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Avances en ginecología regenerativa: Aplicaciones clínicas de PRP, Células Madre y Scaffolds Biodegradables. Revisión Sistemática

Advances in Regenerative Gynecology: Clinical Applications of PRP, Stem Cells, and Biodegradable Scaffolds. Systematic Review

Avanços em ginecologia regenerativa: aplicações clínicas de PRP, células-tronco e arcabouços biodegradáveis. Revisão sistemática

Julio Gustavo Rojas Zambrano [I]
drjuliorojasz@gmail.com
https://orcid.org/0000-0003-0195-1994

Augusto Roger Rojas Zambrano [II]
dr.augusto.rojas9@gmail.com
https://orcid.org/0000-0001-8324-3283

José Eduardo Grijalva Proaño [III]
eduardogrijalva397@gmail.com
https://orcid.org/0009-0008-3128-118X

Jhosselin Andrea Colcha Colcha [IV]
jandre.selin@gmail.com
https://orcid.org/0009-0002-8320-4959

Correspondencia: drjuliorojasz@gmail.com

Ciencias de la Salud
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I. Maestro en Gestión de los Servicios de la Salud; Especialista en Medicina (Ginecología y Obstetricia); Medico; CEO del Centro de Medicina Bio regenerativa y Antienvejecimiento "Dr. Regeneración"; New Jersey, Estados Unidos
II. Especialista en Medicina Funcional; Médico General; Administrador del Centro de Medicina Bio regenerativa y Antienvejecimiento "Dr. Regeneración"; Guayaquil, Ecuador
III. Médico Cirujano; Médico General en Kaplan Medical; Nueva York, Estados Unidos
IV. Magíster en Salud Pública; Médica Cirujana; Médica General en Centro Integral Alterfisio; Riobamba, Ecuador

Resumen

La medicina regenerativa en ginecología, un campo interdisciplinario en rápida expansión, busca restaurar la función de órganos y tejidos mediante el uso de terapias biológicas. El objetivo principal de esta investigación es realizar una evaluación exhaustiva de la literatura publicada entre 2015 y 2025 para consolidar la evidencia sobre las aplicaciones clínicas de la medicina regenerativa en ginecología. Esta revisión sistemática de la literatura, se ha elaborado, siguiendo las pautas de la metodología PRISMA, se realizó una búsqueda exhaustiva en múltiples bases de datos para consolidar la evidencia sobre su eficacia, seguridad y aplicabilidad clínica en patologías como la disfunción sexual, el prolapso de órganos pélvicos y la insuficiencia ovárica. La ginecología regenerativa es un campo emergente que utiliza terapias como el plasma rico en plaquetas, las células madre y los biomateriales para tratar diversas afecciones ginecológicas. Si bien estas terapias son prometedoras en la reparación de tejidos y la restauración de la función, el campo aún se encuentra en una etapa inicial. Es crucial cerrar la brecha entre la investigación y la práctica clínica mediante la estandarización de protocolos y la realización de ensayos clínicos rigurosos, ya que actualmente la evidencia es limitada y las agencias reguladoras mantienen una postura cautelosa para proteger a los pacientes de terapias no probadas.

Palabras claves: Medicina regenerativa, ginecología regenerativa, plasma rico en plaquetas, PRP, células madre, células madre mesenquimales.

Abstract

Regenerative medicine in gynecology, a rapidly expanding interdisciplinary field, seeks to restore organ and tissue function through the use of biological therapies. The main objective of this research is to conduct a comprehensive evaluation of the literature published between 2015 and 2025 to consolidate evidence on the clinical applications of regenerative medicine in gynecology. This systematic literature review, developed following PRISMA methodology guidelines, conducted an exhaustive search across multiple databases to consolidate evidence on its efficacy, safety, and clinical applicability in pathologies such as sexual dysfunction, pelvic organ prolapse, and ovarian insufficiency. Regenerative gynecology is an emerging field that uses therapies like platelet-rich plasma, stem cells, and biomaterials to treat various gynecological conditions. While these therapies show promise in tissue repair and function restoration, the field is still in its early

stages. It is crucial to close the gap between research and clinical practice by standardizing protocols and conducting rigorous clinical trials, as the current evidence is limited and regulatory agencies maintain a cautious stance to protect patients from unproven therapies.

