The Pharma Innovation Journal 2018; 7(6): 247-250

www.ThePharmaJournal.com

The Pharma Innovation

ISSN (E): 2277- 7695
ISSN (P): 2349-8242
NAAS Rating: 5.03
TPI 2018; 7(6): 247-250
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www.thepharmajournal.com
Received: 19-04-2018
Accepted: 20-05-2018

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New approaches to treatment of sensitivity failure due to diabetic polyneuropathy

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Abstract
Timely diagnosis and effective treatment of diabetic polyneuropathy are important for patients with diabetes mellitus.
The aim of the study was to increase the effectiveness of treatment of tactile, vibrational, pain and temperature sensitivity by incorporating the drug Keltican and polarizing light into the complex therapy of diabetic polyneuropathy.
Research results 130 patients with type 2 diabetes mellitus, complicated by diabetic polyneuropathy were examined. Patients were divided into 4 groups: 32 patients received standard treatment in group 1, 32 patients in group 2 additionally received 1 capsule of Keltican three times a day for one month. 12 therapeutic procedures with polarizing light were additionally assigned for 35 diabetics of group 3. 31 patients in the 4th group, in addition to standard treatment, received both Keltican and a course of polarizing light therapy at the same time.
Evaluation of vibration, tactile, pain and temperature sensitivity was performed using tuning fork, monofilament, atraumatic needle and Tip-Term cylinder respectively.
In the initial state, a significant decrease was observed mainly in vibration and tactile sensitivity. The use of the proposed treatment programs has shown its positive clinical effect in the groups of patients. Patients receiving standard therapy veritably recovered only in pain sensation. Patients who were additionally assigned keltican showed an improvement in temperature, pain and tactile sensitivity. The best clinical effect of treatment (a reliable restoration of all types of sensitivity) was achieved in patients who, in addition to standard therapy, received light therapy treatment or its combination with keltican.
Conclusions the use of keltican and light therapy (polarizing light) in the complex treatment of diabetic polyneuropathy contributes to more effective restoration of sensory impairment in patients with diabetes mellitus.

Keywords: Sensitivity, diabetic polyneuropathy, keltican, polarizing light

Introduction
Diabetic polyneuropathy (DPN) is one of the most common complications of diabetes mellitus [1, 2, 3]. It is characterized by progressive death of nerve fibers and leads to impairment of vibration, tactile, pain and temperature sensitivity, in particular its distal form [4, 5]. That is why its timely diagnosis and proper treatment is of great importance in patients with diabetes.
Modern pathogenetic DPN therapy includes the prescription of alpha lipoic acid, Actovegin and B vitamins [6]. However, the clinical effect is not always achievable, which requires the search for new therapies for the treatment of diabetic polyneuropathy. To date, in the arsenal of doctors there are few drugs that would act at the level of peripheral nerves and contribute to their physiological regeneration. Therefore, the use of the drug made of the mixture of active components of a number of amino acids, such as cytidine-5'-disodium monophosphate; uridine-5'-trinatrium triphosphate, uridine-5'-disodium diphosphate, uridine-5'-disodium monophosphate with regeneratory, trophic and analgesic effects [7,8] in combination therapy of DPN can improve the efficacy of treatment of this neurological complication of diabetes. In addition, in modern conditions, more and more attention is paid to the means of non-traditional therapy, in particular, performing therapeutic manipulations using polarizing light (PL) [9, 10, 11] in the treatment of neuropathy of different etiologies [12].
The purpose of the study is to optimize the complex treatment of sensitivity disorders in patients with diabetic polyneuropathy by incorporating keltican and polarizing light.

Materials and methods
130 patients with type 2 diabetes mellitus (DM) and diabetic polyneuropathy were examined. The age of the examined persons ranged from 45 to 65 years (mean age 56.46 ± 5.79 years).

