Case Report

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Eribulin in Heavily Pre-Treated Metastatic Breast Cancer: A Case Series

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Abstract

Background: Treatment options are limited for heavily pre-treated metastatic breast cancer patients, with Eribulin showing promise in improving survival outcomes.

Objective: To evaluate Eribulin outcomes in patients with MBC. Metastatic or incurable diseases are observed in 4% to 10% of women despite advances in breast cancer treatment. To address this problem, EMBRACE, an important randomized phase III clinical trial was carried out by comparing eribulin to the treatment selected by physicians for individuals with previously treated locally recurrent or metastatic breast cancer (MBC). The results showed a significant and prolonged increase in median overall survival among patients treated with eribulin, compared to those who received the physician's selected treatment.

Case Series: This study presents three patients who showed favorable outcomes after treatment with eribulin, despite multiple lines of previous therapy. Patient 1 was diagnosed with triple-negative breast cancer and initially achieved remission before experiencing a recurrence involving a chest lesion and enlarged lymph nodes. After two cycles of eribulin, the patient showed significant improvement. Patient 2 developed brain and liver metastases following the completion of hormonal therapy, prompting the initiation of eribulin as the next line of treatment. Patient 3 had disease progression despite undergoing multiple lines of hormonal and chemotherapy. Eribulin was administered and patient remained stable.

Conclusion: Patients with MBC tend to have substantially favorable outcomes with eribulin chemotherapy even after extensive previous treatment.

Keywords: Breast cancer, eribulin, heavily pre-treated, metastases

Introduction

According to GLOBOCAN 2020 data, breast cancer is the most commonly diagnosed cancer worldwide and ranks as the fifth leading cause of cancer-related death, with an estimated 2.3 million cases.[1] Despite advances in treatment, metastatic or incurable diseases are observed in 4% to 10% of women. The three subtypes for treatment stratification are hormone receptor positive/human epidermal growth factor receptor 2 (HER2) negative (treated with endocrine targeted therapy and/or targeted therapy), HER2 positive (treated with HER2-directed therapy), and triple negative. Briefly, for patients presenting with hormone receptor–positive/HER2-negative MBC, early therapy relies on endocrine therapy either alone or in combination with agents targeting phosphoinositide 3-kinase, mechanistic target of rapamycin, or cyclin-dependent kinase [CDK] 4/6 inhibitors.

Chemotherapy is reserved for patients with hormone receptor–positive/HER2-negative MBC either refractory to endocrine therapy or for patients with extensive symptomatic visceral involvement. In this context, eribulin, a synthetic analog of halichondrin B, falls within the halichondrin class and serves as an inhibitor of microtubule dynamics. The drug has a distinctive binding site, setting it apart from other agents that target microtubules.[2-4] In the European Union, eribulin is approved for treating patients with locally advanced or metastatic breast cancer (MBC) whose disease has progressed following at least one previous chemotherapeutic regimen for advanced stages.

In the United States, eribulin is indicated for MBC following the failure of at least two prior chemotherapy regimens. In Japan, it is approved for inoperable or recurrent breast cancer. EMBRACE, an important randomized phase III clinical trial comparing eribulin to the treatment selected by physicians was carried out for individuals with previously treated locally recurrent or MBC. The results showed a significant and prolonged increase in median overall survival among patients treated with eribulin, compared to those who received the physician's selected treatment (13.1 months vs. 10.6 months, respectively; hazard ratio [HR], 0.81; 95% CI, 0.66-0.99; p=.041).[5] Until recently, eribulin use was limited in certain regions due to accessibility constraints. In 2023, eribulin was included under national universal health coverage in Indonesia, allowing broader clinical application in patients with MBC. Physicians can now observe and evaluate disease progression and assess potential side effects associated with eribulin chemotherapy, especially in Indonesia. This case series describes three patients with heavily pre-treated MBC who achieved favorable clinical outcomes with eribulin therapy. Treatment timelines are presented in Fig. 1.

Cases

Patient 1

A 48-year-old Chinese woman was admitted with a left breast lump and underwent modified radical mastectomy in 2015, without additional chemotherapy. Histopathology and immunochemistry was done and confirmed stage IIA triple-negative invasive breast cancer (ER-negative, PR-negative, HER2-negative). Medical and psychosocial history were remarkable, and there was no family history of breast cancer. Four years later, cancer recurrence occurred in the chest wall and was treated with four cycles of doxorubicin and cyclophosphamide, leading to complete remission.

