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### Introduction

Therapeutic decision-making in diverse BPH patients may be informed by real-world outcomes in understudied populations.

In this analysis, we utilize a large retrospective real-world database to examine PUL outcomes in understudied patient groups with comorbidities including diabetes mellitus, and Parkinson's disease, and in various racial cohorts.

### Methods and Materials

The Real-World Retrospective (RWR) study included **3,226** patients spanning across **22 international sites** who underwent PUL after market clearance

Patients must have had baseline IPSS and at least one IPSS post-treatment. Average follow up post-PUL was within 9-12 month with longest available follow up through 36 months.

Patient stratification was performed as shown below and determined by medical history records:

- Diabetes mellitus subgroups
  - Controlled diabetes (DM, n=362), uncontrolled diabetes (UN, n=33), non-diabetic (ND, n=1917)
- Parkinson's disease diagnosis at baseline (PD, n=16)
  - Compared to non-Parkinson's patients
- Race cohorts
  - White (n=1737), Hispanic or Latino (n=107), Black (n=80), and Asian (n=24))

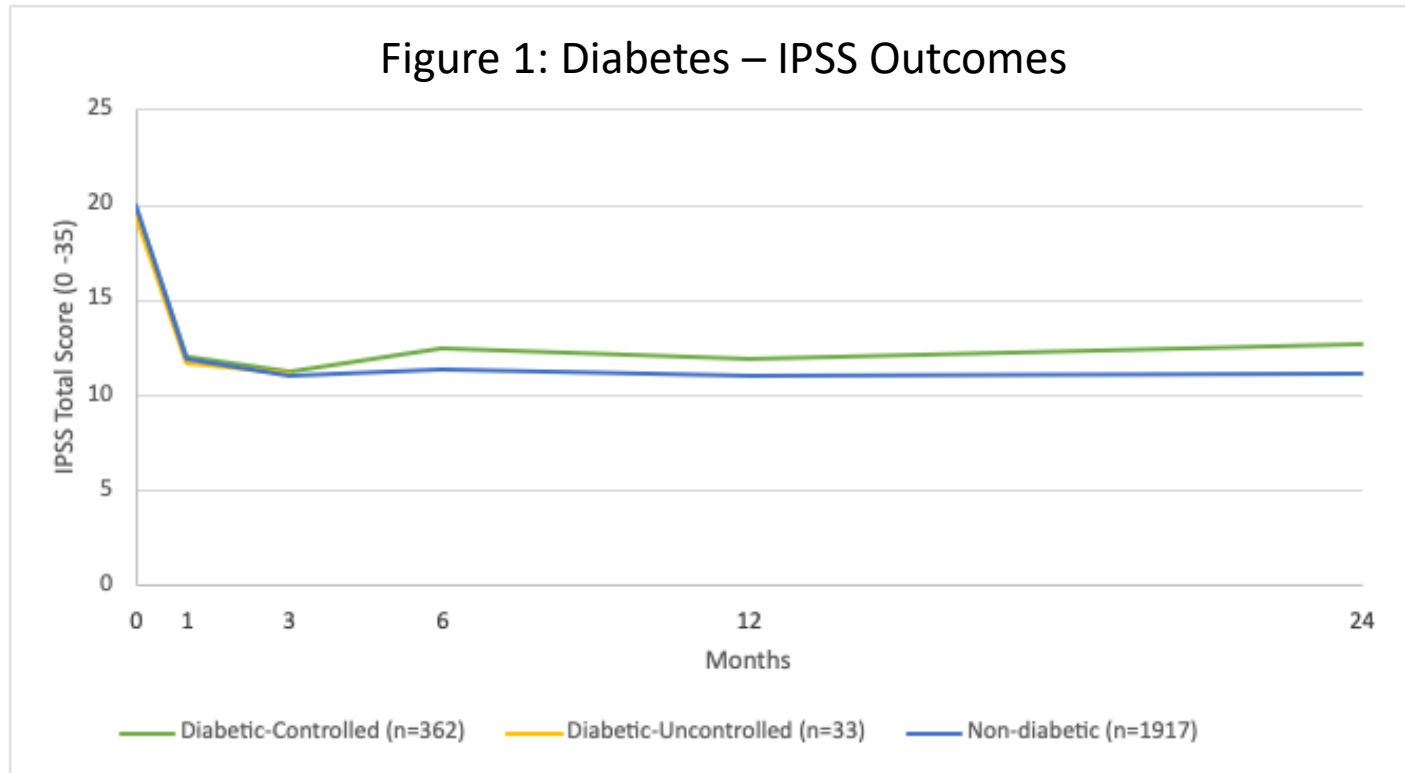
### Results

#### Diabetes mellitus

Table 1. Diabetes - Baseline Demographics.

