INTERNATIONAL JOURNAL OF
RADIATION ONCOLOGY • BIOLOGY • PHYSICS
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BRIEF REPORT

Ureter Tolerance in Patients Treated with Stereotactic Body Radiation Therapy on Abdominopelvic Lymph Nodes: Analysis on Dose-related Late Effects

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Received Feb 12, 2025; Revised May 16, 2025; Accepted for publication May 30, 2025

Purpose: This study evaluated late ureteral toxicity in relation to dose in patients treated with stereotactic body radiation therapy (SBRT) on abdominopelvic lymph node (A-P LN) oligometastases and assessed differences between planned and received ureteral dose.

Methods and Materials: Patients treated between 2011 and 2023 with SBRT on A-P LN oligometastases from various primary tumors were retrospectively reviewed. Toxicity was graded using the Common Terminology Criteria for Adverse Events version 5.0. Dose-volume histogram parameters (maximum dose to the ureter [D_{max}] maximum dose to 0.1 cc of the ureter [$D_{0.1cc}$], and maximum dose to 0.5 cc of the ureter [$D_{0.5cc}$]) from ureters receiving >10 Gy were extracted and compared with published ureteral constraints (D_{max} 108, $D_{0.1cc}$ 108, and $D_{0.1cc}$ 77 Gy equivalent dose of 2 Gy per fraction with a:b ratio of 3 Gy [$EQD2_3$]). Interfraction dose variation was derived from patients who were treated with online adaptive SBRT.

Results: The study included 144 patients, of whom 121 had a total of 137 ureters that were treated with <10 Gy. Most patients (85%) received 45 Gy in 5 fractions. The median ureter D_{max} and $D_{0.1cc}$ were 60 and 42 Gy $EQD2_3$, respectively. No grade (G) ≥ 4 toxicities were observed. Three patients (2%) developed G3 ureteral obstruction, with D_{max} values of 121, 97, and 74 Gy $EQD2_3$. Five patients (4%) experienced any G of late urinary toxicity, but only 1 of them exceeded the D_{max} of 108 Gy $EQD2_3$. In total, 31 (23%) patients did not experience late toxicity, despite exceeding this parameter. No significant difference was found between the planned and received ureter dose ($D_{0.1cc}$ 25 vs 22 Gy $EQD2_3$, $P = .23$). The median follow-up was 28 months.

Conclusions: The incidence of G3 ureteral toxicity after SBRT on A-P LN oligometastases is low (2%). Published dose constraints were violated in 23% of the patients without reported toxicity, suggesting other factors may contribute. Furthermore, no difference was found between the planned and received ureter dose, indicating that the planned dose is a reliable estimate of the dose received.

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Disclosures: L.A.van W. reports a payment to the institution from Accuray Inc for a presentation. C.M. has nothing to disclose. M.T.W.M. reports a consulting fee with payment to the institution from the Accuray Inc advisory board. M.L. has nothing to disclose. J.J.N. reports a payment to the institution from Accuray Inc for a presentation and is a board member of the AEX board.

Data Sharing Statement: Research data are stored in an institutional repository and will be shared on request to the corresponding author.

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Int J Radiation Oncol Biol Phys, Vol. 125, No. 2, pp. 457–463, 2026
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https://doi.org/10.1016/j.ijrobp.2025.05.087

Introduction

Stereotactic body radiation therapy (SBRT) is widely used for treating oligometastatic disease, but dose constraints for some organs, including the ureter, remain unvalidated.[1-3] Anatomically, the ureter is categorized as a serial organ, so determinants of injury are more likely to be dependent on a critical dose irrespective of the volume that is irradiated.[1] According to this idea, published dose constraints focus on the maximum dose to 0.1 cc of the ureter ($D_{0.1cc}$) and the maximum dose to the ureter (D_{max}).[1-3] Severe ureteral toxicity, such as grade (G) 3 obstruction, may lead to serious complications such as intra-abdominal or pelvic sepsis, urinary fistulas, renal failure, or even death. Furthermore, when the obstruction is discovered late, the chances of a curative treatment for this condition are low.[4,5] Despite that, the ureter is rarely contoured in radiation planning. Studies focusing on SBRT directed to the ureter reported no severe urinary toxicity.[6-8] A study on SBRT to abdominal-pelvic lymph node (A-P LN) oligometastases reported a G3 ureteral obstruction incidence of 2%.[9] Studies for cervical cancers reported a severe ureteral obstruction rate of 0.3% to 7%.[10-15] Hydronephrosis at baseline was the only factor associated with G ≥ 3 ureteral obstruction, whereas the relationship with dose is less clear.[11,12] Only 1 statistically significant dose-relation with ureteral obstruction was reported, for an equivalent dose of 2 Gy per fraction (EQD2) with a:b ratio of 3 Gy ($EQD2_3$) > 77 Gy.[12] Reported dose constraints in literature for 5 fractions are a D_{max} and $D_{0.1cc}$ of 108 Gy $EQD2_3$.[1,3]