One year later, a second recurrence in the chest wall was treated with paclitaxel and carboplatin, resulting in partial remission sustained for one year. Lung metastasis occurred one year after remission, and docetaxel chemotherapy was implemented, leading to partial remission. Another chest wall recurrence occurred after two years and radiotherapy was executed with a partial response. Four months after the end of radiotherapy, the patient developed progressive disease with left arm edema, chest wall lesions, and lymph nodes in the supraclavicular and axillary regions with PD-L1 expression >10%. Laboratory findings were

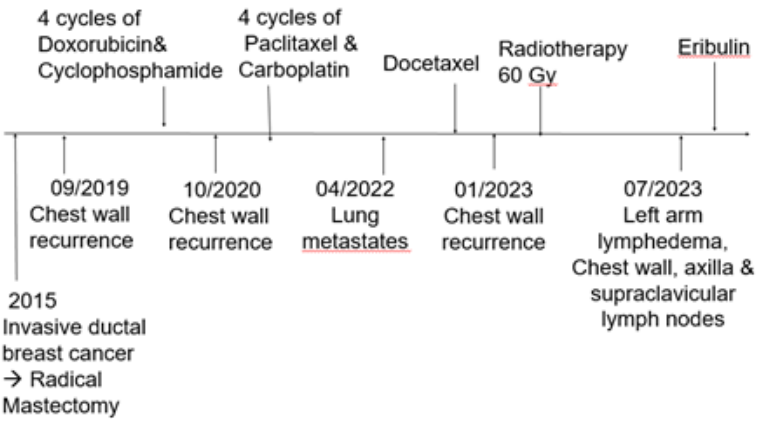

Fig. 1A. Timeline Case Report for Patient 1

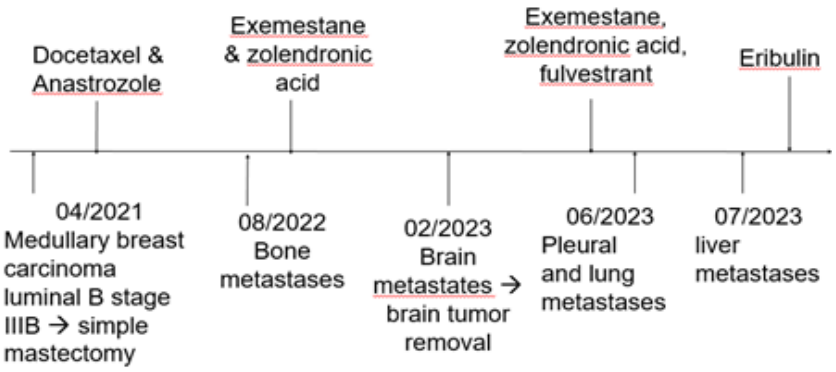

Fig. 1B. Timeline Case Report for Patient 2

within normal limit. On breast ultrasound showed solid lesion with cystic component 18x9x4.18cm on right parasternal extended to left parasternal. Treatment was carried out with eribulin chemotherapy (1.4 mg/m^2 day 1 and 8 every 21 days, administered as IV bolus 2–5 minutes) and granulocyte-colony stimulating factor (GCSF) support. After two cycles of eribulin treatment, the chest lesions improved and the axillary lymph nodes showed a decrease in size by> 50% as depicted in Fig. 2-3. The patient experienced grade I chills, constipation, and anemia as adverse events. The patient remained under follow-up for eight years (2015–2023) from initial diagnosis through eribulin therapy.

Patient 2

A 54-year-old Chinese woman was present with right breast lump. Past medical and psychosocial history were remarkable, and there was no family history of breast cancer. The patient diagnosed with luminal B stage IIIB medullary breast carcinoma in April 2021 and was subjected to simple mastectomy in October 2021. Treatment was carried out using docetaxel followed by anastrozole, and then 16 months later, bone metastasis occurred. Exemestane and zoledronic acid were administered for four months, after which fulvestrant was added. Two months later, the patient experienced a severe headache, and brain imaging showed metastases in left frontoparietalis sized 3.64 x 4.40 x 2.29cm. Brain tumor removal was performed three months after the diagnosis and one month later, pleural and lung metastases were detected on radiographic examinations.

