

Supplementary Information

Table S1. Concomitant diseases at baseline by treatment group (iterative matching sample), n (%).

	TAM (n = 353)	HESr (n = 384)	p value
<i>Patients with any concomitant illness, n (%)</i>	131 (37.1)	120 (31.2)	0.110
High blood pressure	68 (19.3)	60 (15.6)	0.228
Dyslipidemia	55 (15.6)	50 (13.0)	0.375
Diabetes mellitus	38 (10.8)	32 (8.3)	0.318
Other	8 (2.3)	8 (2.1)	0.604

TAM: tamsulosin; HESr: hexanic extract of *Serenoa repens*

Table S2. Patient baseline characteristics by treatment group (propensity score matching sample).

	TAM		HESr		p value
	n	mean (SD)	n	mean (SD)	
Age, mean (SD) years	115	63.1 (8.0)	114	62.7 (8.2)	0.713
BMI (Kg/m ²), mean (SD)	113	26.9 (2.8)	114	26.4 (2.6)	0.122
IPSS, mean (SD)	128	16.7 (4.5)	128	16.3 (4.9)	0.579
IPSS voiding sub-score	128	9.6 (3.2)	128	9.3 (3.1)	0.448
IPSS storage sub-score	128	7.1 (2.0)	128	7.1 (2.6)	0.914
Nocturia	128	2.4 (0.9)	128	2.3 (1.0)	0.520
BII, mean (SD)	128	7.2 (2.2)	128	7.0 (2.4)	0.499
IPSS item 8 (QoL)	128	3.5 (1.1)	128	3.4 (1.1)	0.465
Time since diagnosis (years)	115	0.8 (1.6)	114	1.3 (3.0)	0.094
Qmax (ml/s)	128	12.0 (3.4)	128	12.5 (3.5)	0.300
Prostate volume (cm ³)	128	49.5 (16.8)	128	47.7 (15.6)	0.352
PSA (ng/ml)	128	2.3 (1.2)	128	2.3 (1.2)	0.932

TAM: tamsulosin; HESr: hexanic extract of *Serenoa repens*. BMI: body mass index; IPSS: International Prostate Symptom Score; BII: Benign Prostatic Hyperplasia Impact Index; QoL: quality of life; Qmax: maximum urinary flow rate; PSA: prostate-specific antigen.

Table S3. Improvements in symptoms, quality of life, and clinical parameters from baseline to 6-month follow-up by treatment group (propensity score matching sample).

	TAM		HESr		p value
	n	Mean (SD)	n	Mean (SD)	
IPSS total	124	5.1 (4.6)	125	4.9 (4.6)	0.718
IPSS voiding sub-score	124	3.0 (3.0)	125	2.7 (2.9)	0.400
IPSS storage sub-score	124	2.1 (2.1)	125	2.2 (2.2)	0.691
Nocturia	124	0.7 (0.9)	125	0.7 (1.0)	0.964
BII total	124	2.6 (2.4)	125	2.4 (2.5)	0.494
IPSS item 8	124	1.3 (1.2)	125	1.2 (1.2)	0.559
Qmax (ml/sec)	51	3.2 (3.6)	65	3.0 (4.2)	0.805
Prostate volume (cm ³)	20	-1.9 (3.4)	36	-2.3 (10.6)	0.824
PSA (ng/ml)	42	-0.3 (0.7)	35	0.0 (0.9)	0.127

TAM: tamsulosin; HESr: hexanic extract of *Serenoa repens*; IPSS: International Prostate Symptom Score; BII: Benign Prostatic Hyperplasia Impact Index; Qmax: maximum urinary flow rate; PSA: prostate-specific antigen.

Table S4. Improvements from baseline to 6-month follow-up in symptoms and quality of life scores by treatment arm, in patients with severe (IPSS > 19) baseline symptoms (propensity score matching sample).

	TAM		HESr		p value
	n	mean (SD)	n	mean (SD)	
IPSS total	35	9.1 (5.3)	28	9.0 (5.4)	0.929
IPSS voiding sub-score	35	5.6 (3.2)	28	5.3 (3.3)	0.731
IPSS storage sub-score	35	3.5 (2.6)	28	3.7 (2.5)	0.799
Nocturia	35	1.1 (1.1)	28	1.0 (1.2)	0.633
BII total	35	3.3 (2.8)	28	3.6 (2.8)	0.593
IPSS item 8	35	1.8 (1.2)	28	1.5 (1.3)	0.306
Qmax (ml/sec)	16	3.5 (3.1)	18	5.5 (3.9)	0.103

TAM: tamsulosin; HESr: hexanic extract of *Serenoa repens*; IPSS: International Prostate Symptom Score; BII: Benign Prostatic Hyperplasia Impact Index; Qmax: maximum urinary flow rate.

Table S5. Reported adverse effects for the study sample overall and by treatment group (propensity score matching sample).