Our study aimed to evaluate late ureteral toxicity in patients treated with SBRT for A-P LN oligometastases and to correlate this toxicity with the planned ureter dose. In addition, the difference between the planned and received dose was examined.

Methods and Materials

This study was approved by the institutional review board (MEC-2024-0785) of the Erasmus Medical Center. We retrospectively enrolled patients treated for A-P LN oligometastases from prostate and colorectal cancer with SBRT between 2011 and 2023 and patients included in the Phase 2 clinical STEAL trial, who were treated with online adaptive SBRT.[16] Oligometastatic disease was defined as a controlled primary tumor with ≤5 metastases located in ≤2 organs. Patients were included in the full analysis if one or both ureters received a dose of ≥10 Gy. When the dose was <10 Gy, they were included in a subanalysis looking at only the late ureter toxicity incidence.

No constraints for the ureter were used during treatment planning. The treatment schedules used were 48 Gy/6 fractions, 45 Gy/5 fractions, 40 Gy/5 fractions, or 35 Gy/5 fractions. Patients included in the STEAL trial were treated with computed tomography (CT) scan-guided online adaptive SBRT with 45 Gy/5 fractions. In this trial, a library of 3 plans was created for each patient, and a prefraction CT scan was acquired with the CT-on-rails to select the plan of the day. An extensive description of the workflow is reported.[16]

For data analysis, the physical dose was converted into an EQD_2 using the formula $EQD_2 = D \times (d + \alpha/\beta)/(2 + \alpha/\beta)$, with D = total dose, d = dose per fraction, and α:β ratio of 3 (late toxicity) (Gy_3). To extract dose-volume histogram (DVH) parameters, the part of the ureters receiving at least 10 Gy was contoured on the planning CT scan for all patients, for patients from the STEAL trial, and also on all prefraction CT scans. Extracted DVH parameters for the ureter included the D_{max}, $D_{0.1cc}$, $D_{0.5cc}$, V_{70Gy3}, and V_{54Gy3}. Furthermore, our results were compared with the current published ureter constraints: D_{max} and $D_{0.1cc}$ of 45 Gy in 5 fractions (108 Gy_3) and a $D_{0.1cc}$ of 77 Gy_3.[1,3,12]

The first goal was to evaluate toxicity and correlate these results with the planned ureter dose. For this endpoint we retrieved the ureter dose using the DVH parameters from the planning CT scan or, if treated with online adaptive radiation therapy, from the planning CT scan with the standard of care (SOC) plan (= planned dose).

The second goal was to examine the difference between the planned and received ureter doses during online adaptive treatment. The received ureter dose was retrieved by averaging the various DVH parameters calculated over the 5 sessions with the prefraction CT scan and the chosen plan for each fraction (Fig. 1). However, ureter motion and/or the choice of the plan for each fraction might affect the

