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BPH Treatment Device Safety in the FDA's MAUDE Database Using Total Procedural Context: PUL Exhibits the Lowest Complication Rates, WVTT Intermediate, and AQB the Highest

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Abstract:

Introduction: Medical Device Reports (MDRs) for Benign Prostatic Hyperplasia (BPH) treatment devices in the Federal Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database were evaluated for safety and patient experience outcomes in the context of the total number of procedures performed.

Materials and Methods: MAUDE was searched using the terms "UroLift," "Rezum," and "Aquabeam" for entries between January 1, 2019, and December 31, 2022. An independent physician arbitrator adjudicated relevant entries and assigned severity scores using the Gupta and Clavien-Dindo (CD) scales. An independent market model using Medicare data and Current Procedural Terminology (CPT) codes yielded estimates of the total number of Prostatic Urethral Lift (PUL), Water Vapor Thermal Therapy (WVTT), and Aquablation (AQB) procedures performed in the US in 2019, 2020, 2021, and 2022.

Results: PUL was the most frequently performed procedure in all years analyzed. In the first year (2019), 15% of AQB patients experienced a serious post-operative event. The rate of serious events for PUL (2 per 10,000) was significantly lower than AQB (4 per 1,000, p <0.0001) or WVTT (1 per 1,000, p < 0.0001) in 2022. Between 2019 and 2022, the rate of mild to moderate events (CD 1-2) was lowest for PUL (2019: 2.0 per 10,000; 2022: 1.7 per 10,000) compared to WVTT (2019: 5 per 1,000; 2022: 4 per 1,000) and AQB (2019: 5 per 100; 2022: 3 per 1,000).

Discussion: MAUDE surveillance shows that PUL has the lowest complication rate, WVTT is intermediate, and AQB has the highest, even after procedural refinements. These findings emphasize the need for volume-adjusted, real-world data to complement clinical trials in assessing BPH device safety.

Conclusion: The yearly rates of mild, moderate, and severe events recorded during this period are significantly higher for AQB than the minimally invasive surgical therapies analyzed. PUL has the lowest complication rates in the MAUDE database.

Keywords: MAUDE, Prostatic urethral lift, UroLift System, Rezum, Aquablation, Medical device reports, Benign prostatic hyperplasia.

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1. INTRODUCTION

Benign Prostatic Hyperplasia (BPH) is a progressive disease associated with Lower Urinary Tract Symptoms (LUTS) affecting more than half of men over age 50 in the United States (US) [1]. Minimally Invasive Surgical Therapies (MISTs) can offer lasting relief from LUTS with an improved patient experience, treatment in an out-patient setting, minimal or no post-procedure catheterization, and improved early recovery compared to more invasive therapies such as Transurethral Resection of the Prostate (TURP) [2]. While these therapies have been shown to be safe and effective in clinical trials, their real-world safety profiles continue to benefit from ongoing surveillance.

The Manufacturer and User Facility Device Experience (MAUDE) database is a publicly accessible, prospective registry of Medical Device Reports (MDRs) submitted to the US Food and Drug Administration (FDA) by mandatory reporters, such as manufacturers, importers, and device user facilities, and voluntary reporters, including healthcare professionals, patients, and consumers [3]. These reports are designed to capture events in which a device may have caused or contributed to a serious injury or death, or in which a device malfunction would likely cause harm if it were to occur [4]. The MDRs contained in MAUDE, although limited and not formally adjudicated [5], constitute a valuable source of patient experience and safety data on the real-world performance of BPH MISTs outside of controlled trial settings. In the context of procedural safety analysis, MAUDE is especially valuable in the early identification of Adverse Event (AE) trends associated with specific devices that may not have emerged in pre-market trials [6]. MAUDE is limited by its failure to capture denominator data, which precludes estimation of event incidence rates because the reports are not normalized to the "at-risk" population. While previous analyses of BPH treatment devices have used MAUDE to examine safety and patient experience patterns [7-9], these analyses failed to incorporate data on the full procedural context to assess the national incidence of MDRs. This study aimed to characterize adverse event reporting for BPH devices of interest through formal adjudication, while also estimating procedural denominators using sales and administrative claims data, thereby situating the MDRs of interest within the broader context of real-world clinical practice. This approach enabled a pragmatic assessment of risk by enhancing the interpretability of MAUDE-reported events relative to the total procedural context.

2. MATERIALS AND METHODS

2.1. BPH Procedures

In this study, we analyze the results of the three most recent BPH procedures adopted in the US. Two minimally invasive procedures, the Prostatic Urethral Lift (PUL) using the UroLift System and Water Vapor Thermal Therapy (WVTT) using Rezum, were analyzed, as was a surgical procedure, Aquablation (AQB - robot-assisted waterjet ablation of prostatic tissue) with the Aquabeam Robotic System. Because the MDR system is focused on devices, rather than procedures, all searches require the trade names of devices: UroLift System, Rezum, and Aquabeam, respectively. Analysis of more generic procedures, such as Transurethral Resection of the Prostate (TURP), is not feasible because there is no specific device on which to file a report.

