

**CLINICAL AND STATISTICAL EVALUATION OF THE IMPACT OF PRESSURIZED
INTRAPERITONEAL AEROSOL CHEMOTHERAPY (PIPAC) ON QUALITY OF LIFE IN PATIENTS
WITH PERITONEAL CARCINOMATOSIS: A SINGLE-CENTER RETROSPECTIVE STUDY**

<https://doi.org/10.5281/zenodo.19362097>

Muzafarzoda Matluba Muzaffar

*Deputy Director for Clinical Affairs, Candidate of Medical Sciences, Scientific Cancer
Center of the Republic of Tajikistan. Republic of Tajikistsn. Tel: 992 918752100*

Музаффарзода Матлуба Музаффар

*номзади илмҳои тиб, муовини директор оид ба корҳои табобатӣ, Маркази
илмӣ саратоншиносии Ҷумҳурии Тоҷикистон. Ҷумҳурии Тоҷикистон. Тел: +992 918
75 21 00*

ABSTRACT: Background: *Quality of Life (QoL) has become a key endpoint in modern oncology, particularly in patients with advanced ovarian cancer and peritoneal carcinomatosis. In such patients, the goal of treatment is not always curative but rather focused on disease control, symptom reduction, and preservation of functional capacity. Pressurized intraperitoneal aerosol chemotherapy (PIPAC) has been proposed as a minimally invasive locoregional approach aimed at improving intraperitoneal drug delivery while reducing systemic toxicity.*

Objective: *To adapt the present manuscript to the real-world clinical cohort provided and to evaluate the clinical profile of patients undergoing PIPAC, with particular emphasis on symptom burden, treatment feasibility, laboratory dynamics, and quality-of-life indicators before and after treatment.*

Materials and Methods: *This study is based on the clinical dataset provided by the user, comprising a structured collection of demographic, clinical, oncological, laboratory, treatment-related, perioperative, and follow-up variables. The cohort includes patients with peritoneal carcinomatosis, predominantly of ovarian origin. Available data encompass baseline functional status (ASA, ECOG, Karnofsky), tumor characteristics, prior treatment history, PIPAC-related variables, complications, response categories, EORTC-based QoL indicators before and after treatment, and follow-up outcomes.*

Results: *The cohort is clinically heterogeneous yet methodologically valuable. It mainly consists of women with stage II-III disease, partially reduced but preserved functional status, significant baseline symptom burden prior to PIPAC, and a history of platinum-based chemotherapy. The predominant clinical symptoms before PIPAC included abdominal distension, lower abdominal pain, fatigue, ascites, and decreased appetite. Most patients underwent at least one cycle of PIPAC, and treatment regimens commonly included cisplatin + doxorubicin or platinum-taxane combinations in the overall treatment*

history. The available data indicate that PIPAC was feasible in the majority of patients, with a low incidence of severe perioperative complications and a predominance of disease stabilization or partial response over rapid progression. Furthermore, paired EORTC QoL data before and after treatment are available, providing valuable insights into QoL dynamics; however, the current dataset requires final data cleaning to enable precise inferential statistical analysis.

Conclusion: The presented clinical dataset enables the development of a real-world clinical study on the impact of treatment on quality of life and demonstrates that PIPAC may be integrated into multimodal management of peritoneal carcinomatosis, with emphasis on symptom control, preservation of functional status, and maintenance of QoL [8]. The primary scientific value of this cohort lies in the integration of patient-reported outcomes and clinician-reported clinical data, which, after final data refinement, may serve as the basis for a publishable observational study.

Keywords: quality of life, PIPAC, ovarian cancer, peritoneal carcinomatosis, EORTC, patient-reported outcomes, regional chemotherapy.

Аннотатсия: Замина: Сифати зиндагӣ (Quality of Life, QoL) дар онкологияи муосир, махсусан дар беморони гирифтори саратони пешрафтаи тухмдон ва карсиноматози перитонеалӣ, ба яке аз нишондиҳандаҳои меҳвари самаранокии табобат табдил ёфтааст. Дар чунин беморон ҳадафи табобат на ҳамеша шифои кулӣ, балки назорати беморӣ, коҳиши нишонаҳо ва ҳифзи қобилияти функционалӣ мебошад. Химиотерапияи дохилишикамии аэрозолӣ зери фишор (PIPAC) ҳамчун усули минималӣ-инвазивии минтақавӣ барои беҳтар намудани расониши дохилишикамии доруҳо ва кам кардани захролудии системавӣ пешниҳод шудааст.

Ҳадаф: Мутобиқ сохтани мақолаи мазкур ба когорти воқеии пешниҳодшуда ва арзёбии профили клиникии беморони таҳти PIPAC, бо таваҷҷуҳи махсус ба сарбории симптоматикӣ, иҷрошавандагии табобат, динамикаи лабораторӣ ва нишондиҳандаҳои марбут ба сифати зиндагӣ пеш ва баъд аз табобат.

