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Quality of Life in Women with Early Triple-Negative Breast Cancer and Pembrolizumab Therapy – Preliminary Analysis

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ABSTRACT

Introduction: Triple-negative breast cancer is an aggressive tumor with a high rate of recurrence and metastasis. The addition of pembrolizumab in the neoadjuvant setting is the current standard treatment for early-stage triple-negative breast cancer. Although immunotherapy improves treatment efficacy, its toxicity may impair patients' quality of life.
Objective: To investigate the quality of life of women with early-stage triple-negative breast cancer receiving immunotherapy and to compare it with the quality of life of women with early hormone receptor-positive, HER2-negative breast cancer who do not receive immunotherapy as part of their treatment.
Materials and Methods: The study included 44 women with early-stage breast cancer divided into two groups: the study group, comprising patients with early-stage triple-negative breast cancer receiving pembrolizumab, and the control group, comprising women with hormone receptor-positive, HER2-negative breast cancer treated with chemotherapy alone. Quality of life was assessed using the EORTC QLQ-C30 and EORTC QLQ-BR23 questionnaires. Microsoft Excel and IBM SPSS Statistics version 26 were used for data processing and analysis.
Results: Grade 1–2 immune-mediated toxicity was detected in four patients. Cognitive function in women with triple-negative breast cancer was affected by fatigue ($r = .722$, $p = .000$) and emotional difficulties ($r = .723$, $p = .000$). Fatigue was strongly correlated with existing social problems ($r = .715$, $p = .000$), role functioning ($r = .735$, $p = .000$), loss of appetite ($r = .736$, $p = .000$), and diarrhea ($r = .758$, $p = .000$). Diarrhea affected women's role functioning ($r = .765$, $p = .000$) and showed correlations with anorexia ($r = .883$, $p = .000$), nausea ($r = .747$, $p = .000$), and vomiting ($r = .682$, $p = .000$). The incidence of treatment-related adverse events was higher in the pembrolizumab group. Pembrolizumab treatment resulted in a higher incidence of cognitive impairment, sexual dysfunction, fatigue, sleep disturbances, dyspnea, and diarrhea than chemotherapy alone.
Conclusion: Immunotherapy is a standard treatment for triple-negative breast cancer, with good tolerability and a manageable safety profile. Patients in the present study demonstrated preserved quality of life during pembrolizumab treatment, and further research on this topic is warranted.

Keywords: Pembrolizumab, immunotherapy, triple-negative breast cancer, quality of life

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INTRODUCTION

Triple-negative breast cancer (TNBC) is an aggressive tumor type associated with a high rate of recurrence and metastasis. Patients with histologically confirmed early-stage TNBC have poorer overall survival and progression-free survival than patients with other breast cancer subtypes (1). One study reported a recurrence rate of nearly 50% (locoregional recurrence or distant metastasis) in patients with early-stage TNBC despite treatment with neoadjuvant and adjuvant chemotherapy (2). Strategies to improve outcomes in patients with early-stage TNBC, including the addition of immunotherapy (programmed cell death protein 1 [PD-1] inhibitors or programmed cell death ligand 1 [PD-L1] inhibitors) to chemotherapy and the use of targeted therapies (e.g., poly [ADP-ribose] polymerase inhibitors), have been investigated in recent years, with some already approved for clinical use (3).

The addition of the anti-PD-1 antibody pembrolizumab to neoadjuvant chemotherapy has demonstrated manageable safety and clinical benefit in several studies involving patients with high-risk, early-stage TNBC (4-9). Patients received neoadjuvant pembrolizumab plus chemotherapy, followed by surgery and adjuvant pembrolizumab (7). Treatment with pembrolizumab resulted in clinically meaningful and statistically significant improvements in this patient population (10). The frequency and severity of adverse events were consistent with the known safety profiles of the individual treatment components (7).

Neoadjuvant chemotherapy (NAC) combined with pembrolizumab (anti-PD-1) is the current standard treatment for early-stage TNBC. Although immunotherapy improves treatment efficacy, its toxicity must be considered, as many adverse events are long-lasting in this patient population and may impair quality of life.

