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Original article

Pain Dynamics in Patients with Breast Cancer–Related Spinal Metastases Following Standard and Extended Multimodal Treatment: Results of a Prospective Cohort Study

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Abstract

Spinal metastases represent one of the most severe complications of advanced breast cancer and are associated with persistent chronic pain, impaired functional status, and reduced quality of life. Contemporary management involves a multimodal approach integrating local, systemic, and supportive treatment modalities. However, the contribution of individual components of multimodal therapy to pain control remains to be fully elucidated.

Objective. To evaluate changes in pain intensity in patients with breast cancer–related spinal metastases following standard and extended multimodal treatment.

Materials and Methods. A prospective, open-label, controlled, non-randomized cohort study with parallel-group comparison was conducted. Seventy-five patients with histologically confirmed stage IV breast cancer and radiologically verified spinal metastases were enrolled. All participants received standard multimodal treatment consisting of percutaneous vertebroplasty, radiotherapy, and antiresorptive therapy. Patients in the intervention group (n=30) additionally received nutritional supplementation with freeze-dried mare's milk (Saumal), whereas those in the control group (n=45) received no additional nutritional support. Pain intensity was assessed using the Visual Analog Scale (VAS) before treatment and at 2 weeks, 1 month, 3 months, and 6 months after treatment initiation.

Results. Baseline pain intensity was comparable between the groups, with mean VAS scores of 7.37±0.56 in the intervention group and 7.40 ± 0.62 in the control group (p=0.927). During follow-up, both groups demonstrated a statistically significant reduction in pain intensity compared with baseline (p<0.001). At the 6-month assessment, mean VAS scores decreased to 3.23 ± 0.73 in the intervention group and 3.16 ± 0.64 in the control group. No significant between-group differences in pain reduction were observed throughout the study period (p=0.761). A clinically meaningful reduction in pain

intensity exceeding 2 VAS points was achieved as early as 2 weeks after treatment initiation and was maintained throughout the 6-month follow-up.
Conclusions. Standard multimodal treatment provides substantial and sustained pain relief in patients with breast cancer–related spinal metastases over a six-month follow-up period. The addition of freeze-dried mare's milk (Saumal) to the treatment regimen did not result in a statistically significant improvement in VAS pain scores but did not interfere with the beneficial effects of the standard multimodal therapeutic approach.

Keywords: breast cancer, spinal metastases, pain syndrome, Visual Analog Scale (VAS), percutaneous vertebroplasty, multimodal treatment.

1. Introduction

Breast cancer is the most common malignancy among women worldwide and remains one of the leading causes of cancer-related mortality. Despite substantial advances in diagnosis and treatment, a considerable proportion of patients eventually develop advanced disease with dis distant metastases. The skeletal system is one of the most frequent sites of metastaticead in breast cancer, with the spine representing the predominant location of bone involvement [1].

Spinal metastases are associated with a broad spectrum of severe clinical manifestations, among which chronic pain is the most prominent and disabling symptom [2]. Pain resulting from metastatic involvement of the spine is multifactorial and is caused by several pathophysiological mechanisms, including tumor-induced bone destruction, mechanical instability of the affected vertebral segment, compression of neural structures, and local inflammatory changes within the metastatic lesion [3,4]. Persistent pain markedly limits patients' mobility, reduces their ability to perform activities of daily living, impairs sleep quality, negatively affects psychological well-being, and may compromise tolerance to subsequent anticancer treatment.

Current management strategies for patients with spinal metastases are based on a multimodal therapeutic approach combining local and systemic treatment modalities. One of the principal methods of symptomatic management is percutaneous vertebroplasty [7], which provides mechanical stabilization of the affected vertebra and effective pain relief. In combination with radiotherapy and bone-modifying agents, this approach targets multiple mechanisms involved in the pathogenesis of metastatic bone pain and contributes to improved functional outcomes.

