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Review

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EFFICACY AND SAFETY OF FLASH GLUCOSE MONITORING (FGM) SYSTEMS ON DIABETES MANAGEMENT AMONG PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES IN SAUDI ARABIA: A SYSTEMATIC REVIEW STUDY

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Abstract:

Acceptability and use of flash glucose monitoring devices among diabetic patients has been gaining popularity since its introduction. The efficacy and safety of these devices have been studied by many researchers and published data from Saudi Arabia. However, there is hardly any systematic review conducted to gather all literature published from Saudi Arabia over this topic. Therefore, present study conducted with the aim to systematically review the safety and efficacy of FGM devices from the published studies between 2020 and 2025 from Saudi Arabia. Literature search was conducted by using Web of Science and Scopus databases. The MeSH terms were derived first for each database to search the literature. Inclusion and exclusion criteria were then applied to the searched literature, and 13 studies were passed through the criterion and included in the present systematic review. From the extracted data, it was observed that most of the studies were conducted on type 1 diabetic patients and pediatric diabetic patients were barely focused. However, all included studies reported that HbA1c level at the start and end of study period and data showed significant reduction in HbA1c level except 2 out of 13 studies. Moreover, reduction in diabetic related adverse events was clearly evident in the included studies. Frequency of hypoglycemic events or diabetic ketoacidosis reduced significantly. Hence, it was found that FGM devices play a significant role in reducing HbA1c level. Moreover, these devices also found beneficial in reducing diabetes related adverse events. Therefore, it can be concluded from the review of the literature published from Saudi Arabia that FGM devices are safe and effective for the management of type 1 and type 2 diabetes.

Keywords: Flash glucose monitoring, Efficacy, Safety, Diabetes, Review, Saudi Arabia

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INTRODUCTION:

Glycemic control pertains to the regulation of blood glucose levels within a normal range. Traditionally, blood samples are used for monitoring, either in a lab setting where HbA1c, random blood glucose, and fasting blood glucose tests are conducted, or through finger pricking for self-monitoring of blood glucose (SMBG) [1]. Laboratory results for blood glucose monitoring have several drawbacks, including the inability to provide information on intraday glycemic variability [2,3]. However, using SMBG devices to measure blood sugar levels necessitates using a fingerstick to draw a capillary sample, which only allows sporadic "point-in-time" measurements and cannot present trend either retrospectively or prospectively [2,3].

The management of diabetes has been completely transformed by the advent of flash glucose monitoring (FGM) and real-time continuous glucose monitoring (RT-CGM) devices [4]. It is a sensor-based device that displays blood glucose levels as of right now as well as the trend over the previous eight hours [5]. Key trends in hypo-, normo-, and hyperglycemia are displayed in the glucose profiles generated by these devices. Physicians can be given access to data and information [6,7].

Studies to track the devices' efficacy and acceptability among diabetic patients have been carried out since their introduction. According to Al Hayek et al. from Saudi Arabia, glycemic patients preferred to use FGM devices more frequently because they found them to be more convenient and easier to use than the finger-pricking method for blood glucose monitoring [8]. In addition, studies also reported that the increased number of FGM scans per day is associated with improved HbA1c levels and consequently reduces the chances of diabetic related complications [9,10]. A study by Al-Harbi et al. from Saudi Arabia sought to determine the prevalence of FGM and how it related to a drop in blood sugar levels. It was discovered that improved glycemic markers are linked to higher time in range (TIR), lower eA1c, and more frequent daily scanning [11]. Research from a number of

European nations also demonstrated that a lower eA1c was linked to a higher scanning frequency, and that a significantly higher eA1c was found in those with a lower daily scanning frequency [12,13].

Castellana et al. conducted a systematic review and meta-analysis to examine the safety and effectiveness of FGM devices. In their review, the authors came to the conclusion that the reviewed literature had few serious adverse events and adverse events related to device [1]. Scott et al. investigated the safety and accuracy of FGM devices

in pregnant diabetic women. According to study results, there is no risk of harm when using FGM devices during pregnancy [14].

