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THE ROLE OF INTRAOPERATIVE RADIATION THERAPY IN BREAST CANCER TREATMENT: A LITERATURE REVIEW

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ABSTRACT

Relevance: *Breast cancer is one of the most common cancers in women. In 2022, GLOBOCAN reported 2,296,842 new cases of breast cancer and 666,103 deaths from this disease. Breast cancer ranks 1st in the world in the structure of oncopathologies in women.*

In the Republic of Kazakhstan, 37,038 new cancer cases were registered in 2023, except for skin cancer. The number of cases of malignant neoplasms increased by 1,959, or 5.6%, compared to the previous year. The "stable" incidence per 100,000 population was 186.1 per year, with a growth rate of 3.5%; the standardized rate was 0.8%, with a growth rate of 159.6.

It is also worth paying attention to the main directions and principles of SCC treatment. The types of SCC treatment depend on the stage of the disease. Tumor treatment includes surgical removal, radiation therapy, chemotherapy, and hormonal therapy. Currently, intraoperative radiation therapy (IRT) is relevant as an op-timal method of SCC treatment. According to oncologists, mammologists, and radiation oncologists, this treatment method also requires in-depth analysis to improve treatment outcomes and five-year survival rates for this disease.

The study aimed to *examine the world experience in the use of IORT in the treatment of breast cancer.*

Methods: *This article reviews PubMed sources from 2003 to 2023 on the use of IORT in treating breast can-cer.*

Results: *This review presents the results of large studies, including multicenter prospective ones, on evaluat-ing the efficacy, the effect on survival, and the features and possible limitations of IORT in treating breast cancer.*

Conclusion: *IORT is a fairly promising and innovative treatment method that reduces the risk of side effects and the duration of treatment. Considering the positive short-term and long-term results of IORT application, it is advisable to recommend its full use in clinical protocols within Kazakhstan's healthcare system.*

Keywords: *intraoperative radiation therapy (IORT), breast cancer, survival rate, long-term results, recurrence rate.*

Introduction: Every year, about 2.3 million new cases of breast cancer (BC) are registered in the world, and the number of deaths exceeds 700 thousand. Countries with high prevalence include the USA, Denmark, France, Australia, New Zealand, Sweden, and Canada. Countries with low incidence rates include the Democratic Republic of the Congo, Mali, China, Vietnam, and India. Countries with a high incidence in the CIS countries include Armenia, Moldova, Kyrgyzstan, and Ukraine. Breast cancer ranks first. It is followed by: lung and bronchial cancer, colorectal cancer, stomach cancer, cervical cancer, esophageal cancer, prostate cancer, kidney, ovarian, pancreatic, endometrial, and liver cancer [1]. According to data in our country: According to the latest data, in 2023, 37,038 cases of almost all types of cancer, except for skin cancer, were detected for the first time in the Republic of Kazakhstan (in 2022 - 35,079 cases). The number of cases increased by 1959, or 5.6%, compared to the previous year (2507 cases, or 7.7%). The normal incidence rate per 100,000 population was 186.1 (2022 – 179.9), with a growth rate of 3.5% (+5.6%) per year. The standard rate was 159.6 (158.4), with a growth rate of 0.8% (+3.8%) (Table 1) [2].

Table 1 – Incidence of certain types of malignant neoplasms (excluding skin cancer) among the population of the Republic of Kazakhstan ("normal" indicators) (the table presents data on the most common types of cancer)

Location of tumors	Number of people diagnosed with cancer for the first time in their lives				Growth rates
	Absolute number		Per 100,000		
	Total cases – 15,885 (2022)	Total cases – 16,336 (2023)	2022	2023	
High-risk areas for cancer development include:	13951	14301	81.3	82.2	3.5
Breast	5171	5505	26.5	27.7	4.3
Lung and respiratory tract cancer	3925	3873	20.1	19.5	-3.3
Stomach	2915	2873	14.9	14.4	-3.4
Colon	1940	2050	9.9	10.3	3.6

Due to the high prevalence of this type of cancer, it is necessary to make certain efforts for its early diagnosis and treatment. Radiation therapy is a widely used method of treating all types of cancer, even for palliative care. The use of intraoperative radiation therapy (IRT) in the treatment of breast cancer is becoming increasingly relevant. IRT is a method of treating breast cancer using direct radiation therapy during surgery. It can be used as an alternative or an addition to standard adjuvant radiation therapy after surgery. A variety of high-tech methods are used for adjuvant radiation therapy. For example, adjuvant radiation therapy is intensively modulated and image-guided, and hypofractionated breast treatment is used instead of the traditional total dose of 50 Gy (2 Gy x 25 days). This type of treatment has a set of features that enable the near-complete cure of almost all tumors, regardless of their location and severity [3]. However, the role of IOST in the treatment of squamous cell breast cancer has been studied in several clinical trials and has shown positive results as an alternative or adjunct to adjuvant radiotherapy [4].

