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Quality of life in patients with chronic slow-transit constipation according to the PAC-QOL questionnaire and the effectiveness of conservative therapy

I. M. Leshchyshyn, L. Y. Markulan, O. I. Okhotska, P. L. Byk

Bogomolets National Medical University

✉ Pavlo Byk: byckpavlo@gmail.com

I. M. Leshchyshyn, http://orcid.org/0000-0003-1429-2756
L. Y. Markulan, http://orcid.org/0000-0003-2879-5012
O. I. Okhotska, http://orcid.org/0000-0002-3468-8179
P. L. Byk, http://orcid.org/0000-0002-2215-3978

Objective — to assess the quality of life (QOL) of patients with chronic slow-transit constipation (CTC) according to the PAC-QOL (Patient Assessment of Constipation Quality of Life) questionnaire, as well as the effectiveness of conservative therapy.

Materials and methods. The study included 246 patients with chronic (more than 5 years) slow-transit constipation (CSTC group) and 70 patients without CSTC (reference group). These individuals were examined and treated in the clinics of Bogomolets National Medical University from 2014 to 2023. The onset of chronic slow-transit constipation often occurred at an average age of 22.2 ± 0.8 years (from 1 year to 67 years) and lasted 20.2 ± 0.7 years (from 5 to 53 years). The average duration of the delayed passage of stool was 9.4 ± 0.3 days (from 3 to 22 days). All patients received an adjusted course of conservative treatment according to the Rome guidelines. The nosospecific PAC-QOL questionnaire was used to evaluate the patients' quality of life on their initial visit and 6—8 months after conservative therapy.

Results. During the initial assessment, the CSTC group had a mean score of 3.03 ± 0.56 on the «Physical Discomfort» subscale, while the reference group had a mean score of 1.19 ± 0.29. On the «Psychosocial Discomfort» subscale, the CSTC group had a mean score of 2.21 ± 0.52 compared to 0.84 ± 0.18 in the reference group. The mean score for the «Worries and Concerns» subscale was 2.49 ± 0.41 in the CSTC group and 0.77 ± 0.24 in the reference group. The mean score for the «Satisfaction» subscale was 3.31 ± 0.43 in the CSTC group and 0.86 ± 0.28 in the reference group. The PAC-QOL questionnaire total score was 2.63 ± 0.26 in the CSTC group and 0.87 ± 0.12 in the reference group ($p < 0.001$ for all). After conservative treatment, the PAC-QOL scores improved by an average of 40.4 ± 20.0 % (to 0.68—2.71 points). The cluster analysis revealed that after the course of conservative therapy, the PAC-QOL questionnaire scores formed three distinct clusters: Cluster I—0.68—1.39 points (49.2 % of patients), Cluster II—1.40—1.99 points (17.5 % of patients), and Cluster III—2.0—2.8 points (33.3 % of patients). These clusters represent good, satisfactory, and unsatisfactory results.

Conclusions. The PAC-QOL questionnaire revealed a statistically significant decline in QOL in patients with CSTC (2.63 ± 0.26 points compared to 0.87 ± 0.12 points in the reference group). Modern conservative treatment improved quality of life in 49.2 % of cases. 17.5 % of cases showed a satisfactory result, while the remaining ones exhibited insignificant or no improvement. Other treatment options, including surgery, should be considered for patients who do not respond to conservative therapy.

Keywords
chronic slow-transit constipation, quality of life, PAC-QOL questionnaire, conservative therapy, results.

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Chronic constipation affects approximately 10—15 % of the population and is one of the most common gastrointestinal diseases that are treated in primary and secondary care [12]. It negatively affects quality of life (QOL) and is associated with a significant healthcare burden [16].

The term «constipation» is used to describe symptoms associated with difficulties in defecation. These include infrequent bowel movements, hard or lumpy stools, excessive straining, a feeling of incomplete evacuation or blockage, and, in some cases, the use of manual manoeuvres to facilitate evacuation [11]. Symptoms can be acute when they typically last less than a week and are caused by dietary and/or lifestyle changes (e.g., reduced fibre intake, reduced physical activity, stress, toileting in unfamiliar surroundings) [15]. In contrast, chronic constipation is usually characterised by symptoms that persist for at least 3 months [3].

The Rome criteria of the fourth revision classify chronic constipation disorders into four subtypes: (a) functional constipation (FC), (b) irritable bowel syndrome with constipation (IBS-C), (c) opioid-induced constipation (OIC), (d) functional bowel movements, including inadequate defecation propulsion and dyssynergic bowel movements [18].

The initial approach to the treatment of these disorders is the same, consisting of diet, lifestyle changes, and the use of standard over-the-counter laxatives. If the treatment is ineffective, additional therapy is prescribed based on the subtype [1, 2, 6—10, 13, 22].

