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Abstract

Background: In the available literature there are only few reports on the effect - on blood glucose level - of the physical activity and "optimal" high-fat diet in patients with type 1 diabetes mellitus. However, there are no data concerning the effect of insulin type in patients following different diets and engaging in different level of physical activity.

Objective: Our study aimed at evaluating the effect of an insulin type on health and blood glucose parameters in patients with type 1 diabetes engaging in different levels of physical activity and following different diets.

Materials and Methods: A group of 119 patients with type 1 diabetes mellitus aged 26 - 43 was studied (66 women and 53 men). All of them completed our own survey (Wiśniewski 2015). Among the surveyed subjects, 66% used insulin analogues, and 34% human insulin; 72% complied with the dietetic instructions issued by their diabetologists, and 28% followed a so-called "optimal" diet.

Results: The statistical analysis was performed using the χ^2 test and Tchuprov's test. We found 80 statistically significant dependencies (p < 0,05), including 29 evident ones (Tchuprov's T > 0,38), including 10 depending on insulin used.

Conclusion:

- 1) Particularly great health improvement involving the declared blood glucose parameters (fasting blood glucose level, frequency of hypo- and hyperglycaemic incidents and glycated haemoglobin level) was brought about by using insulin analogues rather than human insulin.
- 2) It occurred both in the patients following a "standard diabetology" diet and in the followers of the "optimal" diet.
- 3) Both health and blood glucose parameters were improved by increased physical activity; this effect was more evident in insulin analogue users.

Our results indicate at least a moderate synergistic effect of insulin analogues and physical activity on blood glucose level. The improvement caused by the "optimal" diet was observed mainly in persons who were physically active and received insulin analogues rather than human insulin.

Keywords: Type 1 Diabetes Mellitus; Insulin Analogues; Physical Activity; Diet; So-Called "Optimal" Low-Carbohydrate High-Fat Diet

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Introduction

Type 1 diabetes is common especially in children and young people. It develops as a result of the destruction of pancreatic beta cells by the patient's immune system. Therefore, it is classified as an autoimmune disease [1]. Forecasts predict that in 2030 nearly 4.5% of all people in the world will suffer from diabetes. Patients with type 1 diabetes account for nearly 10% of cases [2].

The elements of diabetes therapy include mainly: diabetes education of the patient and his relatives, self-control, insulin therapy (more broadly pharmacological therapy), adherence to dietary recommendations, physical activity, as well as treatment of disorders accompanying diabetes.

Many clinical trials have proven that kinesiotherapy and physical therapy significantly improve the quality of life of patients with type I diabetes, bringing them many benefits. This is evidenced by the research of Kumar [3] or Herreros [4]. Both authors observed that TENS currents contributed to the reduction of pain caused by diabetic neuropathy in the majority of patients. However, there are few publications indicating what increases the effectiveness of rehabilitation treatments.

The study of Franciscato., *et al.* [5] in 2014 would indicate that antioxidant protection (against free radicals) increases - under the influence of physical exercise.

There is a growing body of data that lack of physical activity is an independent risk factor for the development of insulin resistance and type II diabetes [6]. Recently, a non-linear negative correlation between the incidence of diabetes and the duration of physical activity per week was demonstrated [7]. It is likely that the anti-inflammatory myokines released by contracting muscle fibers are responsible for the mechanism of the influence of physical activity; the anti-apoptotic and anti-inflammatory effects induced by exercise, the so-called heat shock proteins [6]. But already in 1994 Gryglewski., *et al.* [8] considered the protective effect of these proteins in the pathomechanisms of type I diabetes, reactive and rheumatoid arthritis, schizophrenia and a number of cancers.

Until today, however, "diabetics" have not been given the golden mean in the form of specific dietary recommendations. The American Diabetes Association believes that the optimal ratio of carbohydrates, proteins and fats appears to be varied and individually variable [9]. The Polish Diabetes Society indicates that carbohydrates should constitute approx. 50% of the diet, fats approxiametly 30%, and proteins 15 - 20% [1].