Some studies have also shown that IOST can be safe and convenient for patients. Since it allows for a single dose of radiotherapy to be delivered during surgery, whereas standard radiotherapy is administered a few weeks after surgery and is carried out over several weeks [5]. According to oncologists, mammologists, and radiologists, this approach is an optimal option, requiring an in-depth analysis of both the treatment and the five-year survival rate after treatment. Numerous studies confirm this. The use of IOST immediately after surgical removal of breast cancer was widely studied in this scientific study, which led to a positive attitude towards IOST among specialists. In squamous cell breast cancer, 44,752 patients were treated with IOST in 35 countries over 20 years, with the administration of intraoperative radiotherapy immediately after tumor removal. Evidence suggests that the treatment has saved 30 million kilometers of travel time and approximately 2,000 lives [6].

The study aimed to examine the world experience in the use of IORT in the treatment of breast cancer.

Materials and methods: We searched the PubMed database from 2003 to 2023 using the following keywords: intraoperative radiotherapy, "IOST and breast cancer", "breast cancer treatment", "IOST application", "IOST side effects", "IOST advantages". Based on the critical analysis, 28 literature references were included in this review.

Results: IOST was first used to treat squamous cell carcinoma in 1998. It is designed to replace traditional radiation therapy after surgery. IOST is a method that delivers radiation directly during surgery, reducing the amount of tissue exposed to radiation and shortening the treatment time. This method was originally proposed by the Medical College of Ohio (MCO) in the United States and the Montpellier Regional Cancer Center (CRLC) in France, based on reports of 72 patients treated with intraoperative electron beam therapy. Compared with SCC, SCC shows different sensitivity to high doses. In the 2000s, Fowler proposed an alpha/beta ratio of 4 for SCC, which is the best approximation to the 10-point scale for most SCCs. Clinical results from Canadian and British hypofractionation studies further support this value. A lower dose per fraction may result in greater sensitivity compared to a higher dose. This is a clear argument in favor of IOST. In a linear-quadratic model using an alpha/beta value of 4, the IOST dose per 10 Gy is 35 QED. Therefore, a single dose of 10 Gy of IOST is equivalent to approximately 24 Gy of ablation [7]. Despite evidence of improved treatment efficacy and patient quality of life, concerns remain regarding long-term outcomes and local recurrence rates [8]. IOST can be delivered in several ways. The most common is electronic IOST. IOST is currently the standard therapeutic approach for patients with early-stage, low-risk squamous cell carcinoma as part of breast-conserving surgery. Studies have shown that IOST is an effective treatment for squamous cell carcinoma. One study found that IOST reduced the risk of squamous cell carcinoma recurrence by 80% [9]. Other studies have also demonstrated that IOST achieves high control rates and favorable survival rates for squamous cell carcinoma [10,11]. However, there are several limitations to the use of IOST in the treatment of squamous cell breast cancer. First, IOST is designed for relatively small tumors, making it difficult to use. Second, not all centers offer IOST, making it inaccessible to some patients. Despite the above limitations, IOST is still an effective treatment option for squamous cell breast cancer. For patients with relatively small tumors, IOST has proven to be more cost-effective than traditional radiation therapy. IOST is also very useful for patients who cannot undergo long courses of traditional radiation therapy, including those who live far from the cancer center or have transportation and mobility issues [12]. However, IOST is not effective for all patients and may not be completely suitable for all cases of squamous cell breast cancer. Some studies have also shown an increased risk of disease recurrence after IOST. However, these studies did not take into account tumor characteristics, age, geographic location, and race [13]. Limitations of radiotherapy dosing regimens may be associated with certain risks and limitations, such as limited availability of IOST for some patients [14]. Overall, numerous studies and data suggest that IOST may be an effective and convenient treatment option for squamous cell carcinoma. However, further studies and evaluations are needed to better understand its efficacy and safety, as well as to identify patients suitable for this treatment. One of the most well-known studies is the randomized TARGIT-A trial. This study assessed the effectiveness of low-energy IOST on treatment outcomes. Initially, 3451 women were randomized to IOST or total breast irradiation. 15% of patients received additional IOST. It is worth noting that the study included 2 groups: those who received IOST during surgery and those who received IOST

