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Efficacy and safety of 12-week adjuvant docetaxel plus trastuzumab in patients with node-negative HER2-positive breast cancer (tumors ≤1cm): results from the SOBER prospective single-arm trial

Shuning Ding, MD, PhD[1]; Jiayi Wu, MD[2]; Li Zhu, MD,[1]

[1]Shanghai General Hospital, Shanghai Jiao Tong Universirty School of Medicine, [2]Ruijin Hospital, Shanghai Jiao Tong Universirty School of Medicine,

Introduction

- Approximately 15–20% of breast cancers are HER2-positive, historically associated with poor prognosis[1].
- While trastuzumab-based chemotherapy is standard for tumors >1 cm or node-positive disease, optimal management of small (≤1 cm), node-negative HER2-positive tumors remains undefined[2].
- New anti-HER2 agents (e.g., pertuzumab, T-DM1, neratinib) improve outcomes but increase toxicity, highlighting the need for de-escalation strategies in low-risk patients.
- Evidence from retrospective studies and trials such as APT supports the potential of shortened therapy in selected populations[3,4], though prospective data in T1a/bN0 patients are limited.
- To evaluate the efficacy and safety of a 12-week adjuvant regimen of docetaxel plus trastuzumab in patients with node-negative, HER2-positive breast cancer with tumor size ≤1 cm.

Methods and Materials

Study Design

Trial: single-arm, open-label, phase II study (NCT03367676)
Enrollment: node-negative, HER2-positive breast cancer patients with tumor size ≤1 cm
Intervention: 12-week adjuvant docetaxel (100 mg/m²) + trastuzumab (loading 8 mg/kg → 6 mg/kg)
Primary endpoint: 3-year disease-free survival (DFS)

Methodology

Sample size: Initially planned 112 patients; early termination with 76 enrolled
Statistical analysis: Kaplan-Meier survival estimates, log-rank test, Cox proportional hazards model
Safety monitoring: LVEF by echocardiography (baseline, 3 months); AEs graded per CTCAE v4.0

Results

Table 1. Baseline characteristics and treatment information of the patients

Characteristic	Patients(N=76) No. (%)	Characteristic	Patients(N=76) No. (%)
Age		**ER status**	
>55	34(44.7)	Positive	29(38.2)
≤55	42(55.3)	Negative	47(61.8)
Menopausal status		**PR status**	
Premenopausal	28(36.8)	Positive	17(22.4)
Postmenopausal	48(63.2)	Negative	59(77.6)
Surgery		**Subtype**	
Mastectomy	65(85.5)	HR+HER2+	29(38.2)
Breast conserving surgery	11(14.5)	HR-HER2+	47(61.8)
Tumor size		**Ki67 index**	
T1mi	36(47.4)	>20%	30(39.5)
T1a	27(35.5)	≤20%	46(60.5)
T1b	13(17.1)	**Adjuvant ET**	
Radiation therapy		Yes	29(38.2)
Yes	11(14.5)	No	47(61.8)
No	65(85.5)		

A total of 78 patients with T1a–T1b HER2-positive, node-negative breast cancer were enrolled. Tumor staging included T1mic (47.4%), T1a (35.5%), and T1b (17.1%). After a median follow-up of 45.2 months, the 3-year and 5-year disease-free survival rates were 96.9% and 91.7%, respectively. Overall survival was 100% at 3 years and 96.0% at 5 years, with no breast cancer-specific deaths.

Table 2. Most common adverse events occurring during protocol therapy.

Adverse event	Maximum Grade N (%)				Total
	Grade 1	Grade 2	Grade 3	Grade4	
Neutropenia	4(5.3)	6(7.9)	6(7.9)	2(2.6)	18(23.7)
Anemia	3(3.9)	1(1.3)	0	1(1.3)	5(6.5)
Elevated alanine amino transferase level	1(1.3)	4(5.3)	1(1.3)	0	6(7.9)
Alopecia	10(13.2)	8(10.5)	0	0	18(23.7)
Nausea	10(13.2)	4(5.3)	0	0	14(18.5)
Vomiting	5(6.6)	3(3.9)	0	0	8(10.5)
Anorexia	5(6.6)	1(1.3)	0	0	6(7.9)
Diarrhea	1(1.3)	1(1.3)	0	0	2(2.6)
Fatigue	1(1.3)	1(1.3)	0	0	2(2.6)
Myalgia/Arthralgia	0	2(2.6)	0	0	2(2.6)

Figure1. Probabilities of disease-free survival and overall survival for overall population.
A) Disease-free survival curve. **B)** Overall survival curve.

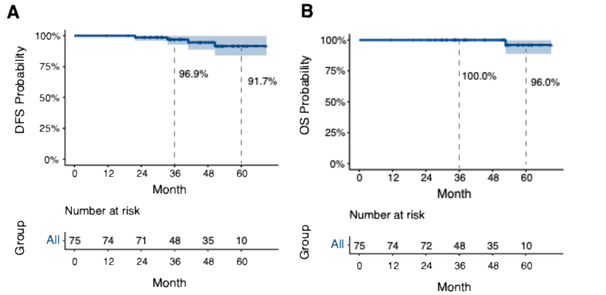
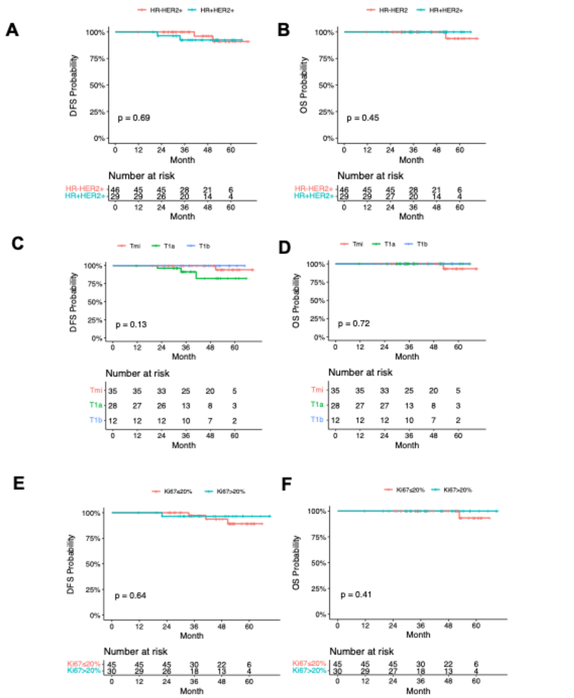


Figure 2. Survival curves in subgroup patients stratified by clinical factors. DFS and OS curves for patients with different molecular subtypes(A.B), with different tumor sizes(C.D) and with different Ki-67 levels(E.F)



Conclusions

In conclusion, 12-week docetaxel combined with trastuzumab might be an optional regimen for HER2-positive node-negative patients with tumor smaller than 1 cm, with favorable prognosis and less cardiac toxicity.

Contact Li Zhu
Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine
Email: zhuli8@yeah.net
Shuning Ding
Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine
Email: nannanyard@163.com

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