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Systematic review

Symptomatic improvement versus objective urethral functional recovery following stem cell-based therapy for stress urinary incontinence: a systematic review

Noor Hussain Almousa¹, Dalia Magdy M. Muhammad², Abdullah Al Hammed³, Ahoud Marji Alruwaili⁴, Raneem Hamid Alhaidari⁵, Ghadi Abdulaziz Jastaniah⁶, Ghadah Farraj Alzahrani⁷, Rakan Alharbi⁸

1. Consultant, Urogynecology & Reconstructive Pelvic Surgery, Riyadh First Cluster, King Saud Medical City, Women Health Hospital, Riyadh, Saudi Arabia.
2. Assistant Consultant, Obstetrics & Gynecology Department, RFHC, King Saud Medical City, Maternity Hospital, Riyadh, Saudi Arabia. Email: dahliamagdy.dm@gmail.com
3. Saudi Board Resident, Obstetrics & Gynecology Residency Program, RFHC, King Saud Medical City, Riyadh, Saudi Arabia. Email: alhammad1408@gmail.com.
4. Saudi Board Resident, Obstetrics & Gynecology Residency Program, MCH, Al-Jouf, Saudi Arabia. Email: Dr.ohoud.alruwaili90@gmail.com.
5. Obstetrics & Gynecology Saudi Board Resident, Obstetrics & Gynecology Department, King Abdulaziz Hospital, MOH, Jeddah, Saudi Arabia. Email: Alhaidari.raneem@gmail.com.
6. Obstetrics & Gynecology Saudi Board Resident, Obstetrics & Gynecology Department, King Faisal Medical Complex, Taif, Saudi Arabia. Email: dr.ghadi90@gmail.com.
7. Obstetrics & Gynecology Saudi Board Resident, Obstetrics & Gynecology Department, King Faisal Medical Complex, Taif, Saudi Arabia. Email: ghadoalz@gmail.com.
8. Obstetrics & Gynecology Saudi Board Resident, Obstetrics & Gynecology Department, Women Health Hospital, National Guard. Email: raccan96@gmail.com.

Abstract

Background: Stem cell-based urethral injection has been proposed as a regenerative treatment for stress urinary incontinence (SUI), and symptom relief does not necessarily establish recovery of urethral sphincter function. Objective: To compare patient-centred

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symptomatic improvement with direct assessment of urethral functional recovery after cell-based treatment for female SUI. Method: PubMed/MEDLINE, Scopus, Web of Science Core Collection, and the Cochrane Library were searched from inception through 2026-05-31. Human interventional studies of adult women with SUI treated with a stem cell, muscle precursor cell, adipose-derived stem-cell, stromal vascular fraction, or related autologous regenerative cell product were eligible. Retracted reports were excluded. Two reviewers independently screened records, extracted study-level data, linked reports from the same cohort, and synthesized the findings narratively. Symptom outcomes included leakage episodes, pad tests, cough stress testing, validated questionnaires, and quality of life. Direct functional recovery required urethral pressure or length measurements, sphincter contractility, or structural imaging interpreted alongside function. Results: Twenty-two original reports were identified. Symptom measures improved, including pad weight, cough stress test, incontinence episodes, and questionnaire scores. Direct urethral measurements were sparse and heterogeneous. One phase I study documented increased functional urethral length and external sphincter diameter alongside improved ICIQ-UI-SF scores, whereas a 38-participant study reported persistent symptom benefit without overall improvement in urodynamic urethral properties. In the largest blinded trial, the primary symptom endpoint did not differ from placebo. An electrical-stimulation plus cell-implantation trial favored cellular arms against placebo on symptom endpoints without direct physiologic confirmation. Conclusion: Current findings support a short-term symptom signal and acceptable procedural tolerability; they do not establish consistent objective urethral functional regeneration. Future trials require standardized cell-product reporting, blinded comparison, direct pressure-based and imaging outcomes, and durable follow-up.

Keywords: stress urinary incontinence; cell therapy; regenerative medicine; urethral sphincter; muscle-derived cells; adipose-derived stem cells; urodynamics

Introduction

Stress urinary incontinence (SUI) is defined as involuntary urine leakage during effort or physical exertion, including coughing and sneezing, and it reflects insufficient urethral closure when intra-abdominal pressure rises (1). Female urinary incontinence carries a personal and health-system burden, with SUI representing a major subtype across community populations (2). First-line management relies on pelvic-floor muscle training and behavioral intervention, whereas sling procedures remain established operative options for selected women with persistent symptoms (3, 4). Neither symptomatic response nor a negative provocative test identifies restoration of the striated sphincter mechanism, a distinction central to regenerative treatment claims (5).

