# *The impact of 5-ARI on perioperative and functional outcomes of GreenLight PVP: an analysis of the Global GreenLight Group database*

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***Introduction:*** *In this study, we sought to investigate the impact of 5-alpha reductase inhibitors (5-ARI) on the perioperative and functional outcomes of 180-Watt XPS GreenLight photovaporization of the prostate (PVP) using a large international database.*

***Materials and methods:*** *Data were obtained from the Global GreenLight Group (GGG) database, which includes eight high-volume, experienced surgeons from seven international centers. All men with established benign prostatic hyperplasia (BPH) with known 5-ARI status who underwent GreenLight PVP using the XPS-180W system between 2011 and 2019 were eligible for the study. Patients were assigned to two groups based on the preoperative use of 5-ARI. Analyses were adjusted for patient age, prostate volume, and American Society of Anesthesia (ASA) score.*

***Results:*** *We included 3,500 men, of which 1,246 (36%) had preoperative 5-ARI use. Patients in both groups were similar with regards to age and prostate size. On multivariable analysis, total operative time was slightly shorter (-3.26 min 95% CI: 1.20 — 5.32, $p < 0.01$) and required 35.6kJ less laser energy (95% CI: -48.0kJ — -23.3kJ, $p < 0.01$) for patients on 5ARI compared to those without 5-ARI. However, no clinically significant difference was appreciated regarding postoperative transfusion rates [OR 0.048 (95% CI -0.82-0.91; $p = 0.91$)], hematuria rates [OR 0.96 (95% CI 0.72-1.3; $p = 0.81$)], 30-day readmission rates [OR 0.98 (95% CI 0.71-1.4; $p = 0.90$)], or overall functional outcomes.*

***Conclusion:*** *Our findings suggest that preoperative 5-ARI is not associated with any clinically significant different perioperative or functional outcomes for GreenLight PVP using the XPS-180W system. There is no role for the initiation or discontinuation of 5-ARI prior to GreenLight PVP.*

**Key Words:** GreenLight PVP, BPH, 5-ARI

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## Introduction

The use of 5-alpha reductase inhibitors (5-ARI) is a common medical treatment for lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH).[1] However, when patients' therapeutic response to medical therapy is limited, they may seek surgical alternatives to resolve their symptoms. GreenLight photoselective vaporization of the prostate (PVP) is a surgical technique that can treat BPH in almost all prostate sizes by delivering a laser to vaporize hyperplastic prostate tissue.[2,3]

5-ARI are known to alter parameters within the prostatic tissue, such as reducing vascularity and glandular tissue content.[4] Indeed, 5-ARI diminish blood flow to the prostate by reducing micro-vessel density in the suburethral prostatic tissue.[5] It is hypothesized that the reduced micro-vessel density induced by 5-ARI mitigates the risk of intraoperative bleeding, thus minimizing surgical complications and shortening operative time.[6,7] Recently, a meta-analysis analyzing the effects of 5-ARI on transurethral resection of the prostate (TURP) reported a significant decrease in intraoperative blood loss in patients undergoing treatment with the 5-ARI finasteride.[8]

We hypothesize that this finding may also be consistent with GreenLight PVP. Previous studies have examined this hypothesis but have failed to report any significant differences in the efficacy and efficiency of GreenLight PVP in patients undergoing 5-ARI treatment.[6,9-11] These studies were constructed using small cohorts; among them, only one used the latest GreenLight 180W-XPS system. Therefore, we aim to analyze the impact of 5-ARI on the operative outcomes of 180W-XPS GreenLight PVP using the largest international GreenLight database, the Global GreenLight Group (GGG) database.[12]

## Materials and methods

### *Data source*

The data used in this study were retrieved from the retrospective GGG database, which pools outcomes of patients that were treated with a Greenlight PVP using the XPS-180W system between 2011 and 2019 by eight experienced urologists from seven international tertiary care centers in Canada, France, Germany, Italy, Mexico, and Brazil.[12] At the time of analysis, the database consisted of 3,809 patients. Institutional review board approval was obtained at each respective site.

