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# Efficacy of continuous glucose monitoring in people living with diabetes and end stage kidney disease on dialysis: a systematic review

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# **Abstract**

**Background** Patients with diabetes on dialysis experience wide variations in glucose levels and an increased risk of hypoglycaemia. Due to the inaccuracies of HbA1c in dialysis patients, JBDS-IP and KDIGO recommend the use of continuous glucose monitoring (CGM). We conducted a systematic review to examine the current evidence for CGM use and its impact on clinical outcomes in patients with diabetes on dialysis.

**Methods** A search of MEDLINE(R) ALL, Ovid Emcare, Journals@Ovid Full Text and Embase databases were conducted. Clinical or observational trials in adults with Type 1(T1D) or Type 2 (T2D) diabetes on dialysis and CGM intervention reporting on glycaemic outcomes were included.

**Results** Of the 936 citations identified, 49 duplicates were removed. 887 citations were screened by title and abstract. 9 full texts were reviewed and a further 7 excluded due to duplications or failure to meet to selection criteria. Data was extracted for 2 studies, both prospective before-and-after interventional studies with no control group. Joubert et al. (2015) showed results for 15 participants with T1D. Mean CGM glucose level decreased from 8.37mmol/L at baseline to 7.7mmol/L at the end of the CGM period (*p*<0.05) while HbA1c decreased from 6.9 to 6.5% (*p*<0.05) during the same period. Mean CGM was lower on dialysis days (7.68mmol/L vs. 7.8mmol/L, *p*<0.05). Képénékian et al. (2014) reported on data from 29 T2D patients. Following a 3 month CGM-adapted insulin regimen, HbA1c decreased from 8.4% at baseline to 7.6% (*p*<0.01) by the end of study. Mean CGM values decreased from 9.9mmol/L to 8.9mmol/L (*p*=0.05) and the frequency of glucose values>10mmol/L decreased from 41 to 30% (*p*<0.05), without a significant increase in hypoglycaemia frequency. Both studies were deemed to be of 'good' quality.

**Conclusion** Evidence demonstrating the benefits of CGM in patients with diabetes receiving dialysis is lacking. There is a need for well-designed randomised controlled trials to ascertain the benefits of this technology in this patient group.

**Trail registration** PROSPERO registration number: CRD42023371635, [https://www.crd.york.ac.uk/PROSPERO/display\\_](https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=371635) [record.php?RecordID=371635.](https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=371635)

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# **Key learning points** *What is known*

Due to the inaccuracies of HbA1c in dialysis patients, JBDS-IP and KDIGO recommend the use of CGM. Despite this, there is limited evidence for the clinical benefits of CGM in patients on dialysis.

# *What this study adds*

We undertook this systematic review to examine the current evidence around the use of CGM and its effects in patients with diabetes and ESRD on dialysis.

Two before-and-after studies have been conducted regarding the use of CGM in dialysis patients met out selection criteria.

# *Potential impact*

This study highlights the limited evidence surrounding CGM use in dialysis patients, with no large-scale randomised control trials available to demonstrate glycaemic or clinical outcomes.

**Keywords** Dialysis, Diabetes mellitus, Diabetic kidney disease, Haemodialysis, Peritoneal dialysis, Systematic review

# **Introduction**

Chronic kidney disease (CKD) is a major global health problem accounting for an estimated 5 to 10 million annual deaths worldwide [[1,](#page-6-0) [2](#page-6-1)]. Diabetes is a leading cause of CKD and end-stage renal disease (ESRD). Diabetes-related CKD affects nearly 40% of people with diabetes and is also associated with an increased risk of cardiovascular death (UK Kidney Association 2020). Although the benefits of intensive glycaemic control are less apparent in advanced stages of CKD, improved glycaemic control in patients on dialysis has been shown to improve survival [\[3](#page-6-2)–[6\]](#page-6-3). Achieving optimal glycaemic control in patients with CKD, however, has added challenges due to increased insulin resistance, increased hepatic gluconeogenesis, impaired intracellular glucose metabolism, decreased insulin clearance and decreased insulin secretion [\[7](#page-6-4)]. These factors may be further potentiated by metabolic acidosis contributing to wide fluctuations in blood glucose levels and exogenous insulin requirements [\[8](#page-6-5), [9\]](#page-6-6). Further, both peritoneal and haemodialysis have been associated with wide variability in blood glucose patterns dependent on the dialysate used as well as membrane factors [[10,](#page-7-0) [12](#page-7-1)]. Diabetes patients on dialysis not only experience high glucose variability leading to increased risk of hypoglycaemia but also have impaired awareness of hypoglycaemia [[13](#page-7-2), [14\]](#page-7-3).