Many patients with diabetes are more and more willing to eat low-carbohydrate diets, such as the Atkins, Lutz or Kwasniewski diet (the so-called "optimal" [10]; see our papers for type 2 [11], but also type 1 diabetes [12]). There is little research on the mechanisms of their toxicity, apart from the common belief that there may be an increase in ketonemia. Many doctors indicate that the "optimal" diet has a detrimental effect on the body and does not bring therapeutic effects to people with diabetes. The limited consumption of carbohydrates in it in favor of a greater supply of fats, especially animal fats, is the main cause of many metabolic diseases and not their treatment or prevention, as Kwaśniewski, its author believes [10]. The risks and benefits of using such diets have recently been discussed [13].

On the other hand, a number of studies show that an optimal diet is not a threat to our body. Noakes [14] analyzed 127 cases of people on low-carbohydrate diets. A number of respondents claim that they have recovered mainly from type II diabetes, hypertension and hypercholesterolemia. However, patients with type I diabetes also noted some improvement. Many studies prove that diet plays a fundamental role in the prevention and prevention of diabetes [15], especially type 2, especially low-carbohydrate, because it helps to stabilize hyperglycaemia [16].

In the available literature, there are few reports on the effect of physical activity and the "optimal" high-fat (ketogenic) diet in people with type 1 diabetes on the glycemic status. However, there are no data on the effect of the type of insulin in such patients with different diets and levels of physical activity.

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It should be emphasized that not a single job in the Pubmed database deals with the "triad": type 1 diabetes - physical activity - insulin analogues.

There are a number of studies on significantly improving glycemia, especially postprandial (and reducing the frequency of hypoglycemia) with the use of fast-acting analogues [17].

However, a large meta-analysis [18] indicates that the effects of using these analogues are, on average, only insignificant compared to the effects of natural insulin. Moreover, they emphasize that there are still many uncertainties, especially as regards the impact on the broadly understood quality of life.

The review by Tibaldi [19] emphasizes that despite the use of various insulin analogues, the excessive frequency of hypoglycemia remains a serious problem - usually only in a certain group of patients. But which ones? This is what is not known.

Goals of the Work

The aim of our study was to check the effect of the type of insulin used on the health status and glycemic parameters (in self-assessment) in patients with type 1 diabetes with different physical activity and diet ie low carbohydrate high fat ketogenic [so called "optimal"]diet. In addition, we have undertaken pilot studies to demonstrate the effectiveness of selected physical treatments in relation to the diet, insulin and the level of physical activity.

Research Groups and Methods

The study involved 119 people with type I diabetes, aged 26 - 51, of which 66 (55.5%) were women and 53 (44.5%) were men. Among the surveyed, 78 people (65.5%) declared less than average physical activity they lead a passive lifestyle and do not follow the daily exercises recommended by physiotherapists. 86 subjects (72.3%) followed the diabetic diet and 33 people (27.7%) followed the low carbohydrate high fat ketogenic [so called "optimal"] diet. Moreover, 42 people (35.3%) were subject to rehabilitation processes, but only a few due to diabetic complications. The research was conducted in Warsaw and Mazowieckie Voivodeship.

Patients using the commonly accepted diabetes diet came from the SZPZLO diabetes clinic in Warsaw, as well as from the diabetic clinic of the Ostrow Provincial Hospital in Ostrów Mazowiecka. People on the optimal diet were tested among the participants of the action "My diabetes" held in Ostrów Mazowiecka in 2014, most of whom belonged to the regional Optimal Fraternities.

Of the respondents, 79 (66.4%) used insulin analogues and 40 (33.6%) human insulin.

They all completed our own questionnaire [20] (Wiśniewski 2015 in cooperation with Turski). All questions contained in it - 47 in total, were closed. The questionnaire consisted of three parts. In the first part of the questionnaire, the respondents answered questions about their well-being, treatment, and also indicated the clinical picture of their disease (in their self-assessment). The second part of the questionnaire related to physical activity (or lack of it), its forms and diet and was, similarly to the first part, addressed to all respondents included in the research. The third part was intended only for patients who declared to follow the optimal diet. The questions contained in it raised the issue of the optimal diet, as well as its impact on the current state of health.

The results were statistically analyzed using the χ^2 test and the Tschuprov test (to determine the strength of the relationship) [21,22].

