

# **5-year outcomes from PACE-B:**

## **An international phase III randomized controlled trial comparing stereotactic body radiotherapy (SBRT) vs conventionally fractionated or moderately hypofractionated external beam radiotherapy for localised prostate cancer**

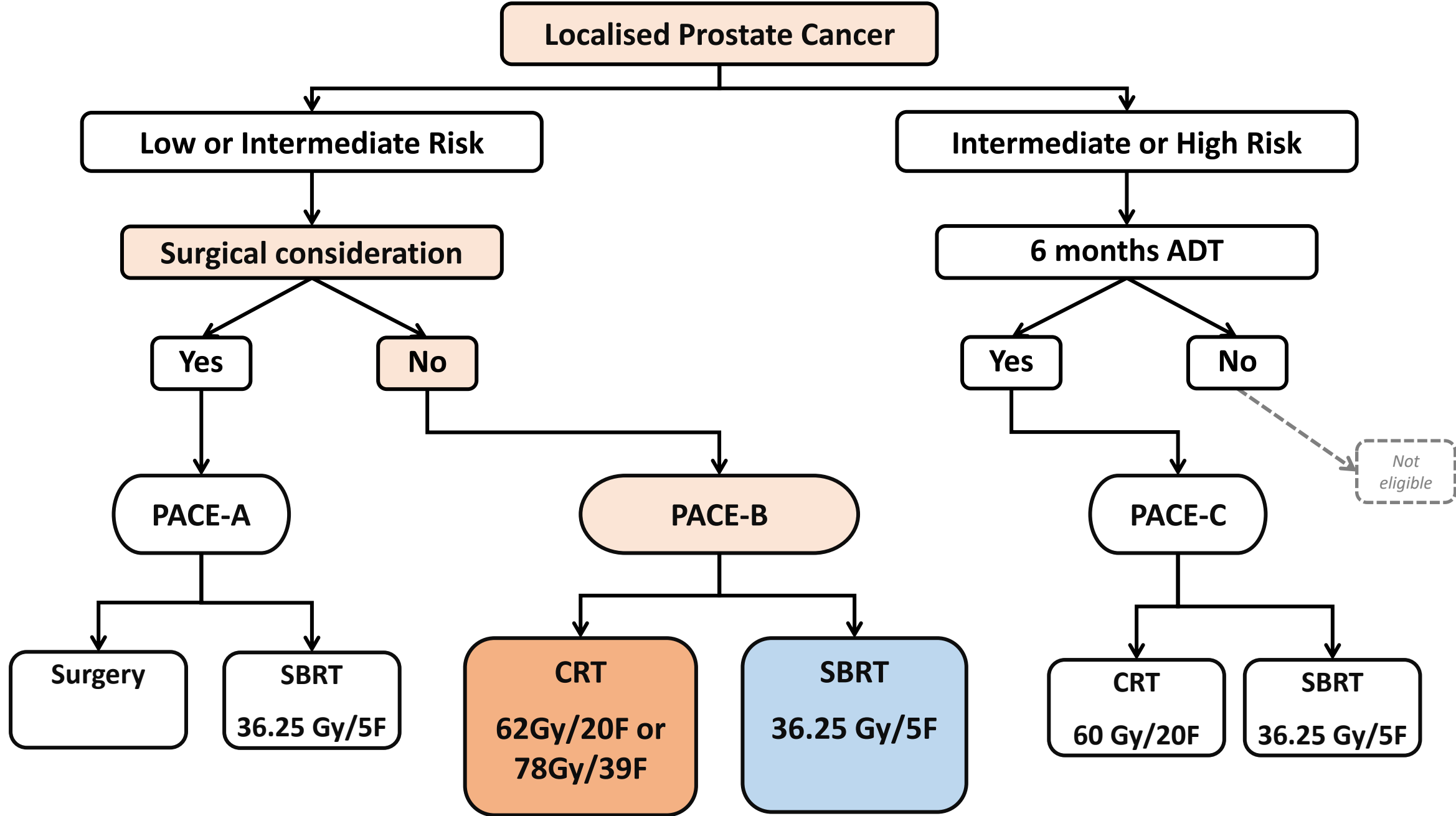
Nicholas van As, Alison Tree, Jaymini Patel, Peter Ostler, Hans van der Voet, Andrew Loblaw, William Chu, Daniel Ford, Shaun Tolan, Suneil Jain, John G Armstrong, Philip Camilleri, Kiran Kancherla, John Frew, Andrew Chan, Olivia Naismith, Georgina Manning, Stephanie Brown, Clare Griffin, Emma Hall