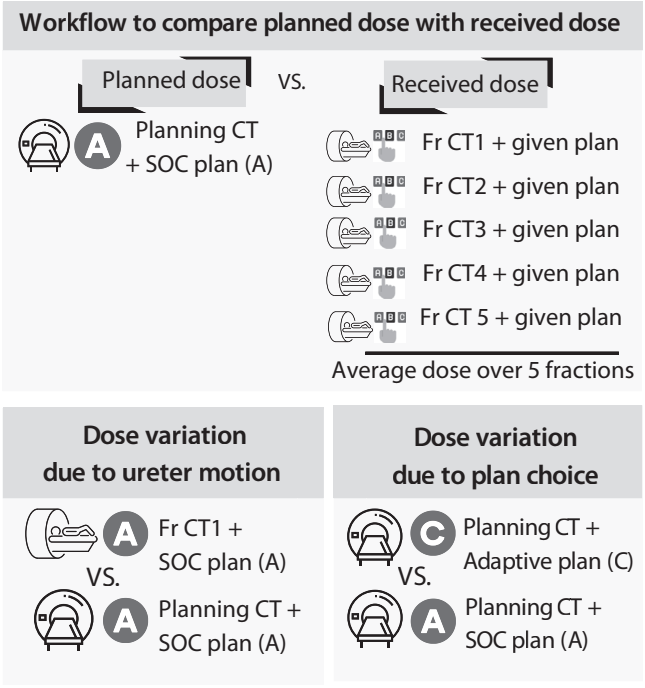

Fig. 1. Workflow of comparisons between planned dose with received dose.
Abbreviations: SOC= standard of care; Fr CT = fraction CT

Table 1 Patient and tumor characteristics

Patient characteristics	Patients with ureter planned dose of ≥ 10 Gy (N = 121)	Patients with both ureters planned a dose of < 10 Gy (N = 23)
Primary tumor (N, %)		
Prostate	84 (69%)	4 (17%)
Colorectal	30 (25%)	13 (57%)
Other*	7 (6%)	6 (26%)
Median age (y, IQR)	70.2 (63.6-73.1)	67.8 (60.4-73.6)
Number of ureters receiving a planned dose of ≥ 10 Gy		
One per patient	105 (87%)	NA
Two per patient	16 (13%)	NA
History of hydronephrosis before the start of treatment (N,%)		
Yes	4 (3%)	0 (0%)
No	117 (97%)	23 (100%)
Prior abdominal/pelvic surgery for primary tumor (N, %)		
Yes	107 (88%)	20 (87%)
No	14 (12%)	3 (13%)
Location of lymph node (N, %)		
Para-aortic	27 (22%)	15 (65%)
Iliac (common/internal/external iliac) or obturatory	83 (69%)	0 (0%)
Mesenteric	11 (9%)	8 (35%)
Treatment schedule (N, %)		
48 Gy in 6 fractions	5 (4%)	0 (0%)
45 Gy in 5 fractions	101 (84%)	21 (92%)
35 Gy in 5 fractions	15 (12%)	1 (4%)
40 Gy in 5 fractions	0 (0%)	1 (4%)
Type of treatment (N, %)		
Nonadaptive treatment	84 (69%)	9 (39%)
Online adaptive treatment	37 (31%)	14 (61%)
Systemic therapy during follow-up (N, %)		
Chemotherapy	26 (21%)	8 (35%)
Hormonal therapy	27 (22%)	2 (9%)
Immunotherapy	13 (11%)	7 (30%)
Unknown	12 (10%)	0 (0%)
Abdominal/pelvic surgery during follow-up (N, %)		
Yes	6 (5%)	1 (4%)
No	103 (85%)	22 (96%)
Unknown	12 (10%)	0 (0%)
Disease progression affecting urinary function (N, %)		
Yes	6 (5%)	0 (0%)
No	103 (85%)	23 (100%)
Unknown	12 (10%)	0 (0%)

Abbreviations: NA= not applicable; N = number.

* Other primary tumors included hepatocellular carcinoma, esophagus carcinoma, neuroendocrine carcinoma of the appendix, sarcoma, gallbladder carcinoma, mesothelioma, pyelum carcinoma, lung, and pancreas carcinoma.

planned and received dose. To distinguish the dose difference caused by the day-to-day anatomic variations, the dose to the ureter on the first fraction CT scan with the SOC plan (received dose SOC plan) was compared with the received dose. To assess the dose variation caused by the choice of treatment plan, the planned dose was compared with the dose of the ureter on the planning CT scan with plan C as an adaptive plan (planned adaptive dose).

Toxicity was graded according to the Common Terminology Criteria for Adverse Events version 5.0. G ≥ 3 toxicities were scored to be possibly, probably, or definitely related to treatment. Late toxicity was defined as toxicity occurring ≥3 months after treatment.

Statistical analysis was performed using IBM SPSS Statistics (version 28.0.1.0). Medians were compared using the Mann-Whitney *U* test or the Wilcoxon test. Results with a 2-sided *P* value <.05 were considered statistically significant.

