ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Prescription Pattern, Efficacy, And Safety Of Oral Antidiabetic Drugs in A North Indian Tertiary Care Hospital: A Prospective Observational Study.

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ABSTRACT

To evaluate the prescription pattern, efficacy and safety of oral antidiabetic drugs among patients with Type 2 Diabetes Mellitus attending a tertiary care teaching hospital. A prospective observational study was conducted in the Department of Pharmacology in collaboration with General Medicine Department at SGT Hospital, Gurugram, Haryana, over a period of 12 months. A total of 150 adult T2DM patients visiting General Medicine Outpatient department receiving oral antidiabetic drugs were enrolled and were followed up for three months. Demographic characteristics, prescription patterns, fasting blood sugar (FBS), glycated haemoglobin (HbA1c) and adverse drug reactions (ADRs) were recorded. Statistical analysis was performed using SPSS version 30, with $p < 0.05$ considered statistically significant. Participants were mostly aged 50-59 years (37.4%) and predominantly male (65.3%). Their education level was largely limited to secondary school (33.3%) and homemakers formed 27.4% of the group. Combination therapy was prescribed more frequently than monotherapy at enrolment (83.4% vs. 16.6%) and at follow-up (84.0% vs. 16.0%). The most commonly prescribed regimen was combination of metformin plus glimepiride (32.7% at enrolment and 32.0% at follow-up). An increasing trend in the use of SGLT-2 inhibitors was observed during follow-up. The statistically significant improvements were noted in glycaemic parameters, with mean FBS decreasing from 169.96 ± 25.55 mg/dL to 156.69 ± 27.58 mg/dL ($p < 0.001$) and mean HbA1c decreasing from 7.65 ± 0.68% to 7.14 ± 0.78% ($p < 0.001$). No significant difference in glycaemic improvement was observed between monotherapy and combination therapy groups. Patients without comorbidities showed significantly greater short-term improvement in glycaemic parameters compared with those with comorbid conditions over the 3-month follow-up period. ADRs were reported in 11 patients (7.3%), with hypoglycaemia, diarrhoea, headache, fatigue, abdominal discomfort and weight loss being the most common events. All ADRs were classified as mild (according to Hartwig's Severity scale) and categorized as possible according to the WHO-UMC causality assessment scale. Oral antidiabetic drugs demonstrated significant efficacy in improving glycaemic control with a favourable safety profile. Regular prescription audits and pharmacovigilance activities are essential to promote rational prescribing and optimize diabetes management.

Keywords: Type 2 Diabetes Mellitus, Oral Antidiabetic Drugs, Prescription Pattern, Glycaemic Control, HbA1c, Adverse Drug Reactions, Pharmacovigilance.

https://doi.org/10.33887/rjpbcs/2026.17.4.8

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ISSN: 0975-8585

INTRODUCTION

Diabetes mellitus comprises a heterogeneous group of metabolic disorders characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action or a combination of both mechanisms. Globally, type 2 diabetes mellitus (T2DM) is the major form of diabetes constituting nearly 90% to 95% cases worldwide [1]. The ICMR–INDIAB study highlighted the considerable burden of diabetes and prediabetes in India, emphasizing the significant public health challenge posed by T2DM in the country [2]. T2DM is marked by a combination of insulin resistance, gradually progressing beta cell dysfunction and impaired glucose regulation, necessitating sustained pharmacological and non-pharmacological interventions. The therapeutic landscape for T2DM has evolved from early dietary interventions to a range of pharmacological regimens targeting multiple pathophysiological pathways. The discovery of insulin in 1922 provided therapy for individuals with type 1 diabetes and severe T2DM. The recognition that many individuals with T2DM retained some insulin secretory capacity led to the development of oral hypoglycaemic agents, starting with sulfonylureas in the 1940s [3].

The treatment algorithm for T2DM now incorporates considerations beyond glycemic control. Established cardiovascular disease, heart failure and chronic kidney disease are indications for specific drug classes, regardless of baseline HbA1c. SGLT-2 inhibitors and GLP-1 receptor agonists are considered preferable agents in patients with established atherosclerotic cardiovascular disease as outcome trials have shown significant therapeutic benefits [4]. Despite available treatment guidelines, real-world prescription patterns often deviate from recommended practices. Studies show variations in drug utilization influenced by factors such as physician specialty, practice setting and patient demographics [5].