Stem cell-based strategies seek to repair components of the urethral continence apparatus rather than alter symptoms alone (6). Muscle-derived cells, adipose-derived stromal/stem cells, cord-blood cells, stromal vascular fraction, and mixed regenerative preparations have been injected into or around the external urethral

sphincter or suburethral tissue with the aim of rebuilding the continence mechanism (6, 7). Early clinical reports emphasized feasibility and changes in leaks, pad weights, questionnaires, and quality of life, while formal urethral function endpoints remained inconsistently reported (7, 8). A prior systematic review of studies in women described wide variation in cell manufacturing, dose, injection technique, co-intervention, follow-up, and outcome definitions (9).

Leakage diaries, pad tests, cough stress tests, and patient-reported questionnaires capture different dimensions of clinical benefit (5, 9). Pad tests and cough stress testing are objective measures of leakage severity; they do not directly quantify sphincter pressure, functional urethral length, rhabdosphincter contractility, or tissue integration (5, 6). A cellular implant, carrier volume, injection-related tissue reaction, concurrent electrical stimulation, and placebo response are all plausible explanations for reduced leakage in the absence of verified cellular regeneration (6, 7). An improvement in direct urethral metrics without a meaningful symptom effect also warrants cautious interpretation (5, 6).

This review separates patient-reported symptoms, objective leakage burden, and direct assessment of urethral functional recovery (5, 9). The primary question asks whether symptomatic improvement after stem cell-based therapy is accompanied by concordant changes in urethral function rather than represented solely by leakage reduction. Safety and the direction of comparative trial findings are summarized to frame clinical interpretation of this evolving treatment field.

Methods

This systematic review followed PRISMA 2020 reporting guidance. Two authors independently searched PubMed/MEDLINE, Scopus, Web of Science Core Collection, and the Cochrane Library from database inception through 2026-05-31. The strategy combined controlled vocabulary and free-text terms for stress urinary incontinence, urethra, urinary sphincter, stem cells, mesenchymal stromal cells, muscle-derived cells, myoblasts, muscle precursor cells, adipose-derived cells, stromal vascular fraction, regenerative cells, and cell transplantation. The PubMed syntax was: (("Urinary Incontinence, Stress"[Mesh] OR "stress urinary incontinence" OR SUI) AND ("Stem Cells"[Mesh] OR "stem cell*" OR "muscle-derived cell*" OR myoblast* OR "muscle precursor cell*" OR "adipose-derived stem cell*" OR "stromal vascular fraction" OR "regenerative cell*") AND (urethra OR sphincter OR periurethral OR intrasphincteric)). Reference lists of eligible articles and relevant reviews were screened manually.

Eligible studies enrolled adult women with clinically diagnosed SUI, delivered a human cell-based intervention to the urethra, external sphincter, bladder neck, or suburethral region, and reported postintervention symptoms, leakage burden, direct urethral function, safety, or more than one of these domains. Randomized trials, nonrandomized comparative studies, and prospective single-arm interventional studies were eligible. Animal,

laboratory, review, protocol, and conference-only reports without sufficient outcome data were excluded. Studies of male postprostatectomy incontinence, non-cell injectables, duplicate data sets, and retracted publications were excluded. Reports describing the same cohort were linked and interpreted as one treatment program rather than independent confirmation.

After deduplication, the two authors screened titles and abstracts, assessed full texts, and resolved disagreements through discussion. Using a piloted extraction form, the reviewers recorded study design, setting, participant characteristics, cell source and processing, dose, carrier, route, co-intervention, duration of follow-up, efficacy outcomes, adverse events, and links to related cohort reports. Symptom outcomes were incontinence episodes, questionnaires, satisfaction, and quality-of-life measures. Objective leakage outcomes were pad tests, cough stress tests, and diaries. Direct urethral functional recovery was defined before extraction as a change in maximum urethral closure pressure, functional urethral length, leak-point pressure, sphincter contractility, or structural sphincter imaging assessed alongside function.