Results

Baseline characteristics

We included a total of 121 patients, with one or both ureters receiving a planned dose of <10 Gy. The median follow-up duration was 28.4 months. In this group, the primary tumor was prostate in 84 patients (69%), colorectal cancer in 30 patients (25%), and 7 patients (6%) had other primary tumors. We included a total of 23 patients who underwent SBRT on A-P LN oligometastases but had a ureter dose of < 10 Gy. The incidence of late urinary toxicities was 0% in this patient group. Patient and tumor characteristics for both groups are shown in Table 1.

Planned dose and toxicity

The median D_{max}, $D_{0.1cc}$, and $D_{0.5cc}$ of the ureter were 60 Gy_3 (range, 12-156 Gy_3), 42 Gy_3 (range, 7-151 Gy_3), and 21 Gy_3 (range, 2-129 Gy_3), respectively (Table 2). The median volumes receiving 70 Gy $EQD2_3$ (V_{70Gy3}) and 54 Gy $EQD2_3$ (V_{54Gy3}) were 0.00 cc (IQR, 0.00-0.25 cc) and 0.00 (IQR, 0.00-0.43 cc). There was no significant difference between the V_{70Gy3} and the V_{54Gy3} in the patient group with toxicity and in the one without. A total of 32 patients received a D_{max} exceeding 108 Gy_3; the median D_{max} in this group of patients was 123 Gy_3 (IQR, 115-129 Gy_3). The $D_{0.1cc}$ was >108 Gy_3 in 16 patients with a median dose of 114.4 Gy_3 (IQR, 111.3-126.4 Gy_3) and >77 Gy_3 in 39 patients with a median dose of 103.1 Gy_3 (IQR, 91-113 Gy_3) (Fig. 2).

Three patients (2%) had G3 ureteral obstruction with hydroureteronephrosis, requiring JJ catheter placement. The ureters of these 3 patients received a D_{max} of 121, 97, and 74 Gy_3 and a $D_{0.1cc}$ of 112, 76, and 48 Gy_3, respectively. These patients had a previous history of

Table 2 Dose to ureter and late toxicity

Group	D_{max} in $EQD2_3$, Median (range)	$D_{0.1}$ in $EQD2_3$, Median (range)	$D_{0.5}$ in $EQD2_3$, Median (range)	$D_{max} \geq 108$ $EQD2_3$, N (%)	$D_{0.1cc} \geq 108$ $EQD2_3$, N (%)	$D_{0.1cc} \geq 77$ $EQD2_3$, N (%)	V70 Gy $EQD2_3$ Median (range)	V54 Gy $EQD2_3$ Median (range)
All ureters (n = 137)	60 Gy (12-156)	42.4 Gy (7-151)	21 Gy (2-129)	32 (23%)	16 (12%)	39 (28%)	0.00 cc (0.00-3.37)	0.00 cc (0.00-4.42)
Patients with late toxicity (n = 5)	86 Gy (74-121)	66 Gy (48-112)	34 Gy (18-104)	1 (20%)	1 (20%)	1 (20%)	0.03 cc (0.00-1.35)	0.30 (0.05-1.88)
Patients without late toxicity (n = 132)	55 Gy (12-156)	40 Gy (7-151)	20 Gy (2-129)	31 (23%)	15 (11%)	38 (29%)	0.00 cc (0.00-3.37)	0.0 cc (0.00-4.42)
P value*	.20	.16	.16	NA	NA	NA	.22	.08

Abbreviations: DVH = dose-volume histogram; IQR= interquartile range; D_{max} = maximum dose to the ureter; $D_{0.1cc}$ = maximum dose to 0.1 cc of the ureter; $D_{0.5cc}$ = maximum dose to 0.5 cc of the ureter; $EQD2_3$ = equivalent dose of 2 Gy per fraction with a:b ratio of 3 Gy; NA = not applicable; N = number of patients.
* The difference in the median from the patient group with and without toxicity was tested with the Mann-Whitney *U* test.

