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RESEARCH ARTICLE

EFFECTIVENESS OF CONTINUOUS GLUCOSE MONITORING IN UNCONTROLLED TYPE-2 DIABETICS IN TERTIARY HEALTHCARE CENTRE

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Abstract

Long term diabetic complications can be prevented or reduced by achieving good metabolic control, reflected by HbA1c <6.5Â– 7.0%.1-3 Glucose excursions might also contribute to the development of diabetic complications.4,5 Fear of hypoglycemia limits the ability to reach strict glycemic control, because it is usually accompanied by reluctance of the patient to intensify insulin therapy. Indeed, the goal of intensive therapy is to normalize HbA1c and control fasting and postprandial glycemia, while concurrently limiting the number and severity of hypoglycemic events. To reach tight glycemic control, frequent self- monitoring of blood glucose (SMBG) must be performed.6 SMBG devices provide the patient with accurate but discreet blood glucose levels. They do not provide trend information nor do they reflect glycemic fluctuations, which is possible by using continuous glucose monitoring (CGM) systems. Thus, implementation of strict glycemic control may be facilitated by a CGM device. This manuscript critically reviews the proposed benefits and indications of CGM and the current evidence of CGM on health outcomes in diabetic patients.

Introduction:-

Long term diabetic complications can be prevented or reduced by achieving good metabolic control, reflected by HbA1c <6.5–7.0%.[1-3] Glucose excursions might also contribute to the development of diabetic complications.[4,5] Fear of hypoglycemia limits the ability to reach strict glycemic control, because it is usually accompanied by reluctance of the patient to intensify insulin therapy. Indeed, the goal of intensive therapy is to normalize HbA1c and control fasting and postprandial glycemia, while concurrently limiting the number and severity of hypoglycemic events. To reach tight glycemic control, frequent self- monitoring of blood glucose (SMBG) must be performed.[6] SMBG devices provide the patient with accurate but discreet blood glucose levels. They do not provide trend information nor do they reflect glycemic fluctuations, which is possible by using continuous glucose monitoring (CGM) systems. Thus, implementation of strict glycemic control may be facilitated by a CGM device. This manuscript critically reviews the proposed benefits and indications of CGM and the current evidence of CGM on health outcomes in diabetic patients.

Advantages of CGM

Current CGM systems display the glucose level, the direction and magnitude of change of glucose levels and can be used as a tool to predict impending glucose excursions (hypo and hyperglycemia) and to assess glycemic

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variability.[7,8] In addition, reliable alarm signals of low or high glucose values warn the patient to take action.[9] All this is being executed on a near-continuous basis, throughout the day, and this for several days, thereby facilitating pattern recognition, and helping the patient (and physician) to optimize therapy and improve metabolic control. In the future, by means of complex mathematical trend analysis, the course of glycemic excursions may be predicted for longer time periods ahead, allowing the patient to take preventative actions in case of impending hypoglycemia.[10] Quality of life might also improve by using real-time CGM via reducing the fear of unexpected hypoglycemia.A number of therapeutic recommendations can be made using CGM to improve metabolic control and to avoid hypoglycemia. These could include changing the insulin regimen (from regular to rapid-acting insulin analogs, from Neutral Protamine Hagedorn to long-acting insulin analogs, changing the number of daily injections, starting insulin pump with appropriate basal and bolus insulin dosages), adapting the mealtime insulin bolus dosage, changing the insulin-to-glucose correction algorithm, changing the carbohydrate content of the meal, altering the insulin dosage for exercise, adapting the nighttime insulin dosage to avoid the dawn phenomenon, etc.[8,11-13] CGM data also show the effect of exercise and food composition on glucose levels. Use of CGM in adolescent outpatients with diabetes achieved a significant improvement in metabolic control, not only by providing accurate data for adjustment of insulin treatment but also by promoting patient communication and motivation.[12,14]

Material & Methods:-

This study was conducted in The Department of General Medicine, at Nayati Multi Super Speciality Hospital and Northern Railway Central Hospital. All the patients who gave consent and agreed for CGM devices were chosen for CGM device application. In our study we used Freestyle Libre Pro CGM device, a sensor based flash glucose monitoring device that captures glucose readings every 15 minutes for upto 14 days and gives a complete glucose profile. This device consists of a sensor , a coin sized device applied on the back of the arm subcutaneously and a reader, that reads sensor data which thereby can be collected on a computer. After CGM application, patients were called after 3 days for follow up. During these 3 days patients were told to do SMBG three times in a day and during the symptoms of hypoglycemia. Patients were also asked to maintain the log book for meal timings, sugars, insulin doses and timing of symptoms of hypoglycemia and exercise. On the 14th day patients were called again for the removal of the device and all the readings were noted.