as a second treatment (after pathological examination). The authors published the first results after 5 years (29 months of follow-up). It showed an increase in recurrence. (Note that 3.3% in the IOST group and 1.3% in the TBBI group, but within the non-inferiority criteria) for the entire study population. In the post-pathology cohort, there was an increased recurrence rate with IOST (5.4% for IOST and 1.7% for TBBI, which exceeded the efficacy threshold), as observed in the surgery cohort (2.1% vs 1.1%, respectively, with efficacy criteria not being weak) [15]. Later, the TARGIT-A investigators published an update. However, the results were criticized and questioned by oncologists because they were not in the same population [16]. In the post-cohort (1153 patients), 5-year follow-up revealed an increased recurrence rate in the IOST group (IOST 3.96%, TBBI 1.05%), which is below the efficacy threshold and should not be recommended for patients at this time [17, 18]. In the IOST surgical cohort, the 5-year recurrence rates were 0.95%–2.11%, but within the non-inferiority criteria. Long-term Kaplan-Meier curves were not presented at the time [19]. However, a major concern with the methodology of these updates is that the study reported local recurrence-free survival (LRFS) rather than long-term absolute recurrence rates. This is an important study because concerns have been raised about composite endpoints such as LRFS that include mortality. Additionally, other breast or breast radiotherapy studies have shown long-term recurrence rates, highlighting the importance of counseling patients about radiotherapy options [19, 20]. The results that formed the basis for e-IOST are the largest multicenter trial to date, the ELIOT trial. In it, 1305 women were randomized to IOST or ablation. At 5 years, IOST was associated with an increased local recurrence rate (4.4% vs. 0.4%) [21]. However, long-term results of the ELIOT trial have not yet been published. On the other hand, Leonardi et al followed 1822 patients who underwent IOST at a single institution outside the context of a clinical trial. They found that patients who met the criteria of the American Society for Radiation Oncology (ASTRO) had lower 5-year recurrence rates [22]. This clearly indicates that IOST treatment requires further study. Clinicians, including breast surgeons and radiation oncologists, may wonder what the role of IOST is for patients with early-stage squamous cell carcinoma. Current ASTRO guidelines recommend that patients with IOST should always seek medical advice if they are at increased risk of local recurrence. ASTRO guidelines emphasize that IOST should only be used in prospective studies and that only eligible patients should be considered for its use. The American Brachytherapy Society does not support IOST outside of prospective studies (although this was published before the TARGIT-A trial updates were released). The guidelines emphasize that IOST using electronic devices should be limited to eligible patients [16, 21, 22]. One of the most important recent studies is ELIOT (Electronic Intraoperative Radiotherapy for Breast Cancer) [21]. This study investigated the use of IOST in patients with early squamous cell breast cancer. The study results showed a 5-year overall survival of 95.5% and a disease-free survival of 98.1%. These results were compared with standard radiotherapy, and the authors concluded that IOST is a safe and effective treatment option for patients with early squamous cell breast cancer [21]. Another study from 2018 showed that IOST may be an effective treatment option for patients with multiple, non-bulky breast tumors. This study included 203 patients who were given IOST instead of standard radiotherapy. The study results showed a 5-year local recurrence-free survival rate of 96.4%. This is comparable to standard radiotherapy. The researchers concluded that IOST may be an effective treatment option for this patient group [18]. A study was also conducted to evaluate the efficacy of IOST in combination with liposomal doxorubicin (L-Dox) for the treatment of patients with localized squamous cell carcinoma [23]. This study included 79 patients who were randomly assigned to two groups: one group received IOST in combination with L-Dox, and the other group received IOST alone. The study results showed that patients who received IOST plus L-Dox had a higher rate of local recurrence and poorer disease-free survival compared to patients who received IOST alone. These results suggest that the combination of IOST and L-Dox may be a more effective treatment option for patients with localized squamous cell carcinoma. Some studies have also investigated the use of IOST as an alternative to standard radiation therapy for patients with other types of squamous cell carcinoma. For example, a 2016 study [24] demonstrated that IOST may be a safe and effective treatment option for patients with low rates of locoregional recurrence. This study also found that patients treated with IOST had higher treatment satisfaction than those treated with standard radiation therapy. However, not all studies support the effectiveness of IOST in treating squamous cell carcinoma. A 2020 study found no statistically significant differences in survival or disease recurrence between patients treated with IOST and those treated with standard radiation therapy [25].

