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VAPEUR RCT

High level overview

Romain MATHIEU (PI) / **Evanguelos XYLINAS** (Co-PI)

CONSENT
Baseline visit

RANDOMIZATION
With in 72 hours from consent

151 **Enrolled BPH Patients**
(All patients who failed alpha-blockers therapy)

Single-agent therapy (alpha-blockers) until treatment

TREATMENT

Combination therapy (CP)
N = 76
(Alpha-blockers + 5-ARIs)
within 7 days of randomization

Rezūm™
N=75
Water Vapour Therapy Treatment (WVTT)
within 90 days of randomization

21 sites in France and Australia

Endpoints

Primary **Change in IPSS*, Change in MSHQ****
Between baseline and 1 year

Secondary Disease Progression 4 Components: • Worsening of IPSS (4 points) • Catheterization beyond 90 days post-procedure • Surgical retreatment • New medication for urinary symptoms

* IPSS: Measure of lower urinary tract symptoms; ** MSHQ: Measure of sexual function

PROSPECTIVE FOLLOW-UP
(Intent-to-treat)

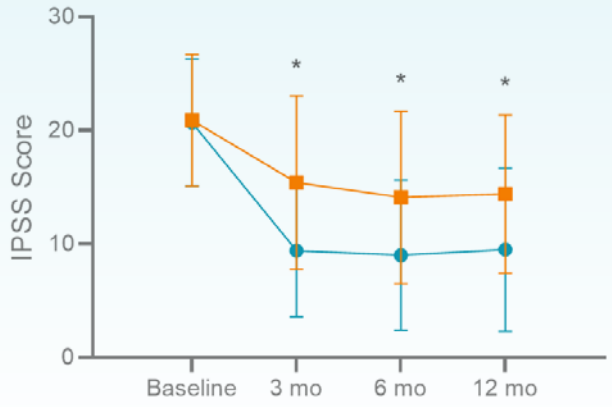
3-, 6-, 12-, 24-months in-hospital visits

24-month total follow-up

Last follow-up December 2026

END OF STUDY

PRIMARY ENDPOINT RESULT – IPSS



Analysis (ITT population)	Mean Difference at 12m (95% CI)	p-value
LOCF	-5.1 (-7.5, -2.8)	<.0001
MICE	-6.5 (-9.8, -3.2)	<.0001

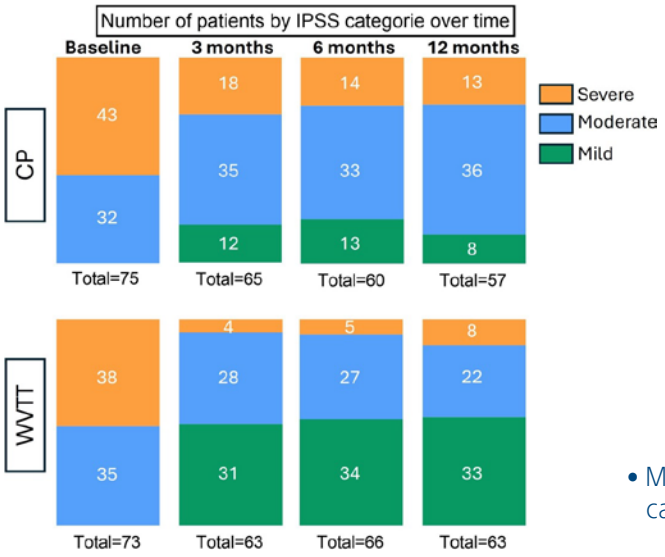
LOCF: Last Observation Carried Forward
MICE: Multiple Imputation by Chained Equations

CP
WVTT

*p<0.001

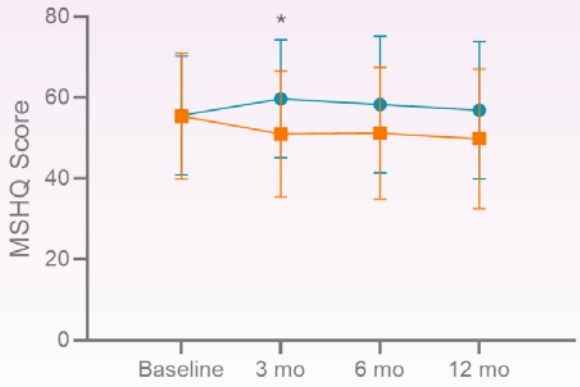
- Non-inferiority and superiority both met on IPSS change

Patient distribution by IPSS symptoms categories



- More than half of patients in the Mild category after Rezūm at 1 year

PRIMARY ENDPOINT RESULT – MSHQ



Analysis (ITT population)	Mean Difference at 12mo (95% CI)	p-value
LOCF	6.3 (0.5, 12.0)	0.0077
MICE	7.0 (-0.8, 14.7)	0.0220

LOCF: Last Observation Carried Forward
MICE: Multiple Imputation by Chained Equations

CP
WVTT

*p=0.0022

- Superiority met in LOCF but not MICE
- Sexual function preserved after Rezūm at 1 year

