-1.5% with the combination of dapagliflozin (10 mg) and vildagliptin (100 mg), while 38.46% observed a reduction greater than 1.5%. Similarly, the triple combination of vildagliptin, dapagliflozin, and metformin yielded comparable outcomes, with 49.04% of HCPs noting an HbA1c reduction of 1.25%-1.5% and 39.42% reporting a decrease greater than 1.5%. For the combination of dapagliflozin, metformin, and glimepiride, more than half of the HCPs (54.81%) observed an HbA1c reduction of 1.25%-1.5%, while 17.31% reported a reduction exceeding 1.5% (Figure 2).



HbA1c, glycated hemoglobin.

Figure 2 Magnitude of HbA1c reduction across different dapagliflozin combination regimens

3.4. Safety profile and metabolic benefits of dapagliflozin-based combinations

The safety outcomes of dapagliflozin-based combinations, as reported by HCPs, indicate a favourable tolerability profile. A majority of HCPs (77.88%) reported no side effects. Most HCPs (72.12%) stated that only 1-2 patients discontinued therapy due to adverse effects, and 73.08% reported no need for dose adjustments related to efficacy or tolerability. In terms of metabolic benefits, 66.35% of HCPs observed weight loss in 6-10 patients receiving dapagliflozin-based therapy. Furthermore, hypoglycaemic episodes were uncommon, with 66.35% of HCPs reporting that such events never occurred and only 2.88% noting frequent episodes (Table 3).

Table 3 Safety outcome of dapagliflozin combinations

Parameter	Response of HCPs (N=104)
Most commonly observed side effects	
Urinary tract infections	12 (11.54)
Hypotension	3 (2.88)
Diabetic ketoacidosis	8 (7.69)
No significant side effects	81 (77.88)
Patients discontinue therapy due to side effects	
1-2 patients	75 (72.12)
3-5 patients	10 (9.62)
6-10 patients	15 (14.42)
None	4 (3.85)
Patients' redose adjustments due to efficacy or side effects	
1-2 patients	9 (8.65)
3-5 patients	11 (10.58)
6-10 patients	8 (7.69)
None	76 (73.08)
Patients experiencing weight loss as a benefit	
1-2 patients	7 (6.73)
3-5 patients	17 (16.35)
6-10 patients	69 (66.35)
None	11 (10.58)
Frequency of hypoglycaemic episodes	
Frequently	3 (2.88)
Occasionally	9 (8.65)
Rarely	23 (22.12)
Never	69 (66.35)
Data represented as n (%). HCPs, healthcare professionals.	

4. Discussion

The present study provides valuable insights into the real-world clinical use, safety, and perceived effectiveness of dapagliflozin-based regimens among HCPs in the management of T2DM in Indian patients. The majority of HCPs (63.46%) reported that most patients were older than 55 years, and a significant proportion observed that patients had been living with diabetes for more than three years. These findings are comparable to a cross-sectional study by Xuelin et al., which reported a mean (SD) age of 56.96 (10.02) years and an average age at diagnosis of 52.91 (10.25) years [14]. Similarly, another study found that the mean age of participants was 42.8 (14.4) years, with an average disease duration of 7.7 (7.2) years (median 5 years) [15]. Chronic kidney disease and dyslipidaemia were frequently common comorbidities reported by HCPs. These observations are consistent with findings from Al-Ozairi et al., who reported

CKD as the most prevalent comorbidity (44.3%) [16]. Likewise, the CREDO study documented dyslipidaemia in 71% of patients and CKD in 47.9% [17].

A significant proportion of HCPs (62.50%) indicated that 6-10 of their patients were non-compliant with dietary recommendations, likely resulting in suboptimal time-in-range values on CGM. This finding aligns with the study by Abose et al., which reported that 64.2% of patients with T2DM were non-adherent to prescribed dietary regimens [18]. Regarding glycaemic control, nearly half of the HCPs reported that 6-10 patients failed to achieve HbA1c levels below 7.0% despite adherence to diet and metformin therapy, while 50.96% of HCPs observed that 6-10 patients had HbA1c values exceeding 8.5%. These findings are in line with a study by Brown et al., where 42% of patients who initially achieved HbA1c <7% with metformin monotherapy experienced secondary failure within a 2-5-year follow-up period [19]. Likewise, a study conducted in Oman by Al-Lawati et al. reported a mean HbA1c of 8.2% (2.0), with 68% of patients having HbA1c >7% [20]. Treatment decisions and combination choices in T2DM are influenced by multiple clinical parameters. About 37.5% of HCPs reported considering all relevant factors, including HbA1c levels, duration of diabetes, age, CV complications, and comorbid conditions, when selecting combination therapy. These practices align with ADA 2025 guidelines recommendations for combination therapy for patients above HbA1c targets and to prioritise agents with strong glycaemic, cardiovascular, or renal benefits, supporting personalised, safe, and effective treatment intensification [7].