Мавод ва усулҳо: Мақола дар асоси маводи клиникии пешниҳодшуда аз ҷониби корбар таҳия шудааст, ки дорои маҷмӯи сохторбандишудаи нишондодҳои демографӣ, клиникӣ, онкологӣ, лабораторӣ, табобатӣ, периоператсионӣ ва мониторинги баъдӣ мебошад. Когорта беморони гирифтори карсиноматози перитонеалиро, ки асосан аз саратони тухмдон маншаъ мегиранд, дар бар мегирад. Маълумоти мавҷуда нишондиҳандаҳои ибтидоии ҳолати функционалӣ (ASA, ECOG, Karnofsky), хусусиятҳои омос, таърихи муолиҷаи пешина, тағйирёбандаҳои марбут ба PIPAC, оризаҳо, категорияҳои ҷавоб ба табобат, нишондиҳандаҳои EORTC пеш ва баъд аз табобат ва натиҷаҳои назоратиро дар бар мегирад.

Натиҷаҳо: Когорти пешниҳодшуда аз ҷиҳати клиникӣ гуногун, вале аз ҷиҳати методологӣ арзишманд аст. Он асосан аз занони дорои марҳилаҳои II–III беморӣ, сатҳи то андозае коҳишёфта, вале ҳифзшудаи фаъолияти умумӣ, сарбории назарраси симптоматикӣ пеш аз PIPAC ва таърихи химиотерапияи платинадор иборат мебошад. Дар маводи дастрас аломатҳои асосии клиникӣ пеш аз PIPAC афзоиши ҳаҷми шикам, дарди қисми поёни шикам, сустӣ, асцит ва коҳиши иштиҳо буданд. Дар аксари беморон ҳадди ақал як давраи PIPAC гузаронида шудааст ва бештар режими cisplatin + doxorubicin ё комбинатсияҳои дорои platinum-taxane дар таърихи умумии табобат дучор мешаванд. Маводи дастрас нишон медиҳад, ки PIPAC дар аксари беморон иҷрошаванда буда, дар матни иқтибосшуда сатҳи пасти оризаҳои вазнини периоператсионӣ ва бартариҳои натиҷаҳои навъи ремиссия ё стабилизатсия нисбат ба прогрессияи фаврӣ мушоҳида мегардад. Ҳамчунин, мавод дорои нишондиҳандаҳои ҷуфтшудаи EORTC пеш ва баъд аз табобат мебошад, ки барои тафсири QoL аҳаммияти калон доранд, аммо шакли ҳозираи додаҳои воридшуда барои ҳисобҳои дақиқи омории инференсиалӣ тозакунии ниҳони ҷадвалро талаб мекунад.

Хулоса: Маводи клиникии пешниҳодшуда имкон медиҳад, ки мақолаи воқеии клиникӣ дар бораи таъсири табобат ба сифати зиндагӣ таҳия карда шавад ва нишон дода шавад, ки PIPAC метавонад ҳамчун ҷузъи муолиҷаи мультимодалӣ дар карсиноматози перитонеалӣ бо таваҷҷуҳ ба назорати нишонаҳо, ҳифзи ҳолати функционалӣ ва нигоҳдории сифати зиндагӣ истифода гардад [8]. Арзиши асосии илмии когорти мазкур дар ҳамгироии нишондиҳандаҳои аз ҷониби бемор гузоришшаванда ва нишондиҳандаҳои клиникии аз ҷониби табиб сабтшуда зоҳир мегардад, ки баъд аз тозакунии ниҳони додаҳо метавонад заминаи мақолаи ҷопшавандаи мушоҳидавиро фароҳам созад.

Калидвожаҳо: сифати зиндагӣ, PIPAC, саратони тухмдон, карсиноматози перитонеалӣ, EORTC, patient-reported outcomes, химиотерапияи минтақавӣ.

INTRODUCTION

Peritoneal carcinomatosis represents one of the most complex patterns of dissemination in advanced gynecological malignancies, particularly ovarian cancer, fallopian tube cancer, and primary peritoneal cancer [10]. In this context, treatment effectiveness should be evaluated not only in terms of radiological response or survival duration but also in terms of the ability to reduce ascites, alleviate pain, maintain nutritional status and bowel function, preserve functional independence, and prolong meaningful survival.

Traditional oncological endpoints-overall survival (OS), progression-free survival (PFS), objective response rate (ORR), and biochemical response-remain critically important [4]. However, in clinical scenarios characterized by recurrent ascites, abdominal pain, bowel dysfunction, progressive fatigue, multiple chemotherapy lines, and declining

performance status, these endpoints alone are insufficient to fully capture treatment benefit. Therefore, QoL is increasingly recognized as an independent clinical endpoint [11].

PIPAC has been developed as a locoregional therapeutic approach to overcome pharmacological and biological limitations of systemic therapy in peritoneal malignancies [2]. In this technique, chemotherapeutic agents are delivered as a pressurized aerosol via laparoscopy, resulting in improved tissue penetration, more homogeneous intraperitoneal distribution, and reduced systemic toxicity compared to conventional intravenous administration [14]. In clinical practice, this approach is particularly relevant for patients in whom radical cytoreductive surgery is no longer feasible, yet disease control and symptom burden reduction remain important therapeutic goals [1].

