WHAT DOES REAL WORLD EVIDENCE TELLS?
A CASE ANALYSIS IN BREAST CANCER USING PHARMACEUTICAL CONSULTATION DATA

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OBJECTIVES:

Real World Evidence (RWE) use in both safety and effectiveness evaluations is recognized by EMA and FDA. **Pharmaceutical consultation (PC)** can be a good source of RWE, as it contains observations regarding adherence, adverse reactions, and response to therapy.

There is extensive evidence RWE use in oncology, but observational studies focused on PC and breast cancer are lacking.

Palbociclib, Ribociclib, and Abemaciclib are novel oral agents in hormone receptor-positive metastatic breast cancer (MBC). **The objective of this study is to evaluate RWE regarding the effectiveness and safety of these agents in MBC context**.

METHODS:

This retrospective observational study included patients followed in PC between 2017 and 2021. Data were collected from the electronic health records (EHR), the electronic database of drug dispensing, and from the structured PC's database.

Baseline demographic variables, histopathological variables and previous therapies were collected. The main clinical outcomes were Progression-Free Survival (PFS) and treatment tolerability.

The analysis of possible confounding factors was performed with Chi-Square test for categorical variables and T-student test for continuous numerical variables, with subsequent multivariate analysis. Statistical analysis was done with python 3.8.8.

RESULTS:

The study included 32 patients with MBC (Baseline distribution is described on table 1). PFS was 37 months for the total sample, 38 months for Palbociclib and 36 months for Ribociclib (log-rank, p = 0.65). Of the total sample, 26 patients (81%) presented at least one Drug Related Problem (DRP).