A randomised open-label study by Gautam et al. compared dapagliflozin and vildagliptin as add-ons to metformin in T2DM patients over 24 weeks, reporting HbA1c reductions of about 1.19% and 1.28% from baseline values of 8.2-8.3% [21]. These findings demonstrate the efficacy of the triple combination of dapagliflozin, vildagliptin, and metformin for substantial glycemic improvement [21]. These findings align well with the present study,53.85% of HCPs (prescribed the triple combination of dapagliflozin (10 mg), metformin (500 mg), and vildagliptin (100 mg) for patients with HbA1c levels greater than 8.5%, highlighting its perceived effectiveness in real-world clinical practice.

A significant portion of HCPs in the present study observed that dapagliflozin-based combinations provided consistent glycaemic control in T2DM. Nearly half reported an HbA1c reduction of 1.25%- 1.5% with dapagliflozin (10 mg) and vildagliptin (100 mg), while 59.62% preferred the triple combination with metformin (500 mg) for patients with high glycaemic variability and CVD prevention. This observation is consistent with findings from a large observational study conducted by Aravind et al., where a fixed-dose combination (FDC) of vildagliptin and dapagliflozin demonstrated a mean HbA1c reduction of approximately 1.2% at six months from a baseline of 8.4%, along with improvements in fasting and postprandial glucose over 24 weeks [22]. Additionally, findings from a survey study of Indian physicians reported that FDCs, including dapagliflozin and vildagliptin with metformin, are preferred by HCPS (about 59.62%) for patients with high glycaemic variability to reduce CV risk [23].

The triple combination of vildagliptin, dapagliflozin, and metformin yielded comparable outcomes, with 49.04% of HCPs reporting an HbA1c reduction of 1.25%-1.5% and 39.42% noting a decrease greater than 1.5%. These findings align with a survey-based study of Indian physicians regarding the prescription of triple oral antidiabetic therapy for uncontrolled T2DM, in which approximately 40% of clinicians observed an HbA1c reduction of 1-1.5% with vildagliptin, dapagliflozin, and metformin therapy [23]. For the combination of dapagliflozin, metformin, and glimepiride, more than half of HCPs (54.81%) reported an HbA1c reduction of 1.25%-1.5%, while 17.31% observed a reduction exceeding 1.5%. These results are consistent with a phase III randomised clinical study in India, which demonstrated that an FDC of dapagliflozin (10 mg), glimepiride, and metformin led to HbA1c reductions at week 16, with 54.81% of patients experiencing a 1.25%-1.5% drop and 17.31% achieving reductions greater than 1.5% [24].

Dapagliflozin-based combinations showed a favourable safety profile, with most HCPs (77.88%) reporting no side effects. Similarly, a Phase IV study from India by Wangnoo et al. found that 77.88% of patients on dapagliflozin-saxagliptin plus metformin had no serious adverse events, with only mild, infrequent cases of urinary tract infections, genital infections, or nasopharyngitis and no serious events [25]. Most HCPs (72.12%) reported that only 1-2 patients discontinued therapy due to adverse effects, while 73.08% noted no need for dose adjustments for efficacy or tolerability. Hypoglycaemic episodes were rare. These results are comparable to those reported in a previous retrospective study documented that dapagliflozin–vildagliptin FDC showed excellent tolerability, with no therapy discontinuations due to safety, only 3.7% experiencing manageable adverse events, with no changes in vital parameters [22]. In terms of metabolic benefits, 66.35% of HCPs observed weight loss in 6-10 patients receiving dapagliflozin-based therapy. This aligns with Bolinder et al., who reported a placebo-corrected mean weight loss of 2.08 kg with dapagliflozin 10 mg daily, and 26.2% of patients achieving ≥5% weight loss [26].

5. Conclusion

The findings from this study indicate that dapagliflozin-based combinations are well tolerated and effective in achieving glycaemic control and improving metabolic outcomes among Indian patients with T2DM. Most HCP reported notable HbA1c reductions, weight benefits, and minimal adverse effects, with rare discontinuations. Combinations with vildagliptin and metformin were particularly preferred for patients with higher HbA1c, glycaemic variability, and cardiovascular risk, aligning with current treatment practices. These insights highlight the clinical value and safety of dapagliflozin-based therapies, though larger, long-term studies are needed to confirm these findings.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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