Hospital-based studies often show adherence to guideline recommendations, with metformin as the most commonly prescribed first-line agent. However, variations exist in the selection of second-line therapies. Some practitioners favour agents like sulfonylureas due to familiarity and cost, while others prescribe newer agents based on benefits beyond glucose lowering. The use of combination therapy has increased, reflecting the progressive nature of T2DM. Fixed-dose combinations have gained popularity for their potential to improve adherence. However, concerns exist regarding the inappropriate use of combination therapies [6].

The assessment of treatment efficacy in clinical practice requires considering parameters beyond glycaemic control. Patient-reported outcomes, such as quality of life and treatment satisfaction, provide insights into the impact of therapeutic interventions. Evaluation of diabetes-related complications, healthcare utilization offers a comprehensive perspective. The safety profile of oral antidiabetic drugs is an important consideration as therapy duration and regimen complexity increase. Each class of medication is associated with distinct adverse effect profiles, such as gastrointestinal intolerance with metformin or hypoglycaemia with insulin secretagogues [7].

The systematic evaluation of adverse drug reactions (ADRs) in clinical practice requires robust pharmacovigilance systems and standardized assessment tools. WHO-UMC causality assessment scale provides a framework for evaluating the relationship between drug exposure and adverse events [8].

Despite extensive literature on diabetes therapeutics, significant knowledge gaps remain regarding the real-world utilization, effectiveness and safety of oral antidiabetic drugs. Most randomized controlled trials are conducted in selected patient populations under tightly controlled conditions, limiting the generalizability of their findings to diverse clinical settings. The present study seeks to address these gaps by thoroughly investigating the prescription patterns, efficacy and safety of oral antidiabetic drugs in a tertiary care teaching hospital. By assessing multiple domains, including drug utilization trends, glycemic control and adverse drug reactions, this investigation aims to generate a holistic understanding of diabetes management in real-world clinical practice.

MATERIAL AND METHODS

A prospective observational study was conducted in the Department of Pharmacology in collaboration with General Medicine Department at SGT Hospital, a semi-urban tertiary healthcare centre located in Gurugram, Haryana. The study enrolled Type 2 Diabetes Mellitus patients on oral antidiabetic drugs attending the General Medicine Outpatient Department (OPD) for a duration of 12 months after obtaining approval from the Institutional Ethics Committee (IEC No.: IEC/FMHS/MD/MS/2023-17). The study was conducted in accordance with established ethical standards, including the principles of Good Clinical Practice (GCP) and the Declaration of Helsinki. Each patient was followed up once after 3 months from the date of enrolment. Patients were advised to report any adverse drug reaction (ADR) experienced during treatment, either telephonically or by visiting the OPD.

Inclusion Criteria included patients diagnosed with Type 2 Diabetes Mellitus on oral antidiabetic drugs ≥ 18 years and with HbA1c ranging between 6.5 and 9.

Exclusion Criteria included patients on Insulin or other parenteral antidiabetic drugs, patients with comorbid conditions such as CKD, arrhythmias, COPD, asthma, diabetic ketoacidosis or psychiatric illness and pregnant and lactating females.

The sample size for this study was 150 patients (95% confidence interval, ±10% margin of error) in accordance with World Health Organization (WHO) manual to assess drug use in individual facilities. [9]

On a daily basis, the Principal Investigator screened patients attending the medicine OPD using a predefined eligibility checklist. Individuals fulfilling the inclusion criteria were approached and provided with detailed information regarding the objectives and procedures of the study.

Written informed consent was obtained from those willing to participate. Each enrolled participant was assigned a unique identification number and baseline information was subsequently recorded. In cases where an eligible patient declined participation, the next suitable patient meeting the inclusion criteria was considered for enrolment. After 3 months (at follow-up) again the required information was recorded subsequently and the patient was inquired about the ADR using a predefined ADR checklist. Patient confidentiality was maintained throughout the study.