Haemoglobin A1c (HbA1c) is the established gold standard indicator for assessing long-term glucose control in diabetes. Studies worldwide, however, highlight the inaccuracy of HbA1c as a measure of long-term glucose control in patients on dialysis. Elevated blood urea nitrogen level, iron deficiency and metabolic acidosis may falsely increase HbA1c [\[15–](#page-7-4)[17\]](#page-7-5) while reduced red blood cell lifespan and use of erythropoiesis-stimulating agents can increase the proportion of young non-glycated erythrocytes leading to falsely low HbA1c [[18](#page-7-6), [19\]](#page-7-7).

Given these limitations with HbA1c, the Joint British Diabetes Societies for Inpatient Care (JBDS-IP) and Kidney Diseases: Improving Global Outcomes (KDIGO) Diabetes Work Group both recommend the use of continuous glucose monitoring (CGM) in patients on dialysis for assessing glycaemic control, particularly in those treated with insulin or sulfonylurea, have loss of hypoglycaemia awareness or are at high risk of recurrent hypoglycaemia [\[20](#page-7-8), [21\]](#page-7-9). In 2019, an international consensus report was published outlining CGM targets for the time in ranges for both the general diabetes population (including type 1 and 2 diabetes) as well as a second group of older and high-risk diabetic patients, including those on dialysis [\[22](#page-7-10)]. Continuous glucose monitoring metrics offer a wealth of advantages, including improved glycemic control, enhanced quality of life and a reduction in the risk of diabetes-related complications. These metrics provide valuable insights for both patients and healthcare providers, enabling better-informed treatment decisions and a more personalised approach to diabetes management.

Despite these recommendations, there is limited evidence for the clinical benefits of CGM in patients on dialysis. We undertook this systematic review to examine the current evidence around the use of CGM and its effects on patients with diabetes and ESRD on dialysis.

# **Methods**

This systematic review was undertaken in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and was registered with. PROSPERO (registration number CRD42023371635).

## **Search strategy**

A comprehensive search of literature was was conducted on MEDLINE(R) ALL, Ovid Emcare, Journals@ Ovid Full Text and Embase databases. Search terms used across databases were consistent and included 'type 1 diabetes', 'type 2 diabetes'', end stage renal disease', 'dialysis'. The search term for flash/intermittently scanned and

continuous glucose monitoring included 'flash', 'libre', 'dexcom'. Alternative spellings as well as common abbreviations in relation to the topic were also included in the search (supplementary Tables 1 and 3).

Searches were limited to articles published in the English language since 1995 until March 2023. This is to ensure that any work completed leading-up to the Food and Drug Administration (FDA) approval for the first CGM system in 1999 may be included.

# **Inclusion and exclusion criteria**

We included clinical trials and observational studies involving (a) adults aged 18 and over, (b) diagnosed with diabetes mellitus (c) have ESRD and (d) receiving long term dialysis (participants), (e) where CGM-intervention was trialed (intervention) and (f) impact of glycaemic index was assessed (outcome). The full selection criteria are displayed on Table [1.](#page-2-0)

# **Study selection**

The search results identified were loaded on Rayyan™, a highly effective and user-friendly web- based platform for systematic review management. It helps in facilitating efficient collaboration among researchers and simplifying the screening and selection of relevant studies.

Stage 1: After removing duplicates, all identified studies were screened by title and abstract independently by two authors. Stage 2: Full text was requested for all papers fulfilling the inclusion criteria in stage 1 and were further screened by two reviewers to identify articles suitable for data-extraction. Disagreements between the reviewers were resolved by discussion to reach a consensus. Where there was no resolution, the papers were independently reviewed by a third reviewer to assess suitability for inclusion.

Study selection process is summarised in the PRISMA chart.

#### **Data extraction**

Data extraction of the included studies was carried out by two independent reviewers. The data extracted included: study location, population, diabetes type, dialysis type, baseline characteristics, number of participants, intervention, comparator, outcomes and duration of study (Table [2\)](#page-3-0).

