Impact of Diabetes Educator on Diabetes Management: Findings from Diabetes Educator Assisted Management Study of Diabetes

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Abstract

The aim of the study was to determine the efficacy of a diabetes educator-assisted management study of diabetes in low and middle-income countries (Pakistan). A randomized controlled trial was carried out on 150 patients, who received diabetes care from an endocrinologist. Diabetes educators followed a stepwise approach: setting priorities for patient care, assessing patients' specific educational needs, developing of individualized diet plan, benefits of self-monitoring blood glucose, addressing the concerns related to diabetes treatment, foot care, and hypoglycaemia. In the intervention group, the diabetes educator trained patients for 6 months (follow-up visits and phone calls). The primary outcome was A1C, and the secondary outcomes included medication adherence, health-related quality of life, blood glucose, blood pressure, and lipid profile. Most of the participants were from the age range of 40-60 years (57.3%) and were male (53.3%). There was a significant improvement in the HbA1c (p<0.0001), blood glucose (p<0.0001), blood pressure (p<0.0001), and lipid profile (p<0.0001) in the intervention group. A significant improvement in the health-related quality of life and patients' adherence level was also seen after diabetes educator intervention. Glycaemic control in type 2 diabetes mellitus patients requires ongoing education. This study is an effort to enhance self-management of poorly controlled type 2 diabetes mellitus patients who are at higher risk of diabetes-associated complications.

Keywords: Medication adherence, Diabetes educator, HbA1c, Type 2 diabetes mellitus, Health-related quality of life

INTRODUCTION

Diabetes is a chronic metabolic disorder that is growing at a rapid pace. It has been linked to the deaths of nearly 5 million individuals worldwide in the past year [1]. In 2021, it was estimated that there are 536.6 million people with diabetes in the age range of 20–79 in 215 countries and territories. And it projects that 783.2 million people will have diabetes in 2045 [2]. A high proportion of people with diabetes (80.6%, 432.7 million) live in low- and middle-income countries. Pakistan is ranked #1 with 30.8% diabetes prevalence and is expected to reach 33.6% in the year 2045. And it is ranked #3 with 33 million people with diabetes in 2021 and estimated at 62.2 million in 2045 with China and India leading the table [3].

The American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) recommends treatment initiation with non-pharmacological management i.e., lifestyle modification, such as weight loss and exercise; however, the long-term effectiveness of lifestyle modification alone is restricted, often needing the addition of drug therapy to maintain or reach the goal of A1C of <7% [4]. Pharmacologically, Metformin is a well-recognized first-line drug for treatment. Based on long practice, effectiveness, and

modest cost, sulfonylureas are second treatment options for patients whose A1C remains high on metformin. The guidelines recommend injectable insulin as a second-step treatment option for patients who are not well controlled on metformin alone or as a third-step treatment option for patients who still do not achieve the A1C target goal on oral combination therapy. DPP-4 inhibitors, Meglitinides, Thiazolidinediones, and Incretin mimetics are the other treatment options for diabetes mellitus type 2 [5].

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However, to promote self-care and assist diabetes patients, pharmacists have expanded their roles in assisting and providing diabetes education and care [6-8]. There is an example of the American Diabetes Association, which has registered and recognized pharmacists to deliver diabetes education and care [9]. The pharmacist plays an essential role in educating the patients about their self-care [10, 11]. This education aids the patients in adhering to the treatment and improving their lifestyle that helps in improving the overall quality of life (QoL) of the patients [8, 12-14]. Therefore, the current study aimed to assess the Pharmacist's role as a diabetes educator by educating and assisting diabetes patients in self-care, treatment adherence, and diet. Moreover, to determine the impact of diabetes educator's intervention on treatment adherence, clinical parameters, and health-related quality of life.

MATERIALS AND METHODS

Research Design and Sampling

A quantitative randomized control trial was used for the current study. The calculated sample size for this study was 150; however, 10% of the total sample size was added to manage the dropout, resulting in the final sample size of 165.

The sample size was calculated by using the following formula [15].

$$n = Z^2 \times p\,(1\text{-}p)\,/d^2 \qquad (1)$$

where n = sample size, Z^2 = confidence interval, p =prevalence of type 2 diabetes mellitus, d^2 = margin of error.

