RESEARCH ARTICLE

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Differential Clinical Outcomes of Palliative Radiotherapy among Different Molecular Subtypes of Metastatic Breast Cancer: A Prospective Study

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Abstract

Background: Molecular classification is used to tailor systemic therapy in breast cancer (BC). However, there is a paucity of literature correlating the response to radiotherapy with molecular subtypes of metastatic breast cancer (MBC) This prospective study intends to evaluate the differences in clinical outcomes in the different molecular subtypes of MBC to hypofractionated palliative radiotherapy (HPRT). **Methods:** MBC patients between December 2021 to September 2022, with Karnofsky Performance status > 70, were enrolled and treated with HPRT. All patients received systemic therapy. All patients were evaluated until 12 months post-radiotherapy. The molecular subtype of BC, local control (LC), and progression-free survival (PFS) were documented. **Result:** Eighty patients were recruited, with a mean age of 51 ± 10.48 years. Twelve of 80 patients expired, and 16 of 80 patients were lost to follow-up. The molecular subtypes were: Luminal B (37.5%), Luminal A (30%), TNBC (20%) and HER2+ (12.5%). At 6 months post-RT, 61.5% patients had local control (LC) at their metastatic site, whereas 38.5% had Progressive disease (PD). At 12 months, 71.1% had LC at the metastatic site, and 28.9% had progression. Local control at 6 months by subtype: Luminal A - 83%, Luminal B - 60%, HER2+ – 50% and TNBC – 31.2% (p = 0.01). The median progression-free survival (PFS) of the study group was 6 months (95% CI: 4.78-7.22), with TNBC patients performing the poorest. **Conclusion:** Luminal subtypes have better local control and progression-free survival post-HPRT compared to TNBC and HER2+ subtypes, which can further be used to stratify radiotherapy fractionation schedules.

Keywords: Molecular subtypes- Metastatic Breast Cancer- Palliative Radiotherapy

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Introduction

Breast cancer is the most common cancer in women, with an estimated global incidence of 2.3 million new cases in 2020, representing 11.7% of all cancers [1]. Metastatic breast cancer (MBC) has been reported in approximately 5% to 25% of patients across various centers in India [2]. The most common initial site of distant spread is bone (51%), followed by lung (17%), brain (16%), and liver (6%) [3]. The remaining 10% of patients present with multiple metastatic sites.

Molecular analysis of breast cancers using immunohistochemistry (IHC) has enabled sub-classification into distinct subtypes. Broadly, these include Luminal Estrogen Receptor (ER)-positive (Luminal A and Luminal B), Human Epidermal Growth Factor Receptor 2 (HER2)-enriched, and Basal-like (triple-negative breast cancer, TNBC) subtypes [4]. Prognostic differences among these subtypes are largely attributed to their varying degrees of radio-sensitivity and biological aggressiveness [5].

Each subtype demonstrates a preferential pattern of metastatic spread. Luminal A (LA) and Luminal B (LB) subtypes are more likely to exhibit bone-only metastases, whereas Basal-like (TNBC) and HER2-positive subtypes have a higher propensity for visceral metastases, particularly to the brain, liver, and lungs [6]. Brain metastases are estimated to occur in 10%–15% of all breast cancer cases with brain involvement, rising to 30% in stage IV disease. Notably, patients with TNBC have a 25%–45% estimated risk of developing brain metastases [7].

Oligometastatic breast cancer (OMBC) refers to a subset of MBC characterized by ≤5 metastatic lesions [8].

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These patients generally have a more favorable prognosis and prolonged overall survival compared to those with polymetastatic disease (>5 metastatic sites).

Metastatic sites in MBC are commonly treated with radiotherapy, typically with palliative intent. However, with the improvement in survival outcomes, the role of metastasis-directed radiotherapy in MBC is evolving. Ultra-hypofractionated radiotherapy, delivered using stereotactic techniques as ablative treatment, has shown a survival benefit in OMBC compared to standard palliative regimens [9].

Based on molecular profiling, metastatic breast cancers (stage IV) are more frequently HER2+/ER−PR−, Luminal B, or TNBC/Basal subtypes—accounting for approximately 40% of metastatic cases, while these subtypes constitute only 26% of stage I–III breast cancers [10]. This distribution aligns with the increased aggressiveness of these tumor subtypes relative to the Luminal A variant.

