STEM CELLS AND INTERSTITIAL CYSTITIS CHRONIC BLADDER PAIN

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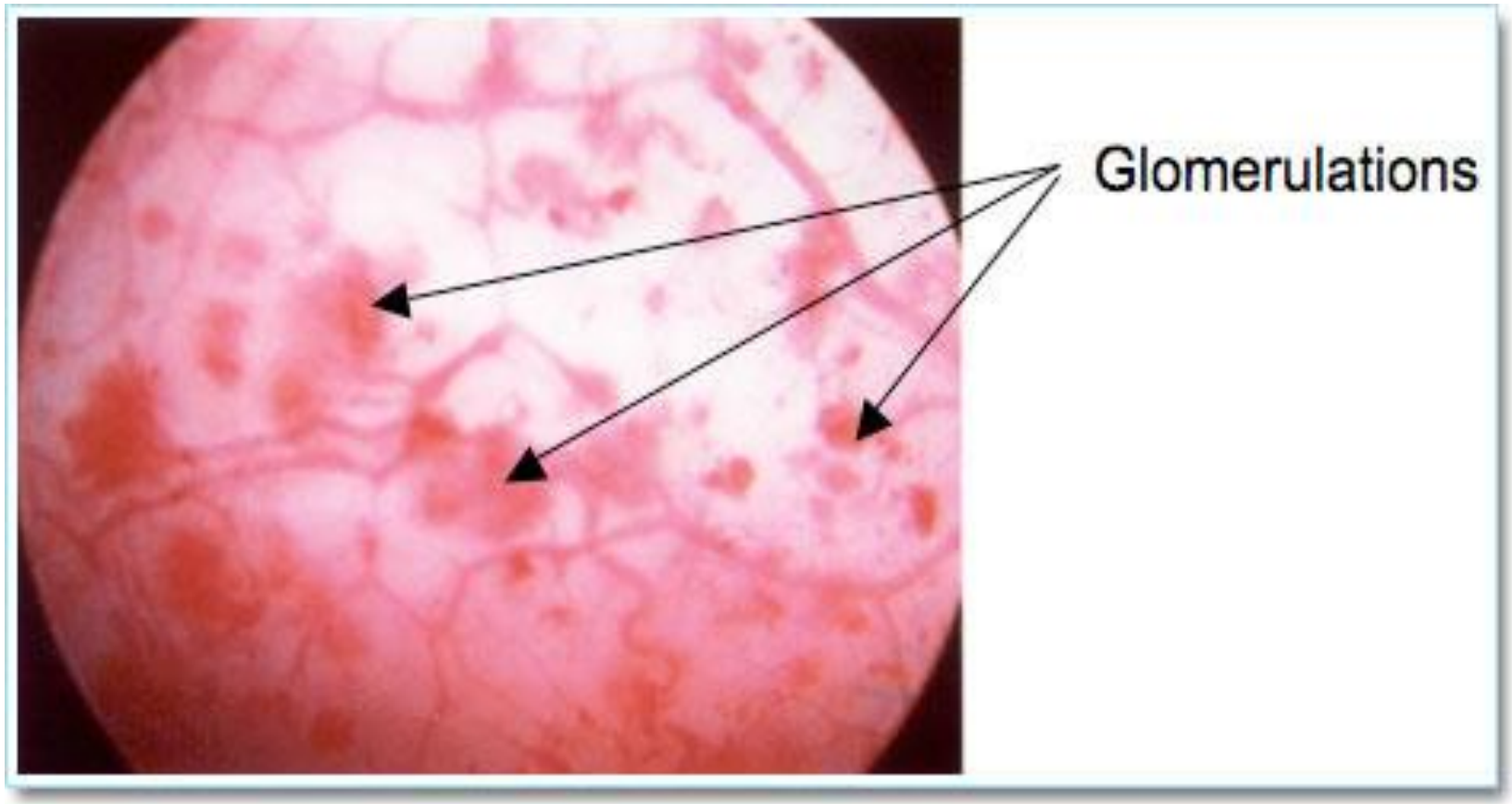
UNDERSTANDING CELL THERAPY AS A TREATMENT FOR CHRONIC BLADDER PAIN