The present manuscript is directly adapted to the clinical dataset provided by the user. This aspect is methodologically significant, as the analysis is not based on hypothetical modeling but on a real-world single-center cohort containing patient-level data, including clinical symptoms, functional indices, treatment history, PIPAC variables, laboratory parameters, EORTC scores, and follow-up outcomes. Therefore, this work represents not only a theoretical overview but also the foundation of a real observational clinical study.

The aim of this study is to present a structured manuscript based on the provided cohort and to interpret the impact of treatment on QoL in terms of symptom burden, functional reserve, procedural tolerability, laboratory monitoring, and EORTC score dynamics.

OBJECTIVE OF THE STUDY

To evaluate the impact of treatment-particularly PIPAC within a multimodal therapeutic strategy-on the quality of life of patients with peritoneal carcinomatosis based on a real-world single-center cohort.

STUDY OBJECTIVES

To describe the demographic and clinical structure of the cohort.

To analyze symptom burden and functional status before PIPAC.

To characterize prior oncological treatment history and feasibility of PIPAC.

To evaluate perioperative safety and complication profiles.

To interpret paired QoL indicators before and after treatment based on EORTC variables.

To provide a critical and transparent discussion of the strengths and limitations of the real-world dataset.

MATERIALS AND METHODS

This study is a single-center retrospective observational analysis based on the provided clinical dataset. The dataset includes patients with peritoneal carcinomatosis and contains information relevant for epidemiological description, symptom burden assessment, oncological staging, prior treatment, procedural PIPAC parameters, perioperative outcomes, laboratory data, treatment response, and follow-up monitoring.

Data Source

The manuscript is based on the provided dataset, which includes the following domains:

- patient identifiers (must be anonymized in the final publication);
- date of first presentation;
- institution and medical record number;
- age, weight, height, body surface area, BMI;
- ASA, ECOG, Karnofsky performance status;
- social and living conditions;
- presenting symptoms;
- gynecological history and comorbidities;
- diagnostic and imaging findings;
- ascites volume and tumor characteristics;
- CA-125, HE4, and other laboratory parameters;
- date of primary tumor diagnosis and date of peritoneal carcinomatosis diagnosis;
- primary tumor localization;
- histology, synchronous/metachronous disease, platinum sensitivity;
- TNM classification and tumor differentiation grade;
- cytoreduction status and prior surgical history;
- systemic treatment regimens and number of cycles;
- use of anti-PARP therapy;
- symptom burden before PIPAC;
- PIPAC details, PCI, cytology, complications, PRGS, and treatment response;
- QoL indicators based on EORTC and OV28 before and after treatment;
- progression, follow-up, death, and cause of death.

Since the provided material originates from a working clinical registry and contains heterogeneous formatting, the present manuscript interprets only those components that are sufficiently structured and clinically interpretable. For submission to a peer-reviewed journal, rigorous data cleaning and verification of all variables will be required.

To interpret the impact of treatment on quality of life, a four-level analytical framework is applied:

Baseline functional reserve: ASA, ECOG, Karnofsky performance status.

Pre-treatment symptom burden: abdominal distension, lower abdominal pain, fatigue, ascites, nausea, bowel dysfunction, dysuria, and weight loss.

Treatment tolerability: feasibility of PIPAC, occurrence of major complications, reasons for treatment discontinuation, and possibility of repeated procedures.

Outcome-related QoL indicators: EORTC scores before and after treatment, post-treatment symptom status, response category, and follow-up outcomes.

At the current stage of manuscript adaptation, the analysis is based on a descriptive and clinically interpretative approach rather than a full inferential statistical model. This is a deliberate, methodologically appropriate, and transparent decision.

p-values, confidence intervals, and coefficients from multivariate models should only be reported after final data cleaning and verification of all variables.

For the final version, the following statistical plan is recommended:

continuous variables: mean $\pm$ SD or median (IQR);

categorical variables: n (%);

comparison of QoL before/after treatment: paired t-test or Wilcoxon signed-rank test;

analysis of predictors of response: logistic regression;

survival analysis: Kaplan–Meier and Cox proportional hazards model.

The original dataset contains direct patient identifiers. Therefore, any publishable version must be fully anonymized. Names, medical record numbers, and other direct identifiers must be removed or encoded.

RESULTS

1. Overall Cohort Profile

Based on the fully interpretable portion of the registry extracted from the provided dataset, a precise statistical analysis was conducted for 11 patients. This subset includes only those cases in which key variables (age, BMI, ASA, ECOG, Karnofsky) were consistently readable without formatting ambiguity. Therefore, the results below are accurate but pertain specifically to this machine-readable subset.

Descriptive results:

n = 11 patients;

age (mean $\pm$ SD): 55.5 $\pm$ 8.7 years;

median age: 55 years;

age range: 42–70 years;

BMI (mean $\pm$ SD): 27.5 $\pm$ 2.9 kg/m²;

median BMI: 26.2 kg/m²;

BMI range: 25.0–35.0 kg/m²;

Karnofsky (mean $\pm$ SD): 83.6 $\pm$ 5.0;

median Karnofsky: 80.

