PROCEPT BioRobotics

AUA 2023

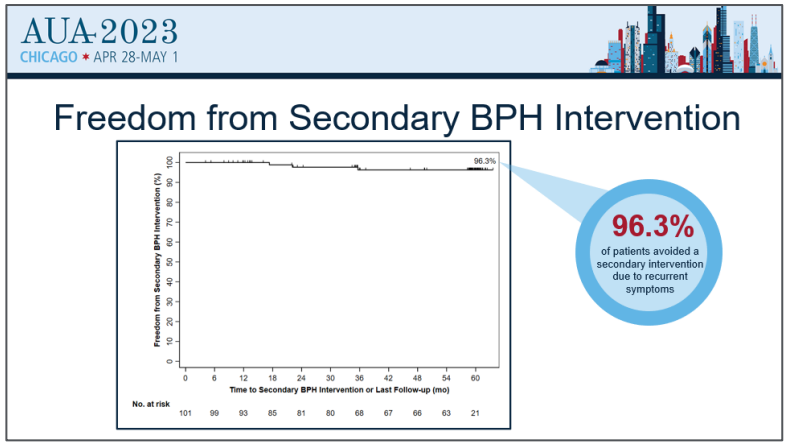
Highlights from the podium

Key Outcomes Overview

5-year Results for WATER II:

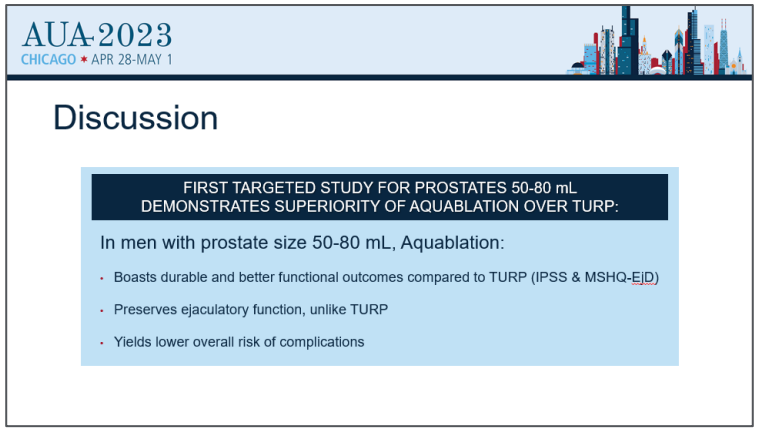
96.3%

of patients avoided secondary intervention due to recurrent symptoms



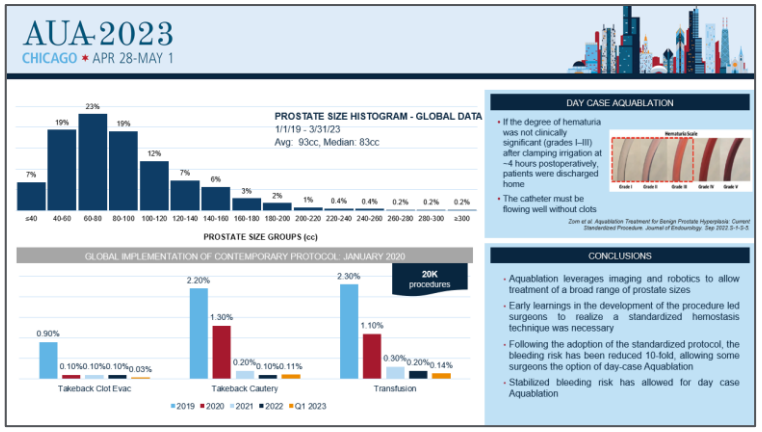
WATER 50-80mL subset analysis:

Aquablation has better long-term efficacy and safety outcomes than TURP for the management of LUTS due to BPH in men with prostates 50-80 mL



Post-op bleeding risk reduction:

In analyzing 20k+ Aquablation procedures with standardized hemostasis protocol, bleeding risk was reduced 10-fold, allowing for day case Aquablation



AUA 2023

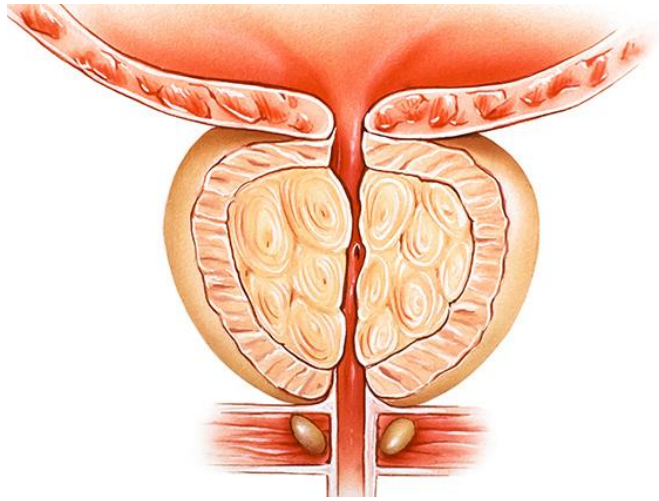
CHICAGO ★ APR 28-MAY 1

Aquablation Therapy vs Transurethral Resection of the Prostate: 5-Year Outcomes of the WATER Randomized Clinical Trial for Medium-Sized Prostates

Kussil Oumedjbeur, M.D./M.Sc. Candidate

McGill University, CA

Background



- High quality evidence of **safety** and **efficacy** for robotic waterjet ablation therapy (Aquablation®) in management of BPH-associated LUTS
- Recommended in North American guidelines since 2019
  - 30-80 mL prostates (AUA 2019)
  - < 150 mL prostates (CUA 2022)
- Lack of long-term data (> 3 years) targeted for 50-80 mL prostates subgroup

Objective

WATER STUDY SUBGROUP ANALYSIS:

To compare the 5-year **safety** and **efficacy** of Aquablation vs. gold standard (TURP) for 50–80 mL prostates

Methodology:

WATER STUDY DESIGN	• International, multi-center, double-blinded prospective randomized control trial
	• Subset analysis of 96 men ages 45-80, moderate-to-severe LUTS with prostates 50–80 mL
	  • Randomized 2:1 to either Aquablation or TURP
	  • Follow up at 1, 3, 6, 12 months and then annually until 5-years

PRIMARY SAFETY ENDPOINT	• Clavien-Dindo postoperative complications at 6 months
	  • Grade 1 persistent (CD1P)
	  • Grade 2 (CD2) or higher

PRIMARY EFFICACY ENDPOINT	• Reduction of IPSS across 5-years
SECONDARY EFFICACY ENDPOINTS	• Δ IPSS-QoL (quality of life) • Δ MSHQ-EjD (ejaculatory dysfunction) • Δ IIEF-5 (erectile function) • Δ Qmax (peak flow rate) • Δ PVR (post-void residual) • Δ PSA • Δ Prostate size