- **IC affects 4 to 12 million people with women affected ten times more than men.**
- **Many of the current IC/PBS treatments clinically focus on masking symptoms of pain, contributing to patient reliance on narcotics.**
- **IC patients are known to endure multiple invasive medical and surgical procedures.**
- **There appear to be few treatment options for associated with high levels of evidence of efficacy.**
- **IC is often associated with depression, suicidal ideation, and the adverse financial effects of chronic pain and disability.**

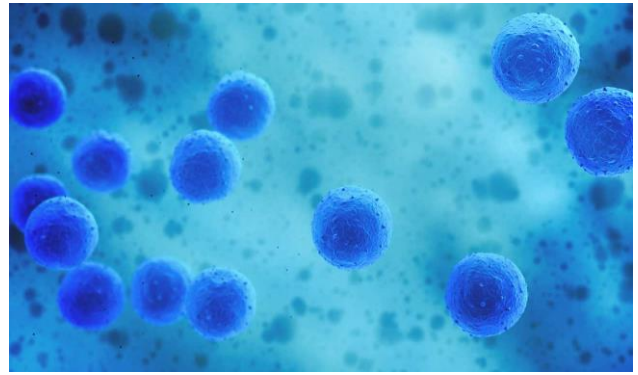
PATIENTS WITH IC HAVE DEFICIENT BLADDER WALL PROTECTIVE GLYCOSAMINOCLYCAN LAYER



THE GOAL OF OUR PILOT STUDY

Since Interstitial Cystitis/Painful Bladder Syndrome has degenerative aspects, auto-immune features, and is clinically associated with significant pain and inflammation, an investigation is indicated to determine whether autologous (SVF-stem cells from fat) can mitigate IC symptoms in 109 individuals.

What is a Stem Cell?



- These are repair cells that are "looking for a job"
- Stem cells can proliferate (replicate into more stem cells)
- Stem cells can differentiate (turn into other specific cells or tissues)
- These actions are based on signals (Growth Factors) from damaged tissues
- Adult stem cells are abundant in fat

What Is Regenerative Medicine?

- Uses stem cells to repair or replace damaged and defective tissues and organs.

- Stem Cells create living and functional tissues (not scar).

BIOLOGIC SURVIVAL DEPENDS ON TWO SYSTEMS

WHITE BLOOD CELLS

DEFENSE AGAINST DAMAGE- THIS IS OUR IMMUNE SYSTEMS

STEM CELLS

HEALING FROM DAMAGE- THIS IS OUR REPAIR SYSTEMS

ENEMIES OF SURVIVAL ON PLANET EARTH

injuries and accidents
radiation
surgery
violence
infection
drugs and medications
behavioral (tobacco and vaping),
overuse of body
genetic conditions
toxins
cancer
Aging
Immune system treachery

How Do Stem Cells Heal?