According to a large meta-analysis of 45 population-based surveys covering 261,040 adults, the global prevalence of chronic constipation is estimated at 14 % (95 % confidence interval, 12—17 %) [21]. Chronic constipation is more common in women, the elderly, and people with lower socioeconomic status [5]. However, it can be argued that due to considerable heterogeneity between studies, caused by differences in sample size, duration of symptoms, definition criteria, and methods used to collect symptom data, the prevalence of chronic constipation worldwide is uncertain. Large studies, including large multinational collaborative studies with a common research methodology, are needed to clarify this. Recent data from a cross-population survey in three countries using a modern diagnostic questionnaire according to the Rome IV criteria showed that the prevalence of chronic constipation is approximately 9 %, with ~6 % being FC and the remaining cases being IBS-C and OIC, which occur with equal frequency [17]. A global epidemiological study of functional gastrointestinal disorders is ongoing. The prevalence of functional bowel movement disorders in the population is not known, as the diagnosis requires laboratory tests. In tertiary care centres, half of the cases of chronic constipation are not registered due to the absence of clear statistical information [3].

Patients usually have a long history of CSTC, most of it dating back to childhood. The disease is progressive in nature. It is characterised by numerous courses of conservative therapy with ambiguous (variable, unpredictable) effectiveness. CSTC negatively affects the QOL of patients, but there is a lack of research on this issue. The studies mainly used The Short Form-36 (SF-6) questionnaire, which is not nosospecific [19]. Only a few studies have been devoted to the assessment of QOL in patients with chronic constipation using the nosospecific PAC-QOL (Patient Assessment of Constipation Quality of Life) questionnaire, without focusing on the problem of CSTC. There is also a lack of information on the impact of conservative therapy on the QOL of people with CSTC, according to the PAC-QOL scale.

Objective — to assess the quality of life (QOL) of patients with chronic slow-transit constipation (CTC) according to the PAC-QOL (Patient Assessment of Constipation Quality of Life) questionnaire, as well as the effectiveness of conservative therapy.

Materials and methods

The study included 246 patients with chronic (more than 5 years) slow-transit constipation (CSTC group) and 70 patients without CSTC (reference group). These individuals were examined and treated according to the Rome criteria in the clinics of Bogomolets National Medical University from 2014 to 2023 [3, 19].

The study groups did not differ statistically significantly in terms of sex ratio, mean age, and body mass index. Women predominated in both groups: 233 (94.7 %) in the CSTC group and 65 (92.9 %) in the reference group ($p = 0.554$). The mean age was 42.8 and 41.5 years, respectively ($p = 0.458$). The body mass index was 22.7 ± 4.2 and 22.2 ± 2.0 kg/m^2, respectively ($p = 0.424$).

According to the anamnestic data, constipation occurred at different ages, on average at 22.2 ± 0.8 years (from 1 to 67 years), the duration of the disease before the visit to the clinic was on average 20.2 ± 0.7 years (from 5 to 53 years), and the delayed passage of stool before admission to the clinic was 9.4 ± 0.3 days (from 3 to 22 days). Stool consistency according to the Bristol Stool Form Scale corresponded to type I in 152 (61.8 %) patients, type 2 in 63 (25.6 %), type 3 in 21 (8.5 %), type 4 in 7 (2.8 %), and type 5 in 3 (1.2 %).

Before seeking medical assistance in our clinic, all patients received permanent conservative therapy, which gradually lost its effectiveness. 236 (95.9 %) patients used a high-fibre diet, 237 (96.3 %) used pharmacological agents, and 183 (74.4 %) used cleansing enemas.

The nosospecific PAC-QOL questionnaire was used to evaluate the patients' quality of life on their initial visit and 6—8 months after an adjusted course of conservative therapy.

The original English version of the Patient Assessment of Constipation Quality of Life (PAC-QOL, © PAC-QOL, 2005 Mapi Research Trust, all rights reserved) is a questionnaire that is often used to assess the impact of chronic constipation on QOL and daily activities using a simple structure and scoring system. It was developed and validated by R. Marquis et al. in 2005 [14]. The PAC-QOL questionnaire has been translated into different languages and validated in many countries. We used the PAC-QOL questionnaire to improve the clinical assessment of constipation in patients.

The PAC-QOL questionnaire contains 28 items grouped into 4 subscales: worries and concerns (11 items), physical discomfort (4 items), psychosocial discomfort (8 items), and treatment satisfaction (5 items). A five-point Likert response scale ranging from 0 (not at all/never) to 4 (strongly/all the time) is used over a 2-week period (a higher score indicates a worsening of QOL due to constipation). The total score and scores for each subscale were calculated according to the original PAC-QOL document. The test took 10—14 minutes to complete [14].

All patients received conservative treatment according to the Rome criteria [3, 13], taking into account drugs licensed in Ukraine.