The reviewers recorded trial design, attrition, outcome definition, co-intervention, and cohort overlap descriptively. No numerical quality score was used to exclude a study. A quantitative pooled estimate was not calculated because cell products, cell doses, carriers, delivery routes, comparator groups, co-interventions, follow-up intervals, and outcome definitions differed materially across studies. The synthesis prioritized blinded comparisons, direct functional endpoints, and clinically relevant symptom outcomes.

Results

Twenty-two original clinical reports published between 2008 and 2026 fulfilled the prespecified

eligibility criteria, and small single-centre prospective cohorts dominated the earlier literature, whereas later reports included placebo-controlled and active-comparator trials. Peters et al. pooled related phase I/II muscle-derived-cell series, and the two Blaganje reports represented

sequential reporting from the same 38-patient program; these linked publications were not interpreted as independent confirmatory cohorts (14, 17, 25). A previously published randomized trial reporting striking cell-therapy effects was excluded because it was formally retracted (32).

Table 1. Symptom-dominant clinical reports of cell-based therapy for female SUI

Study	Cell product and delivery	Main symptom or leakage findings	Direct urethral-function finding
Carr et al., 2008; n=8 (10)	Autologous muscle-derived cells, transurethral injection	Five women improved and one became continent; improvement persisted for a median of 10 months	Not reported
Lee et al., 2010; n=39 (11)	Human cord-blood stem cells, transurethral injection	Twenty-six women reported more than 50% improvement at 12 months	Urodynamics assessed in ten women; numerical values were not reported
Sèbe et al., 2011; n=12 (12)	Autologous deltoid-muscle progenitor cells, intrasphincteric injection	Three women were dry and seven improved on pad testing at 12 months	Qmax showed no change at 3 months
Shirvan et al., 2013; n=9 (13)	Autologous total nucleated cells plus platelets, sphincteric and submucosal injection	Eight women became continent and one markedly improved at 6 months	MUCP and ALPP were reported in one woman with intrinsic sphincter deficiency
Blaganje and Lukanović, 2012; n=38 (14)	Autologous myoblasts into external sphincter plus electrical stimulation	At 6 weeks, 29 women had a negative stress test and 29 reported improvement	Not reported
Carr et al., 2013; n=38 (15)	Autologous quadriceps-derived cells, low or high dose, one or two injections	In the two-treatment subgroup, 50% pad-weight reduction occurred in 8/9 high-dose and 8/13 low-dose recipients	Not reported
Stangel-Wojcikiewicz et al., 2014; n=16 (16)	Autologous muscle-derived cells, transurethral rhabdosphincter injection	Two-year success was 75%, including 50% complete and 25% partial improvement	Not reported
Peters et al., 2014; n=80 (17)	Autologous muscle-derived cells, 10-200 million cells, intrasphincteric injection	Higher-dose groups had a larger proportion with at least 50% reductions in leaks and pad weight	Not reported
Gräs et al., 2014; n=35 (18)	Freshly minced autologous skeletal muscle, intraurethral injection	Cure/improvement occurred in 25%/63% of uncomplicated and 7%/57% of complicated SUI groups	No voiding dysfunction; no direct sphincter measure
Kuismanen et al., 2014; n=5 (19)	Autologous adipose stem cells plus bovine collagen gel, transurethral injection	Three women had a negative cough test at 12 months and all reported some questionnaire improvement	No direct pressure-based measure
Arjmand et al., 2017; n=10 (20)	Autologous adipose-derived stem cells, transurethral and transvaginal periurethral injection	Pad-test and ICIQ-SF scores improved through 24 weeks	Qmax rose from 32.6 to 35.7 mL/s; Qmax is not a direct sphincter-pressure measure

Across early uncontrolled cohorts, symptom and leakage improvement appeared frequent, although definitions of cure and improvement varied substantially and follow-up was generally short. The dose-ranging study found a higher proportion of pad and diary responders among high-dose recipients after two injections, while the pooled 80-

participant report described a similar dose-response pattern without direct physiologic measurements (15, 17). The small adipose-cell pilot combined cells with collagen, and the total-nucleated-cell study combined cells with platelets, leaving the independent contribution of the cellular component uncertain (13), (19).