HOMING PROPERTY-

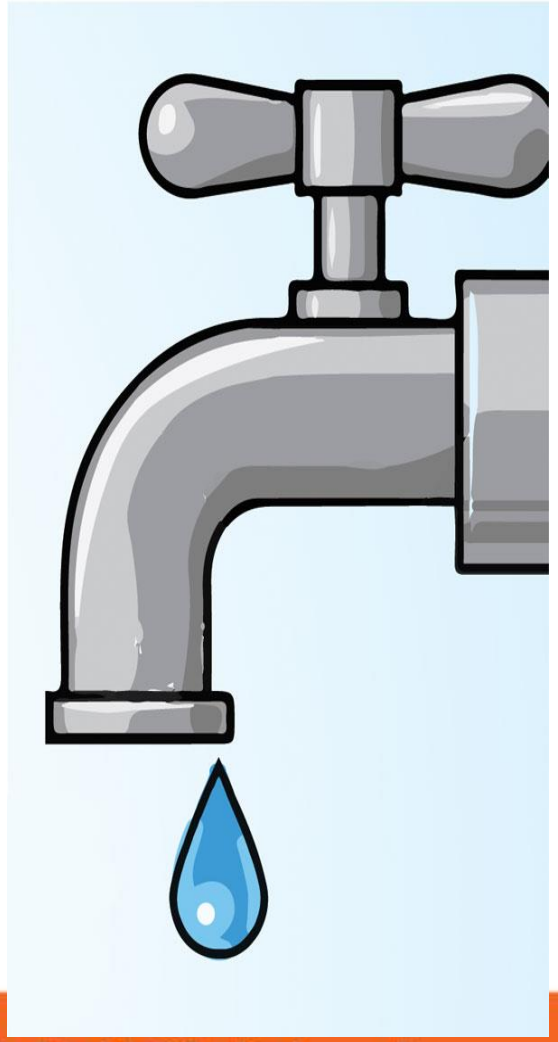
Cells respond to appropriate biochemical signals released from tissue injury, inflammation, degeneration, disease, or cell death.