Data collection included:

- Personal details: Age, gender and demographic profile.
- Medical history: Duration of diabetes, treatment history, past medical history and family history.
- Laboratory investigations: FBS and HbA1c. (as per protocol)

Statistical Analysis

All the collected data was entered into Microsoft Excel (2019) and were carefully verified for completeness and accuracy. Following data cleaning, coding and recoding were performed and statistical analysis was carried out using Statistical Package for the Social Sciences (SPSS) version 30.

Continuous variables were summarized as mean with standard deviation, whereas categorical variables were expressed as proportions or percentages. The distribution of continuous variables was assessed for normality prior to analysis. Depending on the distribution, parametric tests of significance such as the paired t-test and unpaired t-test were applied to compare continuous variables. Chi-square test was used for categorical variables. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Sociodemographic Characteristics of Study Participants

Among the 150 study participants, the largest proportion i-e 37.4% (56 of 150) belonged to the 50-59 years age group, followed by those aged ≥60 years with 34% (51 of 150) whereas participants aged <50 years of age group constituted the smallest group with a percentage of 28.6 (43 of 150). 65.3% of the study participants were males (98 of 150) having majority, while females accounted for 34.7% (52 of 150) of the study population.

The highest proportion i-e. 34% of diabetes cases was observed among individuals with secondary level education (50 of 150 patients), followed by 26.7% of graduates (40 of 150 patients) and 21.3% with primary education (32 of 150 patients). Illiterate participants constituted 10.7% of the study population (16 of 150), while the lowest proportion with 8% was observed among postgraduates (12 of 150).

With respect to occupation, the majority of participants i-e. 27.4% were homemakers (41 of 150), followed by 24% of service workers (36 of 150 patients) and 20% of self-employed individuals (30 of 150 patients). Unemployed participants constituted (23 of 150) 15.3% of the study population, while (12 of 150) 8.0% were retired individuals and (8 of 150) 5.3% were farmers.

Nearly half of the participants i-e. 49.3% (74 of 150) did not report any comorbid condition. Among those with comorbidities, dyslipidaemia was the most commonly observed condition with 24% (36 of 150), followed by 16% with hypertension (24 of 150). A smaller proportion i-e 8.0% of participants had both dyslipidaemia and hypertension (12 of 150), while hypothyroidism was observed in only (4 of 150) 2.7% of the participants.

Nearly half, 48.0% (72 of 150) of the participants did not report any family history of chronic illness. Among those with a positive family history, (40 of 150 patients) 26.6% reported having type 2 diabetes mellitus, while (38 of 150 patients) 25.4% reported both type 2 diabetes mellitus and hypertension.

Prescription Pattern of Oral Antidiabetic Drugs in Study Participants

The prescription pattern of oral antidiabetic drugs was analysed at enrolment and at three-month follow-up. Out of the total 150 participants, combination therapy was the predominant treatment modality. 83.4% (125 of 150 patients) of patients were prescribed combination therapy at enrolment which increased to 84% (126 of 150 patients) at follow up (after 3 month). While monotherapy was prescribed to 16.6% (25 of 150 patients) of patients at enrolment which decreased to 16% (26 of 150 patients) at the three-month follow-up. The change in treatment category between enrolment and follow-up was not statistically significant (p=1.000), indicating no meaningful shift in the overall treatment pattern during the 3-month follow-up period.

Among the monotherapy regimens, metformin sustained release (SR) was the most commonly prescribed drug (8.7%), followed by metformin (8.0%). Among the combination therapies, metformin with glimepiride was the most frequently prescribed regimen (32.7%), followed by metformin with teneligliptin (17.3%), metformin with dapagliflozin (12.0%), metformin with vildagliptin (10%), metformin with empagliflozin (8%) and the least prescribed combination therapy was metformin with sitagliptin (3.3%).

At the third month (follow up), among the monotherapy regimens, metformin sustained release (SR) was the most commonly prescribed drug (8.7%), followed by metformin (7.3%). Also, among the combination therapies, metformin with glimepiride was the most frequently prescribed regimen (32%), followed by metformin with teneligliptin (19.3%) and metformin with dapagliflozin (15.3%), metformin with empagliflozin (10.7%), metformin with vildagliptin (4.7%) and the least prescribed combination therapy was metformin with sitagliptin (2%).