Similar Baseline Characteristics

PATIENT DEMOGRAPHICS

	Aquablation n = 62	TURP n = 34	P-Value
Age (years) Mean ±SD	**67.9 ± 6.8**	66.4 ± 7.2	0.2893
Body Mass Index Mean ±SD	**28.5 ± 3.9**	28.2 ± 4.5	0.7181
Prostate Size (mL) Mean ±SD	**66.4 ± 9.2**	61.7 ± 8.8	0.0181*
Obstructive Median Lobe	**67.7%**	70.6%	0.8216
PSA (ng/mL) Mean ±SD	**4.5 ± 3.1**	3.9 ± 2.5	0.3709

BASELINE QUESTIONNAIRE SCORES

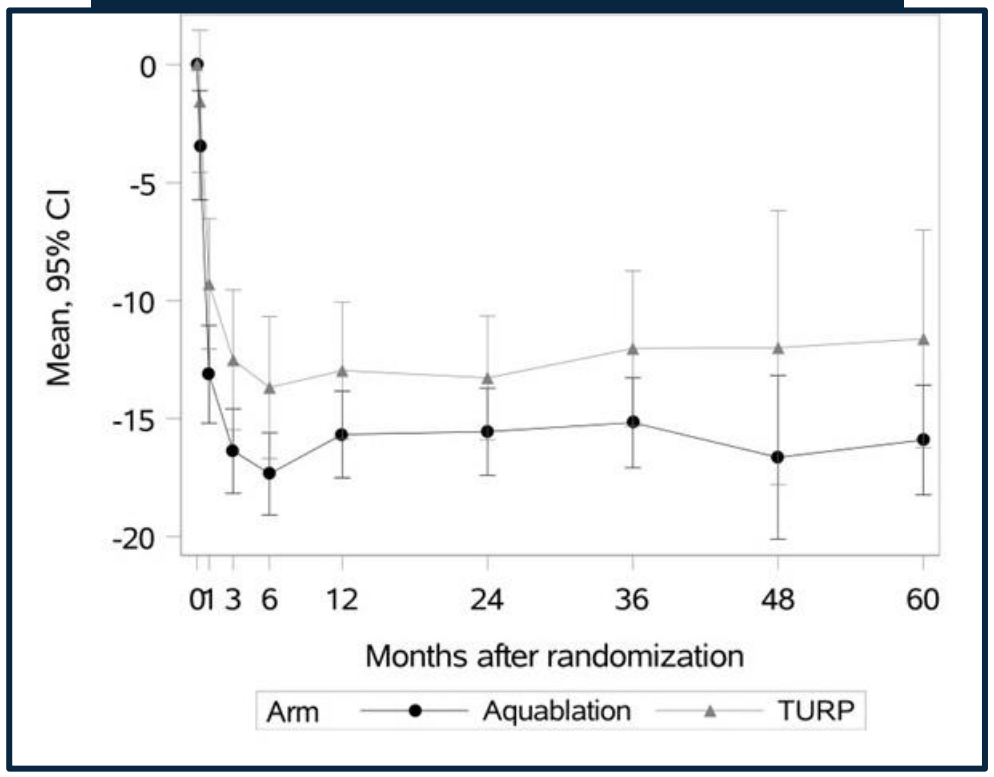
	Aquablation n = 62	TURP n = 34	P-Value
IPSS Score Mean ±SD	**23.3 ± 6.0**	20.9 ± 6.2	0.0667
IPSS QoL Mean ±SD	**4.8 ± 1.0**	4.8 ± 0.9	0.8330
Sexually Active (MSHQ-EjD)	**80.6%**	85.3%	0.7807
MSHQ-EjD Mean ±SD	**8.2 ± 3.8**	8.1 ± 4.0	0.9102
IIEF-5 Mean ±SD	**16.1 ± 7.0**	13.3 ± 9.1	0.1325

Results: IPSS Score Reduction

	Aquablation n = 62	TURP n = 34	P-Value
1-Month Postop	**-13.1**	-9.3	0.0284
Across 5-Years	**-14.1**	-10.8	0.0201*

