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Original Research Article

Analysis of fixed dose combinations and price variations of oral antidiabetic agents in the Indian pharmaceutical market

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ABSTRACT

Aim: The objective of this study was to analyse the price variations of Fixed Dose Combinations (FDCs) of oral antidiabetic agents in India to highlight the percentage price variations among different brands offering the same formulations of oral antidiabetic FDCs.

Background: Diabetes is a metabolic disorder requiring consistent medication for blood glucose control. The wide cost variation among antidiabetic agents affects patient access and adherence, underscoring the importance of evaluating price differences to support affordable, effective diabetes management.

Materials and Methods: This analytical study was conducted from August to September 2024, reviewing prices of 118 formulations across 34 oral antidiabetic FDCs sourced from the National Pharmaceutical Pricing Authority's (NPPA) 'Pharma Sahi Daam' a public database. FDCs produced by multiple manufacturers were included, excluding single manufacturers. Microsoft Excel 2021 was used throughout the analysis.

Results: Among two-drug combinations, the highest percentage cost variation was observed in glimepiride + metformin (2mg + 1000mg) as 15958.33% and the lowest variation was found with empagliflozin + metformin as 0%. For three-drug combinations, the highest price variation was founded in voglibose + metformin + glimepiride (0.3mg + 500mg + 1mg) as 209900% and the least price variation was found in dapagliflozin + linagliptin + metformin (10mg + 5mg + 500mg) as 0%. The highest brand availability was recorded for glimepiride + metformin with 447 brands, and the lowest for pioglitazone + vildagliptin and teneligliptin + dapagliflozin, with only 2 brands each.

Conclusion: This study highlights significant price variations among oral antidiabetic FDCs in India, which can affect patient's treatment adherence. These findings underscore the need for intervention by regulatory authorities to enforce stricter measures in the pharmaceutical market to manage these price variations.

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1. Introduction

Diabetes mellitus (DM) is a group of metabolic disorders characterized by chronically high blood glucose levels. It is associated with abnormal fat and protein metabolism,

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leading to acute complications like diabetic ketoacidosis and hyperosmolar hyperglycemic syndrome, as well as chronic vascular and nerve damage. Diabetes is a growing health concern globally, affecting 537 million adults (10.5%) worldwide in 2021, with projections indicating this will rise to 783 million by 2045. In South-East Asia, including India, the incidence of diabetes has been steadily increasing for

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over 20 years. Specifically, in India, the diabetes prevalence was 9.6% in 2021 and is expected to rise to 10.9% by 2045, highlighting the urgent need for improved management and access to affordable treatments for this chronic condition.²

The management of DM typically begins with monotherapy; however, as the disease progresses, polytherapy often becomes necessary to achieve optimal glycemic control. A major challenge in managing chronic conditions like diabetes is patient non-adherence, especially when multiple medications are required.³ Nonadherence to polytherapy in diabetes management worsens glycemic control, increasing the risk of complications like cardiovascular disease. Simplified treatment regimens, such as Fixed Dose Combinations (FDCs) are crucial to improving adherence and reducing hospitalizations.⁴ FDCs provide a potential solution by combining two or more drugs into a single pill, which simplifies treatment regimens, reduces the pill burden and can improve both adherence and tolerability.⁵ This long-term treatment of diabetes places a significant economic burden on patients, especially in a country like India where a large portion of the population belongs to lower and middle-income groups. For many patients, the cumulative costs of medication, regular monitoring, and doctor visits can be overwhelming.⁶

In the Indian pharmaceutical market, the wide variation in the prices of oral antidiabetic drugs, especially FDCs, which can significantly affect the patient's ability to access these medications, regardless of their therapeutic merits. This price disparity can lead to treatment discontinuation or switching to less effective alternatives, which can have serious health implications. Addressing these price variations is essential to ensure that all patients, regardless of their financial situation, have access to necessary diabetes medications. 8

This study aims to analyse the price variations of FDCs of oral antidiabetic agents in India. By evaluating these cost disparities, the study intends to highlight the percentage price variations in different brands of same formulations of orals antidiabetic FDCs. This is especially important in India, where the affordability of long-term diabetes management plays a crucial role in enhancing patient outcomes and reducing the impact of diabetes-related complications.

