Combining
MR-Imaging & TULSA-PRO®
for the most efficient
incision-free solution for Prostate Disease

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TULSA-PRO®

Inside-Out Prostate Ablation

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TACT: Clinical Trial Design

Pivotal study of whole-gland ablation in a clinically-significant patient population

Study Population

- n = 115, 13 clinical sites, 5 countries
- 45 – 80 years old
- Low (33%) & intermediate risk (67%) prostate cancer

Ablation Treatment Plan

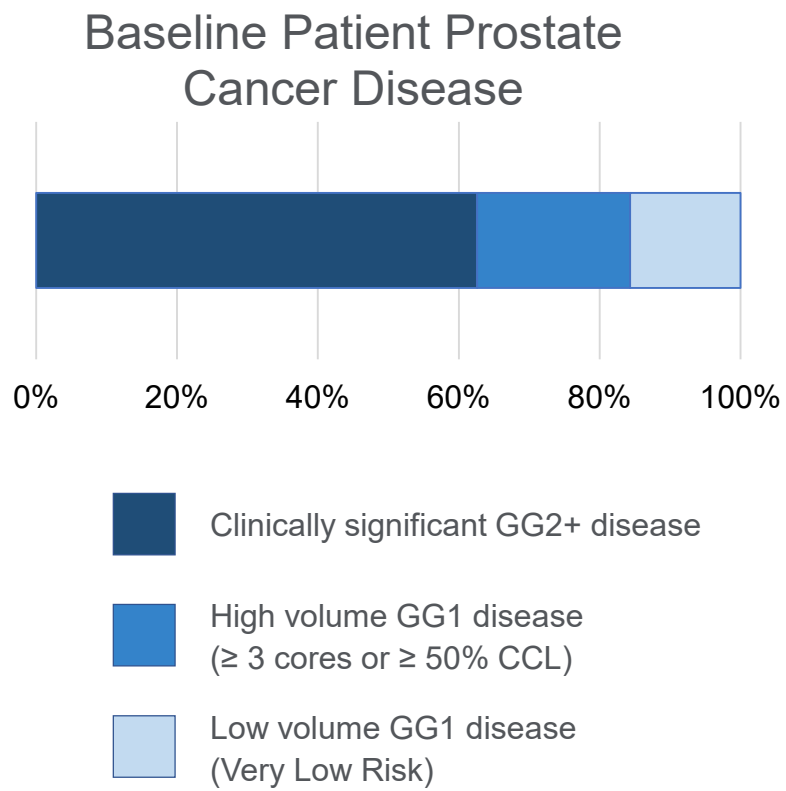
- Treatment intent was whole-gland ablation with sparing of the urethra and urinary sphincter
- Recommended by FDA to determine substantial equivalence with predicate devices and comparison with standard of care

Primary Endpoints (12 months)

- Safety: Frequency and severity of adverse events
- Efficacy: PSA reduction ≥ 75% (in > 50% of patients)

Secondary Endpoints (to 5 years)

- Prostate volume reduction at 1 year
- Prostate biopsy at 1 year in all patients
- Multi-parametric MRI at 1 year (Central Radiology Lab, Cleveland Clinic)
- Functional Disability: EPIC, IIEF, IPSS



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TACT: Prostate Ablation Efficacy

PSA primary efficacy endpoint resolutely met:

- Primary endpoint of PSA reduction ≥75% was achieved in 110 of 115 (96%)
- Median (IQR) PSA reduction was 95% (91-98%)
- Median PSA nadir was 0.34 (0.12-0.56) ng/ml

	Pre-Treatment	12 Month	PSA Nadir
N	115	115	115
Median	**6.26**	**0.53**	**0.34**
IQR	4.65 – 7.95	0.28 – 1.25	0.12 – 0.56
Average	**6.72**	**0.93**	**0.51**
T-Test against baseline		<0.001	<0.001