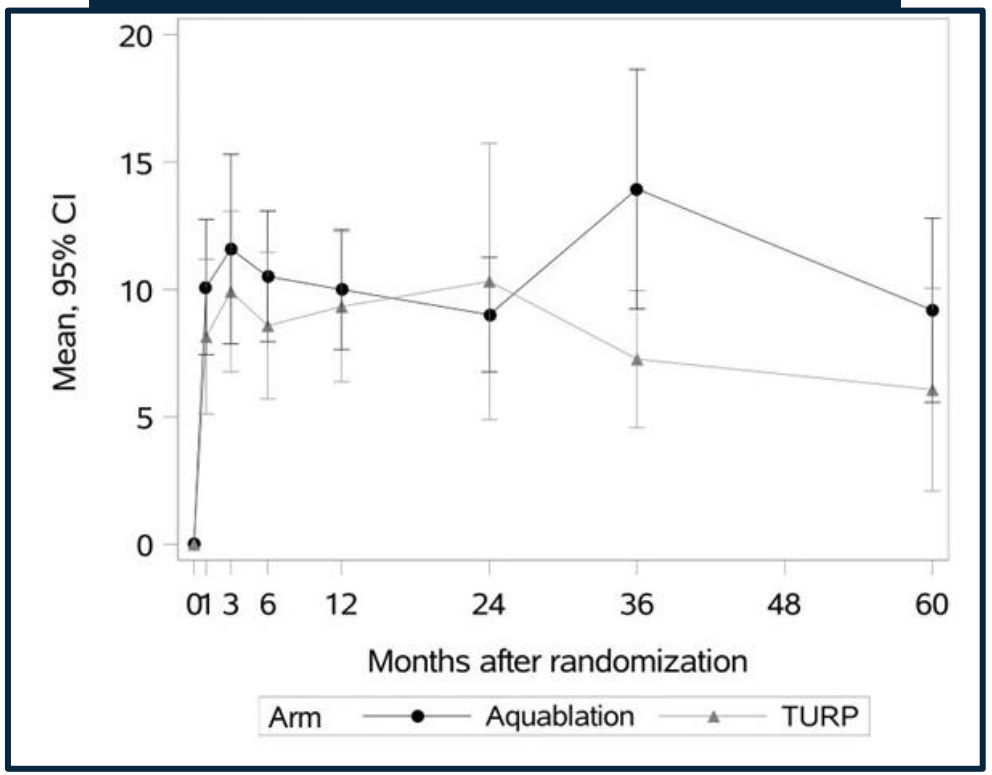
*Repeated measures ANOVA

CHANGES IN IPSS SCORE OVER 5 YEARS

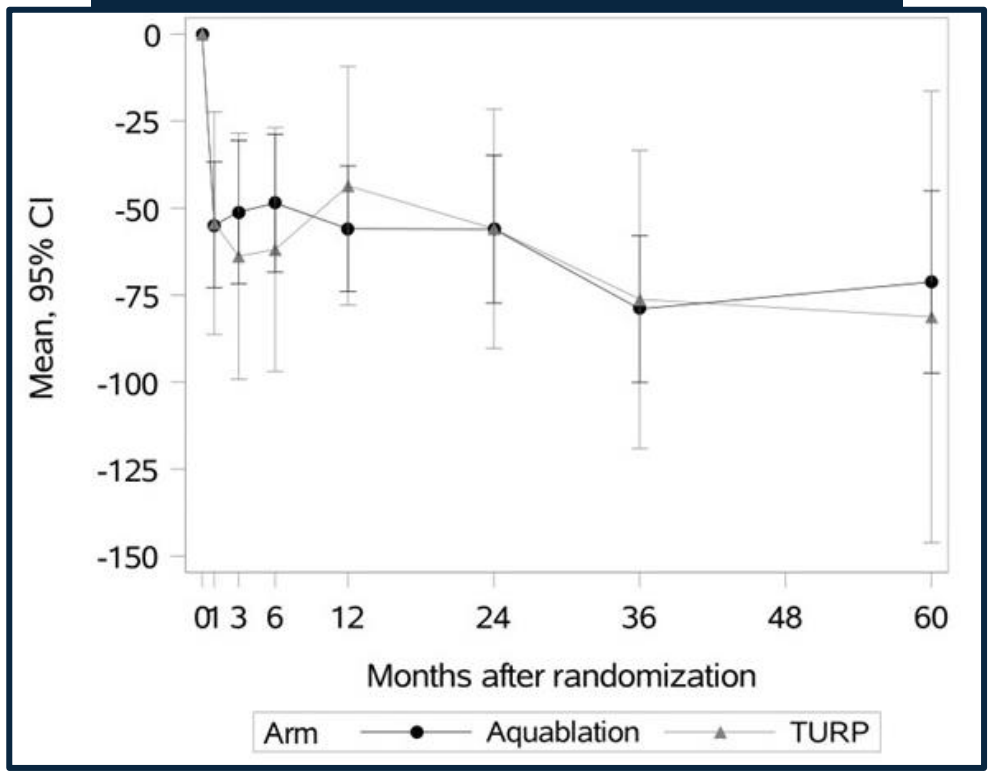


Results: Q_{max} and PVR

CHANGES IN Q_{max} OVER 5 YEARS



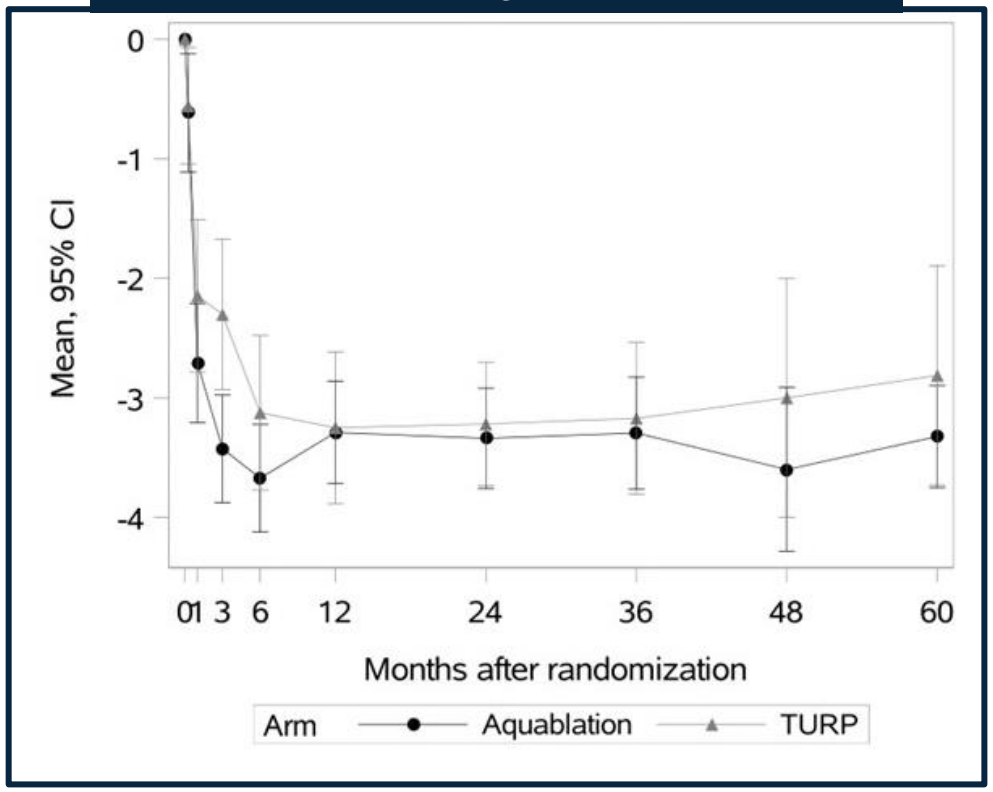
CHANGES IN PVR OVER 5 YEARS



- No statistically significant difference, $p>0.05$

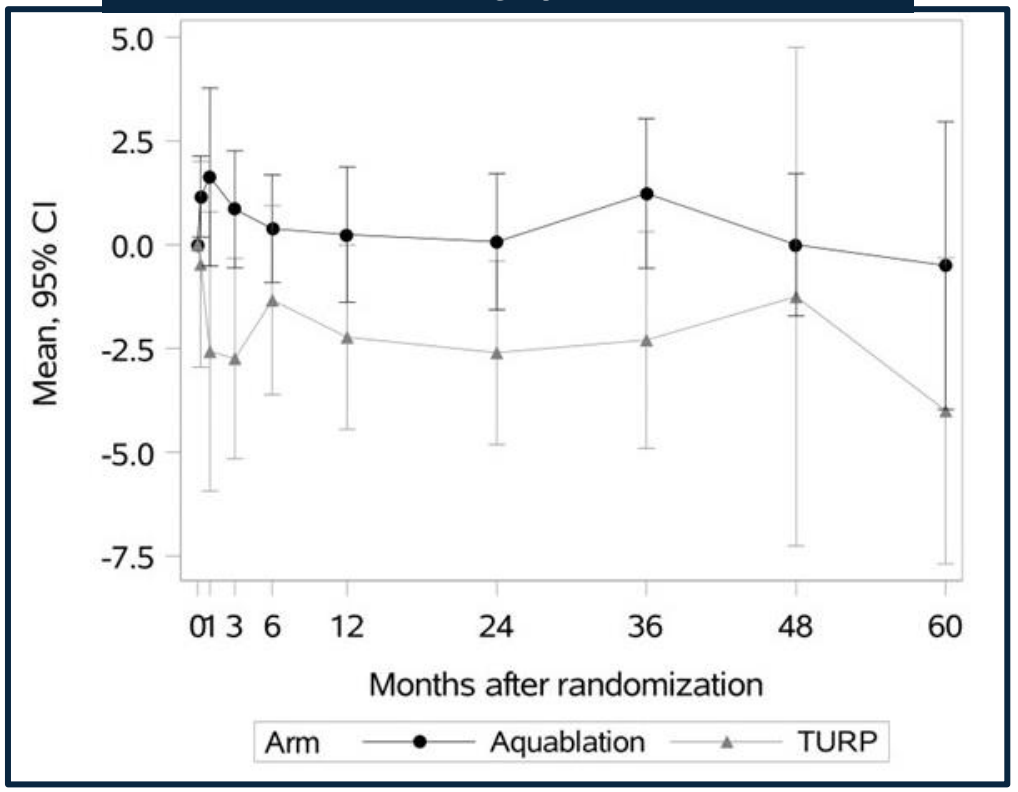
Results: IPSS-QoL and MSHQ-EjD

CHANGES IN IPSS-QOL OVER 5 YEARS



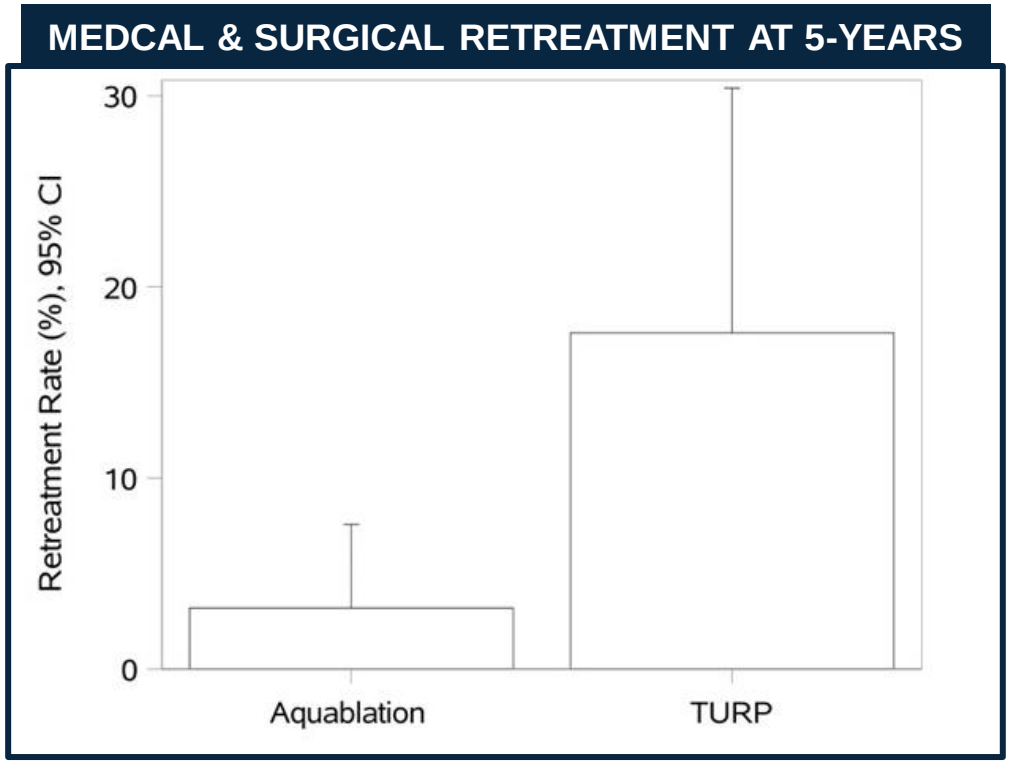
- No statistically significant difference, $p>0.05$

CHANGES IN MSHQ-EjD OVER 5 YEARS



- Across 5-years: 0.6 (Aquablation) vs -2.1 (TURP), $p=.0.01$

Results: Retreatment Rate



- Risk difference= -14.4%; 95% CI [-2.29, -30.4], *p*=0.015

Results: 6-Month Complications

	Aquablation n = 62	**TURP** n = 34	**Risk Difference** (95% CO)	**P-value**
CD1P events and CD2 or higher events	**21.0%**	44.1%	-23.1% [-29.9,-15.5]	0.018

- Significantly lower risk of CD1P and CD2 or higher events with Aquablation
- Among recorded complications:
  - Ejaculatory dysfunction: -21.0% risk difference in the Aquablation arm (95% CI: -32.5 to-10.7%)
  - Erectile dysfunction: 0 events
  - Bleeding rates: No significant difference

Discussion

FIRST TARGETED STUDY FOR PROSTATES 50-80 mL DEMONSTRATES SUPERIORITY OF AQUABLATION OVER TURP:

In men with prostate size 50-80 mL, Aquablation:

- Boasts durable and better functional outcomes compared to TURP (IPSS & MSHQ-EjD)
- Preserves ejaculatory function, unlike TURP
- Yields lower overall risk of complications

Discussion

STUDY MERITS

- International and multicentric data
- Study design (RCT)
- Large sample size to detect superiority in efficacy
- Long-term outcomes

LIMITATIONS

- Blinding up to three years