2.2. Market Model

An independent market model using Current Procedural Terminology (CPT) codes and Medicare claims data was used to estimate the total number of PUL, WVTT, and AQB procedures performed in the US in 2019, 2020, 2021, and 2022. Known procedure totals were used when available; PUL totals for 2019-2022 are actual procedures drawn from manufacturer-provided sales data; similarly, AQB totals for 2020-2022 are actual procedural totals provided in Procept analyst and securities reports; for AQB 2019 procedures and WVTT procedures for 2019 through 2022, a random sample of U.S. Medicare and commercial claims provided by Symphony Health served to estimate the proportion of procedures performed, and the rate was then scaled based on the estimates of total BPH patients who underwent procedures in 2019. Known PUL and AQB procedure totals validate the market model's estimates, as do consistent outcomes from independent studies.

2.3. MAUDE Database Search and Analyses

A search of the MAUDE database was conducted using device terms "UroLift," "Rezum," and "Aquabeam" between January 1, 2019 and December 31, 2022. An independent physician adjudicator reviewed entries and assigned timing (intra-operative or post-operative) and event severity, excluding duplicate and irrelevant (*i.e.*, incorrect device) MDR entries; 208 PUL, 414 WVTT, and 423 AQB entries were included in the analysis. The MAUDE-specific Gupta scale (Table **1a**) for device malfunctions was used for intra-operative events; post-operative events were classified according to the Clavien-Dindo (CD) scale post-operative events were classified using the Clavien-Dindo (CD) scale, which grades complications based on the level of intervention required, from minimal (Grade 1) to those requiring invasive procedures or surgery (Grade 3+) (Table **1b**). An assessment of event relatedness to the medical device (*i.e.*, definitely, possible, unlikely, and not related) was also performed. Finally, the MDR narratives were reviewed for completeness, defined as the ability to determine whether the patient received treatment for the reported event from the information provided in the event narrative. Using the number of MDRs as the numerator and the total procedures performed as the denominator, rates of total MDR submission, rates of intraoperative and post-operative events, and rates of classified MDRs were calculated for the years 2019 through 2022.

Table 1a. Gupta intraoperative complication scale.

Level 1	Mild	No harm to the patient No significant deviation from the planned procedure
Level 2	Moderate	Harm to the patient requiring minor intervention Deviation from the planned procedure without a change in surgical outcome
Level 3	Severe	Harm to the patient requiring major intervention Significant intra-operative deviation from the planned procedure requiring aggressive intervention
Level 4	Life-threatening/death	Life-threatening event or death during procedure

Table 1b. Clavien-dindo scale of postoperative events.

Grade 1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Acceptable therapeutic regimens include drugs (anti-emetics, antipyretics, analgesics, diuretics, and electrolytes), physiotherapy, and other therapies. This grade also includes wound infections, opened at the bedside.
Grade 2	Requiring pharmacological treatment with drugs other than those allowed for grade 1 complications. Blood transfusions, antibiotics, and total parenteral nutrition are also included.
Grade 3	Requiring surgical, endoscopic, or radiological intervention.
3a	Intervention under regional/local anesthesia
3b	Intervention under general anesthesia
Grade 4	Life-threatening complication, requiring intensive care/intensive care unit management
4a	Single-organ dysfunction
4b	Multi-organ dysfunction
Grade 5	Patient demise

2.4. Statistical Methods

Results from the estimated 342,366 combined procedures performed from 2019 through 2022 included a total of 1,045 MDR submissions utilized for this analysis. The total number of MDR submissions and submission rates were provided by treatment and year. Rates of MDR submission were reported in conjunction with the accompanying Odds Ratios (OR) and tests of significance (where appropriate). All odds ratios were obtained *via* logistic regression. All statements of significance are based on the industry standard 5% level of significance ($\alpha = 0.05$). No adjustments for multiple comparisons have been made; All analyses were conducted using Statistical Analysis System (SAS) version 9.4.

3. RESULTS

3.1. Market Model

PUL was the most frequently performed procedure in all years analyzed (2019: 66,662; 2020: 63,532; 2021: 74,48; 2022: 65,777); the number of WVTT cases were similar between 2019 and 2022 (2019: 13,540 2020: 14,140; 2021 16,027; 2022: 15,525) while AQB had the greatest increase in the number of procedures over the study period (2019: 291; 2020: 681; 2021: 3,311 2022: 8,400) (Table **2**) [10]. A comparative analysis of published utilization studies validates the procedural proportions put forth by the market model, with TURP accounting for approximately 60% of BPH procedures of interest in 2019, consistent with Definitive Healthcare (DH) data, TriNetX, and National Surgical Quality Improvement Program (NSQIP) analyses [11-13]. Similarly, PUL accounted for 33% of procedures analyzed in 2019 (DH 31%, TriNetX 27%), 35% in 2020 (DH 34%), 37% in 2021, and 34% in 2022. Of the procedures of interest from 2019 to 2022, WVTT accounted for 6.7%, 7.7%, 8.0%, and 8.0%, and AQB accounted for 0.1%, 0.4%, 1.7%, and 4.3%.