Despite the widespread implementation of multimodal treatment strategies, optimization of therapeutic approaches for patients with breast cancer–related spinal metastases remains an important clinical challenge. Particular attention has recently been directed toward the evaluation of adjunctive supportive interventions that may improve treatment tolerance, patients' general condition, and overall clinical outcomes. Nevertheless, effective pain control remains the primary indicator of therapeutic success in this patient population, as pain reduction is one of the most important determinants of quality of life.

At present, evidence directly comparing standard multimodal treatment with an extended multimodal approach incorporating additional supportive interventions in patients with breast cancer metastatic to the spine remains limited. Clarifying the impact of these treatment strategies on pain dynamics may contribute to further optimization of symptomatic management and improve the quality of care for this patient population.

The aim of this study was to evaluate changes in pain intensity in patients with breast cancer–related spinal metastases following standard and extended multimodal treatment.

2. Materials and methods

Study Design

A prospective, open-label, controlled, non-randomized cohort study with parallel-group comparison was conducted to evaluate changes in pain intensity among patients with breast cancer–related spinal metastases following standard and extended multimodal treatment.

The study was conducted between 2022 and 2025 at clinical centers in Astana, Republic of Kazakhstan. Each patient was followed for a period of six months after treatment initiation. The study was performed in accordance with the principles of the Declaration of Helsinki [5], the Good Clinical Practice (GCP) guidelines [5], and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)

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Statement for observational studies [6]. The study protocol was approved by the Local Bioethics Committee (Protocol No. 11, July 1, 2024). Written informed consent was obtained from all patients before study enrollment.

A total of 75 patients with histologically confirmed stage IV breast cancer and radiologically confirmed spinal metastases were included. According to the treatment received, patients were assigned to one of two groups:

Intervention group (n=30): patients receiving standard multimodal treatment supplemented with nutritional support using freeze-dried mare's milk (Saumal) [8].

Control group (n=45): patients receiving standard multimodal treatment without additional nutritional support.

Group allocation was based on the treatment protocol and the availability of the additional nutritional intervention. No randomization was performed.

Inclusion Criteria

Patients were eligible for inclusion if they met all of the following criteria:

-female sex;

-age ≥18 years;

-histologically confirmed invasive breast cancer;

-stage IV disease;

-radiologically confirmed spinal metastases on magnetic resonance imaging (MRI) and/or computed tomography (CT);

-baseline pain intensity ≥4 on the Visual Analog Scale (VAS);

-Spinal Instability Neoplastic Score (SINS) ≤12;

-preserved or moderately impaired neurological function (Frankel grades D–E);

-ability to complete clinical questionnaires;

-provision of written informed consent.

Exclusion Criteria

Patients were excluded if any of the following criteria were present:

-severe spinal instability (SINS ≥13) requiring open surgical stabilization;

-complete spinal cord injury (Frankel grades A–B);

-active infection;

-uncorrectable coagulopathy;

-contraindications to percutaneous vertebroplasty;

-previous vertebroplasty at the target vertebral level;

-expected survival of less than 3 months;

-inability to assess pain intensity;

-pregnancy or breastfeeding;

-allergy or intolerance to the components of Saumal (intervention group only).

Treatment Protocol

All patients received a standard multimodal treatment regimen consisting of:

Percutaneous vertebroplasty, performed to stabilize the affected vertebral segments and reduce mechanically induced pain. The procedure was carried out under fluoroscopic guidance using polymethyl methacrylate (PMMA) bone cement. A transpedicular approach was used in the majority of cases.

Radiotherapy directed to the affected spinal segments. The standard radiation schedule consisted of a total dose of 30 Gy delivered in 10 fractions (3 Gy per fraction).

Bone-modifying therapy, including bisphosphonates or denosumab administered in combination with calcium and vitamin D supplementation according to current clinical indications.

In addition to the standard treatment regimen, patients in the intervention group received freeze-dried mare's milk (Saumal) throughout the entire six-month follow-up period.

Pain Assessment

The primary study endpoint was the change in pain intensity over time.

Pain intensity was assessed using the Visual Analog Scale (VAS), ranging from 0 to 10, where:

0 = no pain;

1–3 = mild pain;

4–6 = moderate pain;

7–10 = severe pain.