- Follow up at years 4 and 5 related to COVID-19

Conclusions

- Aquablation has better long-term efficacy and safety outcomes than TURP for the management of LUTS due to BPH in men with prostates 50-80 mL
- Our study further supports adoption of Aquablation over TURP for a subset of men having 50-80 mL prostates and interested in preserving ejaculatory function

AUA 2023

CHICAGO ★ APR 28-MAY 1

Aquablation for Benign Prostatic Hyperplasia in Large Prostates (80-150mL): FINAL 5-Year Results

Dr. Naeem Bhojani

on behalf of the WATER II Investigators

Introduction & Objective

FINAL 5-YEAR DATA FROM THE WATER II CLINICAL TRIAL:

Aquablation therapy in large prostates (80-150mL) for lower urinary tract symptoms due to BPH

Methods: Study Design

OBJECTIVE	• Prospective, multi-center, international trial • 101 men with moderate-to severe BPH symptoms and prostates 80–150mL
PRIMARY SAFETY ENDPOINT	• Occurrence or persistence CD Grade 1, Grade 2 or higher at 3 months • Measured against an objective performance criteria (OPC) with 80% power
PRIMARY EFFICACY ENDPOINT	• Reduction in IPSS score at 3 months • Measured against an objective performance criteria (OPC) with 99% power

Baseline Demographics

	AQUABLATION (N=101)	
BASELINE DEMOGRAPHICS	MEAN	SD
Age, years	67.5	6.6
Prostate volume, mL	107.4	22.1
Middle Lobe, %	83.2	-
IPSS, points	23.2	6.3
Qmax, mL/sec	8.7	3.4
PVR, mL	131	125
MSHQ-EjD, range 0-15	8.1	3.9
IIEF-5 (SHIM), range 0-25	15.1	7.4

	AQUABLATION (N=101)	
MEDICATION USAGE	N	%
Anticoagulant	4	4.0%
Antiplatelet (NSAID)	21	20.8%
Aspirin (≤100 mg)	18	17.8%
Any of the Above	**43**	**42.6%**
Alpha Blocker	41	40.6%
5-ARI	4	4.0%
Alpha Blocker/5-ARI	29	28.7%
Any of the Above	**74**	**73.3%**