Characteristic: Mean ± SD	Diabetic - Controlled (N=362)	Diabetic - Uncontrolled (N=33)	Non-diabetic (N=1917)	P-value
Age (years)	69.9 ± 8.3	66.9 ± 8.5	68.7 ± 9.1	0.03
BMI (kg/m²)	31.1 ± 6.2	31.8 ± 4.9	28.7 ± 5.6	<0.0001
Prostate Vol (cc)	44.6 ± 17.7	42.1 ± 15.0	46.7 ± 19.9	0.2
PSA (ng/mL)	2.1 ± 2.4	2.0 ± 1.7	2.5 ± 3.3	0.3
PUL Implants	4.7 ± 1.3	4.7 ± 1.2	4.8 ± 1.4	0.6

- At baseline, uncontrolled diabetics (UN) were significantly younger with higher BMI vs controlled diabetics (DM) and non-diabetics (ND) (**Table 1**)
- More uncontrolled diabetic patients were treated under general anesthesia (80% UN, 52.4% DM, 56.0% ND)



- IPSS and QoL were equivalent across diabetic and non-diabetic patients with durable improvement through 24 months post-procedure (**Figure 1**)

Table 2: Diabetes - Most Common Adverse Events

Type of AE	Diabetic – Controlled (n=362)	Diabetic – Uncontrolled (N=33)	Non-Diabetic (N=1917)
Any AE	143 (39.5%)	19 (57.6%)	694 (36.2%)
Bladder spasm	0 ( 0.0%)	0 ( 0.0%)	26 ( 1.4%)
Dysuria	34 ( 9.4%)	2 ( 6.1%)	139 ( 7.3%)
Hematuria	71 (19.6%)	9 (27.3%)	320 (16.7%)
Incontinence*	13 ( 3.6%)	2 ( 6.1%)	53 ( 2.8%)
Urinary tract infection (UTI)	26 ( 7.2%)	3 ( 9.1%)	84 ( 4.4%)

- Uncontrolled diabetic patients experienced a significantly higher rate of overall adverse events compared to controlled diabetic and non-diabetic patients (**Table 2**)
- Most patients did not require a post-operative catheter (days 0-3), and there was no significant difference in catheter-free rates based on diabetes status

