

A randomized, three-arm phase III trial of paclitaxel/carboplatin followed by observation compared with paclitaxel/carboplatin followed by maintenance letrozole versus letrozole monotherapy in patients with stage II-IV, primary low-grade serous carcinoma of the ovary or peritoneum

---

**David M. Gershenson, MD**

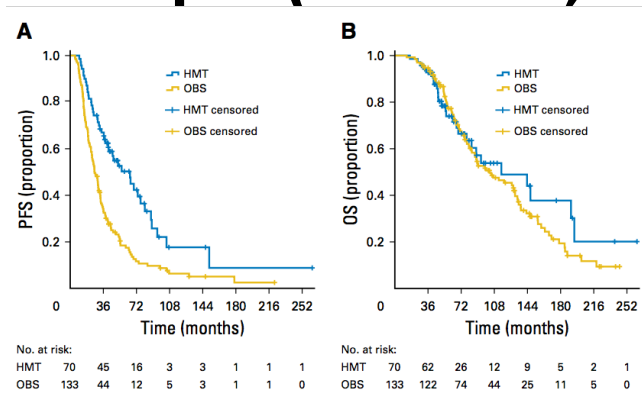
**The University of Texas**

**MD Anderson Cancer Center**

# Hormonal Therapy: Maintenance or Adjuvant

## MD Anderson Study

- 203 pts (133 OBS, 70



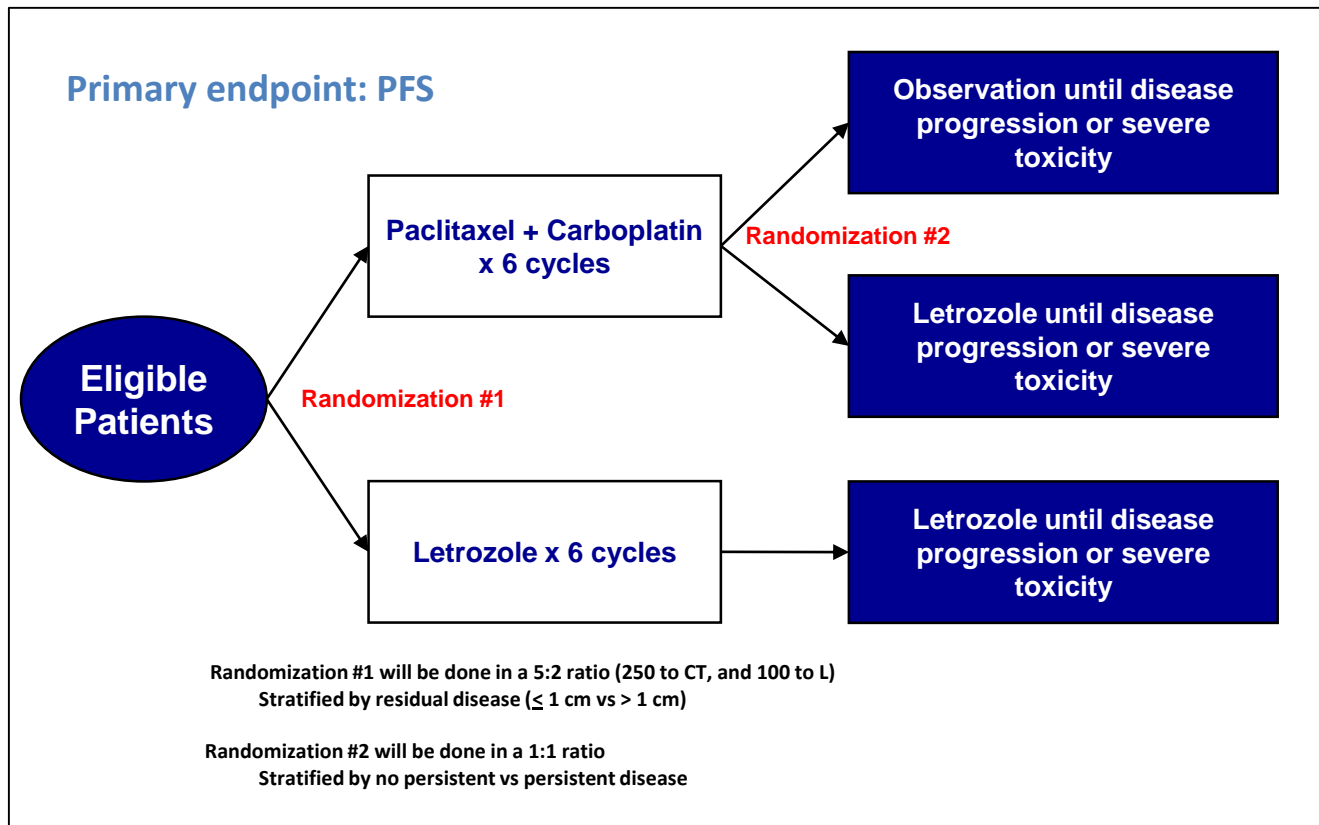
***Gershenson et al.  
J Clin Oncol 2017***

