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Two Years of Anti-Androgen Treatment Increases Other-Cause Mortality in Men Receiving Early Salvage Radiotherapy:

A Secondary Analysis of the NRG Oncology/ RTOG 9601 Randomized Phase III Trial

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Disclosures for Dr. Spratt

- Employee at the University of Michigan
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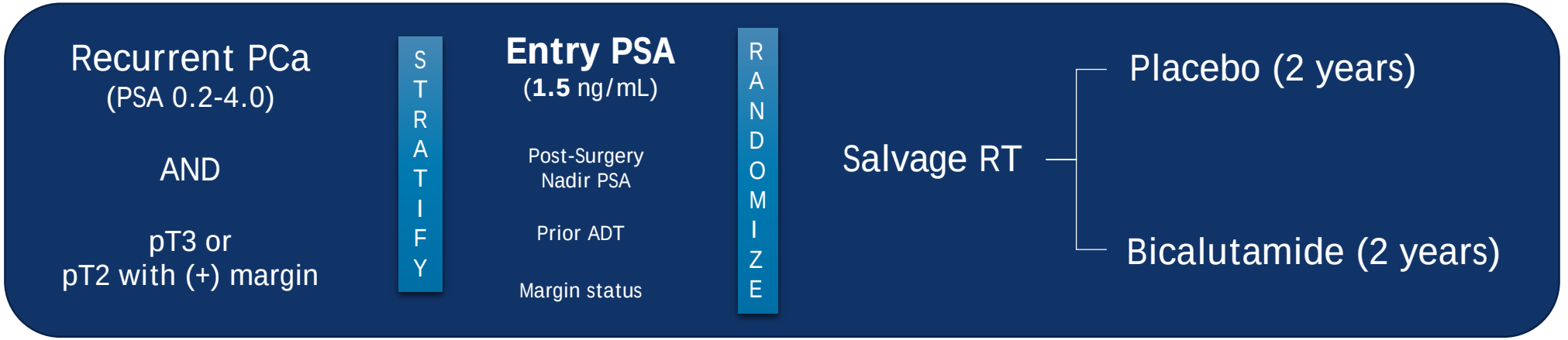
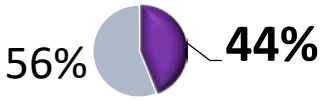
Background

NRG Oncology/RTOG 96-01



Sample size: 760 patients
Median follow up: 13 years
Primary endpoint: Overall Survival



Persistently elevated PSA post-RP of >0.1 ng/mL
Undetectable PSA

Late salvage RT (PSA >0.5 ng/mL)
Early salvage RT (PSA ≤0.5 ng/mL)

Methods

Secondary analysis of NRG Oncology/RTOG 9601 approval through the NCI

Developed ***a priori*** statistical plan to determine differential benefit and harm of antiandrogen treatment in men by entry PSA via statistical interaction tests

Early Salvage RT PSA subgroups:

Pre-specified protocol stratum:	**0.2-1.5 ng/mL**
Median PSA on RTOG 9601:	**0.2-0.6 ng/mL**
Median PSA of GETUG-16 & SPPORT:	**0.2-0.3 ng/mL**

Endpoints Assessed:

- Overall Survival
- Other-Cause Mortality
- Distant Metastasis

Toxicity Assessment:

