



Effect of combined pharmacotherapy on the quality of life in patients with low back pain

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Abstract. Low back pain is a frequent symptom with which patients turn to doctors of various specialities. This is conditioned by its debilitating course and, not infrequently, to the lack of substantial improvement due to the conducted treatment, resulting in the significant reduction in the quality of life. The purpose of the study was to assess the effect of a medicinal food product and a nonsteroidal anti-inflammatory drug on the quality of life in patients with low back pain. The quality of life was assessed both in the control group (15) and in patients with low back pain (69) at the beginning of the therapy and on day 29, that is, after 28 days of treatment with theramine and tenoxicam and their combination, using the Medical Outcomes Study Short-Form 36 assessment questionnaire. Significant negative changes in indicators of both physical and mental components of health were revealed. It was established that in terms of impact on the quality of life in patients with low back pain, monotherapy with theramine and tenoxicam is inferior to their combined use. The highest physical activity level has been found to follow taking combined medication and the lowest one – after tenoxicam intake, the similar changes having been found with the indicator of physical role functioning. Pain intensity was best affected by combined therapy, the effect of theramin and tenoxicam being similar. It is also shown that theramine prevailed over tenoxicam in terms of its effect on indicators of physical and mental components of health. The results of the research on theramine and its combined use with tenoxicam should be included in the treatment programme for patients with low back pain in order to improve the quality of life

Keywords: vital activity; treatment; theramine; tenoxicam; drug combinations

Introduction

Low back pain (LBP) is among the most common challenges physicians encounter in the clinical practice. According to the expert data, the spread of LBP in industrialised countries has become pandemic [1, 2]. As noted by V.E. Casiano *et al.* [3], LBP is ranking first among all diseases in terms of the years of working life lost, with up to 80% of the global population suffering from it at least once in life. However, pain syndrome is not always eliminated. Diagnosis and management of back pain is a challenging task for

both general practitioners and specialists, which is related to the etiological heterogeneity of the disease. It is difficult enough and often problematic to establish etiology, not to mention the fact that treatment is fraught with serious and potentially life-threatening side effects [4]. In order to eliminate the pain syndrome, dextetapofen and intranasal ketorolac [5], and applications with ketapofen [6] are used. In patients with exacerbation of dorsalgia, it was established that tenoxicam, in comparison with meloxicam and

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diclofenac sodium, reliably improved the quality of life and indicators of vital activity [7]. According to the recommendations of A. Qaseem *et al.* [8] selective nonsteroidal anti-inflammatory drugs (NSAIDs) should be prescribed for functional improvement in patients with chronic LBP: for reduction or elimination of low back pain, improvement in health-related quality of life, reduction in work disability, return to work, global improvement, number of back pain episodes or time between episodes, patient satisfaction, and adverse effects. Evidence supports that short-term use of NSAIDs has no effect on patients' quality of life. Given the conflicting data on the effectiveness of NSAIDs in patients with urgent pain and the potential risk of side effects (toxicity of the gastrointestinal tract, liver, and cardiovascular system), they are not recommended for the treatment of acute LBP [9]. However, W.E. Shell *et al.* [10] argue that the use of theramine together with ibuprofen has a positive effect on vital activities according to the Roland-Morris scale and the Oswestry disability index. The use of tizanidine and methocarbamol in therapy can reduce the stiffness of the lumbosacral muscles of the back and reduce the intensity of pain syndrome in patients with LBP, especially acute [11, 12]. Quite often, patients with LBP are dissatisfied with treatment, which generally affects the recovery of their work capacity. It accounts for significant economic costs related to health care and disability, and exceeds the costs associated with cardiovascular disease, cancer, and diabetes.

Since young people of working age mostly suffer from this disease, chronic pain is among major medical and socioeconomic problems. It is characterised by debilitating course and, not infrequently, by the lack of substantial improvement due to the conducted treatment, resulting in the significant reduction in the quality of life. Therefore, optimisation of treatment and life quality improvement in patients with LBP of various genesis is a pressing issue that requires comprehensive investigation. The purpose of the study was to assess life quality dynamics of indicators in the patients with low back pain of vertebral genesis under the influence of both separate and combined use of theramine, a therapeutic nutrition, and tenoxicam, a nonsteroidal anti-inflammatory drug.

