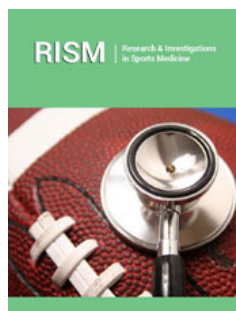


ISSN: 2577-1914



# Comparative Evaluation of the Effectiveness of the Treatment of Acute Pain Syndrome with a Selective COX1 and COX2 Inhibitor - Celecoxib without and against the Background of the Addition of a Combined Vitamin Complex of Group “B” In Patients with Nonspecific Pain Syndrome in the Lower Back

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**Submission:** 📅 July 22, 2022

**Published:** 📅 December 14, 2022

Volume 9 - Issue 2

**How to cite this article:** Antonen EG\* and Kruchek MM. Comparative Evaluation of the Effectiveness of the Treatment of Acute Pain Syndrome with a Selective COX1 and COX2 Inhibitor - Celecoxib without and against the Background of the Addition of a Combined Vitamin Complex of Group “B” In Patients with Nonspecific Pain Syndrome in the Lower Back. *Res Inves Sports Med.* 9(2), RISM.000709. 2022.  
DOI: [10.31031/RISM.2022.09.000709](https://doi.org/10.31031/RISM.2022.09.000709)

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## Abstract

In the course of a cohort prospective comparative study (n=41; of them 58.54%; n=24 - women and 41.46%; n=17 - men; mean age - 42.71±6.42 years) of the effectiveness of influence on acute pain in the structure of the muscular-tonic syndrome of celecoxib without and with the addition of a combined vitamin complex of group “B” (B1, B6, B12) in comparison with meloxicam, in patients with acute nonspecific pain syndrome in the lower back, it was found that in the absence of comorbid pathology, both drugs are equally effective and safe, and the duration of therapy should be at least 10-11 days. The combination of celecoxib with a combined vitamin complex (group “B” - Neuromultivit) gives the best result (p<0.05). Miscellaneous Pain Rating (MPR) according to MPQ (characterization of the feelings that cause pain, the impact of pain on the psyche of patients) is of great importance for the degree of pain perception in OPS in the structure of the muscular-tonic syndrome with HADS <7 p., i.e., accentuation of the patient’s personality.

**Keywords:** Acute pain syndrome; Celecoxib; Meloxicam; B Vitamins

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## Introduction

### Relevance

Pain in the lower back often occurs acutely after playing sports or physical exertion at the workplace or at home, it is part of the structure of the muscular-tonic syndrome, which is associated with the unpreparedness of the musculoskeletal system for movement. Non-steroidal anti-inflammatory drugs (NSAIDs) are often used to treat acute low back pain (ABS): non-selective NSAIDs and COX-2 selective NSAIDs [1-7]. The selective inhibitor of COX1 and COX2, celecoxib, and the moderately selective inhibitor of COX1 and selective COX2, meloxicam, have a positive effect on nonspecific OPS in the lower back [2,7,8]. The question arises about the advisability of prescribing vitamin complexes (group B) in combination with NSAIDs in the treatment of nonspecific OPS in the lower back [5,9,10].

### Purpose of the study

To evaluate the effectiveness of celecoxib influence on OPS in the structure of musculo-tonic syndrome without and with the addition of a combined vitamin complex of group B

(B1, B6, B12) in comparison with meloxicam in patients with acute nonspecific pain syndrome in the lower back.

## Materials and Methods

A cohort prospective comparative study (n=41; of which 58.54%; n=24 - women and 41.46%; n=17 - men; mean age - 42.71±6.42 years), which was performed on at the clinical base of the ChUZ "KB "RZD-Medicine", Petrozavodsk, Russia, at an outpatient appointment with a neurologist, after a neurological examination and the conclusion of a voluntary informed consent. Data were recorded by visits: 1<sup>st</sup> visit - initial treatment, before treatment; 2<sup>nd</sup> visit - on the 7<sup>th</sup> day (±2 days) from the start of treatment; 3<sup>rd</sup> visit - if pain persists on day 14±2 from the start of treatment; 4<sup>th</sup> visit - if pain persists on day 21±2 from the start of treatment; evaluated the indicators of the Visual Analogue Scale (VAS) (daily); McGill Pain Questionnaire (MPQ) [cit. According to 4], clinical symptoms, terms of treatment (by visits).