Results and Discussion

We found 80 statistically significant relationships (p < 0.05), including 29 expressive ones ($T_{T_{Schuprov}} > 0.38$). As many as 29 dependencies, including 10 clear ones, were related to the type of insulin used.

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The most important results, which give statistically significant dependencies, are shown - in the form of the number and% of answers to specific questions in the questionnaire of our survey - in table 1. There are 12 of them (from 1/ to 12/).

Table 1 influence of variables (type of insulin, physical activity and type of diet) on each other and on other data (answers to survey questions).

Questions 5 and 6 include only patients using the so-called optimal diet.

Empty table windows mean no data (ie not applicable).

The data collected in table 1 allow for a number of observations:

- 1) 1/ In the group of patients using insulin analogues the % of physically active people is much higher [see 1/ and 2/].
- 2/ a/ in this group (subgroup) there is a lower % of obese people and a higher % of people not suffering from any diseases other than diabetes than in people using natural human insulin [see 3/].
- 3) b/ as many as 80% of physically inactive people suffer from obesity, which practically does not occur in physically active people; the latter usually do not suffer from any diseases other than diabetes [see 3/].
- 4) 3/ a/ patients following the optimal diet are slightly less physically active than those following a diabetic diet (just those who generally follow the guidelines of diabetologists/official dietitians [see 4/ and 5/].
- 5) b/ It is very interesting that about 90% of the patients studied followed the optimal diet for only one month, and only a few 2 3 months. This diet gives a number of benefits (compare further), but after about 4 6 weeks patients give up, perhaps from due to severe ketonaemia.
- 6) c/ Optimal diet is chosen by many obese people (55%) wanting to lose weight, what they manage to do (see below); they choose a diet probably under the influence of data from the Internet or from friends who use this diet, regardless of the type of diabetes; among people on a diabetic diet only one in five is obese; people on an optimal diet more often than others have atherosclerosis and hypertension [see 6/].
- 4/ a/ Patients using insulin analogues are capable of significantly longer single effort than patients using natural human insulin [see 7/].
- 8) b/ Conversely, patients on the optimal diet are capable of significantly, though not much, shorter physical effort than those not on this diet [see 8/].
- 9) 5/ a/ The reasons for switching to the optimal diet are similar in those who use natural insulin and synthetic analogues with in the fact that (a case) as many as 20% of people using human insulin (0% analogues) decided on the optimal diet due to being overweight [see 9/].
- 10) b/ As many as 53% of physically inactive people chose the optimal diet to get rid of excess weight [see 9/].
- 11) c/ Among patients on an optimal diet, as many as 46% of patients using insulin analogues and as many as 67% of physically inactive patients declare that they got rid of excess weight during a short (usually about a month) use of the optimal diet [see 10/].
- 12) 6/ More than half of the patients on an optimal diet, but using insulin analogues, claim that the optimal diet improved their condition, regulated glycemia, improved sleep, and even increased immunity; this is the case only in 10% of "optimal people", but using human insulin [see 10/].
- 13) c/ Half of the physically active patients do not see any benefits on an optimal diet, and the other half feel that they have a number of benefits; while in physically inactive patients, the only perceived but visible benefit (in 2/3 of these patients) is shedding excess weight.