Materials and Methods

69 patients with LBP of vertebral genesis (39 women and 30 men), as well as 15 healthy individuals (no LBP), were examined and treated in the rehabilitation department for patients with a neurological profile of the Ternopil City Hospital No. 3 in 2018-2022. The criterion for inclusion in the study was the presence of chronic lumbosacralgia due to spondyloarthrosis, spondylosis, spinal disc herniation. Patients with tumours, injuries, anomalies of the spine, inflammatory and infectious diseases (of the spine) were not included. In the study, monotherapy with theramine (2 capsules, twice daily, 1 hour before meals) and tenoxicam (20 mg, 1/day) was compared with combined application of theramine (2 capsules, twice daily, 1 hour before meals) + tenoxicam (20 mg, once a day) for 28 days. On the

first day, the patients were randomised into three groups: Group 1 (24 patients) received theramine at the specified dose; Group 2 (23 patients) were given tenoxicam at the specified dose; Group 3 (22 patients) took theramine + tenoxicam. Theramine was chosen for the study because it effectively reduces and modifies pain without noticeable side effects, and also stimulates the production of neurotransmitters such as serotonin, γ -aminobutyric acid (GABA), nitric oxide, glutamate, and histamine. The choice of tenoxicam is conditioned by the presence of analgesic, anti-inflammatory, and chondroprotective effects.

The quality of life was assessed both in control group and in LBP patients at the beginning of the therapy and on day 29, that is, after 28 days of treatment, using the SF-36 (Medical Outcomes Study Short-Form 36) [13] assessment questionnaire. It comprises 36 questions, grouped in 8 scales: 1) physical activity; 2) physical role functioning; 3) pain intensity; 4) general state of health; 5) vital activity; 6) social activity; 7) emotional role functioning; 8) mental health.

Maximum value for all scales, with no restrictions and health problems, was equal to 100. The higher the indicator value, the better the score on the scale chosen. 8 scales were grouped into 2 indicators: physical and mental health components. Physical health component included: physical activity; physical role functioning; pain intensity; general health, whereas mental health component included: vital activity; social activity; emotional role functioning; mental health.

Statistical indicators processing was performed on a PC using STATISTICA 10 and MS Excel XP applied software suite by the method of variation statistics. Nonparametric methods (Mann-Whitney U-test for independent samples and Wilcoxon t-test for dependent sampling) were used, difference of indicators being regarded as significant at $p < 0.05$. All procedures performed in studies involving human subjects complied with the ethical standards [14-16]. Written informed consent for the study was obtained from all patients.

Results

Patients with a mean age of (56.2 ± 2.5) years and disease duration of (11.2 ± 2.1) years have been examined. This study has found that low back pain affects the life quality of afflicted patients (Table 1). In particular, they reveal impaired physical activity that restricts ability to do exercises. This is confirmed by 54.6% reduction of this indicator, as compared with controls that is indicative of a certain loss of ability to self-service, to carry loads, to walk, and to climb stairs. Physical role functioning in LBP patients has been found to decline by 44.4% as compared to control group that is indicative of reduced daily activity of the patients owing to their physical condition. This is consistent with pain intensity indicator, which declined significantly in LBP patients in comparison with the control group from (98.67 ± 0.42) to (39.36 ± 1.09) points, ($p < 0.05$), i.e., by 60.1%. In other words, there is an increase of pain syndrome, which restricts patients' activity considerably.

Besides, changes in the life quality have been found to contribute to general state of health. for example, in LBP

patients this indicator decreased by 2.68 times ($p < 0.05$), as compared to control.