While receptor status is routinely used to guide systemic therapy, there is limited literature correlating radiation response with molecular subtypes in metastatic breast cancer. This gap in knowledge forms the rationale for the present study, which aims to evaluate the differential radiotherapeutic response among various molecular subtypes of breast cancer in the metastatic setting.

Materials and Methods

Patients diagnosed with metastatic breast cancer referred to the Department of Radiation Oncology between December 2021 and September 2022 were recruited for the current study after obtaining written informed consent. Patients with a Karnofsky Performance Status below 70, those previously irradiated to metastatic sites and patients receiving radiopharmaceutical therapy were excluded from the study.

Complete metastatic evaluation was done with Contrast enhanced Computed tomography scan (CECT scan) of Neck, Thorax, Abdomen, Pelvis or whole body PET-CT for patients who were affordable for the same. Gadolinium enhanced Magnetic Resonance Imaging (MRI) was done for brain metastases.

CT Simulation

Patients were immobilised with a thermoplastic mask or vacloc where applicable. CT simulation imaging was taken without contrast with 3 mm slice thickness.

Target volume delineation and Treatment Planning

Extracranial Gross metastatic disease was contoured based on radiological investigations and a Planning Target Volume (PTV) margin of 1 cm was given for the conventional plans. Surrounding OARs (organs at risk) were contoured. RT planning was done by 3 Dimensional Conformal techniques.

A dose of 30 Gy /10 Fr was used for all cases of Whole Brain Radiotherapy (WBRT) and bone radiotherapy delivered conventionally. Ultra Hypofractionated regimen was used on a case to case basis.

Follow up

All patients were evaluated at 1 month , 3 month, 6 month and 12 month (when available) after completion of radiotherapy. Local control (LC) and Progression free survival (PFS) were documented after radiation to the metastatic site at each interval and further correlated with each subtype of breast cancer.

Follow up imaging was done and the diseases assessment was done by Response Assessment in Neuro Oncology (RANO) criteria [11] and Response Assessment Criteria in Solid Tumours (RECIST 1.1) criteria [12] under the following heading - Complete response (CR), Stable disease (SD), partial response (PR) and Progressive disease (PD)

Statistical analysis

Data was analysed and statistically evaluated using the SPSS-PC-20 version. Normal distribution of different parameters was tested by the Shapiro-Wilk normality test. Quantitative data was expressed in mean±standard deviation. Qualitative data were expressed in frequency and percentage and statistical differences between the proportions was tested by chi square test. Kaplan meir curve was used to calculate progression free survival and log rank test was used to compare PFS between different molecular subtypes. p value less than 0.05 was considered statistically significant.

Results

80 patients were recruited for the current study. Baseline characteristics of the patients are given in Table 1. Mean age of the patients was 51±10.48 years. Out of the 80 patients, 1 patient expired before 1 month, 2 patients at 3 months, 8 patients at 6 months and 1 patient at 12 month follow up period. 16 patients were lost to follow up at 12 months. The most common histological grade was grade 2 (68.8%) followed by grade 3 (28.7%).

53/80 (66.25%) patients had oligometastases and 27/80 (33.75%) had polymetastases. 39/80 (48.75%) of patients had KPS between 70-79, 27/80 (33.75%) between 80-89 and 14/80 (17.5%) above 90. Most common molecular subtype was Luminal B(37.5%) followed by Luminal A(30%), HER2 (12.5%) and TNBC (20%) . Mean Ki-67% was 35 ± 24. The most common site of metastases was bone (50%) followed by brain (42%), Node (3.8%) and rare metastatic sites were observed in 3 patients (3.8%) . 20/80 patients were upfront MBC cases and 60/80 patients presented after having locoregional and systemic therapy. Out of 40 bone metastases patients 34 received conventional hypofractionated RT (30Gy/10Fr), 6 patients received Stereotactic Ablative Radiotherapy(SABR)- 25Gy/5Fr . 34/80 patients had brain metastases out of which 31 patients received conventional hypofractionated regimen (30Gy/10Fr) ; 2 patients received 25Gy/5Fr and 1 patient received 24Gy/1Fr. 3/80 patients had Nodal metastasis received 30Gy/10Fr. 3/80 had rare metastatic sites and received 30Gy/10fr. Table 2 shows the most common site of metastases was to the bones in Luminal A [19/80 patients (79.2%)] and B subtypes [14/80 patients (46.7%)]. For HER 2 and TNBC,

Table 1. Baseline Characteristics of Patients (n= 80)

