Enrolment of Patients with Metastatic Lobular Breast Cancer in Clinical Trials in the Multicenter ESME Cohort

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Introduction

Invasive lobular carcinoma (ILC) represents about 15% of breast cancers and is the second most common histological subtype after invasive carcinoma of no special type (NST). ILC differs from NST in clinical presentation, histological features, and molecular profile [1] . Nevertheless, ILC-specific characteristics are often overlooked when making treatment decisions in clinical practice [2]. Available evidence suggests that patients (pts) with ILC are under represented in clinical trials [3]. **This study aimed to evaluate clinical trial enrolment among pts with metastatic breast cancer (MBC) HR+/HER2– according histological subtypes: NST and ILC.**

Methods and Materials

Patients included in the ESME MBC (Epidemiological Strategy and Medical Economics – Metastatic Breast Cancer), a national registry collecting individual-level patient data from 18 French Comprehensive Cancer Centers (NCT03275311).

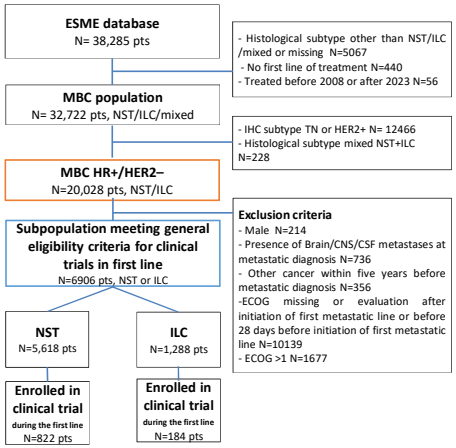
Primary objective:

- To evaluate the proportion of patients enrolled in clinical trials for MBC HR+/HER2– according to histological subtype : NST and ILC

Secondary objectives:

- To evaluate the proportion of patients enrolled in clinical trials conducted in first line for MBC HR+/HER2– according to histological subtype
- To evaluate the proportion of patients enrolled in clinical trials according to treatment period and by histological subtype
- To describe the characteristics of clinical trials for each histological subtype
- To describe the characteristics and treatments of patients with MBC HR+/HER2– NST or ILC enrolled or not in clinical trials during the first line.
- To identify factors associated with the enrolment in clinical trials during the first line MBC HR+/HER2– in NST and ILC patients and in a sub-population of ILC patients eligible to clinical trials.

We assessed and compare clinical trial enrolment rates according to histological subtype, considering trials initiated at any treatment line and specifically at first line.
Within this population, patients meeting general eligibility criteria for clinical trials (female, ECOG 0–1, no CNS metastases, no recent other malignancy) were identified among both NST and ILC subtypes to investigate clinical characteristics, treatment patterns and determinants of trial participation. Comparisons between NST and ILC were assessed using Kruskal Wallis test for continuous variables and Chi-squared or Fisher's exact test for qualitative variables. Multivariate analyses were performed using a logistic regression model.



Results

Population MBC HR+/HER2– N= 20,028

Table 1. Patient and disease characteristics

	NST n (%)	ILC n (%)
Total	16 160	3 868
Female	15950 (98.7%)	3864 (99.9%)
Median age at metastatic diagnosis, yrs	62.0	65.0
Post-menopausal	11376 (71.3%)	3199 (82.8%)
ECOG PS 0	3192 (43.1%)	634 (36.5%)
Histological grade I	2140 (13.7%)	507 (14.1%)
Histological grade II	9455 (60.4%)	2760 (77.0%)
Histological grade III	4054 (25.9%)	318 (8.9%)
≥2 metastatic sites	7390 (45.7%)	1528 (39.5%)
Visceral metastases	7267 (45.0%)	1239 (32.0%)
Serous or bone only	5550 (34.3%)	1655 (42.8%)

Figure 1. Patients enrolled in clinical trials

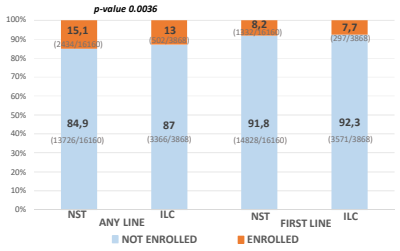


Table 2. Characteristics of clinical trials in first line

	NST n (%)	ILC n (%)
Total	1332	297
Trial phase in first line		
I	50 (3.8%)	9 (3.0%)
II	175 (13.2%)	38 (12.8%)
III	471 (35.4%)	122 (41.1%)
IV	25 (1.9%)	4 (1.3%)
Not available	604 (45.4%)	123 (41.4%)
Therapy in first line		
Endocrine therapy	779 (58.5%)	210 (70.7%)
Chemotherapy	407 (30.6%)	63 (21.2%)
Targeted therapy	880 (66.1%)	211 (71.0%)
Immunotherapy	22 (1.7%)	2 (0.7%)