Prof Nicholas van As  
on behalf of the PACE Trial Investigators

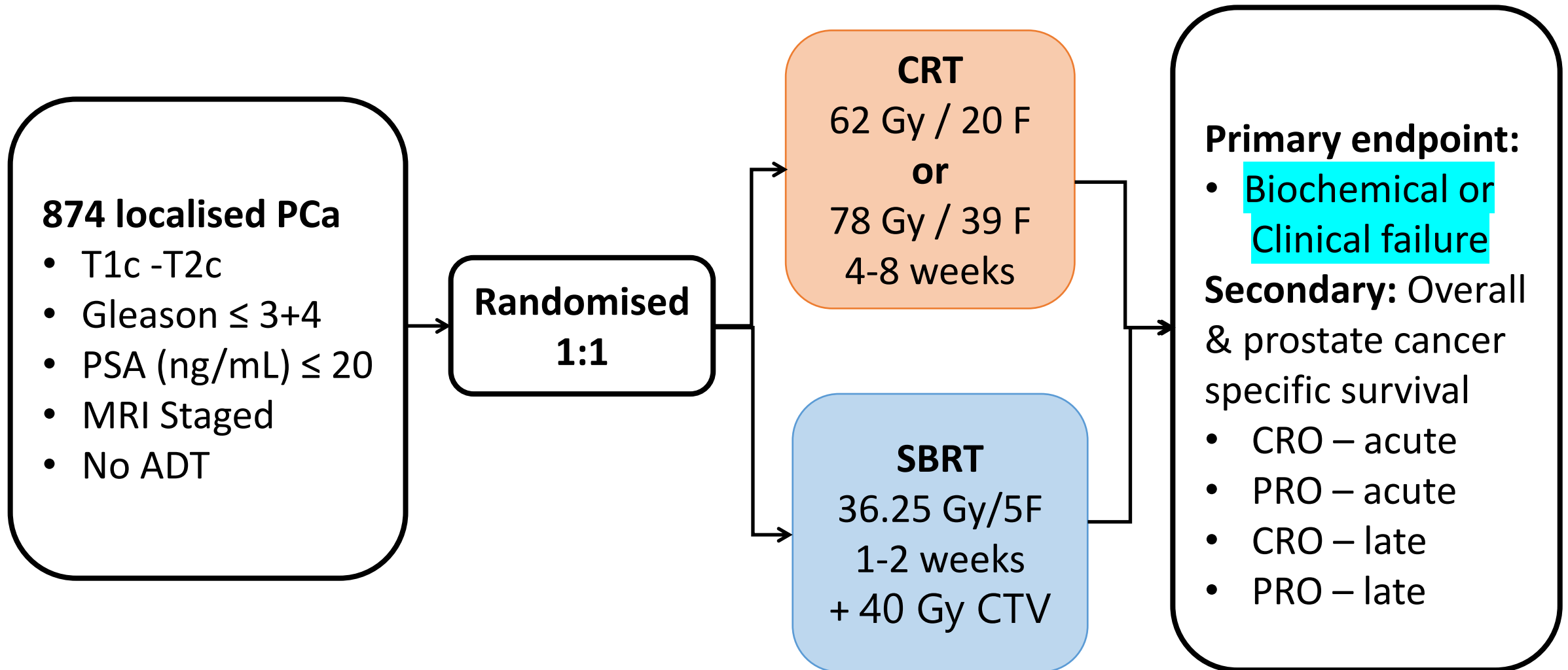
# Disclosures

PACE-B is funded by Accuray. The funders have no access to trial data.

