Adverse Events	Placebo		Rapamycin (0.5 mg)		Rapamycin (2.0 mg)	
	Grade 1	Grade 2	Grade 1	Grade 2	Grade 1	Grade 2
Voiding Dysfunction	0	0	8	0	4	2
Voiding/Sexual Pain or Infection	1	2	5	1	6	1
Hematuria	1	0	1	1	1	0
Flu-like/ Other Syndromes	3	0	3	3	4	1
Gastrointestinal	1	0	4	0	2	0
Paresthesia	0	1	0	0	0	0
Allergic/ Dermatologic	1	0	1	0	1	0
Pain (not urologic or gastrointestinal)	0	0	1	0	0	1
Peripheral Edema	0	0	0	0	2	1

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table 52. Quantitative summary	y of adverse event incidence among all groups

Patients could have experienced more than one adverse event (AE). There was one grade 3 AE in the placebo group (broken wrist) not related to the study drug. There were no grade 4 or 5 AEs in any group. Five placebo, three Rapamycin 0.5 mg, and zero Rapamycin 2.0 mg patients reported no AEs. Grade 1 indicates mild (such as minimal hematuria or urinary frequency that resolved either without treatment or with temporary changes of behavior such as drinking more fluid or reducing activity); grade 2, moderate (such as symptomatic bacteriuria treated with an oral antibiotic); grade 3, severe (such as hematuria which required hospitalization for catheter irrigation); grade 4, life threatening/disabling; and grade 5, death.