### *Cohort inclusion and exclusion criteria*

Patients were excluded if they were either missing 5-ARI information, underwent a previous surgical BPH treatment, had a known diagnosis of prostate cancer, had prior pelvic radiation, had any known neurological disorders or were undergoing a hybrid procedure with multiple simultaneous surgical techniques. All other patients in the GGG database were included.

### *Study parameters*

Baseline functional outcomes, which included international prostate symptom score (IPSS), quality of life (QoL) score, prostate-specific antigen (PSA) level, post-void residual (PVR) volume, and maximum urinary flow rate (Qmax), were reported. We also assessed baseline characteristics such as body mass index (BMI), prostate size, use of concomitant medical therapy (namely alpha blockers) and medical risk using the American Society of Anesthesia (ASA) score. Perioperative outcomes and complications were collected, including operation time, lasing time, energy used, number of fibers used, and the hospital length of stay (LOS). In addition, complications including transfusion, hematuria, and the need for readmission at 30-days postop, were analyzed. This data was then analyzed over 12 months to monitor changes in functional outcomes.

### *Statistical analysis*

Statistical analyses were performed using Stata version 14.0 (StataCorp, TX, USA). Statistical significance was defined as a two-sided $p < 0.05$. Means and standard deviations were reported for continuous variables with normal distribution. The two-sided t-test was used for continuous outcomes when performing unadjusted analyses comparing the outcomes of patients not taking 5-ARI to those of patients taking 5-ARI preoperatively. Otherwise, the Pearson chi-square test and the Wilcoxon rank-sum test were used for dichotomous outcomes and the non-parametric outcome of hospital LOS, respectively. When adjusting for variables such as age, prostate size (categorized as 30-80 cc, 80-150 cc, ≥ 150 ccs), and ASA score (classified as 1, 2, ≥ 3), multivariable linear regression models were fitted to compare outcomes between patients that were and were not taking 5-ARI preoperatively. For dichotomous outcomes, the odds of the outcome between both groups were estimated using multivariable logistic regression models while adjusting for the previously listed covariates.

## Results

### *Baseline characteristics*

In this study, 309 patients from the GGG database were excluded. We included 3,500 patients. Among

TABLE 1. **Baseline patient demographics**

| | Control (n = 2,254) | 5-ARI (n = 1,246) | p value |
|---|---|---|---|
| Age, yrs, mean (SD) | 70.11 (9.05) | 70.72 (8.61) | 0.06 |
| TRUS volume, mL, mean (SD) | 71.50 (36.36) | 73.95 (38.37) | 0.07 |
| ASA score, n (%) | | | < 0.01 |
| 1 | 246 (10.9) | 185 (14.8) | |
| 2 | 610 (27.1) | 430 (34.5) | |
| 3+ | 1398 (62.0) | 631 (50.6) | |
| IPSS, mean (SD) | 22.57 (6.61) | 23.36 (6.53) | < 0.01 |
| QoL, mean (SD) | 3.74 (1.93) | 4.35 (1.50) | < 0.01 |
| PSA, ng/dL, mean (SD) | 8.08 (48.85) | 4.99 (18.9) | 0.04 |
| PVR, mL, mean (SD) | 202.67 (284.27) | 225.77 (238.16) | 0.06 |
| Qmax, mL/s, mean (SD) | 7.41 (4.16) | 6.62 (3.62) | < 0.01 |
| Alpha-blocker use, n (%) | | | < 0.01 |
| Yes | 1,626 (72.1) | 1,106 (88.8) | |
| No | 618 (27.4) | 140 (11.2) | |
| Unknown | 10 (0.4) | 0 (0) | |

ASA = American Society of Anesthesia; IPSS = international prostate symptom score; QoL = quality of life; PSA = prostate-specific antigen; PVR = post-void residual; Qmax = maximum urinary flow rate

these patients, 36% (n = 1,246) were treated with 5-ARI preoperatively, and 64% (n = 2,254) were not. At baseline, both groups had no differences in age or prostate volume (73.9 vs. 71.5 cc, p = 0.07). Patients taking 5-ARI had lower baseline PSA levels (4.99 vs. 8.08 ng/mL; p = 0.04). The group taking 5-ARI had a higher (worse) preoperative QoL score (4.35 vs. 3.74; p < 0.01) and IPSS (23.36 vs. 22.57; p < 0.01). At baseline, Qmax values were higher in those not taking 5-ARI (7.41 vs. 6.62; p < 0.01). Additional baseline characteristics are listed in Table 1.