Statistical analysis was performed using IBM SPSS Statistics, V 22. Discriminant statistics were calculated. The data were assessed for normality using the Shapiro-Wilk test. Mean values are presented as M ± SD. Categorical data were expressed as numbers (%). Comparison of mean values of quantitative variables was performed using the Student's t-test for data whose distribution does not differ from normal; for data whose distribution differs from normal, comparison of variables was performed using the Wilcoxon-Mann-Whitney U-test. To identify groups of similar objects, a two-stage cluster analysis was performed. A comparison of relative values was performed using Pearson's χ^2 test. The null hypothesis of equality of variables was rejected at $p < 0.05$.

Results

Despite the fact that patients with CSTC had a long history of conservative treatment, when they came to the clinic, they had unsatisfactory QOL indicators for all subscales of the PAC-QOL questionnaire, which significantly exceeded the reference ones. Thus, according to the Physical Discomfort subscale (Fig. 1), the mean score in the CSTC group was 3.03 ± 0.56 (from 1.5 to 4.0 points), while in the reference group it was 1.19 ± 0.29 (from 0.25 to 1.75 points, $p < 0.001$).

According to the Psychosocial Discomfort subscale (Fig. 2), the mean score in the CSTC group was 2.21 ± 0.52 (from 1.13 to 3.38 points), while in the reference group it was 0.84 ± 0.18 (from 0.5 to 1.38 points, $p < 0.001$).

According to the Worries and Concerns subscale (Fig. 3), the mean score in the CSTC group was 2.49 ± 0.41 (from 1.55 to 3.45 points), while in the

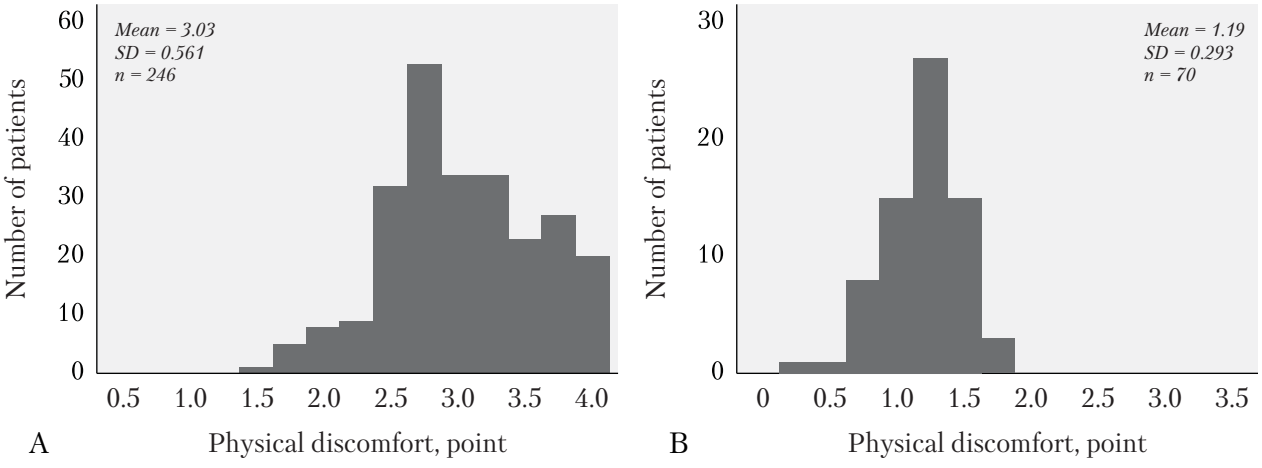

Figure 1. **Distribution by the mean score of the Physical Discomfort subscale in the CSTC group (A) and the reference group (B) before the course of conservative therapy**