Pain assessments were performed at the following time points:

V0: baseline (before treatment initiation);

V1: 2 weeks after treatment initiation;

V2: 1 month after treatment initiation;

V3: 3 months after treatment initiation;

V4: 6 months after treatment initiation.

A reduction of at least 2 points on the Visual Analog Scale (VAS) compared with baseline was considered a clinically meaningful improvement.

Statistical Analysis

Statistical analyses were performed using descriptive and comparative statistical methods.

Continuous variables are presented as the mean ± standard deviation (SD). Appropriate statistical tests were applied to compare the study groups according to the distribution of the data.

Changes in VAS scores over time were evaluated within each group at the predefined follow-up visits. Between-group comparisons were performed at each assessment time point.

A two-sided p value of <0.05 was considered statistically significant.

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3. Results

Baseline Characteristics of the Study Population

A total of 75 patients with breast cancer–related spinal metastases were included in the study. The intervention group comprised 30 patients, whereas the control group included 45 patients.

The mean age was 53.7 ± 3.7 years in the intervention group and 55.2 ± 4.4 years in the control group, with no statistically significant difference between the groups (p>0.05).

Table 1 - Baseline pain intensity assessed using the Visual Analog Scale (VAS)

Variable	Intervention Group (n=30)	Control Group (n=45)	p value
VAS score	7.37 ± 0.56	7.40 ± 0.62	0.927

The two groups were also comparable with respect to body mass index (BMI), Ki-67 proliferation index, Spinal Instability Neoplastic Score (SINS), the number of treated vertebral levels, and the volume of injected bone cement (all p>0.05).

Table 2 - Baseline demographic and clinical characteristics of the study groups

Variable	Intervention Group (n=30)	Control Group (n=45)	p value
Age, years	53.7 ± 3.7	55.2 ± 4.4	>0.05
BMI, kg/m²	20.1 ± 1.5	19.8 ± 1.5	>0.05
Ki-67, %	37.8 ± 15.5	40.8 ± 14.1	>0.05
SINS	6.5 ± 0.8	6.6 ± 0.7	>0.05
Number of treated vertebral levels	2.2 ± 0.5	2.0 ± 0.8	>0.05
Bone cement volume, mL	4.6 ± 1.8	4.2 ± 2.2	>0.05

Overall, no statistically significant differences were observed between the intervention and control groups with respect to baseline clinical or procedural characteristics.

Baseline Pain Intensity

Before treatment, all patients experienced severe pain.

The mean baseline VAS score was 7.37 ± 0.56 in the intervention group and 7.40 ± 0.62 in the control group. There was no statistically significant difference in baseline pain intensity between the groups (p=0.927).

Changes in Pain Intensity During Follow-up.

Table 3 - Changes in Visual Analog Scale (VAS) scores during follow-up

Follow-up visit	Intervention Group (n=30)	VAS Control Group (n=45)	VAS p value
Baseline	7.37 ± 0.56	7.40 ± 0.62	0.927
2 weeks	5.13 ± 0.57	5.20 ± 0.55	-
1 month	3.60 ± 0.89	3.51 ± 0.76	-
3 months	3.00 ± 0.59	2.98 ± 0.50	-
6 months	3.23 ± 0.73	2.98 ± 0.50	-

Following multimodal treatment, both groups demonstrated a progressive reduction in pain intensity throughout the follow-up period. At 2 weeks after treatment initiation, the mean VAS score decreased to 5.13 ± 0.57 in the intervention group and 5.20 ± 0.55 in the control group, corresponding to reductions of 2.24 and 2.20 points from baseline, respectively.

At 1 month, the mean VAS score further decreased to 3.60 ± 0.89 in the intervention group and 3.51 ± 0.76 in the control group.

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At 3 months, continued improvement was observed, with mean VAS scores of 3.00 ± 0.59 and 2.98 ± 0.50 in the intervention and control groups, respectively.

At the 6-month follow-up, mean VAS scores were 3.23 ± 0.73 in the intervention group and 3.16 ± 0.64 in the control group.

