IVYSPRING INTERNATIONAL PUBLISHER

International Journal of Medical Sciences

2018; 15(3): 195-204. doi: 10.7150/ijms.22130

Review

Cell Therapy Clinical Trials for Stress Urinary Incontinence: Current Status and Perspectives

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Received: 2017.07.28; Accepted: 2017.11.22; Published: 2018.01.01

Abstract

Stress urinary incontinence (SUI) affects 200 million people worldwide. Standard therapies often provide symptomatic relief, but without targeting the underlying etiology, and show tremendous patient-to-patient variability, limited success and complications associated with the procedures. We review in this article the latest clinical trials performed to treat SUI using cell-based therapies. These therapies, despite typically including only a small number of patients and short term evaluation of results, have proven to be feasible and safe. However, there is not yet a consensus for the best cell source to be used to treat SUI and not all patients may be suitable for these therapies. Therefore, more clinical trials should be promoted recruiting large number of patients and evaluating long term results.

Key words: Clinical trial, Cell therapy, Stress Urinary incontinence, Stem cells

Introduction

Urinary incontinence (UI) is an extremely common urological disorder that affects more than 200 million people worldwide [1]. Approximately, 17 million people suffer from this condition in the United States [2] with an annual direct cost estimated at more than $16 billion [3]. Based on the International Continence Society there are three UI subtypes: urgency UI (UUI), stress UI (SUI), and mixed UI (MUI). SUI, defined as the involuntary leakage of urine in the absence of a detrusor contraction, generally due to the weakness of the urethral sphincter and pelvic floor [4], has been reported as the most common type of UI [3]. SUI occurs three times more often in women than in men [5]. The prevalence of SUI increases with age. For women, both pregnancy and vaginal delivery are risk factors for urinary sphincter injury. In men, SUI is also a common problem caused by injury to the neurovascular bundles and fasciae during radical prostatectomy [6]. Smoking, obesity and constipation contribute to SUI as well [7]. The severity of SUI influences the quality of life and medical treatment decisions [8]. Today, several SUI non-surgical and surgical treatment options are available. Mild-moderate SUI can be treated with pelvic floor muscle training, biofeedback training and/or electrical stimulation. Pharmacologic therapy for SUI such as Duloxetine hydrochloride, a selective reuptake inhibitor of serotonin and norepinephrine, was approved by the regulatory agency in the European Union in 2004, while it failed approval by the Food and Drug Administration in the United States due to security concerns [9]. Other pharmacologic treatments like alpha1-adrenoceptor agonists are being abandoned due to side effects [10]. For severe SUI, surgical interventions have been the most recommended medical treatment option. Urethral bulking agents including polytetrafluoroethylene, silicone, bovine collagen, carbon beads and autologous ear chondrocytes are the least invasive surgical intervention; however, its disadvantages include lower cure rate and complications, such as urinary tract infection, chronic inflammatory reactions, severe voiding dys-