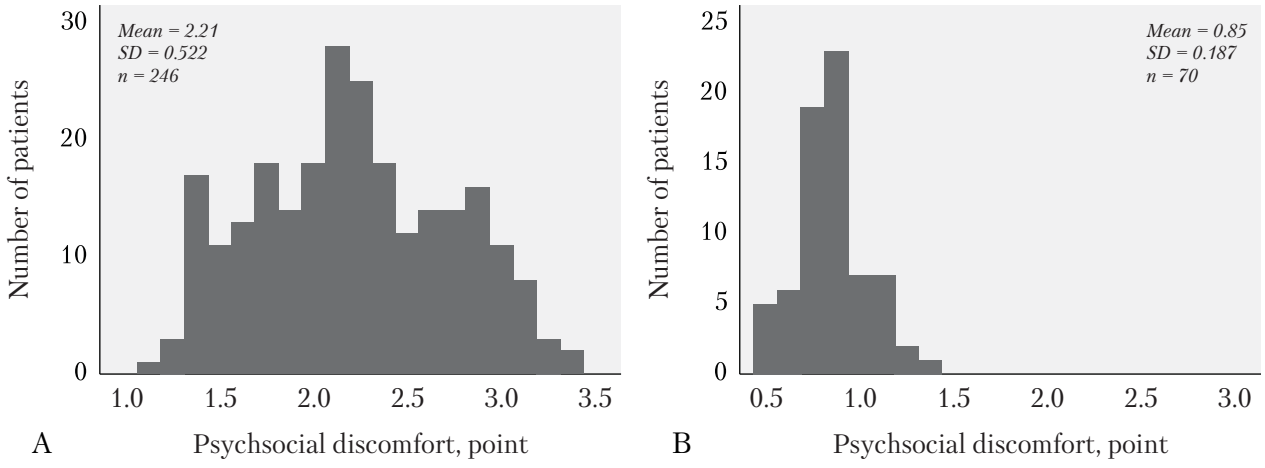

Figure 2. **Distribution by the mean score of the Psychosocial Discomfort subscale in the CSTC group (A) and the reference group (B) before the course of conservative therapy**

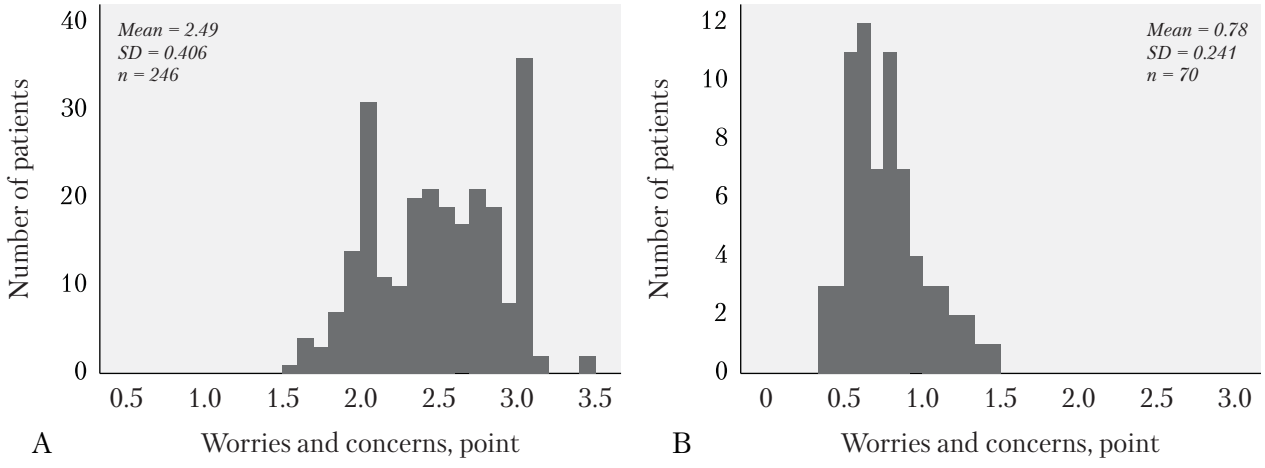

Figure 3. **Distribution by the mean score of the Worries and Concerns subscale in the CSTC group (A) and the reference group (B) before conservative therapy**

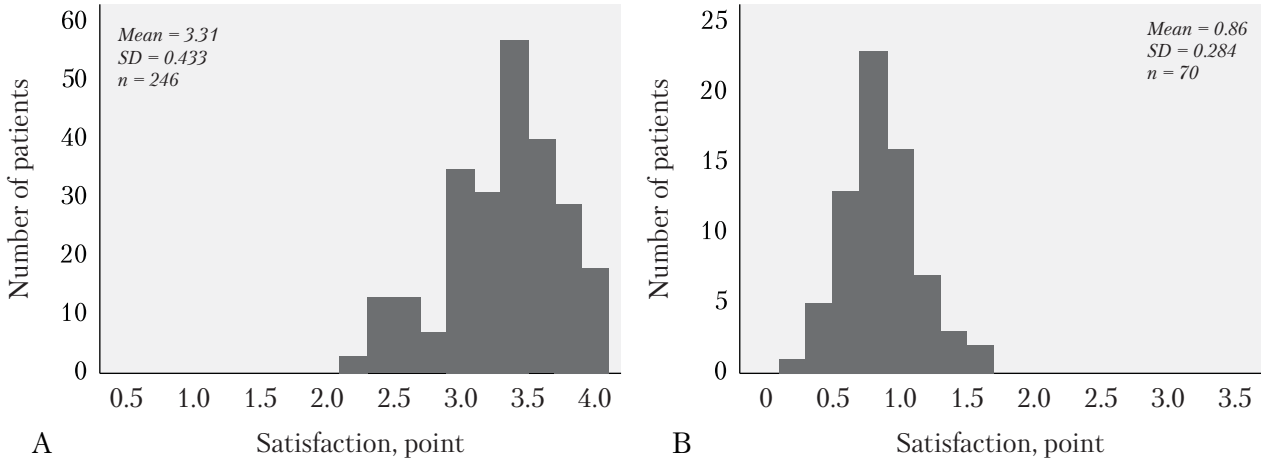

Figure 4. **Distribution by the mean score of the Satisfaction subscale in the CSTC group (A) and the reference group (B) before conservative therapy**