2. Materials and Methods

This is an analytical study, conducted from August to September 2024. The prices of 118 different formulations of 34 oral antidiabetic FDCs were examined. Price data for each drug (per 10 tablets), in the same strength and dosage form produced by various manufacturers, were collected from "Pharma Sahi Daam", an openly accessible platform provided by the NPPA. 9

Only FDCs were included, while single drug combinations and drugs produced by a single manufacturer

were excluded from the analysis. The minimum and maximum costs, total number of brands for each FDCs were analysed. Microsoft Excel Office 2021 was used for the statistical analysis throughout the study.

The cost ratio, which compares the highest to the lowest cost of the FDCs, was calculated by

$$Cost\ ratio = \frac{Maximum\ \cos t}{Minimum\ \cos t}$$

The percentage cost variation between the maximum and minimum prices of FDCs was calculated by

% Cost variation =
$$\frac{(Maximum \cos t - Minimum \cos t)}{Minimum \cos t} \times 100$$

3. Results

This study analysed the prices of all oral antidiabetic FDCs and observed significant price variations among different brands of the same formulations. The highest percentage cost variation in SGLT2 inhibitors combinations was founded in dapagliflozin + sitagliptin (5 mg + 50 mg) as 1722.5% followed by dapagliflozin + metformin (10 mg + 500 mg) as 1591.54% and the least percentage cost variation was founded in empagliflozin + metformin (12.5 mg + 500 mg and 12.5 mg + 1000 mg) as 0% (Table 1).

The highest price variation in sulfonylureas combinations was founded in glimepiride + metformin (2 mg + 1000 mg) as 15958.33% followed by glimepiride + metformin (1 mg + 1000 mg) as 9665% and the least price variation was founded in gliclazide + metformin 60 mg + 1000 mg) as 5.88% (Table 2). Similarly, the highest price variation in DPP-4 Inhibitors, thiazolidinediones, and other combinations were founded in vildagliptin + metformin (50 mg + 500 mg) as 2207.69% followed by voglibose + metformin (20 mg + 500 mg) as 1349.63% and the least price variation was founded in teneligliptin + metformin (0.2 mg + 1000 mg) as 0.22% (Table 3).

In SGLT2, DPP-4, biguanides and others (3 drug combinations), the highest price variation was founded in sitagliptin + dapagliflozin + metformin (100 mg + 10 mg + 500 mg) as 2553.85% and the least price variation was founded in dapagliflozin + linagliptin + metformin (10 mg + 5 mg + 500 mg) as 0% (Table 4). Similarly, in sulfonylureas, alpha-glucosidase inhibitors and others (3 drug combinations), the highest price variation was found in voglibose + metformin + glimepiride (0.3 mg + 500 mg + 1 mg) as 209900% and the least percentage price variation was founded in voglibose + metformin + gliclazide (0.2 mg + 500 mg + 60 mg) as 4.17% (Table 5).

Following price variations, the highest number of brands available for oral antidiabetic FDCs in the Indian market is for glimepiride + metformin with 447 brands in total followed by voglibose + metformin + glimepiride with 239 brands in total. The least number of brands was founded in pioglitazone + vildagliptin and teneligliptin + dapagliflozin with 2 brands each (Table 6).

 Table 1: SGLT2 inhibitors combination drugs

Name of the drug	Strength (mg)	Min. price	Max. price	Cost ratio	% cost variation
Dapagliflozin +	5 mg + 5 mg	15.9	16.2	1.02	1.89
Linagliptin	10 mg + 5 mg	9.9	23.8	2.40	140.40
	5 mg + 500 mg	7	18.4	2.63	162.86
Dapagliflozin +	5 mg + 1000 mg	1.35	14.27	10.57	957.04
Metformin	10 mg + 500 mg	1.3	21.99	16.92	1591.54
	10 mg+ 1000 mg	7.9	22.99	2.91	191.01
	5 mg + 50 mg	1.2	21.87	18.23	1722.50
Dapagliflozin +	5 mg + 100 mg	15	19.5	1.30	30.00
Sitagliptin	10 mg + 50 mg	12	19.9	1.66	65.83
	10 mg + 100 mg	9.6	24	2.50	150.00
Dapagliflozin +	5 mg + 100 mg	13.28	20.79	1.57	56.55
Vildagliptin	10 mg + 100 mg	7.9	27.59	3.49	249.24
Empagliflozin +	25 mg + 5 mg	25	86.1	3.44	244.40
Linagliptin	10 mg + 5 mg	75	78.8	1.05	5.07
Empagliflozin +	12.5 mg + 500 mg	41.6	41.6	1.00	0
Metformin	12.5 mg + 1000 mg	43.7	43.7	1.00	0
Teneligliptin + Dapagliflozin	20 mg + 10 mg	10.95	13.9	1.27	26.94