There is barely any systematic review of the Saudi Arabian literature that examines the safety and effectiveness of FGM devices, even though numerous studies have been published there that document the effectiveness of these devices. The purpose of the current study was to conduct a systematic review of the safety and effectiveness of FGM devices from Saudi Arabian published studies conducted between 2020 and 2025.

METHODS:

For the extraction of the studies to be included in this systematic review, the literature search was started in August 2025. This systematic review included the observational studies which recorded and reported the change in HbA1c level after using the FGM devices. The databases used for the literature search were Web of Science (WOS) and Scopus. However, MeSH (medical subject headings) terms were derived first for each database separately. A set of keywords were listed first which were aligned with the study title and objectives. Hence, the keywords were "flash glucose monitoring", "diabetes", "efficacy and safety" and "Saudi Arabia". The possible variations in each keyword, which could possibly occur in the published studies, were also added in the MeSH terms. Moreover, Boolean operators "AND" and "OR" used strategically to refine and expand the search results.

Therefore, the derived MeSH term for Scopus was TITLE-ABS-KEY (("flash glucose monitoring" OR "FGM" OR "FreeStyle Libre" OR "intermittently scanned continuous glucose monitoring") AND ("type 1 diabetes" OR "type 2 diabetes" OR "T1D" OR "T2D" OR "diabetes mellitus") AND ("efficacy" OR "effectiveness" OR "safety" OR "glycemic control" OR "HbA1c" OR "time in range" OR "diabetes management") AND ("Saudi Arabia" OR "KSA")). The MeSH term for WOS was TS=(("flash glucose monitoring" OR "FreeStyle Libre" OR "intermittently scanned continuous glucose monitoring" OR "intermittently scanned") AND ("type 1 diabetes" OR "type 2 diabetes" OR T1D OR T2D) AND (efficacy OR effectiveness OR safety OR "adverse event" OR "glycemic control" OR HbA1c OR A1c OR "glycated hemoglobin" OR "glycated haemoglobin" OR "time in range" OR TIR OR hypoglyc* OR hyperglyc* OR "diabetes management") AND CU=("Saudi Arabia" OR "Kingdom of Saudi Arabia" OR KSA).