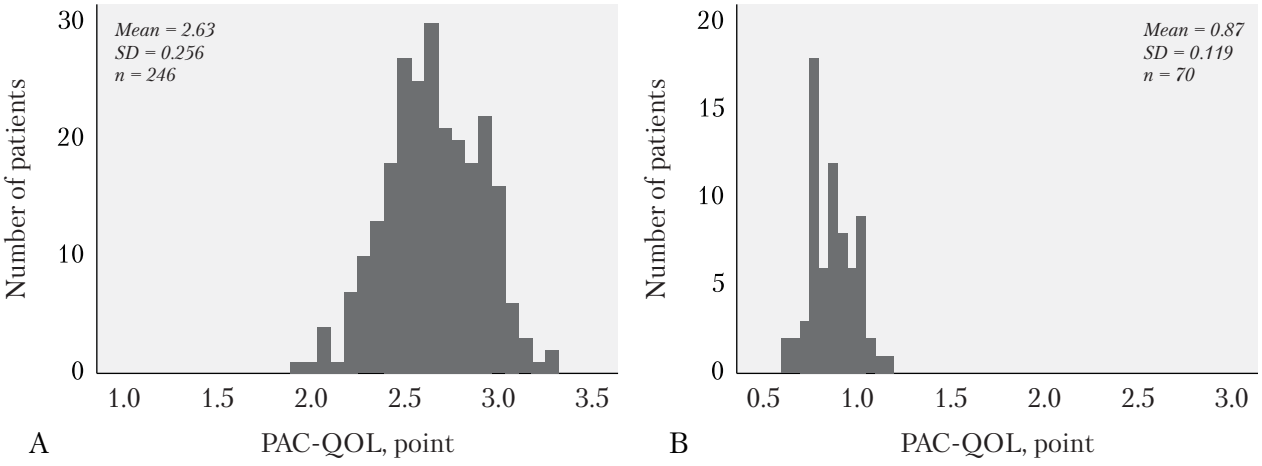

Figure 5. **Distribution by the total PAC-QOL questionnaire score in the CSTC group (A) and the reference group (B) before conservative therapy**

reference group it was 0.77 ± 0.24 (from 0.36 to 1.45 points, $p < 0.001$).

According to the Satisfaction subscale (Fig. 4), the mean score in the CSTC group was 3.31 ± 0.43 (from 2.20 to 4 points), while in the reference group it was 0.86 ± 0.28 (from 0.20 to 1.60 points, $p < 0.001$).

The total PAC-QOL questionnaire score (Fig. 5) averaged 2.63 ± 0.26 in the CSTC group (from 1.93 to 3.29 points) and 0.87 ± 0.12 in the reference group (from 0.61 to 1.18 points, $p < 0.001$).

After conservative treatment, a decrease in the PAC-QOL questionnaire score was noted in all patients by an average of 40.4 ± 20.0 % (Table 1, Fig. 6).

According to the PAC-QOL questionnaire and all its subscales, the mean values of QOL indicators after the course of conservative treatment were statistically significantly better than before treatment ($p < 0.001$ for all), but worse than the corresponding indicators in the reference group ($p < 0.001$ for all).

After conservative treatment, there was significant variability in the mean scores for all subscales

Table 1. **Score reduction on the PAC-QOL questionnaire and its subscales after conservative treatment**

Variable	Mean ± StD	Min—Max
Physical discomfort	29.0 ±20.9	0.0—88.9
Psychosocial discomfort	31.7 ±19.2	0.0—66.7
Worries and concerns	45.9 ±28.0	–31.6 ... +96.2
Satisfaction	47.8 ±22.2	14.3—94.7
PAC-QOL	40.4 ±20.1	3.7—69.9