Characteristics	
Age	51.10 ± 10.48 years
KPS 70-79	39 (48.75%)
KPS 80-89	27 (33.75%)
KPS 90 and above	14 (17.5%)
Histological Grade	
I	2 (2.5%)
II	55 (68.8%)
III	23 (28.7%)
Molecular Subtypes	
LUMINAL A	24 (30%)
LUMINAL B	30 (37.5%)
HER 2	10 (12.5%)
TNBC	16 (20%)
Ki- 67	35 ± 24
Metastatic site	
Bone	40 (50%)
Brain	34 (42.5%)
Other sites	3 (3.8%)
Node	3 (3.8%)
Types of Metastases	
Oligometastases	53 (66.25%)
Polymetastases	27 (33.75%)
Surgery vs Upfront	
Surgery	60 (80%)
Upfront	20 (25%)

Table 2. Percentage of Different Metastatic Sites In Different Molecular Subtypes

	Luminal A	Luminal B	HER2	TNBC
Bone	19 (79.2%)	14 (46.7%)	2 (20%)	5 (31.2%)
Brain	3 (12.5%)	12 (40%)	8 (80%)	11 (68.8%)
Node	1 (4.2%)	2 (6.7%)	0	0
Other sites	1 (4.2%)	2 (6.7%)	0	0

Table 3. Response to Radiotherapy At 1, 3, 6, 12 Months (RANO/ RECIST 1.1 criteria)

Response	1 month	3 month	6 months	12 months
CR	1 (1.3%)	3 (3.8%)	-	-
PR	3 (3.8%)	18 (22.5%)	6 (7.5%)	-
SD	74 (92.5%)	36 (45%)	42 (52.5%)	37 (46.3%)
PD	1 (1.3%)	21 (26.3%)	22 (27.5%)	14 (17.5%)
EXPIRED	1 (1.3%)	2 (2.6%)	8 (10%)	1 (1.3%)
NA	-	1 (1.3%)	2 (2.5%)	28 (35%)

the most common metastatic site was the Brain.

Table 3 and Table 4 show the response to radiotherapy at 1, 3, 6 and 12 months and in each subtypes of breast cancer, respectively. During the 3rd month, 26.3% patients had progressive disease (PD), 22.5% had a partial response (PR) and 3.8 had CR. At 6 months 27.5% patients had PD and 7.5% of patients had PR. Basal type (TNBC) had 43.8% PD at 3 months and 37.5% at 6 months interval. Maximum loss to follow up was at 12 months in each subtypes.(Figure 1) Patients with oligometastases fared better with 64.2% patients (34/53) having stable disease