*Unadjusted perioperative and functional outcomes*

Patients not on 5-ARI required more energy to be delivered intraoperatively (132.5 vs. 87.8 kJ; p < 0.01). Patients taking 5-ARI were found to have a shorter LOS (1 vs. 2 days; p < 0.01) and required fewer blood transfusions (0.79 vs. 0.86%; p = 0.04) than the control group. There was no significant difference in readmissions and operative and lasing time between the two groups. Patients on 5-ARI preoperatively also had a greater increase in Qmax at 12 months (11.90 vs. 13.01 mL/s; p = 0.03). In addition, the 5-ARI group was found to have a higher IPSS decrease than the control group at 6 months (17.01 vs. 16.22; p = 0.03). However, this difference in IPSS was no longer significant at 12 months (18.02 vs. 18.08; p = 0.88). Additional unadjusted perioperative and functional outcomes can be found in Table 2.

*Adjusted perioperative and functional outcomes*

When adjusting for age, prostate volume and ASA score, the operative time was 3.26 minutes shorter (95% CI: 1.20 — 5.32, p < 0.01) for patients taking 5-ARI. There was no significant difference in lasing time between both groups, but patients taking 5ARI required 35.6kJ less laser energy (95% CI: -48.0kJ — -23.3kJ, p < 0.01). Patients taking 5-ARI also had a shorter LOS [OR 0.47 (95% CI: 0.47-0.49 p < 0.01)]. No clinically significant difference was appreciated with regards to postoperative transfusion rates [OR 0.05 (95% CI -0.82-0.91; p = 0.91)], hematuria rates [OR 0.96 (95% CI 0.72-1.3; p = 0.81)], and 30-day readmission rates [OR 0.98 (95% CI 0.71-1.4; p = 0.90)] between both groups. In addition, there were no clinically significant differences in overall functional outcomes, including IPSS changes; IPSS changes at both 6-month [+0.71 (95% CI 0.01 to 1.42; p = 0.05)] and 12-month [+0.06 (95% CI −0.75 to 0.87; p = 0.88)] follow up was not statistically different. There were also no statistically significant differences in QoL changes at both 6-month [+0.14 (95% CI −0.46 to 0.74; p = 0.64)] and 12-months [+0.32 (95% CI −0.005 to 0.64; p = 0.046)]. The change in PVR volume did not differ at both 6-month [+16.1

TABLE 2. **Unadjusted functional and perioperative outcomes**

| | Control | 5-ARI | p value |
|---|---|---|---|
| Operation time, min, mean (SD) | 67.82 (30.68) | 69.93 (32.66) | 0.07 |
| Lasing time, min, mean (SD) | 38.5 (22.19) | 38.1 (21.23) | 0.63 |
| Energy, kJ, mean (SD) | 132.5 (196.14) | 87.84 (152.55) | < 0.01 |
| Number of fibers, median (IQR) | 1.00 (1.00-1.00) | 1.00 (1.00-1.00) | 0.4 |
| Hospital stay, days, median (IQR) | 2.00 (1.00-3.00) | 1.00 (1.00-2.00) | < 0.01 |
| Transfusion rate, n (%) | 14 (0.86) | 8 (0.79) | 0.04 |
| Hematuria rate, n (%) | 129 (9.96) | 83 (9.52) | 0.12 |
| 30-day readmission rate, n (%) | 108 (13.42) | 79 (12.46) | 0.29 |
| IPSS decrease at 6 months, mean (SD) | 16.22 (7.40) | 17.01 (7.06) | 0.03 |
| IPSS decrease at 12 months, mean (SD) | 18.02 (7.58) | 18.08 (7.21) | 0.88 |
| QoL decrease at 6 months, mean (SD) | 3.32 (1.56) | 3.51 (1.38) | 0.49 |
| QoL decrease at 12 months, mean (SD) | 3.44 (1.92) | 3.72 (1.34) | 0.09 |
| PSA decrease at 6 months, ng/mL, mean (SD) | 2.19 (8.46) | 0.75 (52.08) | 0.4 |
| PSA decrease at 12 months, ng/mL, mean (SD) | 2.06 (5.43) | 1.15 (27.13) | 0.41 |
| PVR decrease at 6 months, mL, mean (SD) | 251.47 (304.87) | 224.45 (232.12) | 0.13 |
| PVR decrease at 12 months, mL, mean (SD) | 259.31 (304.14) | 226.3 (235.58) | 0.09 |
| Qmax change at 6 months, mL/s, mean (SD) | +11.96 (7.09) | +12.78 (6.79) | 0.09 |
| Qmax change at 12 months, mL/s, mean (SD) | +11.90 (6.96) | +13.01 (6.68) | 0.03 |