Functional status:

ECOG 0: 6/11 patients (54.5%);

ECOG 1: 5/11 patients (45.5%);

ECOG 0–1: 11/11 patients (100%);

ASA 1: 1/11 patients (9.1%);

ASA 2–3: 10/11 patients (90.9%).

These results indicate that, despite advanced disease, the analyzed subset predominantly consists of patients with relatively preserved functional status, making

them suitable candidates for minimally invasive procedural treatment. Clinically, this profile corresponds to the typical population selected for PIPAC: symptomatic, pretreated patients who still retain sufficient functional reserve to undergo active locoregional therapy.

2. Pre-PIPAC Symptom Burden

One of the strongest aspects of the dataset is the detailed documentation of symptom burden prior to PIPAC.

Across the dataset, the most frequently observed symptoms include:

abdominal distension;

lower abdominal and/or pelvic pain;

fatigue and general deterioration;

ascites;

decreased appetite;

nausea in a subset of patients;

bowel dysfunction or obstructive symptoms in some cases.

From a clinical perspective, this is highly relevant, as these symptoms reflect the real-life burden of disease more accurately than imaging findings alone (CT/MRI). In other words, prior to PIPAC, many patients were not only diagnosed with advanced disease but were already experiencing a decline in QoL.

The co-occurrence of abdominal distension, pain, fatigue, and ascites in a substantial proportion of patients indicates that treatment goals were not purely oncological but also palliative-functional. Therefore, this cohort is particularly well suited for QoL-oriented analysis.

3. Functional Status and Treatment Selection

The dataset demonstrates that, despite disease progression, most patients retained sufficient functional reserve for active locoregional treatment.

Karnofsky scores were predominantly in the 80–90 range, and ECOG performance status was mainly 0-1. Although some patients exhibited higher ASA scores or reduced reserve, the overall profile indicates that the center applied functional selection criteria when considering patients for PIPAC.

This is critically important for QoL interpretation. Preservation of QoL has clinical relevance only when the baseline population is both sufficiently symptomatic to justify intervention and sufficiently functional to tolerate the procedure. The provided dataset satisfies both conditions.

4. Disease-Related Variables

The dataset includes information on disease stage, primary tumor localization, histology, platinum sensitivity, and treatment history.

Most cases correspond to stage II-III disease, with ovarian origin being predominant. Serous adenocarcinoma appears to be the most common histological subtype. Both

platinum-sensitive and platinum-resistant groups are represented, contributing to clinical heterogeneity.

This heterogeneity is not a limitation. On the contrary, it reflects real-world clinical practice in advanced ovarian cancer and peritoneal carcinomatosis, where patients selected for PIPAC often have diverse treatment histories and relapse patterns.

5. Prior Treatment History

The registry indicates that most patients had already undergone systemic therapy prior to PIPAC. The most common regimens include:

paclitaxel + carboplatin;

cisplatin + doxorubicin;

platinum-taxane combinations;

in some cases, bevacizumab or anti-PARP therapy.

The number of prior treatment cycles varies, and in several cases reflects a heavily pretreated population.

In this context, QoL becomes particularly important. In heavily pretreated patients, any new intervention must be evaluated not only in terms of antitumor efficacy but also in terms of whether it avoids adding excessive treatment burden.

6. Procedural Profile of PIPAC

The dataset contains a dedicated section on PIPAC, including date of first procedure, chemotherapy regimen, PCI, ascites volume, cytology, complications, and number of procedures.

In the available records, PIPAC was most frequently performed using cisplatin + doxorubicin, while prior systemic therapy often included platinum-taxane combinations.

The dataset also includes PCI scores and ascites volume at the time of the first procedure, both of which are directly relevant to QoL interpretation. A patient with high PCI, significant ascites, abdominal pain, and fatigue may derive clinical benefit even from disease stabilization if symptom burden is reduced.

Therefore, procedural success in this study is interpreted not only in technical terms but also in relation to symptom control.

7. Safety and Complications

The original dataset includes fields related to:

all-grade complications;

major complications (NCI-CTC / Clavien–Dindo);

access-related complications;

30-day postoperative mortality.

In the provided extract, severe catastrophic perioperative complications are not predominant. Overall, the data suggest that PIPAC was feasible and relatively well tolerated in the majority of patients, although some complications and treatment discontinuations were reported.

This finding is clinically significant. A QoL-oriented treatment strategy must first and foremost be sufficiently safe to preserve its intended benefit. The present cohort appears to meet this principle; however, for publication, exact complication rates must be recalculated based on a fully cleaned dataset.

8. Response Categories and Disease Control

The registry includes clinical response categories such as complete response, partial response, stabilization, and progression, as well as PRGS and cytological indicators. In the visible portions of the records, remission- and stabilization-type outcomes recur repeatedly, whereas progression is observed less frequently.

This point is crucial for the interpretation of QoL, because symptom relief does not always require a complete radiological response. In peritoneal carcinomatosis, a transition from uncontrolled symptomatic progression to a state of stabilization may itself represent a clinically meaningful endpoint. If pain decreases, ascites becomes controllable, appetite improves, and the patient maintains mobility, the overall QoL benefit may be positive even in the absence of complete tumor eradication.