I have received research grants from Accuray and Varian and consultants fees from Accuray



# PACE B trial schema & endpoints



# PACE-B statistical design

- Non-inferiority design
- 80% power to exclude a critical **hazard ratio 1.45** (1-sided 5% alpha)
- 858 participants required
- Time point of primary interest is **5 years** from randomisation

# Baseline characteristics

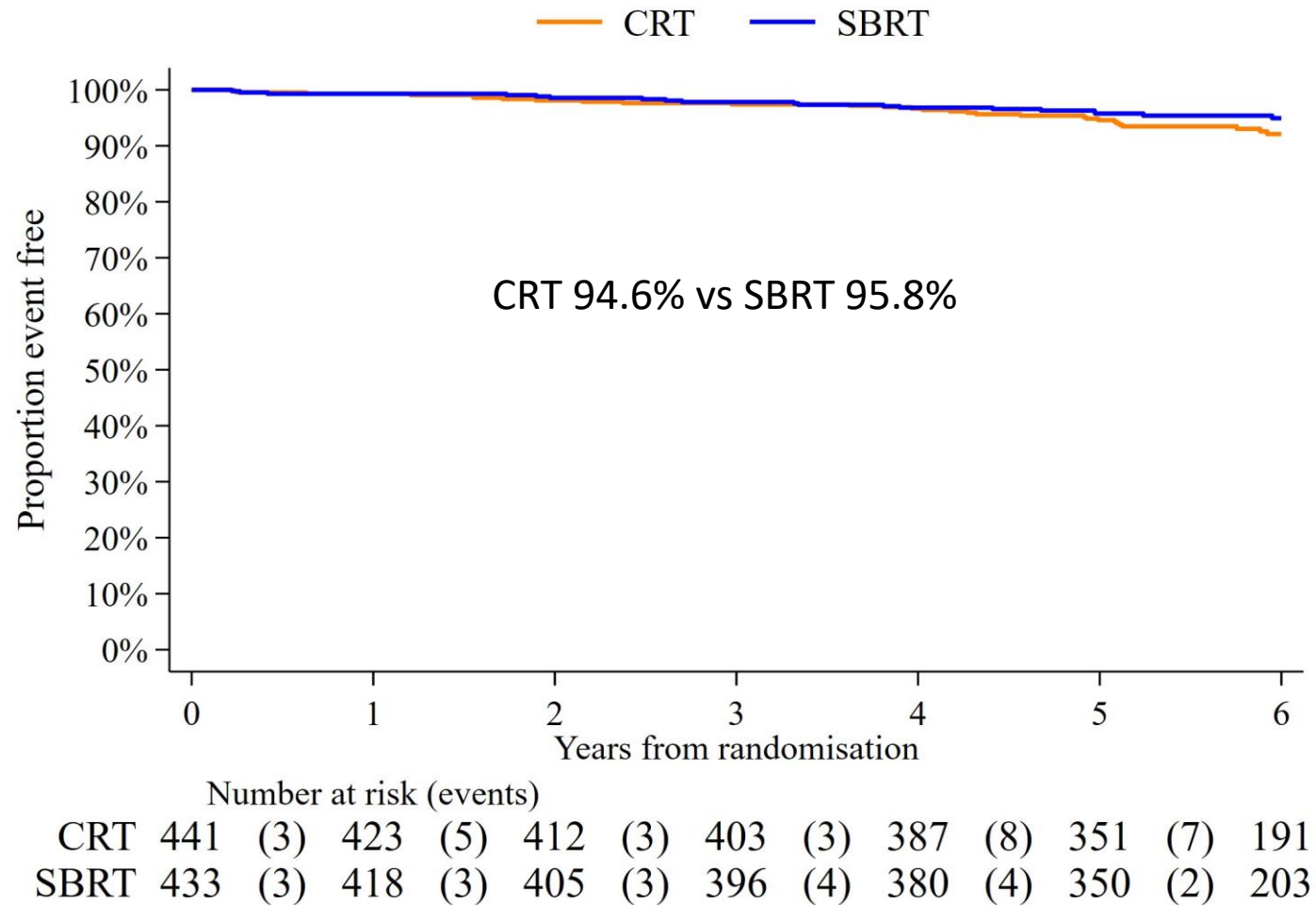
		<b>CRT</b> <b>N= 441</b>	<b>SBRT</b> <b>N=433</b>	<b>Total</b> <b>N= 874</b>
<b>Age (years): Median (IQR)</b>		70 (65.6, 73.9)	70 (65.4, 74.1)	70 (65.4, 74.0)
<b>Risk group</b>	<b>Low</b>	10%	9%	9%
	<b>Intermediate</b>	90%	91%	91%
<b>Gleason</b>	<b>3+3</b>	20%	15%	18%
	<b>3+4</b>	80%	85%	82%
<b>PSA (ng/mL)</b>	<b>&lt;10</b>	69%	69%	69%
	<b>10 - 20</b>	31%	31%	31%
<b>T – Stage</b>	<b>T1c</b>	10%	11%	11%
	<b>T2a</b>	31%	25%	28%
	<b>T2b</b>	15%	21%	18%
	<b>T2c</b>	44%	43%	43%