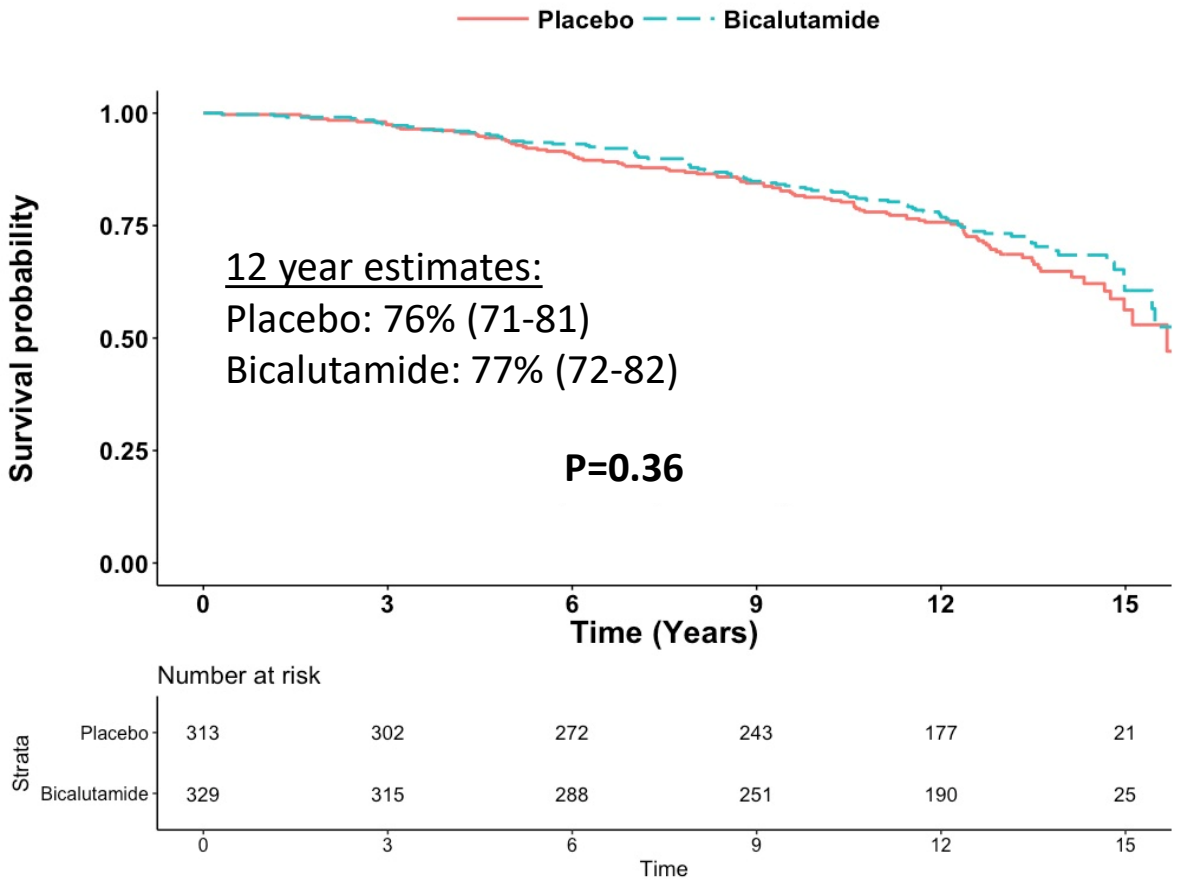
- Grade 3-5 Cardiac Events
- Grade 3-5 Neurologic Events