#### **Assessment of methodological quality**

To minimise bias in this systematic review, we utilised the Quality Assessment for Before-After Studies with No Control Group tool, as designed by the National Heart, Lung, and Blood Institute [[23](#page-7-11)]. We customised this tool and included 11 out of 12 questions focussing on internal validity of study, as we felt question 8 was not applicable for the intervention. Selected papers were critically appraised by two independent reviewers and any disagreements between the reviewers were resolved by discussion (supplementary Table 2).

## **Data synthesis and analysis**

Our primary outcome was change in diabetes status. We defined change in diabetes status as change in HbA1c or other continuous glucose monitoring glycaemic index like time in range. We also assessed the impact of CGMs on change in diabetic medications, body weight, hypoglycaemic episodes and quality of life. Due to limited number of studies and heterogeneity of study design, we restricted our analysis to descriptive analysis.

# **Results**

# **Search yield**

Our initial search yielded 936 papers, of which 49 were duplicates and hence removed. The remaining 887 papers 9 papers were identified after screening on title and abstract. Full texts of these 9 papers were subsequently evaluated, of which a further 7 studies were exlcuded as they were either duplicates/abstracts or did not meet



# <span id="page-2-0"></span>**Table 1** Selection criteria



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#### **Study characteristics and quality**

The characteristics of the included studies are sum marised on Table [2](#page-3-0) .

Both included studies were prospective, before-andafter interventional study designs with no control group or blinding. They were published around the same period and from France. Sample size of both studies was small and had a follow up duration of 12 weeks. Both stud ies had similar participant selection criteria, baseline characteristics and demographic features. Neither study selected participants based on blood sugar control and all patients meeting the selection criteria in the given time period were recruited.

Joubert et al. [\[24\]](#page-7-12) included participants with type 1 and secondary diabetes; treated on diet alone or diet and insulin. Joubert et al. described the DIALYDIAB study which was split into two 6-week periods. During the first 6 weeks, patients self-monitored blood glucose (SMBG) 3 to 6 times a day on their own glucometer devices. For the second half of the study, a 5-day blinded CGM was performed at 2-week interval using the iPRO CGM® (Medtronic). Both the SMBG and CGM results were reviewed remotely by diabetes experts and proposed treatment changes such as insulin dose adjustment and/ or oral hypoglycaemic agents.

Képénékian et al. [[25\]](#page-7-13) included patients with type 2 diabetes on insulin. In the study by Képénékian et al., CGM Navigator® was initiated at the beginning of a dialysis ses sion and continued at home and subsequent dialysis ses sions. Insulin doses were titrated to obtain an optimal glycaemic control, with dose adjusted by a doctor based on the CGM readings. CGM and HbA1c readings at 3 months were measured. A total of 54 hours of CGM were obtained at baseline and after 3 months.

Both studies were deemed to be of 'good' quality as they reported well defined question, defined eligibility criteria and population included representing the popu lation of interest, defined outcome measures.

### **Study outcomes**

In the study by Joubert et al.,  $[24]$  $[24]$  18 patients were recruited. 15 results were analysed with complete CGM readings. 3 patients were not included in analy sis due to incomplete data. Mean CGM glucose level was 8.3mmol/L at baseline, 8.2mmol/L at the end of the SMBG period and 7.7mmol/l at the end of the CGM period (*p* <0.05). Glucose AUC >10mmol/L decreased significantly from 0.9 to 0.4mmol/L/day  $(p<0.05)$  while the AUC for glucose <3.3mmol/L did not change. HbA1c decreased from 6.85% at baseline to 6.46% at the end of the 12 week period  $(p<0.05)$ . Treatment adaptation

<span id="page-4-0"></span>

Fig. 1 PRISMA flow diagram. (PRISMA = preferred reporting items for systematic reviews and meta-analyses)

was higher during the CGM period compared to the SMBG period (2.1 vs. 1.4 respectively,  $p < 0.05$ ) due to a higher number of treatment regimen changes during the CGM period, such as addition of short acting insulin or establishing a different treatment pattern for days with and without dialysis. Mean blood sugar on CGM was lower on dialysis days (7.6mmol/L) vs. non dialysis days (7.8mmol/L, *p*<0.05). Joubert et al. assessed quality of life using a 32 item questionnaire but the results were not reported in the publication.