Duration of DM was from 5 to 21 years (average duration 9.82 ± 3.85 years), and DPN lasted from 1 to 13 years (average duration 5.55 ± 2.94 years). 64 (49.23%) men and 66 (50.77%) women were among the patients surveyed. All patients were divided into 4 groups depending on the received treatment program: 32 patients in the control group (group I) received standard treatment according to the unified clinical protocol of primary and secondary (specialized) medical care (№1118 dated December 21, 2012) [6]. 32 patients in the experimental group II were additionally treated with keltican (cytidine-5'-disodium monophosphate 5.0 mg, trihydrate uridine-5'-trinatrium triphosphate, uridine-5'-disodium diphosphate, uridine-5'-disodium monophosphate) in a dose equivalent to 1.330 mg of uridine - 1 capsule three times a day for one month [7,8]. 35 patients of the group III were additionally assigned 12 treatment procedures with polarizing light. 31 patients with diabetes mellitus (group IV), besides standard treatment, received keltican and polarized light at the same time. Groups were comparable according to age, duration of diabetes, and severity of clinical manifestations of DPN (Table 1).

Table 1: General characteristics of patients with type 2 diabetes mellitus (M ± σ)

Characteristic	Group I n=32	Group II n=32	Group III n=35	Group IVn=31	F	P
Age, years	58.66±5.20	55.53±6.5	55.60±4.86	56.13±5.96	2.15	$p>0.05$
Duration of DM, years	8.56± 3.25	10.13±3.4	10.09±4.01	10.58±3.97	1.72	$p>0.05$
Duration of DPN, years	4.91± 2.82	5.19± 2.91	6.00 ±3.08	6.07± 2.89	1.27	$p>0.05$

The evaluation of the neurological status was performed by determining the surface (tactile, pain, temperature) and deep (vibration) sensitivity.

Tactile sensitivity was determined with the help of caliber 5.07 monofilament (which bends under the influence of force of 10 g), on symmetrical parts of the foot (the back surface, the planar surface of the pleural phalangeal joints, apical surfaces of the fingers and heel). Impairment of tactile sensitivity was recorded when the patient did not feel touches of monofilament at least at one point of the foot (free from hyperkeratosis and calluses) [14].

Pain sensitivity was determined using a dull (atraumatic) needle, which was applied to perform light punctures.

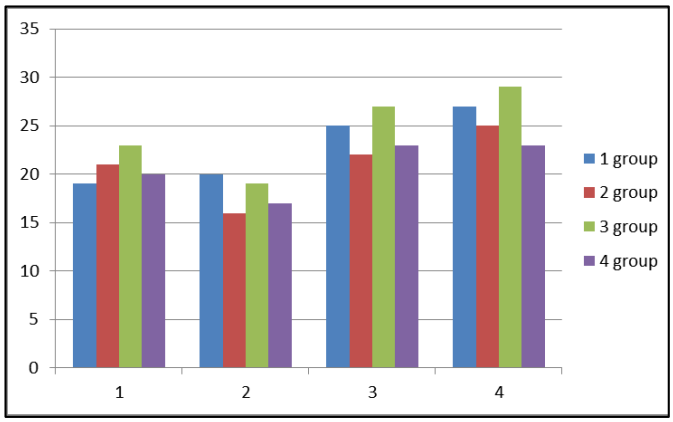
Temperature sensitivity disturbances were measured by the alternating touch to the symmetrical foot sections using the Tip-Term cylinder, the ends of which have different temperatures. Temperature sensitivity was considered lost when the patient was unable to distinguish these stimuli.

To estimate the vibrational sensitivity, the 128 Hz tuning fork was used. For this purpose its leg was placed on symmetrical areas of the skin in the projection of bone protuberances and the time of the vibration sensation was measured. The tuning fork vibration perception reduction (which normally lasts for 15-20 seconds) and the difference in perception at the symmetric points were considered to be objective signs of the vibrational sensitivity impairment [13].

The analysis and processing of statistical data of clinical examinations were carried out on a personal computer using the package of applications STATISTICA 10 and MS Excel XP. Comparison of relative values and values expressed in percentages in the group was done using the c^2 Pearson criterion. The comparison between the groups was done by comparing the average rank values. The difference in the rates was considered credible at $p<0.05$.

Results: Objective examination showed a decrease in vibration sensitivity in 104 (80%) patients, temperature sensitivity in 83 (63.8%), tactile sensitivity in 97 (74.6%), and pain sensitivity in 72 (55.4%) patients.