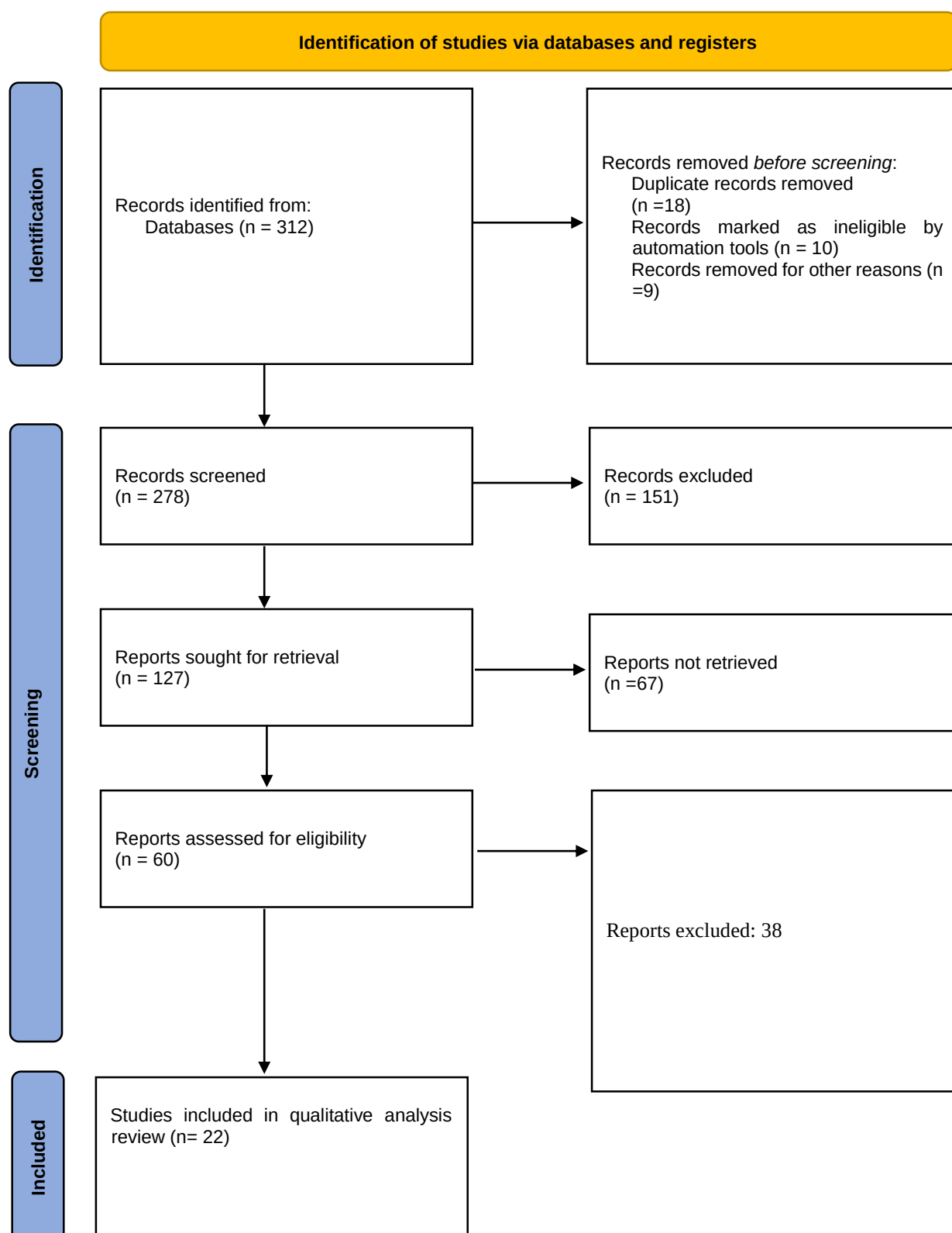


Figure 1: PRISMA flow chart

Table 2. Comparative and function-focused reports: concordance between symptoms and urethral recovery

