



ASTRO 2015
technology meets
patient care

57TH ANNUAL MEETING

MEETING DATES: OCTOBER 18-21, 2015

EXHIBIT DATES: OCTOBER 18-20, 2015

HENRY B. GONZÁLEZ CONVENTION CENTER

SAN ANTONIO


TARGETING CANCER CARE

NRG Oncology/RTOG 96-01

A Phase III trial in patients following Radical Prostatectomy (RP) with pT2-3, pN0 prostate cancer and elevated PSA levels: Anti-Androgen Therapy (AAT) with Bicalutamide during and after salvage Radiation Therapy (RT) compared to Placebo + salvage RT

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Method

<p><u>Stratification Variables</u></p> <ul style="list-style-type: none"> • Surgical margins: positive or not • Nadir PSA level: < 0.5: yes or no • Entry PSA level: < 1.6 or 1.6 – 4.0 • Pre RP neoadjuvant STAD: yes or no 	R A N D O M I Z E	<p>Arm 1</p>	<p>RT (64.8 Gy) plus AAT* (Bicalutamide 150 mg) QD**</p>
		<p>Arm 2</p>	<p>RT (64.8 Gy) plus placebo QD**</p>

*AAT: Anti Androgen Therapy (peripheral androgen blockade)

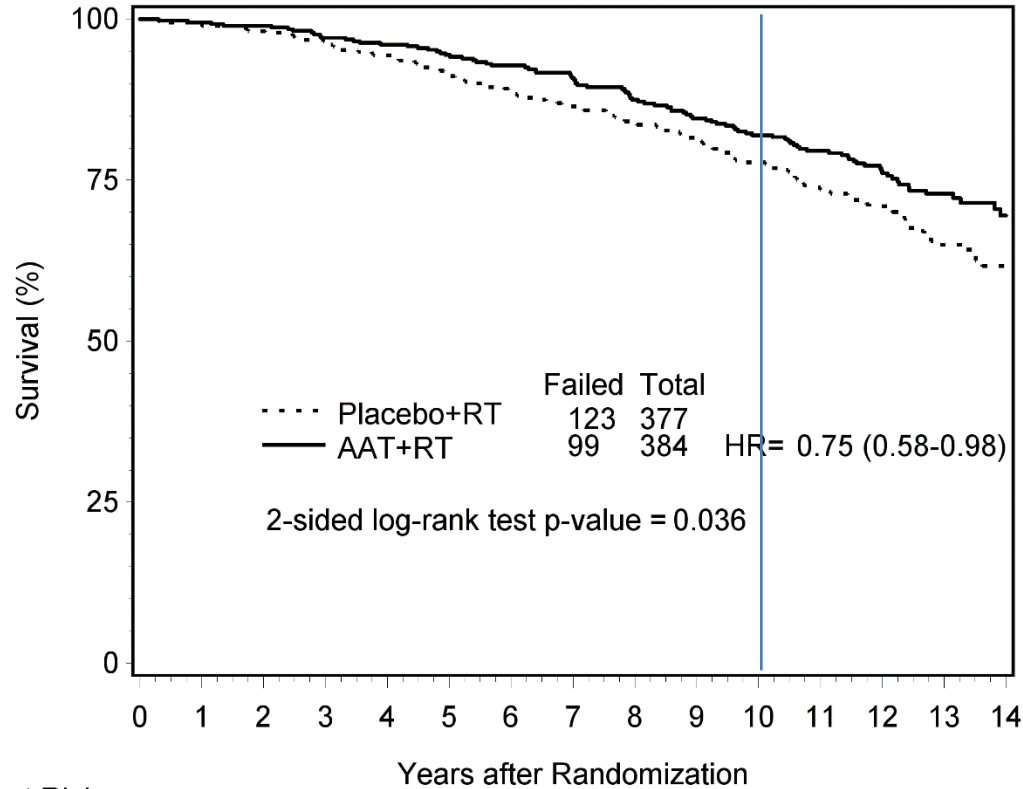
** During and after RT for 24 months

Patients

- Enrolled March 1998 – March 2003
- 761 eligible patients were randomized to Bicalutamide & RT or to Placebo & RT
- Median age at entry: 65 yrs
- Median follow-up of surviving patients: 12.6 yrs
- Median interval between RP and study entry: 2.1 yrs
- Median interval between RP and first detectable PSA: 1.4 yrs
- Median entry PSA was 0.6 ng/ml; with 25th to 75th percentiles of 0.4 and 1.1 ng/ml

Results

Overall Survival



**OS at 10 yrs:
82% vs 78%**

Patients at Risk

Placebo+RT	377	373	369	360	351	333	320	308	295	281	261	234	174	99	48
AAT+RT	384	382	376	368	362	347	337	326	308	294	279	253	190	123	60

Conclusions

- With a median F/U of greater than 12 years, the addition of 24 mos. of peripheral androgen blockage (AAT) during and after salvage RT significantly:
 - **Improved Overall Survival (p = 0.036)**
 - **Reduced metastatic PC**
 - **Reduced death from PC – [from 7.5% to 2.3%; NNT = 17]**
 - **Reduced tumor progression and the incidence of local regrowth**
- GI or GU toxicity observed during AAT or placebo treatments were low and similar
- Gynecomastia was extremely common in the bicalutamide arm