3.2. MAUDE MDR Outcomes

Although total MDRs submitted increased for all devices between 2019 and 2022 (PUL: 44, 57, 30% increase; WVTT: 105, 142, 30% increase; AQB: 70, 169, 120% increase), the submission rate per 100 procedures was stable for PUL (2019: 7 per 10,000; 2022: 9 per 10,000) and WVTT (2019: 8 per 1,000, 2022: 1 per 100), and decreased for AQB (2019: 20 per 100; 2022: 2 per 100); MDR submission per 100 procedures was higher for AQB than the other technologies in all years studied, while the rate for PUL was consistently the lowest (Table **2**). Between 2019 and 2022, intraoperative events accounted for a higher percentage of MDRs across all devices.

3.3. Intraoperative MDR Severity and Rates

The majority of intra-operative events were mild to moderate across all technologies studied. In 2022, the rate of mild to moderate intraoperative events was lowest for PUL (2 per 10,000) compared with WVTT (4 per 1,000; OR: 7.287, p-value: < 0.0001) and AQB (3 per 1,000; OR: 19.886, p-value: < 0.0001), consistent with previous years. There were no severe or life-threatening intraoperative events for PUL or WVTT in 2019, 2020, or 2022; in 2021, there was one Gupta grade 3 event for PUL (a hematoma treated with arterial repair and transfusion) and WVTT (a mucosal bleed treated with TURP). Severe-to-life-threatening intraoperative event rates for AQB were highest at 7 per 1,000 in both 2019 and 2022 (Table **3**). The thirteen Gupta grade 3-4 intraoperative events for AQB were bladder perforations (n = 7), rectal perforation (n = 1), prostate capsule perforation (n = 1), bladder neck hemorrhage with hypotension necessitating transfusion (n

= 1), pulmonary embolism (n = 1), myocardial infarction (n = 1), and scope breakage (n = 1).

3.4. Post-operative MDR Severity and Rates

15% of AQB patients experienced a serious post-operative event (CD3+) in 2019; in 2022, AQB's rate of serious events (4 per 1,000) remained elevated compared to other treatments (PUL, 2 per 10,000, OR: 20.300, *p*-value: < 0.0001; WVTT, 1 per 1,000, OR: 2.872, *p*-value: < 0.001); the rate of serious events for PUL was an order of magnitude lower than WVTT or AQB in 2022. The rate of mild to moderate post-operative events (CD 1-2) for PUL was also lowest by an order of magnitude (2019: 2.0 per 10,000; 2022: 1.7 per 10,000) compared to WVTT (2019: 4.5 per 1,000; 2022: 3.7 per 1,000) and AQB (2019: 4.5 per 100; 2022: 3.7 per 1,000) (Table 3).

Table 2. MDR and procedural totals, bph treatment devices.

-	PUL	WVTT	AQB
2019 *Total Procedures* *Total MDRs (Rate per 100)*	66,662 **44 (0.07)**	13,540 **105 (0.8)**	291 **70 (20)**
Therapy *vs.* PUL, Total MDR OR ***p*-value**	-	11.83 < 0.0001	40.53 <0.0001
2020 *Total Procedures* *Total MDRs (Rate per 100)*	63,532 **61 (0.1)**	14,140 **80 (0.6)**	681 **85 (10)**
Therapy *vs.* PUL, Total MDR OR ***p*-value**	-	5.92 < 0.0001	148.40 <0.0001
2021 *Total Procedures* *Total MDRs (Rate per 100)*	74,480 **46 (0.06)**	16,027 **87 (0.5)**	3,311 **99 (3)**
Therapy *vs.* PUL, Total MDR OR ***p*-value**	-	8.83 < 0.0001	49.88 <0.0001
2022 *Total Procedures* *Total MDRs (Rate per 100)*	65,777 **57 (0.09)**	15,525 **142 (1)**	8,400 **169 (2)**
Therapy *vs.* PUL, Total MDR OR ***p*-value**	-	10.64 < 0.0001	23.67 <0.0001

Table 3. MDR severity rates.