	Overall	TAM	HESr	p value
	n = 256	n = 128	n = 128	
Any adverse effect	24 (9.4%)	21 (16.4%)	3 (2.3%)	<0.001*
Anejaculation	11 (4.3%)	11 (8.6%)	0	0.002*
Reduced ejaculatory volume	11 (3.4%)	10 (7.8%)	1 (0.8%)	0.014*
Erectile dysfunction	2 (0.8%)	1 (0.8%)	1 (0.8%)	1.000
Orthostatic hypotension	3 (1.2%)	3 (2.3%)	0	0.247
Reduced libido	4 (1.6%)	3 (2.3%)	1 (0.8%)	0.622
Dizziness	1 (0.4%)	1 (0.8%)	0	1.000

TAM: tamsulosin; HESr: hexanic extract of *Serenoa repens*

*Statistically significant

Supplementary figure

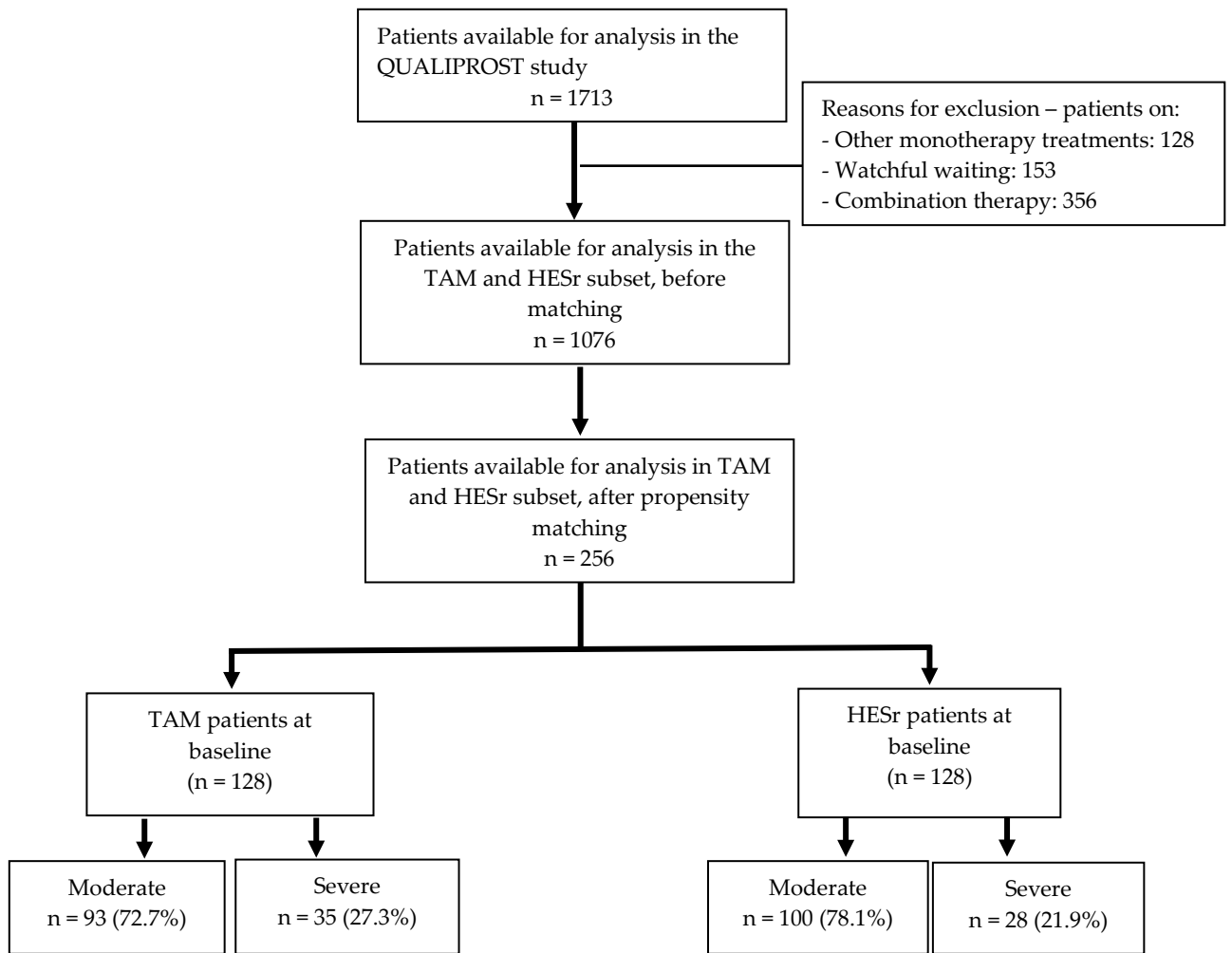


Figure S1. Study flow-chart: propensity matching based on IPSS (total, voiding and storage sub-scores, and item 8) and BII scores, maximum urinary flow (Qmax), prostate-specific antigen (PSA), and prostate volume at baseline.

