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Six- Month Report Assessing the Feasibility and Effectiveness of Amniotic Bladder Therapy in Patients with Chronic Radiation Cystitis

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Introduction: In view of the pathophysiology of chronic radiation cystitis (CRC) that is mainly caused by activation of an inflammatory cascade leading to chronic inflammation, vascular damage and fibrosis, amniotic membrane (AM) based therapy has emerged as a potential therapeutic approach for radiation-induced tissue injury due to its immunomodulatory, vasculogenic and anti-fibrotic properties. We have previously reported that amniotic bladder therapy (ABT) provides symptomatic improvement in refractory CRC patients for up to 3 months. Herein, we evaluated the durability of ABT up to 6 months.

Methods: CRC patients recalcitrant to multiple therapies were eligible for the study and received intra-detrusor injections under general anesthesia of reconstituted 100mg micronized AM. The Interstitial Cystitis Symptom Index (ICSI), Interstitial Cystitis Problem Index (ICPI), Bladder Pain/ Interstitial Cystitis Symptom Score (BPIC-SS), Overactive Bladder (OAB) Assessment Tool, SF-12 Health Survey were repeated at pre-op and up to 36 weeks post-injection. Cystoscopy and uroflow were done pre-injection, 12, 24, and 36 weeks.

Results: Five consecutive patients (average age: 64 ± 20 years) exhibited a progressive improvement from their baseline lower urinary tract symptoms to 20 weeks (Figure 1). At 24 weeks, the improvement was maintained in four of the patients, however diminishing benefit of ABT was seen at 36 weeks. This coincided with an initial improvement in uroflow assessment (Table 2). One patient's symptoms rebounded at 24 weeks and worsened at 36 weeks.

Conclusion: This data suggests most CRC patients have durable benefit after ABT, however some patients may have symptoms rebound at 36 weeks.

Figure 1. Average Lower Urinary Tract Symptom Questionnaire Scores before and after ABT.

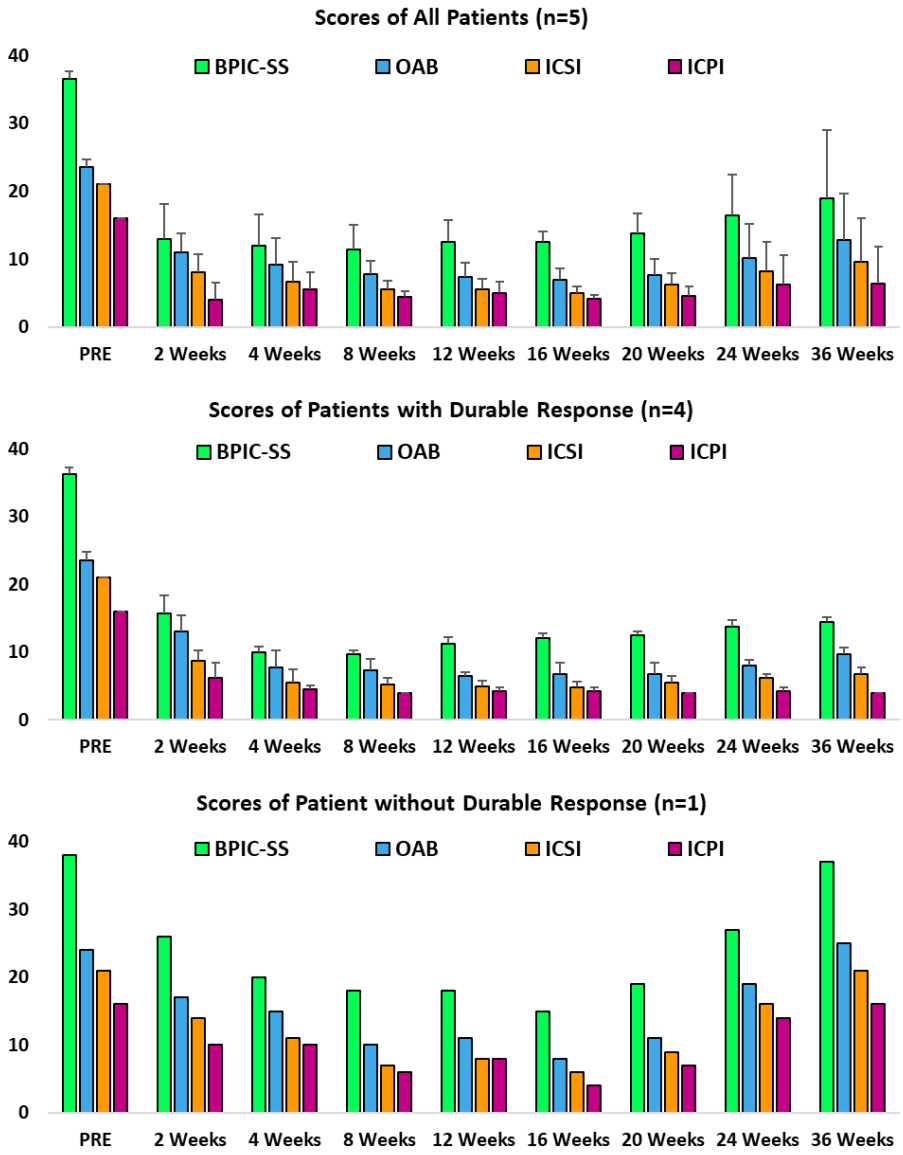

Table 2. Uroflow parameters at baseline, 3 months, 6 months, and 9 months post-injection

Patient Number	Maximum Flow Rate (mL/sec)				Average Flow Rate (mL/sec)				Voiding time (sec)				Voided volume (mL)			
	Baseline	3 Months	6 Months	9 months	Baseline	3 Months	6 Months	9 Months	Baseline	3 Months	6 Months	9 Months	Baseline	3 Months	6 Months	9 Months
#1	20.2	21.8	20.1	19.8	11.8	12.3	12.2	12.1	24	35	34	38	120	300	290	310
#2	21.4	19.9	22.4	21.5	11.4	12.7	12.4	12.2	22	42	40	40	140	345	310	300
#3	23	24.5	23.1	22.2	10.9	12.2	12.1	12.1	25	41	43	38	125	360	300	320
#4	21	23.6	20	21.4	11	13.4	10.9	12.1	22	40	23	19	90	230	100	100
#5	22.2	25.5	24.2	23.1	13	12.8	12.6	13.2	29	45	40	39	145	380	320	310