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Porównanie wykorzystania czujników do ciągłego monitorowania glikemii (Dexcom G6 i Guardian Connect) u pacjentów ze schyłkową niewydolnością nerek

Rozprawa na stopień doktora nauk medycznych i nauk o zdrowiu w dyscyplinie nauki medyczne

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V. SUMMARY

Chronic kidney disease is one of the most common chronic diseases, affecting approximately 10% of the world's population. Chronic kidney disease in stage G5 is referred to as end-stage kidney disease. Diabetic kidney disease with its organ complications is currently the main cause of end-stage kidney failure and the need for chronic dialysis. A very important element of diabetes therapy in this group is a precise method of assessing glycemic control, and the methods used so far, such as glycated hemoglobin or self-monitoring of blood glucose, have their limited accuracy and application. The answer to this need to use other, new methods of assessing glycemic control could be continuous glucose monitoring (CGM) sensors. Continuous glucose monitoring is a system that uses a sensor to measure glucose levels in the interstitial fluid. Over the last decade, not only the availability of CGM systems has significantly increased, but also their accuracy. So far, in the available literature, there are no studies on the long-term and independent use of systems for continuous glucose monitoring in dialysis patients and modification of normoglycemic therapy based on CGM data. In addition, the available literature lacks detailed analyzes of glycemic profiles in people with diabetes after kidney transplantation and data on the use of CGM systems. The aim of the study was to assess glycemic profiles using continuous glucose monitoring systems (Dexcom G6 and Guardian™ Connect by Medtronic) in people with diabetes undergoing peritoneal dialysis, hemodialysis, and kidney transplantation. The specific aim of the study was to assess the impact of monthly use of CGM systems on glycemic control and quality of life in people with diabetes on peritoneal dialysis, hemodialysis, and kidney transplantation, and to assess the usefulness of CGM in these populations. In addition, the authors of the study wanted to analyze the impact of hemodialysis on glycemic variability in hemodialysis patients. A minor goal of the project was also to educate people with end-stage renal disease and diabetes about the available new diabetes technologies. The study protocol was in line with the assumptions of the project approved during recruitment to the program. Positive opinions of the Bioethics Committee were obtained for its implementation (resolution KB/182/2020 of November 16, 2020 and KB/8/A2023 of February 6, 2023). The total duration of the project is 20 months (10/2021-05/2023). Eleven subjects were enrolled in this two-center study, with a female-to-male ratio of 8/3 and a mean age of 58.9±14. The

average duration of renal replacement therapy was 42.8±81.8 months, while in the group of patients after kidney transplantation, the average time since kidney transplantation was 6.5±7.4 months. The treatment was a diabetic diet alone (9%) or a diabetic diet with pharmacotherapy (89%). The Dexcom G6 system and Guardian Connect were used for the project. The G6 system consists of a Dexcom G6 sensor and a Dexcom G6 transmitter that transmits data to the Dexcom G6 app on a person with diabetes's smartphone. Then, thanks to the Dexcom Clarity system, it was possible to analyze it by medical professionals. The Guardian Connect system consists of an Enlite sensor and a Guardian Connect transmitter that transmits data to the Guardian Connect app linked to your CareLink™ Personal account. The data can then be uploaded to the CareLink™ System for statistical analysis. The quality of life of the project participants was assessed three times (at the beginning of the study and after the end of use of each CGM system) using the World Health Organization's shortened quality of life assessment questionnaire (WHOQOL-BREF), consisting of 26 questions. Design limitations were the small number of participants, limited CGM data on very low and very high blood glucose levels, technical issues, and premature termination of participants from the study. The study showed a positive correlation between HbA1c and parameters of glycemic control obtained thanks to CGM, i.e. GMI and average glycemia, and a negative correlation between HbA1c and TIR, which confirmed the safety of using CGM systems in people with end-stage kidney disease noted by other authors. In addition, the use of the Dexcom G6 system was not shown to have a positive effect on HbA1c in the group of patients with end-stage kidney disease and in the group of patients after kidney transplantation (t=-1.39 p=0.21; t=-2.35 p=0.08). Similarly, the use of the Guardian Connect system did not show a positive effect on HbA1c in patients with SNN and in the group after kidney transplantation (t=-0.98 p=0.36; t=-0.62 p=0.57). A positive impact of using Dexcom G6 on all detailed domains of the quality of life examined using the questionnaire, i.e. physical, mental, social, environmental (r=0.72 p=.04; r=0.9 p=0.02; r=0 .79 p=0.02; r=0.91 p=002). There was also a positive impact of using Guardian Connect on all of the above domains (r=0.85 p=0.008; r=0.98 p<001; r=0.92 p=0.001; r=0.9 p=0.003). Data on TIR in dialysis patients indicated very poor glycemic control, none of the records met even the most liberal criteria for good glycemic control. Over half a thousand readings were non-numerical data, i.e. informing only that the blood glucose level is above 400mg/dl or

below 40mg/dl. The standard deviation was at least 54 and the glycemic coefficient of variation was at least 33.4%. This proves the high variability of glycemia in this group of people. Although the project did not show a greater number of hypoglycemia during hemodialysis or in the peridialysis period, dialysis patients were very often unaware of hypoglycemia in the Dialysis Centre. Therefore, not only modifications of the ambulatory care system at the Dialysis Center should be considered, but also the introduction of diabetes re-education programs among hemodialysis patients. Pressure-induced sensor attenuations (PISAs) were observed in some study participants. Despite the existing PISAs detection algorithms, the pressure exerted on the sensor puncture site (usually during sleep) may cause inaccurate glucose measurements, which may falsify the parameters of the adjustment or be the reason for incorrect therapeutic decisions. Two people with diabetes on dialysis so far have reported difficulties with glycemic assessment due to advanced vision problems, which has led to difficulties in using the glucometer, abandonment of regular SMBG, and frequent episodes (2-4 episodes per month) of severe hypoglycemia (requiring assistance from other people). Thanks to the use of the CGM and the smartphone voice assistant during both periods of CGM use, both people with diabetes did not experience any severe hypoglycemia, which significantly influenced the greater sense of security of therapy reported mainly by partners of the treatment of people with diabetes. Four people decided to continue using continuous glucose monitoring systems after completing their participation in the study. However, the greatest difficulty and at the same time the discovery of the study was the problem of medicalization of everyday life among people with diabetes and end-stage kidney disease. A significant number of dialysis patients did not agree to participate in the study precisely because of the feeling of constant medicalization, the need to regularly use medical devices, and the fear of "robotization". The above concerns overshadowed all the presented benefits and advantages of the devices. This indicates the need for greater care for compliance with the principles of quaternary health prevention, i.e. identification of people at risk of excessive medicalization of everyday life and implementation of activities aimed at avoiding excessive medicalization.