The participant was recruited through simple random sampling. To avoid confounding variables, the inclusion criteria were strictly followed. The inclusion criteria for the participant were:

- Patients with Type 2 Diabetes
- Patients taking oral hypoglycaemic medications and already using insulin

- Patients with A1C >7% within the preceding month of this study
- Patients must be able to use a self-administering blood glucose monitoring device

Trial Design and Data Collection

The methods used for analyzing the effects of the proposed pharmacist as a diabetes educator for a diabetic patient have been done through a randomized controlled trial, utilized to assess the impact of diabetes educator's provided diabetes education on the management of diabetes. The study participants were divided into groups, i.e., the interventional group (A) and the control group (B). The interventional group (A) received education from diabetes educators, while the control group (B) was only evaluated for their baseline knowledge on diabetes, management of sugar levels, and QoL. Patients in the control group (B) received the usual/conventional care offered by the physicians, which included routine laboratory tests, review of diagnosis and medications, prescription of drugs. The control group was not offered any education/training on their diseases and drugs. Patients in the intervention group (A) followed a stepwise approach: setting priorities for patient care, assessing patients' specific educational needs, developing of individualized diet plan, benefits of self-monitoring blood glucose, addressing the concerns related to diabetes treatment, foot care, hypoglycaemia, and the demonstration to the device if using insulin. The education/training program for patients was preferably one time 30 mins face-to-face and followed by the telephonic contact weekly until the next follow-up visit to the physician.

The data was collected between March 2020 and December 2020 at City hospital Multan. This hospital majorly deals with endocrinology, especially diabetes. After the baseline data collection, the pharmacist intervention was given using global guidelines for type 2 diabetes [16]. The follow-up data were collected and maintained at different time slots. The detail can be seen in **Figure 1** and **Table 1**.
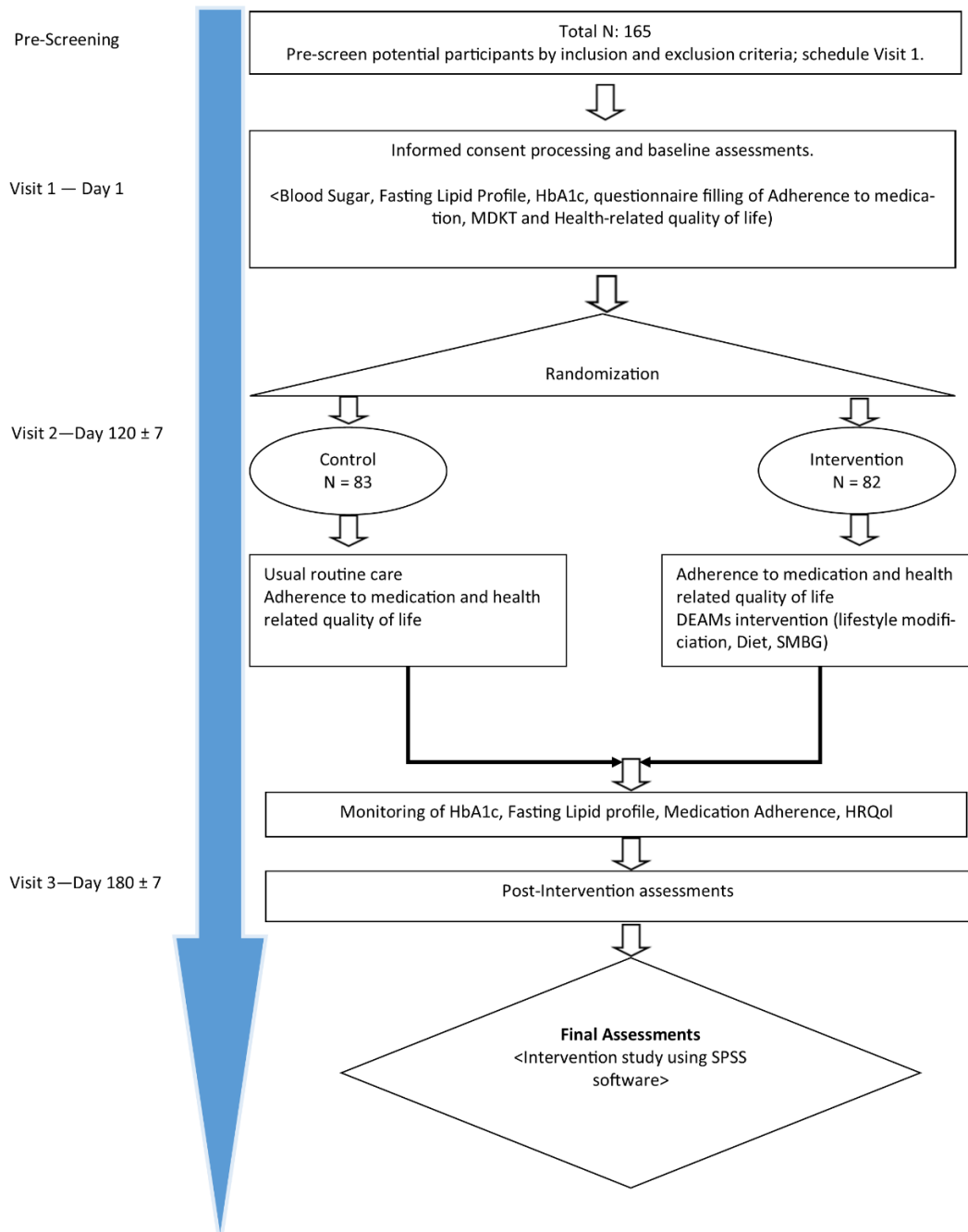
Pre-Screening