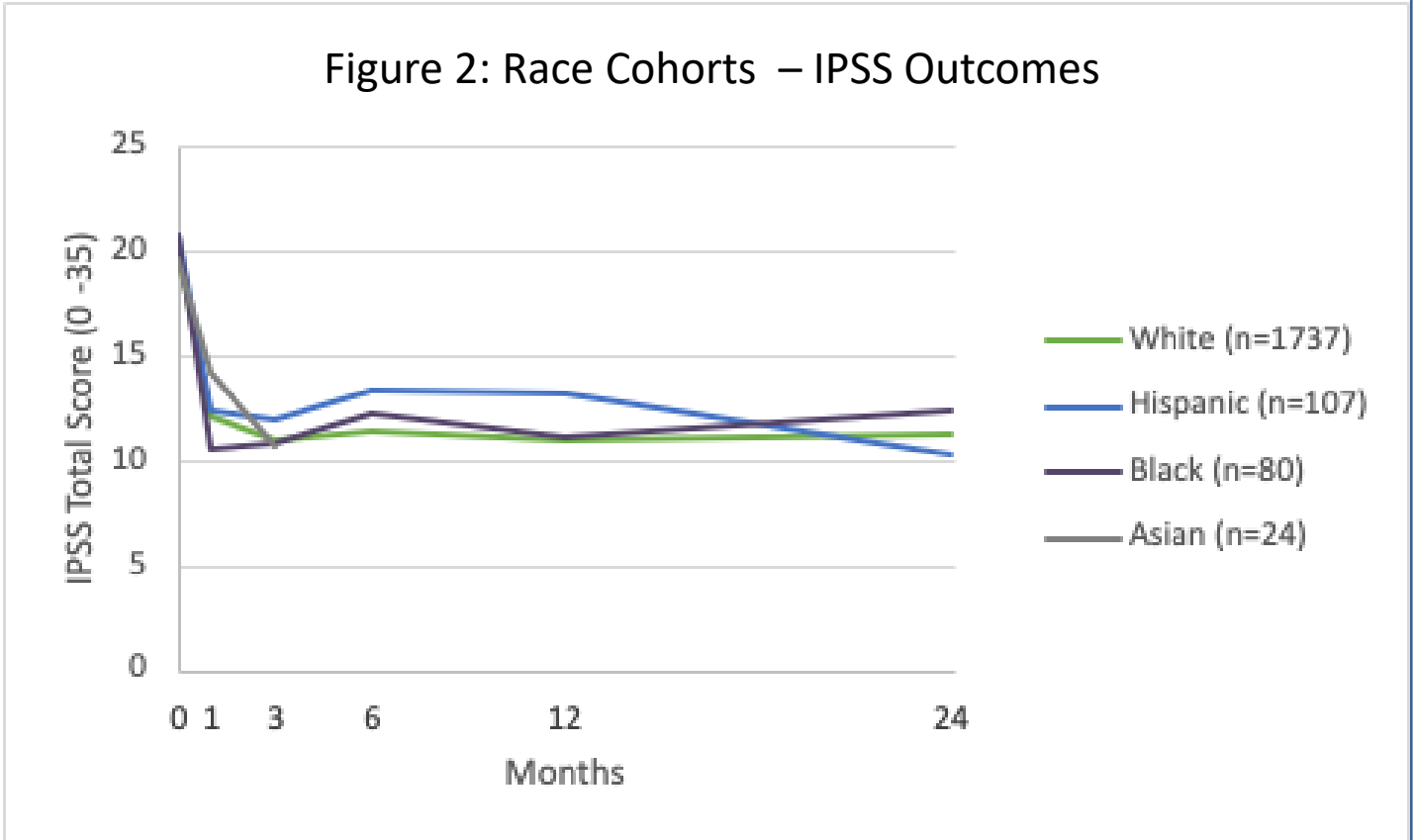
### Results

#### Race Cohorts

Table 3. Race cohorts - Baseline Demographics.

Characteristic: Mean ± SD	White (N=1737)	Hispanic/Latino (N=107)	Black (N=80)	Asian (N=24)	P-value
Age (years)	69.3 ± 8.9	66.1 ± 9.0	69.9 ± 9.9	67.5 ± 11.4	<0.01
BMI (kg/m²)	29.0 ± 5.6	29.5 ± 5.5	29.8 ± 6.9	25.4 ± 2.4	<0.01
Prostate Vol (cc)	46.0 ± 19.9	47.6 ± 18.6	46.3 ± 18.8	42.1 ± 12.5	0.8
PSA (ng/mL)	2.4 ± 3.4	2.3 ± 2.7	2.0 ± 2.1	2.2 ± 2.1	0.8
No. of Implants	4.7 ± 1.3	4.8 ± 1.2	4.8 ± 1.3	4.3 ± 1.2	0.4