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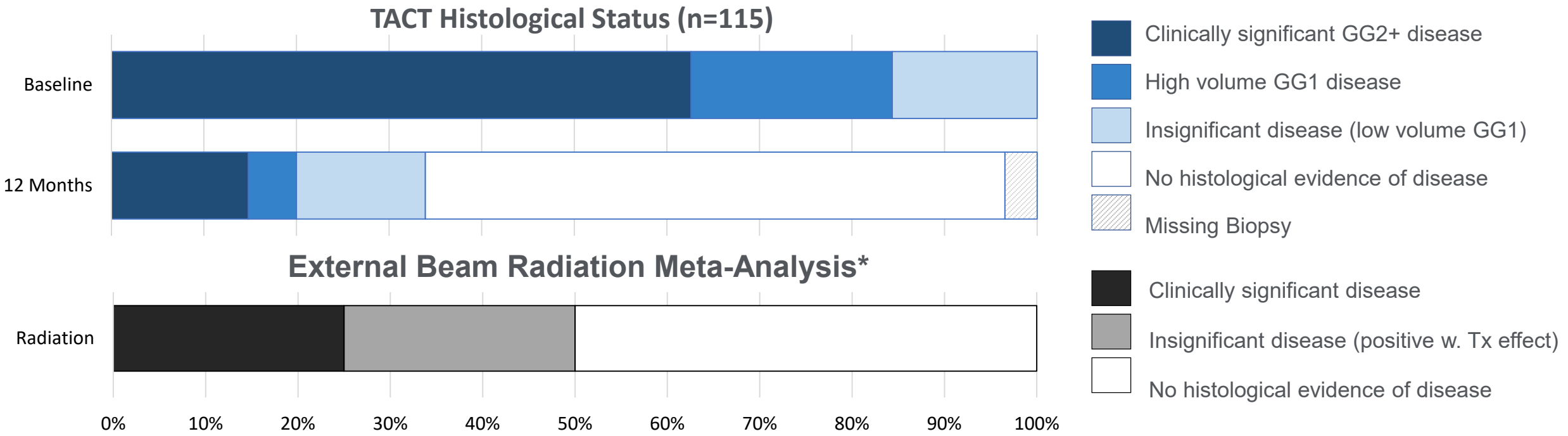
TACT: Histological Response

Biopsy Outcomes (1-year, 10-core TRUS, High Sampling Density 0.4 cc / core)

- Only 4 of 115 follow-up biopsies are missing, all due to patient refusal
- Among men with pre-treatment intermediate-risk GG2 disease, **54 of 68 (79%)** were free of GG2 disease
- Of men with one-year biopsy data, 72 of 111 (65%) had complete histological response and were free of any evidence of cancer
- 41% (16 of 39) of positive biopsies were clinically insignificant (Very Low Risk)
- Multivariate Analysis: Among men with pre-Tx GG2 disease and w/o calcifications at screening, **51 of 60 (85%)** were free of GG2 disease



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*GCP-10102 available upon request