> **Total N: 165**
> Pre-screen potential participants by inclusion and exclusion criteria; schedule Visit 1.

Visit 1 — Day 1

> Informed consent processing and baseline assessments.
>
> <Blood Sugar, Fasting Lipid Profile, HbA1c, questionnaire filling of Adherence to medication, MDKT and Health-related quality of life)

Randomization

Visit 2—Day 120 ± 7

> Control
> N = 83

> Intervention
> N = 82

> Usual routine care
> Adherence to medication and health related quality of life

> Adherence to medication and health related quality of life
> DEAMs intervention (lifestyle modification, Diet, SMBG)

> Monitoring of HbA1c, Fasting Lipid profile, Medication Adherence, HRQol

Visit 3—Day 180 ± 7

> Post-Intervention assessments

> **Final Assessments**
> <Intervention study using SPSS software>

Figure 1. Patient recruitment and follow-up procedure

Table 1. Summary of the outcomes from the Control and Interventional study

	Control group			Intervention group		
	0 month	3 months	6 months	0 month	3 months	6 months
Demography data	✓			✓		
HbA1c	✓		✓	✓		✓
Lipid Profile	✓		✓	✓		✓
Medication adherence (DAI-10)	✓		✓	✓		✓
Quality of life (EQ5D)	✓		✓	✓		✓

| Review of patients' knowledge about diabetes (MDKT) | ✓ | | ✓ | |
| DEAMS intervention | | | ✓ | ✓ |

Research Instrument

The Michigan diabetes knowledge test (MDKT) was used to assess diabetes-related knowledge. The MDKT comprises 14 items highlighting different perspectives on the socio-cultural and medical aspects of diabetes [17]. The drug adherence inventory (DAI-10) scale was used to measure the drug adherence level [18]. To assess the quality of life, the EQ-5D-3l instrument was used [19].

Ethical Consideration

The study was approved by the Department of Pharmacy Practice Bahauddin Zakariya University, Multan (Reference No: 173-A/Pharmacy Practice 02/20). The study was conducted as per the Declaration of Helsinki. Informed consent was taken from the participants before recruiting patients in the control trial. The confidentiality of the participants was maintained throughout the study.

Data Analysis

For statistical analysis, statistical package for social science (SPSS v26). The categorical variable was presented as a frequency and percentage, while the continuous variable was presented as mean and standard deviation. The paired sample t-test was applied to assess the difference between pre and post variables. The p-value ≤ 0.05 was set as significant.

