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COMMENTARY

A Podcast on the Use of CGM in Optimizing Type 2 Diabetes Management with Non-intensive Insulin Treatment in the Primary Care Setting

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ABSTRACT

Introduction: Type 2 diabetes is a widespread health concern with significant implications for patient well-being. Poor glycaemic control can lead to long-term complications, hypoglycaemia and glycaemic variability, highlighting the importance of setting treatment goals. This podcast, "The use of CGM in optimizing type 2 diabetes management with non-intensive insulin treatment in the primary care setting", introduces non-intensive insulin treatment and continuous glucose monitoring (CGM) as crucial tools in achieving these goals.

Objectives and Rationale: The advantages of CGM over blood glucose monitoring (BGM) are explored, emphasizing its real-time glucose data provision and how it empowers patients to make informed treatment decisions. Drawing on randomized controlled trials (RCTs), the compelling evidence of CGM's effectiveness in patients with type 2 diabetes on basal insulin treatment are discussed. Additionally, the real-world evidence, comparing outcomes between insulin-treated and non-insulin-treated patients are also addressed. The podcast examines the link between glycaemic control and acute complications requiring hospitalizations and how CGM contributes to a better quality of life for patients with type 2 diabetes. Empowering patients is central to this podcast, with a focus on education, engagement and strategies for integrating CGM data into treatment plans. The pivotal role of healthcare providers in supporting patients on non-intensive insulin treatment and CGM in the primary care setting is addressed. Addressing challenges and barriers in CGM adoption, including cost considerations, technology accessibility and patient concerns, is vital to its widespread use. There is also a consideration of the cost-effectiveness of CGM in type 2 diabetes management. The podcast provides insights into when to consider CGM, including intermittent use and data integration with other health technologies. It emphasizes the potential for improved patient outcomes and a reduced burden of type 2 diabetes. Practical tips for interpreting the Ambulatory Glucose Profile (AGP) report are shared, benefitting primary care healthcare professionals new to CGM.

Conclusion: The podcast "The use of CGM in optimizing type 2 diabetes management with non-intensive insulin treatment in the primary care setting" highlights the transformative potential of CGM in type 2 diabetes care. It encourages patients and healthcare providers to

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consider CGM as an integral part of treatment plans, ultimately improving the lives of those living with type 2 diabetes.

Keywords: Continuous glucose monitoring; Type 2 diabetes; Non-intensive therapy; Primary care; Telemedicine

DIGITAL FEATURES

This article is published with digital features, including the podcast audio, to facilitate understanding of the article. To view digital features for this article, go to https://doi.org/10.6084/m9.figshare.24794184.

PODCAST TRANSCRIPT

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Charley Lai (CL): Managing Editor of *Diabetes Therapy*, Adis, Springer Healthcare.

CL: Hello everyone and welcome to the Adis Rapid+ podcast series. This podcast was supported by educational funding from Abbott Diabetes Care. Joining us today is Professor Sam Seidu from Leicester General Hospital and today we will be discussing the topic of the use of continuous glucose monitoring (CGM) in optimizing type 2 diabetes management with non-intensive insulin treatment in the primary care setting. So Sam, thank you so much for taking the time to join us on this podcast where we'll be talking about non-intensive insulin treatments and CGM as crucial tools in achieving treatment goals in primary care. We will touch upon various things in this podcast, including randomized clinical trial evidence and real-world evidence, addressing the challenges and barriers to adopting CGM in the primary care setting, and finally rounding off with some practical tips for interpreting the Ambulatory Glucose Profile (AGP) report.

So to start off with, let's set the scene a little Sam: why should one consider CGM in type 2 diabetes?

SS: Thank you very much Charley. So CGM used in type 2 diabetes is actually very crucial in the sense that for every type of diabetes, you will need some sort of monitoring. And as we shall see in more detail later on, monitoring actually requires some continuous assessment of the glucose profiles, so that the patient will know what is happening daily and minute by minute on their system and they can make changes as appropriate. I think that is the main reason for considering CGM in type 2 diabetes.

CL: But we know that type 2 diabetes is largely asymptomatic. So why should one bother treating it?