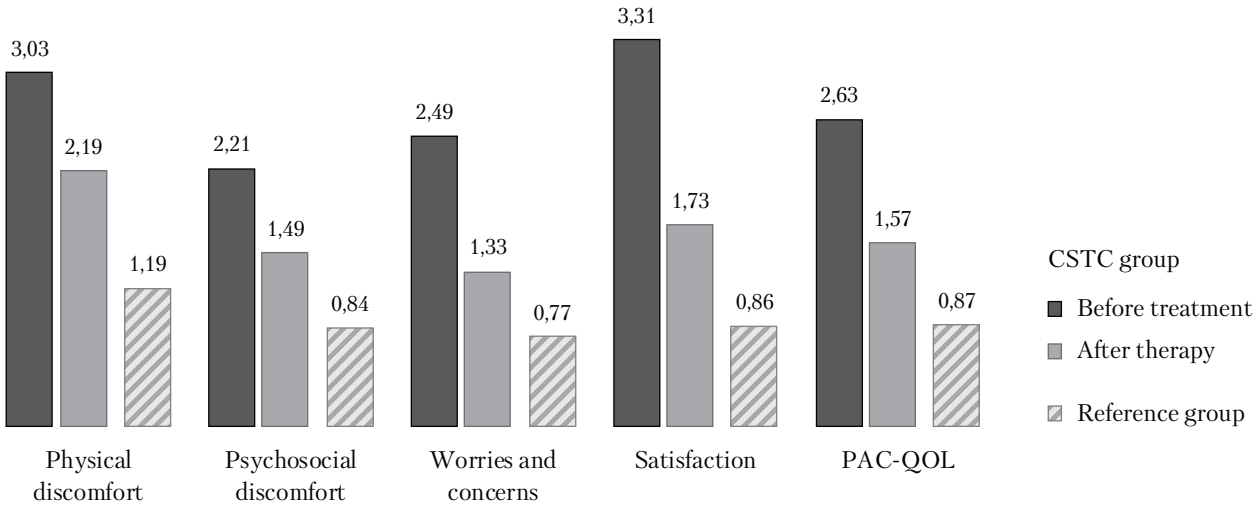

Figure 6. **Average scores of quality of life indicators before and after treatment in the CSTC group and in the reference group**

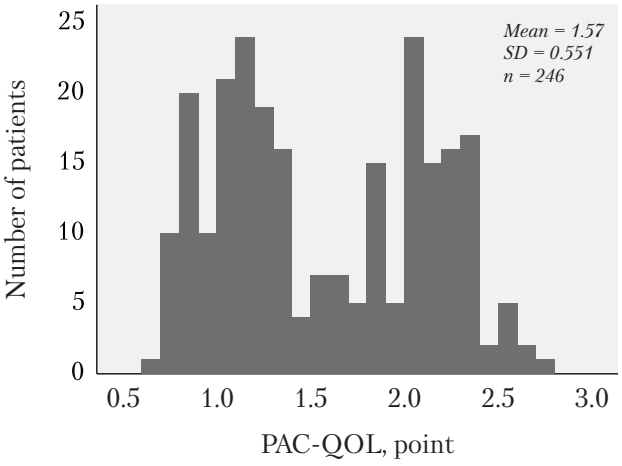

Figure 7. **Distribution of the average score on the PAC-QOL questionnaire in patients in the CSTC group after a course of conservative therapy**

and the PAC-QOL questionnaire. In particular, the total score on the PAC-QOL questionnaire ranged from 0.68 to 2.71 (Fig. 7).

It is noteworthy that only 86 (35 %) patients had mean values of the total PAC-QOL score within the reference values (from 0.61 to 1.18).

The cluster analysis revealed that after conservative therapy, the PAC-QOL questionnaire scores formed three distinct clusters with a good silhouette measure of connectivity and cluster separation: Cluster I — 0.68—1.39 points; Cluster II — 1.40—1.99 points; and Cluster III — 2.0—2.8 points. This indicates that conservative treatment has a different impact on QOL. In 121 (49.2 %) patients, the total score on the PAC-QOL questionnaire belonged to the first cluster, in 43 (17.5 %) to the second cluster, in 82 (33.3 %) to the third cluster, which may correspond to good, satisfactory, and unsatisfactory results.

This variability in the results of conservative treatment was recorded for all subscales of the PAC-QOL questionnaire (Table 2).

Thus, the PAC-QOL questionnaire revealed that modern conservative treatment improved quality of life in 49.2 % of cases. 17.5 % of cases showed a satisfactory result, while the remaining ones exhibited insignificant or no improvement.

Discussion

Conservative treatment of patients with FC should alleviate certain symptoms and improve QOL, but for some patients with CSTC who already have extensive experience with conservative treatment and still seek help, modern conservative treatment regimens do not always have the desired effect.

Using the PAC-QOL questionnaire, we analysed the QOL of patients with CSTC before and after conservative treatment. We did not find information on the use of this questionnaire in patients with CSTC to compare the results of conservative treatment with baseline.

The authors used various questionnaires to assess the severity of constipation [20, 23]. In particular, in 2015, an article was published in which the authors used the PAC-QOL and SF-36 questionnaires to analyse patients with chronic FC and IBS-C according to the Rome III criteria. The PAC-QOL questionnaire was filled out by 43 patients (14 % with IBS-C, 37 % with FC, and 49 % with unclassified constipation) and the SF-36 questionnaire was filled out by 93 patients (23 % with IBS-C, 27 % with FC, and 51 % with unclassified constipation) [19].