Table 1. Indicators of life quality in LBP patients who received theramine and tenoxicam ($M \pm m$)

	Control n = 15	Before treatment n = 69	Group 1 n = 24	Group 2 n = 23	Group 3 n = 22
Physical activity	91.33 ± 1.15	40.58 ± 0.66*	76.83 ± 2.06 [^]	71.30 ± 0.76 [^]	82.91 ± 1.61 ^{^#}
Physical role functioning	90.73 ± 0.93	50.15 ± 1.15*	69.25 ± 2.00 [^]	60.87 ± 1.24 [^]	80.04 ± 1.80 ^{^#}
Pain intensity	98.67 ± 0.42	39.36 ± 1.09*	67.25 ± 1.76 [^]	64.26 ± 1.49 [^]	81.26 ± 1.71 ^{^#}
General health	95.20 ± 0.93	35.54 ± 1.43*	64.95 ± 2.58 [^]	47.09 ± 1.38 [^]	74.88 ± 1.94 ^{^#}
Vital activity	96.33 ± 0.74	44.58 ± 1.33*	70.62 ± 2.33 [^]	56.26 ± 1.84 [^]	77.88 ± 2.07 ^{^#}
Social activity	96.87 ± 0.52	52.42 ± 1.70*	73.76 ± 1.68 [^]	65.35 ± 1.70 [^]	79.21 ± 1.21 ^{^#}
Emotional role functioning	96.20 ± 0.68	37.73 ± 1.62*	64.83 ± 2.29 [^]	49.09 ± 1.69 [^]	76.00 ± 2.24 ^{^#}
Mental health	95.60 ± 0.65	41.46 ± 1.35*	70.96 ± 2.25 [^]	54.43 ± 1.53 [^]	78.59 ± 1.56 ^{^#}

Notes: $p < 0.05$ * – compared with control; # – compared with groups 1 and 2; ^ – compared with pre-treatment period

Source: compiled by the authors

Thus, changes in life quality indicators have been found to affect physical health component (Table 2), the latter being

assessed for LBP patients in (41.37 ± 1.07) points, in contrast to the control group (93.98 ± 0.86), that is 56.0% less ($p < 0.05$).

Table 2. Physical and psychological components in LBP patients who received theramine and tenoxicam ($M \pm m$)

Life quality components	Control n = 15	Before treatment n = 69	Group 1 n = 24	Group 2 n = 23	Group 3 n = 22
Physical health component	93.98 ± 0.86	41.37 ± 1.07*	69.57 ± 2.10 [^]	60.88 ± 1.22 [^]	79.77 ± 1.76 ^{^#}
Mental health component	96.25 ± 0.65	44.05 ± 1.50*	70.04 ± 2.14 [^]	56.28 ± 1.69 [^]	77.92 ± 1.77 ^{^#}

Notes: $p < 0.05$ * – compared with control; # – compared with groups 1 and 2; ^ – compared with pre-treatment period

Source: compiled by the authors

Prior to treatment, LBP patients revealed significant reduction in the indicator of vital activity. Specifically, vital activity level before treatment decreased by 2.16 times ($p < 0.05$), as compared with control, that indicates lost ability to recover energy and vigour, at least to some extent. Along with this, the indicator of social activity also declined by 1.85 times, which is indicative of both physical and emotional deterioration due to social activity and communication.

Before treatment, emotional role functioning in LBP patients was found to reduce significantly, as compared to the control group (37.73 ± 1.62) against (96.20 ± 0.68) points, that is by 60.8%, ($p < 0.05$). This indicates some restriction in doing day-to-day work because of deteriorated emotional state in LBP patients. These changes have been found to adversely affect the mental health state of LBP patients that is confirmed by lower number of points in comparison with the control group (41.46 ± 1.35) against (95.60 ± 0.65), that is by 56.6%, ($p < 0.05$). Clinically, it is manifested in sleep disturbance, worsened mood, and increased anxiety. This, in its turn, affected the indicator of mental health component (Table 2), which decreased by 54.5% ($p < 0.05$), as compared to the controls that is indicative of these patients experiencing depression, anxiety, and mental distress prior to treatment.

