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Urogynaecologia
Urogynaecologia 2026; 38:374
doi:10.4081/uij.2026.374

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Adipose-derived stem cells for female stress urinary incontinence: a systematic review of clinical outcomes and safety

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Abstract

Stress urinary incontinence (SUI) is defined as the involuntary leakage of urine during effort or physical exertion. As an alternative therapy, tissue engineering is one of the attractive options for treating SUI. Therefore, this systematic review aims to determine the impact of autologous adipose-derived stem cells (ASCs) for female SUI. This systematic review was conducted in accordance with PRISMA guidelines. A comprehensive electronic literature search was performed in PubMed, the Cochrane Library, ScienceDirect, and ProQuest. We included women with especially mild-to-moderate SUI undergoing ASCs therapy. The primary outcome was improvement in SUI symptoms, assessed using objective and subjective measurement. The exclusion criteria included non-human or purely laboratory-based studies, studies that did not include female participants with SUI, studies that did not evaluate ASCs, and records available only as abstracts or conference proceedings without sufficient data for extraction, were not available as full-text articles, or were not published in English. The database search yielded a total of 1093 records, and finally only 4 studies were included. All included studies were early-phase (phase I or II) clinical trials. For the objective outcomes, all studies depicted the improvement after administration of the ASCs, although it could not be determined statistically due to the small sample size. Meanwhile, subjective outcomes regarding symptoms and QoL showed statistically inconsistent improvements; however, patients reported feeling better based on subjective measurement through various SUI questionnaires. Periurethral injection of ASCs represents a promising regenerative therapy for SUI, with encouraging functional outcomes and acceptable safety.

Key words: stress urinary incontinence, stem cell, adipose-derived stem cell, quality of life.

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Introduction

Stress urinary incontinence (SUI) is defined as involuntary leakage of urine on effort or physical exertion such as sporting activities, sneezing, coughing, or laughing.[1] In the world, the prevalence of urinary incontinence (UI) was 25.7% [95% confidence interval (CI) 22.3-29.5%), with 12.6% (95% CI 10.3-15.4%) of SUI.[2] In Indonesia, a study conducted in Pekanbaru reported that the prevalence of postpartum SUI was around 8.8%.[3] Although it does not impact mortality, SUI is associated with significant impairment in quality of life (QoL), self-esteem, and social engagement.[4]

The conservative management for SUI consists of pelvic floor physical therapy, biofeedback, pessaries, and observational management.[5] Meanwhile, the gold standard treatment for surgical therapy is mid-urethral slings (MUSs), including retropubic slings and trans-obturator approaches, with high cure rates up to 91% objective and very low surgical risk.[6] However, the rate of complications related to mesh erosion/ irritation, unresponsive to operative treatment, and patients who are not suitable for surgical procedures make the problem of this treatment choice.[7] Despite high cure rates of MUSs, concerns regarding complications and patient preference have driven the search for minimally invasive regenerative therapies. As an alternative therapy, tissue engineering, such as skeletal muscle-derived stem cells (SkMSCs), mesenchymal stem cells [derived from bone marrow (BMSCs) or adipose stem cells (ASCs)], is one of the attractive options for treating SUI. Compared with ASCs, the difficulty in obtaining SkMSCs and BMSCs in large quantities and the isolation site injury become another issue in developing these stem cells.[8] Adipose-derived stem cells are also multipotent and capable of differentiating into myogenic, neurogenic, and angiogenic cells at the site of implantation. Previous studies showed promising effects in treating SUI and improving urethral function.[9,10] Unfortunately, studies investigating the effect of ASCs in SUI remain scarce. Therefore, this systematic review aims to determine the impact of autologous ASCs for female SUI.