Table 2: Sulfonylureascombination drugs

Name of the drug	Strength (mg)	Min. price	Max. price	Cost ratio	% cost variation
C1:1	2.5 mg + 400 mg	3.2	5.05	1.58	57.81
Glibenclamide + Metformin	5 mg + 500 mg	0.75	6.55	8.73	773.33
Metroriiii	5 mg + 850 mg	5.5	8.9	1.62	61.82
	30 mg + 500 mg	6.1	10.6	1.74	73.77
	40 mg + 500 mg	4.9	11.05	2.26	125.51
Gliclazide +	60 mg + 1000 mg	11.9	12.6	1.06	5.88
Metformin	60 mg + 500 mg	7.99	17.5	2.19	119.02
	80 mg + 1000 mg	8.85	12.9	1.46	45.76
	80 mg + 500 mg	0.99	17.41	17.59	1658.59
	0.5 mg + 500 mg	5.80	17.55	3.03	202.59
	1 mg + 500 mg	0.91	19.96	21.93	2093.41
	1 mg + 850 mg	3.9	8.9	2.28	128.21
	1 mg + 1000 mg	0.2	19.53	97.65	9665.00
	2 mg + 500 mg	1.06	24.2	22.83	2183.02
Glimepiride +	2 mg + 850 mg	5.84	13.55	2.32	132.02
Metformin	2 mg + 1000 mg	0.12	19.27	160.58	15958.33
	3 mg + 500 mg	6.17	20.29	3.29	228.85
	3 mg + 850 mg	7.9	20.48	2.59	159.24
	3 mg + 1000 mg	2.4	15.1	6.29	529.17
	4 mg + 500 mg	2.95	19.2	6.51	550.85
	4 mg + 1000 mg	3.4	15.25	4.49	348.53
Glipizide +	2.5 mg + 400 mg	2.2	5	2.27	127.27
Metformin	5 mg + 500 mg	0.51	11	21.57	2056.86
Pioglitazone +	15 mg + 1 mg	6.65	20.56	3.09	209.17
Glimepiride	15 mg + 2 mg	5	36	7.20	620.00

Table 3: DPP-4 Inhibitors, Thiazolidinediones, andother combinations

Name of the drug	Strength (mg)	Min. price	Max. price	Cost ratio	% cost variation
	2.5 mg + 500 mg	7.4	19.5	2.64	163.51
Linagliptin +	2.5 mg + 850 mg	18.6	20	1.08	7.53
Metformin	2.5 mg + 1000 mg	3.7	14.9	4.03	302.70
	5 mg + 1000 mg	7.5	14.9	1.99	98.67
	7.5 mg + 500 mg	1.99	7.32	3.68	267.84
Pioglitazone +	15 mg + 500 mg	2.96	14.15	4.78	378.04
Metformin	15 mg + 1000 mg	7.59	17.38	2.29	128.99
	30 mg + 500 mg	6.22	11.4	1.83	83.28
Pioglitazone + Teneligliptin	15 mg + 20 mg	11.9	14	1.18	17.65
Pioglitazone + Vildagliptin	15 mg + 50 mg	15.38	17.8	1.16	15.73
	0.2 mg + 0.5 mg	11.75	15.2	1.29	29.36
	0.2 mg + 1 mg	15.2	15.35	1.01	0.99
	0.3 mg + 0.5 mg	7.9	16.8	2.13	112.66
Repaglinide +	0.3 mg + 1 mg	9.9	17.4	1.76	75.76
Voglibose	0.5 mg + 0.2 mg	13.14	15.5	1.18	17.96
	0.5 mg + 0.3 mg	11.62	16.8	1.45	44.58
	1 mg + 0.2 mg	14.79	19.05	1.29	28.80
	1 mg +0.3 mg	14.9	21.2	1.42	42.28
	50 mg + 500 mg	1.35	19.2	14.22	1322.22
Sitagliptin +	50 mg + 1000 mg	9.5	22.93	2.41	141.37
Metformin	100 mg + 500 mg	12.4	19.5	1.57	57.26
	100 mg + 1000 mg	12	21.7	1.81	80.83
Voglibose +	20 mg + 500 mg	1.35	19.57	14.50	1349.63
Metformin	20 mg + 1000 mg	6.37	29.38	4.61	361.22
	50 mg + 500 mg	1.3	30	23.08	2207.69
Vildagliptin +	50 mg + 850 mg	7	25.94	3.71	270.57
Metformin	50 mg + 1000 mg	5.1	31.8	6.24	523.53
	100 mg + 500 mg	8.24	14.2	1.72	72.33
	100 mg + 1000 mg	9.96	15.46	1.55	55.22
	0.2 mg + 500 mg	2.92	18.02	6.17	517.12
Teneligliptin +	0.2 mg + 1000 mg	13.37	13.4	1.00	0.22
Metformin	0.3 mg + 500 mg	2.92	21.01	7.20	619.52
	0.3 mg + 1000 mg	14.545	18.4	1.27	26.50