On 3rd day post CGM application as well as on 14th day during the time of removal of the CGM device, all the readings were downloaded on desktop using compatible software and therapy was adjusted in presence of a senior physician. The decision of use of CGM for the patients was taken by a Senior Physician. The recommendations were based on CGM reading as well as our HbA1C levels in the form of;

1- Re-emphasizing and reinforcing the need for dietary patterns.
2- Re-adjusting insulin therapy.
3- Modification in the need of physical activity; if required.

Base-line characteristics of the patients including age, sex, BMI, duration of diabetes, treatment in form of Basal or BASAL + multiple bolus insulin injections were noted

Inclusion criteria:

1. All type 2 Diabetic patients aged more than 18 years on insulin therapy.
2. Duration of Diabetes more than 1 year.
3. Patients with HBA1C levels of >8 %

Exclusion criteria:

1. Type I Diabetic,
2. Patients with cancer or severe illness.
3. Renal failure or any other co-morbidity impairing the quality of life 4- Patients who underwent CGM study within the last 3 months.

Methods:-

Information Imparted - All the eligible participants were told about the goals of the study

Informed consent - Informed consent was obtained from the participants as per standard protocols before starting the evaluation of the patient

All the patients were subjected to a detailed history and thorough physical examination through a preset Performa.
Investigations:

1. Haemoglobin (by fully automated biochemical analyser)
2. Kidney function test - Blood Urea , Serum Creatinine ((by fully automated biochemical analyser)
3. Lipid Profile (by fully automated biochemical analyser)
4. Fasting Blood Sugar (by fully automated biochemical analyser)
5. Post Prandial Blood Sugar (by fully automated biochemical analyser)
6. HBA1C (by fully automated biochemical analyser)
7. Urine Routine and Microscopy

Records of all the test reports as well as major CGM parameters such as Hypoglycemic events (<70 mg/dl), hyperglycemic episodes (>250 mg/dl) average blood glucose, time in target (time spent in target range glucose i.e. 70-180 mg/dl), glycemic variability were maintained.

Study Design :
Prospective Cross Sectional Study.

Study Area:
Nayati Multi Super Speciality Hospital and Northern Railway Central Hospital

Study Population:
Patients who attended Medicine department with type 2, diabetes mellitus

Sample Size :
50 but a total of 100 participants were enrolled

Study Duration :
12 months (January 2020 to January 2021)

Data Collection Tool And Technique:
After taking consent from the patient the CGM device was applied on to the patient's back of the arm. The data was collected using a reader, which was further connected to a desktop using a USB cable and the data so collected was saved in the desktop using compatible software.

Records of all the test reports as well as major CGM parameters such as Hypoglycemic events (<70 mg/dl), hyperglycemic episodes (>250 mg/dl) average blood glucose, time in target (time spent in target range glucose i.e. 70-180 mg/dl), glycemic variability were maintained.

All the observations were made under the direct supervision of the senior consultant

Discussion:-

Diabetes is emerging as one of the most important public health problems of the 21st century; hence a complete picture of their blood sugar control is required in people living with diabetes, which can lead to better short and long-term treatment decisions and health outcomes. This strict monitoring of blood sugar is made possible by using CGM.