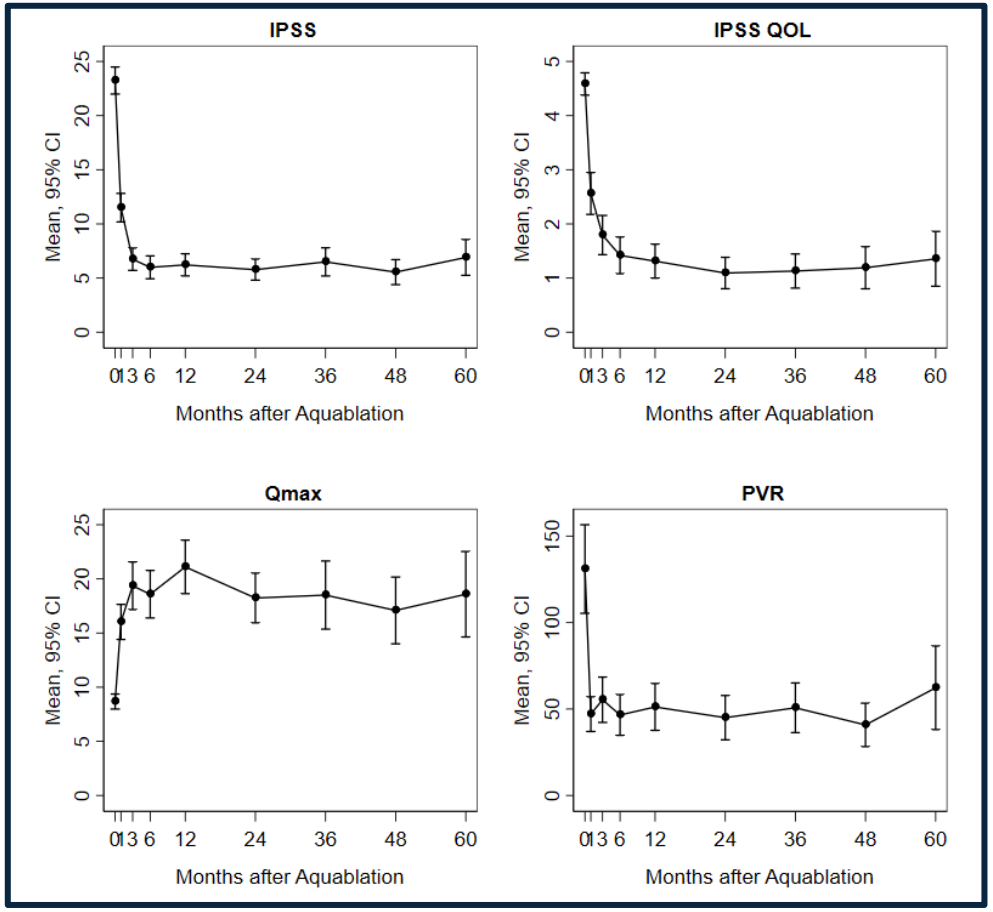
Procedure & Safety Data

OPERATIVE DATA	
Mean volume, mL	107 (20)
TRUS insertion to final catheter, min	55 (19)
Mean resection time, min	8 (3)

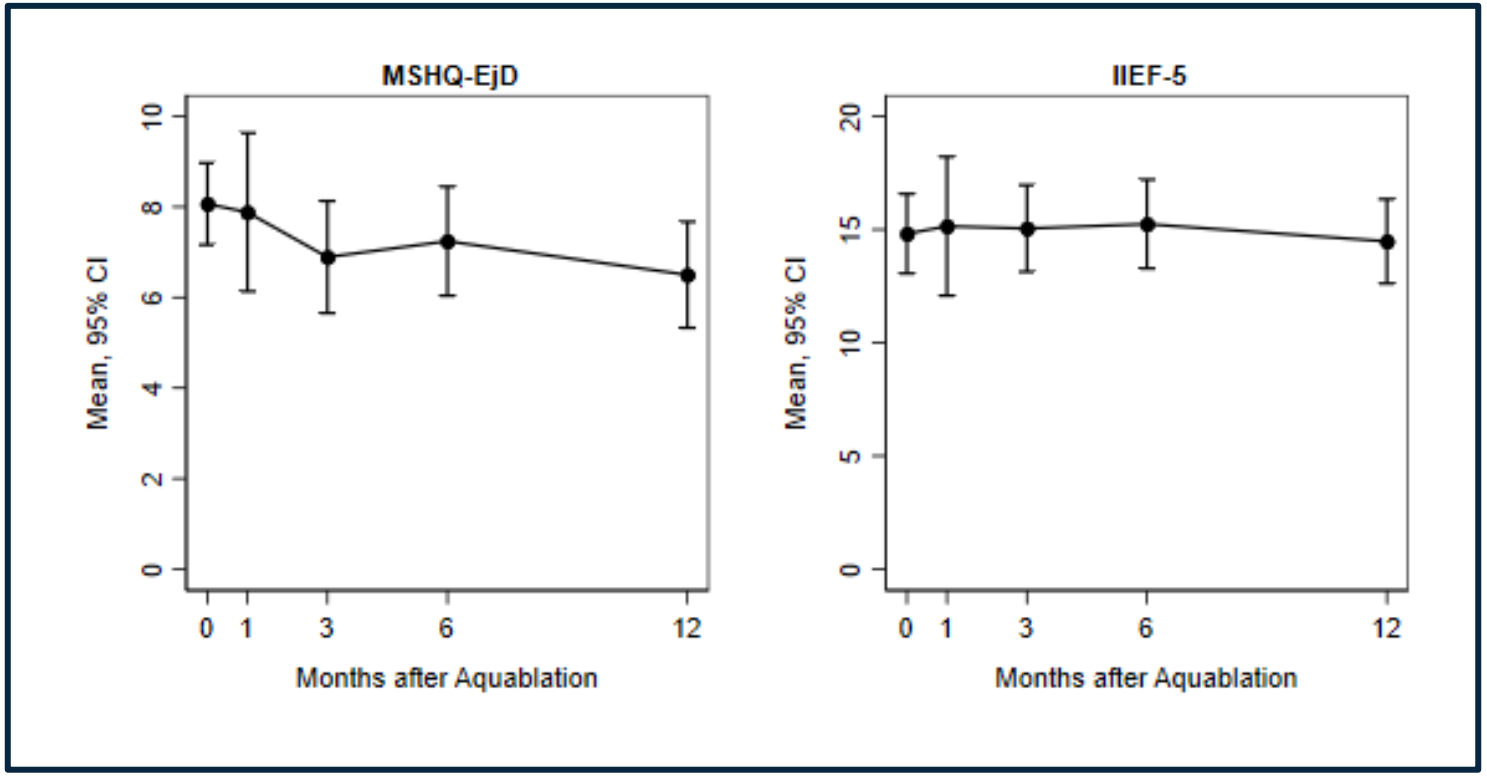
IRREVERSIBLE COMPLICATIONS	
Stress Incontinence (pad-use)	0%
Urge Incontinence (pad-use, non-trans)	2%
Erectile Dysfunction	0%
Ejaculatory Dysfunction	15%