The disease continued to progress, and a 1-month abdominal ultrasound examination showed liver metastasis on right right hepatic lobe, 1.42x1.27x1.32cm. She also had slight anemia [Hemoglobin 11.6g/dL [(normal value 12.3-15.3 g/dL)]. One month after

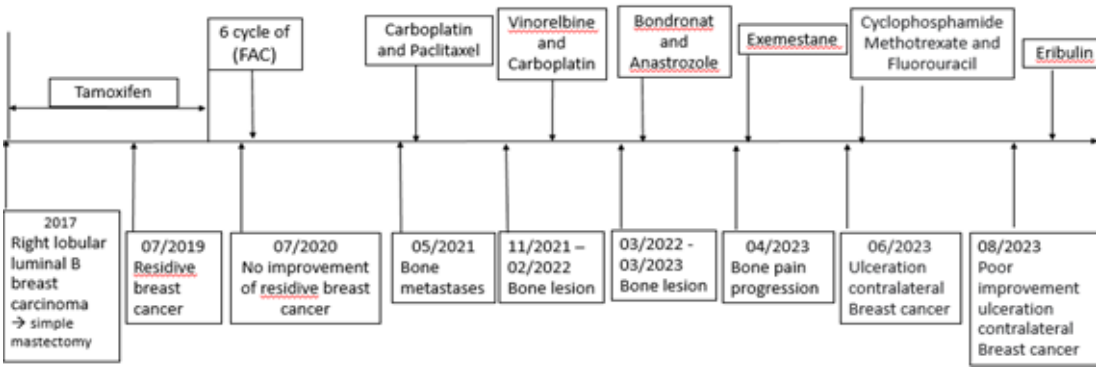

Fig. 1C. Timeline Case Report for Patient 3

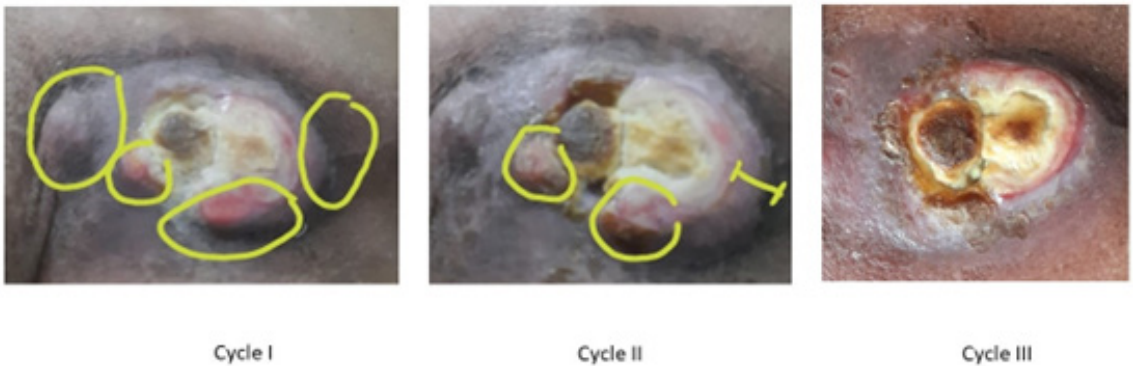

Fig. 2. Chest Wall Lesion of Patient 1

the development of the liver metastases, eribulin (1.4 mg/m^2 day 1 and 8 every 21 days, administered as IV bolus 2-5 minutes) was initiated and a partial response was observed after three cycles of treatment. No adverse events were observed. The patient was followed for two years (2021–2023) from initial diagnosis through eribulin therapy.

Patient 3

A 45-year-old Batak woman presented wwith a right breast mass and a history of type II diabetes mellitus managed with insulin. Histopathology and immunohistochemistry confirmed right invasive lobular breast carcinoma luminal B-stage IIB in 2017 and was subjected to simple mastectomy. Tamoxifen was administered as hormonal therapy and two years later, the patient experienced recurrent left breast cancer. Although tamoxifen was continued, the drug did not improve the condition, leading to six cycles of fluorouracil, adriamycin, and cyclophosphamide chemotherapy initiated in July 2020. Nine months later, the patient developed bone metastases and received carboplatin, paclitaxel, along with zoledronic acid.

After six months, the regimen was changed to vinorelbine and carboplatin for three months due to bone lesion progression followed by hormonal therapy with anastrozole for one year. Anastrozole was replaced with exemestane for two months due to the progression of bone pain. In June 2023, the patient received cyclophosphamide, methotrexate, and fluorouracil due to disease progression in the left breast with an ulcer in the tumor mass but no improvement in the lesion. She had anemia [Hemoglobin 10.3g/dL (normal value 12.3-15.3 g/dL)]. Chest CT showed bone litic lesion on vertebrae C6, C7 and T1 and sclerotic lesion on manubrium and corpus strernum (bone metastases). Eribulin (1.4 mg/m^2 on days 1 and 8 every 21 days, administered as IV bolus for 2–5 minutes) was initiated. Disease stabilization was achieved with no adverse events reported. The patient was followed for six years (2017–2023).