SS: It is extremely important to treat type 2 diabetes, Charley, because the prevalence is so high globally, talking about over 500 million people are the world with the condition. Here in the UK, we have about 4.7 million people with the condition and that takes about 10 billion GBP (British pound sterling), which is a tenth of the total NHS (UK National Health System) budget. About 8 billion of this 10 billion GBP is spent on managing complications, and these complications normally occur because of poor control [1]. In people with type 2 diabetes, some data suggest that about 36% of patients do not achieve adequate control, and that results in complications [2]. So when you talk about heart attacks, for example, some data have suggested that about 530 diabetes-related heart attacks are experienced in the UK per week, and for amputations, some data suggest that about 175 amputations are noted in the UK per week due to diabetes [1]. About 20% of hospital beds are occupied by someone with diabetes at any particular time, and so there are huge implications for this [3]. The problem is that most patients with type 2 diabetes do not necessarily have intensive insulin treatment and that a lot of the guidelines, until recently, focus the use of CGM on people who have multiple daily injections of insulin. But like I said, the vast majority of patients with type 2 diabetes are not in this category. The vast

majority of patients will be on non-insulin treatment or even if they are on insulin treatment, it's non-intensive insulin treatment, and so focusing on using CGM for only a small fraction of patients with type 2 diabetes like this will not avert the complications that were outlined earlier on.

CL: But there are however other diabetes monitoring options, aren't there? What are the benefits then of CGM, over other diabetes monitoring options that are out there?

SS: That's an important question Charley. The main one that we know of is the haemoglobin A1c (HbA1c) value. HbA1c is actually a good predictor of long-term outcomes, both microvascular outcomes and macrovascular outcomes. What it doesn't do, however, is address the day to day or minute by minute hypoglycaemia and hyperglycaemic excursions that you would find in a person with type 2 diabetes. It tends to miss that minute by minute variability, so it's pointless to rely on the HbA1c test to determine if a patient is still having hypoglycaemia or hyperglycaemia.

Then comes capillary blood glucose monitoring. AS with the HbA1c test, most patients who do this would be pricking their fingers and testing their capillary blood glucose levels, probably a few times a day. Most people would rarely do it more than a couple of times a day, but if they are very dedicated and they do it properly, they might do it seven to eight times a day. What happens in between the testing periods, no one knows, especially at night when they are in bed. You could actually get hypoglycaemia in those periods when you're not testing without actually realizing it. So this monitoring option has also got its own limitations. Also, some patients are asked to keep a log book and bring their readings to their healthcare professional (HCP) so they can assess control their patient's diabetes by just looking at the profiles in their log books. Unfortunately, these log books are usually very difficult to interpret, and one cannot really be very sure whether what is written in the log books is actually accurate because sometimes the patient keeps records to impress their HCP—especially when it comes to concerns regarding driving licenses, they want to keep a good record, that they do not have hypoglycaemia, so they can maintain their license. So those are the problems with capillary blood glucose testing and HbA1c testing. And so that calls for a form of monitoring that records data continuously in a way that you can be able to see those minute by minute variations in glucose profiles in the patients, and that is where CGM is very useful.

CL: Thank you very much, Sam. It's really great to hear of the advantages of CGM and how it's useful. But what research evidence is out there to support the use of CGM in people with type 2 diabetes?

SS: So the research evidence for the use of CGM in people with type 2 diabetes is increasing pretty fast. A lot of people have always associated the use of CGM with type 1 diabetes, but the data in type 2 is also increasing.

The most recent findings that I'm aware of are from the IMMEDIATE study, which is a randomized control trial which demonstrated that intermittently scanned CGM in patients with type 2 diabetes on non-insulin treatment improved glycaemic control [4]. This improvement was consistent across factors such as diabetes duration and medication count.

Then came the MOBILE study which echoed similar findings, but in this case, in a population of patients who were on basal insulin treatment and who also showed some improvement in HbA1c after the follow-up period, suggesting behavioural change as a cause of improvement [5]. The reason I say this is that in the MOBILE study, the baseline HbA1c in the patients who were on CGM was 9.1% and, at 8 months of follow-up, that dropped to 8.0%, whereas in the blood glucose monitoring group, the HbA1c dropped from 9.0% to 8.4% and the difference was statistically significant. The interesting thing about the MOBILE study was that the intervention arm that had CGM was further split into two arms. After the 8 months of follow-up, patients in one arm stopped using CGM and those in the other arm continued to use the CGM. The patients were then followed up for an

extra 6 months, so a total of 14 months; it should be noted here that those patients who initially started a trial on capillary blood glucose monitoring continued on that through the 14-month period. After the first 8 months of follow-up during the 14-month follow-up period, those patient who discontinued their CGM saw their time in range drop from 62% to 50%. So that 12% drop was noted in the patients who stopped using the CGM. And interestingly, that drop did not actually come all the way back down to the baseline of those who were originally on capillary blood glucose monitoring, leading to the question 'Why did that not happen?'. My assumption is that these patients who were initially given CGM had learned some behavioural changes. This learnt behaviour sort of carried through some legacy benefit during the remaining 6 months of follow-up. So that is where I actually changed my practice by not just using continuous glucose monitoring continuously throughout, but even for short periods. You can actually argue that the patients on CGM can achieve good behavioural changes that would improve their glycaemic control and their CGM metrics going forward.

