Retrospective Evaluation of the Efficacy and Safety of Micronized Adipose Tissue Obtained with the Matrigen Device in the Treatment of Patients with Interstitial Cystitis

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1. Introduction and Rationale

Interstitial cystitis (IC) is a chronic, multifactorial urological condition characterized by bladder pain, pressure, and persistent urinary symptoms. Its complex and not yet fully understood pathophysiology involves autoimmune mechanisms, dysfunction of the urothelial barrier, alterations in sensory neural pathways, muscle abnormalities, and degradation of subepithelial connective tissue. Epidemiological data show a significant prevalence, often affecting adults of working age and disproportionately impacting women, with a major effect on quality of life. Conventional treatments (including behavioral modifications, pharmacotherapy, and invasive procedures) frequently fail to provide lasting relief, underscoring the need for alternative therapeutic strategies. Regenerative medicine has emerged as a promising field capable of targeting the underlying pathophysiology of chronic diseases. Among its tools, mesenchymal stromal cells (MSCs) derived from adipose tissue are of particular interest due to their availability, regenerative potential, and immunomodulatory properties. Through paracrine signaling, secretion of trophic factors, soluble mediators, and exosomes, MSCs may support tissue repair and reduce inflammation. Micronized adipose tissue (MAT), obtained through minimal manipulation using intraoperative techniques, provides a scaffold-rich environment that preserves stromal cell integrity and enhances therapeutic potential. The Matrigen device allows the processing of autologous fat into MAT that meets the European Regulation (EC) No. 1394/2007 criteria for “non-substantial manipulation.” Preclinical and early clinical studies have highlighted the potential of adipose-derived MSCs in treating IC/bladder pain syndrome (Wen et al., 2021; Dayem et al., 2022) and urinary incontinence (Garcia-Arranz et al., 2019), showing both regenerative and anti-inflammatory effects.

2. Objective

To retrospectively evaluate the safety and effectiveness of micronized adipose tissue obtained with the Matrigen device in improving symptoms and urodynamic outcomes in patients previously treated for interstitial cystitis at our institution.

3. Study Design

This is a **retrospective observational cohort study** involving **20 adult patients** diagnosed with interstitial cystitis, treated between 04 April 2024 and 08 October 2024 at our center with intraoperative infiltration of micronized adipose tissue obtained using the Matrigen system. Clinical, procedural, and follow-up data were collected from electronic medical records and anonymized prior to analysis.

4. Endpoints

Primary Endpoints

- Urodynamic testing results at baseline and 6 months post-treatment
- Cystoscopic findings at baseline and 6 months post-treatment

Secondary Endpoints

- Patient-reported pain and symptom scores using VAS, GLOBE SF-36, O’Leary IC Symptom/Problem Index, and MOS Sexual Functioning Scale at baseline and 1, 2, and 3 months post-treatment
- Physical examination at baseline and 3 months post-treatment

- Evaluation of bladder capacity, detrusor pressure, compliance, urinary flow, and post-void residual volume at baseline and 6 months
- Cystoscopic evaluation of mucosal condition and lesion status at baseline and 6 months

5. Inclusion Criteria

- Adult patients (≥18 years) diagnosed with interstitial cystitis
- History of treatment with micronized adipose tissue using the Matrigen device
- Complete clinical documentation, including surgical and follow-up data
- Informed consent previously obtained for data use in clinical research

6. Exclusion Criteria

- Active urinary tract infections at time of treatment
- Corticosteroid therapy within 3 months prior to the intervention
- History of tuberculosis, malignancy, or severe systemic disease
- Pregnancy or lactation at the time of the procedure

7. Clinical Procedures

7.1 Lipoaspiration and MAT Preparation

During the same surgical session, subcutaneous adipose tissue (approximately 50 mL) was harvested from the abdominal or proximal thigh regions under local anesthesia (500 mL saline + 2 vials of 2% Marcaine or Lidocaine + 1 vial of epinephrine 1 mg/mL). Harvesting was performed with a 13G cannula connected to a syringe to minimize cellular damage. The lipoaspirate was processed using the Matrigen device according to manufacturer instructions to obtain micronized adipose tissue (MAT).

7.2 MAT Injection

The prepared MAT was injected into the bladder wall under direct visualization using a 5 Fr injection needle during urethrocystoscopy. The bladder was divided into four quadrants, with 5–6 injections per quadrant (0.2–0.3 mL each) placed 0.5 mm submucosally to ensure even distribution.

In patients with Hunner lesions, injections were targeted circumferentially around each lesion, spaced at least 1 cm apart, using the same volume and depth to optimize local regenerative effects.

8. Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki and relevant ethical standards. Institutional review board (IRB) approval was obtained. All patients had previously provided informed consent for clinical data use.

9. References

1. Dayem AA, et al. *New therapeutic approach with extracellular vesicles from stem cells for interstitial cystitis/bladder pain syndrome.* BMB Rep. 2022;55(5):205–212.
2. Garcia-Arranz M, et al. *Two phase I/II clinical trials for the treatment of urinary incontinence with autologous mesenchymal stem cells.* Stem Cells Transl Med. 2020;9(12):1500–1508.

3. Wen C, et al. *Roles of mesenchymal stem cells and exosomes in interstitial cystitis/bladder pain syndrome.* J Cell Mol Med. 2022;26(3):624–635.