4. Discussion

The Indian market for oral antidiabetic FDCs exhibits significant price variability influenced by market dynamics, regulatory factors, and brand positioning. Key factors of pharmaceutical expenditures include the number of prescribed medicines, the introduction of new drugs, and fluctuations in drug prices and utilization patterns. 10 Additionally, demographic trends, such as an aging population and varying socio-economic statuses, impact consumption patterns. Health care reforms and directto-consumer advertising may also boost demand for specialized medications, contributing to further variations in drug prices. 11 Price variations in essential medications have long been a significant challenge in healthcare, often affecting both the affordability and accessibility of treatments. These disparities can directly impact patient adherence, as higher costs may lead to delayed

treatment initiation, inconsistent medication use, or even complete discontinuation, particularly among economically disadvantaged populations. ¹²

In our analysis, we observed significant variations in the cost of oral antidiabetic FDCs. Existing literature by Jadhav NB et al., ¹³, Mehani R et al., ¹⁴, Thacker et al., ¹⁵, Veena et al., ¹⁶ and Amaravati et al., ¹⁷ spanning from 2012 to 2023, has consistently demonstrated significant variations in the pricing of oral antidiabetic agents, which aligns with our findings. Notably, these studies highlight that price fluctuations and percentage variations are not static but have shown changes annually. Furthermore, the data indicate a clear upward trend in price variations over the years, suggesting a progressive increase in the cost of these medications. This trend underscores the growing economic burden on patients.

Table 4: SGLT2, DPP-4, Biguanides and others (3 drug combinations)

Name of the drug	Strength (mg)	Min. price	Max. price	Cost ratio	% cost variation
Dapagliflozin +	5 mg + 10 mg + 500 mg	20.9	21.99	1.05	5.22
Linagliptin + Metformin	10 mg + 5 mg + 500 mg	19.9	19.9	1.00	0
D 1'd ' .	1 mg + 500 mg + 1 mg	10.6	15	1.42	41.51
Dapagliflozin + Metformin +	1 mg + 500 mg + 2 mg	12	16	1.33	33.33
Glimepiride	1 mg + 1000 mg + 1 mg	10.6	16.15	1.52	52.36
Omnephiae	1 mg + 1000 mg + 2 mg	12	17.9	1.49	49.17
	5 mg + 100 mg + 500 mg	12.4	18.12	1.46	46.13
Dapagliflozin + Vildagliptin	5 mg + 100 mg + 1000 mg	13.4	19.08	1.42	42.39
+ Metformin	10 mg + 100 mg + 500 mg	9	22.8	2.53	153.33
. 1/10/10/11/11	10 mg + 100 mg + 1000 mg	13	24.8	1.91	90.77
Metformin +	500 mg + 7.5 mg + 0.2 mg	8.14	9.4	1.15	15.48
Pioglitazone + Voglibose	500 mg + 7.5 mg + 0.3 mg	11.31	12	1.06	6.10
Sitagliptin +	100 mg + 10 mg + 500 mg	1.3	34.5	26.54	2553.85
Dapaglifloz n + Metformin	100 mg + 10 mg + 1000 mg	12.5	31.51	2.52	152.08
Sitagliptin +	50 mg + 1000 mg + 1 mg	10.6	14.95	1.41	41.04
Metformin + Glimepiride	50 mg + 1000 mg + 2 mg	13.5	16.83	1.25	24.67
Sitagliptin +	100 mg + 15 mg + 500 mg	16.9	18.5	1.09	9.47
Pioglitazone+ Metformin	100 mg + 15 mg + 1000 mg	18.5	20.3	1.10	9.73
Teneligliptin+	20 mg + 15 mg + 500 mg	16.37	17.99	1.10	9.90
Pioglitazone+ Metformin	20 mg + 15 mg + 1000 mg	17.47	19.99	1.14	14.42