Subpopulation meeting general eligibility criteria for clinical trials in first line N= 6,906

Table 3. Patient and disease characteristics

	NST n (%)		p-value	ILC n (%)		p-value
	NOT ENROLLED	ENROLLED		NOT ENROLLED	ENROLLED	
Total	4796	822		1104	184	
Median age at metastatic diagnosis, yrs	60	58	0.003	64	62	0.004
Post-menopausal	3287(68.5%)	550 (66.9%)	0.354	885 (80.2%)	143 (77.7%)	0.44
ECOG PS 0	2573(53.6%)	488 (59.4%)	0.002	518 (46.9%)	98 (53.3%)	0.11
Histological grade I	640 (13.7%)	103 (12.8%)	0.048	157 (15.0%)	18 (10.3%)	0.056
Histological grade II	2802(59.8%)	519 (64.3%)		784 (75.1%)	146 (83.4%)	
Histological grade III	1241(26.5%)	185 (22.9%)		103 (9.9%)	11 (6.3%)	
≥2 metastatic sites	2223(46.3%)	422(51.3%)	0.008	452 (40.9%)	91(49.5%)	0.030
Visceral metastases	2049(42.7%)	406 (49.4%)	0.0004	345 (31.2%)	57 (31.0%)	0.94
Serous or bone only	1632(34.0%)	242 (29.4%)	0.010	472 (42.8%)	73 (39.7%)	0.434

Figure 2. Patients enrolled in a clinical trials

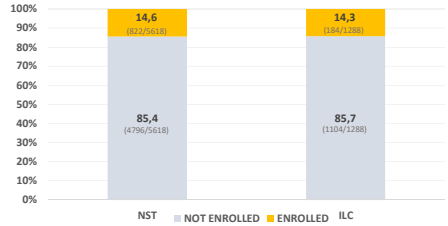


Figure 3. Characteristics of clinical trials

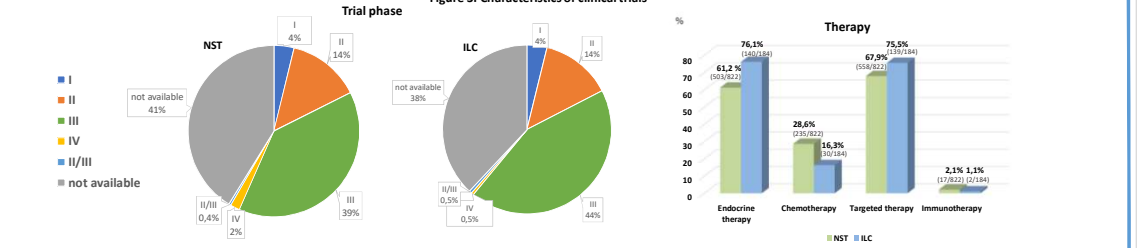


Table 4. Factors associated with the enrolment in clinical trials

	NST Odds Ratio [95%CI]	p-value	ILC Odds Ratio [95%CI]	p-value
Age at metastatic disease diagnosis (cl.)				
< 65 years	1.00		1.00	
>= 65 years	0.87	0.090	0.68 [0.49; 0.95]	0.023
Performance status within 28 days before initiation of first metastatic line				
0	1.00		1.00	
1	0.77	0.001	0.82 [0.59; 1.14]	0.235
Histological grade of initial diagnosis				
I	1.00		1.00	
II	1.16 [0.92; 1.46]	0.200	1.60 [0.95; 2.70]	0.077
III	0.91 [0.70; 1.18]	0.475	0.93 [0.42; 2.05]	0.849
Type of metastases				
Visceral	1.00		1.00	
Serous or bone only	0.75 [0.63; 0.90]	0.002	0.95 [0.65; 1.40]	0.794
Other	0.79 [0.65; 0.96]	0.018	1.19 [0.78; 1.82]	0.409
De Novo metastatic				
No	1.00		1.00	
Yes	0.80 [0.68; 0.94]	0.006	1.07 [0.77; 1.49]	0.704

Discussion and Conclusions

In this large real-world French cohort, we confirmed that patients with ILC are less frequently enrolled in clinical trials compared with those with NST MBC.
However, when applying eligibility criteria for potential clinical trial participation (female, ECOG 0–1, no CNS metastases, no recent other malignancy), the proportion of ILC patients enrolled was similar to that of NST patients.
The multivariable analyses identified older age as an independent factor associated with lower trial participation in ILC.

This suggests that the under representation of ILC patients in clinical trials is largely driven by clinical characteristics affecting eligibility, as well as by the lower prevalence of this histological subtype. Once patients with favorable characteristics are selected, trial enrollment is comparable between ILC and NST.

References:

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