Discussion: In summary, several studies have demonstrated the efficacy of IOST in treating SCC, although all aspects of the treatment method have not yet been thoroughly studied. Radiation therapy is rapidly evolving every day. This is evidenced by the capabilities of spiral tomotherapy, adjuvant radiotherapy (which is performed with intensity-modulated and image-guided techniques), and adjuvant ionizing radiation. However, additional studies are certainly needed to determine the best indications for the use of IOST and to assess its long-term impact on the survival and quality of life of patients with SCC. An important aspect of using IOST in the treatment of SCC is the selection of patients who can effectively benefit from the treatment method. In the main studies, we observed that IOST may be more effective in patients with small tum-

ors, a low invasion rate, the absence of lymphatic metastases, and high sensitivity to radiotherapy [18, 23]. It has also been shown that several other factors need to be taken into account, including the patient's age, general health condition, presence of comorbidities, and their treatment. Another important aspect of using IOST in the treatment of squamous cell carcinoma is controlling the optimal dose and distribution of radiation [26]. Compared with adjuvant radiotherapy, IOST allows for more precise delivery of radiation to the tumor, reducing the amount of radiation received by healthy tissues. The use of IOST in the treatment of breast cancer is becoming increasingly relevant. Since IOST is a method of treating squamous cell carcinoma with direct radiation therapy during surgery, it can be used as an alternative or in addition to standard adjuvant radiotherapy after surgery [3]. The role of IOST in treating squamous cell carcinoma has been investigated in several clinical trials. The results of many studies suggest that IOST may be an effective alternative to standard radiotherapy.

Additionally, the optimal dose of radiotherapy may vary depending on several factors, including tumor size and location, the presence of metastases, and the level of sensitivity to radiotherapy. Additional aspects to consider include skin burns, edema, and changes in skin texture. In some cases, the above-mentioned side effects can be significant and affect the patient's quality of life [27, 28]. However, it is known that modern technologies and methods of using IOST can reduce side effects and increase the safety of this treatment method.

Conclusion: Overall, IOST is safer and more effective than standard radiation therapy in some cases. It is also an effective treatment for patients with locally advanced squamous cell carcinoma. Numerous studies have demonstrated that IOST can enhance survival and decrease the risk of recurrence in squamous cell carcinoma. However, the limitations of IOST may make it inaccessible to some patients. Given the currently available results and evidence-based recommendations, the use of IOST in early-stage squamous cell carcinoma certainly requires additional practical studies. As part of shared decision-making, oncologists should inform patients about potential concerns related to the IOST results.

Nevertheless, the method is quite promising and innovative, reducing the risk of side effects and shortening the treatment period. Despite this, there are limitations to the use of IOST. Additional theoretical and experimental studies are necessary for a more comprehensive understanding of the application of this technique in the treatment of squamous cell carcinoma in our country. Once the research has a solid foundation and evidence base regarding the immediate and long-term patient outcomes, the method will undoubtedly be introduced into clinical protocols as an alternative to traditional ablative radiotherapy, and guidelines and recommendations for consultation will be developed.

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АҢДАТПА

СҮТ БЕЗІ ҚАТЕРЛІ ІСІГІН ЕМДЕУДЕГІ ИНТРАОПЕРАЦИЯЛЫҚ СӘУЛЕЛІ ТЕРАПИЯНЫҢ РӨЛІ: ӘДЕБИЕТКЕ ШОЛУ

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Өзектілігі: *Сүт безі қатерлі (СБҚ) ісігі әйелдерде жиі кездесетін ісіктердің бірі. GLOBOCAN деректері бойынша 2022 жылы сүт безі обырының 2 296 842 жаңа жағдайы және осы аурудан 666 103 өлім тіркелді. Әйелдер арасында онкопатология құрылымында таралуы бойынша әлемде 1-ші орында.*

Қазақстан Республикасында 2023 жылы тері қатерлі ісігін қоспағанда ең алғаш рет қатерлі ісікпен тіркелген аурудың саны 37 038 жағдай анықталды. Алдыңғы жылдың деңгейіне қарағанда қатерлі дертке шалдыққандар саны 1959-ға немесе 5,6%-ға өсті. Сырқаттанушылықтың 100 мың халыққа шаққандағы «қалыпты» көрсеткіші 186,1 құрады өсу қарқынымен жылына 3,5%, стандартты көрсеткіші – 0,8%-дық өсу қарқынымен 159,6-ны құрады.

Сондай-ақ СБҚ ісігін емдеудегі негізгі бағыттар мен принциптерге назар аударған жөн. СБҚ ісігін емдеу түрлері аурудың сатысына байланысты. Ісікті емдеу: хирургиялық алып тастау, сәулелі терапия, химиотерапия және гормондық терапияны қамтиды. Қазіргі уақытта интраоперациялық сәулелі терапияны (ИОСТ) СБҚ ісігін емдеуде оңтайлы әдіс ретінде қолдану өзекті болып отыр. Онкологтардың, маммологтардың және радиациялық онкологтардың пікірінше, бұл емдеу тәсілі, ем нәтижесі мен бес жылдық өмір сүру мерзімі көрстекішін жақсарту үшін де терең талдауды қажет етеді.