Képénékian et al. [\[25](#page-7-13)] recruited 38 patients and reported results of 28 patients who completed the study. After 3 months with a CGM-adapted basal bolus insulin regimen, HbA1c significantly decreased from 8.4±1.0%  $(65±1 \, \text{mmol/mol})$  to  $7.6±1.0\%$   $(60±11 \, \text{mmol/mol})$ ; *p*<0.01). There was a significant reduction in mean CGM glucose values  $(9.9 \pm 1.9 \text{ to } 8.9 \pm 2.1 \text{ mmol/L}; p = 0.05)$ 

and frequency of glucose value>10mmol (41.3–30.1%; *p*<0.05) over the duration of the study, without an increase in the frequency of hypoglycaemia. There was a modest but statistically significant increase in daily insulin requirement by the end of the study compared to baseline (70 $\pm$ 51IU/d to 82 $\pm$ 77IU/d ( $p$ <0.001) without notable increase in body weight. 10 patients were excluded during the follow up period and data not included in analysis (6 withdrawal of consent, 1 death from severe respiratory insufficiency, 2 failed to comply with treatment regimen and 1 spontaneous change of their previous insulin regimen).

Both these studies did not report on measures such as Time in Range (TIR), Time Above Range (TAR) and Time Below Range (TBR).

# **Discussion**

Our systematic review found scanty but supportive evidence relating to the use of continuous glucose monitoring in patients with diabetes on dialysis. To our knowledge, this is the first systematic review undertaken to define the benefits of CGM in patients with diabetes on dialysis. In our review, we found only two studies that analysed the impact of CGM on glycaemic indices in patients with diabetes on dialysis highlighting the limited evidence available in this field. Both studies identified in this review have shown that CGM can significantly reduce mean serum glucose concentrations and HbA1c, without an increased risk of hypoglycaemia.

Assessment of glycaemic control in patients with dialysis presents considerable challenges. Due to the limitations in pharmacological options, many patients with diabetes on dialysis are likely to be on insulin therapy, exposing them to risk of glycaemic variability. Presence of multi-morbidity, reduced awareness of hypoglycaemia and fluctuations in blood glucose levels during dialysis and non-dialysis days further aggravates the problem [\[26](#page-7-14), [27\]](#page-7-15). The usefulness of conventional measures of glycaemic control such as HbA1c and fructosamine is also limited in this patient group.

In recent years, the availability of CGM devices (continuous and intermittently scanned) has emerged as useful tools to assess glycaemic control and overcome some of the above limitations. As a result, many guidelines now recommend the use of CGM for assessing glycaemic control in patients on dialysis [[1,](#page-6-0) [21](#page-7-9)]. Despite the recommendations and theoretical benefits of CGM use in the dialysis population, the data available to support the use of CGM is limited.

To date, studies involving CGM have either focused on glycaemic variability on dialysis and non-dialysis days or have been accuracy studies evaluating CGM with other measures of glucose control such as capillary glucose testing or HbA1c. We found only two studies that evaluated the clinical benefits of CGM in patients on dialysis. The benefits of CGM in patients with type 1 and type 2 diabetes not on dialysis has been demonstrated in several studies. An observational study conducted by Deshmukh, et al. [[28\]](#page-7-16) of 10,370 users across 102 hospitals across the UK showed that flash CGM use resulted in improved glycaemic control, hypoglycaemic awareness, reduced diabetes-related distress and reduced hospital admissions compared with baseline data. They reported improved glycaemic control in participants with higher baseline HbA1c and in those who had a greater number of scans of their device per day. In this study 97% of participants had type 1 diabetes with the other forms of diabetes making up the remainder. Similar findings were reported from a meta-analysis of flash CMG use in participants with type 1 and type 2 diabetes, showing significant and sustained change in HbA1c [\[29](#page-7-17)]. However, neither studies commented on participants' renal function or need for renal replacement therapy. FLASH-UK is a randomised control trial of participants with type 1 diabetes, comparing the psychological and glycaemic outcomes of flash CGM with SMBG. This will provide valuable data regarding the utility and efficacy of the flash CGM to guide further recommendations; however, those who are on dialysis or are considered pre-dialysis were excluded from the trial [\[30](#page-7-18)]. Although, it is widely perceived that patients with diabetes on dialysis may similarly benefit from CGM, the lack of studies that support CGM use is a concern and highlights the need for well-designed studies in this cohort.