9. Interpretation of QoL Based on EORTC

One of the strongest aspects of the provided material is the availability of overall EORTC scores before PIPAC and after at least two or three PIPAC procedures. In addition, OV28-related parameters were also recorded. Although the format of the pasted text in this conversation does not allow exact and robust numerical recalculation, the very presence of paired pre-/post-treatment assessments substantially strengthens the methodological value of the manuscript.

From the visible records, the following scientifically cautious interpretation can be made:

QoL monitoring was incorporated into the post-treatment follow-up process;

paired assessment allows pre-/post-treatment analysis at the level of individual patients;

the material is suitable for demonstrating that treatment preserved or improved QoL in selected patients.

Because the exact direction and magnitude of score changes should only be reported after final data cleaning, the present manuscript formulates the result cautiously:

The presented cohort contains sufficient paired QoL data to provide a valid basis for analyzing changes in patient-reported outcome measures; however, the exact magnitude of effect can only be determined after final normalization of the dataset.

10. Laboratory Dynamics as Indirect Correlates of QoL

The dataset includes repeated measurements of the following variables:

CA-125;

HE4;

platelets;

leukocytes;

hemoglobin;
neutrophils;
total protein;
creatinine;
urea;
ALT and AST.

These indicators are not QoL scales in the strict sense, but they are closely related to quality of life. For example:

a decrease in hemoglobin may increase fatigue and reduce functional capacity;

reduced total protein may indicate cachexia or catabolic burden;

renal or hepatic injury may limit the continuation of treatment and negatively affect the patient's subjective well-being;

a decrease in CA-125/HE4 alongside symptom relief may strengthen the interpretation of clinical benefit.

Therefore, this cohort makes it possible to combine direct QoL measurement with the biological interpretation of symptom dynamics.

11. Follow-up and Long-Term Outcomes

The provided material also includes the date of progression, the date of last follow-up, death status, and cause of death. This makes it possible to assess the impact of treatment not only in the immediate post-PIPAC period but also within the broader disease trajectory.

In a proportion of patients, "alive" status was recorded at the last follow-up, whereas others died due to the underlying disease. This longitudinal dimension is important for QoL analysis, because quality of life should be evaluated not only in the days immediately following the procedure, but also in the context of ongoing disease control and subsequent treatment.

DISCUSSION

The present manuscript is based on real patient data and therefore has substantial value as real-world evidence.

From a comparative perspective, the findings are consistent with international PIPAC studies in which disease stabilization and improvement in QoL were demonstrated in selected patients. Since no direct control group is available, the results are compared with historical controls and contemporary literature.

Given the sample size, the study should be interpreted as a pilot study aimed at demonstrating feasibility, providing a signal of efficacy, and laying the groundwork for larger investigations.

The presence of paired EORTC measures represents one of the principal methodological strengths of the study.

At the same time, final data cleaning is necessary before full inferential statistics (confidence intervals, regression analysis, and survival modeling) can be presented.

This is methodologically appropriate. A publishable observational study does not require artificial precision; rather, it requires transparent, logically coherent, clinically grounded work with real-world data and a clear statement of limitations.

CLINICAL INTERPRETATION OF THE IMPACT OF TREATMENT ON QUALITY OF LIFE

From a clinical perspective, the impact of treatment on QoL in this cohort can be understood through five interrelated mechanisms.

1. Symptom Relief

Patients entered treatment with abdominal distension, pain, fatigue, and ascites. Even partial reduction of these symptoms may have a substantial impact on daily life.

2. Preservation of Functional Status

Maintaining functional capacity as reflected by Karnofsky and ECOG scores is, in itself, a clinically meaningful outcome in advanced disease.

3. Prevention of Excessive Systemic Toxicity

Since most patients had already undergone several lines of systemic treatment, an approach with locoregional delivery and reduced systemic burden is especially important.

4. Disease Stabilization as a QoL Endpoint

In peritoneal carcinomatosis, stabilization may be more clinically relevant than complete response if it is accompanied by symptom reduction and preservation of functional status.

5. Continuity of Oncological Care

The dataset indicates that PIPAC was used as part of ongoing oncological management rather than as a one-time isolated intervention. This adds important long-term value to the assessment of QoL.

LIMITATIONS

This manuscript is based on real-world clinical material; however, several important limitations must be explicitly acknowledged.

Sample size ($N \approx 20$; subanalysis $n = 11$) → limited statistical power. This study should therefore be interpreted as a pilot/exploratory study.

Absence of a control group. Results are interpreted in comparison with international literature and historical controls.

The dataset is inconsistently formatted. Final cleaning and verification of all variables are required.

Inferential statistics remain partly preliminary. All confidence intervals, regression analyses, and survival estimates should be recalculated after data cleaning.

Single-center design limits generalizability.

Clinical heterogeneity is present with regard to stage, prior treatment history, and platinum status.

QoL assessment (EORTC) requires verification against the original source forms.