Table 4 - Changes in Visual Analog Scale (VAS) scores during follow-up

Follow-up	Intervention Group	Control Group	p value
Baseline	7.37 ± 0.56	7.40 ± 0.62	0.927
2 weeks	5.13 ± 0.57	5.20 ± 0.55	0.781
1 month	3.60 ± 0.89	3.51 ± 0.76	0.812
3 months	3.00 ± 0.59	2.98 ± 0.50	0.904
6 months	3.23 ± 0.73	3.16 ± 0.64	0.761

Statistical analysis demonstrated a significant reduction in pain intensity compared with baseline at all follow-up time points in both groups ($p<0.001$).

No statistically significant differences in VAS scores were observed between the intervention and control groups at 2 weeks, 1 month, 3 months, or 6 months after treatment initiation (all $p>0.05$).

Clinically Meaningful Pain Reduction

A clinically meaningful reduction in pain intensity, defined as a decrease of at least 2 VAS points, was observed as early as 2 weeks after treatment initiation in both groups.

At the 6-month follow-up, the absolute reduction in VAS score from baseline was:

- 4.14 points in the intervention group;
- 4.24 points in the control group.

Overall, both treatment strategies provided substantial and sustained pain relief throughout the six-month follow-up period.

4. Discussion

Pain is one of the most prominent clinical manifestations of breast cancer–related spinal metastases and has a substantial impact on patients' functional status and quality of life. In the present study, we evaluated changes in pain intensity following multimodal treatment consisting of percutaneous vertebroplasty, radiotherapy, and bone-modifying therapy, with additional nutritional supplementation using freeze-dried mare's milk (Saumal) in the intervention group.

The findings demonstrated a marked reduction in pain intensity in both study groups. At baseline, patients experienced severe pain, with mean VAS scores exceeding 7 points in both groups. A clinically meaningful reduction in pain was observed as early as two weeks after treatment initiation, and by the end of the six-month follow-up, pain intensity had decreased by more than 4 VAS points compared with baseline.

These results support the effectiveness of a comprehensive multimodal treatment strategy for patients with breast cancer–related spinal metastases. Percutaneous vertebroplasty represents a key component of this approach, providing mechanical stabilization of the affected vertebral segment and rapid relief of pain associated with spinal instability and pathological micromotion. Previous studies have likewise demonstrated the significant analgesic efficacy of vertebroplasty in patients with metastatic spinal tumors.

The addition of radiotherapy to the multimodal treatment regimen is intended to achieve local tumor control and reduce pain associated with tumor activity. The combined use of mechanical stabilization and local antitumor treatment addresses multiple pathophysiological mechanisms underlying pain in patients with spinal metastases, thereby enhancing overall symptom control.

In the present study, no statistically significant differences in pain reduction were observed between the intervention and control groups. At the six-month follow-up, mean VAS scores were 3.23 ± 0.73 and 3.16 ± 0.64 in the intervention and control groups, respectively ($p=0.761$). These findings indicate that the addition of freeze-dried mare's milk (Saumal) to the extended multimodal treatment regimen did not provide a significant additional benefit with respect to pain reduction.

Nevertheless, the absence of statistically significant between-group differences does not diminish the clinical relevance of the findings. The

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principal therapeutic benefit appears to have been attributable to the standard multimodal treatment regimen, which provided sustained pain relief throughout the follow-up period. The potential effects of adjunctive nutritional supplementation on other clinically relevant outcomes, including quality of life, bone metabolism, and radiological response, warrant further investigation.

The present findings are consistent with current evidence supporting a comprehensive multimodal approach to the management of patients with spinal metastases. Rather than relying on a single therapeutic modality, multimodal treatment simultaneously targets the mechanical, neoplastic, and metabolic mechanisms contributing to metastatic bone pain.

Several limitations of this study should be acknowledged. First, the study employed a non-randomized design. Second, the sample size was relatively small, and the study groups were unequal in size. Third, the open-label design may have introduced potential sources of bias. Finally, pain intensity was assessed using the VAS, a validated and widely accepted patient-reported outcome measure that nevertheless remains subject to individual variability in pain perception.