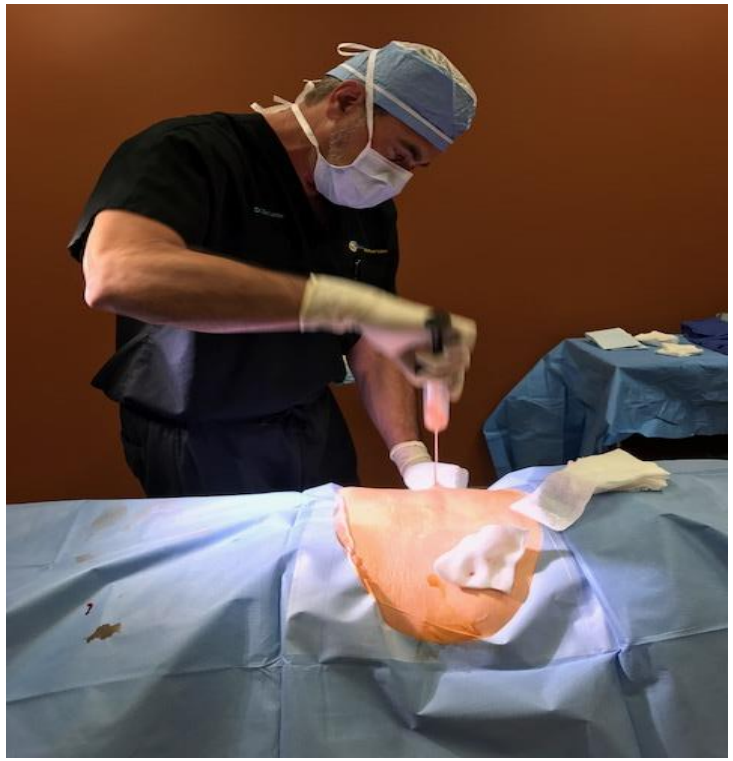
ACTIVATION PROPERTY-

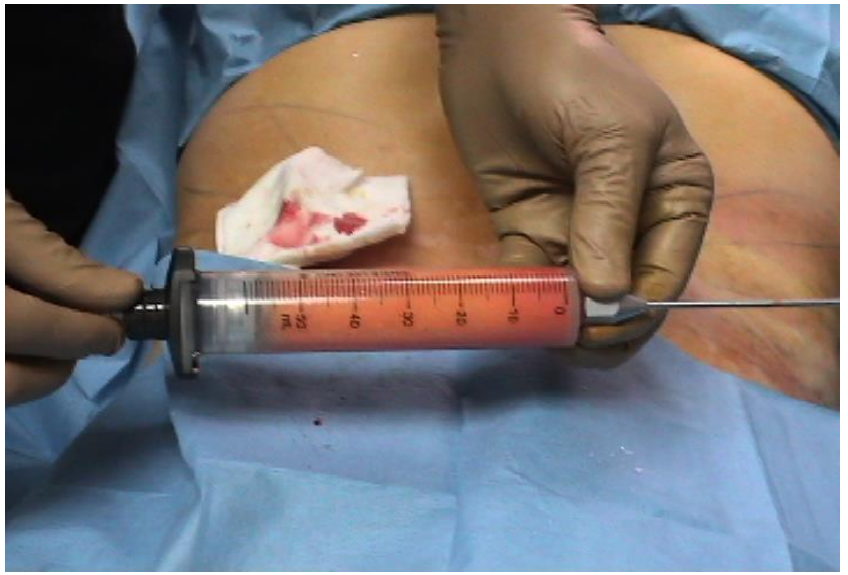
Cells promote signal mediated effects to repair damaged target tissue. Cells may also form new cells and tissues.

EFFECTS OF STEM CELLS ON THE BODY

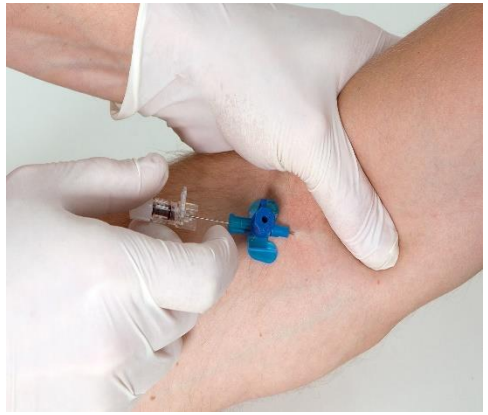
- **ANTI-INFLAMMATORY**
- **TISSUE REPAIR AND REGENERATION (HEALING)**
- **IMMUNO-MODULATION**
- **DECREASE IN OVER-STIMULATION OF AFFERENT PAIN C FIBERS**

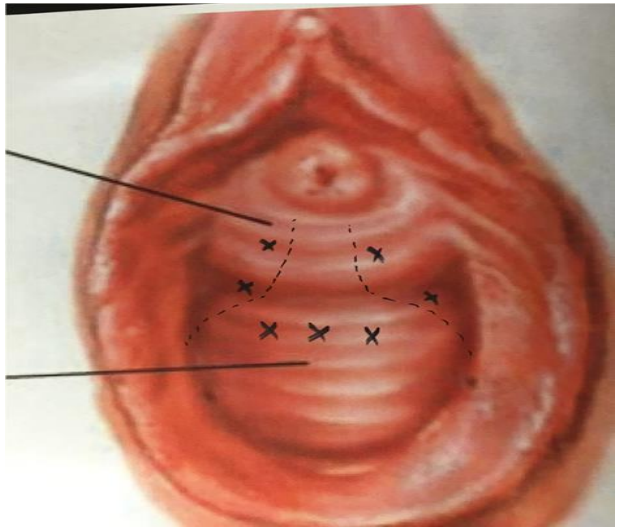


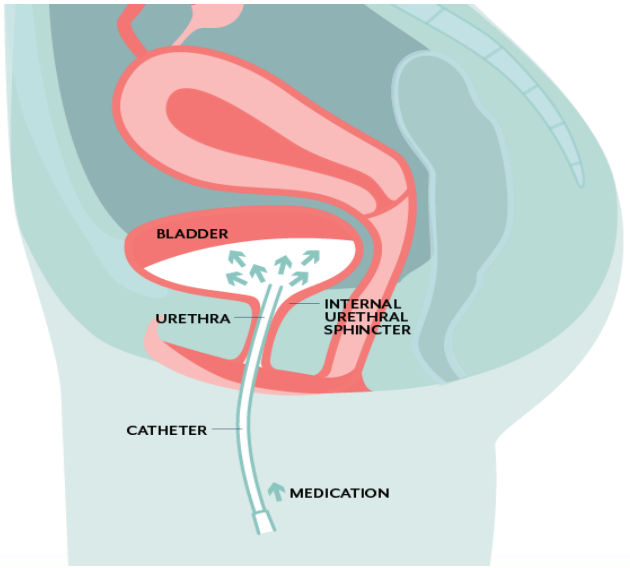




Interstitial Cystitis 3 pronged attack







91 women and 18 men diagnosed with IC were enrolled in the IRB approved research study.