RESULTS AND DISCUSSION

A total of 150 participants were included in the final analysis. Amongst which, most of the participants were from the age range of 40-60 years (57.3%) and were male (53.3%). Moreover, most of the participants had a primary level of education (38.0%), and many of the respondents worked in the office (62.7%). The detail of the demographic characteristics is given in **Table 2**.

Table 2. Demographic characteristics of the participants

		Overall		Control		Intervention	
		N	%	N	%	N	%
Age	20-40	36	24.0	18	23.1	18	25.0
	41-60	86	57.3	42	53.8	44	61.1
	61-80	28	18.7	18	23.1	10	13.9
Gender	Male	80	53.3	46	59.0	34	47.2
	Female	70	46.7	32	41.0	38	52.8
Marital status	Single	5	3.3	3	3.8	2	2.8
	Married	145	96.7	75	96.2	70	97.2
Education	Primary	57	38.0	32	41.0	25	34.7
	Secondary	40	26.7	17	21.8	23	31.9
	Graduation	36	24.0	21	26.9	15	20.8
	Masters	16	10.7	8	10.3	8	11.1
	Illiterate	1	0.7	0	0.0	1	1.4
Smoking status	Yes	35	23.3	18	23.1	17	23.6
	No	115	76.7	60	76.9	55	76.4
Living status	Urban	123	82.0	65	83.3	58	80.6
	Rural	27	18.0	13	16.7	14	19.4
Occupation	Public sector	27	18.0	13	16.7	14	19.4
	Private sector	39	26.0	22	28.2	17	23.6
	Business/self-employed	48	32.0	26	33.3	22	30.6
	Housewife	24	16.0	10	12.8	14	19.4
	Unemployed	12	8.0	7	9.0	5	6.9
Job nature	Office job	94	62.7	46	59.0	48	66.7
	Field + office Job	11	7.3	8	10.3	3	4.2
	Physical Labour	5	3.3	3	3.8	2	2.8
	Household	39	26.0	20	25.6	19	26.4
Monthly income (PKR)	N/A	34	22.7	19	24.4	15	20.8
	20,000-60,000	84	56.0	42	53.8	42	58.3

	60,001-100,000	32	21.3	17	21.8	15	20.8
	>100,000	0	0.0	0	0.0	0	0.0
Family History	Yes	150	100.0	78	100.0	72	100.0
	No	0	0.0	0	0.0	0	0.0
	Parents	119	79.3	58	74.4	61	84.7
Family Members	Siblings	31	20.7	20	25.6	11	15.3
	N/A	0	0.0	0	0.0	0	0.0
	Hypertension/cardiac problems	124	82.7	63	80.8	61	84.7
Concomitant disease	Dyslipidaemia	12	8.0	8	10.3	4	5.6
	N/A	14	9.3	7	9.0	7	9.7
	1 to 5	63	42.0	31	39.7	32	44.4
Duration of diabetes (Years)	5 to 10	71	47.3	37	47.4	34	47.2
	>10	15	10.0	9	11.5	6	8.3
	11.00	1	0.7	1	1.3	0	0.0

It has been observed in the current study that there was a significant improvement in the HbA1c ($p<0.0001$), blood glucose ($p<0.0001$), blood pressure ($p<0.0001$), and lipid profile ($p<0.0001$) after diabetes educator intervention. The detail can be seen in **Table 3**.

Table 3. Comparison of lab Parameter before and after Pharmacist intervention

Lab parameters	values	Pre	Post	Pre	Post	p-value
HbA1c	<6.6			3(2)	12(8)	
	6.6-8.0			24(16)	39(26)	
	8.1-9.0			33(22)	43(28.7)	<0.0001
	9.1-11.0			63(42)	33(22)	
	>11.0			27(18)	23(15.3)	
Blood Glucose	<100			6(4)	14(9.3)	
	100-200			52(34.7)	65(43.3)	<0.0001
	201-300			59(39.3)	47(31.3)	
	>300			33(22)	24(16)	
Diastolic blood pressure	<80			60(40)	57(38)	
	80-89			79(52.7)	61(40.7)	<0.0001
	90-99			10(6.7)	23(15.3)	
	>100			1(0.7)	9(6)	
Systolic blood pressure	<120			60(40)	56(37.3)	
	120-139			79(52.7)	62(41.3)	<0.0001
	140-159			10(6.7)	23(15.3)	
	>160			1(0.7)	9(6)	
Cholesterol	<200			91(60.7)	60(40)	
	200-239			53(35.3)	72(48)	<0.0001
	>240			6(4)	18(12)	
Triglycerides	<150			74(49.3)	63(42)	
	150-199			60(40)	54(36)	<0.0001
	200-499			16(10.7)	24(16)	
	>500			0(0)	9(6)	
Low-density lipoproteins	60-130			102 (68)	57(38)	<0.0001
	131-159			21 (14)	59 (39.3)	