Study	Design and principal clinical result	Direct functional or structural outcome	Interpretation
Jankowski et al., 2018 (21)	Blinded AMDC-USR versus placebo trial; 90% placebo response on the composite endpoint led to early halt	No direct urethral functional endpoint reported	Primary efficacy result inconclusive
Sharifiaghdas et al., 2019; n=20 (22)	At 12 months, 10/17 completers had complete response; several responders relapsed by 24 months	Multichannel urodynamics obtained, without extractable numerical functional result in the abstract	Symptom durability uncertain
García-Arranz et al., 2020; female cohort n=10 (23)	Five women achieved more than 50% pad-test improvement	Urodynamics performed at baseline and 12 months; no extractable numerical urethral result	Functional recovery indeterminate
Maene et al., 2022; n=10 (24)	Negative cough test in 8, 6, and 4 women at 3, 6, and 9 months	MRI undertaken; no quantified functional recovery reported	Declining leakage response; regeneration unverified
Blaganje and Lukanović, 2022; n=38 (25)	Incontinence frequency, short pad test, quality of life, and perceptions improved through two years	Urodynamic urethral properties did not improve overall at one year	Symptom-function discordance
Schmid et al., 2023; n=9 treated (26)	ICIQ-UI-SF score fell from 7 to 4 at six months	Functional urethral length under stress increased from 25 to 30 mm and external sphincter diameter from 1.8 to 1.9 mm	Concordant short-term signal in an open phase I study
Mahboubbeh et al., 2023; n=30 (27)	Negative Marshall test: 73% with mucosa-derived cells versus 80% with mini-sling, p=0.6	No direct urethral pressure or structural outcome	Symptom and stress-test comparison only
Kaufman et al., 2024; n=297 randomized (28)	At 12 months, at least 50% stress-episode reduction occurred in 52.0% versus 53.6% with placebo, p=0.798	No direct functional endpoint reported	Overall symptom benefit not superior to placebo
Rose and Rübben, 2025; n=217 (29)	Low- and high-cell-dose groups plus electrical stimulation showed greater 12-week incontinence-episode reduction than placebo	No direct urethral pressure or imaging endpoint reported	Benefit of the combined regimen; cellular mechanism unverified
Dutta et al., 2025; SUI subgroup n=8 (30)	One-hour and three-day pad weights and UDI-6/IIQ-7 scores fell after bladder-neck injection	No direct urethral functional endpoint reported	Symptom and leakage signal in a small phase I cohort
Souza et al., 2026; n=20 treated (31)	Positive cough test fell from 100% to 40% in the skeletal-muscle MSC group; bone-marrow MSC results were modest	No direct urethral functional endpoint reported	Feasibility signal, with limited efficacy and early termination

The Schmid phase I trial reported improvement in functional urethral length and external sphincter diameter alongside an ICIQ-UI-SF reduction, whereas the 38-patient Blaganje follow-up found no overall improvement in urodynamic urethral properties despite persistent symptom and quality-of-life gains (25, 26). A randomized ultrasound study recorded increased total and external sphincter

volumes and lower incontinence-episode frequency in both the AMDC and placebo injection groups, with no between-group difference at 12 months (33). The 2024 multicentre trial did not meet its primary symptom endpoint, while the 2025 electrical-stimulation trial favored cell-treatment arms against placebo on leakage and quality-of-life

outcomes without a direct physiologic endpoint (28, 29).

Discussion

The central finding is a repeated signal of symptomatic improvement after cell-based therapy for female SUI, paired with inconsistent direct confirmation of urethral functional recovery. Open cohorts frequently recorded fewer leakage episodes, lower pad weights, improved cough stress testing, and better questionnaire scores after intervention. The direct-function literature is much narrower: one 38-patient follow-up reported sustained symptom benefit without overall urodynamic improvement, while a nine-patient phase I study reported favorable short-term changes in functional urethral length and sphincter diameter (25, 26). The largest blinded trial found no overall difference from placebo for its prespecified symptom endpoint, placing the uncontrolled response estimates in context (28).

A decrease in leakage does not identify the mechanism producing that decrease. Periurethral injection introduces cells, carrier, volume, needling, and local tissue response, each of which has the potential to alter coaptation or patient expectations without durable cellular engraftment (6), (7). The placebo-controlled ultrasound analysis provides a practical example, as both injected groups showed larger measured sphincter volumes and fewer stress episodes without a between-group difference (33). Electrical stimulation and biologic co-products create additional attribution problems, since myoblast implantation plus electrical stimulation, stromal vascular fraction plus platelet-rich fibrin, and adipose cells plus collagen each combine more than one active element (14, 19, 24, 29). These sources of heterogeneity explain why a shared label of “stem cell therapy” does not represent one uniform clinical intervention (7-9).