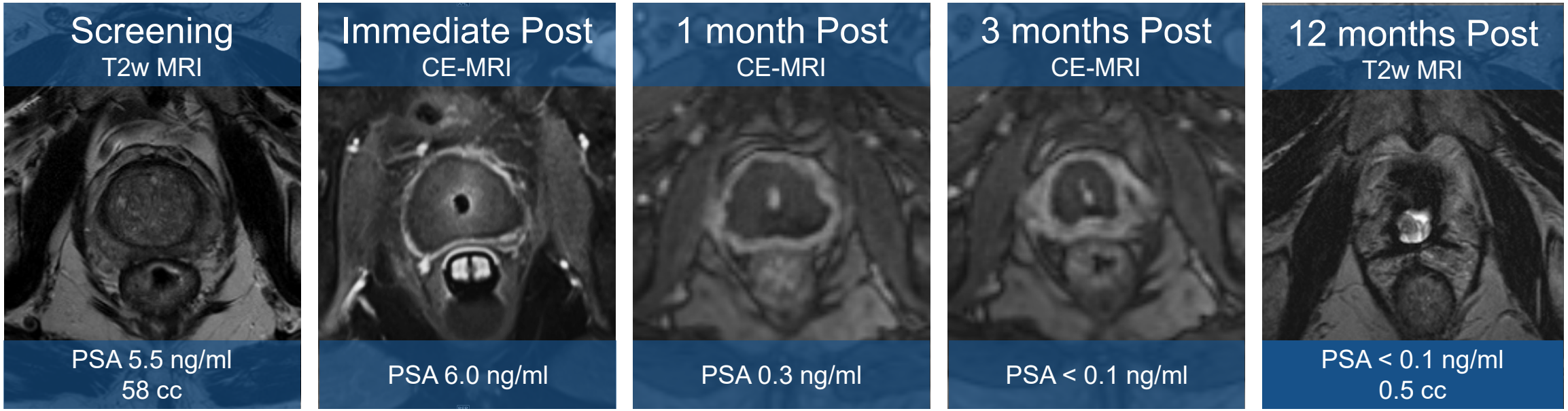
TACT: Prostate Volume Reduction

Prostate volume significantly reduced demonstrating effective prostate ablation

- Median perfused prostate volume decreased 91% from 37 cc to 3 cc, on MRI at 1 year (central radiology)
- Prostate ablation confirmed on Contrast Enhanced MRI immediately after TULSA and during follow-up

Follow-up prostate MRI predicts clinically significant disease on biopsy

- Multivariate Analysis: Absence of PIRADS ≥ 3 lesion at 1-year post-treatment MRI has 92% Negative Predictive Value for absence of GG2 disease on 1-year biopsy (local radiologists, same as diagnostic PIRADS)
- Ongoing work: Adjusting PIRARDS for post-ablation setting, MRI has **96% Negative Predictive Value** for absence of GG2 disease on 1-year biopsy (central radiology)



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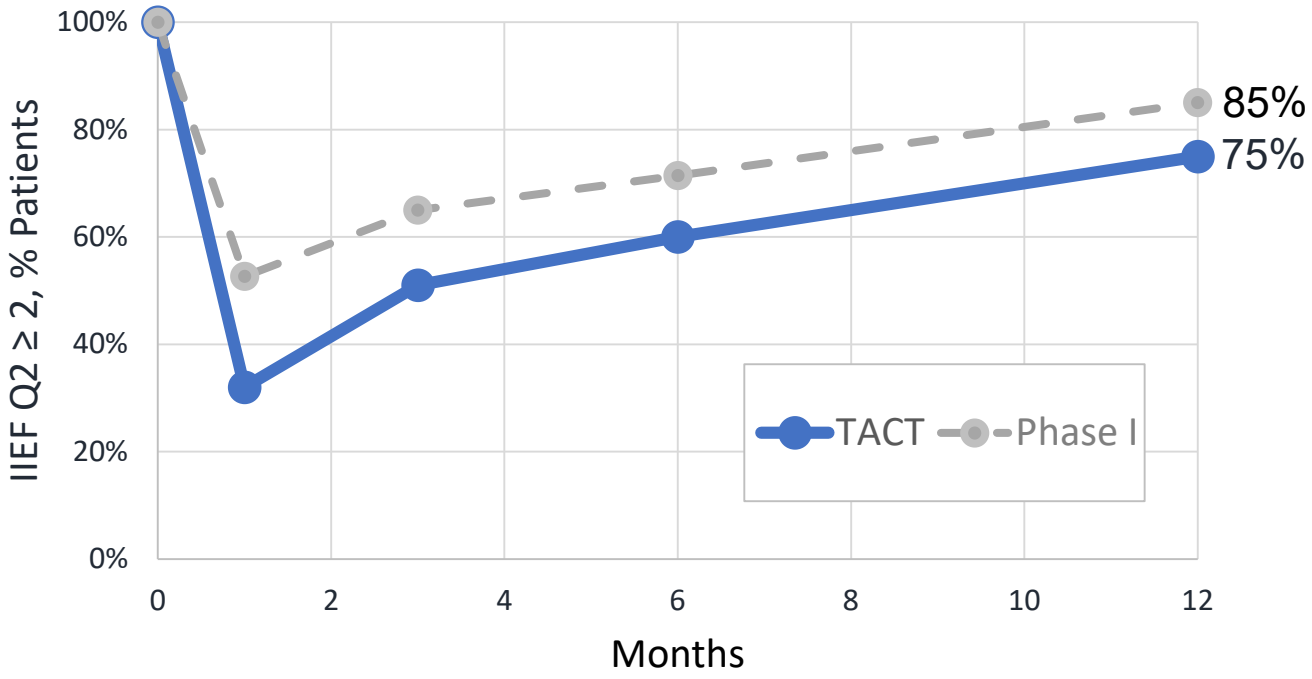
TACT: Erectile Function