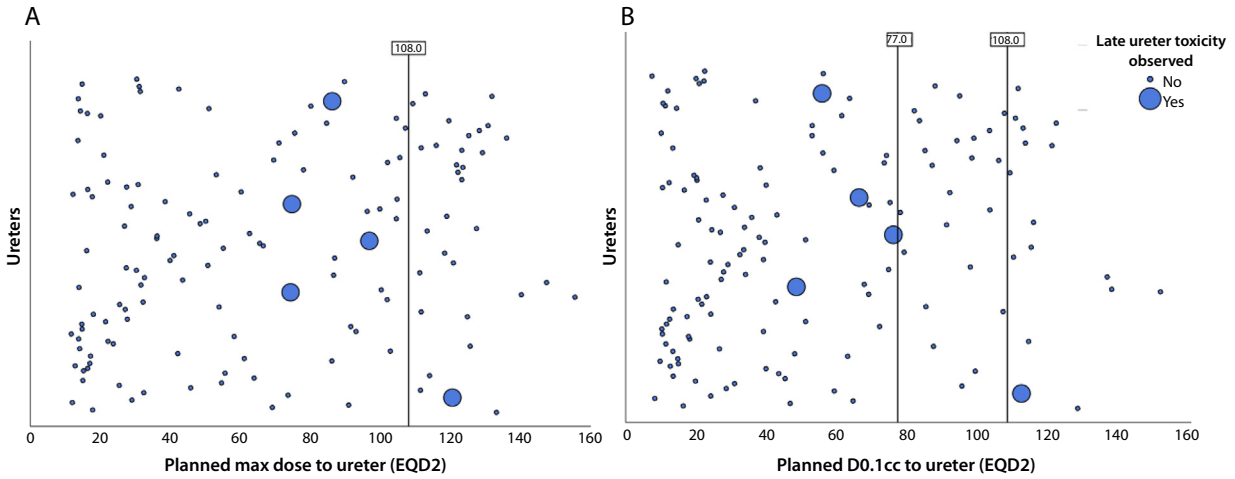

Fig. 2. Dose to the ureter in $EQD2_3$ per ureter (N = 137). (A) Planned max dose to the ureter per ureter. The vertical line represents the 108 Gy $EQD2_3$ constraint. (B) Planned $D_{0.1cc}$ to the ureter per ureter. The vertical lines present the 108 Gy and 77 Gy $EQD2_3$ constraints.
Abbreviations:$D_{0.1cc}$ = maximum dose to 0.1 cc of the ureter; $EQD2_3$ = equivalent dose of 2 Gy per fraction with a:b ratio of 3 Gy.
Tested with Wilcoxon.

surgery and/or chemotherapy, but none of them presented with hydronephrosis at the start of treatment (Table 3). No G ≥ 4 toxicities were found. Other observed late toxicities were 1 G1 urinary tract obstruction and a case of G1 hematuria (0.7%) in a patient with a known history of hematuria, which got worse after SBRT. The bladder of this patient received a D_{max} of 5.4 Gy_3. Only 1 of the 5 patients (20%) presenting with toxicity exceeded both the D_{max} 108 Gy_3, $D_{0.1cc}$ 108 Gy_3, and $D_{0.1cc}$ 77 Gy_3, whereas these DVH parameters were exceeded by 31 (23%), 15 (11%), and 38 (29%) of the patients who presented without late toxicity.

Received dose

Thirty-seven patients (31%), with a total of 47 ureters receiving >10 Gy, underwent an adaptive treatment. In this patient group, the median planned doses for D_{max}, $D_{0.1cc}$, and $D_{0.5cc}$ were higher than the median received doses, although the differences were not statistically significant (Table 4). To assess the impact of ureteral motion on ureter dose, the median planned dose was compared with the received dose with the SOC plan. For this comparison, no significant differences were found for the D_{max}, $D_{0.1cc}$, or $D_{0.5cc}$ (32.3 vs. 28.6 Gy_3, $P = .99$; 25.3 vs 22.6 Gy_3, $P = .46$; 14.1 vs 14.0 Gy_3, $P = .70$). The impact of the treatment plan on ureter dose was evaluated by comparing the median planned dose with the median planned adaptive dose. We found that both the median planned $D_{0.1cc}$ and $D_{0.5cc}$ were significantly higher compared with the median planned adaptive doses (25.3 vs 23.0 Gy_3, $P = .004$; 14.1 vs 13.2 Gy_3, $P < .001$) (Table 4).