The SF-36 questionnaire showed that patients with IBS-C had a worse quality of life compared to the groups of people with functional and

Table 2. **Results of cluster analysis of the PAC-QOL questionnaire after a course of conservative treatment (Min—Max)**

Variable	Cluster I	Cluster II	Cluster III
Physical Discomfort	0.25—1.75 n = 85 (34.6 %)	2.00—2.75 n = 112 (45.5 %)	3.00—3.75 n = 49 (19.9 %)
Psychosocial Discomfort	0.75—1.38 n = 128 (52.0 %)	1.50—2.00 n = 83 (37.7 %)	2.13—2.88 n = 35 (14.2 %)
Worries and Concerns	0.90—1.09 n = 124 (50.4 %)	1.27—1.82 n = 44 (17.9 %)	1.91—2.64 n = 78 (31.7 %)
Satisfaction	0.2—1.4 n = 104 (42.3 %)	1.6—2.2 n = 76 (30.9 %)	2.4—3.4 n = 66 (26.8 %)
Total	0.68—1.39 n = 121 (49.2 %)	1.40—1.99 n = 43 (17.5 %)	2.0—2.8 n = 82 (33.3 %)

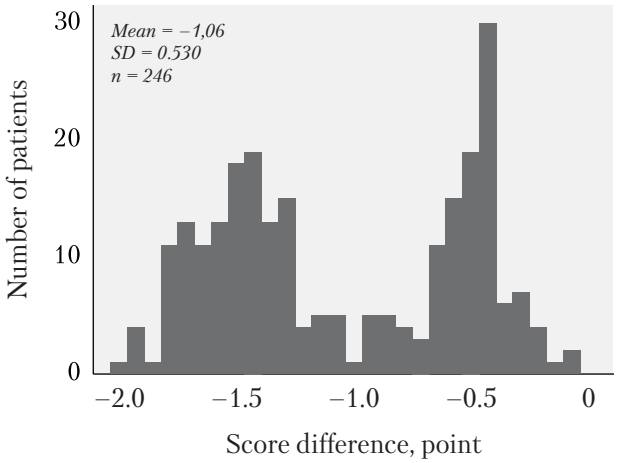

Figure 8. **Distribution of patients by absolute decrease in the total score on the PAC-QOL questionnaire after a course of conservative therapy**

unclassified constipation. Statistically significant differences were found on the fatigue/energy scale between patients with IBS-C and patients with functional constipation in favour of the latter (41.67 ± 3.386 vs. 55.20 ± 4.383; p = 0.0221) and on the pain scale between patients with IBS-C and patients with unclassified constipation (49.64 ± 5.290 vs. 63.62 ± 3.673; p = 0.0362).

The PAC-QOL questionnaire also showed worse results in patients with IBS-C than in patients with FC in terms of the physical component (10.00 ± 1.125 vs. 4.938 ± 0.8086; p = 0.0029), psychosocial component (14.33 ± 2.704 vs. 7.438 ± 1. 469; p = 0.0278), concerns and worries score (17.33 ± 4.410 vs. 9.375 ± 1.494; p = 0.0379), treatment satisfaction (16.50 ± 0.4282 vs. 10.31 ± 1.440; p = 0.0180), and overall PAC-QOL score (2.077 ± 0.2704 vs. 1.146 ± 0.1391; p = 0.0034) [19].

In 2017, Italian gastroenterologists provided data on patients with FC, IBS-C, and unclassified constipation who received various conservative therapies using the Bristol Scale, the Patient Assessment of Constipation Symptoms (PAC-SYM), and the PAC-QOL questionnaires. The authors concluded that patients with IBS-C had worse QOL than those with FC and unclassified constipation, according to all questionnaires [4].

Unfortunately, we have not found any articles in the literature that provide data on QOL determination by the PAC-QOL questionnaire in patients with CSTC before and after conservative treatment.

According to our data, QOL in patients with CSTC is significantly impaired. During the initial assessment, the CSTC group had a mean score of 3.03 ± 0.56 on the «Physical Discomfort» subscale, while the reference group had a mean score of 1.19 ± 0.29. On the «Psychosocial Discomfort» subscale, the CSTC group had a mean score of 2.21 ± 0.52 compared to 0.84 ± 0.18 in the reference group. The mean score for the «Worries and Concerns» subscale was 2.49 ± 0.41 in the CSTC group and 0.77 ± 0.24 in the reference group. The mean score for the «Satisfaction» subscale was 3.31 ± 0.43 in the CSTC group and 0.86 ± 0.28 in the reference group. The PAC-QOL questionnaire total score was 2.63 ± 0.26 in the CSTC group and 0.87 ± 0.12 in the reference group ($p < 0.001$ for all). After adjusted conservative therapy, only 86 (35 %) patients registered a total score on the PAC-QOL questionnaire that reached the limits of reference values (from 0.61 to 1.18). If the QOL of all patients is assessed using cluster analysis, the proportion of patients with relatively good results is 49.2 %, with insignificant or no improvement — 33.3 %. The original article [14] suggests that the effect of conservative treatment should be assessed by a reduction in the PAC-QOL score, with a decrease of 0.5 in the total score considered a minimally significant improvement. According to this assessment, 69 (28.0 %) patients had insignificant or no improvement (Fig. 8).