Fig. 3. Lymph Node Enlargement of Patient 1

Table 1 Summary of Reported Cases of Metastatic Breast Cancer Treated with Eribulin

Author, Year of Diagnosis	Age/ sex	Histo-logy	Stage	Subtype	Eribulin ChT	Time from Diagnosis to Eribulin	Outcome	AE
Garrido, 1994[8]	90/F	IDC	IV	ER+/ PR+/ HER2-	5th line	19 years	Alive (partial response)	Grade III febrile neutropenia
Karasuno, 2006[9]	79/F	None	IV	TNBC	3rd line	28 months	Alive	Alopecia, anemia Hb 10
Garrido, 2007[8]	70/F	MIC	IV	ER+/ PR+/ HER2-	3rd line	7 years	Alive (Stable disease)	Febrile neutropenia
Wee, 2009[10]	56/F	IDC	IV	TNBC	3rd line	7 years	Alive	No AE
Garrido, 2010[8]	80/F	IDC	IV	ER+/ PR+/ HER2-	4th line	5 years	Alive (Stable disease)	Polyneuropa-thy
Fumet, 2010[11]	37/F	None	IV	ER+/ PR+/ HER2-	5th line	5 years	Death	No AE
Medici, 2012[12]	55/F	IDC	IV	ER+/ PR+/ HER-2	5th line	3 years	Partial response	No AE
Feng Xie, 2012[13]	55/F	None	IV	TNBC	8th line	4 years	Death	No AE
Tran, 2013[14]	61/F	None	IV	TNBC	4th line	3 years	Alive	Severe skin rash
Sancho, 2014[15]	68/F	IDC	IV	TNBC	3rd line	1 year	Death	No AE
Patient 1, 2015	48/F	ILC	IV	TNBC	4th line	8 years	Alive	Chill, constipation, Anemia
Borgonovo, 2015[16]	59/F	IDC	IV	ER+/ PR+/ HER2-	4th line	2 years	Partial response	Alopecia
Manthri, 2015[17]	48/F	IDC	IV	TNBC	3rd line	32 months	Alive (partial response)	No AE
Yoshinori, 2018[18]	42/F	SCC	IIIC	TNBC	3rd line	20 months	Complete Response	No AE
Sheik, 2019[19]	49/F	None	IV	ER+/ PR+/ HER2-	2nd line	1 year	Alive	Confusion
Kitada, 2020[20]	75/M	IDC	IV	ER-/ PR-/ HER2+	2nd line	6 months	Alive (partial response)	No AE

Abbreviations: AE = adverse event; ChT = chemotherapy; Dx = diagnosis; ER = estrogen receptor; HER2 = human epidermal growth factor receptor 2; Histol = histology; IDC = invasive ductal carcinoma; ILC = invasive lobular carcinoma; MIC = mixed invasive carcinoma; PR = progesterone receptor; SCC = squamous cell carcinoma; TNBC = triple-negative breast cancer

Discussion

Patient 1 had triple-negative breast cancer (TNBC) with PD-L1 positivity and disease progression after anthracycline, taxane, and radiotherapy. Due to financial limitations, anti–PD-L1 therapy was not administered. Eribulin was used as fourth-line chemotherapy. Meanwhile, patients 2 and 3 had hormone receptor-positive, HER-2 negative breast cancer, with imminent organ failure and progressive disease after several lines of ET (estrogen therapy). However, none of the patients was treated with a CDK 4/6 or an mTOR inhibitor due to the unavailability of national health insurance coverage. Eribulin was given as second-line therapy in patient 2 and as fifth-line in patient 3. The time from diagnosis to eribulin treatment was eight, three, and six years in patients 1, 2, and 3, respectively.

To the best of current knowledge, this is the first case report of MBC patients in Indonesia from various ethnic backgrounds who underwent Eribulin chemotherapy since its inclusion in the government health insurance program. These three cases showed substantial benefit from Eribulin. According to previous reports, patients with MBC often show resistance to anthracyclines and taxanes, which are typically used as the initial treatment options. Treatment failure frequently occurs in most patients even when these medications are used. However, cytotoxic chemotherapy remains the predominant approach for managing MBC, particularly in women with hormone receptor-positive breast cancer who do not respond to endocrine therapy, those experiencing visceral crisis, and TNBC.[6]

