Original Research Article

Use of Therapy Diary as a Method for Monitoring and Improving Adherence to Metformin Therapy

ABSTRACT

Aims: Determine the influence of using the therapy diary on adherence and blood glucose.
Study design: A randomized multicenter study.
Place and Duration of Study: The research was conducted in the Health Centers of Tuzla Canton, from March to August 2024.
Methodology: The sample consisted of 44 subjects age 35-65. Respondentsincluded in the reserach: use metformin for diabetes mellitus type 2 at least 6 months, use metformin irregularly, do not suffer from a malignant disease or a severe mental disorder,gave written consent to participate in the research. A therapy diary was used for monitoring adherence to metformin over a period of 3 months. Respondents were trained to independently measure blood glucose with a glucometer every morning for 3 months.
Results:32 (72.73%) respondents had adherence greater than 80% after 3 months, while 12 (27.27%) respondents had adherence less than 80%, which is considered insufficient adherence to therapy. The average value of blood glucose for all respondents at the beginning of the study was 8.9 mmol/L. The mean value of morning blood glucose for all respondents after 3 months is lower by 0.6 mmol/l. The mean value of morning blood glucose in adherent patients (32 respondents) after 3 months was 8.2 mmol/L, which shows that morning glucose decreased by 0.7 mmol/L on average. The mean value of morning blood glucose in non-adherent patients (12 respondents) was 9.1 mmol/L, which is on average 0.2 mmol/L higher than the mean value of measured morning blood sugar at the beginning of the study.
Conclusion: Method of writing a therapy diary can improve adherence to therapy, but this method should not be the method of first choice, considering the fact that we have a large part of respondents without improvement in adherence.

Keywords: adherence; metformin; diary; therapy; diabetes.

1. INTRODUCTION

One of the most common forms of medication error is patient non-adherence. Adherence is defined as the degree of the patient's adherence to the measures and recommendations of the healthcare worker related to taking medicine, implementing dietary measures and/or changing lifestyle. The definition was presented by the World Health Organization (WHO) in 2006, emphasizing the importance of adherence in the success of therapy and highlighting non-adherence as a significant global health and economic problem [1].
Patients were considered adherent if the percentage, defined as the number of doses missing in a certain time period divided by the number of doses prescribed by the doctor in the same time period, was greater than 80% [2].] The number of missing doses means doses used by the patient, which does not show whether the patient took that dose correctly and whether he took the missing dose at all.

The need for the development of numerous types of methods for assessing adherence is increasing every day, however, there is still no method that will unequivocally prove whether a patient is adherent or not, and that this method is at the same time available to every individual, reliable, authoritative and economically acceptable.
The methods that have been developed and applied so far can be divided into two groups: direct and indirect [3]. Direct methods include the determination of the amount of the drug or its metabolites in tissues or body fluids, most often in blood, urine or saliva. Indirect methods include procedures such as various questionnaires and surveys for patients, pill counters, patient notes, monitoring the frequency of taking medications, and various electronic programs for monitoring therapy intake. Although these methods are more available and cost-effective, their disadvantage is susceptibility to data manipulation and lack of objectivity [3,6].
It is important to note that none of the methods applied so far are ideal and there is currently no standardized procedure for assessing adherence that could cover all aspects and determine all causes of non-adherence [3]. In addition, there are numerous variations of certain methods for examining adherence, and over the years of research they are used inconsistently, the data are not systematized according to common guidelines, and the defined thresholds of the level of adherence may differ from study to study, which makes it difficult to interpret the data obtained and use them in clinical practice [4].
The World Health Organization, informed by the trials conducted so far, concluded that an increase in the degree of adherence can affect the patient's health more than any change in medication [5]. In the USA, as many as two-thirds of patients are hospitalized precisely because of the consequences of non-adherence, which indicates the importance of implementing already available interventions to improve adherence, as well as the development of new techniques and interventions [2].

2. MATERIAL AND METHODS

The research was conducted in the family medicine centers of the Health Centers of Tuzla Canton. The sample consisted of 44 respondents of middle age (35-65), who have been using metformin for a minimum of 6 months in the treatment of type 2 diabetes mellitus.
The criteria for the inclusion of respondents in the research are: information that the respondent suffers from diabetes mellitus type 2 for at least 6 months, that the respondent uses metformin for more than 6 months, that the respondent uses metformin irregularly during the last 6 months, that the respondent does not suffer from a malignant disease, that the respondent does not suffer from a severe mental disorder and voluntary written consent to participate in the research. The research used a therapy diary to monitor metformin intake, as an indirect method for monitoring adherence over a period of 3 months. Respondents were given glucometers and strips for measuring blood glucose and were trained to independently measure blood glucose every morning for 3 months and to record glucose values in a table. The inclusion of respondents in the research and the research itself lasted from March to August 2024. Before the start of the study, all included respondents had a level of adherence to metformin of less than 80% (they were late in taking monthly therapy for at least 6 days). The research was carried out with the voluntary written consent of the respondents to participate in the study. The respondents were informed about the purpose of the research and it was explained to them that the obtained data will be used exclusively for the purpose of the research, and they also had their blood glucose levels measured at the beginning of the research and after three months of writing a diary of metformin therapy.