CL: Thank you Sam for that overview of the research evidence. But what about the real-world evidence, are the findings in randomized controlled trials similar to those from real-world observational studies at all?

SS: That's an interesting question. So again, the real-world evidence is gathering pace week by week and month by month. Every day you wake up, there is another publication somewhere in the world reporting real-world evidence. Eugene Wright did some work recently looking at the use of CGM in the real world in a population of patients under the age of 65 years who had poorly controlled Hba1c above 8% [6]. And what they found was that at baseline, in the population of patients, which I think comprised about 1034 patients, the HbA1c dropped during the follow-up from 10.1% to 8.6%. An interesting thing about this study was that the both patients who were both on insulin treatment and those not on insulin treatment were included and that in the group of patients who were on insulin, the drop in HbA1c only went from 10.1% to 9%; while this drop was statistically significant, the drop in the HbA1c in the patients who were not on insulin treatment dropped from 10.1% to 8.5%. So the drop in the non-insulin treated group was actually more significant than the drop in the insulin-treated group, which was interesting because up to then every time we talked about CGM, people started thinking about insulin use and multiple daily injections, probably because of the association of insulin with hypoglycaemia. But now we're seeing benefits even with the non-insulin treatment in the real-world setting. And that opens up the question—and I know this is a real-world observational study and that there are a lot of bias and confounding factors that can be associated with the study—but it does actually bring out another research question: 'Is there a case to actually consider the widespread use of CGM in patients with type 2 diabetes who are not actually on insulin treatment?' Probably not to avoid hypoglycaemia, but to focus on the behavioural changes that I talked about, things like medication adherence and other behavioural changes. All those may come into play in improving glycaemia when you're using CGM in that population.

CL: Thank you, Sam, for that overview of evidence. But looking beyond glucose control now, are there any benefits of using CGM in type 2 diabetes?

SS: Yes, there are some benefits. Indeed, regarding the acute benefits, the ones benefitting acute complications that lead to acute hospital admissions, we have a lot of data coming from various countries. In France, the RELIEF study has now collected 2 years of data [7–9]. So in the RELIEF study what the researchers did was they assessed the use of CGM and looked at the reductions in hospitalizations for acute events in patients with type 1 and type 2 diabetes. In the type 2 diabetes population, when they looked at the annual proportion of patients with hospitalizations and focused on the acute complications, such as diabetic ketoacidosis (DKA), there was a drop from 1.7% in the year prior to the initiation of

the CGM to 0.8% by year 1 of the study; this drop was sustained at 0.9% in year 2. Similar trends were found in hypoglycaemic events, coma and hyperglycaemia. So, yes, there are benefits. It's not just the glucose metrics and HbA1c that we've seen, there are some benefits with respect to acute hospitalizations for diabetes complications.

CL: That's great. It's really nice to hear that there are additional benefits to CGM use beyond just glucose control. It's also important though to hear some advice for primary care HCPs. Do you have any advice on this topic or any simple strategies for HCPs in primary care to interpret the CGM data at all?

SS: Yes the advice is just to basically re-emphasize the benefits of CGM, like I said, not just with respect to glucose metrics, but beyond that, to acute complications and, indeed, I haven't even mentioned the quality of life data. So I recently presented data at ATTD (International Conference on Advanced Technologies & Treatments for Diabetes) showing that the use of CGM, especially in the elderly population, led to improved satisfaction with treatment, convenience in the treatment and flexibility and so many other patient satisfaction measures [10]. So those benefits have got to be sold to the HCPs.