5-Year Efficacy Results

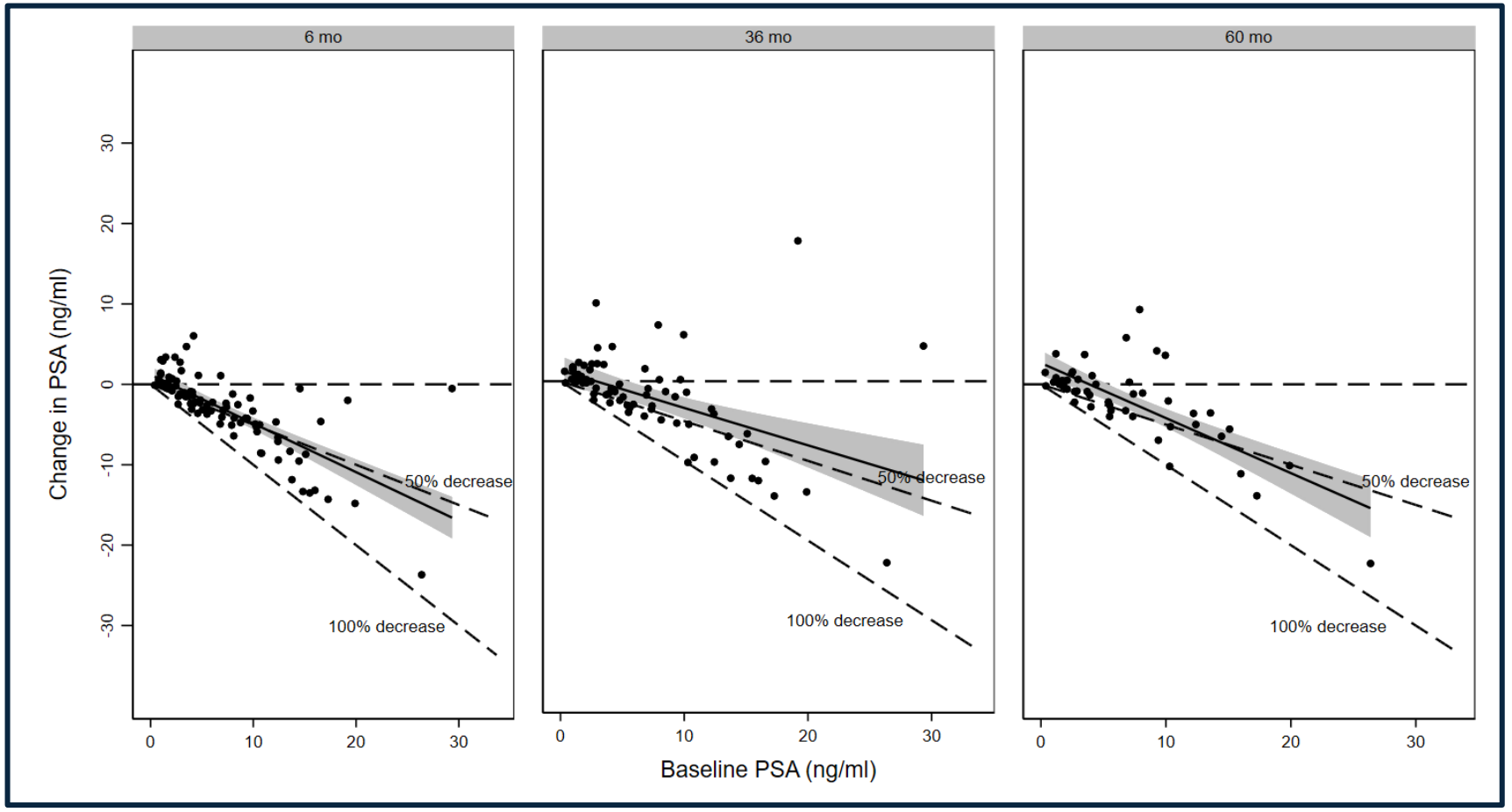
AQUABLATION 5Y Cohort	
IPSS improvement	15.9, p < 0.0001
IPSS baseline (SD)	22.6 (6.4)
IPSS at 60-months (SD)	6.8 (4.6)
Qmax improvement	9.2, p < 0.0001
Qmax baseline, mL/sec (SD)	8.6 (3.4)
Qmax 60-mo, mL/sec (SD)	17.1 (9.8)



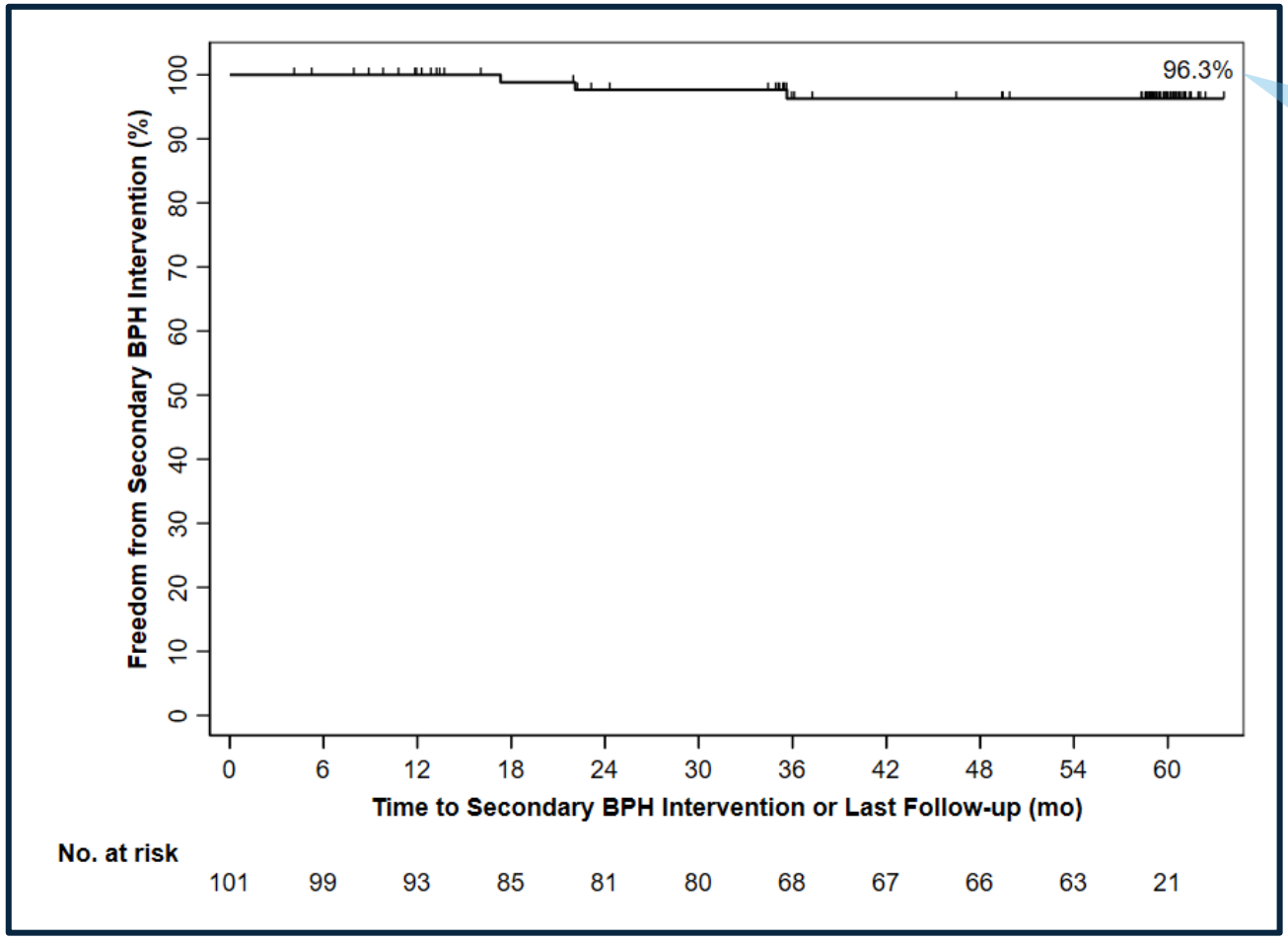
Sexual Function



PSA


6 mo
36 mo
60 mo
Change in PSA (ng/ml)
30
20
10
0
-10
-20
-30
50% decrease
100% decrease
0
10
20
30
Baseline PSA (ng/ml)