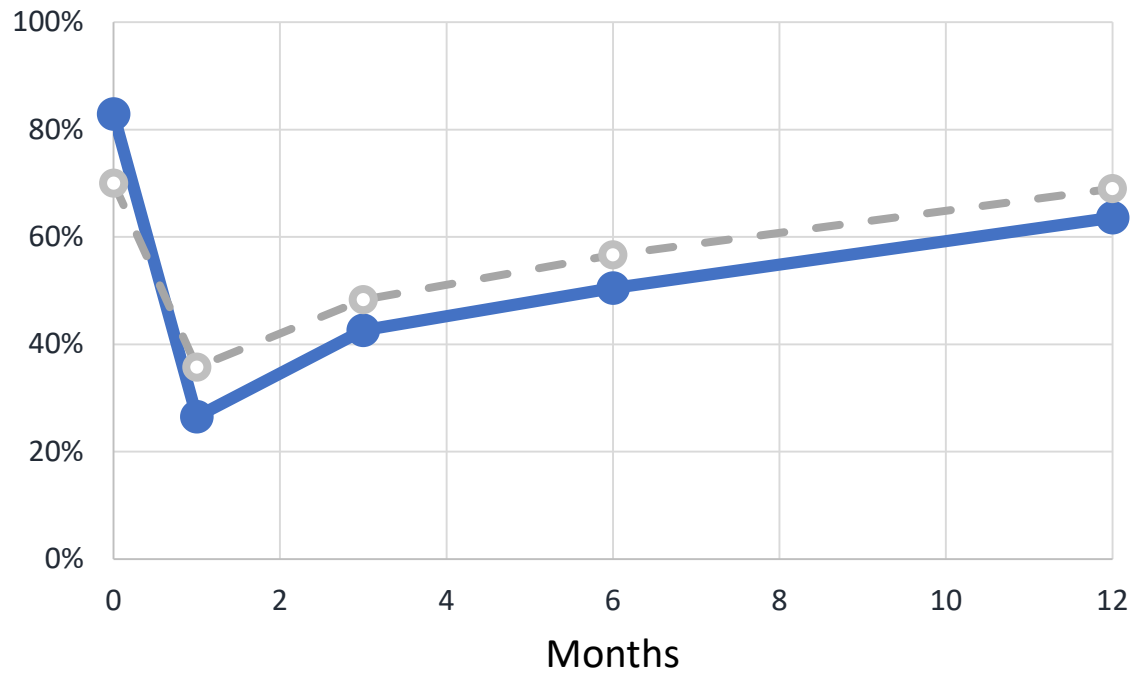
Erectile Function, at one year:

- 23% surgeon-assessed moderate erectile dysfunction (CTCAE Grade 2, intervention such as medication indicated)
- 0% any occurrence of severe erectile dysfunction (CTCAE Grade 3, intervention such as medication not helpful)
- 75% (69/92) of previously potent patients maintained erections sufficient for penetration
- Phase I 90% ablation, TACT whole gland ablation

Patients Potent at Baseline (n=92)



All Patients (n=110)