For patients with breast cancer, quality of life is an important consideration in treatment decision-making (11). Breast cancer treatment, including chemotherapy, can increase symptom severity and negatively affect quality of life, while immunotherapy may further impair patients' normal functioning (12-14).

Aim and Objectives

The aim of this study was to investigate the quality of life of women with early-stage TNBC receiving chemotherapy in combination with immunotherapy (pembrolizumab) or adjuvant immunotherapy (pembrolizumab) and to compare it with the quality of life of women with early-stage hormone receptor-positive, HER2-negative breast cancer who did not receive immunotherapy as part of their treatment.

Patients with early-stage TNBC were compared with patients with early-stage hormone receptor-positive, HER2-negative breast cancer because the chemotherapy regimens administered in both groups included anthracyclines and taxanes. Therefore, the expected adverse reactions to chemotherapy and their impact on quality of life were considered to be comparable.

A comparison between patients with TNBC treated with immunotherapy and a control group of patients with TNBC not receiving immunotherapy could not be performed because immunotherapy is the current standard treatment for early-stage triple-negative breast cancer.

The objectives of the study were:

- To investigate the quality of life of patients treated with and without immunotherapy.
- To determine the presence or absence of interrelationships between the studied variables in patients receiving pembrolizumab.

MATERIAL AND METHODS

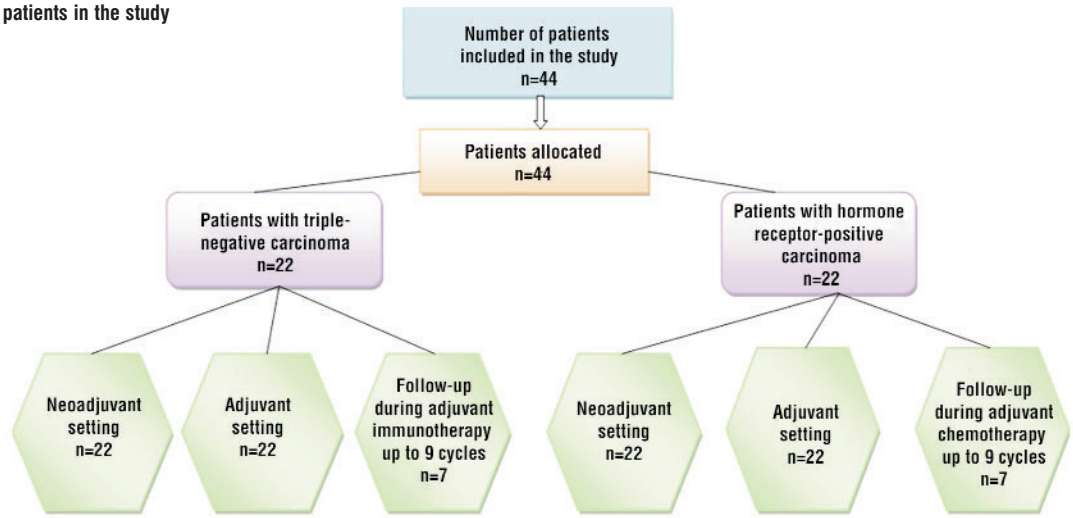
The present study was a prospective, single-center study conducted between January 2024 and August 2025. A total of 44 women with early-stage breast cancer were included and divided into two groups: the study group, comprising patients with early-stage TNBC receiving pembrolizumab in the neoadjuvant and adjuvant settings, and the control group, comprising women with hormone receptor-positive, HER2-negative breast cancer treated with chemotherapy alone, without pembrolizumab (*fig. 1*).

The study investigated the relationships, interrelationships, and patterns between disease- and treatment-related factors and their effects. The study was conducted at the Department of Medical Oncology, University Hospital – Pleven. The research protocol was developed and approved by the Ethics Committee of the Medical University of Pleven. Patients who agreed to participate in the study were provided with information about its purpose and procedures and subsequently signed a written informed consent form (*table 1*).