We used celecoxib (celexib®; LLC "Bausch Health"; at a dose: 1<sup>st</sup> day - 600mg in two doses (400mg + 200mg), 2-14 days - 400mg each (200mg + 200mg) - 1- observation group (n=12); celexib with a combined complex of vitamins "B" (Neuromultivit ®; 1st stage - IM 2.0 1 time per day, No. 10; then orally - 1 tablet 3 times a day day (1 ampoule: thiamine hydrochloride (B1) - 100mg, pyridoxine hydrochloride (B6) - 100mg, cyanocobalamin (B12) - 1mg; 1 tablet: B1 - 100mg, B6 - 200mg, B12 - 0.2mg) (n=9) - the 3<sup>rd</sup> observation group, and meloxicam at a dose of 15mg per day - the 2<sup>nd</sup> observation group (n=20), taking into account the terms of treatment of patients (for 5±1 days). free motor regimen, tolperisone (300mg per day), physiotherapy exercises (after pain relief - less than 4 points according to VAS), physiotherapy [1-3,6-8]. The exclusion group consisted of patients with traditional restrictions on prescription of NSAIDs, SARS-CoV-2 convalescents - at least 6 months; after vaccination (up to 4 weeks from the fact of the case), as well as persons who had ≥7 points on the Hospital Anxiety and Depression Scale (HADS).

Statistical data processing was carried out using the methods of parametric and non-parametric statistics using the standard static analysis software package Statistica 10 and MS Excel 2016. The level of statistical significance was fixed at the error probability level p=0.05. Categorical variables were described by absolute values and fractions of the whole - n (%). For variables with a continuous distribution, the mean value and standard deviation ( $m \pm \sigma$ ) were determined; for discrete and ordered data, the median and interquartile range Me [LQ; HQ]. Comparisons of two independent groups on quantitative scales were carried out using the nonparametric Mann-Whitney test (U). Comparisons of three or more groups on quantitative scales were carried out on the basis of the nonparametric Kruskal-Wallis test (Kr-W). The statistical significance of different values for binary and nominal indicators was determined using Pearson's Chi-square test. Correlation analysis was carried out on the basis of Spearman's nonparametric rank correlation.

## Research result

The intensity of OPS (according to VAS / MPQ index - "real feeling of pain intensity - NIB on a scale from 0 to 5 points) corresponded to the average values (1gr. - 5.52b./2.13 ± 0.67; 2gr. - 5.91b./1.85±0.49; 3gr. - 5.34b./2.24±0.72; p≥0.05). Therapy with NSAIDs in all 3 groups led to a decrease in the intensity of OPS only on days 10-11 of therapy (p<0.01). In groups 1 and 2, the decrease in BP was of a remitting undulating nature (between 6 and 9 days) and was associated with the expansion of motor load by patients (by day 21 according to VAS / MPQ - group 1 -1.3b. / 0.72±0, 59; group 2-1.8 b./0.75±0.55), in group 3 - already by the third day the threshold was overcome <4 points (mild), with the dynamics of a smooth decrease in pain preserved (by day 21 according to VAS / MPQ - 0.5 b. / 0.74 ± 0.62).