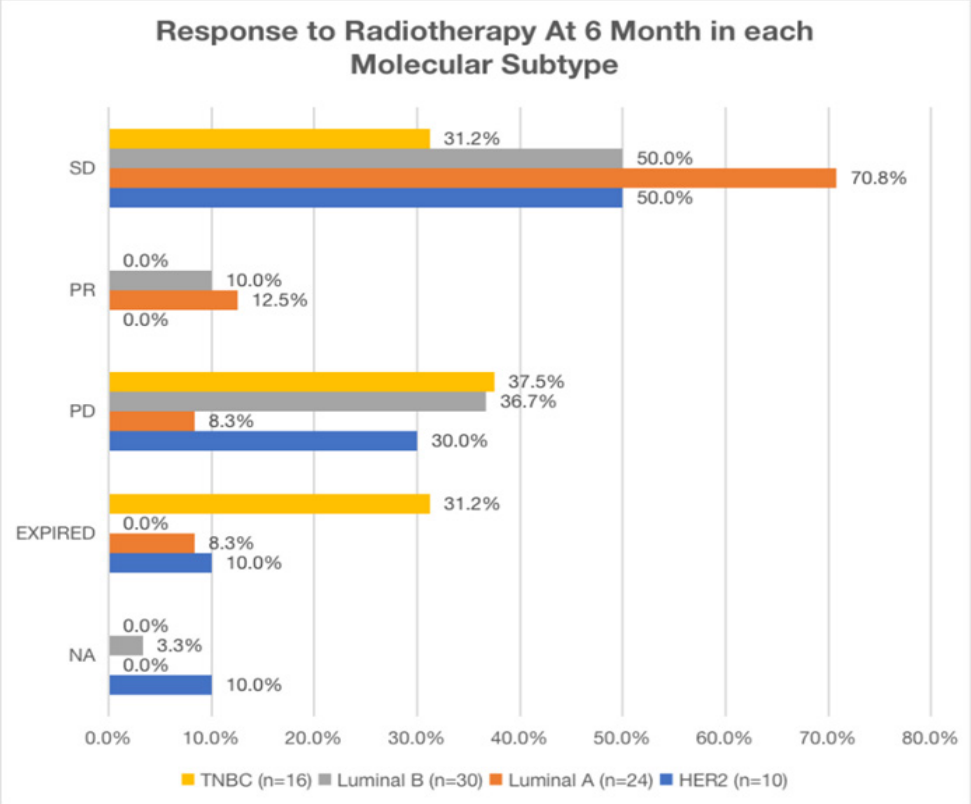

Figure 1. Bar Graph of Response to Radiotherapy at 6 Month Follow up Interval in Each Molecular subtype

Table 4. Response to Radiotherapy at 1, 3, 6, 12 Months in each Molecular Subtype (RANO/ RECIST 1.1 criteria)

Response	HER2 (n=10)	Luminal A (n=24)	Luminal B (n=30)	TNBC (n=16)
At 1 month				
CR	0	1	0	0
PR	0	2	1	0
SD	9	21	29	15
PD	0	0	0	1
EXPIRED	1	0	0	0
At 3 month				
CR	0	1	2	0
PR	1	9	7	0
SD	4	10	14	8
PD	4	4	6	7
EXPIRED	0	0	1	1
NA	1	0	0	0
At 6 month				
PR	0	3	3	0
SD	5	17	15	5
PD	3	2	11	6
EXPIRED	1	2	0	5
NA	1	0	1	0
At 12 month				
SD	3	16	16	2
PD	2	4	6	2
EXPIRED	0	0	0	1
NA	5	4	8	11

in comparison to poly metastatic patients with 29.6% patients(8/27) having stable disease at 6 months.

Patients with CR or PR at their metastatic site were considered to have Local Control. At 6 months, 48/80 had local control with Luminal subtypes having the highest LC as shown in Table 5. At 12 months, 52/80 remained alive, 37/52 (71.1%) had local control at the metastatic site and 15/52 (28.9%) had progression. All patients continued to receive systemic therapy/ hormonal therapy.

Median PFS of the entire study group of 80 patients was 6 months (95% CI: 4.78-7.22) (Table 5). The Kaplan-Meier survival curve in Figure 2 illustrates Progression-Free Survival (PFS) over a 12-month follow-up period among patients stratified by molecular subtypes of breast

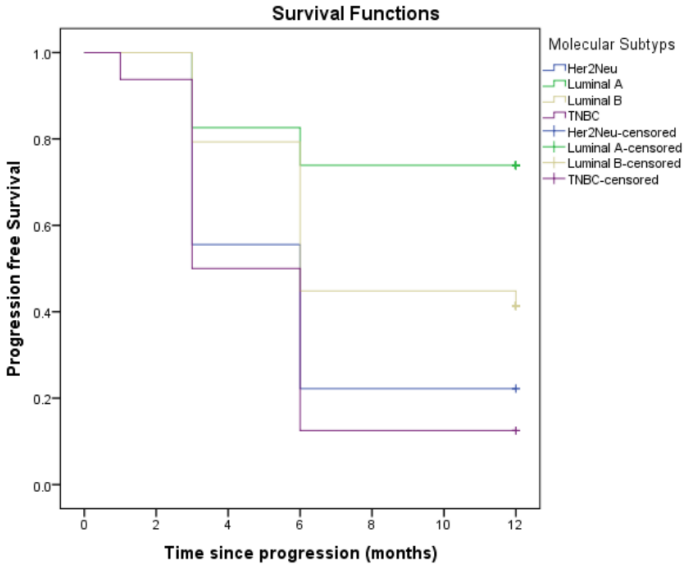

Figure 2. Kaplan Meir Analysis Showing Comparison of PFS Till 12 Months between Molecular Subtypes