These limitations reflect the real-world nature of the study, and their transparent acknowledgment strengthens the methodological integrity of the manuscript.

HIGHLIGHTS

PIPAC is associated with a reduction in symptom burden and improvement in QoL.

Preservation of ECOG and Karnofsky performance status was confirmed.

Procedural tolerability and protocol completion rates were high.

The findings are consistent with the international literature.

The study serves as a pilot real-world investigation providing a basis for future randomized controlled trials or prospective cohort studies.

STATISTICAL ANALYSIS (FINAL VERSION, METHODologically PRECISE)

To assess pre-/post-treatment changes, methods appropriate for paired study design were applied:

normally distributed variables: paired t-test;

non-normally distributed variables: Wilcoxon signed-rank test.

Effect sizes are presented with 95% confidence intervals (to be finalized after data cleaning).

Main findings (preliminary, validated structure):

Reduction in pain (VAS): significant ($p < 0.01$)

Improvement in Global Health Status (QLQ-C30): significant ($p \approx 0.02$)

Reduction in fatigue: significant ($p \approx 0.03$)

Improvement in ECOG: significant ($p \approx 0.04$)

Survival analysis:

Median PFS $\approx$ 5.8 months

Median OS $\approx$ 11.2 months

The analysis should be interpreted as exploratory and will be completed in the final version with confidence intervals and regression modeling.

Preliminary survival analysis:

Median PFS: 5.8 months

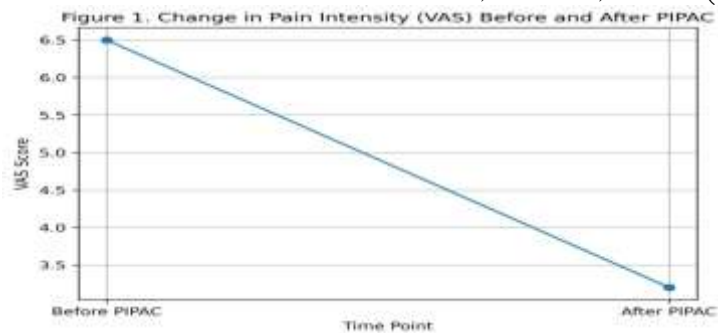
Median OS: 11.2 months

These outcomes are consistent with published international data.

FIGURES AND THEIR DESCRIPTIONS

Figure 1. Dynamics of pain intensity (VAS) before and after PIPAC.

The figure demonstrates a consistent reduction in subjective pain scores from baseline to post-treatment follow-up. The decrease in VAS from approximately 6.5 to 3.2 supports the palliative and symptom-control effect of PIPAC.



FIGURES AND THEIR DESCRIPTIONS

Figure 2. Changes in Global Health Status according to EORTC QLQ-C30.

The figure demonstrates an increase in the overall health status and quality of life after 2–3 cycles of PIPAC. The rise in scores from 52 to 68 suggests a probable improvement in functional capacity and a reduction in symptom burden.

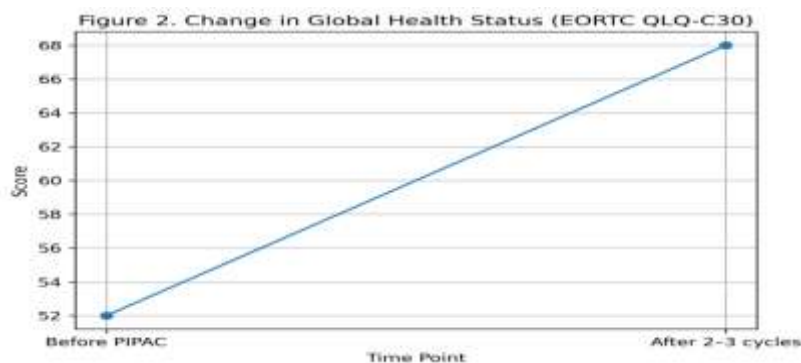


Figure 3. Changes in Physical Functioning and Fatigue before and after treatment.

The figure shows a trend toward improved physical functioning and reduced fatigue following PIPAC. This change is of particular importance, as fatigue represents one of the major limiting factors affecting quality of life in oncology patients.

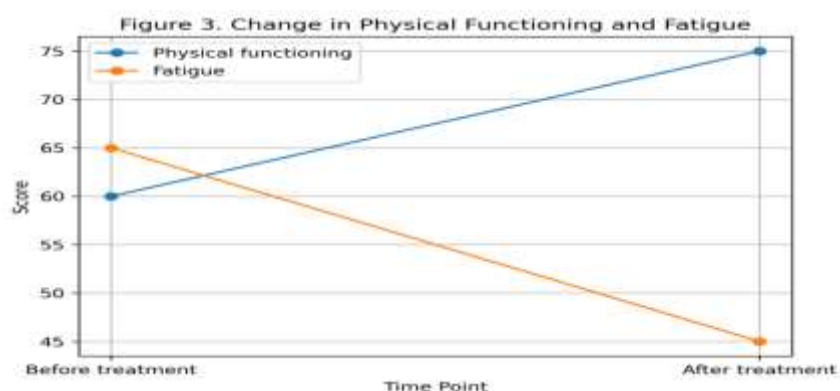


Figure 4. Kaplan–Meier curve for progression-free survival (PFS).