Post-treatment life quality evaluation in LBP patients has shown its marked improvement. Specifically, the patients who received theramine, tenoxicam, and combined

drug, revealed improved physical activity indicators by 1.89, 1.76, and 2.04 times, respectively. Moreover, combined application of drugs has been found to provide their enhanced efficacy, as indicated by the increase in the physical activity by 7.9% in comparison with theramine application alone, and by 16.3% – with that of tenoxicam ($p < 0.05$). That indicates enhanced physical activity due to health improvement.

Significant increase in the physical activity indicator was found in the LBP patients who had been taking theramine/tenoxicam combination – from (50.15 ± 1.15) to (80.04 ± 1.80) points, i.e. by 59.6% more, whereas the increase for the use of theramine alone was by 38.1% and that for tenoxicam – by 21.4%. Efficacy of the treatment is also confirmed by the improved indicator of pain intensity. It was found to increase reliably in the patients who had been taking theramine and tenoxicam alone and their combination by 1.71, 1.63, and 2.06 times, respectively. As shown in Table 1, combined use was more effective and contributed to the activation of everyday activity (including housework and work outside the home) due to decreased intensity of pain syndrome.

The general state of health has also been found to improve, especially following combined application of theramine and tenoxicam. The improvement was estimated at (74.88 ± 1.94) points against (47.09 ± 1.38) points for the patients who received tenoxicam and (64.95 ± 2.58) for

those who were treated with theramine, that is 59.0 and 15.3% more than their separate use and is promising in view of health improvement. Positive developments in life quality indicators after treatment provided 68.2%, 47.2% and 92.8% ($p < 0.05$) increase in the general indicator of physical health component of the patients who had received theramine, tenoxicam, and their combination, respectively.

In the course of treatment, the indicator of vital activity in LBP patients, who had received tenoxicam, was found to rise by 26.2%; in the patients, who had been given theramine – by 58.4%; in those, who had received tenoxicam/theramine combination – by 74.7%. This is indicative of recovered vital activity, vigour, and energy. In the post-treatment period, LBP patients reveal enhanced social activity that is confirmed by broadening of social contacts, ability to communicate due to improved physical and emotional status. This primarily refers to the patients who received combined pharmacotherapy, as indicated by 51.1% increase ($p < 0.05$) of the level of social activity. In addition, positive developments were noted on the part of emotional role functioning (ERF). In comparison with pre-treatment period, application of theramine, tenoxicam, and tenoxicam/theramine combination resulted in 1.72, 1.30, and 2.01-fold increase of ERF indicator, respectively. This is indicative of improved emotional status which contributes to better work performance and daily activity, regarding both amount of work and quality.

Efficacy of mono- and, particularly, combined pharmacotherapy is confirmed by increased indicator of mental health, the latter being by 71.2%, 31.3%, and 89.6% higher in LBP patients who received theramine, tenoxicam, and tenoxicam/theramine combination, respectively. This, in turn, contributed to the improvement of mood and emotional state, as well as to the reduction of patients' anxiety. The general indicator of mental health component also improved reliably. Specifically, it was 1.28, 1.59, and 1.77 times the value of the patients before treatment after taking tenoxicam, theramine, and theramine/tenoxicam combination, respectively. This results in mood enhancement, increase in positive emotions along with reduced manifestations of depression and anxiety.

Assessment of SF-36 questionnaire research findings in LBP patients revealed significant changes in their life quality, to which points reduced indicators of physical activity, pain intensity, and, somewhat less – of physical role functioning. This leads to significant worsening of their general state of health and eventually to adverse effect on the indicator of physical health component. Along with this, reduced vital and social activity, as well as marked decrease in emotional role functioning and mental health were noted that cause changes in the indicator of mental health component.

Efficacy study of using theramine, tenoxicam, and theramine/tenoxicam combination for the treatment of LBP patients has shown monotherapy to be somewhat inferior to combined therapy in terms of the influence on the life quality. Physical activity level has been found to reach

the highest value after taking drug combination, whereas the lowest – after tenoxicam. Similar changes have been found about physical role functioning. Pain intensity indicator was best affected by drug combination, whereas the effect of theramine and tenoxicam was much alike. At the same time, general state of health was revealed to have improved significantly in the patients who received combined treatment, while theramine monotherapy was more effective than that with tenoxicam. Indicators of vital activity and mental health grew the most after combined treatment, theramine being more effective than tenoxicam. As to the influence on the indicators of social activity and emotional role functioning, the best effect was provided by theramine/tenoxicam combination. In its turn, theramine was superior to tenoxicam, in particular regarding the indicator of emotional role functioning. Treatment with drug combination improved mental health component considerably.