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Question and ↓ answer		Subgroup of patients A-I	Subgroup of patients A-II	Subgroup of patients B-I	Subgroup of patients B-II
1. Are you physically active?		Using human insulin N (%)	Using insulin analogues N (%)	Physically active N (%)	Physically inactive N (%)
	Yes	22 (50)	56 (75)		
	No	22 (50)	19 (25)		
	Total	44 (100)	75 (100)		
2. How often are	Very often	4 (9)	32 (43)		
you physically	Often	18 (41)	24 (32)		
active?	Rarely	17 (39)	19 (25)		
	Almost never	5 (11)	0 (00		
	Total	44 (100)	75 (100)		
3. Do you suffer	Obesity	25 (58)	11 (15)	3 (4)	33 (80)
from other diseases except for diabetes?	Atherosclerosis	2 (5)	0 (0)	2 (2)	0 (0)
except for diabetes:	Neoplasms	0 (0)	0 (0)	0 (0)	0 (0)
	Hypertension	3 (7)	9 (12)	6 (8)	6 (15)
	Neurosis	0 (0)	0 (0)	0 (0)	0 (0)
	Gastrointestinal diseases	0 (0)	0 (0)	0 (0)	0 (0)
	I have no other diseases	14 (32)	55 (73)	67 (86)	2 (5)
	Total	44 (100)	75 (100)	78 (100)	41 9100)
4. What is the	60 min and more	3 (7)	17 (23)	20 (26)	0 (0)
duration of a single episode of physical	40-60 min	15 (34)	32 (43)	47 (60)	0 (0)
activity?	20-40 min	4 (9)	7 (9)	11 (14)	0 (0)
-	< 20 min	22 (50)	19 (25)	0 (0)	41 (100)
	Total	44 (100)	75 (100)	78 (100)	41 (100)
5. I have opted for	Feeling unwell	11 (55)	6 (46)	10 (56)	7 (47)
the optimal diet because of	So-Called brittle diabetes mellitus	0 (0)	0 (0)	0 (0)	0 (0)
	Overweight	4 (20)	4 (31)	0 (0)	8 (53)
	High cholesterol	0 (0)	0 (0)	0 (0)	0 (0)
	The diet did not suit me	5 (25)	3 (23)	8 (44)	0 (0)
	Total	20 (100)	13 (100)	18 (100)	15 (100)
6. What advantages have	Putting an end to overweight	4 (20)	6 (46)	0 (0)	10 (67)
you experienced by following the optimal diet?	Glucose level control	0 (0)	0 (0)	0 (0)	0 (0)
	I sleep better	0 (0)	0 (0)	0 (0)	0 (0)
	Improved resistance to infection	0 (0)	0 (0)	0 (0)	0 (0)
	Most of the above	2 (10)	7 (54)	9 (50)	0 (0)
	None of the above	14 (70)	0 (0)	9 (50)	5 (33)
	total	20 (100)	13 (100)	18 (100)	15 (100)

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Question and↓ answer		Subgroup of patients C-I	Subgroup of patients C-II	
		Following a diabetology diet N (%)	Following so- called optimal diet N (%)	
7. Are you	Yes	60 (70)	18 (55)	
physically active?	No	26 (30)	15 (45)	
	Total	86 (100)	33 (100)	
8. How often are	Very Often	35 (41)	1 (4)	
you physically active?	Often	25 (29)	17 (51)	
active:	Rarely	21 (24)	15 (45)	
	Almost Never	5 (6)	0 (0)	
	Total	86 (100)	33 (100)	
9. Do you have	Obesity	18 (21)	18 (55)	
other disorders except for diabetes?	Atherosclerosis	0 (0)	2 (6)	
except for unaberes.	Neoplasms	0 (0)	0 (0)	
	Hypertension	6 (7)	6 (18)	
	Neurosis	0 (0)	0 (0)	
	Gastrointestinal diseases	0 (0)	0 (0)	
	I have no other diseases	62 (72)	7 (21)	
	Total	86 (100)	33 (100)	
10. What is the duration of a single episode of physical activity?	60 min and more	20 (23)	0 (0)	
	40-60 min	39 (45)	8 (24)	
	20-40 min	1 (2)	10 (30)	
	< 20 min	26 (30)	15 (46)	
	Total	86 (100)	33 (100)	

Table 1: The effect of variables (insulin type, physical activity and diet type) on each other and on other data

(answers to the survey questions).

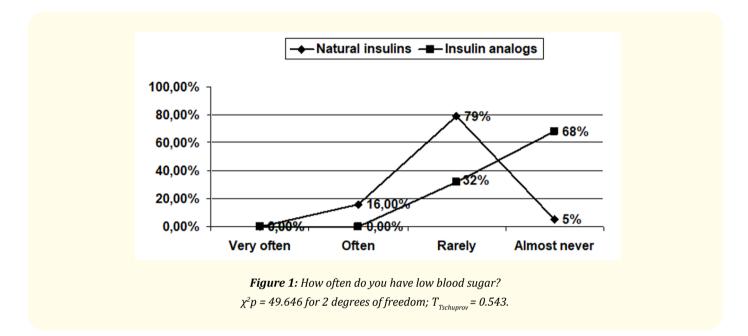
In questions 5 and 6 there are only patients following so-called optimal diet.