Prior to treatment, decrease in temperature sensitivity occurred in 19 (59.38%) patients in the 1st group, 21 (65.6%) in the 2nd group, 23 (65.7%) in the 3rd group, 20 (64.5%) in the 4th group; pain sensitivity in 20 (62.5%) patients, 16 (50%) surveyed, 19 (54.3%) 3rd and 17 (54.8%) patients in the corresponding groups. Tactile and vibrational sensitivity was decreased in 25 (78.1%) and 27 (84.4%) patients in the 1st group and 22 (68.5%) and 25 (78.1%) patients in the 2nd group, 27 (77.1%) and 29 (82.9%) of the 3rd group and 3 (74.2%) of the examined group 4. There was no significant difference between the groups before treatment ($p>0.05$) (Fig.1).

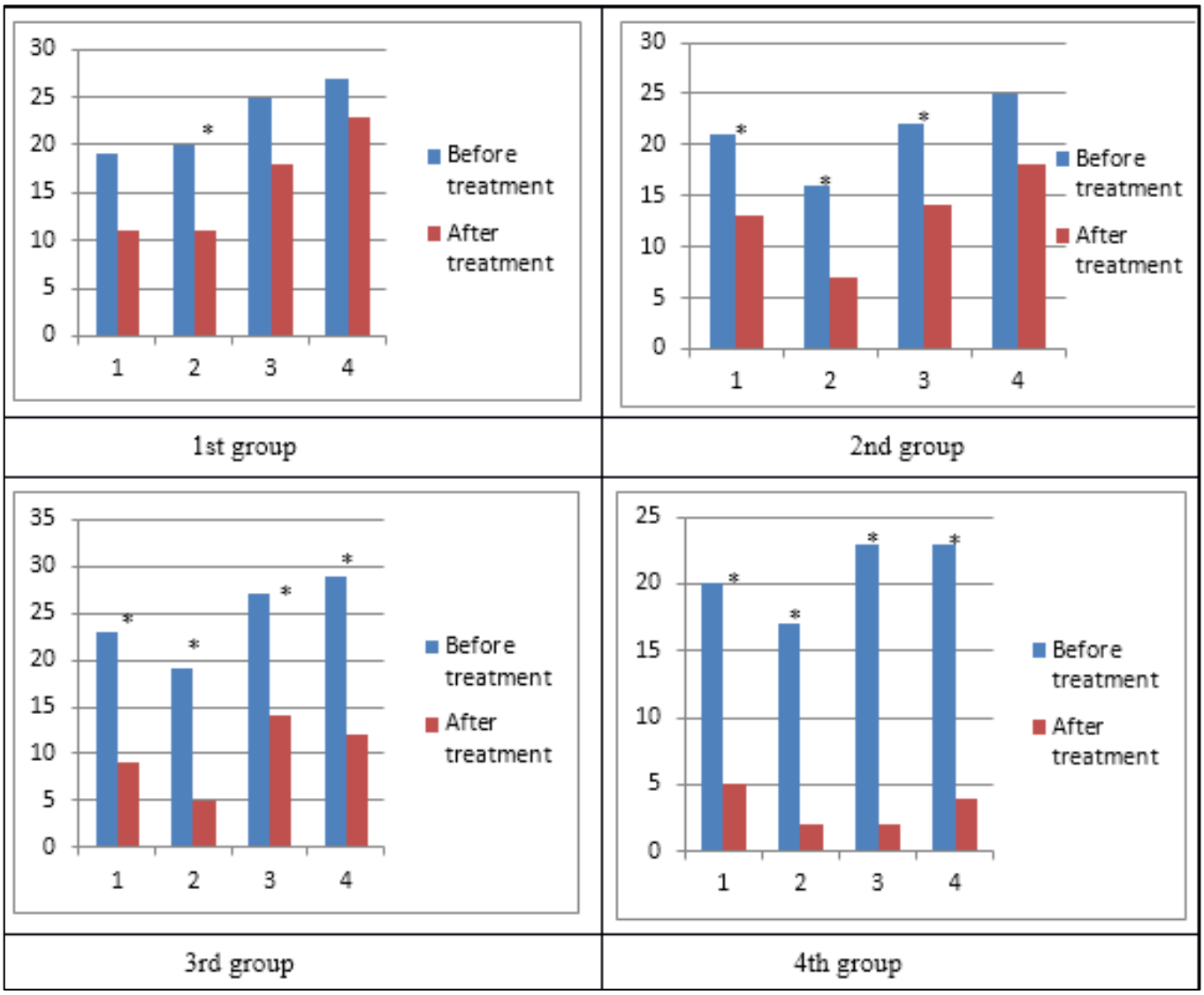


Notes: 1-temperature sensitivity; 2- pain sensitivity; 3- tactile sensitivity; 4. vibration sensitivity. * - the difference of indexes between the groups before treatment is credible ($p<0.05$).