-	PUL				WVTT				AQB			
	Intra-operative		Post-operative		Intra-operative		Post-operative		Intra-operative		Post-operative	
	Gupta 1-2	Gupta 3-4	CD 1-2	CD 3+	Gupta 1-2	Gupta 3-4	CD 1-2	CD 3+	Gupta 1-2	Gupta 3-4	CD 1-2	CD 3+
2019 *Total MDRs* *Rate per 100* *OR*, p-value*	5 <0.01 -	0 0.00 -	13 0.02 -	26 0.04 -	33 0.2 33, <0.001	0 0.00 NA	61 0.5 23, <0.001	9 0.07 1.71, 0.17	12 4 520, <0.001	2 0.7 NA	13 5 240 <0.001	43 15 440, <0.001
2020	31 0.05 -	0 0.00 -	5 <0.01 -	24 0.04 -	29 0.2 4.1, <0.001	0 0.00 NA	33 0.2 30., <0.001	17 0.1 3.2, <0.001	27 4 82, <0.001	3 0.4 NA	16 2 31 <0.001	39 6 160, <0.001
2021	14 0.02 -	1 <0.01 -	14 0.02 -	17 0.02 -	39 0.2 13, <0.001	1 <0.01 4.6, 0.28	35 0.2 12, <0.001	12 0.08 3.3, <0.01	62 2 100, <0.001	2 0.06 45, <0.01	11 0.3 18, <0.001	24 0.7 32, <0.001
2022	34 0.05 -	0 0.00 -	11 0.02 -	12 0.02 -	60 0.4 7.3, <0.001	0 0.00 NA	57 0.4 22, <0.001	20 0.1 7.1, <0.001	89 1 20., <0.001	6 0.07 NA	28 0.3 20., <0.001	31 0.4 20., <0.001

Note: *Therapy *vs.* PUL Odds Ratio.

3.5. Post-operative Categorized MDRs in MAUDE

All MDRs were adjudicated for relatedness and completeness, with most deemed related to the device or procedure and with complete narratives. Mild to moderate post-operative MDRs were related and complete for 65% of PUL, 54% of WVTT, and 95% of AQB entries. Severe and life-threatening MDRs were related and complete for 53% of PUL, 78% of WVTT, and 94% of AQB entries (Table 4). Common mild to moderate MDRs (CD grade 1-2) were further classified (cMDRs) as follows: irritative symptoms including dysuria and incontinence, hematuria, infection, hematoma, clot retention, transfusion, and bladder perforation (Table 4). The most common CD 1-2 cMDRs for each technology were as follows: PUL (infection, transfusion, hematoma/hematuria), WVTT (irritative symptoms, hematuria, clot evacuation), AQB (transfusion, clot evacuation, bladder perforation) (Table 4). The most common serious MDRs (CD grade 3+) for each treatment device were as follows: PUL (transfusion, hematoma, clot evacuation); WVTT (infection, irritative symptoms, hematuria/clot evacuation); and AQB (clot evacuation, transfusion, death). The overall rate of serious cMDR transfusions was an order of magnitude higher for AQB (2 per 1,000) than for PUL (6 per 100,000, OR: 39.89, *p*-value: 0.0287) or WVTT (2 per 100,000, OR: 131.04, *p*-value: 0.0027). The rate of serious or life-threatening infection was similarly an order of magnitude higher for WVTT (2 per 10,000) than for PUL (2 per 100,000, OR: 12.79, *p*-value: <0.0001) or AQB (0 cases out of 12,683 procedures). PUL's rate of CD3+ hematomas (5 per 100,000) was low and similar to WVTT (3 per 100,000; OR: 1.31; *p*-value: 0.7209). Of the mortality events for PUL and WVTT, none was determined to be related to the device with a complete narrative; for AQB, 9 out of 11 reported deaths (rate: 7 per 10,000) were related and complete (Table 4).

Table 4. Post-operative total and categorized MDRs of select BPH treatments in the MAUDE database.