Despite these limitations, the present study demonstrates that multimodal treatment provides substantial and sustained pain relief in patients with breast cancer–related spinal metastases. These findings further support the clinical value of an integrated multimodal treatment strategy for effective pain management in this patient population.

5. Conclusions

Multimodal treatment provides substantial and sustained pain relief in patients with breast cancer–related spinal metastases throughout a six-month follow-up period.

A comprehensive treatment strategy incorporating percutaneous vertebroplasty, radiotherapy, and bone-modifying therapy was associated with a clinically meaningful reduction in pain intensity as early as the initial stages of treatment, with the therapeutic effect maintained throughout the follow-up period.

The addition of nutritional supplementation with freeze-dried mare's milk (Saumal) to the extended multimodal treatment regimen did not demonstrate a statistically significant advantage over standard therapy with respect to pain reduction.

These findings support the effectiveness of a multimodal treatment strategy for pain management in patients with breast cancer–related spinal metastases. Further studies are warranted to investigate the potential effects of adjunctive treatment components on other clinically relevant outcomes, including quality of life, functional status, and parameters of bone metabolism.

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AI Declaration. The author declares that no generative AI or AI-assisted tools were used at any stage of the research, data evaluation, or writing of this paper.

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Сүт безі обыры кезінде омыртқаның метастаздық зақымдануы бар науқастардағы ауырсыну синдромының стандартты және кеңейтілген мультимодальды емнен кейінгі динамикасы: Проспективті когорттық зерттеу нәтижелері

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Түйіндеме

Омыртқаға метастаздық зақымдану сүт безі обырының жайылған түріндегі ең ауыр асқынулардың бірі болып табылады және айқын созылмалы ауырсыну синдромымен, функционалдық белсенділіктің төмендеуімен әрі науқастардың өмір сүру сапасының нашарлауымен қатар жүреді. Қазіргі заманғы емдеу тәсілі жергілікті, жүйелі және демеуші терапия әдістерін кешенді түрде қолдануға негізделген. Дегенмен мультимодальды емдеудің жекелеген компоненттерінің тиімділігін бағалау өзекті ғылыми мәселе болып қала береді.

Зерттеудің мақсаты: сүт безі обыры кезінде омыртқаның метастаздық зақымдануы бар науқастарда стандартты және кеңейтілген мультимодальды емнен кейінгі ауырсыну синдромының динамикасын бағалау.

Әдістері. Екі топты параллель салыстырумен жүргізілген проспективті, ашық, бақыланатын, рандомизацияланбаған когорттық зерттеу орындалды. Зерттеуге IV сатыдағы гистологиялық расталған сүт безі обыры және радиологиялық тұрғыдан верификацияланған омыртқа метастаздары бар 75 науқас енгізілді. Барлық науқастарға тері арқылы жасалатын вертебропластиканы, сәулелік терапияны және антиостеорезорбтивті терапияны қамтитын стандартты мультимодальды ем жүргізілді. Негізгі топта (n=30) қосымша ретінде лиофилизацияланған бие сүті – саумал өнімін қолдану арқылы нутритивтік қолдау көрсетілді, ал бақылау тобында (n=45) қосымша нутритивтік қолдау жүргізілген жоқ. Ауырсыну синдромының қарқындылығы ем басталғанға дейін, сондай-ақ ем басталғаннан кейін 2 аптадан соң, 1, 3 және 6 ай өткенде визуалды-аналогтық шкала (ВАШ) бойынша бағаланды.

Нәтижелері. Зерттеудің бастапқы кезеңінде ауырсыну синдромының деңгейі екі топта салыстырмалы болды: негізгі топта ВАШ көрсеткіші 7,37 ± 0,56 баллды, ал бақылау тобында 7,40 ± 0,62 баллды құрады (p=0,927). Бақылау кезеңінде екі топта да бастапқы деңгеймен салыстырғанда ауырсыну қарқындылығының статистикалық тұрғыдан мәнді төмендеуі байқалды (p < 0,001). Алты айдан кейін ВАШ көрсеткіші негізгі топта

3,23 ± 0,73 баллға, ал бақылау тобында 3,16 ± 0,64 баллға дейін төмендеді. Ауырсыну синдромының динамикасы бойынша топтар арасында статистикалық мәнді айырмашылық анықталған жоқ (p=0,761). Ауырсыну қарқындылығының 2 баллдан артық төмендеуі ем басталғаннан кейінгі алғашқы екі аптада-ақ байқалып, бүкіл бақылау кезеңі бойы сақталды.