During follow-up, an increase in the use of SGLT-2 inhibitors such as dapagliflozin and empagliflozin was observed. A statistically significant reduction was noted in the prescription pattern of metformin with vildagliptin (p = 0.008), while changes in the prescription pattern of other regimens were not statistically significant. (Statistically significant p value < 0.05)

The distribution of different oral antidiabetic drug regimens was also studied. Metformin with glimepiride was the most frequently prescribed regimen among study participants with 49 patients at enrolment and 48 patients at the third month follow up, followed by metformin with teneligliptin (26 at enrolment and 29 at follow up). Least frequently prescribed combination was metformin with sitagliptin which was having 5 patients at enrolment and 3 at follow up. The use of SGLT-2 inhibitors showed a gradual increase during follow-up, while prescriptions of DPP-4 inhibitor combinations such as vildagliptin showed a decline and this reduction was statistically significant with a p-value of 0.008. The distribution of study participants based on drugs prescribed at enrolment and after 3 months is shown in Table 1.

Table 1: Distribution of study participants based on drugs prescribed at enrolment and after 3 months (n=150)

Type of Therapy	Prescription Pattern	Number at Enrolment (%) (0 Month)	Number at Follow up (%) (3 months)	Mean Change (n)	p value
Monotherapy	Metformin SR	13 (8.7)	13 (8.7)	0	1.0
	Metformin	12 (8.0)	11 (7.3)	-1	1.0
Combination Therapy	Metformin + Glimepiride	49 (32.7)	48 (32.0)	-1	1.0
	Metformin + Teneligliptin	26 (17.3)	29 (19.3)	3	0.581
	Metformin + Empagliflozin	12 (8.0)	16 (10.7)	4	0.424
	Metformin + Dapagliflozin	18 (12.0)	23 (15.3)	5	0.302
	Metformin + Vildagliptin	15 (10.0)	07 (4.7)	-8	0.008*
	Metformin + Sitagliptin	05 (3.3)	03 (2.0)	-2	0.5

Efficacy of Oral Antidiabetic Drugs in Study Participants

Table 2: Efficacy of oral antidiabetic drugs in the study participants (n=150) {HbA1c% and FBS}

Parameter	Enrolment (0 month) Mean (SD)	Follow up (3 months) Mean (SD)	Mean change	t-statistics	p- value
HbA1c %	7.65 ± 0.68%	7.14 ± 0.78%	-0.51	-13.00	<0.001*
FBS (mg/dL)	169.96 (25.55)	156.69 (27.58)	-13.26	-5.97	<0.001*

* Highly significant p value (< 0.01)

Table 3: Association between Type of Therapy and Glycaemic Control (n=150)

Therapy Type	n	Mean Change in FBS (mg/dL) ± SD	p-value (t-test)	Mean Change in HbA1c (%) ± SD	p-value (t-test)
Monotherapy	25	−18.6 ± 34.7	0.582	-0.47 ± 0.27	0.601
Combination therapy	125	−20.5±38.2		-0.52 ± 0.23	

Table 4: Association between Comorbidity and Glycaemic Control (n=150)

Comorbidity	n	Mean Change in FBS (mg/dL) ± SD	p-value (t-test)	Mean Change in HbA1c (%) ± SD	p-value (t-test)
Absent	**74**	-12.92 ± 27.46	0.018	-0.48 ± 0.47	0.011
Present	**76**	−6.48±27.25		-0.42 ± 0.51	

* Statistically significant p value ($p < 0.05$)

Safety of Oral Antidiabetic Drugs in Study Participants

The total number of patients experiencing ADRs was 11. The study illustrates that among patients who experienced ADRs, the adverse drug reactions included hypoglycemia (n=2), headache (n=1) and diarrhea (n=2). A few participants reported combined symptoms such as hypoglycemia with weight loss (n=1), fatigue with headache (n=1), abdominal discomfort with headache (n=2) and weight loss with fatigue (n=2).

Causality assessment of adverse drug reactions was also performed using the WHO-UMC scale to assess ADRs. Among the 11 patients who reported ADRs, all were categorized as possible.

The preventability assessment of adverse drug reactions was carried out using the Schumock and Thornton preventability scale. The majority of ADRs were classified as probably preventable (72.7%), while 27.3% were categorized as definitely preventable.

The severity of adverse drug reactions in patients was assessed using Hartwig's severity scale and all of the ADRs were classified as being mild in severity.