TAM: tamsulosin; HESr: hexanic extract of *Serenoa repens*

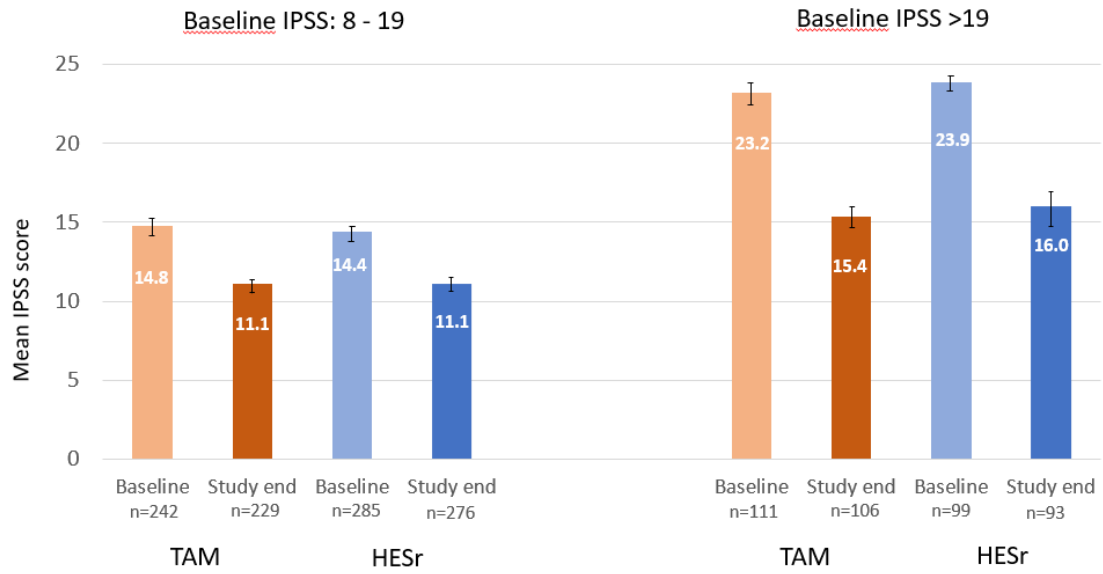


Figure S2. Mean (95% CI) IPSS total score at baseline and study end (6 months) for the treatment groups based on baseline symptom severity (iterative matching sample).

TAM: tamsulosin; HESr: hexanic extract of *Serenoa repens*; IPSS: International Prostate Symptom Score.

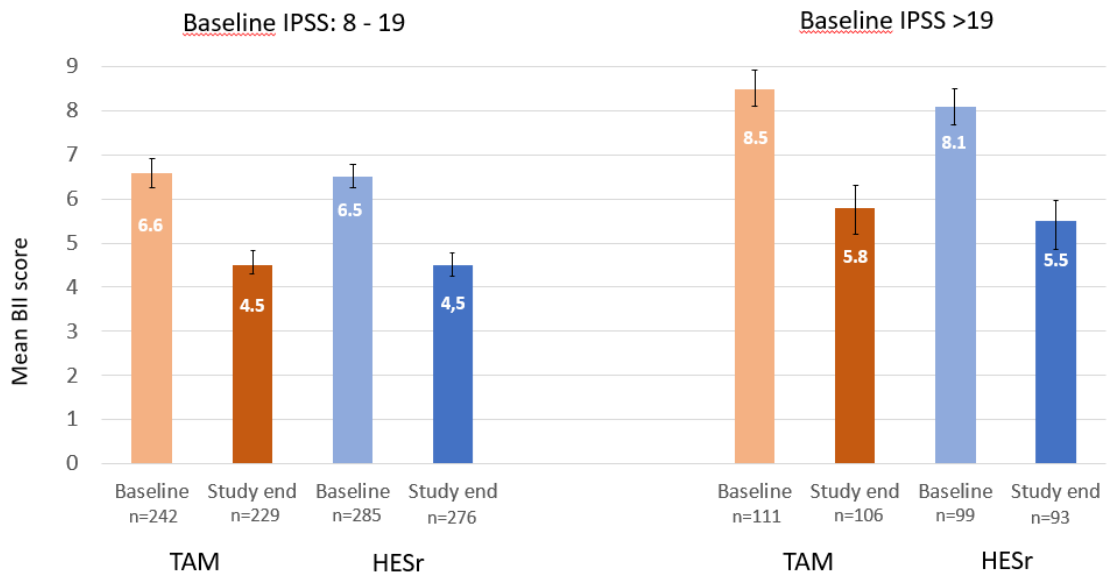


Figure S3. Mean (95% CI) BII score at baseline and study end (6 months) for the treatment groups based on baseline symptom severity (iterative matching sample).

TAM: tamsulosin; HESr: hexanic extract of *Serenoa repens*; IPSS: International Prostate Symptom Score; BII: Benign Prostatic Hyperplasia Impact Index.

Appendix

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