Freedom from Secondary BPH Intervention



96.3%

of patients avoided a secondary intervention due to recurrent symptoms

Conclusions

- 2nd prospective, FDA study confirming Aquablation 5-year outcomes
- Efficacy summary:
  - IPSS, QoL, Qmax, and PVR demonstrated immediate and sustained large improvements
  - 96.3% of patients avoided a secondary intervention due to recurrent symptoms
- At 5-years of prospective follow-up, the Aquablation procedure was shown to be safe, effective, and durable in men with large prostates (80-150mL)

Collaborators

AUTHOR	AFFILIATION
Naeem Bhojani	University of Montréal Hospital Center, Université de Montréal, Montréal, Québec, CAN
Mihir Desai	University of Southern California, Institute of Urology, Los Angeles, CA, US
Mo Bidair	San Diego Clinical Trials, San Diego, CA, US
Kevin C. Zorn	University of Montréal Hospital Center, Université de Montréal, Montréal, Québec, CAN
Eugene Kramolowsky	Virginia Urology, Richmond, VA, US
Leo Doumanian	University of Southern California, Institute of Urology, Los Angeles, CA, US
Dean Elterman	University of Toronto - University Health Network, Toronto, CAN
Ronald P. Kaufman, Jr.	Albany Medical College, Albany, NY, US
James Lingeman	Indiana University Health Physicians, Indianapolis, IN, US
Gregg Eure	Urology of Virginia, Virginia Beach, VA, US
Gopal Badlani	Wake Forest School of Medicine, Winston-Salem, NC, US
Mark Plante	University of Vermont Medical Center, Burlington, VT, US
Edward Uchio	VA Long Beach Healthcare System, Long Beach, CA, US
Greg Gin	VA Long Beach Healthcare System, Long Beach, CA, US
Larry Goldenberg	University of British Columbia, Vancouver, CAN
Ryan Paterson	University of British Columbia, Vancouver, CAN
Alan So	University of British Columbia, Vancouver, CAN
Mitch Humphreys	Mayo Clinic Arizona, Scottsdale, AZ, US
Steven Kaplan	Icahn School of Medicine at Mount Sinai, New York, NY, US
Jay Motola	Icahn School of Medicine at Mount Sinai, New York, NY, US
Claus Roehrborn	UT Southwestern Medical Center, Department of Urology, UT Southwestern, Dallas, TX, US

5-year WATER II outcomes for large prostates (80-150mL)

- **Background**
- Prospective, multi-center, international trial
- 101 men with moderate-to severe BPH symptoms and prostates 80–150mL

- **Outcomes**
- IPSS, QoL, Qmax, and PVR demonstrated immediate and sustained large improvements
- **96.3%** of patients avoided a secondary intervention due to recurrent symptoms
- At 5-years of prospective follow-up, the Aquablation procedure was shown to be **safe, effective, and durable in men with large prostates (80-150mL)**