Price control mechanisms such as the DPCO in India aim to regulate the prices of essential medicines, including FDCs, by capping the prices of drugs listed under the National List of Essential Medicines (NLEM). 18 While this has made some FDCs more affordable and accessible, there are still disparities in price regulation. For example, many drugs outside the NLEM are not subjected to strict price controls, leading to significant price variations. 19 Additionally, implementation gaps in the system allow pharmaceutical companies to introduce new FDCs at premium prices by slightly modifying drug compositions to bypass existing regulations. In fact, pharmaceutical companies often exploit regulatory loopholes by launching reformulated or slightly altered FDCs at premium prices, contributing further to the inconsistency in drug pricing. This creates disparities and challenges in controlling drug costs effectively. 20

The rationality of FDCs is debated, especially when some combinations may not provide any additional therapeutic benefits over individual drugs. Clinical decision-making can be influenced by price variations, particularly when higher-priced combinations offer no significant

advantage. In these cases, prescribers may prefer cheaper alternatives that are equally effective. The lack of clear guidelines regarding the rational use of FDCs further complicates this issue. ²¹ Price disparities may also inadvertently promote irrational prescribing patterns, as healthcare providers might either favour expensive medications due to perceived quality or be limited by patient affordability concerns. When comparing internationally, other nations implement various strategies such as external reference pricing or value-based pricing models, which may offer insights into strengthening India's approach to pharmaceutical cost regulation. ²²

5. Regulatory Recommendations and Future Directions

- 1. Establish standardized pricing frameworks to mitigate price variations among oral antidiabetic FDCs, ensuring affordability for all patients.
- 2. Refine NPPA guidelines to specifically address extreme price disparities in high-demand oral antidiabetic FDCs formulations, ensuring fair pricing practices.

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Name of the drug	Strength (mg)	Min. price	Max. price	Cost ratio	% cost variation
Glibenclamide + Metformin + Pioglitazone	5 mg + 500 mg + 15 mg	7.4	11.9	1.61	60.81
	30 mg + 15 mg + 500 mg	7.57	10.8	1.43	42.67
Gliclazide + Pioglitazone +	60 mg + 7.5 mg + 500 mg	6.70	9.19	1.37	37.16
Metformin	60 mg + 15 mg + 500 mg	9.5	14.1	1.48	48.42
	80 mg + 15 mg + 500 mg	12.6	15.8	1.25	25.40
	1 mg + 500 mg + 7.5 mg	4.39	8.35	1.90	90.21
	1 mg + 500 mg + 15 mg	2.11	15.66	7.42	642.18
	1 mg + 1000 mg + 7.5 mg	7.13	8.9	1.25	24.82
Glimepiride + Metformin +	1 mg + 1000 mg + 15 mg	6.48	15.09	2.33	132.87
Pioglitazone	2 mg + 500 mg + 7.5 mg	5.3	19.5	3.68	267.92
	2 mg + 500 mg + 15 mg	0.12	22.29	185.75	18475
	2 mg + 1000 mg + 7.5 mg	9.3	71.6	1.05	5.05
	2 mg + 1000 mg + 15 mg	10.75	27.53	2.56	156.09
Voglibose + Metformin +	0.2 mg + 500 mg + 60 mg	12	12.5	1.04	4.17
Gliclazide	0.2 mg + 500 mg + 80 mg	13.8	18.3	1.33	32.61
	0.2 mg + 500 mg + 1 mg	3.9	22.2	5.69	469.23
	0.2 mg + 500 mg + 2 mg	3.67	27.76	7.56	656.40
1	0.2 mg + 1000 mg + 1 mg	11.5	13.89	1.21	20.78
Vogilbose + Menorinin +	0.2 mg + 1000 mg + 2 mg	10.25	18.61	1.82	81.56
Girinepinae	0.3 mg + 500 mg + 1 mg	0.01	21	2100	209900
	0.3 mg + 500 mg + 2 mg	5.9	26	4.41	340.68
	0.3 mg + 500 mg + 3 mg	6.37	18.5	2.90	190.42