	160-189	24 (16)	21 (14)	
	>190	3 (2)	13 (8.7)	
	<35	29 (19.3)	32 (21.3)	
High-density lipoproteins	35-60	108 (72)	70 (46.7)	<0.0001
	>60	13 (8.7)	48 (32)	

Regarding the quality of life, a significant improvement has been seen after diabetes educator intervention, as shown in **Table 4**.

Table 4. Comparison of QoL of the participants before and after Pharmacist intervention

		Mean	Standard Deviation	P-value
QoL	Pre	7.77	1.37	<0.0001
	Post	8.30	2.52	
EQVAS	Pre	59.68	12.19	<0.0001
	Post	59.13	14.95	

The patients' adherence level was positively improved after diabetes educator educational intervention. The detail is given in **Table 5**.

Table 5. Comparison of Drug adherence before and after Pharmacist intervention

		N	%	P-value
Adherence Pre	Adherent	55	36.7%	0.028
	Non-adherent	95	63.3%	
Adherence Post	Adherent	89	59.3%	
	Non-adherent	61	40.7%	

Regarding diabetes knowledge, 41.3% of the participant considered a healthy diet for a person living with diabetes. Moreover, most of the participants were known to the compilation not associated with diabetes (36%) and knew the source of carbohydrates (30.7%). The detail can be seen in **Table 6**.

Table 6. Knowledge of study participants regarding diabetes

Diabetes knowledge items (answers)		N	%
The suitable diet for a diabetic is: (A healthy diet for most people)	True	62	41.3
Which of the following is highest in carbohydrates? (Baked potato)	True	46	30.7
Which of the following is highest in fat? (Low-fat milk)	True	51	34.0
Which of the following is free food? (Any food that has less than 20 calories per serving)	True	56	37.3
Glycosylated hemoglobin (Haemoglobin A1) is a test that is a measure of your average blood glucose level for the past: (6-10 weeks)	True	46	30.7
Which is the best method for testing blood glucose? (Blood test)	True	44	29.3
What effect does unsweetened fruit juice have on blood glucose? (Raises it)	True	53	35.3
Which should not be used to treat low blood glucose? (1 cup diet soft drink)	True	49	32.7
For a person in good control, what effect does exercise have on blood glucose? (Raises it)	True	46	30.7
Infection is likely to cause: (A decrease in blood glucose)	True	51	34.0
The best way to take care of your feet is to: (Look at and wash them each day)	True	45	30.0
Eating food lower in fat decrease your risk for (heart disease)	True	48	32.0
Numbness and tingling may be symptoms of: (Nerve disease)	True	52	34.7
Which of the following is usually not associated with diabetes? (Lung problem)	True	54	36.0

Diabetes is affecting the overall life of the individual living with it. It not only affected the individual physically but also impacted mental health significantly. This study was executed to evaluate the role of intervention and counseling in helping the overall health and quality of life of patients. Therefore, it can be claimed that for patients with diabetes in

Pakistan, the factors that lead to low quality of life do not include routine blood glucose checking, but physical exercise has a significant impact. Other physiological factors that decrease quality of life are LDL and HDL, leading to more significant calorie deposits.

The purpose of this study protocol is to investigate the impact of new teaching approaches for delivering a regular diabetic self-management support program. The study will also show that such an educational intervention can be implemented on a bigger scale. In comparison to the control group participants, we expected that intervention arm patients would show improvements in HbA1c, self-care activities, and disease knowledge. As a result, we can anticipate that if a 6-month intervention can result in a large decrease in HbA1c, it will also have a positive impact on patients' long-term results.