Methods

Searching strategy and study selection

This systematic review was conducted in accordance with the PRISMA guidelines.[11] A comprehensive electronic literature search was performed in PubMed, the Cochrane Library,

ScienceDirect, and ProQuest to identify studies evaluating ASC therapy for female SUI (*Supplementary Material - Appendix 1*). Searching was conducted up to 10th March 2026, with no lower date limit applied. In addition, the reference lists of potentially relevant articles were manually screened to identify any additional eligible studies. All retrieved records were exported into a reference manager and duplicates were removed. Two reviewers (RSMSS and RST) independently screened titles and abstracts for eligibility. Full texts of potentially relevant articles were then obtained and assessed independently by the same reviewers. Discrepancies at any stage were resolved through discussion, consensus, and expert opinion (MRAS or EDA).

Eligibility criteria

Eligibility criteria were defined using the patients, intervention, comparison, and outcome (PICO) framework. The population consisted of women with SUI, specifically those with mild-to-moderate severity, who underwent ASC therapy. Studies without a comparator group were eligible. The primary outcome was improvement in SUI symptoms, assessed using objective measures (*e.g.*, pad tests, cough stress test) and/or validated subjective patient-reported outcome measures [*e.g.*, International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF), Urinary Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), symptom severity indices], at any follow-up time point. Secondary outcomes included urodynamic parameters, imaging-based outcomes when performed, and adverse events.

Studies were excluded if they were non-human or purely laboratory-based, did not include SUI women participants, did not evaluate an ASC intervention, were available only as abstracts or conference proceedings without sufficient data for extraction, were not available as full-text articles, or were not published in English.

Definition of stress urinary incontinence severity

When explicitly reported, SUI severity was classified using the definitions provided by each study (*e.g.*, pad test). The International Continence Society (ICS) defined values for the 1-hour pad test where 1 to 10 grams was mild, 11 to 50 grams as moderate, and >50 grams as severe; meanwhile, for the 24-hour pad test, <4 grams was normal, 4 to 20 grams was mild, 21 to 74 grams was moderate, and ≥75 grams was severe.[12] Another classification of SUI based on Stamey was defined as stage I as urinary leak during coughing, sneezing, and lifting heavy objects; stage II as less exhaustive activities such as walking and switching from sitting to standing; stage III as without physical strain.[13] If severity thresholds were not reported or could not be mapped reliably, severity was recorded as "not reported", and the study remained eligible if participants were described as having SUI and met other inclusion criteria.

Data extraction

Data extraction followed recommendations from the Cochrane Handbook for Systematic Reviews of Interventions. Two reviewers independently extracted data using a standardized extraction form, with disagreements resolved by consensus. Extracted information included study characteristics (first author, year of publication, country, recruitment period when available, study design, sample size, and follow-up duration), and participant characteristics (age, incontinence subtype such as SUI or mixed urinary incontinence (MUI), symptom duration, and baseline severity classification when available). Outcomes were extracted at all reported time points, including objective measures (pad test results, cough stress test), patient-reported outcomes [*e.g.*, ICIQ-SF, UDI-6, IIQ-7, visual analog scale (VAS), and other reported instruments], urodynamic findings, imaging outcomes (*e.g.*, magnetic resonance imaging-derived periurethral changes), and safety outcomes including adverse events and complications. Level of evidence for each included study was classified using the Oxford Centre for Evidence-Based Medicine criteria.

Quality assessment

Methodological quality was assessed using tools appropriate to each study design. Case series and single-arm interventional studies were appraised using the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Case Series.[12] If comparative observational studies (cohort or case-control) were identified, the Newcastle-Ottawa Scale was planned for use.[14] For randomized trials, the Cochrane Risk of Bias 2 tool was planned.[15] Two reviewers independently performed the appraisal, with discrepancies resolved by consensus or third-reviewer adjudication.

Statistical analysis

Study and participant characteristics were summarized using counts/percentages for categorical variables and means (standard deviations) or medians (interquartile ranges) for continuous variables, depending on reporting in the original studies. Outcome data were summarized as absolute values at baseline and follow-up and, where available, as changes from baseline. When results were presented only graphically or without extractable numeric data, outcomes were narratively summarized.