SECONDARY ENDPOINT – 4 COMPONENTS*

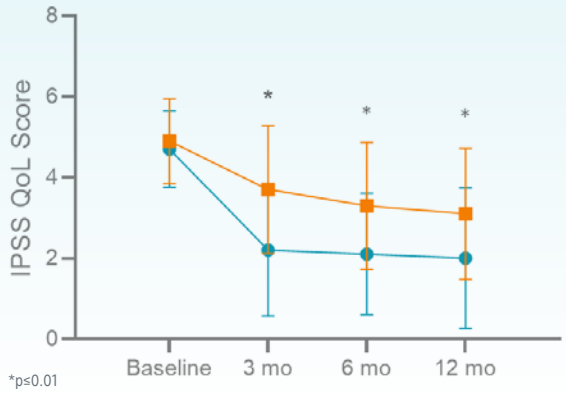
Markers of clinical progression

Component	WVTT (n = 75)	CP (n = 76)
Surgical [re]-treatment for LUTS/BPH	1.3% (1/75)	9.2% (7/76)
Urinary retention requiring urinary catheterization after 90 days post-treatment	0.0% (0/75)	1.3% (1/76)
IPSS increase from baseline by ≥ 4 points	2.7% (2/75)	13.2% (10/76)
Introduction of a new drug agent to treat LUTS/BPH	12.0% (9/75)	1.3% (1/76)

- Low surgical retreatment rate at 1 year after WVTT
- 88% medication-free after WVTT at 1 year

*Total WVTT: 16% (12/75) vs. CP: 25% (19/76), HR = 0.52, p = 0.0784

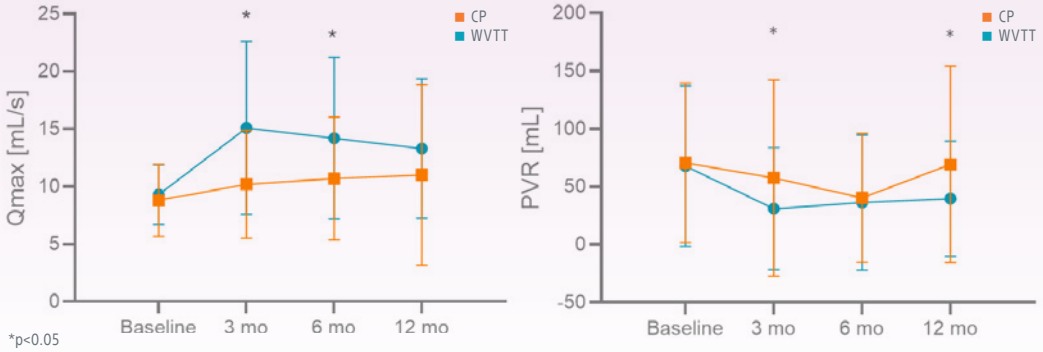
IPSS QOL



*p≤0.01

- Improvement in IPSS QoL in WVTT vs. CP is greater at all time points

URODYNAMICS



*p<0.05

- Urodynamics consistent with previously published data
- Qmax: Sharp improvement and gradual decrease with WVTT (N.S.) vs. slow increase with CP

ADVERSE EVENTS

Adverse events	WVTT (n = 75) # of Events	WVTT (n = 75) Subjects with Event	CP (n = 76) # of Events	CP (n = 76) Subjects with Event	P-value
Total	53	42.7% (32)	42	28.9% (22)	0.079
Serious Adverse Event	9	12.0% (9)	2	1.3% (1)	0.008
Treatment Related	50	40.0% (30)	40	27.6% (21)	0.108
Action taken	39	34.7% (26)	21	15.8% (12)	0.008
Medication	30	30.7% (23)	11	7.9% (6)	<.001
In-patient hospitalization	8	10.7% (8)	1	1.3% (1)	0.015
Catheterization	9	12.0% (9)	1	1.3% (1)	0.008
BPO Procedure	5	6.7% (5)	3	2.6% (2)	0.238
Other action taken	1	1.3% (1)	10	9.2% (7)	0.031
Outcome					
Not Recovered/Not Resolved	4	3/32	13	8/22	0.123
Recovering/Resolving	0	0/32	2	1/22	0.319
Resolved	48	31/32	25	15/22	0.004
Resolved with sequelae	1	1/32	0	0/22	0.312
Unknown	0	0/32	2	1/22	0.319

- Higher rate of adverse events in WVTT vs. CP
- Driven by peri-procedural events

At 1 year:
WVTT: 92% resolved
CP: 60% resolved

TREATMENT-RELATED ADVERSE EVENTS

MEDRA Coding

WVTT vs. CP	Adverse events	WVTT (n = 75) # of Events	WVTT (n = 75) Subjects with Event	CP (n = 76) # of Events	CP (n = 76) Subjects with Event
▲	**Urinary symptoms**	26	25.3% (19)	3	2.6% (2)
▲	**Infections**				
	Urinary tract infection	9	10.7% (9)	0	0.0% (0)
	Bacterial prostatitis	5	6.7% (5)	0	0.0% (0)
	Orchitis	1	1.3% (1)	0	0.0% (0)
▼	**Sexual function-related**				
	Erectile dysfunction	2	2.7% (2)	9	11.8% (9)
	Decreased/ Anejaculation	1	1.3% (1)	1	1.3% (1)
	Sexual dysfunction	1	1.3% (1)	0	0.0% (0)
	Libido decreased	0	0.0% (0)	7	9.2% (7)
	Loss of libido	0	0.0% (0)	1	1.3% (1)
▼	**General health**				
	Dizziness	0	0.0% (0)	4	5.3% (4)
	Headache	0	0.0% (0)	1	1.3% (1)
	Asthenia	0	0.0% (0)	3	3.9% (3)
	Fatigue	0	0.0% (0)	1	1.3% (1)
	Abdominal pain	0	0.0% (0)	1	1.3% (1)
	Constipation	1	1.3% (1)	0	0.0% (0)
	Palpitations	0	0.0% (0)	1	1.3% (1)

- Higher rates of urinary symptoms and infection events in WVTT vs CP
- Lower rates of sexual function-related events
- Adverse events affecting general health higher in CP

WVTT: Rezūm-Water Vapor Thermal Therapy, CP: Combination therapy (Alpha-blocker+5-ARIs)

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

Rezūm™ System Brief Summary

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