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Mitomycin C plus carboplatin followed by paclitaxel vs. standard doxorubicin-cyclophosphamide followed by paclitaxel-carboplatin neoadjuvant therapy in BRCA1/2-associated breast cancer

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Background

BRCA1/2-associated triple-negative breast cancer (TNBC) is an aggressive BC subtype, yet it exhibits high chemosensitivity. Emerging evidence suggest that mitomycin C, either as a monotherapy or combined with platinum agents, demonstrates efficacy in BRCA1/2-driven carcinomas. This clinical trial aimed at comparison of mitomycin C-based versus standard neoadjuvant chemotherapy (NACT) in BRCA1/2-associated TNBC.

Methods

The study included 52 *BRCA1/2* pathogenic allele carriers diagnosed with T1-3N0-3M0 TNBC. Patients were divided into two groups:

1) **an experimental group (n = 26)** that received four cycles of mitomycin C 10 mg/m^2 plus carboplatin (AUC 5) followed by 12 cycles of weekly paclitaxel 80 mg/m^2 (**MCbP-T**);

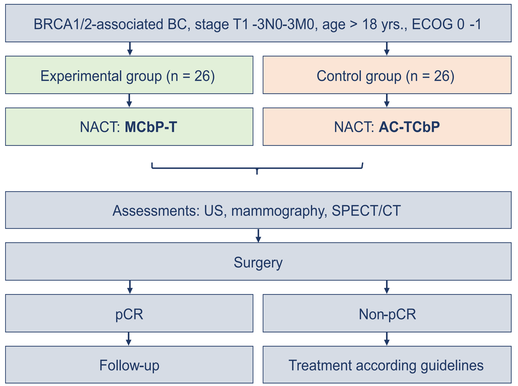
2) **a control group (n = 26)** that received four cycles of doxorubicin 60 mg/m^2 plus cyclophosphamide 600 mg/m^2 followed by 12 cycles of weekly paclitaxel 80 mg/m^2 plus carboplatin (AUC 2) (**AC-TCbP**).

Patient cohorts

	AC-T group (n = 26)	MCbP-T group (n = 26)
Germline pathogenic variant		
BRCA1	23 (89%)	26 (100%)
BRCA2	3 (12%)	0 (0%)
T stage		
T1	5 (19%)	1 (4%)
T2	17 (65%)	23 (88%)
T3	3 (12%)	2 (8%)
T4	1 (4%)	0 (0%)
N stage		
N0	10 (38%)	14 (54%)
N1	7 (27%)	7 (27%)
N2	3 (12%)	3 (12%)
N3	6 (23%)	2 (8%)
Grade		
G2	6 (23%)	5 (19%)
G3	20 (77%)	21 (81%)
Metabolic response		
Complete	18 (69%)	19 (73%)
Partial	8 (31%)	6 (23%)
Stabilization	0 (0%)	1 (4%)
Clinical response (RECIST)		
CR	15 (58%)	18 (69%)
PR	8 (31%)	7 (27%)
SD	3 (12%)	1 (4%)
Pathologic response (RCB class)	n = 26	n = 25
3	5 (19%)	0 (0)
2	3 (12%)	4 (16%)
1	2 (8%)	0 (0)
pCR	16 (62%)	21 (84%)

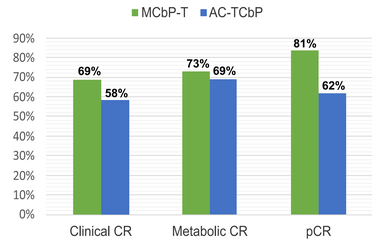
Therapy efficacy was evaluated based on RECIST criteria and the rate of complete pathological response (pCR) upon surgery.

Workflow



Results

Objective responses were recorded in all patients involved in the study. Clinical complete response was achieved in 18/26 (69%) and 15/26 (58%) patients in the **MCbP-T** and **AC-TCbP** arms, respectively (p = 0.57, Fisher's exact test).



In the **MCbP-T** arm, the frequency of pCR was 21/26 (81%). This was numerically but statistically non-significantly higher than that in the **AC-TCbP** group (16/26; 62%; p = 0.11, Fisher's exact test).

In the **AC-TCbP** arm, grade III leukopenia and neutropenia occurred in 11/26 (42%) and 12/26 (46%) patients, respectively. In **MCbP-T** arm, grade III leukopenia and neutropenia were documented in 1/26 (4%; p = 0.002, Fisher's exact test) and 2/26 (8%; p = 0.003, Fisher's exact test) patients, respectively. The frequency of thrombocytopenia of all grades was non-significantly higher in **MCbP-T** group. All patients in the control group had alopecia grade II, whereas patients in the **MCbP-T** group didn't report this side effect.

Adverse events

Adverse Events	AC-TCbP		MCbP-T	
	4AC	12TCarb	4MCarb	12T
Anemia				
Grade 1	65%	65%	46%	4%
Grade 2	8%	0	8%	0
Grade 3	0	0	8%	0
Grade 4	0	0	4%	0
Leukopenia				
Grade 1	12%	38%	69%	69%
Grade 2	42%	46%	19%	4%
Grade 3	**42%**	**15%**	**4%**	**0**
Neutropenia				
Grade 1	12%	38%	69%	69%
Grade 2	31%	0	12%	0
Grade 3	46%	0	8%	0
Grade 4	0	0		0
Thrombocytopenia				
Grade 1	0	19%	38%	0
Grade 2	0	8%	23%	0
Grade 3	0	0	23%	0
Grade 4	0	0	12%	0
Peripheral neuropathy				
Grade 1	0	81%	27%	69%
Grade 2	0	12%	4%	4%
Nausea				
Grade 1	46%	85%	6%	19%
Grade 2	54%	4%	12%	0
Grade 3	0	0	12%	0
Emesis				
Grade 1	6%	19%	19%	0
Grade 2	8%	0	0	0
Grade 3	0%	0	12%	0
Elevated transaminases				
Grade 1	69%	31%	19%	4%
Grade 2	0	4%	8%	0
Grade 3	0	4%	4%	0
Elevated creatinine				
Grade 1	4%	0	4%	0
Grade 2	0	0	4%	0
Grade 3	0	0	8%	0
Alopecia				
Grade 1	100%	0	0	73%
Grade 2	0	100%	0	0

CONCLUSION

In BRCA1/2-associated TNBC, the efficacy of MCbP-T (mitomycin C plus carboplatin followed by paclitaxel) regimen is comparable with standard anthracycline-based platinum-containing chemotherapy but demonstrates a significantly lower rate of adverse effects.

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