Table 6: Total number of brands and formulations of oral antidiabetic FDCs

Name of the drug	Pack size	No. of strengths available	No. of Brands
Dapagliflozin + Linagliptin	10	2	33
Dapagliflozin + Metformin	10	4	146
Dapagliflozin + Sitagliptin	10	4	141
Dapagliflozin + Vildagliptin	10	2	83
Empagliflozin + Linagliptin	10	2	10
Empagliflozin + Metformin	10	2	6
Glibenclamide + Metformin	10	3	29
Gliclazide + Metformin	10	6	107
Glimepiride + Metformin	10	12	447
Glipizide + Metformin	10	3	20
Linagliptin + Metformin	10	4	50
Pioglitazone + Glimepiride	10	2	16
Pioglitazone + Metformin	10	4	32
Pioglitazone + Teneligliptin	10	1	3
Pioglitazone + Vildagliptin	10	1	2
Repaglinide + Voglibose	10	8	40
Sitagliptin + Metformin	10	4	107
Teneligliptin + Dapagliflozin	10	1	2
Teneligliptin + Metformin	10	2	168
Vildagliptin + Metformin	10	5	104
Voglibose + Metformin	10	4	108
Dapagliflozin + Linagliptin + Metformin	10	2	4
Dapagliflozin + Metformin + Glimepiride	10	4	35
Dapagliflozin + Vildagliptin + Metformin	10	4	41
Glibenclamide + Metformin + Pioglitazone	10	1	6
Gliclazide + Pioglitazone + Metformin	10	4	13
Glimepiride + Metformin + Pioglitazone	10	8	178
Metformin + Pioglitazone + Voglibose	10	2	4
Sitagliptin + Dapagliflozin + Metformin	10	2	91
Sitagliptin + Metformin + Glimepiride	10	2	23
Sitagliptin + Pioglitazone + Metformin	10	2	11
Teneligliptin + Pioglitazone + Metformin	10	2	4
Voglibose + Metformin + Gliclazide	10	2	6
Voglibose + Metformin + Glimepiride	10	7	239

- 3. Implement routine assessments to monitor pricing trends and ensure compliance with regulations, allowing for timely interventions when necessary.
- 4. Launch patient education campaigns that not only inform patients of price variations but also promote awareness about the efficacy of more affordable alternatives, which can maintain adherence without sacrificing treatment outcomes.
- 5. Provide training and resources for healthcare providers on price variations among oral antidiabetic medications, encouraging cost-effective prescribing options to improve patient adherence and access.

6. Conclusion

The findings of this study reveal a significant variation in the prices of oral antidiabetic FDCs in the Indian pharmaceutical market. In some cases, the price disparity between different brands of the same formulation is alarmingly high. These substantial differences in cost pose a considerable barrier to patients, particularly in a country like India where affordability is a critical factor in chronic disease management. While FDCs are intended to simplify diabetes management and improve adherence, the wide variation in pricing limits their accessibility, potentially forcing patients to switch to less effective alternatives or abandon treatment altogether. In conclusion, there is an urgent need for pricing control authorities, such as the NPPA, to take immediate and stringent action to address these disparities, ensuring fair and consistent pricing across different brands of oral antidiabetic FDC's.

7. Ethical Approval

This study exclusively utilizes data obtained from public databases, with no involvement of human participants or

identifiable private information. Therefore, the institutional ethics committee has confirmed that ethical approval is not required for this work.

8. Conflict of Interest

None.

9. Source of Funding

None.

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