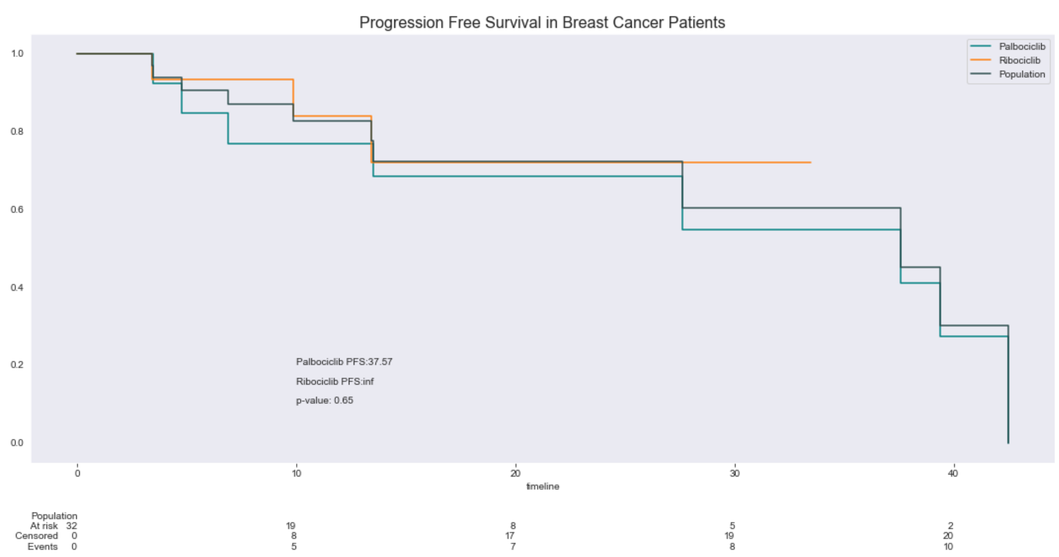

Table 1 – Baseline variables distribution

	Palbociclib	Ribociclib	Abemaciclib	Totals	p-value
Total Patients	13	15	4	32	
Gender					
F	13 (100)	15 (100)	4 (100)	68	
Age					**0,4**
Median	65 [53-94]	72 [54-92]	59 [56-73]	6	
Time from first diagnosis (years)					**0,46**
Median	6 [5-23]	5 [1-27]	11 [1-23]	6	
Histology					**0,63**
Lobular	3 (23)	5 (33.3)	2 (50)	10 (31.2)	
Ductal	5 (38.5)	4 (26.7)	1 (25)	10 (31.2)	
Neuroendocrine	1 (7.7)	0 (0)	0 (0)	1 (3.2)	
NOS (Non Otherwise Specified)	4 (30.8)	5 (33.3)	1 (25)	10 (31.2)	
Unknown	0 (0)	1 (6.7)	0 (0)	1 (3.2)	
Diferentiation Grade					**0,69**
G1 - Well differentiated	1 (7.7)	2 (13.3)	0 (0)	3 (9.3)	
G2 - Moderately differentiated	5 (38.5)	6 (40)	3 (75)	14 (43.8)	
G3 - Poorly differentiated	4 (30.8)	2 (13.4)	0 (0)	6 (18.8)	
Unknown	3 (23)	5 (33.3)	1 (25)	9 (28.1)	
Staging					
Size					**0,37**
T1	4 (30.8)	1 (6.7)	1 (25)	6 (18.8)	
T2	3 (23)	4 (26.7)	1 (25)	8 (25)	
T3	3 (23)	2 (13.3)	0 (0)	5 (15.6)	
T4	1 (7.7)	3 (20)	0 (0)	4 (12.5)	
Unkown	2 (15.5)	5 (33.3)	2 (50)	9 (28.1)	
Lymph Node Involvement					**0,64**
N0	3 (23)	2 (13.3)	0 (0)	5 (15.6)	
N1	4 (30.8)	3 (20)	2 (50)	9 (28.1)	
N2	2 (15.4)	4 (26.7)	0 (0)	6 (18.8)	
N3	2 (15.4)	1 (6.7)	0 (0)	3 (9.2)	
Unknown	2 (15.4)	5 (33.3)	2 (50)	9 (28.1)	
Metastatic Spread					**0,17**
M0	0 (0)	2 (13.3)	0 (0)	2 (6.2)	
M1	13 (100)	13 (86.7)	4 (100)	30 (93.8)	
Metastasis location (Can be more that one)					
Bone	9 (69.2)	7 (46.7)	4 (100)	20 (62.5)	
Liver	6 (46.1)	3 (20)	2 (50)	11 (34.4)	
Lung	1 (7.7)	3 (20)	0 (0)	4 (12.5)	
Skin	1 (7.7)	4 (26.7)	0 (0)	5 (15.6)	
Peritoneum	0 (0)	3 (20)	1 (25)	4 (12.5)	
Gastric	0 (0)	1 (6.7)	1 (25)	2 (6.3)	
BIRADS					**0,27**
2	6 (46.1)	6 (40)	2 (50)	14 (43.8)	
5	2 (15.4)	7 (46.7)	0 (0)	9 (28.1)	
6	1 (7.7)	1 (6.7)	0 (0)	2 (6.2)	
Unknown	4 (30.8)	1 (6.7)	2 (50)	7 (21.9)	
ECOG - PS					**0,26**
0	6 (46.1)	10 (66.7)	2 (50)	18 (56.2)	
1	4 (30.8)	5 (33.3)	1 (25)	10 (31.2)	
2	2 (15.4)	0 (0)	1 (25)	3 (9.4)	
3	1 (7.7)	0 (0)	0 (0)	1 (3.2)	
Hormonal Receptors					
Estrogen Receptors					**0,34**
Positive (80%-100%)	13 (100)	14 (93.3)	3 (75)	30 (93.6)	
Intermediate	0 (0)	0 (0)	1 (25)	1 (3.2)	
Negative (0%-20%)	0 (0)	1 (6.7)	0 (0)	1 (3.2)	
Progesterone Receptors					**0,53**
Positive (80%-100%)	6 (46.1)	4 (26.7)	2 (50)	12 (37.5)	
Intermediate	2 (15.4)	4 (26.7)	1 (25)	7 (21.9)	
Negative (0%-20%)	5 (38.5)	7 (46.7)	1 (25)	13 (40.6)	
Ki67					**0,31**
Low Grade (0%-2%)	1 (7.7)	0 (0)	0 (0)	1 (3.2)	
Intermediate Grade (2%-20%)	2 (15.4)	7 (46.7)	1 (25)	10 (31.2)	
High Grade (20%-100%)	6 (46.1)	5 (33.3)	1 (25)	12 (37.5)	
Unknown	4 (30.8)	3 (20)	2 (50)	9 (28.1)	
Target mutations					
Her2 negative	13 (100)	15 (100)	4 (100)	32 (100)	
BRCA negative	3 (23)	2 (13.3)	1 (25)	6 (18.8)	
Number of Previous Treatments					**0,92**
0	9 (69.3)	10 (66.7)	2 (50)	21 (65.5)	
1	3 (23)	4 (26.7)	0 (0)	7 (21.9)	
2	1 (7.7)	0 (0)	0 (0)	1 (3.2)	
3	0 (0)	1 (6.7)	0 (0)	1 (3.2)	
More than 3	0 (0)	0 (0)	2 (25)	2 (6.2)	
Concomitant Therapy					**0,46**
Anastrozol	0 (0)	0 (0)	1 (25)	1 (3.2)	
Tamoxifen	1 (7.7)	0 (0)	1 (25)	2 (6.2)	
Letrozol	5 (38.5)	8 (53.3)	2 (50)	15 (46.8)	
Fulvestrant	7 (53.8)	7 (46.7)	0 (0)	14 (43.8)	

CONCLUSIONS:

This study provides valuable evidence of the clinical results of oral drugs in MBC and points to the importance and reliability of PC data as a RWE source.