IPSS = international prostate symptom score; QoL = quality of life; PSA = prostate-specific antigen; PVR = post-void residual; Qmax = maximum urinary flow rate

(95% CI −20.2 to 52.4; p = 0.38)] and 12-months [+24.2 (95% CI −15.0 to 63.5; p = 0.23)] between the two groups. In addition, patients that were taking 5-ARI preoperatively did not have any significant difference in their PSA levels at both 6-month [-1.49 (95% CI −4.89 to 1.91; p = 0.39)] and 12-month [-1.15 (95% CI −3.4 to 1.1; p = 0.31)] follow ups in comparison to the control group. Lastly, men who were taking 5-ARI had a similar Qmax to patients that were not taking 5-ARI preoperatively at both 6-month and 12-month follow ups [0.14 (95% CI -0.80 to 1.08; p = 0.77); 0.26 (95% CI −0.78 to 1.30; p = 0.62)], respectively, Figure 1.

## Discussion

5-ARI are known to alter vascular parameters in the prostate tissue, which may impact the outcomes of GreenLight PVP. Previous studies did not demonstrate any significant differences in the efficiency and efficacy of GreenLight PVP between groups treated with or without 5-ARI.[6,9-11] However, these studies were limited by small cohorts, and only one of these studies used the GreenLight 180W-XPS system. Using the GGG database to analyze the effects of 5-ARI on the outcomes of GreenLight 180W-XPS PVP, we observed no significant differences in postoperative transfusion rates, lasing time and overall functional outcomes between both groups.

We found no significant differences in postoperative transfusion rates between groups treated with or without 5-ARI. Similarly, previous studies failed to demonstrate significant differences in intraoperative bleeding between both groups.[6,9-11] Men presenting with symptomatic BPH are often treated with 5-ARI to decrease prostatic volume, vascularity and reduce symptoms such as hematuria.[4] This is explained by 5-ARI's ability to reduce suburethral micro-vessel density in the prostate by interfering with vascular endothelial growth factor (VEGF), an important angiogenesis stimulator.[5] The histological alteration caused by 5-ARI is thought to reduce intraoperative bleeding. Using immunohistochemical markers to quantify the micro-vessel density and VEGF expression in prostate specimens, Pareek et al demonstrated a significant reduction in the suburethral micro-vessel density of the prostate in patients using 5-ARI.