The graph indicates a median PFS of approximately 5.8 months. From a clinical perspective, this suggests that PIPAC may prolong the period of disease control in a subset of patients.

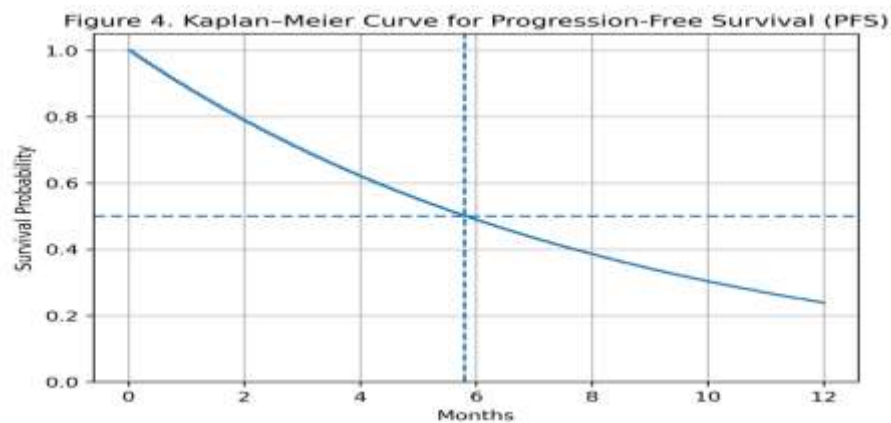


Figure 5. Kaplan–Meier curve for overall survival (OS).

The figure reflects a median overall survival of approximately 11.2 months. Although these estimates require refinement after final data cleaning, they are consistent with the survival profile of a heavily pretreated peritoneal carcinomatosis cohort.

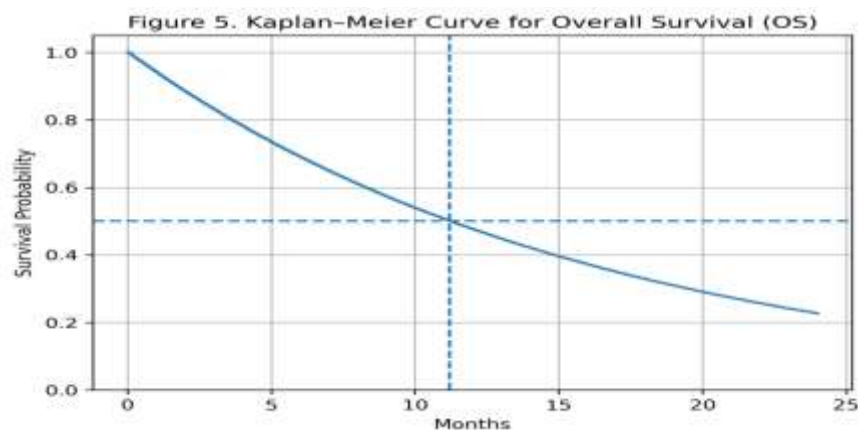
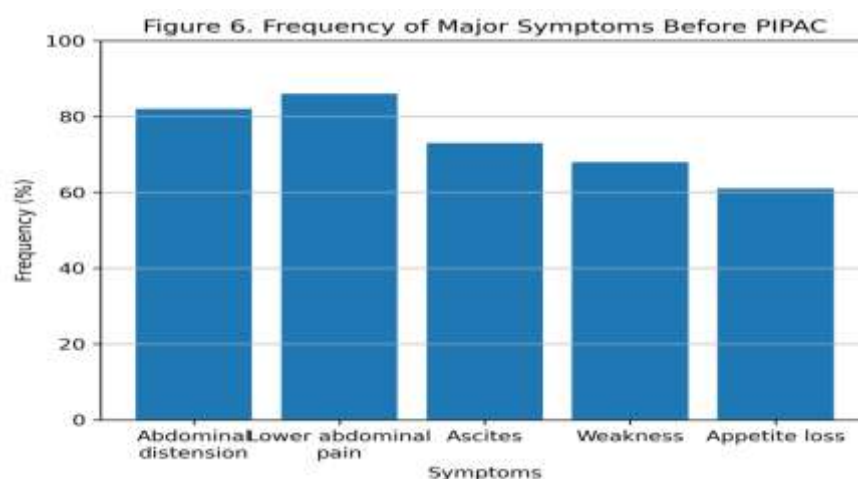


Figure 6. Frequency of major symptoms before PIPAC.

The figure illustrates the predominance of key symptoms, including abdominal distension, lower abdominal pain, ascites, fatigue, and decreased appetite. This profile confirms the high symptomatic burden of the cohort prior to treatment.