There were no significant differences in the level of VAS decline in groups 1 and 2. The combination of celecoxib with a B-group vitamin complex showed significant differences in VAS/MPQ values (p<0.05) from day 10 of therapy. According to the terms of treatment of OPS, in the 1<sup>st</sup>/2<sup>nd</sup>/3<sup>rd</sup> group: by the 14th day, treatment was completed in 16.67% of cases (n=2) / in 35% of cases (n=7) / in 33.33 % of cases (n=3), by day 21 - in 33.33% (n=4) / in 50% of cases (n=10) / in 55.5% of cases (n=5). Thus, by day 14, the best results were recorded in the group of patients receiving meloxicam and a combination of celecoxib with B group vitamins, and by day 21, in the group of patients receiving a combination of celecoxib with B group vitamins (neuromultivit®) (p≤ 0.05). However, it should be noted that, according to VAS, complete relief of OPS by day 21 was not achieved in any group.

Evaluation of the results of treatment of OPS according to MPQ (index - "real feeling of pain intensity - NIB") showed an equivalent positive result (significantly decreases by the 14<sup>th</sup> day; p = 0.03) in groups 1-3, maintaining the trend and by the 21<sup>st</sup> day (G 1: 1.47±0.61b.; D 2: 1.9±0.64b.; D 3: 1.52±0.51b.), i.e. both celecoxib and meloxicam are given a positive result in the treatment of OPS. Pairwise comparison of the effectiveness of drugs on the relief of OPS by MPQ - NIB showed that there were no significant differences in all 3 groups at the stages of 3 visits (p>0.05). The most significant indicator for patients, in assessing their feelings of OPS according to MPQ, at the stages of all visits, was its evaluation characteristic as a "mixed factor - Miscellaneous Pain Rating (MPR) with subclasses 17-20 (characteristic of the feelings that cause pain, the impact of pain on the psyche patients): 1 gr. - 52 ±5.5%; 2 gr. - 52 ±4.8%; 3 gr. - 53 ±7.8%. At the same time, the sensory component of pain - Sensory Pain Rating (SPR) from the 1st to 10th subclass (0-42 points) at all visits was 1g. - 18 ± 2.8%, 2gr. - 14 ± 2.3%, 3gr. - 17 ± 3.6% (average values of % of SPR, MPR indicators are given in the current pain intensity index (PPI) in the "M ± m" format).

Comparing all MPQ indicators in assessing OPS before and during treatment (with a significant decrease in all indicators) (p<0.05), in all three groups and at the stages of all 3 visits, it was found that there were no significant differences in their values (p>

0.05). Undesirable effects in the form of gastropathy (heaviness in the epigastrium, belching, reflux syndrome) occurred in two cases each during therapy with meloxicam (10%) and celecoxib (9.52%) ( $p > 0.05$ ), with a history of gastritis, PPI prescription cured adverse events. Complications from the cardiopulmonary systems, drug interactions were not recorded. All patients continued the started treatment [3,7,11,12].

In conclusion I would like to note that both celecoxib and meloxicam are equally effective and safe for stopping OPS against the background of muscular tonic syndrome in the lower back, in the absence of comorbid pathology; the duration of therapy should be at least 10-11 days. The combination of celecoxib with a combined vitamin complex (group "B" - Neuromultivit) gives the best result ( $p < 0.05$ ). The degree of perception of pain in OPS in the structure of the musculo-tonic syndrome is of great importance to the "mixed factor - Miscellaneous Pain Rating (MPR) according to MPQ (characteristic of the feelings that cause pain, the effect of pain on the psyche of patients), with HADS  $< 7$  p., t. e. accentuation of the patient's personality.

### In Conclusion

I would like to note that both celecoxib and meloxicam are equally effective and safe for stopping OPS against the background of muscular tonic syndrome in the lower back, in the absence of comorbid pathology; the duration of therapy should be at least 10-11 days. The combination of celecoxib with a combined vitamin complex (group "B" - Neuromultivit) gives the best result ( $p < 0.05$ ). The degree of perception of pain in OPS in the structure of the musculo-tonic syndrome is of great importance to the "mixed factor - Miscellaneous Pain Rating (MPR) according to MPQ (characteristic of the feelings that cause pain, the effect of pain on the psyche of patients), with HADS  $< 7$  p., t. e. accentuation of the patient's personality.

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