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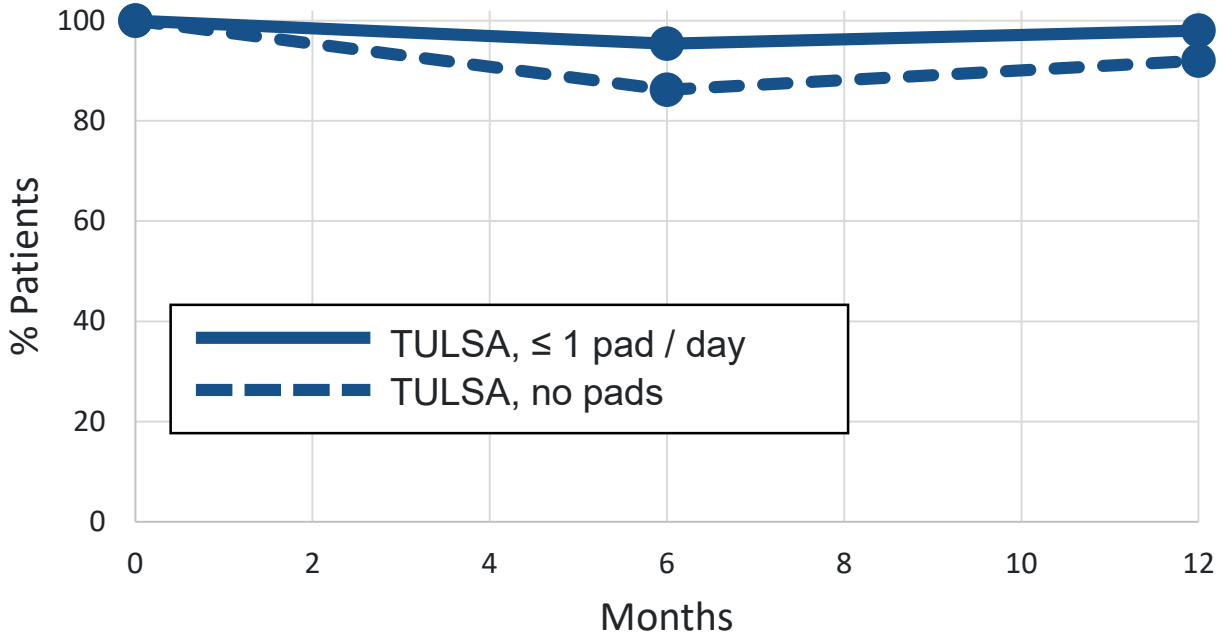
TACT: Urinary Incontinence

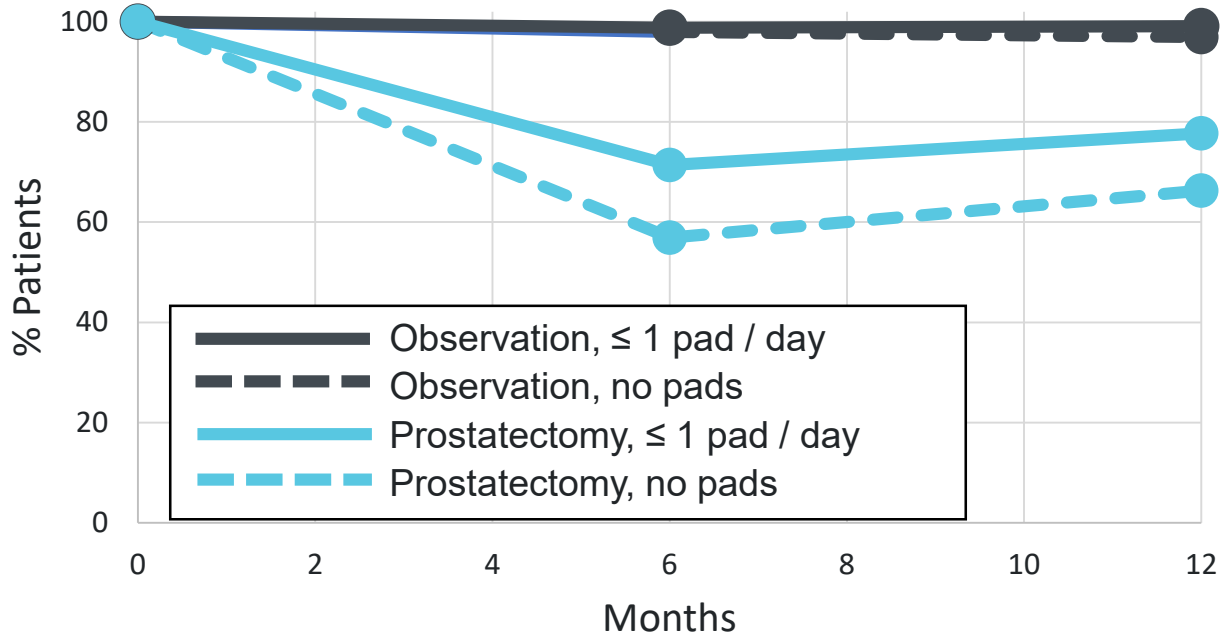
Urinary Incontinence, at one year:

- 2.6% surgeon-assessed moderate urinary incontinence (CTCAE Grade 2, pads indicated)
- 0% any occurrence of severe urinary incontinence (CTCAE Grade 3, operative intervention indicated)
- TACT Urinary Continence (pad use) similar to Observation arm of PIVOT study

TACT



PIVOT [1]



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1. Wilt *et al*, The New England Journal of Medicine, 2017

TACT summary, **Literature review** of other trials provided for context

	TACT Study	Literature Review		
	TULSA	Prostatectomy	Radiation	HIFU
Biopsy / Histology	**21% Clinically significant** **14% Insignificant disease** (GG1, ≤2 cores, < 50% CCL) **65% Negative**	**16 – 24% +Margin** [1] (Meta-Analysis) **10 – 15% +Margin** [2] (RCT) **24% +Margin** [3] (ProtecT)	**28% Clinically significant** [4] **20% Insignificant disease** [4] (Positive w. treatment effect) **52% Negative** [4]	**59 – 61% Negative** [5-6] (Intent to treat) **63% Negative, after 40% having repeat HIFU and 39% ADT** [7]
Erectile Dysfunction erections insufficient for penetration	**23%** Grade 2 medication indicated. No Grade 3 ED	**79%** [9] *(Range: 25 – 100%)* [1-4]	**63%** [9] *(Range: 7 – 85%)* [1-5]	**58%** [7] *(Range: 44 – 67%)* [6-8]
Urinary Incontinence moderate to severe	**2.6%** Grade 2 pads indicated. No Grade 3 Incontinence	**15%** [9] *(Range: 0 – 50%)* [1-4]	**4%** [9] *(Range: 2 – 15%)* [1-5]	**3%** [5] *(Range: 3 – 22%)* [6-8]
Urethral Stricture moderate to severe	**2.6%**	**9%** [11] *(Range: 3 – 26%)* [1-4]	**2%** [11] *(Range: 1 – 9%)* [1-5]	**35%** [5] *(Range: 9 – 35%)* [6-8]
GI Toxicity, moderate to severe diarrhea, urgency, incontinence, fistula	**No GI Toxicity**	**15%** [9] *(Range: 0 – 24%)* [1-4]	**25%** [9, 12] *(Range: 0 – 40%)* [1-5]	**7%** [5] *(Range: 1 – 21%)* [6-8]

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1. 1. Tewari et al 2012 (Meta-Analysis)
2. Yaxley et al 2016 (RCT)
3. Hamdy et al 2016 (ProtecT)
4. Radiation Meta-Analysis (publication pending)
5. FDA IDE Study K153023
6. FDA IDE Study DEN150011
7. Crouzet *et al*, Eur Urol 2014 (1000+ patients, Whole-gland HIFU)
8. Thompson (Chair) *et al,* AUA prostate cancer clinical guideline update panel, J Urol 2007
9. Resnick et al, Prostate Cancer Outcomes Study (PCOS), NEJM 2013
10. Potosky *et al*, Prostate Cancer Outcomes Study (PCOS), J NCI 2004
11. Elliott *et al*, CaPSURE database, J Urol 2007
12. Budaus *et al*, Review, Eur Urol 20012