3. RESULTS AND DISCUSSION

Adherence to therapy and the number of missed daily doses are shown in Table 1. The maximum number of days in which some of the respondents did not take the prescribed daily dose of metformin (they took less or did not take metformin at all) for a period of 3 months was 90 days, which represents 100% of the sample and speaks of an extremely high degree of non-adherence in some respondents. The minimum number of days in which prescribed daily doses of metformin were missed was 0 days. As a definition of good adherence to chronic therapy, the research used a level of 80% of the daily doses of the drug taken at the time prescribed by the doctor's recommendation. 32 (72.73%) respondents had adherence greater than 80% after 3 months, while 12 (27.27%) respondents had adherence less than 80% (more than 17 prescribed daily doses were not taken during 3 months), which is considered insufficient adherence to therapy. From the obtained results, it is evident that even with daily measurement of morning blood glucose and writing a therapy diary, almost a third of the respondents after 3 months still have insufficient adherence to the therapy. It was found that the majority of respondents 20 (45.45%) have from 0 to 5 missed daily doses in a period of 3 months, while 9 respondents (20.45%) have from 6 to 17 missed doses in the same period.
Table 2 shows the influence of the respondent's adherence on blood glucose values. 80% of therapy use in the given period was taken as the criteria of adherence. This means that all respondents who missed therapy for more than 17 days within three months for any reason are characterized as non-adherent, and conversely all those who have less than 18 such days are characterized as adherent. The maximum blood glucose level of the respondents at the beginning of the

test was 16.5 mmol/L, while the lowest value was 2.6 mmol/L. The average value of blood glucose for all respondents at the beginning of the study was 8.9 mmol/L. The range of morning blood glucose values at the beginning of the study was 13.9 mmol/L. After 3 months of monitoring, the maximum blood glucose value was 14.7 mmol/L, the minimum value was 5.0 mmol/L, while the mean value for all respondents was 8.3 mmol/l. The range of morning blood glucose values after 3 months was 9.7 mmol/L. The mean value of morning blood glucose for all respondents after 3 months is lower by 0.6 mmol/L compared to the mean value calculated at the beginning of the study. The mean value of morning blood glucose in adherent patients (32 respondents) after 3 months was 8.2 mmol/L, which shows that morning glucose decreased by 0.7 mmol/L on average in adherent patients for three months. The mean value of morning blood glucose in non-adherent patients (12 respondents) was 9.1 mmol/L, which is on average 0.2 mmol/L higher than the mean value of measured morning blood glucose at the beginning of the study. The obtained results indicate the satisfactory effectiveness of the prescribed therapy when it is taken in accordance with the prescribed regimen, as well as the impact of non-adherence on the lower effectiveness of the therapy and the increase in morning blood glucose levels.

Table 1. Adherence and number of missed daily doses for metformin after 3 months

Respondents n (%)	Adherence (%)	Missed daily doses
Adherent 32 (72.73%)	>80%	0-17
Non-adherent 12 (27.27%)	<80%	>17

Table 2. Influence of the respondent's adherence on blood glucose values

	Average value of blood glucose before research	Average value of blood glucose after 3 months	Range
All respondents	8.9 mmol/L	8.3 mmol/L	-0.6 mmol/L
Adherent	-8.2 mmol/L		-0,7 mmol/L
Non-adherent		-9.1 mmol/L	+0.2 mmol/L

4. CONCLUSION

Although the applied method for monitoring adherence through therapy diary writing is an indirect and non-objective method, it is evident that there was an improvement in adherence in more than two thirds of the respondents. In addition to the above, the fact that almost one-third of the respondents did not improve their adherence even though they wrote a daily therapy diary and measured their morning blood glucose is of greater importance. One of the reasons that can lead to this is the fact that the respondents are suffering from type 2 diabetes mellitus, which is a chronic disease and whose symptoms are often not very pronounced, so the patient does not see a significant change after taking regular therapy. Taking into account the obtained results, it should be pointed out that the method of writing a therapy diary can lead to an improvement in adherence to therapy, but that the same method should not be the method of first choice, considering the fact that we have a large part of respondents without improvement in adherence. It should also be emphasized that the actual degree of adherence of the respondents considered as adherent after 3 months may be lower than the obtained one, because the subjects independently wrote the therapy diaries.Considering that, there is a possibility that the results recorded in the therapy diaries may be manipulated by the respondents. Consequently, it is necessary to work on the development of new and more successful methods for monitoring and improving adherence, especially in patients who are on therapy for chronic diseases such as diabetes mellitus type 2.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

CONSENT

The research was conducted after obtaining the informed consent of the respondents.

ETHICAL APPROVAL

Ethical approval was obtained from the Ethical Committee of the Public Health Institution “Health Center”, Srebrenik andPublic Health Institution “Health Center”, Živinice.

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