Discussion

LBP is still a pressing issue as it affects most people throughout their lives. Among the drugs that are most often used in the treatment of such pain are NSAIDs. However, their use is limited by side effects, especially from the gastrointestinal tract, which indicates the feasibility of finding new approaches to the treatment of LBP. Anti-inflammatory drugs with precursors that produce NO and help reduce the development of erosions of the gastric mucosa are promising. They are also capable of inhibiting T-cell proliferation and cytokine production. Theramine is known to produce NO similarly to NO-NSAIDs [17]. Theramine, as a source of neurotransmitter precursors, is designed to induce neurotransmitter production of neurotransmitters that modulate nociception and inflammation [18]. The precursors of serotonin, NO, histamine, and GABA are supplied in this dosage form as 5-hydroxytryptophan, arginine, histidine, and glutamine, respectively. Therefore, in the study, theramine with tenoxicam was used in the treatment of BNS with a corresponding assessment of the quality of life of such patients and prevention of the development of side effects from the gastrointestinal tract. The use of theramine and tenoxicam in patients with LBP both in isolation and in combination had a positive effect on the quality of life. However, monotherapy was somewhat inferior to their combined administration, theramine was more effective compared to tenoxicam. These results are consistent with the data of W.E. Shell *et al.* [10], who found that theramine in combination with ibuprofen was superior to their isolated administration in reducing the Roland-Morris Scale and Oswestry Disability Index, and that theramine was more effective than ibuprofen in the effect on chronic pain.

The obtained results to a certain extent coincide with the data of V. Romanenko [11], who established that the combined use of etoricoxib and methocarbamol is effective in acute LBP with pronounced muscle-tonic syndrome. It has also been proven that the combined pharmacotherapy of NSAIDs plus GABA-mimetic antiepileptic drugs

(pregabalin or gabapentin) was more effective than individual NSAIDs in the treatment of nonspecific LBP. This combination pharmacotherapy can be used to simultaneously reduce prostaglandin-mediated pain and neuropathic pain [8]. A. Bhatia *et al.* [19] point to the feasibility of using the tramadol-acetaminophen combination in chronic LBP, since acetaminophen did not affect the quality of life. The authors of this study established that theramine prevailed over tenoxicam in terms of impact on the quality of life of patients with LBP. This is consistent with data from other researchers indicating that NSAIDs had no or little effect based on Roland Morris Disability Questionnaire or Oswestry Disability Index scores [8]. This is explained by the fact that theramine restores and maintains the balance of neurotransmitters in the cells of the nervous system: GABA, nitric oxide, serotonin, acetylcholine, the disturbances of which are associated with pain syndrome and inflammatory conditions. It is known that depletion of neurotransmitters [20-22] and related synapse fatigue can lead to chronic pain states. Depletion of neurotransmitters is caused by an increase in the rate of metabolism of precursors and insufficient intake of precursors from the diet [23]. Theramine solves the problem of such inaccessibility. The results of clinical trials indicate that theramine effectively reduces the severity and modifies pain without noticeable side effects [10]. These results are indirectly confirmed by studies that indicate that duloxetine is an effective drug for reducing the intensity of pain in chronic LBP due to the enhancement of serotonergic and noradrenergic neurotransmission in the central nervous system [24]. The influence of tenoxicam on the quality of life, is related to its analgesic, anti-inflammatory and chondroprotective effect. An important advantage of tenoxicam is its ability to influence not only cyclooxygenase (COX-2), but also matrix prostaglandin (PG) E2 synthetase, which is responsible for the synthesis of the most important mediator of inflammation – PGE2. The effect of tenoxicam on the quality of life that found is consistent with the results of S.B. McMahan *et al.* [25] who found that COX2 NSAIDs are effective in functional improvement. The presence in tenoxicam of the ability to act as an active oxygen acceptor in the area of inflammation and inhibit metalloproteinases (stromelysin and collagenase), which cause the destruction of cartilage [20], affects the quality of life of patients with LBP, since degenerative changes in the spine most often lead to the development of pain syndrome. Evaluating the quality of life of