The empty table boxes indicate no data (i.e. not applicable).

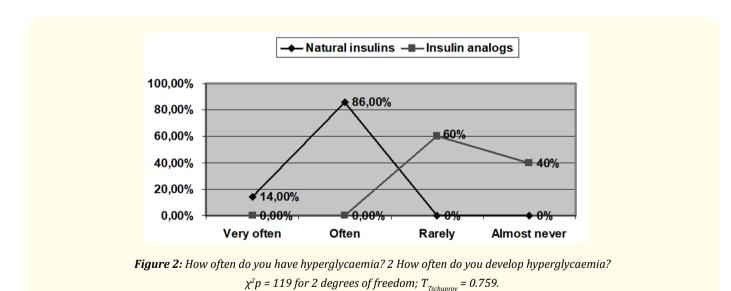
In general: our research is pilot, the group, and thus the subgroups, are too small, so the selection of the group is somewhat random. But: the use of insulin analogues is often accompanied by greater physical activity, the latter less obesity. Patients on an optimal diet are slightly less physically active, at least just before starting this diet, they are more often obese and more often suffer from other conditions besides diabetes. Thus, in further studies, more sophisticated statistical methods, e.g. factor analysis, should be used in order to more precisely determine causality. The influences of the type of insulin used, physical activity, type of diet and accompanying diseases are clearly overlapping. It seems that the observed positive effects of insulin analogs and increased physical activity per se may be overstated, and optimal diets understated. Nevertheless, there appears to be a synergistic effect of insulin analogs and increased physical activity.

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Other important relationships of the main variables of interest to us (insulin type, physical activity, diet type) and the basic parameters of diabetes status are shown in figure 1-7.



As can be seen (Figure 1), hypoglycaemia is much less frequent with the use of insulin analogues compared to the use of human insulin - regardless of the diet and physical activity used.



But it turns out (Figure 2) that hyperglycemia is also much less common in patients using insulin analogues - regardless of diet and physical activity.

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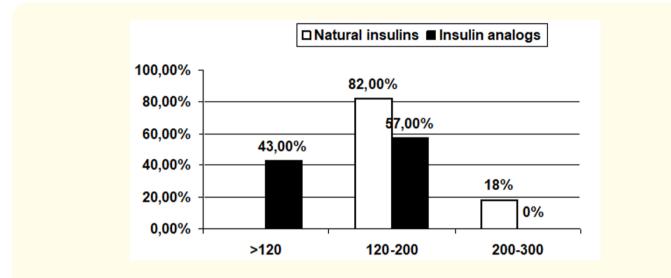
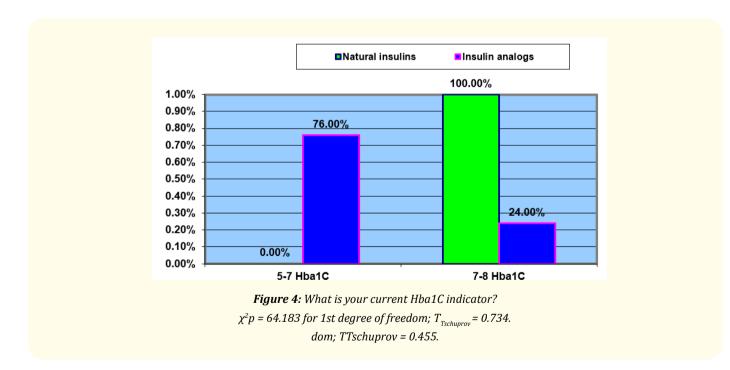
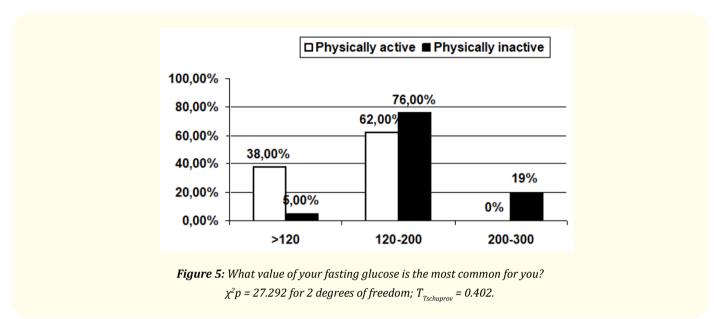


Figure 3: Your most common fasting glucose is: $\chi^2 p = 34.914$ for 2 degrees of freedom; $T_{T_{Schuprov}} = 0.455$.