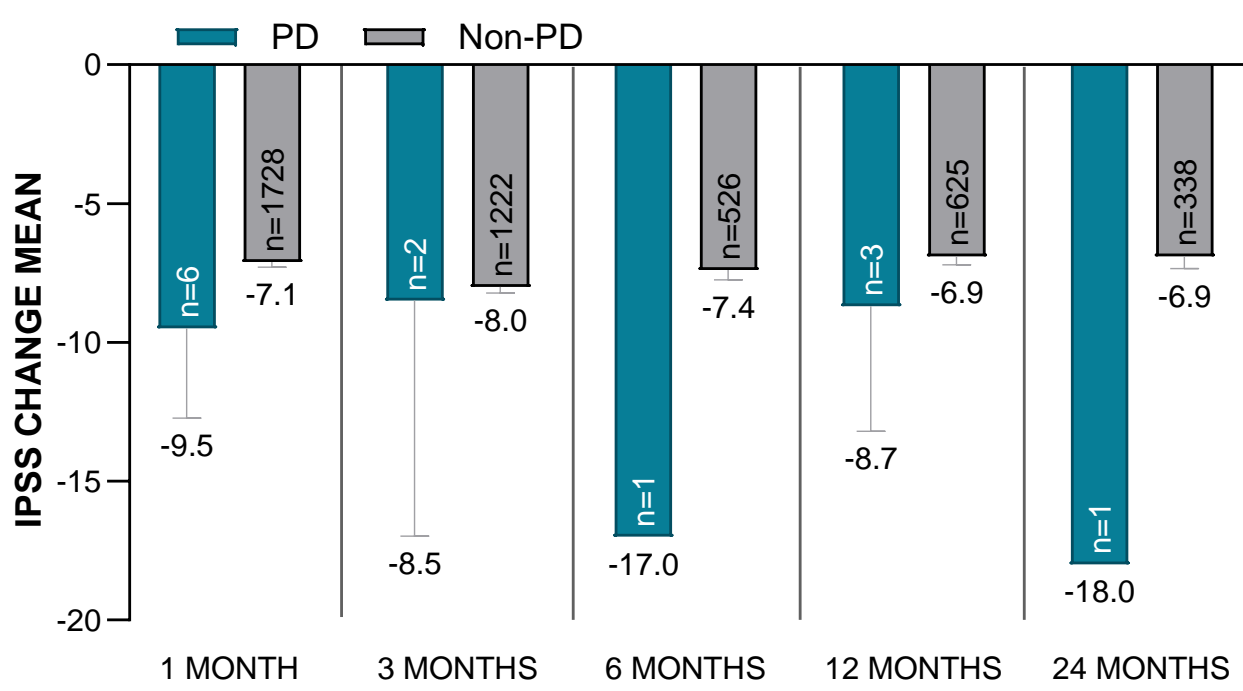
- Hispanic/Latino patients were the youngest while Black patients were the oldest (**Table 3**)
- Black patients had the highest BMI while Asian patients had the lowest BMI
- Prostate volume, PSA and the number of PUL implants placed were similar across groups
- Black and Asian patients were treated in the hospital setting at a higher rate compared to Hispanic and White patients who were mostly treated in the ASC or office
- Asian patients were significantly more likely to be treated under general anesthesia while Hispanic patients were treated under local anesthesia at higher rates compared to other groups



- Symptom improvement was consistent across all racial subgroups and remained durable through 24 months (**Figure 2**)
- The overall rate of adverse events was similar across racial subgroups
- Black patients had the highest rates of post-procedure catheterization performed as standard of care (55.0%) followed by White (38.3%) and Hispanic or Latino (35.5%), while Asian patients had the lowest rate (20.8%), p=<0.01

#### Parkinson's Disease

Figure 3: PD Cohorts – IPSS Mean Change



- PD patients improved similarly to non-PD patients through 1 month
- (reductions in sample size after 1 month limited further analysis of improvement) (**Figure 3**)
- PD patients had similar total AE rates to non-PD patients

### Conclusions

This study evaluated outcomes of various real-world populations who underwent the PUL procedure, with a particular emphasis on patient subgroups which are largely understudied or not included in most controlled clinical trials. These results suggest IPSS significantly improves in all real-world subgroups, including diabetic patients (both controlled and uncontrolled diabetes), and for patients within all racial subgroups evaluated (White, Hispanic or Latino, Black, and Asian). Adverse events were somewhat elevated in uncontrolled diabetic patients but were similar between racial subgroups and between patients with and without a diagnosis of Parkinson's disease. Black and Asian patients were more likely to be treated in a hospital outpatient setting compared to Whites and Hispanics, with Black patients experiencing more post-operative catheters due to standard of care practice. In summary, diverse patient populations can experience durable, safe improvement in BPH-associated LUTS following treatment with PUL.