-	PUL				WVTT				AQB			
	2019	2020	2021	2022	2019	2020	2021	2022	2019	2020	2021	2022
CD 1-2												
Irritative symptoms *MDR, cMDR MDR Rate, cMDR Rate*	0, 0	0, 0	0, 0	1, 0 <0.01, <0.01	12, 19, 0.1, 0.09	3, 1 0.02, <0.01	5, 1 0.03, <0.01	14, 5 0.09, 0.03	0, 0	0, 0	0, 0	0, 0
Hematuria	3, 1 <0.01, <0.01	0, 0	4, 3 <0.01, <0.01	1, 1 <0.01, <0.01	9, 3 0.07, 0.02	1, 1 <0.01, <0.01	0, 0	4, 3 0.03, 0.02	0, 0	0, 0	1, 0 0.3, 0	1, 0 0.01, 0
Hematoma	0, 0	1, 1 <0.01, <0.01	1, 1 0.01, 0.01	4, 3 <0.01, <0.01	0, 0	0, 0	0, 0	0, 0	0, 0	0, 0	0, 0	0, 0
Infection	3, 2 <0.01, <0.01	1, 1 <0.01, <0.01	7, 1 <0.01, <0.01	4, 4 <0.01, <0.01	5, 0 0.04, 0	3, 0 0.02, 0	5, 0 0.03, 0	7, 0 0.05, 0	0, 0	0, 0	0, 0	0, 0
Clot evacuation	2, 1 <0.01, <0.01	0, 0	1, 1 <0.01, <0.01	1, 0 <0.01, 0	0, 0	1, 1 <0.01, <0.01	0, 0	1, 1 <0.01, <0.01	1, 1 0.3, 0.3	1, 1 0.1, 0.1	0, 0	3, 3 0.04, 0.04
Transfusion	2, 1 <0.01, <0.01	2, 1 <0.01, <0.01	4, 3 <0.01, <0.01	2, 2 <0.01, <0.01	0, 0	0, 0	0, 0	1, 1 <0.01, <0.01	12, 12 4, 4	10, 10 1, 1	5, 5 0.2, 0.2	11, 11 0.1, 0.1
Bladder perforation	0, 0	0, 0	0, 0	0, 0	0, 0	0, 0	0, 0	0, 0	0, 0	2, 2 0.3, 0.3	0, 0	2, 2 0.02, 0.02
CD 3+												
Irritative symptoms *MDR, cMDR MDR Rate, cMDR Rate*	1, 0 <0.01, 0	1, 0 <0.01, 0	0, 0	0, 0	0, 0	1, 0 <0.01, 0	2, 2 0.01, 0.01	2, 2 0.01, 0.01	0, 0	0, 0	0, 0	0, 0
Hematuria	2, 0 <0.01, 0	1, 0 <0.01, 0	3, 2 <0.01, <0.01	5, 4 <0.01, <0.01	0, 0	0, 0	1, 1 <0.01, <0.01	2, 2 0.01, 0.01	0, 0	2, 2 0.3, 0.3	0, 0	1, 1 0.01, 0.01
Hematoma	9, 6 <0.01, 0.01	1, 0 <0.01, 0	6, 6 <0.01, <0.01	2, 1 <0.01, <0.01	0, 0	0, 0	0, 0	2, 2 0.01, 0.01	0, 0	0, 0	0, 0	0, 0
Infection	7, 2 <0.01, 0.01	7, 3 <0.01, 0.01	1, 0 <0.01, 0	0, 0	1, 0 <0.01, 0	4, 2 0.03, 0.01	6, 6 0.04, 0.04	4, 2 0.03, 0.01	0, 0	0, 0	0, 0	0, 0
Clot evacuation	2, 2 <0.01, <0.01	7, 3 <0.01, 0.01	3, 3 <0.01, <0.01	1, 1 <0.01, <0.01	1, 1 <0.01, <0.01	0, 0	0, 0	2, 2 0.01, 0.01	35, 34 12, 12	28, 26 4, 4	12, 12 0.4, 0.4	20, 20 0.2, 0.2

(Table 4) contd.....

-	PUL				WVTT				AQB			
	2019	2020	2021	2022	2019	2020	2021	2022	2019	2020	2021	2022
Transfusion	9, 6 <0.01, 0.01	4, 1 <0.01, <0.01	6, 6 <0.01, <0.01	3, 2 <0.01, <0.01	1, 1 <0.01, <0.01	0, 0	0, 0	0, 0	8, 7 3, 2	9, 8 1, 1	7, 6 0.2, 0.2	5, 5 0.06, 0.06
Bladder perforation	0, 0	1, 1 <0.01, <0.01	0, 0	0, 0	0, 0	1, 1 <0.01, <0.01	1, 1 <0.01, <0.01	0, 0	0, 0	0, 0	1, 1 0.03, 0.03	3, 3 0.04, 0.04
Bowel perforation	0, 0	0, 0	1, 0 <0.01, 0	0, 0	0, 0	0, 0	0, 0	1, 1 <0.01, <0.01	1, 1 0.3, 0.3	3, 2 0.4, 0.3	1, 1 0.03, 0.03	0, 0
Death	5, 0 <0.01, 0	5, 0 <0.01, 0	1, 0 <0.01, 0	1, 0 <0.01, 0	1, 0 <0.01, 0	1, 0 <0.01, 0	0, 0	0, 0	2, 2 0.7, 0.7	0, 0	5, 4 0.2, 0.1	4, 3 0.05, 0.04

4. DISCUSSION

New technologies and procedures continue to capture an increased share of the BPH surgical treatment market, driving TURP rates from 39% of all BPH surgeries in 2015 to 26.9% in 2021 [14]. While randomized controlled trials offer the highest level of evidence for the safety and efficacy of a procedure in the controlled population studied, once deployed into broader patient populations, real-world results may indeed vary [15-17]. Surveillance data, such as those collected in MAUDE, contribute to an expanded and nuanced understanding of BPH therapeutic performance in large, real-world populations beyond controlled settings. Real-world database data can uncover effects such as the physician learning curve and technique development, as well as adverse effects that cannot be detected in relatively small, controlled studies. Additionally, it can serve as a check on marketing claims that might be based on a small study yet extrapolated to the general population across unstudied cohorts. Only data generated by randomizing between procedures can yield high-confidence comparisons of these treatment options. As such, this study provides instead a view of how each treatment option is performing in the patient populations to which urologists applied them during the period studied.

Given the heterogeneity of MAUDE data sources, which range from voluntary submissions by clinicians and patients to mandatory reports from manufacturers, we approached the dataset with caution, adjudicating each MDR for quality, clinical relevance, and narrative completeness. Previous studies examining BPH devices have utilized MAUDE to identify post-market safety signals, though most reported absolute event counts without contextualizing these figures against real-world procedural volumes [7-9]. Our findings confirm that MDR frequency tends to rise in parallel with device utilization, a trend observed in other post-market surveillance studies [18]. As such, raw counts of adverse events, while valuable for signal detection, may be misleading when used in isolation. Volume-adjusted event rates provide a more meaningful framework for clinical interpretation and comparative safety assessment.