Fig 1: Results of patients sensitivity examination in the studied groups before treatment.

In 12 days after treatment, the temperature sensitivity was restored in 45 (34.6%) patients, pain and tactile sensitivity in 47 (36.1%) and 39 (30%) patients respectively, and vibration sensitivity in 33 (25.4%) patients with diabetes.

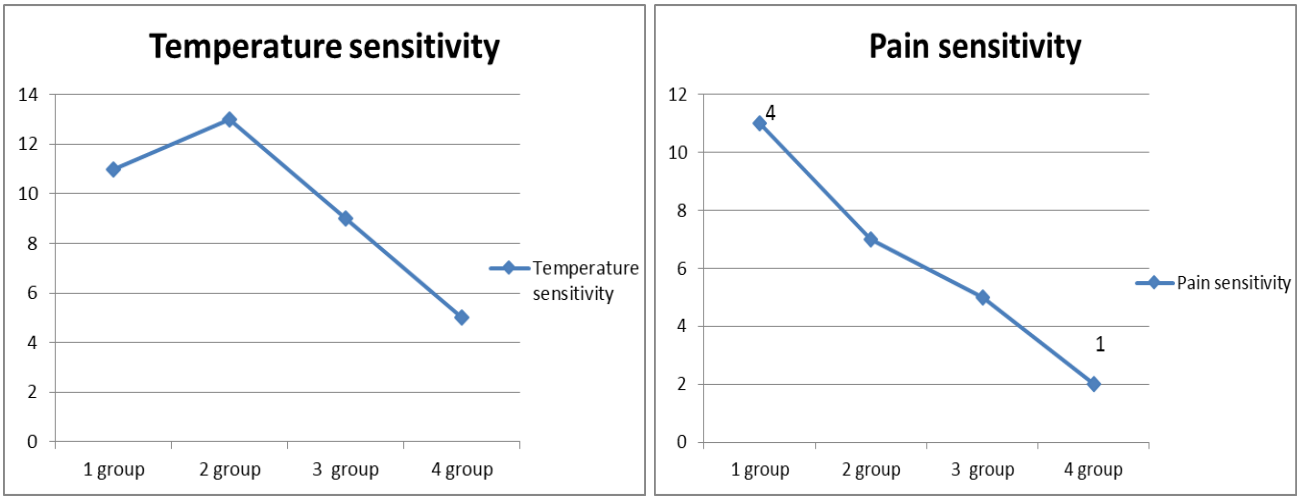
Comparison of the sensitivity index after the treatment showed a decrease in the temperature sensitivity in 11 (34.40%) $\chi^2 = 3.07$ $p>0.05$ patients in the 1st group, 13 (40.60%), $\chi^2 = 4.02$ $p<0.05$, in the 2nd group, 9 (25.70%) $\chi^2 = 11.28$ $p<0.01$ in the 3rd group 20 (64.50%) $\chi^2 = 15.00$ $p<0.05$ in the 4th group. Pain sensitivity in 11 (34.40%) $\chi^2 = 5.07$ $p<0.05$ patients of the 1st group, 7 (21.90%) $\chi^2 = 5.50$ $p<0.05$ those examined in group 2, 5 (14.30%) $\chi^2 = 12.43$ $p<0.01$ of the 3rd group, and 2 (6.50%) $\chi^2 = 17.07$ $p<0.05$ of the 4th group. Tactile and vibrational sensitivity was decreased in 18 (56.25%) $\chi^2 = 3.47$ $p>0.05$ and 23 (71.80%) $\chi^2 = 1.46$ $p>0.05$ patients in the 1st group and 14 (43.75%) $\chi^2 = 4.06$ $p<0.05$ and 18 (56.25%) $\chi^2 = 3.47$ $p>0.05$ patients in the 2nd group, 14 (40.00%) $\chi^2 = 9.95$ $p<0.01$ and 12 (34.30%) $\chi^2 = 17.01$ $p>0.01$ in the 3rd group, and 2 (6.50%) $\chi^2 = 29.56$ $p<0.05$ and 4 (12.9%) $\chi^2 = 23.68$ $p<0.05$ of those examined in the 4th group respectively (Fig. 2).