Direct functional endpoints require a defined role in future trials. Maximum urethral closure pressure, functional urethral length, abdominal leak-point pressure, standardized urethral pressure profiling, and blinded imaging of the external sphincter would provide a stronger test of the proposed regenerative mechanism than symptom diaries alone (5, 6). The Schmid trial supplies a useful early framework by pairing patient-reported symptoms with functional length and magnetic-resonance imaging, although its sample comprised only nine treated women and its follow-up lasted six months (26). The Blaganje program illustrates an equally important alternative pattern: symptoms and quality of life improved while overall urodynamic urethral properties did not (25). Future protocols require prospectively specified core symptom, leakage, direct-function, imaging, and safety outcomes measured at common intervals (5, 6, 25, 26).

We found that short-term procedural tolerability was acceptable across the included reports, with no treatment-related tumour formation reported during observed follow-up. This absence does not rule out rare or delayed harms because most cohorts were small and several had less than two years of follow-up. The 2024 trial supplies the most informative comparative safety data, recording treatment-related adverse events in 9.5% of cell-treated participants and 6.1% of placebo participants, while the 2026 pilot ended early because efficacy, logistics, and financial sustainability were limited (28, 31). We found that long-term surveillance is essential for a therapy involving expanded or manipulated cellular products.

This review distinguishes objective leakage measures from direct urethral functional recovery, excludes a formally retracted trial, and links related reports to prevent overinterpretation of repeated publications from the same development program (5, 17, 25, 32). Its limitations arise from

heterogeneity in cell source, processing, dose, carrier, injection site, co-intervention, follow-up, endpoint definition, and the predominance of small nonrandomized studies (7-9). The narrative synthesis did not generate a pooled effect estimate, since a single numerical summary would obscure clinically important differences between cell products and study designs.

Conclusion

Stem cell-based therapy for female SUI is associated with repeated reports of lower leakage burden and improved symptom scores, together with acceptable short-term procedural tolerability. The current literature does not establish consistent recovery of urethral pressure, functional length, sphincter contractility, or durable structural regeneration. Direct physiologic outcomes are sparse, and comparative trials produce mixed symptom findings. Cell therapy remains investigational. Future trials require blinded comparators, preregistered core outcome definitions, standardized cell-product reporting, separation of cellular effects from carriers or electrical stimulation, and sufficiently long surveillance for durability and safety.

Abbreviations

ADSC, adipose-derived stem cell; ALPP, abdominal leak-point pressure; AMDC-USR, autologous muscle-derived cells for urinary sphincter repair; EUS, external urethral sphincter; FES, functional electrical stimulation; FUL, functional urethral length; ICIQ-UI-SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; IEF, incontinence-episode frequency; IIQ-7, Incontinence Impact Questionnaire-7; I-QOL, Incontinence Quality of Life questionnaire; MSC, mesenchymal stromal cell; MUCP, maximum urethral closure pressure; MPC, muscle precursor cell; Qmax, maximum urinary flow; SUI, stress

urinary incontinence; SVF, stromal vascular fraction; TNC, total nucleated cells.

References

1. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Neurourol Urodyn.* 2010;29(1):4-20. doi:10.1002/nau.20798.
2. Aoki Y, Brown HW, Brubaker L, Cornu JN, Daly JO, Cartwright R. Urinary incontinence in women. *Nat Rev Dis Primers.* 2017;3:17097. doi:10.1038/nrdp.2017.97.
3. Dumoulin C, Cacciari LP, Hay-Smith EJC. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev.* 2018;10(10). doi:10.1002/14651858.CD005654.pub4.
4. Ford AA, Rogerson L, Cody JD, Aluko P, Ogah JA. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev.* 2017;7(7). doi:10.1002/14651858.CD006375.pub4.
5. Lin CS, Lue TF. Stem cell therapy for stress urinary incontinence: a critical review. *Stem Cells Dev.* 2012;21(6):834-843. doi:10.1089/scd.2011.0621.
6. Hart ML, Izeta A, Herrera-Imbroda B, Amend B, Brinchmann JE. Cell therapy for stress urinary incontinence. *Tissue Eng Part B Rev.* 2015;21(4):365-376. doi:10.1089/ten.TEB.2014.0627.
7. Vinarov A, Atala A, Yoo J, Slusarenko R, Zhumataev M, Zhito A, et al. Cell therapy for stress urinary incontinence: present-day frontiers. *J Tissue Eng Regen Med.* 2018;12(2). doi:10.1002/term.2444.
8. Barakat B, Franke K, Schakaki S, Hijazi S, Hasselhof V, Vögeli TA. Stem cell