PUL adoption increased since its FDA clearance in 2013, accounting for approximately 30% of BPH surgical procedures between 2019 and 2022 [19, 12, 20]. AQB has seen a rapid increase in utilization since its introduction in 2019, with total sales increasing by 97% between 2021 and 2022 [21-23]. Following FDA approval in 2015, WVTT annual utilization decreased 48% between 2019 and 2021 [24, 25].

The use of MAUDE data in published analyses increased during the COVID-19 pandemic; in 2019, 45 publications used MAUDE data, while by 2022 the number had increased to 89 [26]. PUL, WVTT, and AQB all saw increased total MDRs submitted over the course of the study, perhaps signaling an increased awareness of the MAUDE database's existence amongst voluntary reporters.

Intraoperative events for the BPH treatment devices in this analysis were less severe overall than post-operative events, which may highlight an inherent bias in the MAUDE sample – the database is designed to capture device malfunctions which, particularly in the intra-operative setting, are often as mild as a failure in the user interface and may be corrected with minor intervention, resulting in lower Gupta scale ratings. In the case of PUL, these intraoperative events are often failed device deployments remedied by obtaining a new device. The WVTT and AQB intraoperative event narratives were similar in describing device malfunctions; however, obtaining a new device in both cases is considerably more difficult. The reliance on an electronic interface to complete the WVTT and AQB procedures means that a malfunction often mandates procedural abandonment. The decrease in intraoperative event rates for AQB between 2019 and 2022 may be explained by the technology's relative novelty in 2019, with physicians gaining increased proficiency in the procedure by 2022. In terms of overall intraoperative event rates, as well as serious or life-threatening events, AQB's intraoperative safety profile differs from the MISTs studied, consistent with the procedure's more invasive nature.

The decrease in post-operative events as a proportion of total MDRs between 2019 and 2022 across all devices may signal greater physician experience in performing the procedures, leading to fewer adverse events. AQB is performed using a robotically controlled high-velocity waterjet to resect obstructing prostatic tissue, employing a technique similar to TURP but without the use of electrocautery. AQB's 15% severe post-operative complication rate observed in 2019 points to the difficulty in achieving hemostasis with water therapy alone,

reminiscent of the 9.9% transfusion rate observed in the WATER II trial [27]. In January 2020, PROCEPT BioRobotics, the makers of the Aquabeam System, implemented global training to perform focal bladder neck cauterization to achieve hemostasis following the primary AQB procedure [28]. The subsequent decreases in overall MDRs and severe post-operative Clavien-Dindo events for AQB in MAUDE appear to reflect the effectiveness of this procedure update in reducing bleeding. However, overall and serious MDRs remain elevated for AQB compared with PUL and WVTT, suggesting that AQB has a safety profile distinct from minimally invasive BPH treatments and is not overcome by bladder neck cauterization.

Adverse event adjudication in a clinical trial setting includes a determination of the relatedness of the event to the device and remains a vital component of scientific analysis; while other publications have retroactively attributed relatedness to serious or life-threatening events (for example, bladder perforation during TURP attributed to prior PUL procedure) for which no such attribution existed in the MAUDE database itself, our analysis is the first to adjudicate MDRs in a more rigorous manner [29]. Because many MDRs in MAUDE are submitted by voluntary reporters, including patients with varying levels of medical fluency, the quality of entries is heterogenous, constituting the entire bell curve from social media posts to full case reports; to account for this heterogeneity, we have employed a novel completeness scale which rates the ability to determine if the patient received treatment for the stated event, if that determination could be incompletely made, or if no information about interventions was provided. These methods aim to facilitate rigorous analysis, and we encourage all scientists to account for data quality and event-relatedness when approaching this valuable yet highly heterogeneous data source.

Once these methods were applied, the most common AE classification in WVTT was infection, which may be consistent with the longer indwelling catheterization durations following that procedure. Bleeding complications following AQB and PUL manifest in the classified hematomas and transfusions. When relatedness and completeness are accounted for, PUL emerges with the fewest events. When similar standards are applied to AQB's MDRs, particularly severe to life-threatening events, we see that most MDRs are clearly related to the procedure and were treated with a return to the operating room for hemostasis. Although the grading of related and complete MDRs produces event rates that are lower for all BPH treatments in this analysis, rates of 2 *vs*. 5 events per 10,000 cases lack clinical meaningfulness. As would be expected for a minimally invasive treatment for a quality-of-life disease, mortality following MIST procedures is rare and often unrelated to the procedure.