The ESMO guideline (2021) states that eribulin is recommended as third-line therapy in mTNBC and beyond the second line in hormone-positive, HER-2-negative MBC. In this context, single-agent chemotherapy agents include anthracyclines, taxanes, capecitabine, eribulin, vinorelbine, and other drugs for patients with imminent organ failure or progressive disease after several lines of endocrine (ET) + targeted therapy. For patients diagnosed with metastatic triple-negative breast cancer (mTNBC), chemotherapy, with or without immune checkpoint inhibitor (ICI) therapy based on PD-L1 status should be considered.[7]

Patient 1 initially developed chest wall recurrence and lymph node enlargement, but experienced improved lesion and size reduction after eribulin chemotherapy. Patient 2 developed brain and liver metastases before treatment with eribulin as second-line chemotherapy. According to previous studies, eribulin showed a significantly higher overall response rate (ORR) in patients with liver and brain metastases (BM). Based on the results, seven instances of complete responses were observed in various metastatic sites such as lung, liver, bone, and others. A partial response was also recorded specifically in cases of brain metastases.[6] A post hoc analysis by Shaughnessy stated that patients with liver metastases randomly assigned to receive eribulin showed a nominally significant difference in overall survival (OS) compared to those randomized to receive TPC or capecitabine (median:13.4 versus 11.3 months; HR, 0.84 [95% CI: 0.72, 0.97]).[4]

A retrospective study used data from Cancer Treatment Centers of America to estimate overall survival (OS) in clinical practice for patients with advanced breast cancer and visceral metastasis (liver or lung) treated in third-line setting with eribulin, gemcitabine, or capecitabine. The results showed that patients treated with eribulin had a numerically higher median OS compared to those who received other regimens. Specifically, the median OS was 9.8 months (95% CI 8.3, 12.8) for eribulin, 7.2 months (95% CI 5.8, 10.3) for gemcitabine, and 9.1 months (95% CI 6.3, 15.4) for capecitabine.[22] Renaud *et al*., in another study, found that 75% of patients experienced progressive brain metastases after eribulin administration. This led to the conclusion that eribulin had a limited impact on brain metastases evolution.[23] Additionally, patients 1 and 3 developed bone metastasis with a nominally significant difference in OS (median: 14.6 versus 12.5 months).[4] All three patients are still alive at present, surviving for four, three, and three months post-erilubin treatment respectively.

The most common side effects of eribulin in the EMBRACE trial were asthenia or fatigue (54%), and neutropenia (52%). Discontinuation of treatment was primarily attributed to peripheral neuropathy, the most frequent adverse event, observed in 5% of patients.[5] In patient 1, the adverse events (AEs) including grade I chills, grade I constipation, and grade II anemia did not lead to eribulin discontinuation. Based on the available literature, chills as AEs have not been previously reported.[5] Despite the associated toxicity, eribulin showed favorable outcomes for most patients. According to Fujii, the drug has a potential antitumor mechanism that may

prevent the development of new metastases as well as a positive impact on the immunological status of patients with breast cancer.[24,2]

Previous reports of patients with breast cancer who received eribulin as both early and late chemotherapy regimens are presented in Table 1.

In phase 3 open-label randomized study, eribulin monotherapy was compared with treatment of physician's choice (TPC) in patients with MBC (EMBRACE). The results showed that eribulin monotherapy caused a clinically significant enhancement in overall survival compared to TPC in women with MBC despite extensive previous treatments.[5] The antitumor activity of eribulin is characterized by a unique interaction with microtubules, specifically inhibiting the growth phase without affecting the shortening phase. In addition to the mitotic effects, in vitro and preclinical studies suggest that eribulin may engage in non-mitotic mechanisms, including vascular remodeling, reversing epithelial-to-mesenchymal transition (EMT), as well as inhibiting cancer cell migration and invasion. Some of these effects have also been observed clinically, for example, in the United States, eribulin is approved for treating patients with MBC after receiving at least two previous chemotherapeutic regimens for metastatic disease, including anthracycline and taxane in either the adjuvant or metastatic setting. Furthermore, the approval of eribulin for MBC has been extended to second-line metastatic settings in other regions, including the European Union.[3,21]

In conclusion, eribulin chemotherapy was associated with favorable clinical outcomes in heavily pre-treated patients with metastatic breast cancer, including those with liver, lung, bone, and brain metastases. This case series provides real-world evidence supporting the use of eribulin in similar clinical settings. Eribulin may be considered for MBC patients who have progressed after two to three prior taxane- or anthracycline-based regimens. Further studies exploring combinations of eribulin with other chemotherapy agents, targeted therapies, or immunotherapy are warranted.

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