Results

Searching results and included studies

The database search yielded a total of 1093 records, including 290 from PubMed, 17 from the Cochrane Library, 90 from ProQuest, and 696 from ScienceDirect. One additional record was identified through handsearching of reference lists, resulting in 1094 records identified overall. After removing duplicates, title and abstract screening, and full-text eligibility assessment, 4 studies met the inclusion criteria and were included in this systematic review. All included studies were early-phase, nonrandomized, single-arm clinical investigations providing level IV evidence. The studies were conducted across 4 countries, with one study each from Finland, Spain, Iran, and Belgium. Follow-up duration ranged from 6 to 12 months. Figure 1 illustrates the progression of the literature search process.

Quality assessment

Using the JBI Critical Appraisal Checklist for Case Series, the included studies generally demonstrated clear inclusion criteria and valid, standardized outcome assessment for SUI, with follow-up outcomes clearly reported in all 4 studies. Key methodological limitations across the body of evidence were uncertain consecutive and complete inclusion, as participant selection processes were not consistently described, which was common in small early-phase single-arm studies. In addition, statistical analysis was clearly described and appropriate in Garcia-Arranz *et al.*,[16] Arjmand *et al.*,[17] and Maene *et al.*,[18] whereas Kuismanen *et al.*[19] primarily reported descriptive results. Overall, the evidence is best interpreted as feasibility- and safety-focused with a moderate risk of bias,

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mainly driven by selection/representativeness concerns and lack of comparators rather than systematic outcome-measurement problems. Table 1 provides the detailed quality assessment of the included studies.

Participants

Among the 4 included studies, 35 women received ASC therapy for SUI, with individual study sample sizes ranging from 5 to 10 participants. The overall age range reported was from 45 to 81 years old. Two of 4 studies involved MUI women; however, they also included the SUI population. Symptom duration was variably reported, with one study requiring at least 12 months of symptoms, one reporting a duration range of 6 to 12 months, and one enrolling participants with a longer history ranging from 2 to more than 5 years. Detailed characteristics of included studies were presented in Table 2.

Outcomes

Objective continence outcomes: cough stress test and pad testing

Objective continence outcomes were generally improved following ASCs therapy, although the durability of effect was varied. Cough stress test was reported in 3 studies. Kuismanen *et al.*[19] reported that the cough test became negative in 1 of 5 women at 6 months and in 3 of 5 women at 12 months. Garcia-Arranz *et al.*[16] reported that cough leakage was negative in 6 of 10 women at the end of follow-up. Maene *et al.*[18] observed that cough test negativity peaked early, which 8 of 10 women tested negative at 3 months, but it declined over time, with 6 of 10 becoming negative at 6 months and the others at 9 months.

Pad test was reported in 3 studies and consistently suggested reduced leakage after treatment. Kuismanen *et al.*[19] reported that the median 24-hour pad-test weight decreased from 10 g at baseline to 4 g at 12 months. Garcia-Arranz *et al.*[16] reported a reduction in pad-test weight from a baseline median of 15.5 g to an endline median of 5.5 g. Using the authors' response definition (>50% reduction), 5 of 10 women met the response criterion by 3 months. Arjmand *et al.*[17] reported a statistically significant improvement in 24-hour pad weight over follow-up, with the greatest reduction occurring early after treatment; however, numerical pad weights were presented graphically rather than tabulated.

Patient-reported outcomes: symptoms and quality of life

Patient-reported outcomes suggested symptom improvement in several studies, although findings were not uniform across instruments. Kuismanen *et al.*[19] reported overall improvement in symptom burden and QoL, with all participants demonstrating improvement on a VAS and most of them showing improvement on condition-specific questionnaires; however, not all instruments were improved in each patient. Garcia-Arranz *et al.*[16] collected ICIQ-SF and SF-36 longitudinally but reported no statistically significant changes during follow-up. Arjmand *et al.*[17] reported significant improvement in ICIQ-SF over time, with the most pronounced improvement occurring early after therapy. Maene *et al.*[18] reported significant improvements in ICIQ-SF subscores and total

