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A Pilot Study Assessing the Efficacy of Amniotic Bladder Therapy in Spinal Cord Injury Patients with Female Sexual Dysfunction

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<u>Title:</u> A Pilot Study Assessing the Efficacy of Amniotic Bladder Therapy in Spinal Cord Injury Patients with Female Sexual Dysfunction

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<u>Introduction and Objectives:</u> Female sexual dysfunction (FSD) following spinal cord injury (SCI) presents with abnormalities in sexual desire, arousal, orgasm, pain, distress, and dissatisfaction. FSD negatively impacts quality of life and is often refractory to available treatment options. Previously, we reported preliminary benefits of intradetrusor micronized amniotic membrane (AM) on detrusor dysfunction following SCI. In this study, we evaluated the effect of intra-detrusor micronized AM injection on FSD symptoms in SCI patients using the multi-domain female sexual function index (FSFI) and pain visual analog scale (VAS).

<u>Methods</u>: Five SCI females (mean age: 32 ± 12 years) with FSD recalcitrant to multiple therapies received intradetrusor injections under general anesthesia of reconstituted 100mg micronized AM. The FSFI questionnaire and pain VAS were obtained preoperatively and at 4, 8, 12, 24, and 36-weeks post-injection.

Results: All five patients exhibited an improvement from baseline FSFI at 12 weeks. All patients relapsed at 24 to 36 weeks. Pain (VAS) associated with intercourse decreased from 8.4 ± 0.9 at baseline to 7.1 ± 0.8 at 4 weeks, 6.7 ± 1.0 at 8 weeks, 6.3 ± 1.2 at 12 weeks, 6.2 ± 0.6 at 24 weeks and then increased to 7.9 ± 0.6 at 36 weeks. No adverse events arose during the study.

<u>Conclusion:</u> ABT therapy in SCI females with severe FSD symptoms holds potential promise, although all patients experience symptomatic relapse at 24 to 36 weeks post-injection. More research is needed to better understand the mechanism through which ABT treats these complex sexual disorders.

Keywords: Amniotic bladder therapy (ABT), female sexual dysfunction (FSD), spinal cord injury (SCI), amniotic membrane (AM), female sexual function index (FSFI), visual analog scale (VAS)

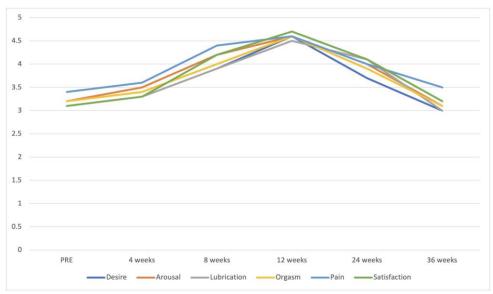


Figure 1. Average FSFI scores before and after ABT