# Results



# Biochemical/clinical failure – primary endpoint



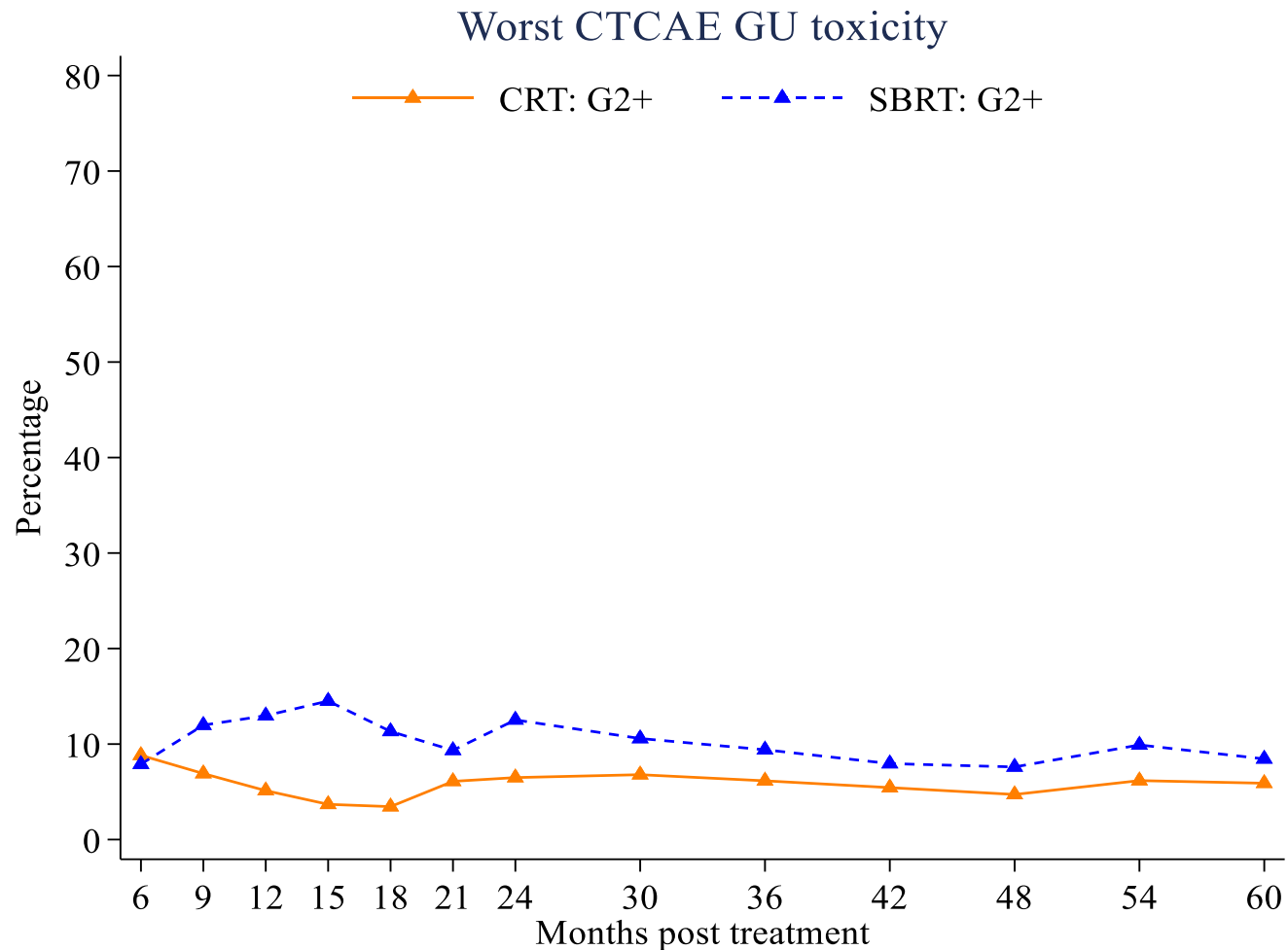


# Biochemical/clinical failure – primary endpoint

<b>Biochemical or clinical failure</b>	<b>CRT N=441</b>	<b>SBRT N=433</b>
Number of events	35	25
KM 5-year event-free estimate (95% CI)	94.6% (91.9, 96.4)	95.8% (93.3, 97.3)
<b>Unadjusted HR (90% CI)</b>	<b>0.73 (0.47, <u>1.12</u>)</b>	
<b>Pr(HR&lt;1.45)</b>	<b>p=0.004</b>	
Log rank p-value	p=0.22	
Absolute difference at 5 years (90% CI)	1.44% (-0.63, 2.81)	

# CTCAE GU toxicity – up to 5 years

CTCAE GU at 5 years	CRT N (%)	SBRT N (%)	P-value
Grade 0/1	335 (94.1)	325 (91.5)	0.19
Grade 2+	21 (5.9)	30 (8.5)	