Assessment of the outcome by the value of the change in the indicator has a disadvantage, since even with a significant change, the absolute value of the indicator may remain high and indicate poor QOL. A comparison of QOL indicators in patients with CSTC with reference values, in our opinion, more clearly assesses their condition, but this requires additional research.

The fact that after prolonged pretreatment, patients came to the clinic with unsatisfactory PAC-QOL scores compared to the reference group, and in 33.3 % of them, they remained at this level after therapy adjusted according to the Rome guidelines, indicates the complexity of the problem and the heterogeneous nature of the disease. Other treatment options, including surgery, should be considered for patients who do not respond to conservative therapy.

Conclusions

The PAC-QOL questionnaire revealed a statistically significant decline in QOL in patients with CSTC (2.63 ± 0.26 points compared to 0.87 ± 0.12 points in the reference group).

Modern conservative treatment improved quality of life in 49.2 % of cases. 17.5 % of cases showed a satisfactory result, while the remaining ones exhibited insignificant or no improvement.

Other treatment options, including surgery, should be considered for patients who do not respond to conservative therapy.

Declaration of interests

The authors declare that they have no conflicts of interest.

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Authors contributions

Conception and design of the study, statistical analysis — I. M. Leshchyshyn, L. Y. Markulan; collection and analysis of data — I. M. Leshchyshyn, P. L. Byk; writing the manuscript — I. M. Leshchyshyn; critical revision — I. M. Leshchyshyn, O. I. Okhotska.

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Якість життя хворих із тривалими повільнотранзитними запорами за опитувальником PAC-QOL та ефективність консервативної терапії

І. М. Лещишин, Л. Ю. Маркулан, О. І. Охоцька, П. Л. Бик

Національний медичний університет імені О. О. Богомольця

Мета — визначити якість життя (ЯЖ) хворих із хронічними повільнотранзитними запорами (ХПТЗ) за опитувальником PAC-QOL (Patient Assessment of Constipation Quality of Life Questionnaire) та ефективність консервативної терапії.

Матеріали та методи. У дослідження було залучено 246 хворих із тривало існуючими (понад 5 років) повільнотранзитними запорами (група ХПТЗ) та 70 пацієнтів без ХПТЗ (референтна група), обстежених і пролікованих на базах клінік Національного медичного університету імені О. О. Богомольця в період з 2014 до 2023 р. Хронічні повільнотранзитні запори виникали в середньому в (22,2 ± 0,8) року (від 1 року до 67 років), та існували (20,2 ± 0,7) року (від 5 до 53 років). Затримка випорожнення становила в середньому (9,4 ± 0,3) доби (від 3 до 22 діб). Усі хворі отримали відкориговане консервативне лікування згідно з Римськими рекомендаціями. Якість життя хворих оцінювали за нозоспецифічним опитувальником PAC-QOL під час першого візиту та після курсу консервативної терапії через 6—8 міс.

Результати. Під час першого візиту середній бал у групі ХПТЗ за субшкалою «Фізичний дискомфорт» становив (3,03 ± 0,56), у референтній групі — (1,19 ± 0,29), за субшкалою «Психологічний дискомфорт» — відповідно (2,21 ± 0,52) та (0,84 ± 0,18), за субшкалою «Тривожність та занепокоєння» — (2,49 ± 0,41) і (0,77 ± 0,24), за субшкалою «Задоволеність» — (3,31 ± 0,43) та (0,86 ± 0,28), загальний бал за опитувальником PAC-QOL — (2,63 ± 0,26) і (0,87 ± 0,12) (усі $p < 0,001$). Після консервативного лікування показники опитувальника PAC-QOL поліпшилися в середньому на (40,4 ± 20,0) % (до 0,68—2,71 бала). Згідно з кластерним аналізом показники опитувальника PAC-QOL після курсу консервативної терапії мали три кластери: перший — 0,68—1,39 бала (49,2 % хворих), другий — 1,40—1,99 бала (17,5 % хворих), третій — 2,0—2,8 бала (33,3 хворих), що може відповідати добрим, задовільним і незадовільним результатам.

Висновки. У хворих із ХПТЗ згідно з показниками опитувальника PAC-QOL статистично значущо погіршилася ЯЖ ((2,63 ± 0,26) бала порівняно з (0,87 ± 0,12) бала в референтній групі). Сучасне консервативне лікування суттєво поліпшило ЯЖ у 49,2 % випадків. Задовільний результат досягнуто в 17,5 % випадків, тоді як у решті випадків зареєстровано слабкий ефект або відсутність поліпшення. У хворих із резистентністю до консервативної терапії слід розглянути інші методи лікування, зокрема оперативне втручання.

Ключові слова: хронічний повільно-транзитний запор, якість життя хворих, опитувальник PAC-QOL, консервативна терапія, результати.

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