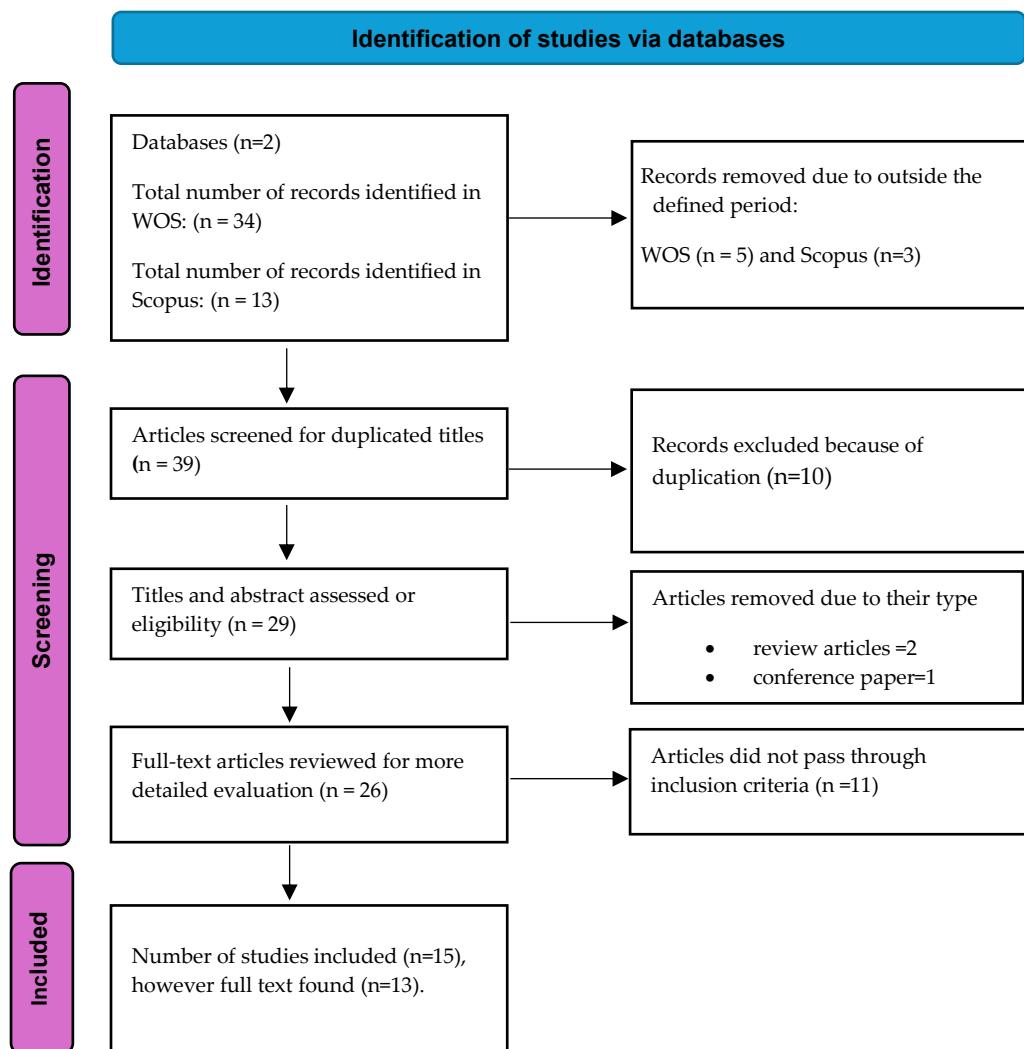
After running the MeSH term in each database, an excel file was developed which consisted of the studies came out as a result. The excel file included authors list, study title, abstract and year of

publication. To screen the studies came out as a search outcome, inclusion and exclusion criteria were developed. Hence the inclusion criteria were (1) studies conducted on the FGM devices, (2) studies included diabetic type I and type II patients, (3) studies included patients from Saudi Arabia and (4) publication year must be between 2020 and 2025. Similarly, the exclusion criteria were (1) studies used monitoring devices other than FGM, (2) studies published before 2020, (3) use of any kind of medication other than usual diabetes medication to reduce HbA1c level, (4) studies did not report the required parameters, (5) studies other than the original article and (6) unavailability of full text article.

After applying the MeSH terms, WOS yielded 34 studies, and 13 titles were found on Scopus. At first, studies published before 2020 were excluded hence 5 studies from WOS and 3 from Scopus were excluded. Hence, a total of 39 records were left all

together. After that, 10 duplicated records were found and removed and thereafter 29 records were left. Types of the studies were checked and found there were 2 review articles, and one was conference paper which were removed. Titles and abstracts were screened for rest of the 26 studies, and 11 studies were excluded in this step due to unavailability of required information. Hence, after the completion of this screening process, full text articles of remaining 15 titles started searching, however 13 full text articles were found and 2 more articles were excluded due to unavailability of full text articles. To perform this entire process PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were adhered to maximize the systematic review's reporting quality and comprehensiveness. Every stage of the study selection procedure was methodically documented using the PRISMA flow diagram. Hence, figure 1 showed the PRISMA flow chart diagram which demonstrated the process of studies filtration.