The participants were evaluated using a direct individual survey. Patients received pembrolizumab treatment in several stages according to the KEYNOTE-522 study protocol (*fig. 2*).

Neoadjuvant chemotherapy consisted of carboplatin at an area under the curve (AUC) of 5 every 3 weeks plus paclitaxel 80 mg/m^2 administered weekly

Figure 1 - Flowchart of patients in the study



for four cycles (12 weeks), followed by epirubicin 90 mg/m^2 every 3 weeks plus cyclophosphamide 600 mg/m^2 every 3 weeks for four cycles (12 weeks). Patients subsequently underwent surgery and continued adjuvant treatment with pembrolizumab 200 mg every 3 weeks for up to nine cycles.

The control arm subjects underwent neoadjuvant chemotherapy:

1. Epirubicin 90 mg/m^2 + Cyclophosphamide 600 mg/m^2 every 21 days for 4 cycles.

Adjuvant treatment continued with:

1. Paclitaxel 175 mg/m^2 4 cycles every 21 days or 12 weeks Paclitaxel 80 mg/m^2.

Table 1 - Inclusion and exclusion criteria

Inclusion criteria:
- age ≥ 18 years;
- histologically confirmed diagnosis;
- stages I-III;
- newly diagnosed, previously untreated, non-metastatic disease (T1-T3, N1-N2);
- easter Cooperative Oncology Group ((ECOG) performance status of 0 or 1;
- adequate organ function;
- eligible for neoadjuvant or adjuvant treatment with anthracyclines, taxanes, and pembrolizumab.
Exclusion criteria:
- active autoimmune disease requiring systemic treatment within the previous 2 years;
- diagnosis of immunodeficiency or use of immunosuppresive therapy in the previous week.