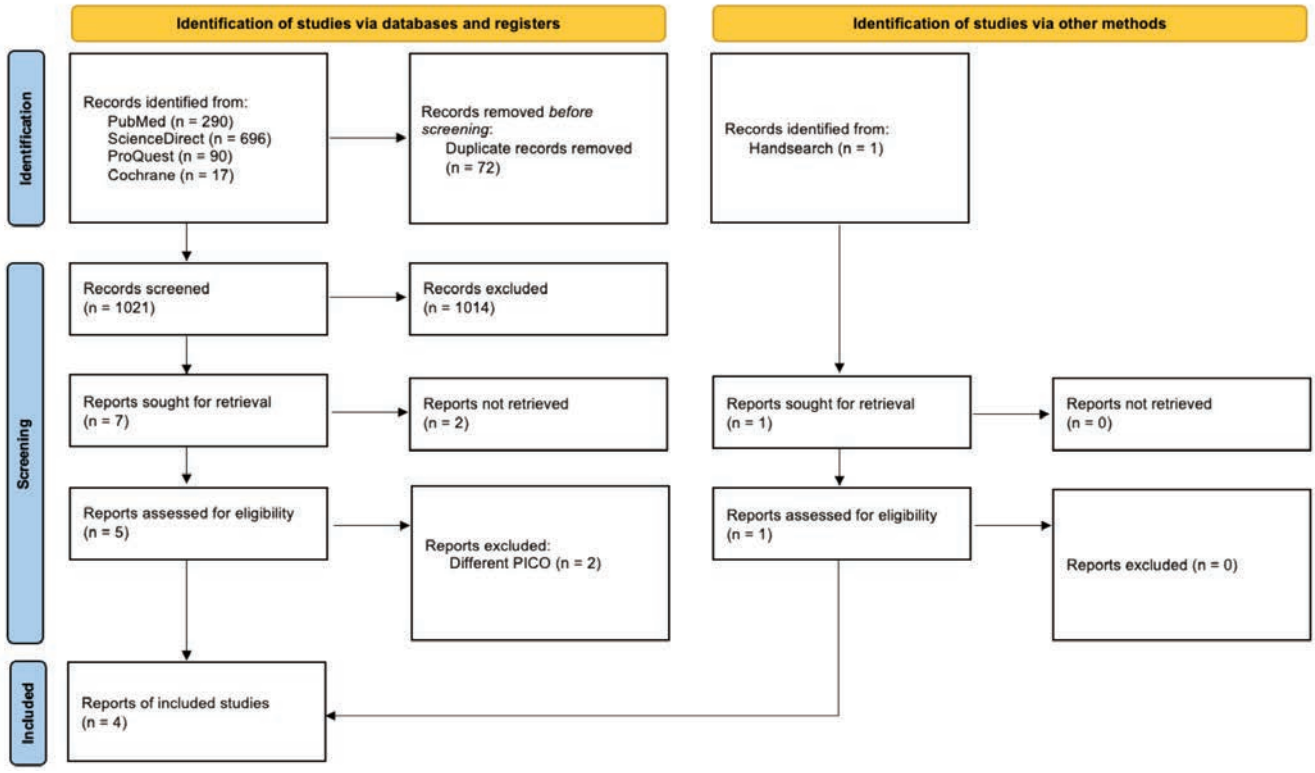


Figure 1. PRISMA flowchart of the literature search.

Table 1. Critical appraisal of the included studies.