Figure 1: The flow of articles identified in the electronic database search



To minimize the chances of any false inclusion or exclusion of the studies, the entire screening process was conducted by two reviewers independently. However, the comparison of excel files generated by both reviewers, it was found that there was no disagreement between the reviewers. The variables extracted from the included studies were first author, year of publication, sample size, age, type of diabetes, time points of data collection, HbA1c value at start of the study, HbA1c value at the end of study, p-value (showing any significant change in the HbA1c level) and adverse event.

To ensure the integrity and quality of the included studies, a rigorous assessment for the risk of bias was conducted using established quality appraisal tool “Joanna Briggs Institute (JBI)”. The JBI assessment findings table indicates that this review predominantly incorporated cross-sectional and primary studies were chosen for their pertinence and application to the research inquiries. The studies were selected based on their high ratings in relevancy and appropriateness, as determined by the JBI assessment criteria (Table 1).

Table 1: JBI Quality Assessment Checklist Scores of Included Studies

Citations	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Score
Mohamed IAA et al., 2021 [15]	yes	yes	yes	yes	no	no	yes	yes	75%
Al Hayek AA & Dawish MA, 2020 [16]	yes	yes	yes	yes	no	no	yes	yes	75%
Al Hayek AA et al., 2021 [17]	yes	yes	yes	yes	no	no	yes	yes	75%
Alharbi MY et al., 2022 [18]	yes	yes	yes	yes	no	no	yes	yes	75%
Al Hayek AA & Dawish MA, 2023 [19]	yes	yes	yes	yes	no	no	yes	yes	75%
Alazmi AA et al., 2024 [20]	yes	yes	yes	yes	no	no	yes	yes	75%
Al Hayek AA et al., 2021 [21]	yes	yes	yes	yes	no	no	yes	yes	75%
Alhodaib HI & Alsulihem S, 2021 [22]	yes	yes	yes	yes	no	no	yes	yes	75%
Al Hayek AA & Dawish MA, 2021 [23]	yes	yes	yes	yes	no	no	yes	yes	75%
Al Hayek AA et al., 2021 [24]	yes	yes	yes	yes	no	no	yes	yes	75%
Al Hayek AA et al., 2022 [25]	yes	yes	yes	yes	no	no	yes	yes	75%
Abulqasim J et al., 2023 [26]	yes	yes	yes	yes	no	no	yes	yes	75%
Alsahl MA et al., 2024 [27]	yes	yes	yes	yes	no	no	yes	no	62.5%

RESULTS:

The total sampled population included in the studies included in the present systematic review was 2859. The minimum sample size was 31 whereas highest sample size was 1307. Moreover, 12 out of 13 studies were conducted on adolescent and/or adult population while only one study was conducted on children (Table 1). Similarly, 9 studies included T1D patients, 3 study included T2D patients while 1 study included both types of diabetic patients.

Table 1: Summary of the collected data from the included studies

Author, year	sample size	age	type	data collection time	Start	End	Significance	Adverse event
Mohamed IAA et al., 2021 [15]	273	11.5(3.8)	T1D	baseline, 6 and 18 months	case 10.47(1.66), control 10.52(2.17)	case 8.22(1.5), control 10.24(2.08)	0.001	hypoglycemia event in case 8.24(7.17), control 14.26(6.7)
Al Hayek AA & Dawish MA, 2020 [16]	95	20.9(2.2)	T1D	baseline and 3 months	8.3	7.7	<0.001	hypoglycemia event at start 3.0 and at End 2.3
Al Hayek AA et al., 2021 [17]	105	45.1(7.9)	T2D	baseline and 3 months	8.2	7.9	0.067	hypoglycemia event at start 3.1 and at End 1.2