DISCUSSION

The present prospective observational study evaluated the prescription pattern, efficacy, and safety of oral antidiabetic drugs among 150 patients with type 2 diabetes mellitus attending a tertiary care hospital.

The study demonstrated a predominance of combination therapy (83.4% at enrolment and 84.0% at follow-up) compared to monotherapy (16.6% at enrolment and 16% at follow up). This finding is consistent with contemporary prescribing trends in tertiary care settings [10]. The American Diabetes Association recommends stepwise intensification of therapy, including combination pharmacotherapy, when glycaemic targets are not achieved with initial treatment [11]. A cross-sectional study conducted in Mexico by Fierro et al also reported that most patients with type 2 diabetes received combination therapy rather than monotherapy, reflecting the need for multiple pharmacological agents to achieve adequate glycaemic control [10].

The predominance of the metformin-glimepiride combination (32.7% at enrolment and 32.0% at follow-up) observed in the present study reflects continued reliance on this regimen in routine clinical practice because of its proven efficacy, affordability, and widespread availability. However, contemporary diabetes management has progressively shifted toward individualized therapy based on cardiovascular and renal risk rather than glycaemic control alone.

In the current study metformin with teneligliptin increased from 17.3% to 19.3% which is in accordance with the study conducted by Kakade et al. which reported that DPP-4 inhibitors

accounted for approximately 19% of antidiabetic prescriptions, with teneligliptin and vildagliptin being commonly used agents [11]. However, prescriptions for certain DPP-4 inhibitor combinations declined in our study like Metformin with vildagliptin decreased from 10.0% to 4.7%, while metformin with sitagliptin decreased from 3.3% to 2.0%. A notable trend observed in the present study was the increasing use of SGLT-2 inhibitors. Prescriptions for metformin plus dapagliflozin increased from 12.0% to 15.3%, while metformin plus empagliflozin increased from 8.0% to 10.7% during follow-up. A gradual increase in dapagliflozin and empagliflozin based combinations observed during follow-up in our study is consistent with evolving international treatment recommendations given by ADA 2024(12) and reflects increasing physician acceptance of these agents in routine clinical practice. A large population-based drug utilization study by Shirabe et al. conducted in Japan also reported changes in prescription patterns and increasing use of newer antidiabetic drug classes, including SGLT-2 inhibitors and DPP-4 inhibitors, over time [13].

Similarly, a Japanese longitudinal database study by Tajima et al. demonstrated a gradual decline in sulfonylurea use and increasing prescriptions of DPP-4 inhibitors and SGLT-2 inhibitors over time [14].

The increasing use of SGLT-2 inhibitors may be attributed to their demonstrated cardiovascular and renal protective effects, as shown in the EMPA-REG OUTCOME trial conducted by Zinman et al., which reported significant reductions in cardiovascular mortality among patients receiving empagliflozin [15].

Similarly, the DECLARE–TIMI 58 trial conducted by Wiviott et al. demonstrated improved cardiovascular outcomes and reduced hospitalization for heart failure among patients treated with dapagliflozin [16].

This trend reflects the growing adoption of newer antidiabetic agents with additional cardiovascular and renal benefits, however the exclusion of patients with cardiovascular and renal diseases was one of the limitations of this study.

A Statistically significant reduction in the mean fasting blood sugar was observed in the present study (mean reduction: 13.26 percentage points; from 169.96mg/dL at enrolment to 156.69mg/dL at follow-up.) demonstrates the efficacy of oral antidiabetic therapy in improving glycaemic controls.