Question	Kuismanen *et al.* (2014)[19]	Arjmand *et al.* (2017)[17]	Garcia-Arranz *et al.* (2020)[16]	Maene *et al.* (2022)[18]
Were there clear criteria for inclusion in the case series?	Yes	Yes	Yes	Unclear
Was the condition measured in a standard, reliable way for all participants included in the case series?	Yes	Yes	Yes	Yes
Were valid methods used for identification of the condition for all participants included in the case series?	Yes	Yes	Yes	Unclear
Did the case series have consecutive inclusion of participants?	Unclear	Unclear	Unclear	Unclear
Did the case series have complete inclusion of participants?	Unclear	Unclear	Unclear	Unclear
Was there clear reporting of the demographics of the participants in the study?	Yes	Yes	Yes	Unclear
Was there clear reporting of the clinical information of the participants?	Yes	Yes	Yes	Unclear
Were the outcomes or follow-up results of cases clearly reported?	Yes	Yes	Yes	Yes
Was there clear reporting of the presenting sites'/clinics' demographic information?	Yes	Yes	Yes	Yes
Was statistical analysis appropriate?	Not applicable	Yes	Yes	Yes

Table 2. Study characteristics and population.

Author (year)	Level of evidence	Duration of study	Country	Study design	Duration of follow-up	Population				
						Subject (n)	Age (years)	Incontinence type	Duration of SUI (months)	MUCP (cmH2O)
Kuismanen *et al.* (2014)[19]	IV	Not reported	Finland	Prospective pilot single-arm case series (pilot study)	12 months (visits at 3, 6, 12 months)	5	Mean 59.2 (SD 13.8); range 45-81	SUI (n=2); MUI (n=3). Severity (pad-test based): mild–moderate	Not reported	Reported as mmHg 20-72 (≈27-98 cmH2O); mean 41.6 mmHg
Arjmand *et al.* (2017)[17]	IV	August-December 2012	Iran	Prospective phase I single-arm clinical trial	24 weeks (assessed at 2, 6, 24 weeks)	10	Mean 45.8 (SD 8.7)	SUI. Severity staging (pad-test/ISI): not reported	2 to >5 years	Not reported
Garcia-Arranz *et al.* (2020)[16]	IV	September 2012-April 2014	Spain	Prospective nonrandomized phase I–IIa single-arm clinical trial	12 months (baseline, 1, 3, 6, 12 months)	10	Mean 56.8 (SD 9.0)	Genuine or combined SUI. Severity staging (pad-test/ISI): not reported	≥12 months	Not reported
Maene *et al.* (2022)[18]	IV	June 2019-May 2020	Belgium	Prospective nonrandomized single-center pilot single-arm	9 months (3, 6, 9 months)	10	Mean 47 (SD 3)	Stamey staging reported: SUI stage 1 (n=2), SUI stage 2 (n=5), MIU stage 2 (n=3). Severity (mild-moderate): Yes (Stamey 1-2)	Range 6-12 (mean 10.2; median 12)	Mean 49.6 (SD 6.3); range 41-58

MUCP, maximum urethral closure pressure; MUI, mixed urinary incontinence; SD, standard deviation; SUI, stress urinary incontinence;

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Table 3. Outcomes of included studies.