Alharbi MY et al., 2022 [18]	1307	11.1(3.6)	T1D	baseline, 3, 6 and 18 months	10.8	9.1	<0.001	
Al Hayek AA & Dawish MA, 2023 [19]	93	47.9(7.5)	T2D	baseline and 12 months	8.3	7.9	<0.001	
Alazmi AA et al., 2024 [20]	327	33.1(17.1)	T1D & T2D	after 3 months		7.57		
Al Hayek AA et al., 2021 [21]	47	15.7(6.1)	T1D	baseline and 3 months	8.3	7.9	0.064	
Alhodaib HI & Alsulihem S, 2021 [22]	195	23.6(8.1)	T1D	baseline and 3 months	9.7	9	<0.001	
Al Hayek AA & Dawish MA, 2021 [23]	47	19.8(6.2)	T1D	baseline and 24 months	9.9	7.4	<0.001	DKA frequency 2.9 at start and 0.2 at end
Al Hayek AA et al., 2021 [24]	54	41.6	T2D	baseline and 3 months	8.22	7.78	<0.001	hypoglycemia 4.43 at start and 1.24 at end
Al Hayek AA et al., 2022 [25]	187	27.7	T1D	baseline and 12 months	8.8	8.2	0.028	hypoglycemia 6.1 at start and 3.7 at end
Abulqasim J et al., 2023 [26]	31	3.88(1.1)	T1D	baseline and 3 months	9.8	8.24	0.02	skin allergy (48.4%), itching (41.9%)
Alsahli MA et al., 2024 [27]	98	26.82(7.7)	T1D	baseline and 6 months	9.83	8.63	<0.001	

Efficacy of FGM devices:

Studies reported the effectiveness of the FGM devices by noted and reported HbA1c levels at different point of time and compared with baseline data. Majority of the included studies showed the change in HbA1c level in comparison of time either descriptively or graphically. In the study by Mohamed AA et al. (2021), T1D patients were divided into two groups, case group was using FGM devices while control group was using traditional methods for diabetic control. The data was collected at start of the study, after 6 months and after 18 months. At the start of the study, the difference in HbA1c level between two groups was not significantly different ($10.47\% \pm 1.66$ vs $10.52\% \pm 2.17$) however at the end of study period the difference in HbA1c level became significantly different between two groups ($8.22\% \pm 1.5$ vs $10.24\% \pm 2.08$, $p=0.001$) [15]. In the study by Al Hayek & Dawish (2020), the average HbA1c level at the start of the study was 8.3% which was reduced to 7.7% after 3 months [16]. In another study by Al Hayek et al. published in 2021, effectiveness of FGM devices was studied among T2D patients and

HbA1c level was noted at the start of the study after the 3 months of the use of FGM devices. Authors found that baseline HbA1c level was 8.2% while after 3 months it was reduced to 7.9% [17]. Moreover, Alharbi et al. (2022) had 1307 T1D patients and HbA1c level at the start of the study was 10.8% which was reduced to 9.1% at the end of study period [18]. Al Hayek & Dawish published another study in 2023 in which T2D patients were included. Patients' baseline HbA1c level was determined at the start of the study which was 8.3% and after completion of study period, HbA1c level was reduced to 7.9% [19].

In the study by Alazmi et al, authors collected the T1D and T2D patients' data who used FGM device for consecutive 3 months. Authors compared the GMI value with HbA1c value after the completion of 3 months to study the accuracy of FGM devices. Hence, GMI value was found to be 7.57% while HbA1c value was 7.86% [20]. Al Hayek et al. published another study in 2021 in which they included T1D patients who were using FGM devices. At the beginning of study HbA1c level was