The study was patient funded.

18 different facilities from around the world.

Pain scores and O'Leary Sant with PUF scores were measured

No serious side effects noted.

This 18 center study is the largest human study to date using cell therapy to treat IC and is the first to use autologous stem cells for the mitigation of IC.

RESULTS AFTER 1 YEAR

When asked whether their condition was improved by the treatment, results showed that 78 out of 109 patients (71.5%) reported improvement in their IC.

Visual analog pain scores decreased (5.14 baseline to 3.67, $p<.05$).

(PUF) Pelvic pain scores demonstrated that symptom and bother scores all improved

The O'Leary-Sant scores decreased from baseline 22.59 to 14.76 ($p<.05$).

There were no significant differences between men and women on the O'Leary-Sant scores.

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Personal cell therapy for interstitial cystitis with autologous stromal vascular fraction stem cells

Elliot B. Lander, Mark H. Berman and Jackie R. See

Abstract

Background: The objective of this study was to evaluate whether autologous stem-cell-based therapy may mitigate the symptoms of interstitial cystitis.

Methods: Stromal vascular fraction (SVF) rich in stem cells and derived from autologous adipose tissue was deployed into 109 men and women with interstitial cystitis/painful bladder syndrome as a surgical procedure. This stem-cell-rich biologic product was injected both systemically and regionally into pelvic floor targets. Patients were queried about quality of life and symptom and bother subjective outcomes tests every 3 months for 2 years.

Results: A total of 78 patients reported a positive response at 1 year. Symptom and bother metrics were statistically improved at 1 year. There were minimal adverse events associated with the harvesting, procurement, and clinical deployment of SVF.

Conclusion: Interstitial cystitis is a complex clinical problem that is known for its resistance to conventional therapies. SVF as an autologous personalized regenerative strategy shows good safety and efficacy and may potentially have a role in the mitigation of interstitial cystitis.

Keywords: autologous stem cells, chronic pelvic pain, interstitial cystitis, stromal vascular fraction

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Introduction

Surgically procured stromal vascular fraction (SVF) derived at the point of care is an autologous biologic product derived from the enzymatic digestion of lipo-aspirate and is widely being investigated for its regenerative, immunomodulatory, antinociceptive, and anti-inflammatory properties. As interstitial cystitis(IC)/painful bladder syndrome (PBS) has degenerative aspects, autoimmune features, and is clinically associated with significant pain and inflammation, an investigation is indicated to determine whether autologous SVF as a form of cell therapy can mitigate IC symptoms. This prospective study consists of a pilot series of 109 IC patients who underwent treatment with combined regional and systemic deployment of autologous SVF and were assessed with self-reported subjective outcomes testing to evaluate safety and clinical efficacy.

Methods

A total of 109 patients (aged 52–70, mean 61) consisting of 91 women and 18 men, all of whom were diagnosed by their primary urologist with IC were enrolled in this study. The study was approved by an IRB (International Cell Surgical Society IRB) and patient funded. Patients underwent basic urologic evaluation with records review and signed IRB approved consents for the investigational deployment of autologous SVF. Most patients in the study had a history of receiving multiple various medications and procedural interventions with generally limited clinical responses. All patients were maintained on their usual and customary medications and no new medications for IC were initiated during the first 180 days of the study. Predeployment cystoscopy was not performed to stratify patients based on the presence or absence of Hunner's ulcers and

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71.5% of the patients reported improvement in quality of life

Any Questions?

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