This is a Prospective cross sectional study conducted at Nayati Multi Super Specialty Hospital, Mathura and Northern Railway Central Hospital, New Delhi. In our study we evaluated the effectiveness of CGM devices in Type 2 diabetics using various parameters. A total of 100 subjects were enrolled in this study based on the inclusion and exclusion criteria and after taking consent from them. Samples were taken for Haemoglobin (by fully automated biochemical analyzer) Kidney function test - Blood Urea, Serum Creatinine ((by fully automated biochemical analyzer) Lipid Profile (by fully automated biochemical analyzer) Fasting Blood Sugar (by fully automated biochemical analyzer) Postprandial Blood Sugar (by fully automated biochemical analyzer) HBA1C (by fully automated biochemical analyzer) Urine Routine and Microscopy. BMI calculation was done for all patients with height being measured by a stadiometer in metres. Weight measured in kilograms using a standardised weighing scale in light clothing. Pearson's Chi square test and Unpaired T test were used was used to find the significance of study parameters

Out of total 100 subjects enrolled in this study 44 were females and 56 were males. The majority of patients in the study were in the age group (61-80) 56%. Minimum is 25 years and maximum age is 88 years with mean age being 60.6 years and standard deviation being 11.1.

Of the total 100 subjects number of patients with normal BMI after application of CGM were 43 i.e., 43 % of the patients, 37 patients came in the criteria of overweight i.e. 37% of patients, 17 subjects were classified as Obese Class 1 ie.17 % and there were no patients in Obese Class 2.

In our study (Mean ± SD) value of Total Cholesterol (198.43±38.83)mg/dl, Triglyceride (146.73±20.866)mg/dl , LDL (112.040±30.885)mg/dl in patients before application of CGM while (Mean ± SD) value of Total Cholesterol (187.470±28.519) mg/dl , Triglyceride (140.890±18.097)mg/dl , LDL (102.410±22.897)mg/dl in patients after 3 months of CGM application and had a $p<0.001$, indicating that these results were significant, reflecting reduction of these three parameters of lipid profile in the patients after application of CGM which was also observed in a study done by Poolsup N, Suksomboon N et al.[35]

The (Mean ± SD) value of HBA1C in our study was (9.873±1.169) % in patients before using CGM, while (Mean ± SD) value of HBA1C in subjects after 3 months of CGM application was (9.410±.8353) % and had p value <0.001 as calculated by Unpaired T Test these findings were also seen in the study done by Langedam M et al.[33]

In our study the mean value of number of episodes of hypoglycaemia in (0-3 days) was 0.24 whereas the mean value of number of episodes of hypoglycaemia in (4-14 days) was 0.03 showing a significant reduction in episodes of hypoglycemia (p value <0.001) in patients which corresponds with the study done by Little SA, Leelarathna L, Walkinshaw E, et al in which there was similar significant improvement in the time that the patients spent in a normoglycemic state, with less time spent in hypoglycaemia and hyperglycaemia. Additionally, CGM decreased the frequency of severe hypoglycemic events in this high-risk population, and produced less glucose variability.

In a study done by Warren RE, Frier BM et al, there was a similar correlation in the reduction of frequency of hypoglycemia in the CGM group. Importantly, this effect occurred without increasing HbA1c, which often is the price paid when trying to avoid hypoglycemia[57]. As demonstrated in our study which was also seen in a study by Little SA, Leelarathna L, Walkinshaw E, et al CGM did not prevent all hypoglycemia, but only reduced its duration and depth. There was also an increase in the total time spent in target glucose which may emerge as a better predictor of complications, since it is a direct measure of glucose in the blood and it is independent on red blood cell turnover.

There was significant reduction in the BMI of the patients when compared to baseline and after 3 months of CGM application which was also stated in a study by H J Yoo, H G An et al, where in addition to glycemic benefits, clinical use of CGM devices significantly reduced body mass index (BMI), total daily calorie intake, weight and an enhanced motivation for improved glycemic control.

Conclusions:-

Continuous glucose monitoring offers advantages over intermittent glucose monitoring when glycemic patterns are poorly understood. The information about direction, magnitude, duration, frequency, and causes of fluctuations in blood glucose levels that can be obtained by continuous glucose monitoring is simply not available with intermittent blood glucose monitoring.

From our study we can infer that use of CGM devices lead to a significant reduction in HBA1C and number of episodes of hypoglycemia. The time spent in the target glucose also increased using CGM devices. We were also able to show that CGM was useful in modifying a patient's diet and exercise habits which was seen in the result as BMI of our patients as well as lipid profile showed significant improvement.

With the advancement in technologies additional evidence regarding the clinical effects of adopting combinations of new technologies from trials and real- world populations is needed to confirm these finding, hence more studies are required to validate the use of CGM.

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