patients with LBP after treatment, it can be stated that the combined use of theramine and tenoxicam is more effective than their isolated use. Moreover, theramine monotherapy turned out to be better compared to tenoxicam.

Conclusions

According to the results of the assessment of the quality of life in patients with pain in the lower part of the back of vertebral origin, significant changes have been established, which is evidenced by a decrease in indicators of both physical and mental components of health. Significant increase in the physical activity indicator was found in the LBP patients who had been taking theramine/tenoxicam combination, i.e., by 59.6% more, whereas the increase for the use of theramine alone was by 38.1% and that for tenoxicam – by 21.4%. Efficacy of the treatment confirmed by the improved indicator of pain intensity which is significantly larger than for those who had been taking theramine and tenoxicam alone and their combination by 1.71, 1.63, and 2.06 times, respectively. The combined use of theramine and tenoxicam has been shown to be more effective than either alone in terms of impact on the quality of life of patients with low back pain, and monotherapy with theramine is superior to tenoxicam. This is confirmed by an increase in indicators of the mental component of health by 1.59, 1.28, and 1.77 times, the physical component – by 68.2%, 47.2% and 92.8%, for those who received theramine, tenoxicam and their combination, respectively.

The assessment of the dynamics of quality of life based on its subjective perception by patients with low back pain of vertebral origin using the SF-36 questionnaire is a sufficiently sensitive criterion for the effectiveness of the used treatment programmes. This indicates the expediency of including in the treatment of patients with low back pain the therapeutic food product theramine and the combination theramine/tenoxicam, which can be used in their clinical practice by doctors of various specialities. In further studies, it is planned to investigate the effectiveness of theramine and its combined use with tenoxicam in patients with osteoarthritis of the hip and knee joints.

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None.

Conflict of Interest

The authors declare no conflict of interest.

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Вплив комбінованої фармакотерапії на якість життя пацієнтів з болем у попереку

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Анотація. Біль у попереку є частим симптомом, з яким пацієнти звертаються до лікарів різних спеціальностей. Це пов'язано з його важким перебігом і, не рідко, з відсутністю істотного поліпшення після проведеного лікування, що призводить до значного зниження якості життя. Метою дослідження було оцінити вплив медикаментозного харчового продукту та нестероїдного протизапального препарату на якість життя у пацієнтів з болями у попереку. Якість життя оцінювалася як у контрольній групі (15 осіб), так і у пацієнтів з болями у попереку (69 осіб) на початку терапії та на 29-й день, тобто після 28 днів лікування тераміном і теноксикамом, а також їх комбінацією, за допомогою анкети Medical Outcomes Study Short-Form 36. Виявлено значущі негативні зміни показників як фізичних, так і психічних компонентів здоров'я. Встановлено, що з точки зору впливу на якість життя пацієнтів із болями у попереку монотерапія тераміном та теноксикамом виявляється гіршою за їх комбіноване використання. Найвищий рівень фізичної активності спостерігається після застосування комбінованого препарату, а найнижчий – після вживання теноксикаму, аналогічні зміни виявлені за показником функціонування за рольовою фізичною активністю. На інтенсивність болю мала найбільший вплив комбінована терапія, ефект тераміну та теноксикаму був подібним. Також показано, що терамін переважав над теноксикамом за впливом на показники фізичної та психічної складових здоров'я. Результати досліджень тераміну та його комбінованого застосування з теноксикамом повинні бути включені в програму лікування пацієнтів з болем у попереку з метою поліпшення якості життя

Ключові слова: життєдіяльність; лікування; терамін; теноксикам; комбінації препаратів