Зерттеудің мақсаты *– сүт безі қатерлі ісігін емдеуде интраоперациялық сәулелі терапияны қолданудың әлемдік тәжірибесін зерттеу.*

Әдістері: *Рандомизациялы ем мен мета-анализ нәтижелері негізінде 2003-2023 жылдардағы PubMed базасынан СБҚ ісігін емдеудегі ИОСТ қолдану туралы дереккөздерге шолу берілді.*

Нәтижелері: *Әдеби шолуда ем тиімділігі, өмір сүру ұзақтығына ем әсерін бағалау бойынша ірі зерттеулердің, соның ішінде көп орталықты оң нәтижелі зерттеулердің, сондай-ақ СБҚ ісігін емдеуде ИОСТ қолданудың ерекшеліктері мен мүмкін болатын шектеулері ұсынылды.*

Қорытынды: *ИОСТ ем алудан кейінгі жанама әсерлердің қаупін төмендетумен қатар, СБҚ ісігін емдеу ұзақтығын азайтады. СБҚ ісігін емдеуде осы әдістемені қолдануды жақсырақ түсіну үшін қосымша зерттеулер қажеті анық. Қысқа мерзімді және ұзақ*

мерзімді оң нәтижелер болған жағдайда, ИОСТ-ны толығымен қолдану мен емдеу мекемелерінде клиникалық хаттамаларға енгізу үшін ұсынылуы хақ.

Түйін сөздер: *интраоперациялық сәулелі терапия (ИОСТ), сүт безі қатерлі ісігі (СБК), өмір сүру деңгейі, ұзақ мерзімді нәтижелер, дерт қайталану жиілігі.*

АННОТАЦИЯ

РОЛЬ ИНТРАОПЕРАЦИОННОЙ ЛУЧЕВОЙ ТЕРАПИИ В ЛЕЧЕНИИ РАКА МОЛОЧНОЙ ЖЕЛЕЗЫ: ОБЗОР ЛИТЕРАТУРЫ

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Актуальность: *Рак молочной железы (РМЖ) является одним из самых распространенных видов рака у женщин. По данным GLOBOCAN за 2022 год зарегистрировано 2,296,842 новых случаев РМЖ и 666,103 случаев смерти от данного заболевания. По распространенности занимает 1-е место в мире в структуре онкопатологии у женщин.*

В Республике Казахстан в 2023 году зарегистрировано 37,038 новых случаев рака, за исключением рака кожи. Число заболевших злокачественными новообразованиями увеличилось на 1,959, или на 5,6% по сравнению с уровнем предыдущего года. «Стандартизированный» показатель заболеваемости на 100 тыс. населения составил 186,1 в год с темпом прироста 3,5%, стандартизированный показатель – 0,8% с темпом прироста 159,6.

Также стоит обратить внимание на основные направления и принципы лечения РМЖ. Виды лечения РМЖ зависят от стадии заболевания. Хирургическое удаление опухоли может включать лучевую терапию, химиотерапию и гормональную терапию. В настоящее время актуальным становится использование интраоперационной лучевой терапии (ИОЛТ) в качестве оптимального метода лечения РМЖ. По мнению онкологов-хирургов, маммологов и радиационных онкологов подход к лечению путем использования ИОЛТ требует глубокого анализа для улучшения результата лечения и пятилетней выживаемости у пациентов с данным недугом.

Цель исследования *– изучение мирового опыта применения интраоперационной лучевой терапии в лечении рака молочной железы.*

Методы: *В статье представлен обзор источников из базы PUBMED за 2003-2023 гг. по применению ИОЛТ в лечении РМЖ.*

Результаты: *В обзоре представлены результаты крупных исследований, в том числе мультицентровых проспективных, по оценке эффективности, влиянии на выживаемость, а также об особенностях и возможных ограничениях применения ИОЛТ в лечении РМЖ.*

Заключение: *ИОЛТ является достаточно перспективным и инновационным методом лечения, который позволяет снизить риск развития побочных эффектов и уменьшить продолжительность лечения. Учитывая положительные краткосрочные и долгосрочные результаты применения ИОЛТ, целесообразно рекомендовать полноценное использование данного метода в клинических протоколах в системе здравоохранения Казахстана.*

Ключевые слова: *интраоперационная лучевая терапия (ИОЛТ), рак молочной железы (РМЖ), выживаемость, отдаленные результаты, частота рецидивов.*

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