Author (year)	Outcomes				
	Cough Test	24-hour Pad Test (g)	Urethral Profile	Urodynamic	Others
Kuismanen *et al.* (2014)[19]	Baseline positive 5/5; negative 2/5 at 6 months; negative 3/5 at 12 months	Baseline: median 10 (IQR 5-28), range 0-70; 12 months: median 4 (IQR 3-9), range 0–28	Not reported	Not reported	QoL/symptoms improved overall at 12 months: - VAS improved in all patients (5/5) - UISS decreased in 3/5 (2/5 unchanged) - IIQ-7 decreased in 3/5 (2/5 increased) - UDI-6 decreased in 3/5 (2/5 increased)
Arjmand *et al.* (2017)[17]	Not reported	24-h pad test: significant overall reduction across time points (overall repeated-measures significant). Pairwise: baseline → 2 weeks significant ($p<0.001$); 2 → 6 weeks not significant ($p=0.146$); 6 → 24 weeks significant ($p=0.018$). (Numeric pad weights not tabulated; shown in figure)	Not reported	Qmax improved: 32.6 → 35.7 at 24 weeks ($p=0.002$). Residual urine generally insignificant except 1 case	ICIQ-SF: significant overall improvement across follow-up; contrast showed baseline→2 weeks significant ($p<0.001$), but no significant change between subsequent adjacent intervals. Safety: 1 mild voiding difficulty requiring catheterization; no UTI/gross hematuria; no chronic retention
Garcia-Arranz *et al.* (2020)[16]	Baseline cough leakage positive 10/10; endline cough leakage negative 6/10	Pad test (g): baseline median 15.5 (IQR 11.7521.0), range 1-96; endline median 5.5 (IQR 1.25-12.75), range 0-69. Clinical response definition: >50% improvement; 5/10 met this at 3 months (cases 4-8)	Reported (cmH2O): baseline range 21-74 (1 case missing); endline range 16-91	Baseline UI 10/10; endline No UI 5/10	ICIQ-SF + SF-36: measured at baseline and visits, but no statistically significant differences detected during follow-up.
Maene *et al.* (2022)[18]	Baseline positive 10/10; negative 8/10 at 3 mo, 6/10 at 6 mo, 4/10 at 9 mo	Not reported	Not reported	None had sphincter insufficiency based on urodynamic assessment	ICIQ-SF (subscores + total): - 3 mo: significant improvement in QoL ($p=0.007$), quantity ($p=0.005$), frequency ($p=0.007$) in 9/10 - 6 mo: 4/10 no urine loss; significant improvement in quantity ($p=0.010$), frequency ($p=0.011$), QoL ($p=0.012$), total score ($p=0.008$) in 8/10 - 9 mo: 2/10 no urine loss; significant improvement in quantity ($p=0.039$), QoL ($p=0.034$), total score ($p=0.038$) in 7/10 MRI (baseline *vs.* 3 mo): no significant urethral thickness change ($p=0.795$); periurethral tissue densification in 8/10. Complications: umbilical peri-ecchymosis in some patients; none later.

IQR, interquartile range; QoL, quality of life; VAS, Visual Analog Scale; UISS, Urinary Incontinence Severity Score; IIQ, Incontinence Impact Questionnaire; UDI, Urinary Distress Inventory; ICIQ-SF, International Consultation on Incontinence Questionnaire – Short Form; UTI, urinary tract infection.

scores at multiple follow-up time points; clinically, 4 of 10 women reported no urine loss at 6 months and 2 of 10 reported no urine loss at 9 months.

Urodynamic and functional outcomes

Urodynamic and functional assessments were variably reported. Garcia-Arranz *et al.*[16] reported improvement on urodynamic assessment such that no urinary incontinence was observed in 5 of 10 women at endline. Maene *et al.*[18] reported baseline urodynamic testing indicating no sphincter insufficiency at enrollment. Arjmand *et al.*[17] reported improving voiding function, including an increase in maximum flow rate over follow-up and residual urine was generally not clinically significant for most participants.

Imaging outcomes

Imaging outcomes were only reported in one study through MRI. Maene *et al*.[18] reported no significant change in urethral thickness between baseline and follow-up, whereas periurethral tissue densification was described in most participants.

Safety outcomes

Safety profile was still limited; although overall studies did not identify major safety concerns. Arjmand *et al.*[17] reported one episode of mild voiding difficulty requiring catheterization and they did not report chronic retention or major infectious complications. Maene *et al*.[18] reported minor postoperative findings such as peri-ecchymosis without late complications. Across the included studies, no serious treatment-related adverse events were highlighted. Detailed outcome measures for individual studies were presented in Table 3.