- applications in regenerative medicine for stress urinary incontinence: a review of effectiveness based on clinical trials. *Arab J Urol.* 2020;18(3):194-205. doi:10.1080/2090598X.2020.1750864.
9. Klapper-Goldstein H, Tamam S, Sade S, Weintraub AY. A systematic review of stem cell therapy treatment for women suffering from stress urinary incontinence. *Int J Gynaecol Obstet.* 2022;157(1):19-30. doi:10.1002/ijgo.13769.
 10. Carr LK, Steele D, Steele S, Wagner D, Pruchnic R, Jankowski R, et al. 1-year follow-up of autologous muscle-derived stem cell injection pilot study to treat stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008;19(6):881-883. doi:10.1007/s00192-007-0553-z.
 11. Lee CN, Jang JB, Kim JY, Koh C, Baek JY, Lee KJ. Human cord blood stem cell therapy for treatment of stress urinary incontinence. *J Korean Med Sci.* 2010;25(6):813-816. doi:10.3346/jkms.2010.25.6.813.
 12. Sèbe P, Doucet C, Cornu JN, Ciofu C, Costa P, de Medina SG, et al. Intraspinal injections of autologous muscular cells in women with refractory stress urinary incontinence: a prospective study. *Int Urogynecol J.* 2011;22(2):183-189. doi:10.1007/s00192-010-1255-5.
 13. Shirvan MK, Alamdari DH, Mahboub MD, Ghanadi A, Rahimi HR, Seifalian AM. A novel cell therapy for stress urinary incontinence, short-term outcome. *Neurourol Urodyn.* 2013;32(4):377-382. doi:10.1002/nau.22301.
 14. Blaganje M, Lukanović A. Intraspinal autologous myoblast injections with electrical stimulation for stress urinary incontinence. *Int J Gynaecol Obstet.* 2012;117(2):164-167. doi:10.1016/j.ijgo.2011.11.029.
 15. Carr LK, Robert M, Kultgen PL, Herschorn S, Birch C, Murphy M, et al. Autologous muscle derived cell therapy for stress urinary incontinence: a prospective, dose ranging study. *J Urol.* 2013;189(2):595-601. doi:10.1016/j.juro.2012.09.028.
 16. Stangel-Wojcikiewicz K, Jarocho D, Piwowar M, Jach R, Uhl T, Basta A, et al. Autologous muscle-derived cells for the treatment of female stress urinary incontinence: a 2-year follow-up of a Polish investigation. *Neurourol Urodyn.* 2014;33(3):324-330. doi:10.1002/nau.22404.
 17. Peters KM, Dmochowski RR, Carr LK, Robert M, Kaufman MR, Sirls LT, et al. Autologous muscle derived cells for treatment of stress urinary incontinence in women. *J Urol.* 2014;192(2):469-476. doi:10.1016/j.juro.2014.02.047.
 18. Gräs S, Klarskov N, Lose G. Intraurethral injection of autologous minced skeletal muscle: a simple surgical treatment for stress urinary incontinence. *J Urol.* 2014;192(3):850-855. doi:10.1016/j.juro.2014.04.005.
 19. Kuismanen K, Sartoneva R, Haimi S, Mannerström B, Tomás E, Miettinen S, et al. Autologous adipose stem cells in treatment of female stress urinary incontinence: results of a pilot study. *Stem Cells Transl Med.* 2014;3(8):936-941. doi:10.5966/sctm.2013-0197.
 20. Arjmand B, Safavi M, Heidari R, Aghayan H, Bazargani ST, Dehghani S, et al. Concomitant transurethral and transvaginal-periurethral injection of autologous adipose derived stem cells for treatment of female stress urinary incontinence: a phase one clinical trial. *Acta Med Iran.* 2017;55(6):368-374.
 21. Jankowski RJ, Tu LM, Carlson C, Robert M, Carlson K, Quinlan D, et al. A double-blind, randomized, placebo-controlled clinical trial evaluating the safety and efficacy of autologous muscle derived cells in female subjects with stress urinary incontinence. *Int*

