

Efficacy of Administering Preoperative Hydroxyprogesterone in Women with Operable Breast Cancer

Presentation discussed in this issue:

Badwe RA et al. **Single injection depot progesterone prior to surgery in women with operable breast cancer: A randomized controlled trial.** San Antonio Breast Cancer Symposium 2009;[Abstract 72](#).

Slides from a presentation at SABCS 2009

Single Injection Depot Progesterone Prior to Surgery in Women with Operable Breast Cancer: A Randomized Controlled Trial

Badwe RA et al.
SABCS 2009;Abstract 72.

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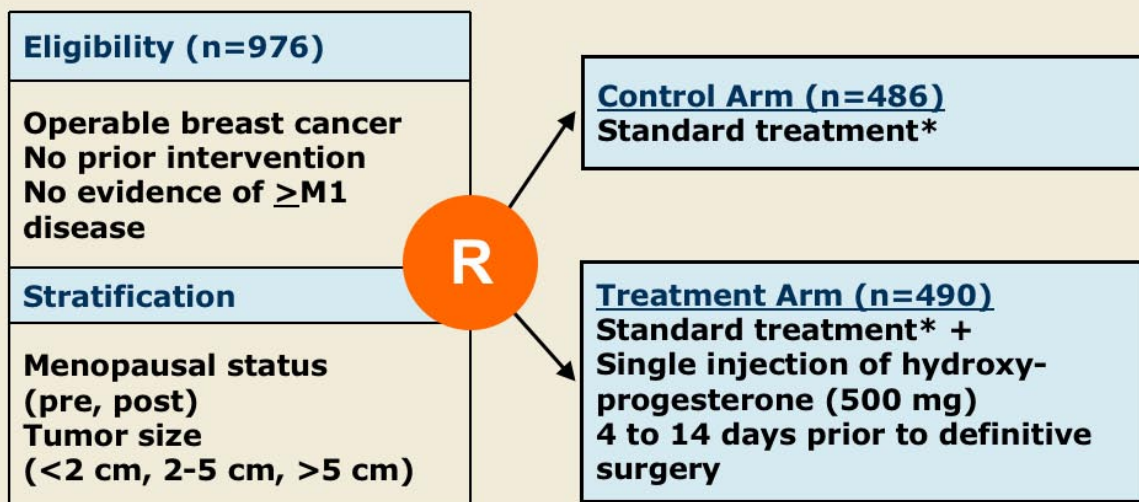
Introduction

- Meta-analysis of 37 retrospective studies demonstrated a 15% reduction in mortality ($p=0.0003$) for patients undergoing surgery during progestogenic phase (*Surg Clin North Am* 1999;79:1047).
- Meta-analysis of the effect of circulating progesterone at the time of surgery showed a 54% survival benefit ($p=0.002$) when progesterone levels were high in women that were node-positive (*Surg Clin North Am* 1999;79:1047).
- Two recent prospective studies did not find an association between timing of breast cancer surgery during the menstrual cycle and survival (*JCO* 2009;27:3620, *BJC* 2008;98:39).
- **Current study objective**
 - To evaluate the effect of pharmacologically inducing a progestogenic environment at the time of surgery on survival in women with operable breast cancer (OBC).

Badwe RA et al. SABCS 2009;Abstract 72.

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Randomized Trial of Preoperative Hydroxy-progesterone



*Standard international guidelines were followed for adjuvant treatment.

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Recurrences and Deaths (median follow-up 65 mos)

Recurrences	Treatment	Control
All Patients (n=490, 486)	128 (26.1%)	145 (29.8%)
Lymph-node positive (n=239, 232)	83 (34.7%)	105 (45.2%)
Deaths		
All Patients (n=490, 486)	97 (19.8%)	105 (21.6%)
Lymph-node positive (n=239, 232)	58 (24.3%)	77 (33.1%)

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Efficacy Results (median follow-up 65 mos)

All patients	Treatment (n=490)	Control (n=486)	Hazard Ratio	95% CI	p-value
Disease-free survival	73.9%	70.2%	0.87	0.68-1.09	0.23
Overall survival	78.4%	80.2%	0.92	0.69-1.21	0.53
Patients with lymph node- positive disease	Treatment (n=239)	Control (n=232)	Hazard Ratio	95% CI	p-value
Disease-free survival	65.3%	54.7%	0.72	0.54-0.97	0.02
Overall survival	75.7%	66.8%	0.70	0.49-0.99	0.04

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Disease-Free Survival: Cox Proportional Hazard Model

Variable	Risk Ratio	p-value	95% CI
Primary tumor size	1.09	0.03	1.01-1.19
Nodal status	2.14	<0.0005	1.53-3.00
Treatment	0.60	0.29	0.24-1.52
Hormone receptor status	1.35	0.006	1.09-1.67
Treatment x nodes	1.16	0.03	1.10-1.33

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Conclusions

- Induction of a progestogenic environment at the time of surgery significantly improved both disease-free and overall survival in women with lymph node-positive OBC.
 - Disease-free survival: 65.3% versus 54.7% ($p=0.02$)
 - Overall survival: 75.7% versus 66.8% ($p=0.04$)
- Disease-free survival is significantly impacted by:
 - Tumor size
 - Lymph node metastases
 - Hormone receptor positivity
 - Interaction between treatment and lymph node metastases
- This approach could be a simple, inexpensive and life-saving intervention for women with OBC.

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