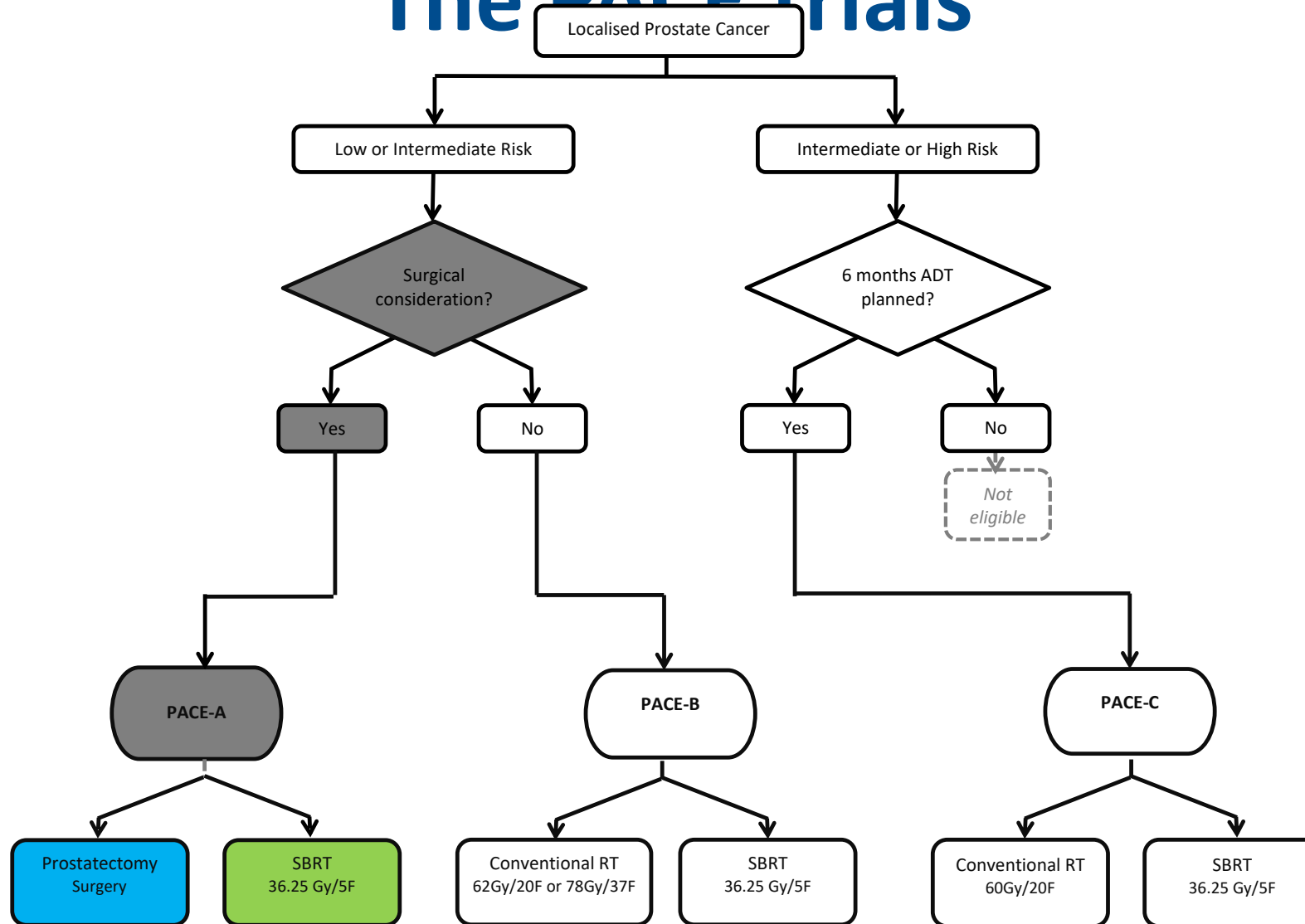


Number of patients

SBRT –	380	384	393	317	362	321	383	359	372	352	355	333	355
CRT –	408	405	390	325	377	328	385	368	390	349	360	340	356

# Looking at PACE A and B together

# The PACE trials



# Results: Urinary incontinence

*Proportion of patients using any urinary pads at 2 years*

*Surgery*

*15/32 (46.8%)*

*SBRT*

*2/44 (4.5%)*

*P=<0.001*

Pre-specified  
significance  
level: 5%