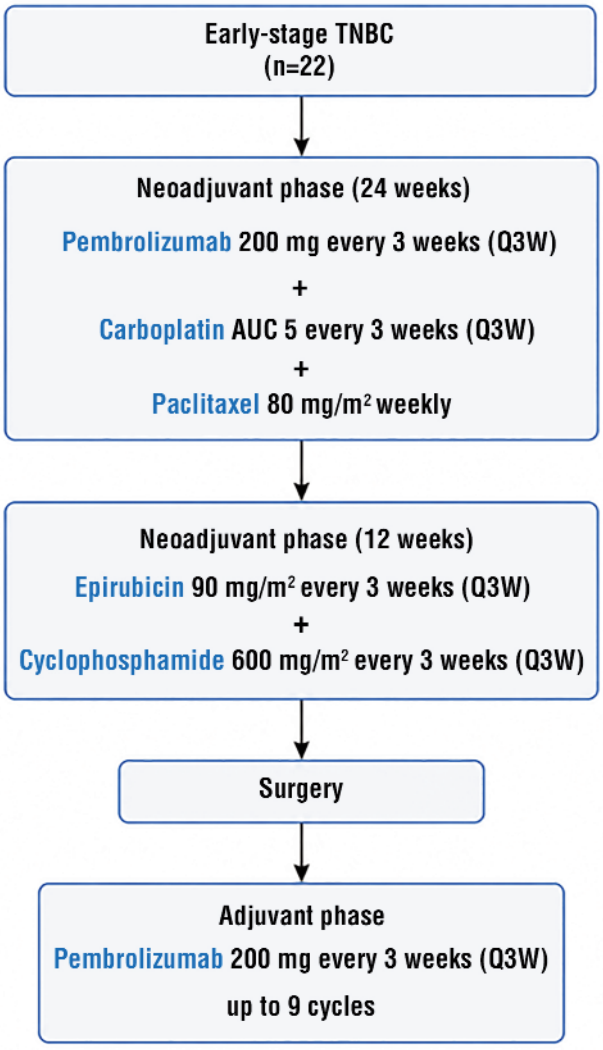


Figure 2 - KEYNOTE-522 study design

Methods

The EORTC QLQ-C30 and EORTC QLQ-BR23 questionnaires were used in this study. The EORTC QLQ-C30 is a self-administered, 30-item, cancer-specific questionnaire that assesses 15 domains, including five functional scales (physical, role, emotional, cognitive, and social functioning), nine symptom scales or single items (fatigue, nausea and vomiting, pain, dyspnea, insomnia, loss of appetite, constipation, diarrhea, and financial difficulties), and global health status/quality of life (GHS/QoL). The EORTC QLQ-BR23 is a breast cancer-specific module consisting of 23 items, including four functional scales (body image, sexual functioning, sexual enjoyment, and future perspective) and four symptom scales (systemic therapy side effects, breast symptoms, arm symptoms, and upset by hair loss). A higher score for the GHS/QoL and functional scales indicates better quality of life and functioning, whereas a higher score for the symptom scales or individual items indicates a greater symptom burden.

Microsoft Excel and IBM SPSS Statistics version 26 were used for data processing and statistical analysis.

The EORTC QLQ-C30 and EORTC QLQ-BR23 questionnaires were completed during active systemic treatment before the scheduled treatment cycle at the study visit.

Demographic Characteristics

Among the patients who underwent surgery at the time of analysis, pathological complete response (pCR) was achieved in 11 of 13 patients (84.6%) with TNBC and in 6 of 16 patients (37.5%) with hormone receptor-positive, HER2-negative breast cancer (*table 2*).

Patient distribution according to tumor biology, disease stage, and treatment phase is presented in *table 3*.

Analysis of Immune-Mediated Toxicity

Grade 1–2 immune-mediated toxicity was identified in four patients. No inter-ruption of pembrolizumab treatment was required. Skin toxicity was observed in three women, and immune-mediated thyroid dysfunction was observed in one patient.

Analysis of the Functional Scales of the EORTC QLQ-C30

Physical functioning

The results of the physical functioning assessment showed that only 3 (13.6%) women receiving immunotherapy reported no difficulties in performing their usual daily physical activities, whereas 19 (86.4%) experienced difficulties in performing daily tasks. Among patients who did not receive immunotherapy, the results were comparable, with 4 women (18%) reporting no difficulties.

Role functioning

Role functioning includes occupational, daily, and social functioning related to hobbies and leisure activities. Among patients receiving pembrolizumab, 8 (36.4%) were unable to perform their usual role-related activities, whereas the remaining 14 (63.6%) were able to maintain their work, daily activities, and social roles. Similar findings were observed in patients treated with chemother-apy alone.

Cognitive functions

Cognitive functioning was assessed using two questions addressing concentration and memory. Cognitive

Table 2 - Demographic characteristics of the study population

Characteristic	Pembrolizumab + Chemotherapy (n = 22)	Chemotherapy Alone (n = 22)
Education		
Primary	2 (9%)	3 (14%)
Secondary	8 (36%)	9 (41%)
College	3 (14%)	1 (5%)
Higher	9 (41%)	6 (27%)
Age Group (years)		
18–35	1 (5%)	2 (9%)
35–50	1 (5%)	4 (18%)
50–65	14 (64%)	11 (50%)
>65	6 (27%)	5 (23%)
Place of Residence		
Capital city	1 (5%)	2 (9%)
Large city	11 (50%)	9 (41%)
Small town	6 (27%)	9 (41%)
Village	4 (18%)	2 (9%)
Marital Status		
Married	14 (64%)	11 (50%)
Divorced	2 (9%)	6 (27%)
Living with parents	1 (5%)	–
Living alone	2 (9%)	4 (18%)
Living with child(ren)	3 (13%)	1 (5%)
Living with relatives	–	–
Living with a friend	–	–
Other	–	–
Employment Status		
Employed	16 (74%)	14 (64%)
Unemployed	6 (26%)	8 (36%)