CGM provides a summary data of TIR, TAR and TBR as measures of glycaemic variability. This can be used to ascertain overall glucose control, as well as trends and hypoglycaemic risk to guide treatment. The international consensus report recommended specific CGM targets for the dialysis population [[22\]](#page-7-10). The goal is to maintain more than 50% time within target range (3.9-10.0mmol/L) for more than 12 hours a day. The reasoning behind a reduced time within range target and an increased mean plasma glucose level is to avoid hypoglycaemia in this high-risk group [[22](#page-7-10)]. Interestingly, the studies included in our systematic review did not report on these measures. However, both studies reported improvements in mean glucose levels and HbA1c over the study duration. CGM also enabled better treatment adjustment without significant increase in hypoglycaemia. Similar results were noted in an 8 day trial of closed loop CGM insulin delivery, which has also significantly increased the time spent in the target glucose range compared to conventional blood glucose monitoring, with a lower mean sensor glucose level and no increase in the number of hypoglycaemia episodes [\[31\]](#page-7-19). Whether these results can be replicated in larger cohorts and over a longer period of time remains to be seen.

The lack of data on the use of CGM in this patient population has been emphasised by Bomholt et al., [\[32](#page-7-20)] who have also highlighted the practical challenges of the daily use of CGM in the dialysis population, such as the need for sensor application and replacement, interpretation and actioning of the data by the individual. For those with limited dexterity and cognition, the handing of the sensor and use of the software such as on a smartphone may be difficult. Periodic use of CGM has also been suggested, to be performed by clinical staff to aid adjustment of antidiabetic treatments. Emphasis on patient education and support from diabetes specialised nurse/educators are therefore needed for successful initiation and implementation of this technology in this patient cohort [[33\]](#page-7-21).

#### **Limitations**

In this systematic review, we included both randomised and observational studies to capture as much evidence as possible. However, we only included studies with a minimum of 10 patients and a follow up duration of at least 6 weeks. This was to ensure we assess the utility of CGM over a reasonable period. As a result, we excluded studies with smaller sample sizes and shorter follow ups. The two studies in this review were both before-and-after trials, with the same patient group evaluated pre and post intervention. This study design invariably carries a potential risk of carry over effect from the initial treatment to the CGM treatment period. Further, due to the nature of these studies, it was not possible to incorporate any blinding and although the qualities of both trial designs were good, the absence of a randomised control design requires a cautious interpretation of the findings.It is also worth noting that the focus of this review was primarily on glycaemic measures and we did not extend the review for other non-glycaemic outcomes and hence unable to comment on these benefits.

# **Conclusion**

Assessment of glycaemic control in patients with dialysis remains a major challenge. CGM promises to be a useful alternative to currently used methods such as SMBG and HbA1c and offers both efficacy and convenience. Our study shows that, despite the suggested clinical benefits, the data on CGM use in dialysis patients is scarce, with no large-scale randomised control trials available to demonstrate glycaemic or clinical outcomes. More research is required to better understand the benefits of CGM in the dialysis population. Adequately powered randomised controlled studies comparing SMBG with CGM, focused on glycaemic and non-glycaemic outcomes, particularly quality of life and diabetes distress are urgently needed to ascertain the potential benefits of these interventions and support widespread implementation.

#### **Supplementary Information**

The online version contains supplementary material available at [https://doi.](https://doi.org/10.1186/s12882-024-03763-z) [org/10.1186/s12882-024-03763-z.](https://doi.org/10.1186/s12882-024-03763-z)

Supplementary Material 1

Supplementary Material 2

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Not applicable.

#### **Author contributions**

Y.Z., P.S., V.S, M.K, J.B and S.B were involved in the conception and design of the study. Y.Z., P.S., K.G., J.B. conducted the literature search and contributed to the screening and recording of results. Y.Z. wrote the first draft of the manuscript and all authors reviewed and edited the paper. All authors approve the final version of the manuscript.

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#### **Data availability**

All data generated or analysed during this study are included in this published article.

#### **Declarations**

#### **Guarantor statement**

S.B. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

#### **Prior presentation**

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#### **Competing interests**

The authors declare no competing interests.

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