The present study also showed statistically significant reduction in HbA1c (i-e mean reduction: 0.51 percentage points; from 7.65% at enrolment to 7.14% at 3-month follow-up) which is consistent with previous studies demonstrating the efficacy of oral antidiabetic therapy in improving glycaemic control [7]. The magnitude of HbA1c reduction varies across studies depending on baseline glycaemic status, duration of diabetes, treatment adherence, and follow-up period. Patients with higher baseline HbA1c generally experience greater absolute reductions, which may explain the larger improvements reported in studies involving newly diagnosed or poorly controlled patients. Furthermore, systematic evidence has demonstrated that combination pharmacotherapy can provide greater glycaemic efficacy than monotherapy in patients with type 2 diabetes mellitus, while maintaining an acceptable overall safety profile [17]. The greater reduction reported in the GLIMPSE study (approximately 1.0% with glimepiride-metformin therapy) may therefore be partly explained by differences in baseline glycaemic status and the inclusion of newly diagnosed patients [18]. Similarly, Kim et al. reported HbA1c reductions of 1.2% with a glimepiride–metformin fixed-dose combination compared with 0.8% with metformin uptitration [19]. These differences may reflect variations in baseline HbA1c levels, patient characteristics, treatment duration, and study design. Interestingly, the present study found no statistically significant difference in glycemic improvement between patients receiving monotherapy and those receiving combination therapy. This finding contrasts with several published studies that report superior glycemic control with combination therapy. Park et al. demonstrated that triple combination therapy achieved HbA1c reductions of 1.41% over 24 weeks [20]. The absence of a significant difference in glycaemic improvement between patients receiving monotherapy and combination therapy in the present study may be explained by several factors, including the relatively short follow-up period of three months, appropriate selection of therapy according to disease severity, and the possibility that patients receiving monotherapy had milder

hyperglycaemia at baseline [19].

The current study also demonstrated that patients without comorbidities achieved greater improvements in glycemic control compared to those with comorbid conditions. This observation aligns with clinical evidence suggesting that the presence of comorbidities complicates diabetes management through factors such as polypharmacy, drug interactions, and advanced metabolic disturbances. Hussain and Chowdhury (2019) reported that coexisting chronic conditions significantly increase treatment complexity and may limit therapeutic options for glycaemic management [21].

The safety analysis revealed that adverse drug reactions were relatively infrequent among the study participants, indicating a favourable safety profile of the prescribed oral antidiabetic regimens. This observation is consistent with the established safety profile of commonly used oral antidiabetic agents [22]. Dhokiya et al. reported a higher incidence of adverse drug reactions (40.3%) among diabetic patients, with hypoglycemia, nausea, and weight gain being the most commonly reported events [23]. The lower incidence observed in the present study may be attributed to differences in patient characteristics and follow-up duration.

Causality assessment using the WHO-UMC scale showed that all the adverse drug reactions were classified as possible. Similar patterns have been reported in pharmacovigilance study of Keezhipadathil et al evaluating antidiabetic medications [24].

Preventability assessment using the Schumock and Thornton scale revealed that 72.7% of ADRs were probably preventable and 27.3% were definitely preventable, indicating opportunities for improving drug safety through better patient counselling, dose optimization, and monitoring [25]. Similar findings have been reported in the pharmacovigilance study by Bouvy et al., indicating that a considerable proportion of ADRs can be avoided through appropriate prescribing practices, dose adjustments, and patient monitoring [26].

Severity assessment showed that all adverse drug reactions experienced by patients were mild (100%), with no moderate or severe reactions reported. Similar findings were reported by Dhokiya et al., where moderate and mild reactions predominated [23].

Certain limitations of the study were relatively smaller sample size which may have restricted the generalizability of the findings. The study was conducted at a single tertiary care centre, which may not adequately represent prescribing practices across different healthcare settings. Patients with significant comorbid conditions like CKD, arrhythmias, COPD, asthma and psychiatric illness, who constitute an important population receiving newer oral antidiabetic drugs, were excluded, thereby limiting the external validity of the findings. The short duration of follow-up precluded assessment of long-term glycaemic durability, cardiovascular and renal outcomes, as well as evolving adverse event patterns. Potential confounders such as duration of diabetes, adherence to medication, lifestyle modification, diet and physical activity were not comprehensively quantified, which may have influenced observed changes in glycaemic control. Furthermore, adverse drug reactions were identified over a limited time frame and partly relied on patient self-reporting, introducing the possibility of recall bias and under-reporting.

CONCLUSION

In this prospective observational study, combination therapy, predominantly Metformin with glimepiride was the mainstay of Oral antidiabetic Drug prescribing. A modest but statistically meaningful improvement in FBS and HbA1c was seen over three months. All the adverse events documented were mild, and most were of a preventable nature. The findings underscore the need for periodic prescription audit and active pharmacovigilance to optimise real-world diabetes care.

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