Table 3 - Clinicopathological characteristics of the study population

Characteristic	Pembrolizumab + Chemotherapy (n = 22)	Chemotherapy Alone (n = 22)
Treatment phase		
Neoadjuvant treatment	9	6
Adjuvant treatment	8	13
Completed neoadjuvant and adjuvant treatment	5	3
ER/PR/HER2 status		
ER-/PR-/HER2 0	14 (64%)	1 (5%)
ER-/PR-/HER2 1+	8 (36%)	1 (5%)
ER-/PR-/HER2 3+	–	4 (18%)
ER+/PR+/HER2 0	–	9 (41%)
ER+/PR+/HER2 1+	–	4 (18%)
ER+/PR+/HER2 3+	–	3 (14%)
Histological type		
Poorly differentiated invasive ductal carcinoma	7 (32%)	9 (40%)
Moderately differentiated invasive ductal carcinoma	6 (27%)	2 (9%)
Lobular carcinoma	3 (14%)	7 (33%)
Invasive ductolobular carcinoma	2 (9%)	2 (9%)
Invasive apocrine carcinoma	2 (9%)	–
TNM stage		
T1N0M0	3 (14%)	–
T1N1M0	2 (9%)	2 (9%)
T2N0M0	3 (14%)	4 (18%)
T2N1M0	6 (26%)	6 (26%)
T3N0M0	3 (14%)	4 (18%)
T2N2M0	4 (18%)	5 (24%)
T3N1M0	1 (5%)	1 (5%)

Abbreviations: ER, estrogen receptor; PR, progesterone receptor; HER2, human epidermal growth factor receptor 2.

problems were absent in 13 (59.1%) patients receiving pembrolizumab, whereas the remaining 9 (40.9%) reported memory impairment of varying severity. In the chemotherapy-alone group, cognitive problems were absent in 19 (86.4%) patients and were reported by 3 (13.6%) women. The difference between the two groups did not reach statistical significance (p = 0.088).

Emotional functions

Emotional functioning was assessed using four questions evaluating anxiety, tension, nervousness, and depression. Among patients receiving immunotherapy, 7 (31.8%) reported no emotional disturbances, whereas the remaining 15 (68.2%) experienced emotional problems of varying severity. These women frequently reported anxiety, tension, and emotional instability. In patients who did not receive immunotherapy, the results were comparable.

Social functions

Social functioning was assessed using two questions evaluating the impact of the disease and treatment on family life and social activities. Among women receiving immunotherapy, 11 (50%) reported that their disease had no effect on their family life or social activities, whereas the remaining 11 (50%) reported limitations in their social contacts and social activities because of their disease. Similar results were observed in patients who did not receive immunotherapy.

Analysis of the EORTC QLQ-30 Symptom Scales

Dyspnea was reported by 5 (22.7%) women receiving immunotherapy and was absent in 17 (77.3%). In the chemotherapy-alone group, no patient reported dyspnea. The difference between the two groups was statistically significant (p = 0.048).

Pain was assessed using two questions: whether the patient experienced pain and whether pain interfered with usual daily activities. Eleven women (50%) reported no pain, whereas the remaining 11 (50%) experienced pain. Similar results were observed in both the pembrolizumab and chemotherapy-alone groups.

Fatigue was assessed using three questions addressing the need for rest, feelings of weakness, and tiredness. Among women receiving immunotherapy, 18 (81.8%) reported fatigue and the need for rest. In the chemotherapy-alone group, fatigue was reported by 11 (50.0%) patients. The difference between the two groups did not reach statistical significance (p = 0.055).

Sleep disturbances related to the disease and its treatment were reported by 14 (63.7%) patients, whereas the remaining 8 (36.3%) experienced no sleep dis-turbances or only minimal symptoms. The results were comparable between the two groups.

Loss of appetite, nausea, and vomiting were absent in 18 (81.8%) women re-ceiving immunotherapy. Similar findings were observed in the chemotherapy-alone group.

Constipation was absent in 17 (77.3%) women in both groups. The remaining 5 (22.7%) patients reported constipation.