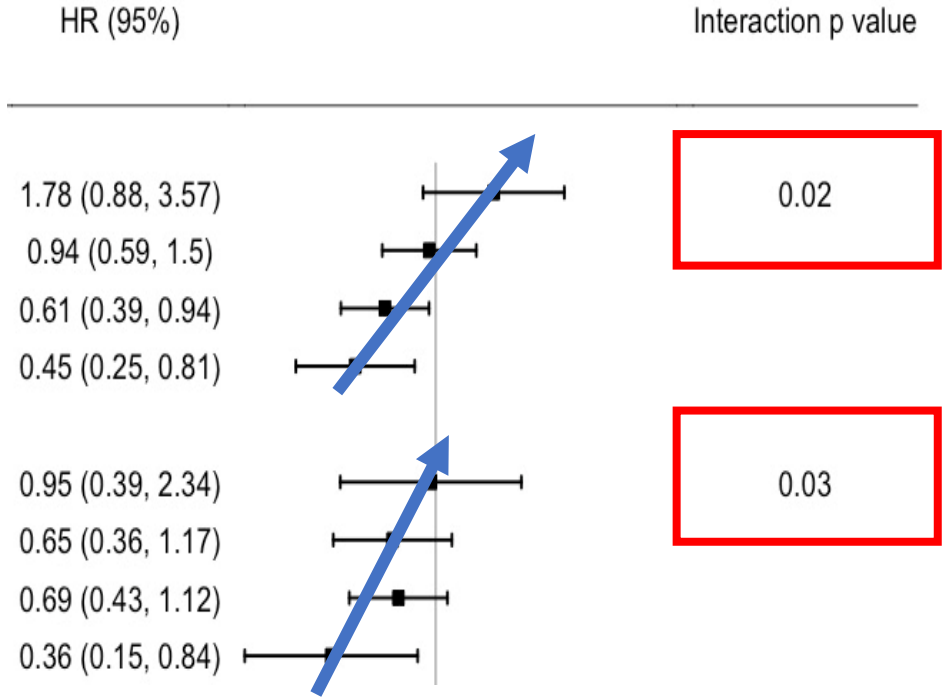
Nguyen P, et al, Euro Urol 2015

Results

85% of trial was in the PSA 0.2-1.5 stratum

PSA 0.2-1.5 ng/mL stratum

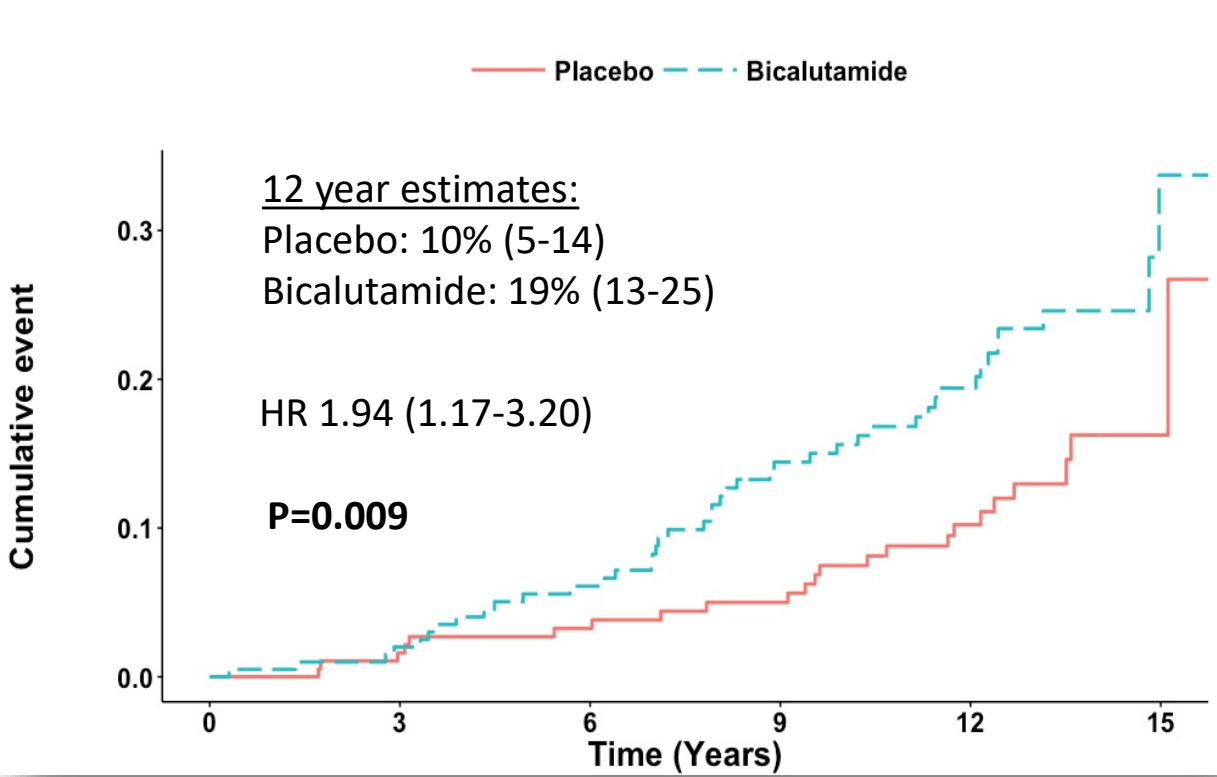




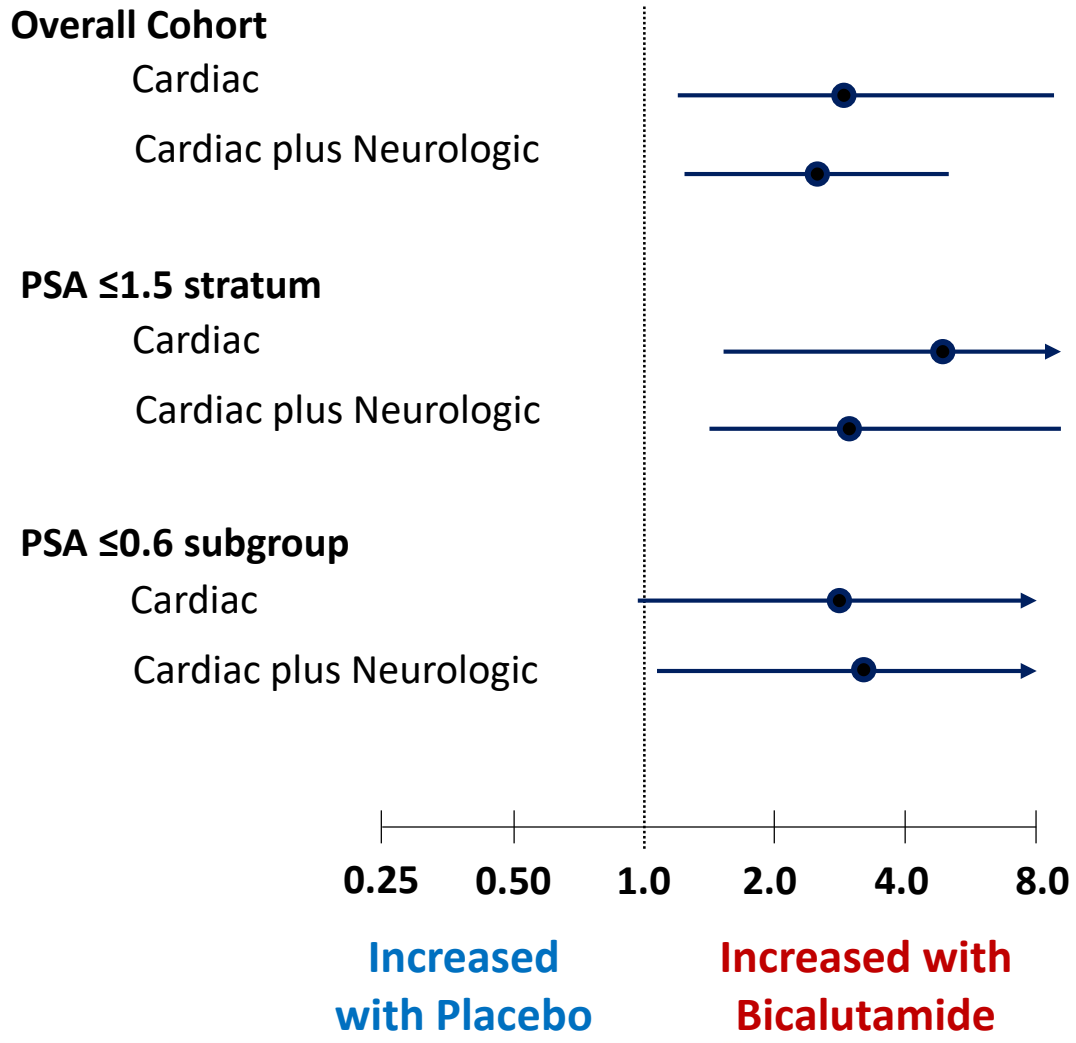
Results

Other-Cause Mortality

PSA 0.2-0.6 ng/mL



Odds Ratio for Grade 3-5 Event



Conclusions

- Current guidelines recommend all men be offered hormone therapy when receiving salvage radiotherapy.
- Our data demonstrate that men with lower PSAs are more harmed then helped by long-term hormone therapy.
- We have now 3 randomized trials with over 2400 men total that do not demonstrate that short or long-term hormone therapy improves overall survival in men receiving early salvage radiotherapy at low PSAs.
- PSA prior to salvage radiotherapy predicts who will benefit most from hormone therapy.
    - ***Guidelines should change to reflect this finding.***