Discussion

To our knowledge, this study is the first to evaluate ureteral toxicity in patients treated with SBRT for AP LN oligometastases. Jereczek-Fossa et al[17] reported 7% of patients with G ≤ 2 urinary toxicity and no G ≥ 3 toxicity using a 24 Gy in 3 fractions schedule, whereas Yang et al[9] reported 2% ureteral stenosis in patients treated with 40 Gy in 5 fractions.[17] In brachytherapy for cervical cancer, Rodriguez et al[12] found a $D_{0.1cc}$ of 77 Gy $EQD2_3$ as a significant threshold for G3 ureteral stenosis, with 28.6% of the risk for higher doses. However, only 1 of 3 patients in our study with G3 obstruction received a dose higher than 77 Gy, and 29% of patients exceeding this dose did not experience late toxicity. This finding suggests that factors beyond dose influence toxicity, even when comparison with this threshold should be made with caution because of the different radiation therapy techniques used. We also observed that none of the G3 patients had hydronephrosis at treatment onset, but all had a history of chemotherapy or surgery, indicating other factors may affect ureteral tolerance. Additionally, no significant differences were found between planned and received doses, whereas the differences in median planned $D_{0.1cc}$ and $D_{0.5cc}$ compared with the median planned adaptive doses were statistically different. This conclusion suggests that variations in treatment plans could be the primary factor influencing dose discrepancies.

Table 3 Toxicity described per case

Group	Type toxicity	Primary diagnosis	Primary treatment	Time interval treatment to SBRT (mo)	Treatment after SBRT	Time interval from SBRT to toxicity (mo)	Previous history of hydronephrosis	D_{max} ureter (Gy, EQD_2^3)	$D_{0.1cc}$ Ureter (Gy, EQD_2^3)	Caused by RT
Case 1	G3 ureteral obstruction with hydroureteronephrosis	Sigmoid carcinoma	Hemicolectomie left + Capecitabine/ bevacizumab	28	Cabecitabine and Irinotecan	15	No	120	112	Definitely
Case 2	G3 ureteral obstruction with hydroureteronephrosis	Rectosigmoid carcinoma	Resection and colo-protectomie + CAPOX	24	-	42	No	74	48	Possibly
Case 3	G3 ureteral obstruction with hydroureteronephrosis	Prostate carcinoma	Prostatectomie	46	-	54	No	97	76	Possibly
Case 4	G1 hematuria	Prostate carcinoma	Prostatectomie + RT (72 Gy in 36 fractions)	81	-	33	No	86.2	56	Possibly
Case 5	G1 ureteral obstruction	Prostate carcinoma	Prostatectomie + RT (72 Gy in 36 fractions)	117	-	10	No	74.7	66	Possibly

Abbreviations: CAPOX = capecitabine and oxaliplatin; $EQD2_3$ = equivalent dose of 2 Gy per fraction with a:b ratio of 3 Gy; G = grade; RT = radiation therapy; SBRT = stereotactic body radiation therapy.

Table 4 Median planned versus delivered ureter dose in 47 ureters

Ureter DVH parameter	Median planned dose	Median received dose	Median received dose SOC plan	Median planned adaptive dose	*P value* planned vs received	*P* value Planned vs received SOC	*P value* Planned vs planned adaptive
D_{max} in $EQD2_3$ (IQR)	32.3 Gy (17.2-87.3)	28.4 Gy (16.7-75.3)	28.6 Gy (17.5-95.2)	28.7 Gy (15.8-84.2)	.39	.99	.3
$D_{0.1}$ in $EQD2_3$ (IQR)	25.3 Gy (14.5-25.3)	22.0 Gy (14.7-58.4)	22.6 Gy (14.7-62.2)	23.0 Gy (12.3-56.3)	.23	.46	**.**004
$D_{0.5}$ in $EQD2_3$ (IQR)	14.1 Gy (10.1-37.2)	14.1 Gy (8.0-31.1)	14.0 Gy (9.0-35.3)	13.2 Gy (7.2-35.1)	.25	.70	< .001

Abbreviations: DVH = dose-volume histogram; IQR = inter quartile range; Dmax = maximum dose to the ureter; $D_{0.1}$cc = maximum dose to 0.1 cc of the ureter; $D_{0.5cc}$= maximum dose to 0.5 cc of the ureter; $EQD2_3$ = equivalent dose of 2 Gy per fraction with a:b ratio of 3 Gy; SOC = standard of care.

Tested with Wilcoxon.

Conclusions

G3 ureteral obstruction was found in 2%. Only 1 of 3 patients with G3 toxicity exceeded dose constraints, whereas 23% without toxicity did. This suggests factors beyond dose affect toxicity. The dose to the ureter was not affected by day-to-day anatomic variations of the ureter. So, contouring the ureter on the planning CT scan could be a simple tool to evaluate ureteral dose.

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