Diarrhea was reported by 19 (86.4%) women receiving pembrolizumab, whereas only 5 (22.7%) women in the chemotherapy-alone group reported this symptom. The difference between the two groups was statistically significant (p < 0.001).

The participants were also asked whether they had financial concerns. Among patients receiving immuno-therapy, 18 (81.8%) reported financial concerns, whereas only 4 (18.2%) did not. In the chemotherapy-alone group, financial concerns were less common, with 5 (22.7%) women reporting anxiety about their financial situation. Financial concerns were significantly more frequent in the pembrolizumab group than in the chemotherapy-alone group ($p < 0.001$).

Participants were asked to rate their overall health on a scale from 1 (very poor) to 7 (excellent). They were also asked to rate their overall quality of life using the same scale. All women reported that their quality of life had been main-tained in both study groups. Responses regarding global health status indicated that most participants perceived their quality of life as preserved despite their disease.

Analysis of the Results of the EORTC QLQ-BR23 Questionnaire

Patients were asked eight questions regarding treatment-related side effects, in-cluding dry mouth, changes in taste, hair loss, watery, painful or irritated eyes, hot flashes, headache, and feeling ill or unwell. Among women receiving pembrolizumab, 2 (9%) reported that they had none of these symptoms and were not bothered by treatment-related side effects. The remaining 20 (91%) reported one or more treat-ment-related adverse effects. In the chemotherapy-alone group, 11 (50%) women reported treatment-related side effects.

Four questions assessed body image, including whether patients felt less femi-nine or attractive because of the disease and its treatment, experienced difficulty looking at themselves naked, or were dissatis-fied with their bodies. None of the women receiving pembrolizumab reported the absence of body image con-cerns. All 22 (100%) reported dissatisfaction with their appearance, feelings of reduced femininity and attractiveness, and difficulty looking at themselves na-ked. Nine women reported severe distress related to these concerns. Body im-age dissatisfaction was common among the study participants as a result of both the disease and its treatment. Similar findings were observed in the chem-otherapy-alone group.

Patients were also asked whether they were concerned about their future health. All 22 (100%) women receiving pembrolizumab reported anxiety and concern about their future health. In the chemo-therapy-alone group, 13 (59%) women reported similar concerns.

Sexual functioning was assessed by asking patients about their interest in sexu-al activity and their level of sexual activity. In both groups, patients reported reduced sexual desire and decreased sexual activity, which were slightly more pronounced among women receiving pembrolizumab. Sixteen women (73%) in the pembrolizumab group reported little or no sexual interest. Sexual satis-faction was absent in all women receiving pembrolizumab (100%; n = 22). Sexual problems were observed in most women with breast cancer regardless of treatment, although they appeared to be more pronounced in patients receiv-ing immunotherapy.

Three questions evaluated arm-related symptoms following breast surgery, in-cluding pain in the arm or shoulder, swelling of the arm or hand, and difficulty moving the arm. Eleven women (50%) reported no arm-related symptoms, whereas the remaining 11 (50%) experienced one or more of these symptoms. These findings were comparable between the two groups and were mainly as-sociated with surgical treatment, particularly radiotherapy.

The final four questions assessed breast-related symptoms, including breast pain, swelling, increased sensitivity, and skin changes such as itching, dryness, and peeling. Nine women (41%) reported no breast-related symptoms because they had not yet undergone surgery. The remaining 13 (59%), all of whom had undergone surgery, reported one or more of these symptoms, which in some cases negatively affected their quality of life.

Analysis of Correlations

Table 4 presents the correlations between the symptom and functional scales in patients with TNBC treated with chemotherapy plus immunotherapy.

The following strong and very strong correlations were identified:

Cognitive functioning in women with TNBC was strongly associated with fa-tigue ($r = .722$, $p = .000$) and emotional difficulties ($r = .723$, $p = .000$).