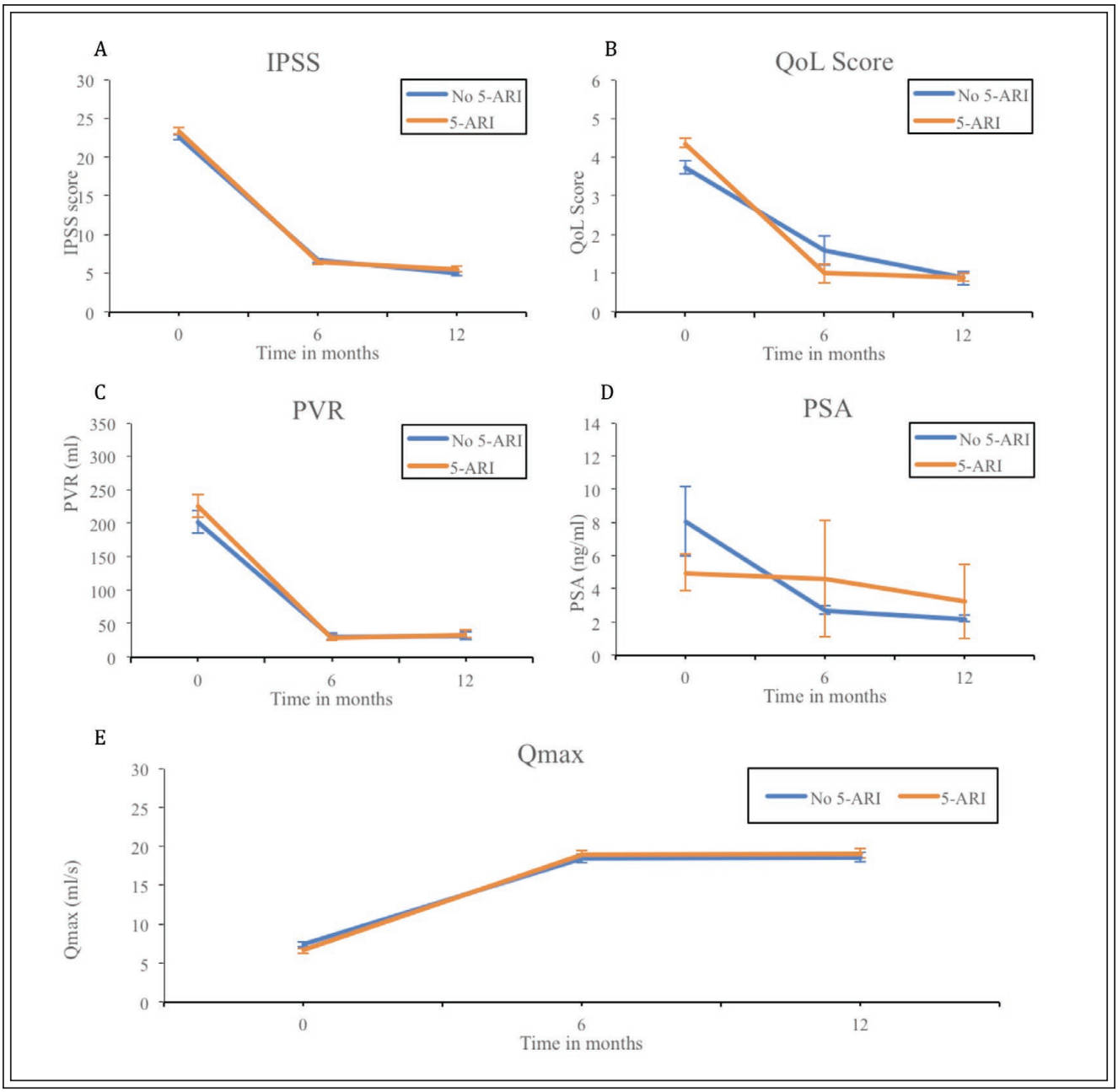


**Figure 1.** Postoperative functional outcomes at 6-month and 12-month follow ups.

However, this reduction was observed to a lesser degree in the gland's hyperplastic portion, which is the tissue targeted by the GreenLight laser.[5] Therefore, this may explain why we observed similar transfusion rates in both groups treated with or without 5-ARI despite their interaction with the prostatic blood supply. Previous GreenLight PVP studies have also demonstrated a non-significant reduction in blood loss for patients undergoing 5-ARI treatment.[9,10] The preoperative use of 5-ARI has been shown to reduce procedural blood loss for other surgical modalities. For instance, a meta-analysis analyzing the effects of 5-ARI on TURP found that finasteride significantly reduced procedural blood loss.[8] The inherent differences between the two surgical modalities' (GreenLight PVP and TURP) mechanism of action may explain why our study did not observe a significant decrease in transfusion rate. Indeed, the GreenLight laser is efficiently absorbed by its chromophore hemoglobin, inducing rapid vaporization and stimulating coagulation in

surrounding tissue.[13-15] GreenLight PVP is known to significantly reduce intraoperative bleeding compared to TURP and is thus an effective and safe procedure for anticoagulated patients regardless of the preoperative administration of 5ARI.[15-17] The inherent hemostatic properties of the GreenLight laser can explain the minimal risk of postoperative transfusions in patients undergoing GreenLight PVP and may explain why significant reductions in blood loss among 5-ARI patients have been challenging to observe despite having seen significant differences among TURP patients receiving preoperative 5-ARI.[6,8-11]