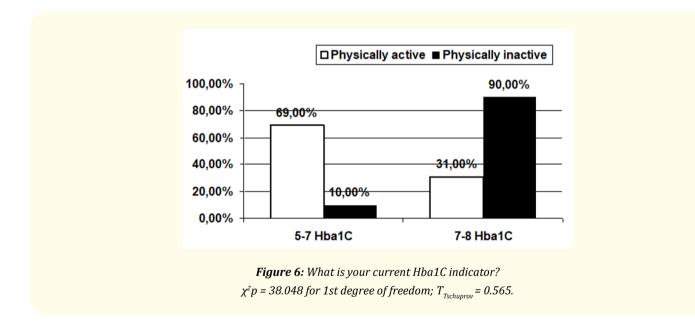
Fasting glucose (Figure 3) is on average significantly lower in the group of patients using insulin analogues compared to the group using natural insulin - regardless of diet and physical activity.



The average level of the most sensitive diabetes progression parameter, ie glycated hemoglobin (Figure 4), is significantly lower in the group of patients using insulin analogues - regardless of diet and physical activity.



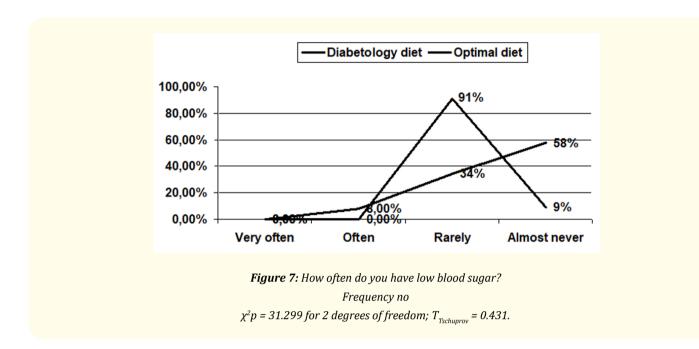
Fasting glucose (Figure 5) is on average significantly lower in the group of physically active patients compared to the group of physically inactive patients - regardless of the diet and type of insulin used.



The mean level of glycated hemoglobin (Figure 6) is significantly lower in the group of physically active patients - regardless of the diet and type of insulin used.

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As can be seen (Figure 7), hypoglycaemia is less frequent in patients on a diabetic diet compared to those on an optimal diet, regardless of the type of insulin and physical activity. Only the level of fasting glucose is somewhat lower in people on an optimal diet than in "ordinary" people. The remaining parameters of diabetes, such as the frequency of hyperglycemia, hypoglycaemia and the level of clay Hb, are slightly or noticeably worse in the "optimal" ones.

The conducted research and in-depth analyzes lead to a reflection that the optimal diet has a real chance to bring benefits in the treatment of diabetes only in combination with daily exercise and appropriately selected pharmacotherapy, i.e. with the use of insulin analogues instead of natural human insulin.

The mutual influence of therapeutic elements, which include diet, physical activity and pharmacotherapy should be the subject of further research to improve the effectiveness of diabetes treatment and its consequences.

Conclusion

- The use of insulin analogues, not just human insulin, resulted in a particularly high improvement in health, including the declared glycemic parameters (fasting glucose level, frequency of hypoglycemia and hyperglycemia, and the level of glycated hemoglobin).
- 2) This happened both in patients following the "classic diabetes" diet and in those following the "optimal" diet.
- 3) Improvement in health and glycemic parameters was brought about by increased physical activity, but especially in people using insulin analogues.
- 4) The research partially confirmed that in physically active patients, treated with insulin analogues, using a diet, the optimal therapeutic effects resulting from rehabilitation lasted longer than in other patients. In a few cases, the analgesic effect lasted up to 6 weeks longer.

Our results indicate a kind of synergism of insulin analogues and physical activity of at least medium level. The "optimal" diet brought improvement mainly in physically active people treated with insulin analogues, and not with human insulin.

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