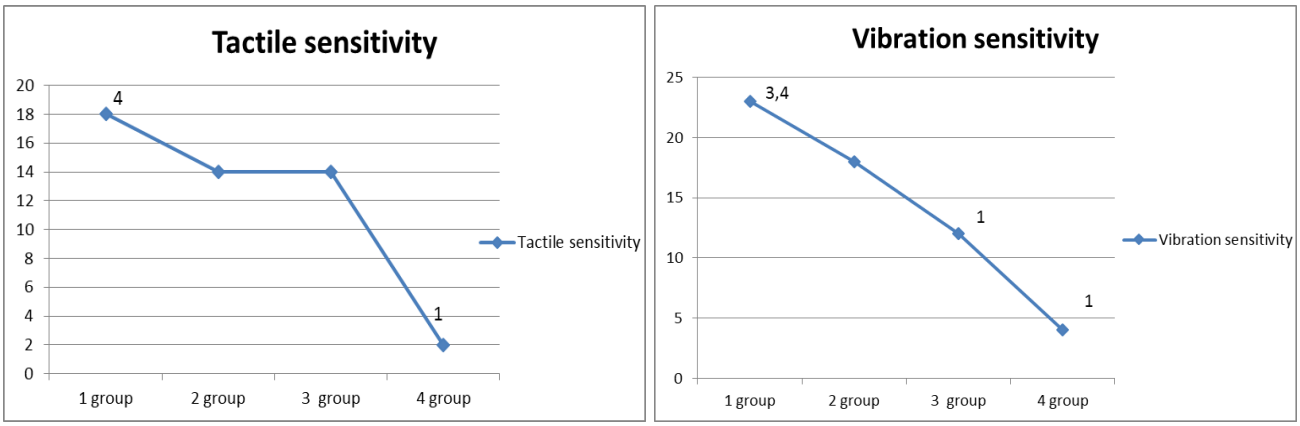


Notes: 1-temperature sensitivity; 2- pain sensitivity; 3- tactile sensitivity; 4. vibration sensitivity. * - the difference of indexes between the groups before treatment is credible (p<0.05).

Fig 2: Dynamics of sensitivity restoration in the examined groups of patients under the influence of applied treatment programs

The results of comparing the sensitivity values between groups after treatment are shown in Figure 3.





Notes: * - the difference between the 2nd and 4th groups in treatment is credible (p<0.05); ** - the difference between 1st and 2nd groups after treatment is credible (p<0.05); *** - the difference between 1st and 3rd groups after treatment is credible (p<0.05); **** - the difference between 1st and 4th groups after treatment is credible (p<0.05).

Fig 3: Frequency of sensitivity restoration in patients of experimental groups.

The research resulted in finding out a substantial decrease in the vibration and tactile sensitivity of all patients examined in the initial state, which corresponds to the literary data, [15, 16, 17].

The use of the proposed treatment programs indicated their positive clinical effect (sensitivity improvement) in all groups of patients. However, it was noted that patients in the 1st group who received standard therapy apparently recovered only pain sensitivity. Patients in the 2nd group, who were additionally treated with keltican, showed an improvement in temperature, pain and tactile sensitivity. The best clinical effect of treatment (a reliable restoration of all types of sensitivity) was achieved in patients in groups 3 and 4 who, in addition to standard therapy, received light therapy or its combination with keltican.

In addition, we note that the best results in tactile sensitivity restoration were achieved in patients who received a combination of standard treatment with keltican. Vibrational sensitivity was reliably restored in patients of all experimental groups, compared with the control group, but the most pronounced and rapid clinical effect was achieved in patients in the 4th experimental group receiving combined treatment using keltican and polarizing light.

Conclusion: The use of keltican and light therapy (polarizing light) in the complex treatment of diabetic polyneuropathy contributes to more effective restoration of sensory impairment in patients with diabetes mellitus, thus giving us all the reasons to recommend this complex at various stages of treatment and rehabilitation of patients.

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