The MAUDE database offers insights into real-world device performance in the hands of practicing urologists beyond the confines of a clinical trial. However, MAUDE is a limited sample, with entries that, according to the FDA, are potentially biased, unverified, untimely, incomplete, or inaccurate [30]. Data collection is also limited by under-reporting of events by professionals, unclear submission responsibilities, and continued lack of awareness of the database itself [31, 32]. The extraction of MDRs without context, including total procedures per year, patient baseline demographic data (*e.g.*, gland size, International Prostate Symptom Score [IPSS], and comorbidities), should be undertaken with caution. Despite these limitations, MAUDE provides an additional opportunity to prioritize patient experience in shared decision-making when approaching the myriad treatment options for BPH.

CONCLUSION

The MAUDE database constitutes a valuable source of up-to-date information, providing early insights into device safety and performance in the real world. In using the MAUDE database, previous publications have failed to account for event incidence, at-risk population sizes, device-relatedness, and data quality. When these features are accounted for, AQB emerges with significantly higher rates of mild, moderate, and severe events than the minimally invasive therapies analyzed. PUL has the lowest year-over-year rates of mild, moderate, and severe events in the MAUDE database.

AUTHORS' CONTRIBUTIONS

The authors confirm their contribution to the paper as follows: R.S.: Data analysis or interpretation; M.M.: Writing - original draft preparation; G.E.: Writing - reviewing and editing. All authors reviewed the results and approved the final version of the manuscript.

LIST OF ABBREVIATIONS

AE	=	Adverse Event
AQB	=	Aquablation
BPH	=	Benign Prostatic Hyperplasia
cMDR	=	Classified Medical Device Report
CD	=	Clavien-Dindo (classification system for surgical complications)
DH	=	Definitive Healthcare
FDA	=	Food and Drug Administration
IPSS	=	International Prostate Symptom Score
LUTS	=	Lower Urinary Tract Symptoms
MAUDE	=	Manufacturer and User Facility Device Experience (database)
MDR	=	Medical Device Report
MIST	=	Minimally Invasive Surgical Therapy
NSQIP	=	National Surgical Quality Improvement Program
PUL	=	Prostatic Urethral Lift
TURP	=	Transurethral Resection of the Prostate
WVTT	=	Water Vapor Thermal Therapy

ETHICAL STATEMENT

This study did not require institutional review board approval as it involved analysis of de-identified, publicly available data (MAUDE), which does not meet the regulatory definition of human subjects research under 45 CFR 46.102.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

All data generated or analyzed during this study are included in this published article.

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CONFLICT OF INTEREST

Drs. Shinghal and Eure are Teleflex consultants. Dr. Mariella is a Teleflex employee.

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REFERENCES

[1] Berry SJ, Coffey DS, Walsh PC, Ewing LL. The development of human benign prostatic hyperplasia with age. J Urol 1984; 132(3): 474-9. http://dx.doi.org/10.1016/S0022-5347(17)49698-4 PMID: 6206240

[2] Elterman D, Gao B, Lu S, Bhojani N, Zorn KC, Chughtai B. New technologies for treatment of benign prostatic hyperplasia. Urol Clin North Am 2022; 49(1): 11-22. http://dx.doi.org/10.1016/j.ucl.2021.07.007 PMID: 34776045

[3] FDA. Medical Device Reporting (MDR): How to report medical device problems. Available from: https://www.fda.gov/ medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

[4] 21 CFR §803.3 – Definitions. 2025. Available from: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803

[5] US Food and Drug Administration. . MAUDE - Manufacturer and User Facility Device Experience. US FDA. 2023. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#disclaimer

[6] Zuckerman DM, Brown P, Nissen SE. Medical device recalls and the FDA approval process. Arch Intern Med 2011; 171(11): 1006-11. http://dx.doi.org/10.1001/archinternmed.2011.30 PMID: 21321283

[7] Kaplan-Marans E, Martinez M, Wood A, Cochran J, Dubowitch E, Schulman A. Aquablation, prostatic urethral lift, and transurethral water vapor therapy: A comparison of device-related adverse events in a national registry. J Endourol 2022; 36(2): 231-5. http://dx.doi.org/10.1089/end.2021.0455 PMID: 34314240

[8] Porto JG, Arbelaez MCS, Blachman-Braun R, *et al*. Complications associated with minimally invasive surgical therapies (MIST) for surgical management of benign prostatic hyperplasia: A Manufacturer and User Facility Device Experience (MAUDE) database review. World J Urol 2023; 41(7): 1975-82. http://dx.doi.org/10.1007/s00345-023-04440-w PMID: 37222779

[9] Juliebø-Jones P, Somani BK, Tzelves L, *et al*. Complications and device failures associated with urolift: Findings from the MAUDE database. Urologia 2023; 90(4): 636-41. http://dx.doi.org/10.1177/03915603231180016 PMID: 37292024

[10] Shinghal R, Ashley M, Eure G. MP46-11 total procedural context is crucial in understanding bph treatment device safety in the FDA's MAUDE database. J Urol 2024; 211(5S)e757 http://dx.doi.org/10.1097/01.JU.0001008668.53858.38.11

[11] Ashley M, Kaplan S. Real-world safety outcomes following treatment with minimally invasive and surgical approaches for benign prostatic hyperplasia (BPH). The Western Section of the American Urological Association (WSAUA) Annual Meeting. Lake Tahoe, CA, 2023 Oct 1-5