Fatigue was strongly correlated with:

- social problems ($r = .715$, $p = .000$);
- role functioning ($r = .735$, $p = .000$);
- loss of appetite ($r = .736$, $p = .000$); and
- diarrhea ($r = .758$, $p = .000$).

Diarrhea was strongly associated with impaired role functioning ($r = .765$, $p = .000$) and was correlated with loss of appetite ($r = .883$, $p = .000$), nausea ($r = .747$, $p = .000$), and vomiting ($r = .682$, $p = .000$).

Table 4 - Corelation analysis of the functional and symptom scales in patients with TNBC treated with Pembrolizumab plus chemotherapy

Correlations	Physical functioning	Emotional functioning	Cognitive functioning	Social functioning	Role functioning	Fatigue	Pain	Loss of apetite	Nausea	Vomiting	Diarrhea
Physical functioning	1	0.417	0.431*	0.383	0.314	0.483*	0.387	0.285	0.310	0.224	0.078
Emotional functioning	0.417	1	0.698**	0.587**	0.692**	0.723**	0.564**	0.500*	0.479*	0.417	0.577**
Cognitive functioning	0.431*	0.698**	1	0.487*	0.422	0.722**	0.479*	0.409	0.258	0.185	0.461*
Social functioning	0.383	0.587**	0.487*	1	0.648**	0.715**	0.387	0.634**	0.565**	0.565**	0.613**
Role functioning	0.314	0.692**	0.422	0.648**	1	0.735**	0.533*	0.711**	0.733**	0.659**	0.765**
Fatigue	0.483*	0.723**	0.722**	0.715**	0.735**	1	0.647**	0.736**	0.582**	0.523*	0.758**
Pain	0.387	0.564**	0.479*	0.387	0.533*	0.647**	1	0.594**	0.275	0.208	0.481*
Loss of apetite	0.285	0.500*	0.409	0.634**	0.711**	0.736**	0.594**	1	.645**	0.518**	0.883**
Nausea	0.310	0.479*	0.258	0.565**	0.733**	0.582**	0.275	0.645**	1	0.948**	0.747**
Vomiting	0.224	0.417	0.185	0.565**	0.659**	0.523*	0.208	0.518*	0.948**	1	0.682**
Diarrhea	0.078	0.577**	0.461*	0.613**	0.765**	0.758**	0.481*	0.883**	0.747**	0.682**	1

DISCUSSION

The most common adverse reactions associated with the medications adminis-tered to the study participants are presented in *table 5*.

TNBC is the most aggressive subtype of breast cancer, and treatment options remain limited. The addition of pembrolizumab to the treatment regimen has been shown to improve the rate of pathological complete response (pCR) (15).

In the present study, which included patients with previously untreated early-stage triple-negative breast cancer, a higher rate of pathological complete re-sponse was observed in the pembrolizumab plus chemotherapy group than in the chemotherapy-alone group.

The adverse reactions observed in the pembro-lizumab plus chemotherapy group were generally consistent with the known safety profiles. The incidence of treatment-related adverse events was higher in the pembrolizumab plus chemotherapy group than in the chemotherapy-alone group, consistent with previous studies (16,17). As previously reported, immune-mediated adverse events were observed during pembrolizumab treatment. In the present study, only four patients experienced immune-mediated toxicity (18,19).

Our findings are generally consistent with the KEYNOTE-522 trial, which demonstrated that the addition of pembrolizumab to neoadjuvant chemo-therapy improves pathological complete response while maintaining a manageable safety profile. Similar to KEYNOTE-522, immune-mediated adverse events in our cohort were infrequent and mostly mild, with no patient requiring treatment discontinuation.

Compared with randomized trials such as KEYNOTE-522, I-SPY2, and IMpassion031, the present study reflects real-world clinical practice and emphasizes patient-reported quality of life. The higher frequency of fatigue, diarrhea, cognitive complaints, and sexual dysfunction observed in our cohort underlines the importance of routine quality-of-life assessment during pembrolizumab treatment. Because of the single-center design and limited sample size, direct comparisons with large randomized trials should be interpreted with caution. More recently, the final overall survival analysis of the KEYNOTE-522 trial confirmed a significant long-term survival benefit with pembrolizumab plus chemotherapy, with an estimated 5-year overall survival of 86.6% compared with 81.7% in the placebo-chemotherapy group, further supporting pembrolizumab as the standard of care for patients with early-stage triple-negative breast cancer (20).