But to emphasize the simplicity of interpreting CGM, I think the consensus report published in *Diabetes Care* in 2019 [11] actually makes it very, very simple for HCPs to be able to interpret these data. The colour coding is actually what I like very much as it actually makes CGM very, very simple. For the vast majority of patients with type 1 and type 2 diabetes who are young, you aim for a time in range of 70% and above, time above range of 25% and time below range of less than 4%; and for level 2 hypoglycaemia, you're looking for time below range of less than 1%. Of course, in the elderly population, you need to relax your targets a little bit. So for the elderly population, a time in range of more than 50% is acceptable and time above range of less than 50% is acceptable as well. Time above range with a target of 10.9 mmol/L should be less than 10% in the elderly population. The sort of figures that you would use for pregnancy are different, and the subject of diabetes in pregnancy is not within the remit of this podcast. So CGM is actually very, very simple, just requiring a focus on the colour codes for the time in range, time above range and time below range. As such, you actually sell the simplicity of CGM very well to the primary care professional.

CL: Thank you Sam. It's great to hear that you think it's quite simple and the colour-coding actually helps make it simple as well. But as with everything, there are challenges that must be considered. What are some of the barriers for adopting CGM In type 2 diabetes?

SS: That's an interesting question. The barriers everywhere you go when talking about this topic normally are cited as cost, cost, cost and cost, so the cost-effectiveness of using CGM in the type 2 diabetes population is predominant. As I said earlier at the beginning of the podcast, the prevalence of the condition is very high, and so if you unleash the use of CGM on a wide scale of patients with this condition, you're probably going to end up in a situation where health economies cannot afford it. So everywhere you go people talk about the cost.

They have, in some studies, looked at the use of CGM in the type 2 diabetes population with a focus on cost-effectiveness data [12, 13]. I think that the initial focus in these studies was on intensive insulin therapy, and people with type 2 diabetes and multiple daily injections of insulin were compared with those with capillary blood glucose monitoring based on a lifetime horizon assumed to be 40 years, with the results showing some cost effectiveness with respect to using CGM [12, 13]. Another single study also included cost due to productivity loss [12], and the use of intermittently-scanned CGM improved the quality-adjusted life years (QALY) for people with type 2 diabetes on intensive treatment, leading to a favourable incremental cost-effectiveness ratio (ICER) [14–16].

In the basal insulin therapy population, again there have been many studies. One analysis focused on patients with type 2 diabetes not

on prandial insulin but just with intermittent use of CGM in four cycles of using the CGM for 2 weeks and then off it for the third week, with the cycle repeated up to four times over a 12-week period [17]. This regimen was followed up by another 40 weeks of observation, comparing these patients with the control arm of patients using capillary glucose monitoring. In this study, the cost inputs included the direct medical costs, treatments for depression due to diabetes complications, life expectancy and quality-adjusted life expectancy outcomes, and the results showed that those for the CGM cohort were all improved. Again, in this study, there were gains in ICER and QALY. This study actually indicates that the intervention was cost-effective and that effectiveness was likely, as I said earlier on in this podcast, due to patients making informed behavioural choices without clinician guidance. So this study involves patients who were on basal insulin.

In the primary care setting, a recently published randomized study, specifically a 6-month prospective study in the USA, was conducted in which participants using CGM were compared with those using capillary testing in the context of usual care in the primary care clinic setting [18]. The vast majority of these patients, that is about 93 out of a total of 99 patients (and this is typical of the population you will see in primary care), had type 2 diabetes. These patients were selected without any consideration given to their dietary or oral medications, or even to their injectable therapy regimens. After 6 months, the CGM users had reduced costs overall for primary care visits, emergency department attendance and laboratory investigations. These savings were not universal or dependent on the health insurance provider in the USA. So we're getting evidence drip by drip that increases support for some cost-effectiveness when it comes to selecting the appropriate cohort of patients in the type 2 population for getting CGM. The other barrier has been the issue around technology adoption and the associated challenges. But again, I think that is overplayed. The vast majority of patients globally, even those in the elderly population, are now tech savvy in most countries; they use smartphones, so that is not usually an issue. Even in situations where you have patients who are incapable of having their own monitors, you can provide monitors from the various CGM companies for these patients. It also helps when HCPs can access these data in their facilities so as to advise the patients better.

CL: Thank you Sam. But if wide-scale use is not feasible, are there any special groups of patients with type 2 diabetes that CGM could be considered?

SS: Yes, that's interesting. Yeah, I would probably say, I mean over here in the UK, the focus is on hypoglycaemia, so the categories of patients that we're meant to use in the type 2 population include patients with recurrent hypoglycaemias and/or hypoglycaemia unawareness, patients who need carers to go in and help with their testing and patients who are testing more than 8 times a day. Those are some of the cohorts that you want to use CGM in the type 2 diabetes population. But even beyond that, I will dare to challenge the system and suggest that because of this behavioural change that can be seen in their initial use of CGM, probably even at diagnosis you can consider the use of CGM for a short period if only so that the patient will see what the changes their glucose metrics as seen on the CGM are having on their lifestyle habits. Then after that, you can take it away from them.