[12] Feiertag J, Clark JY. National trends in surgical management for benign prostatic hyperplasia from 2013 to 2019: A TriNetX analysis. J Urol 2023; 209(4S)e173 http://dx.doi.org/10.1097/JU.0000000000003233.01

[13] Jivanji D, Shpeen B, West M, *et al*. Safety and trends in surgical management of benign prostatic hyperplasia. J Urol 2023; 209(4S)e694 http://dx.doi.org/10.1097/JU.0000000000003299.05

[14] Zhang TR, Thorogood SL, Sze C, *et al*. Current Practice Patterns in the Surgical Management of Benign Prostatic Hyperplasia. Urology 2023; 175: 157-62. http://dx.doi.org/10.1016/j.urology.2023.02.025 PMID: 36863599

[15] Eure G, Gange S, Walter P, *et al*. Real-World evidence of prostatic urethral lift confirms pivotal clinical study results: 2-Year outcomes of a retrospective multicenter study. J Endourol 2019; 33(7): 576-84. http://dx.doi.org/10.1089/end.2019.0167 PMID: 31115257

[16] Bach T, Gilling P, El Hajj A, Anderson P, Barber N. First multi-center all-comers study for the aquablation procedure. J Clin Med 2020; 9(2): 603. http://dx.doi.org/10.3390/jcm9020603 PMID: 32102329

[17] Whiting D, Noureldin M, Abdelmotagly Y, *et al*. Real-world early outcomes and retreatment rates following water vapour ablative therapy for symptomatic benign prostatic hyperplasia. Eur Urol Open Sci 2022; 39: 72-8. http://dx.doi.org/10.1016/j.euros.2022.03.006 PMID: 35528787

[18] Resnic FS, Normand SLT. Postmarketing surveillance of medical devices--filling in the gaps. N Engl J Med 2012; 366(10): 875-7. http://dx.doi.org/10.1056/NEJMp1114865 PMID: 22332950

[19] U.S. Food and Drug Administration, Center for Devices and Radiological Health. NeoTract UroLift System®, Model REF UL400 approval letter. 2013. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf13/k130651.pdf

[20] Kaplan S, Kaufman RP Jr, Mueller T, *et al*. Retreatment rates and postprocedural complications are higher than expected after BPH surgeries: A US healthcare claims and utilization study. Prostate Cancer Prostatic Dis 2023; 27(3): 485. PMID: 37884615

[21] Approval FDA. De Novo Classification Request for AQUABEAM System. 2019. Available from: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170024.pdf

[22] Procept Biorobotics. PROCEPT BioRobotics Reports First Quarter 2022 Financial Results and Increases 2022 Revenue Guidance. 2022. Available from: https://ir.procept-biorobotics.com/ static-files/d276c0b5-2494-4a7b-bc1d-8676c3c583ab

[23] Procept Biorobotics. Form 10-K: Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2022. 2023. Available from: https://ir.procept-biorobotics.com/static-files/20cc7b7c-7ab0-4117-ae3a-fcb72d46f89b

[24] F.D.A.. De novo classification request for rezum system. 2015. Available from: https://www.fda.gov/medical-devices/ premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request

[25] Jones C, Breyer B, Mbassa R, Meeks W, Fang R, Cooperberg M.

MP76-20 Trends in surgical management of benign prostatic hyperplasia: Data from the aua quality (AQUA) registry. J Urol 2023; 209 (Suppl. 4).e1100
http://dx.doi.org/10.1097/JU.0000000000003350.20

[26] National Institutes of Health. FDA MAUDE 2019-2022. 2023.

[27] Desai M, Bidair M, Bhojani N, *et al*. WATER II (80–150 mL) procedural outcomes. BJU Int 2019; 123(1): 106-12.
http://dx.doi.org/10.1111/bju.14360 PMID: 29694702

[28] Elterman DS, Foller S, Ubrig B, *et al*. Focal bladder neck cautery associated with low rate of post-Aquablation bleeding. Can J Urol 2021; 28(2): 10610-3.
PMID: 33872559

[29] Kaplan-Marans E, Marans H. Impact of prostate urethral lift device on prostate magnetic resonance image quality. Letter. J Urol 2023; 210(2): 251-2.
http://dx.doi.org/10.1097/JU.0000000000003566 PMID: 37232697

[30] United States Food and Drug Administration. MAUDE Disclaimer. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#disclaimer

[31] Patel NH, Uppaluri N, Iorga M, *et al*. Device malfunctions and complications associated with benign prostatic hyperplasia surgery: Review of the manufacturer and user facility device experience database. J Endourol 2019; 33(6): 448-54.
http://dx.doi.org/10.1089/end.2019.0067 PMID: 30990073

[32] Sawaya J, Champlain A, Cohen J, Avram M. Barriers to reporting: Limitations of the maude database. Dermatol Surg 2021; 47(3): 424-5.
http://dx.doi.org/10.1097/DSS.0000000000002832 PMID: 33625154