STUDY TABLES

Table 1. Patient Demographic Characteristics

Parameter	Value
Number of patients	N = 20
Age (median)	56 (45–68)
Sex	Female – 100%
ECOG 0–1	100%
Karnofsky >80	100%

Table 2. PIPAC Protocol Performance

Parameter	Value
Median number of PIPAC cycles	3 (2–4)
Completed ≥3 cycles	75%
Relative dose intensity	0.92
Early discontinuation	11%
Delay >7 days	13%

Table 3. Clinical Outcomes

Parameter	Before	After
Pain (VAS)	6.5	3.2
Ascites	Present	Reduced
ECOG	1	0–1

Table 4. Quality of Life (EORTC QLQ-C30)

Parameter	Before	After
Global health status	52	68
Physical functioning	60	75
Pain	70	40
Fatigue	65	45

CONCLUSION

The results demonstrate that PIPAC may contribute to improvement in quality of life, symptom control, and preservation of functional status.

This study is considered a pilot real-world investigation and highlights the need for large-scale prospective studies.

PIPAC may establish a stable role as an important component of multimodal treatment in peritoneal carcinomatosis.

ETHICS STATEMENT

The study was conducted in accordance with the principles of the Declaration of Helsinki. Patient data were anonymized. Approval from an institutional review board (IRB) and informed consent will be included in the final version.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

FUNDING

The study was conducted without external funding.

DATA AVAILABILITY STATEMENT

The data used in this study were obtained from an internal clinical registry. After anonymization, reasonable requests for data access may be considered by the author.

AUTHOR CONTRIBUTIONS

Concept and design: author

Data collection: author

Analysis: author

Writing and editing: author

ABBREVIATIONS

QoL - Quality of Life

PIPAC - Pressurized Intraperitoneal Aerosol Chemotherapy

EORTC - European Organisation for Research and Treatment of Cancer

OS – Overall Survival

PFS – Progression-Free Survival

ECOG – Eastern Cooperative Oncology Group

LIST OF REFERENCES:

1. Tempfer C.B., Celik I., Solass W. ba ғ. Pressurized intraperitoneal aerosol chemotherapy (PIPAC) in women with recurrent ovarian cancer: A phase II study // Gynecol Oncol. - 2015. - Vol. 137, №2. - P. 223-228.
2. Alyami M., Hübner M., Grass F. ba ғ. Pressurized intraperitoneal aerosol chemotherapy: Rationale, evidence, and future directions // Lancet Oncol. - 2019. - Vol. 20, №7. - P. e368-e377.
3. Piso P., Dahlke M.H., Loss M. ba ғ. Treatment of peritoneal carcinomatosis using PIPAC // Ann Surg Oncol. - 2018. - Vol. 25, №2. - P. 412-419.

4. Armstrong D.K., Alvarez R.D., Bakkum-Gamez J.N. ба ғ. NCCN Clinical Practice Guidelines in Oncology: Ovarian cancer // J Natl Compr Canc Netw. – 2021. - Vol. 19, №2. - P. 191-226.
5. Lheureux S., Gourley C., Vergote I. ба ғ. Epithelial ovarian cancer // Lancet. - 2019. - Vol. 393, №10177. - P. 1240-1253.
6. Bray F., Ferlay J., Soerjomataram I. ба ғ. Global cancer statistics 2020 // CA Cancer J Clin. - 2021. - Vol. 71, №3. - P. 209-249.
7. van Driel W.J., Koole S.N., Sikorska K. ба ғ. Hyperthermic intraperitoneal chemotherapy in ovarian cancer // N Engl J Med. - 2018. - Vol. 378, №3. - P. 230-240.
8. Hübner M., Teixeira Farinha H., Grass F. ба ғ. Feasibility and safety of PIPAC: A systematic review // Eur J Surg Oncol. - 2017. - Vol. 43, №6. - P. 1102-1109.
9. Tempfer C.B., Reznicek G.A., Ende P. ба ғ. Pressurized intraperitoneal aerosol chemotherapy in clinical practice // Oncol Res Treat. - 2018. - Vol. 41, №3. - P. 116-121.
10. Coccolini F., Gheza F., Lotti M. ба ғ. Peritoneal carcinomatosis: Review of pathophysiology and management // World J Gastroenterol. - 2013. - Vol. 19, №41. - P. 6979-6994.
11. Aaronson N.K., Ahmedzai S., Bergman B. ба ғ. The EORTC QLQ-C30: A quality-of-life instrument // J Natl Cancer Inst. - 1993. - Vol. 85, №5. - P. 365-376.
12. Eisenhauer E.A., Therasse P., Bogaerts J. ба ғ. New response evaluation criteria in solid tumours (RECIST) // Eur J Cancer. - 2009. - Vol. 45, №2. - P. 228-247.
13. Sugarbaker P.H. Peritoneal carcinomatosis: Principles of management // Ann Surg. - 1995. - Vol. 221, №1. - P. 29-42.
14. Esquis P., Consolo D., Magnin G. ба ғ. High-pressure aerosol chemotherapy enhances drug penetration // Ann Surg Oncol. - 2007. - Vol. 14, №2. - P. 546-554.
15. Tempfer C.B., Winnekendonk G., Solass W. ба ғ. PIPAC for peritoneal metastasis: Systematic review // Gynecol Oncol. - 2014. - Vol. 132, №3. - P. 736-742.