Discussion

Stem cells offer promising treatment due to their ability to self-renew and differentiate into different cell types. The two major types of stem cells consist of pluripotent stem cells (PSCs), including embryonic stem cells and induced PSCs, and MSCs, which can be isolated from various tissues such as bone marrow, umbilical cord, endometrial, and adipose tissue.[20] Adipose-derived stem cells offer advantages to be potentially proliferative and exhibit pluripotent differentiation capacity for regenerative therapies targeting tissue repair.[21]

Although all included studies were conducted in SUI women, they were still phase I or II clinical trials. This implies that phase I studies are usually conducted on a small group of people to evaluate safety, dosage range, and identify side effects; meanwhile, phase II studies determine a safe treatment in phase I, but now require a larger group of human subjects to monitor for any adverse effects.[22]

Of the 4 studies included, only one study by Kuismanen *et al*.[19] involved only 5 women with SUI or MUI, and they were allowed to be recruited after a previous incontinence operation. The other studies included 10 SUI women.[16-18] For the objective outcomes, all studies depicted the improvement after administering the injection of autologous ASC, although it could not be determined statistically due to small sample size. In the meantime, the subjective outcomes through symptoms and QoL showed inconsistent improvement in statistics; however, the patients felt better on the subjective measurement through various SUI questionnaires. In the study by Arjmand *et al*.,[17] the significant overall improvement occurred in the first few weeks and then returned to baseline complaints, after which results appeared promising again. It was predicted because in the first 2 weeks, there would be a bulking effect after injection on the periurethral area and then it was dissolved as a window period.[17] As the ability of ASC is related to immunomodulation, support of growth and differentiation of local stem and progenitor cells, proangiogenic action, chemoattraction, anti-scarring, and anti-apoptosis effects, the results were improved after 24 weeks.[17,23] Several mechanisms proposed to improve SUI symptoms include the mechanical impact of fibrosis after sub-urethral dissection and ASC-induced tissue regeneration.[18] Furthermore, the ability of stem cells to restore damaged tissue provides soluble mediators such as cytokines and growth factors to affect cytoprotection, angiogenesis, tissue repair, and normalization of the extracellular matrix and relief from inflammation.[24] Meanwhile, in an animal model, Cui and colleagues stated that ASC could increase the striated and smooth muscle fibers of the urethra histologically.[25,26]

Due to new insights into SUI treatment, the treatment doses among studies varied from 0.18×106 to 40×106 ASCs. Until now, there is no standardized guideline for ASC doses injected for SUI women. Garcia-Arranz *et al*.[16] proposed that 40 million ASCs might be therapeutic for mild to moderate incontinence and have relative efficacy for moderate or severe incontinence.

The limitation of this systematic review was the protocol variation of injected ASCs in each study, and the included studies were still in phase I or II clinical trials. Apart from that, we did not find any randomized controlled trial that compares the injected ASCs and placebo. Meanwhile, all of these preliminary results showed that autologous ASCs injection to the periurethral region is a feasible and promising treatment choice for women with SUI. Further investigations should include a large number of cases with longer follow-up times, the optimal doses of ASCs to achieve safety and efficacy for the stem-cell therapy, and the balance between cost and benefit.

Conclusions

Periurethral injection of ASCs represents a promising regenerative therapy for SUI, with encouraging functional outcomes and acceptable safety, although high-quality randomized controlled trials are urgently needed.

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Online supplementary material
Appendix 1. Database and keywords using in this searching strategy.

Received: 14 April 2026; Accepted: 5 August 2026.

Contributions: RM Sonny Sasotya, Raymond Surya Tan: determining the topic, appraisal, writing. Mochamad Rizkar Arev Sukarsa: searching the literature, commenting. Eppy Darmadi Achmad: determining the topic, appraisal, editing. Andi Rinaldi: searching the literature, writing. Aria Prasetya Masoem: searching the literature, commenting. Raden Kania Praharsini: commenting, editing

Conflict of interest: the authors declare no potential conflict of interest.

Ethics approval and consent to participate: not applicable.

Informed consent: not applicable.

Patient consent for publication: not applicable.

Availability of data and materials: All data analyzed during this study were included in this published article.

Declaration of generative artificial intelligence and artificial intelligence-assisted technologies in the writing process: the authors use generative artificial intelligence (AI) or AI-assisted technologies in sorting the articles (Rayyan systematic review)

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