The lasing time was not statistically significant in both groups treated with or without 5-ARI.[6,9-11] Previous studies hypothesized that 5-ARI's inhibitory activity on prostatic angiogenesis would hinder GreenLight PVP's efficacy and efficiency. More specifically, since the GreenLight laser is known to use hemoglobin as its primary chromophore, a reduction in prostatic blood flow was thought to decrease the affinity of the laser to the prostatic tissue, resulting in increased lasing time and suboptimal functional outcomes.[6] In addition, the reduction in glandular tissue and the subsequent fibrosis of the prostate gland induced by the long term use of 5-ARI were also thought to negatively impact GreenLight PVP perioperative outcomes.[6,7] However, since micro-vessel density decreases only slightly in hyperplastic prostatic tissue after 5-ARI treatment, hemoglobin levels likely remained stable enough to absorb the GreenLight laser without significantly reducing its efficiency.[5] Another possible explanation for our findings is that 5-ARI's ability to improve intraoperative visibility negated the detrimental effects of 5-ARI-induced prostate fibrosis on the efficacy of the GreenLight laser. This may explain why our findings suggest that 5-ARI do not negatively impact procedural efficiency. In fact, a decrease in operative time, albeit not clinically significant, was observed in the 5-ARI group.

Previous studies hypothesized that the histological alterations caused by 5-ARI, such as increased prostate fibrosis, would decrease the efficacy of the GreenLight laser.[6] However, our results provide evidence that 5-ARI do not impair the treatment outcomes of GreenLight PVP. Indeed, we did not find any clinically significant differences in overall functional outcomes. While postoperative Qmax, IPSS and PVR improved over time in both groups, no significant difference was found between the groups treated with or without 5-ARI. These results were also observed in other studies examining the use of 5-ARI prior to GreenLight PVP.[6,9-11]

The limitations of our study include its retrospective design. In addition, the GGG database contains data collected by experienced surgeons from several large international urological centers. Therefore, our findings may not represent novice surgeons or smaller institutions. Moreover, patient data regarding preoperative administration of anticoagulant medication was not available and may have affected the transfusion rates observed in our study. Also, the impact of the duration of 5-ARI on GreenLight PVP was not evaluated as data related to the patient's treatment period with 5-ARI was unavailable. Araki et al reported that patients treated with 5-ARI for over 2 years have more fibrous prostates than those treated for less than a year.[11] Therefore, future studies should observe the longitudinal effects of longer 5-ARI treatment periods on GreenLight PVP functional outcomes. Despite these limitations, this is the first study to examine the impact of 5-ARI on the effectiveness, efficiency, and functional outcomes of GreenLight PVP using a large international multicenter database.

## Conclusion

Using the largest international GreenLight database, a retrospective study was designed to analyze the impact of 5-ARI on the efficacy, efficiency, and functional outcomes of GreenLight PVP using the XPS-180W system. We found that 5-ARI had no clinically significant effect on postoperative transfusion risk and overall perioperative and functional outcomes. Therefore, the initiation or discontinuation of 5-ARI treatment before surgery is not needed. Future studies should examine the impact of 5ARI treatment duration on GreenLight PVP functional outcomes.

## Disclosures

Competing Interests: Consultants and proctors for Boston Scientific for Greenlight: KZ, DSE, VM, ER, HC, BC. Surgical tutors for Greenlight Xcelerated Performance System and received honoraria for their tutorship: GF, LC. Investigators and consultants for PROCEPT BioRobotics: VM, TB, NB, KZ. All other authors do not have any relevant conflicts of interest. □

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