Pembrolizumab treatment was associated with a

Table 5 - Most common adverse drug reactions associated with the medications used in the study

Medication	Most common adverse drug reactions
Epirubicin	Gastrointestinal toxicity (nausea, vomiting); alopecia; stomatitis/mucositis; hematologic toxicity; extravasation; fatigue
Cyclophosphamide	Hematologic toxicity; alopecia; hemorrhagic cystitis; fever
Paclitaxel	Tachycardia; hematologic toxicity; peripheral neuropathy; gastrointestinal toxicity (nausea, diarrhea, vomiting, constipation, stomatitis); dyspnea; fatigue
Pembrolizumab	Pneumonitis; colitis/diarrhea; endocrinopathies; hepatitis; skin toxicity; fatigue

higher frequency of cognitive impairment than chemotherapy alone; however, the difference was not statistically significant.

Dyspnea and diarrhea were significantly more frequent in the pembrolizumab group, whereas fatigue showed a non-significant trend toward a higher frequency. Sleep disturbances were numerically more common in the pembrolizumab group, most likely reflecting the toxicity profile of pembrolizumab.

Sexual dysfunction appeared to be more pronounced in patients receiving immunotherapy than in the chemotherapy-alone group.

Financial concerns were more frequently reported by women receiving pem-brolizumab, mainly because immunotherapy was perceived as an expensive treatment.

Treatment-related adverse events were observed more frequently in the pembrolizumab combination group than in the control group. Skin toxicity, an immune-mediated adverse event, was observed only in the pembrolizumab group and was not reported in the control group.

The results of the remaining symptom and functional scales were comparable between the two groups.

Changes in physical, emotional, and social functioning were reported in both groups.

All participants reported concerns, fear, and anxiety regarding their future health.

In this preliminary study, a higher rate of pathological complete response was observed in patients receiving immunotherapy, while quality of life was preserved and no patient required treatment discontinuation because of toxicity. These findings should be interpreted with caution because of the limited sample size and require confirmation in larger prospective studies.

Strengths of the Study

The main strength of this study is the assessment of quality of life in women with early-stage TNBC receiving pembrolizumab in routine clinical practice and its comparison with a control group of women with hormone receptor-positive, HER2-negative breast cancer treated without immunotherapy.

Limitations

The present study has several limitations. First, it was conducted at a single center and included a relatively small number of patients (22 per group), limiting the statistical power and generalizability of the findings. Second, the control group consisted of patients with hormone receptor-positive, HER2-negative breast cancer because pembrolizumab is the current standard of care for early-stage triple-negative breast cancer, making a TNBC control group without immunotherapy ethically inappropriate. Differences in tumor biology may therefore represent potential confounding factors. Finally, no multivariate analysis was performed to adjust for age, disease stage, menopausal status, or treatment phase because the small sample size would have resulted in statistically underpowered models. Larger multicenter prospective studies are needed to validate these findings.

CONCLUSION

Quality of life is an important aspect of breast cancer management. Immunotherapy represents a relatively new approach in the treatment of TNBC and is characterized by good tolerability, a manageable safety profile, and a high rate of pathological complete response. Further studies are needed to evaluate the long-term effects and toxicity of pembrolizumab and their impact on the quality of life of patients with early-stage triple-negative breast cancer.

Author's Contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

Conflicts of Interest

The authors declare no competing interests in this work.

Ethical Statement

The study was conducted in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the Ethics Committee of the Medical University – Pleven. Written informed consent was obtained from all participants before enrolment in the study.

Data Sharing Statement

Authors declare that all related data are available

concerning researchers by the corresponding author's email.

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