8.3% which was reduced to 7.9% after the completion of 3 months of study period [21]. In the study by Alhodaib & Alsulihem, T1D patients were included in the study and FGM data was collected at start and after 3 months, the HbA1c level was 9.7% at the start of the study which reduced to 9.0% after the 3 months use of FGM devices [22]. The study period of Alhayek & Dawish was comprised of two years in which T1D patients were included. The FGM data was collected at start and end of the study period and results showed that HbA1c level was 9.9% at start which reduced to 7.4% at the end of the study period [23]. In 2021, Alhayek et al published a study which included T2D patients who were using FGM devices for 3 consecutive months. Hence, HbA1c results were obtained at start (8.22%) and at the end (7.78%) of the study [24]. In another study by Al Hayek et al. published in 2022 included T1D patients and their HbA1c level was noted at the start and after 12 months of being using FGM devices. The HbA1c level was 8.8% at the start and it was reduced to 8.2% after the 12 months of use of FGM devices [25]. Abdulqasim et al., conducted their study on the T1D children who were using FGM devices for monitoring glycemic level. The study collected data at the start of the study and after completion of three months. The HbA1c level was 9.8% at start of the study which was reduced to 8.24% at the end of study period [26]. In their study by Alsahli et al. in 2024, they included T1D patients in their study and HbA1c level was noted at start and after completion of 6 months of study period. The HbA1c level was 9.83% at start and reduced to 8.63% at the end of the study period [27].

Reported adverse events:

Mohamed AA et al. reported the average number of hypoglycemic events during the 18-month study period in each group. Authors reported that in case group the average number of hypoglycemic events was 8.24 while in control group it was 14.26 which was significantly high ($p=0.003$) [15]. The reported average number of hypoglycemic events by Al Hayek & Dawish (2020) at baseline was 3.0 while after 3 months it was 2.3 [16]. Al Hayek et al. in their study noted the hypoglycemic events at the start and end of the study period. It was found that at the start of study, the average hypoglycemic event was 3.1 which was reduced to 1.2 after the completion of 3 months of study period [17].

In another study by Al Hayek & Dawish (2021), frequency of diabetic ketoacidosis (DKA) was also noted at start and end of the study. The reported DKA frequency at the start of the study was 2.9 which was reduced to 0.2 at the end of study period which showed significant reduction ($p<0.001$) [23]. Alhayek et al., in their study included the frequency of hypoglycemic events occurrence at the start and end of the study period. Findings showed that its

frequency dropped to 1.24 which was 4.43 at the start of the study which showed significant reduction in hypoglycemic episodes per month ($p<0.001$) [24]. Al Hayek et al. (2024) reported the hypoglycemic events among the patients included in their study. The authors reported that the average hypoglycemic event at the start of the study was 6.1 and after the completion of 12 months of study period it was reduced to 3.7 [25]. Abulqasim et al., conducted their study on children aged between 3 to 5 years hence they reported the complications faced by the patients and most of them complained about skin allergy (48.4%) followed by Itching (41.9%) [26].

DISCUSSION:

This systematic review study was conducted with the aim of reviewing studies published on the use of FGM devices and their safety and efficacy. To serve the purpose a couple of databases were searched and studies were extracted. Inclusion and exclusion criteria were then applied to filter the studies and found 13 studies which passed through the criteria and information/data was extracted. The reported HbA1c level at the start and end of study period was extracted as well as some demographic statistics reported in the studies. In addition, information about diabetic related complications was also extracted from the studies where it was reported.

Extracted data summarized in table 1 and review of authors and cities from where patients belonged. It was found that a high number of studies (7 out of 13) were published by Al Hayek AA with his team. Moreover, a high number of studies were conducted in capital city of Saudi Arabia and hence patients were also taken from the capital city. There were 10 studies which were conducted and included patients in Riyadh while 2 studies included patients from various cities. Hence, it was observed that most of the studies included patients from a specific city or area of the country. Usually, lifestyle of urban and rural populations varies in regard to eating habits, physical activities etc. [28]. Hence, perhaps it could be a beneficial addition to literature if studies are conducted in the rural areas of the country.