Table 5. Local Control At 6 & 12 Months in each Molecular Subtype

Local control (in months)	HER2 (n=10)	Luminal A (n=24)	Luminal B (n=30)	TNBC (n=16)	P value
6 month (48/80)	5 (50%)	20 (83.3%)	18 (60%)	5 (31.2%)	0.01
12 month (37/80)	3 (30%)	16 (66.7%)	16 (53.3%)	2 (12.5%)	0.32

cancer: Luminal A, Luminal B, Her2Neu, and Triple-Negative Breast Cancer (TNBC). Patients with Luminal A & B subtypes together had a statistically higher PFS (6 months 95% CI 4.42-7.57) compared to Her2 and TNBC patients (3 months 95% CI 1.49-4.50) (p = 0.01). Luminal A demonstrated the highest PFS probability throughout the 12-month period, with minimal early events and most patients remaining progression-free by the end of follow-up. Luminal B and Her2Neu subtypes showed moderate drops in PFS, indicating earlier disease progression in a larger subset of patients compared to Luminal A. TNBC showed a steep decline in PFS within the first 6 months, reflecting early and frequent disease progression. This group had the lowest overall survival probability at 12 months.

Discussion

While systemic therapy remains the mainstay of management of MBC, palliative radiotherapy remains an important modality as an adjunct to systemic therapy, to address the symptoms and improve the quality of life. It can be delivered in the form of Hypofractionated conventional RT with or without high precision techniques to the metastatic site. The differential impact of radiotherapy in MBC has not been evaluated earlier and has been the focus of the current study.

Fan et al. [13] have demonstrated that different molecular subtypes have preferential sites for metastases which allows personalized cancer management and follow-up strategies. Patients with Luminal A (51.1%) and Luminal B (44.7%) were most prone to bone metastasis, whereas liver metastasis was more frequently observed in HER2-enriched breast cancer patients (29.1%) and Triple Negative patients had a higher probability of brain metastasis (HR 3.07, 95% CI: 1.04-9.07). In our study, we had similar observations with Luminal subtypes having higher incidence of bone metastases (79.2%) while TNBC patients predominantly had brain metastases (80%). Brain metastases (80%) were more common than bone metastases (20%) in HER 2 positive patients. The pathophysiology of preferential metastasis of the various molecular subtypes has been elucidated by Smid et al. [14]. A differential expression of genes in the different molecular subtypes is responsible for organ specific metastasis. The WNT pathway was implicated in both basal and luminal B subtypes. The study suggested that active WNT/β-catenin signaling contributes to basal breast tumor metastasizing to the brain, whereas the absence of WNT/β-catenin signaling allows for luminal B type tumors to metastasize to bone. Niwinska A et al also observed that brain metastases was seen more in TNBC (28%) and HER 2 (53%) while Luminal subtype (19%) has less predisposition towards brain [15]. The gene upregulated for bone metastases in HER2 positive cases are different. The differential expression of mammaglobin 1 and lipophilin B genes, both on 11q13 a common amplified region in breast cancer, in HER2 tumors are responsible for bone specific metastasis [14]. This suggests that HER 2 subtype metastasizing to bone follows a different gene expression and biology when compared to hormone positive subtypes.

Luminal subtypes are known to have a better prognosis in comparison with HER2 and TNBC in non metastatic BC. Lower rates of ipsilateral breast tumour recurrence (IBTR) have been observed at 10 years in Luminal subtypes among the Early Breast Cancer patients in Swedish Breast cancer trial who received adjuvant Radiotherapy [16]. IBTR(10 years) for Luminal A-like tumours (19% v 9%; P = .001), luminal B-like tumours (24% v 8%; P < .001) in comparison with triple-negative tumors (21% v 6%; P = .08), and Her2+ tumours (15% v 19%; P = .6). The present study has performed similar comparisons between different molecular subtypes in the metastatic setting. We observed a higher rate of complete response (CR) and partial response (PR) in Luminal subtypes whereas a higher incidence of progressive disease in TNBC and HER2+ cases. This could be due to the differential radiosensitivity and aggressiveness between subtypes.

Radiotherapy causes DNA double-strand breaks (DDSB) in the tumour cells and this DNA damage triggers cell cycle arrest, apoptosis and senescence which ultimately result in cell death. There are multiple mechanisms which impact the effect of radiation upon the tumour cells based on intrinsic radiosensitivity/ radioresistance. Among the luminal subtypes, it is proposed that tumours with high oestrogen would be more sensitive to RT. Oestrogen has been postulated to accelerate Gl to S phase transition of the cell cycle which leaves tumour cells with lesser time to repair RT induced DNA damage thereby promoting apoptosis [17]. Lin He et al. [5] proposed that radiosensitivity in is TNBC largely due to an increase in the ROS level and modulation of DNA double-strand break- and/or apoptosis-related proteins, such as 8-OHdG, γH2AX, and p53. HER2-positive breast cancers, on the other hand, demonstrate high radioresistance that is correlated to the transactivation of the NF- κB-mediated HER2 promoter inducing HER2 overexpression, β-catenin expression during EMT (Epithelial mesenchymal transition) [5] .