Only a few studies using proxies to estimate how self-management interventions affects self-management skills explicitly evaluate how self-management interventions affect self-management skills. The meta-analyses' results have shown that pharmacist-led treatments positively influenced HbA1c levels, self-management abilities, BMI, and blood pressure in general. The findings also imply that pharmacist-led self-management treatments increase medication adherence, diabetes understanding, and overall quality of life.

The studies found that interventions led by pharmacists substantially affect HbA1c levels. The size of this reduction (0.71% [0.91; 0.51]) is clinically significant and can be linked to a reduction in the risk of microvascular problems [20]. These results are consistent with those who found a pooled effect of -1.00±0.28 percent on HbA1c levels [21]. However, all types of interventions by the pharmacist for patients suffering from diabetes were included in their review. According to systematic reviews, the efficacy of self-management interventions led by the pharmacist was nearly three times bigger than the effect of self-management interventions led by a nurse, diabetes educator, or physician [22].

A study found a relative risk (1.83 [1.44; 2.33]) [23] in favor of patients suffering from diabetes getting disease management led by pharmacists, which supports the added value of interventions led by pharmacists for diabetes target achievement. Previous evaluations have emphasized the diversity of intervention material in the included trials [21, 23, 24].

Another important aspect to note in the role of pharmacists as diabetes educators is the monthly income of the patients. Demographics have revealed that 55% of the study population earned less than 60,000 PKR, which does not entail access to high-quality healthcare with adequate knowledge sharing. Similarly, the educational background of the patients also was highest for the primary and secondary levels of education, which again entails lack of access to high-

quality healthcare or even educational facilities. In such a condition, pharmacists are the ultimate and oftentimes the only credible source of information for these patients, which can provide clear and scientific knowledge for the management of diabetes, along with cardiovascular and other issues.

CONCLUSION

The purpose of conducting this study was to analyze the role that a pharmacist as a diabetes educator can play in increasing baseline knowledge of diabetic patients and in turn also improve the quality of life for the participants. For this, the current study carried out randomized controlled trials and tested participant information about key medical terms regarding type 2 diabetes, through DAI scoring, MDKT tests, and EQ-VAS. This information was then analyzed through statistical analysis using SPSS, by first analyzing demographics analysis and then running paired statistics on the sample. Findings from this study have revealed that among the enabling factors that lead to lower quality of life include lack of physical exercise and motivation of self-care among Pakistani patients of diabetes, which along with their existing medical conditions is a necessity for well-being.

Similarly, pharmacists also improve mental well-being through increased awareness, as anxiety has been seen to have a significant impact from the paired t-test. In conclusion, it can therefore be argued that diabetes educators play a considerable role in improving patient management through self-care and improving their physical as well as psychological well-being.

Strengths and Limitations

The strength of this study lies in the fact that scientifically monitored randomized controlled trials were run for analyzing the effect of a pharmacist working in hospitals as diabetes educators on the quality of life of the participants, and improvement in their knowledge. The use of primarily collected data also offered benefits to the study, as first-hand medical information has been reviewed. However, follow-ups were not included in the data collection stage and due to restriction of time, annual or even monthly follow-ups could not be done. Similarly, the limitation also persists in research methodology, as participant perspectives have not been included, either qualitatively or quantitatively. Inclusion of their responses, changes, and self-efficacy shifts would have offered a further in-depth review of the study topic.

Future Implications

Considering the limitations of this study, future implications can be drawn for future research. For instance, the lack of follow-ups can be overcome in further studies, through a long-term study setting, which makes use of weekly, monthly, or annual reviews of information. This will help understand the long-term effects of pharmacy knowledge on diabetes and the quality of life of patients. Apart from this, the inclusion of patient perspectives can also be included in

one of the future implications of this study, as interviews of surveys can be used as data collection instruments. Another future implication for this study lies in the variables chosen in randomized controlled trials. Although the current study has optimally provided the implications of diabetes educator-assisted management of diabetes, it has also opened possible avenues for critical discussion and review of scientific knowledge.

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