Review of the extracted data about HbA1c level showed that there was drop in HbA1c level after completion of study period as compared to HbA1c level in the start of the study. Moreover, 10 out of 13 studies reported a significant decrease in HbA1c level which showed the effectiveness of these FGM devices in the management of diabetes. Castellana et al. conducted a Meta-analysis of type 1 and type 2 diabetic patients who were using FGM devices. Authors reported a significant reduction in the HbA1c level from the baseline to the last available follow-up [1]. The efficacy and safety of FGM devices was reviewed by Mancini et al. in which they included studies published on diabetic patients

using FGM devices. After reviewing the extracted data, it was found that the FGM is an effective tool for the management of T1D both in pediatric and adult patients [5]. However, accuracy of the FGM devices data is largely dependent upon the site of insertion, FGM devices reading in the upper arm demonstrated more accurate data compared to the data obtained from abdominal insertion of the devices [29]. Krakauer et al. published a review article on the flash glucose monitoring in type 2 diabetic patients in which they compared FGM versus self-monitoring of blood glucose (SMBG). It was found that after 6 months compared to baseline data, reduction in HbA1c level was statistically significant among the patients using FGM devices compared with SMBG [30]. In the continuous glucose monitoring devices, optimization of its wearing time is essential to get desirable glycemic control. Therefore, wearing these devices perhaps has some challenges and effects on quality of life. Hence, Diez-Fernandez et al. conducted a review in which they reviewed the published literature on patients' satisfaction towards FGM [31]. From the review of literature, authors found that FGM system improves patients' satisfaction and QoL compared with SMBG [31].

It has been reported by many researchers that one of the clinical benefits of FGM use is to reduce hypoglycemia events. Studies reported the reduction in hypoglycemia among type 2 diabetic patients [32]. Mancini et al. reported in their review article about 38% reduction of hypoglycemic events among type 1 diabetic patients compared to the control group using capillary strips [5]. Studies included in the present systematic review reported the reduction of hypoglycemic events. It was found that reduction in hypoglycemic events was both in type 1 and type 2 diabetic patients furthermore drop in average hypoglycemic event per month (at start of the study and at the end of study) was significant. Similarly, one study reported the DKA frequency and showed 39.3% reduction in DKA after the completion of study period. With regards to the safety of the FGM, one study reported skin allergy and itching issues among the studied population however other studies did not report any issue related to safety. Similarly, less studies in literature reported adverse events among the adult population while some studies did not report any adverse events [33,34]. Moreover, in the pediatric population, events like itching, pressure feeling, erythema and swelling have been reported [35,36]. Similarly, in the present systematic review, only one study which was conducted on pediatric patients reported adverse events like itching, skin allergy etc. while all other included studies had adult population and no adverse events were reported.

The current study also had certain limitations. First a literature search was conducted using two databases; adding more databases could have resulted in a higher number of included studies. Furthermore, the current study only reviewed the published literature; a meta-analysis would help identify a general shift or decline in HbA1c by combining the results of all included studies.

CONCLUSION:

It is clear from the systematic review of the literature that FGM devices hold significant potential for the management of diabetes mellitus. The HbA1c level at the end of the study period was significantly lower than the HbA1c level at the beginning of the study, according to nearly all included studies. Both T1D and T2D patients, as well as patients of different ages, showed this change equally. Furthermore, it was discovered that FGM devices prevented the negative consequences associated with diabetes; therefore, their use is safe. According to studies, there were fewer hypoglycemic or DKA episodes at the conclusion of the study period than at the beginning. Hence, by managing HbA1c level and reducing the diabetic related complications, it can be concluded that there was an improvement in health-related quality of life among diabetic patients who were using FGM devices.

Recommendation:

A few suggestions that may need to be considered in future research have been made after a review of the Saudi Arabian published literature.

1. T1D patients were the subject of many studies, while T2D patients were the subject of relatively few. Therefore, further research on T2D patients is advised.
2. Many studies had smaller sample sizes (less than 100 patients). Therefore, it is advised to use a larger sample size to validate the results.
3. Longer-term studies are recommended to investigate the effects of FGM devices.
4. Additional research is needed on pediatric diabetic patients. This systematic review contains only one study involving pediatric diabetic patients.

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