With improvement in survival of breast cancer, the use of metastases - directed radiotherapy in MBC has been evolving. Ultra-Hypofractionated RT used as Ablative radiotherapy with the aid of stereotactic techniques in OMBC has been demonstrated to offer a survival advantage in comparison with standard palliative care treatments [9] . It is essential to evaluate the plans of prior

radiotherapy schedules before embarking on any palliative radiotherapy in breast cancer patients, who would have often competed RT to the breast or chest-wall in the past [18, 19] . Favourable outcomes with >90% 3 year local control rates have been demonstrated in multiple studies after ablative radiotherapy in the presence of a solitary metastatic lesion, bone only metastases or lesions not progressing on systemic therapy [7, 20] , Milano et al. [21] reported on the outcomes of patients with 5 detectable breast cancer metastases treated with SBRT with curative intent. The 4-year LC, PFS and OS were 89%, 38% and 59%, respectively. Kobayashi et al. [22] in a mixed study of metastasectomy and SBRT, reported an estimated overall survival (OS) of 185.0 months and relapse-free interval (RFI) of 48.0 months. It was seen that patients who have not achieved CR/NED developed progressive disease after 101 months. Long term results of the Stereotactic Ablative Radiotherapy for the Comprehensive Treatment of Oligometastatic Cancers(SABR-COMET) Phase II study has demonstrated SBRT to offer a survival advantage in comparison with standard palliative care treatments (5-year OS rate was 17.7% versus 42.3% P = .006) [9] . However, they included primaries other than breast cancer as well. The present study has only 9/80 (11%) of patients who were treated using SBRT. Hence, a separate analysis of their outcomes has not been performed.

Very few studies have compared the outcomes of MBC with respect to different molecular subtypes. Abdelhakiem et al. [6], reported median survival of 34.1, 28.2, 5.3, and 15.7 months in LA, LB, TNBC and HER2 subtypes respectively ($p < 0.001$) after palliative radiotherapy to the bone metastases. On multivariate analysis, he reported overall survival with TNBC (HR 3.7), HER2 (HR 1.75), and LB (HR 1.28) fairing worse than LA ($p < 0.001$). The current study, on the other hand, has included MBC patients with all actionable metastatic sites. The Local Control at metastatic sites and PFS in our study demonstrate similar patterns in the Indian subset of patients. The impact of palliative RT upon overall survival in the various subtypes has not been evaluated in our study.

To our knowledge, this remains one of the first studies to assess the differential impact of palliative radiotherapy in the different molecular subtypes of MBC patients in the Indian population. The current study, however, has a few limitations. Very few patients were found suitable for SRS/SBRT especially due to clinical and logistic limitations. MBC remains a heterogeneous group of patients and all patients invariably receive some form of systemic therapy after/before radiotherapy. So, the impact of radiotherapy cannot be assessed independently.

In conclusion, luminal subtypes have a tendency to metastasize to the bones and are associated with better local control and progression-free survival following palliative radiotherapy. In contrast, triple-negative breast cancer (TNBC) and HER2-positive subtypes have a higher propensity for brain metastases and are linked to poorer clinical outcomes, reflecting their aggressive biology and relatively lower radiosensitivity.

These differences highlight the potential for more personalized approaches to palliative radiotherapy, including stratification of radiation fractionation regimens based on the molecular subtype of metastatic breast cancer (MBC), with the goal of maximizing therapeutic benefit.

Author Contribution Statement

NT – Study Conception, Data Analysis & Interpretation, Writing and Review of Manuscript; NN - Data Analysis & Interpretation, Writing and Review of Manuscript; AS - Data Collection & Interpretation, Writing of Manuscript; UK - Study Conception, Review of Data Analysis, Review and editing of Manuscript; MK - Case Planning, Data collection, Manuscript review; TP - Data Analysis & Interpretation, Editing of Manuscript; SP - Data Analysis & Interpretation, Editing of Manuscript.

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Ethical committee clearance

KMIO/MEC/012/17.February.2021

Conflict of Interest

None.

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