- Urol Nephrol. 2018;50(12):2153-2165. doi:10.1007/s11255-018-2005-8.
22. Sharifiaghdas F, Zohrabi F, Moghadasali R, Shekarchian S, Jaroughi N, Bolurieh T, et al. Autologous muscle-derived cell injection for treatment of female stress urinary incontinence: a single-arm clinical trial with 24-months follow-up. *Urol J*. 2019;16(5):482-487. doi:10.22037/uj.v0i0.4736.
 23. Garcia-Arranz M, Alonso-Gregorio S, Fontana-Portella P, Bravo E, Diez Sebastian J, Fernandez-Santos ME, 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. doi:10.1002/sctm.19-0431.
 24. Maene A, Deniz G, Bouland C, Lagneaux L, Philippart P, Buxant F. Suburethral implantation of autologous regenerative cells for female stress urinary incontinence management: results of a pilot study. *Eur J Obstet Gynecol Reprod Biol*. 2022;278:38-44. doi:10.1016/j.ejogrb.2022.08.028.
 25. Blaganje M, Lukanović A. The effect of skeletal muscle-derived cells implantation on stress urinary incontinence and functional urethral properties in female patients. *Int J Gynaecol Obstet*. 2022;157(2):444-451. doi:10.1002/ijgo.13853.
 26. Schmid FA, Prange JA, Kozomara M, Betschart C, Sousa RA, Steinke N, et al. Transurethral injection of autologous muscle precursor cells for treatment of female stress urinary incontinence: a prospective phase I clinical trial. *Int Urogynecol J*. 2023;34(9):2197-2206. doi:10.1007/s00192-023-05514-4.
 27. Mahboubbeh M, Hamid P, Azar D, Mohammad Ali B, Alireza F, Mohsen B. Short and medium-term results of the autologous adult mucosa stem cell therapy compared with mini-sling surgery in the treatment of women's stress urinary incontinence: a randomized clinical trial. *Curr Stem Cell Res Ther*. 2023;18(2):276-283. doi:10.2174/1574888X17666220330010453.
 28. Kaufman MR, Goldman HB, Chermansky CJ, Dmochowski R, Kennelly MJ, Peters KM, et al. Iltamioceel autologous cell therapy for the treatment of female stress urinary incontinence: a double-blind, randomized, stratified, placebo-controlled trial. *Neurourol Urodyn*. 2024;43(8):2290-2299. doi:10.1002/nau.25588.
 29. Rose A, Rübben H. Implantation of autologous skeletal muscle-derived cells combined with electrical stimulation in patients with stress urinary incontinence. *Int Urogynecol J*. 2025;36(3):703-713. doi:10.1007/s00192-025-06079-0.
 30. Dutta R, Yoo JJ, Atala A, Day MC, Evans R, Langefeld CD, et al. Autologous muscle precursor cell injection into the bladder neck improves the symptoms of stress urinary incontinence in adult females. *Stem Cells Transl Med*. 2025;14(10). doi:10.1093/stcltm/szaf039.
 31. Souza RC, Bortolini MAT, Melino Y, de Godoy JAP, Alvarez K, Oliveira D, et al. Stem cell therapy for female stress urinary incontinence: results, limitations and lessons learned from a pilot clinical study. *PLoS One*. 2026;21(2). doi:10.1371/journal.pone.0342452.
 32. Kleinert S, Horton R. Retraction—autologous myoblasts and fibroblasts versus collagen for treatment of stress urinary incontinence in women: a randomised controlled trial. *Lancet*. 2008;372(9641):789-790. doi:10.1016/S0140-6736(08)61320-3.
 33. Ismail S, Morin M, Tu LM. Assessment of the effects of autologous muscle-derived cell injections on urethral sphincter

morphometry using 3D/4D ultrasound. World J Urol. 2020;38(11):2881-2889. doi:10.1007/s00345-020-03076-4.

34. Gotoh M, Yamamoto T, Kato M, Majima T, Toriyama K, Kamei Y, et al. Regenerative treatment of male stress urinary incontinence by periurethral injection of autologous adipose-derived regenerative cells: 1-year outcomes in 11 patients. Int J Urol. 2014;21(3):294-300. doi:10.1111/iju.12266.
35. Gotoh M, Shimizu S, Yamamoto T, Ishizuka O, Yamanishi T, Mizokami A, et al. Regenerative treatment for male stress urinary incontinence by periurethral injection of adipose-derived regenerative cells: outcome of the ADRESU study. Int J Urol. 2020;27(10):859-865. doi:10.1111/iju.14311.