Қорытынды. Сүт безі обыры кезінде омыртқаның метастаздық зақымдануы бар науқастарда стандартты мультимодальды ем алты айлық бақылау кезеңінде ауырсыну синдромының айқын әрі тұрақты төмендеуін қамтамасыз етеді. Емдеу кешеніне саумал өнімін қосымша енгізу ВАШ көрсеткіштері бойынша статистикалық тұрғыдан маңызды артықшылық көрсетпегенімен, негізгі мультимодальды емнің оң әсеріне кері ықпал еткен жоқ.

Түйін сөздер: сүт безі обыры, омыртқа метастаздары, ауырсыну синдромы, визуалды-аналогтық шкала, вертебропластика, мультимодальды ем.

Динамика болевого синдрома у пациенток с метастатическим поражением позвоночника при раке молочной железы после стандартного и расширенного мультимодального лечения: Результаты проспективного когортного исследования

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Резюме

Метастатическое поражение позвоночника является одним из наиболее тяжелых осложнений распространенного рака молочной железы и сопровождается выраженным хроническим болевым синдромом, снижением функциональной активности и ухудшением качества жизни пациенток. Современный подход к лечению включает комплексное применение локальных, системных и поддерживающих методов терапии, однако оценка эффективности отдельных компонентов мультимодального лечения остается актуальной задачей.

Цель исследования: оценить динамику болевого синдрома у пациенток с метастатическим поражением позвоночника при раке молочной железы после проведения стандартного и расширенного мультимодального лечения.

Методы. Проведено проспективное открытое контролируемое нерандомизированное когортное исследование с параллельным сравнением двух групп. В исследование включены 75 пациенток с гистологически подтвержденным раком молочной железы IV стадии и радиологически верифицированными метастазами позвоночника. Все пациентки получали стандартное мультимодальное лечение, включавшее чрескожную вертебропластику, лучевую терапию и антиостеорезорбтивную терапию. В основной группе (n=30) дополнительно применялась нутритивная поддержка сублимированным кобыльим молоком - саумал, в контрольной группе (n=45) дополнительная нутритивная поддержка не применялась. Интенсивность болевого синдрома оценивали по визуально-аналоговой шкале (ВАШ) до лечения, через 2 недели, 1, 3 и 6 месяцев после начала терапии.

Результаты. Исходный уровень болевого синдрома был сопоставим между группами: показатель ВАШ составил 7,37 ± 0,56 балла в основной группе и 7,40 ± 0,62 балла в контрольной группе (p=0,927). В процессе наблюдения в обеих группах отмечено статистически значимое снижение интенсивности боли относительно исходного уровня (p<0,001).

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Через 6 месяцев показатель ВАШ составил 3,23 ± 0,73 балла в основной группе и 3,16 ± 0,64 балла в контрольной группе. Различий между группами по динамике болевого синдрома выявлено не было (p=0,761). Снижение интенсивности боли более чем на 2 балла достигалось уже через 2 недели после начала лечения и сохранялось на протяжении всего периода наблюдения.

Выводы. Стандартное мультимодальное лечение пациенток с метастатическим поражением позвоночника при раке молочной железы обеспечивает выраженное и устойчивое снижение болевого синдрома в течение шестимесячного периода наблюдения. Дополнительное включение саумал в лечебный комплекс не продемонстрировало статистически значимого преимущества по показателям ВАШ, однако не изменяло положительный эффект базового мультимодального подхода.

Ключевые слова: рак молочной железы, метастазы позвоночника, болевой синдром, визуально-аналоговая шкала, вертебропластика, мультимодальное лечение.

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