AUA 2023

CHICAGO ★ APR 28-MAY 1

Aquablation Postoperative Bleeding Risk Reduction

Dr. Dean Elterman

University Health Network, University of Toronto, Toronto, CANADA

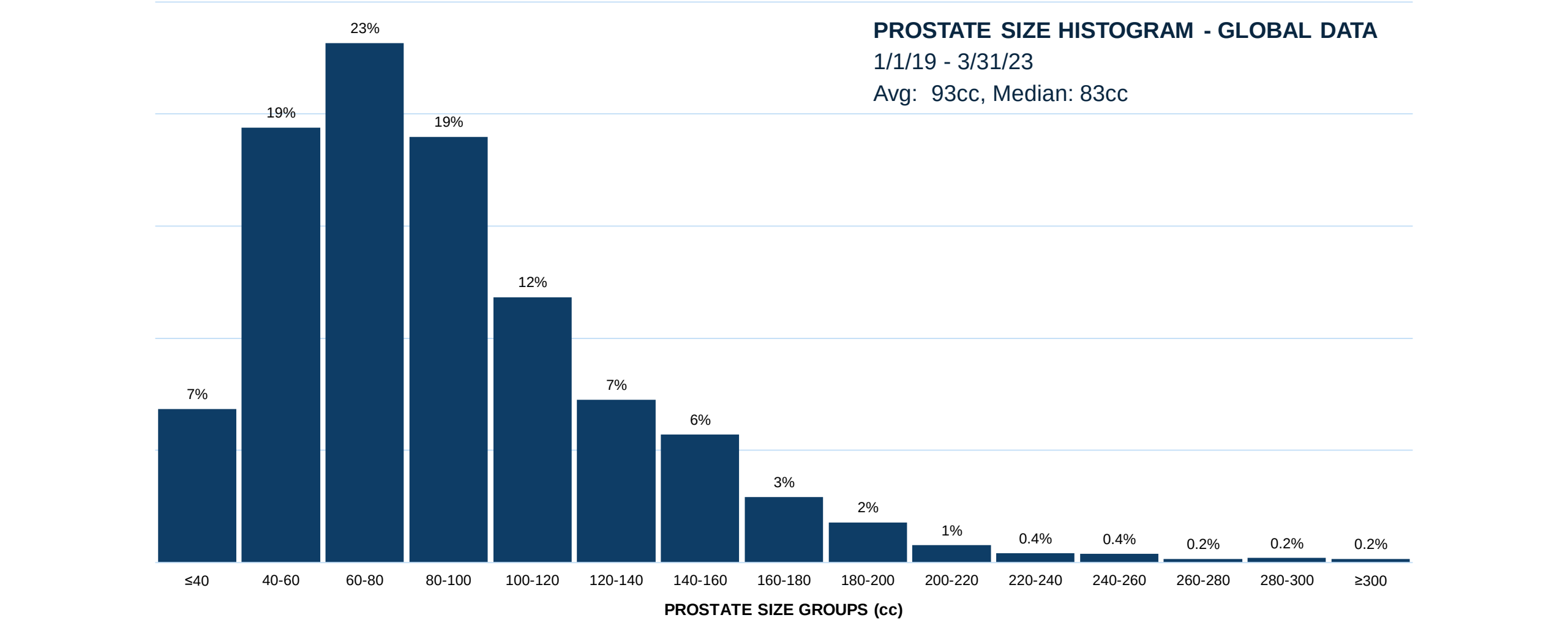
Introduction & Objective

CONTEMPORARY HEMOSTASIS PROTOCOL RESULTS

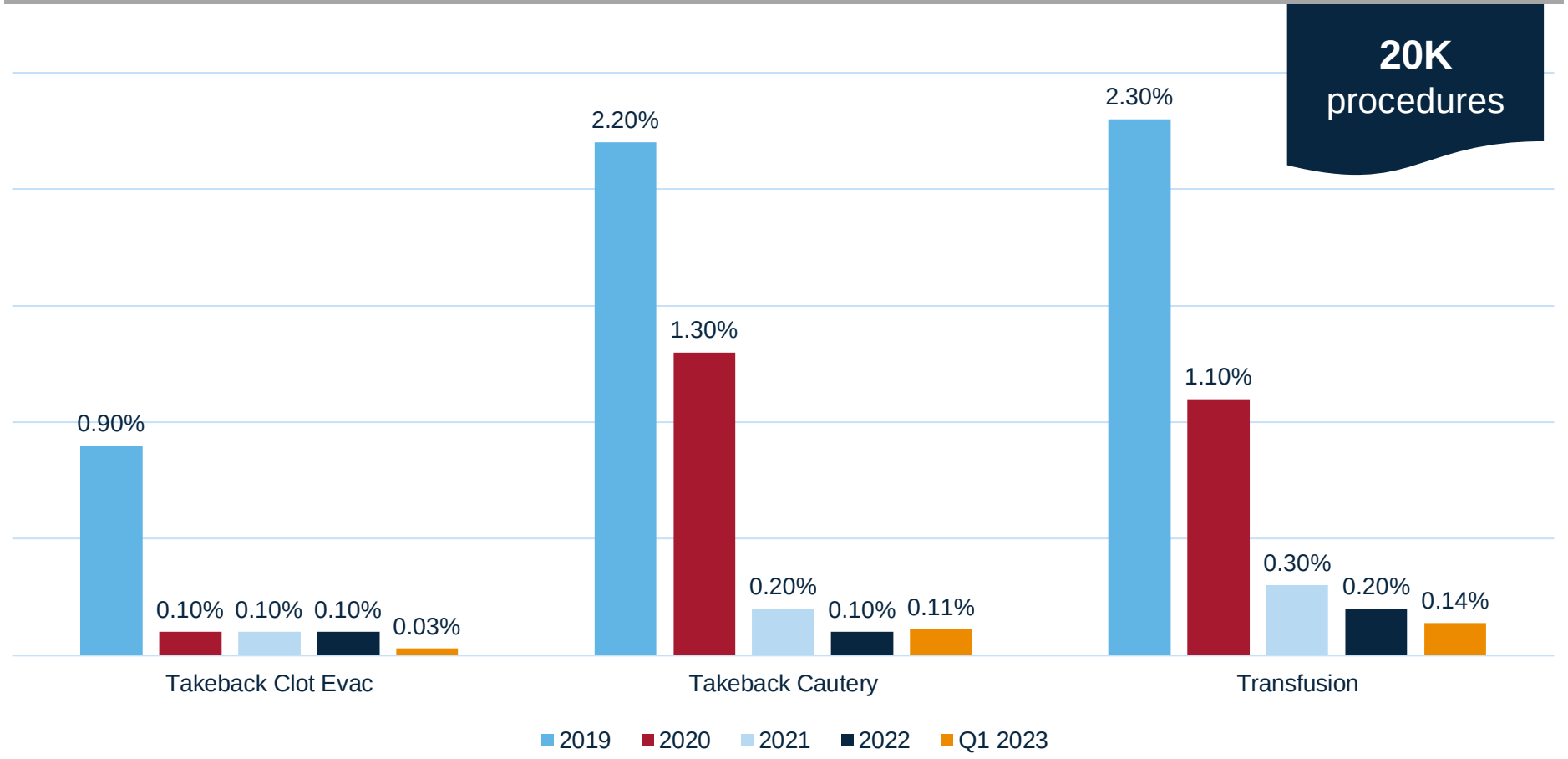
- Aquablation was originally studied in two FDA clinical trials from 2015-2017 (WATER in prostates ≤ 80mL, WATER II in prostates ≥ 80mL)
- Aquablation was granted approval by FDA in December of 2017
- Since approval, commercial users have adopted a refined focal cautery approach for hemostasis

Methods: Study Design

OBJECTIVE	• Consecutive, commercial patients undergoing Aquablation from Asia, Europe, and North America • Evaluation period last four years
PRIMARY OUTCOME	• Risk of transfusion • Risk of takeback for fulguration • Risk of takeback for clot evacuation


PROSTATE SIZE HISTOGRAM - GLOBAL DATA
1/1/19 - 3/31/23
Avg: 93cc, Median: 83cc
7%
19%
23%
19%
12%
7%
6%
3%
2%
1%
0.4%
0.4%
0.2%
0.2%
0.2%
≤40
40-60
60-80
80-100
100-120
120-140
140-160
160-180
180-200
200-220
220-240
240-260
260-280
280-300
≥300
PROSTATE SIZE GROUPS (cc)

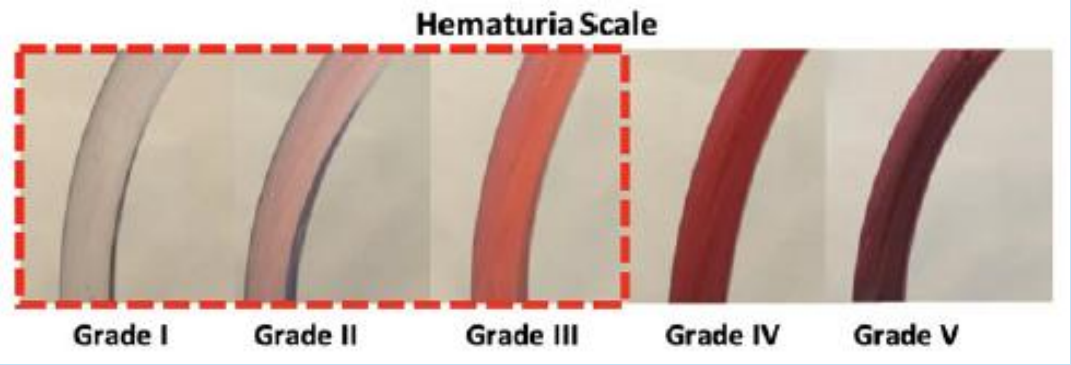
GLOBAL IMPLEMENTATION OF CONTEMPORARY PROTOCOL: JANUARY 2020



Discussion

DAY CASE AQUABLATION

- If the degree of hematuria was not clinically significant (grades I–III) after clamping irrigation at ~4 hours postoperatively, patients were discharged home
- The catheter must be flowing well without clots



Zorn et al. Aquablation Treatment for Benign Prostate Hyperplasia: Current Standardized Procedure. Journal of Endourology. Sep 2022.S-1-S-5.

Conclusions

- Aquablation leverages imaging and robotics to allow treatment of a broad range of prostate sizes
- Early learnings in the development of the procedure led surgeons to realize a standardized hemostasis technique was necessary
- Following the adoption of the standardized protocol, the bleeding risk has been reduced 10-fold, allowing some surgeons the option of day-case Aquablation
- Stabilized bleeding risk has allowed for day case Aquablation