## Johns Hopkins Study

- 27 pts with stage II-IV LGSC
- Primary CRS + HT
- Median duration HT = 18 mo
- After median FU = 41 mo, 6 (22%) pts relapsed
- Median PFS and OS not reached
- 3-yr PFS = 79.0%
- 3-yr OS = 93.1%

***Nickles Fader et al.  
Gynecol Oncol 2017***

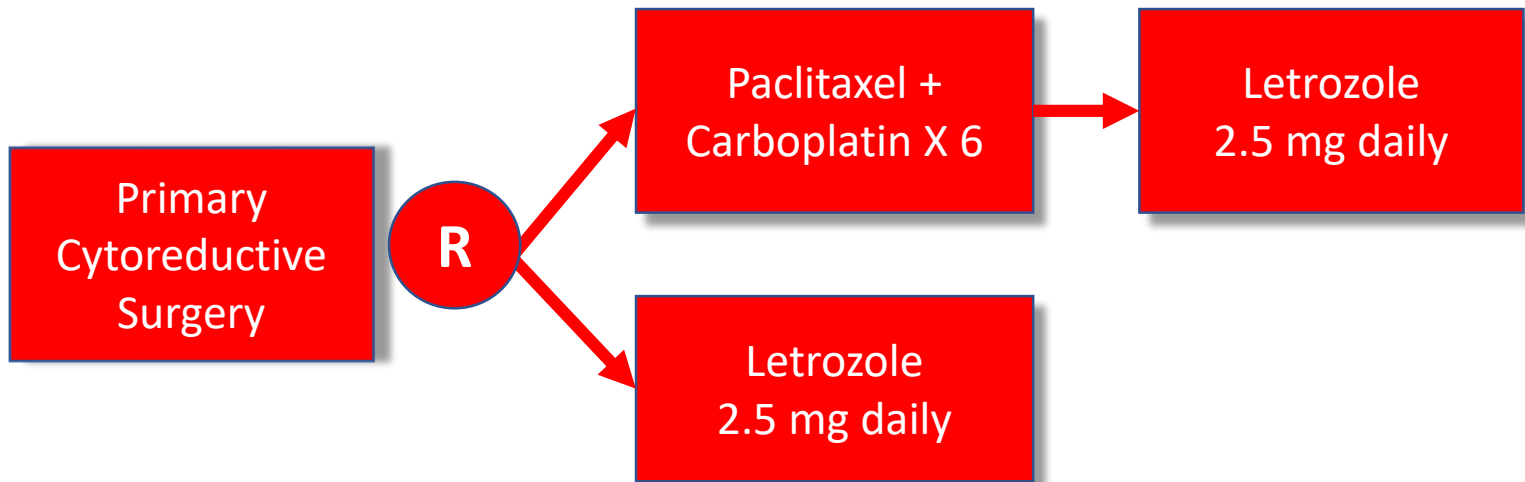
# RT1713



# GCSC Critique

- **Study design too complex**
- **No consensus**
- **2 potential study designs:**
  - **Paclitaxel/carboplatin followed by observation or placebo versus paclitaxel/carboplatin followed by letrozole**
  - **Paclitaxel/carboplatin followed by observation versus letrozole monotherapy with mandatory crossover**

# Consensus Design



# Progression-free Survival

Population/ Study/ Endpoint	HMT following chemo		Obs following chemo	
	<i>n (events)</i>	Median (95% CI)	<i>n (events)</i>	Median (95% CI)
<b>All Patients</b>				
MD Anderson (LGS)	70	65 (44, 86)	133	26 (22, 31)
GOG 0182 (Gr 1 serous)	—	—	189	17 (15, 20)
<b>No gross residual</b>				
MD Anderson (LGS)	14 (4)	3yr: 70%†	34 (28)	25 (18, 33)
GOG 0182 (Gr 1 serous)	—	—	47	33
<b>Hopkins HMT alone, <u>NOT</u> after chemo</b>	<b>27 (8)</b>	<b>3yr: 79%†</b>	—	—
<b>Gross residual</b>				
MD Anderson (LGS)	49 (36)	46 (30, 62) 3yr: 59%	68 (63)	26 (18,34)
GOG 0218 (Gr 1 serous)	—	—	33 (28)	15
GOG 0182 (Gr 1 serous): <b>0.1-1.0 cm</b>	—	—	97	15
GOG 0182 (Gr 1 serous): <b>&gt;1.0 cm</b>	—	—	45	14

†Median not reached