You could also consider using CGM when you are changing doses of medications or deprescribing medications when there can be acute glycaemic excursions. During this period you want to see what happens; as well in some cases when there are diabetes complications, for example dialysis and gastroparesis or patients with diabetic foot ulcers and so on and so forth [19]. Other instances can be when you think of those patients with HbA1c results that are not matching their finger testing numbers; you might want to look at CGM and see what exactly is going on there.

CL: And what about practical tips. Do you perhaps have any practical tips that you could

share with us in interpreting the AGP report for the primary care HCP who is new to CGM?

SS: Yes. Practical tips for integrating CGM actually are useful in the primary care setting because the numbers can be a bit daunting, but it's best to just break it into five single steps:

(1) The first step is basically just validate the data, make sure that the numbers you're looking at are all accurate and that they belong to the patient who you think they should belong to. Look at the patient's name and date of birth and make sure it's the right patient. And then look at the data, make sure you've got a good 10–-14 days of data depending on which CGM system you are using. You should aim to get readings more than 70% of the time to be able to rely on the data. Then you want to look at the glucose management indicator (GMI) and then the glucose variability target which should be less than 36%. And then after that, you can look at your time in range, time below range and time above range. And then after that, you can then talk to your patient.

(2) Step 2 is when you start talking to your patient. The first thing you want to do is to look at the AGP report and look for hypoglycaemia. You look at the times that they are getting hypoglycaemia and investigate the course of this hypoglycaemia. It could be related to medication (the times of medication dosing), their meal times, fasting, alcohol intake or exercise. Then see how these tie in with the hypoglycaemic episodes.

(3) And then, after that, the next step will be to look at the hyperglycaemic episodes. In the type 2 diabetes population, you will find that most of the abnormalities you see on the AGP report would usually be in the hyperglycaemic range—not that hypoglycaemia is not important, actually it's very important, but the vast majority of patients with type 2 diabetes are more likely to have problems with hyperglycaemia rather than hypoglycaemia. So when you get hyperglycaemia, you want to again look at the relationship with food intake, medication, insulin dosing, lifestyle and behavioural changes. And then you can adjust therapy based on that in your discussion with the patient.

(4) You also want to look at the glucose variability, just make sure that the variation in the profiles is not very acute. What you want is to find or have a flat, narrow and in range sort of profile. You don't want one that is undulating too much outside of the recommended ranges.

(5) Finally, when you have done all of the above, you need to agree on an action plan with this patient. So when agreeing the action plan with the patient, having already reviewed your AGP report, you know where the abnormalities are. There may be a few abnormalities that you have picked up on but try not to do too much at one time. Just pick the most urgent ones first. Make sure that the discussions are [25:12] smart, specific, measurable, achievable, and time-bound, and then review the patient at a set time. Then see whether the targets that you agreed on with the patient have been met [25:24]. Once they have been met, you can then take the next problem that you identified from the AGP report and address that. So that is the way to do it, and if you do it that way, you'll find that actually that systematic approach makes it very easy for patients to follow.

CL: Thank you Sam for those practical tips, which I'm sure will be very helpful for the primary care HCP who is also new to CGM. Just to round off this podcast, do you have any final concluding remarks?

SS: Yes, my concluding remarks will be that primary care providers need to familiarize themselves with this new technology. Thirty years ago, the way we monitored glucose was just using a urine test, and at the present time most people would test for or monitor glucose using capillary testing. So I think we're now entering an era where even the capillary testing is going to become obsolete in the next

few years. Therefore, it's worthwhile for primary care clinicians to familiarize themselves with this new technology and on how to utilize it in patients to benefit management of their condition. A shared decision made with a patient can be set and appropriate action plans can be agreed upon with the patient, especially those focused on avoiding hypoglycaemia, but not only that, in the type 2 diabetes population. There should also be a focus on avoiding hyperglycaemia and glycaemic variability, which tends to cause a lot of the long-term complications we see in this population.

CL: That's great. Thank you very much Sam for your final thoughts. It's great to hear your overview of the benefits of CGM in type 2 diabetes management. I look forward to seeing more consideration of CGM as an integral part of treatment plans. It's been a very interesting topic today and thank you so much, Sam, for your time and for being here today. Thank you very much.

SS: Thank you.

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Declarations

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