# Results: EPIC bowel bother subdomain score

*Mean (sd) bowel bother subdomain score at 2 years*

*Surgery: 97.3 (5.5)*

***SBRT: 88.7 (12.7)***

*$p < 0.001$*

Pre-specified  
significance  
level: 5%

# Results: Sexual function

*Epic sexual bother subdomain score at 2 years*

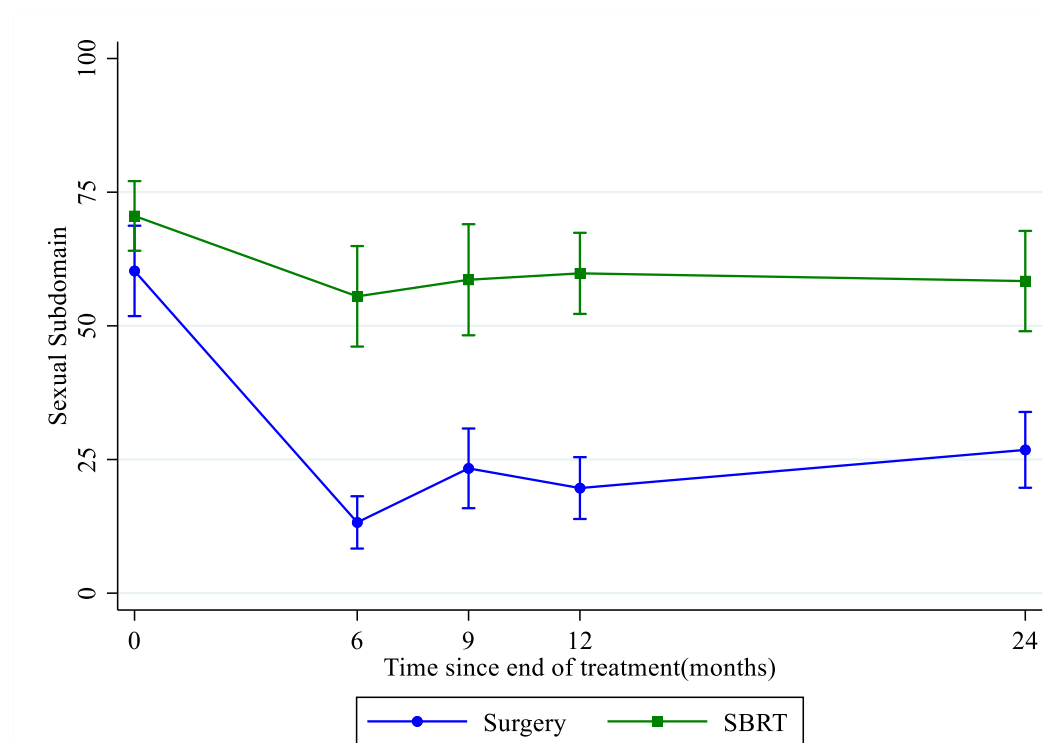
*Surgery: 29.3 (20.5)*

*SBRT: 57.7 (31.9)*

*$p < 0.001$*

Pre-specified  
significance  
level: 5%

# EPIC sexual subdomain scores up to 2 years

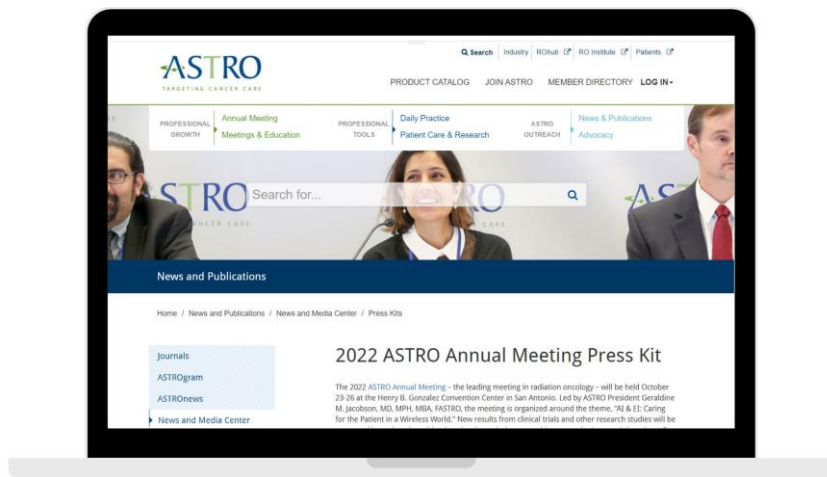




# Conclusions

- **SBRT should be considered a new Standard of care in low and favourable intermediate risk prostate cancer**
- Patients being offered surgery should be given information from these trials before deciding on treatment options

ASTRO 2023  
**PAY IT  
FORWARD**  
PARTNERING WITH OUR PATIENTS



[astro.org/annualmeetingpress](https://astro.org/annualmeetingpress)

[press@astro.org](mailto:press@astro.org)



**#ASTRO23**