Keywords: regenerative medicine, regenerative gynecology, platelet-rich plasma, PRP, stem cells, mesenchymal stem cells.

Resumo

A medicina regenerativa em ginecologia, um campo interdisciplinar em rápida expansão, busca restaurar a função de órgãos e tecidos por meio do uso de terapias biológicas. O principal objetivo desta pesquisa é realizar uma avaliação abrangente da literatura publicada entre 2015 e 2025 para consolidar evidências sobre as aplicações clínicas da medicina regenerativa em ginecologia. Esta revisão sistemática da literatura, desenvolvida seguindo as diretrizes da metodologia PRISMA, conduziu uma busca exaustiva em diversas bases de dados para consolidar evidências sobre sua eficácia, segurança e aplicabilidade clínica em patologias como disfunção sexual, prolapso de órgãos pélvicos e insuficiência ovariana. A ginecologia regenerativa é um campo emergente que utiliza terapias como plasma rico em plaquetas, células-tronco e biomateriais para tratar diversas condições ginecológicas. Embora essas terapias sejam promissoras no reparo tecidual e na restauração da função, o campo ainda está em seus estágios iniciais. É crucial fechar a lacuna entre a pesquisa e a prática clínica, padronizando protocolos e conduzindo ensaios clínicos rigorosos, visto que as evidências atuais são limitadas e as agências reguladoras mantêm uma postura cautelosa para proteger os pacientes de terapias não comprovadas.

Palavras-chave: medicina regenerativa, ginecologia regenerativa, plasma rico em plaquetas, PRP, células-tronco, células-tronco mesenquimais.

Introduction

Regenerative medicine is a paradigm shift in healthcare, moving from symptom management to restoring the physiological function of damaged tissues and organs. In the context of gynecology, this approach has the potential to address a wide range of chronic and degenerative conditions that significantly impact women's quality of life. Among the most explored applications are the

treatment of sexual dysfunction, vulvovaginal atrophy, ovarian insufficiency, pelvic floor disorders like pelvic organ prolapse (POP) and stress urinary incontinence (SUI), as well as improving conditions for fertility (1). Additionally, regenerative medicine is being explored as a promising alternative to address the challenges of infertility, endometriosis, and polycystic ovary syndrome (PCOS) (2). Specifically, stem cell therapies, such as mesenchymal stem cells (MSCs), have shown therapeutic potential in managing endometriosis by suppressing inflammation and promoting the vascularization of lesions (3). In polycystic ovary syndrome, treatment with MSCs has improved angiogenesis, insulin sensitivity, and hormonal imbalance.

The main therapy modalities in this field include platelet-rich plasma (PRP), stem cell therapies, and the use of biodegradable scaffolds or biomaterials. PRP, an autologous preparation derived from the patient's own blood, is based on the concentration of platelets and the growth factors they release, such as platelet-derived growth factor (PDGF), transforming growth factor beta (TGF-β), and vascular endothelial growth factor (VEGF), which are crucial for wound healing and tissue regeneration (1). Stem cells, particularly mesenchymal stem cells (MSCs), have the ability to differentiate into various cell types and, more importantly, to secrete paracrine factors that modulate inflammation and promote tissue repair (3). Finally, biomaterials or scaffolds, such as poly(ϵ-caprolactone) (PCL) threads or porcine intestinal submucosa (SIS), offer mechanical support for damaged tissues and act as frameworks to facilitate the regeneration of new tissues (4).

Despite the notable growth in research on regenerative gynecology (3), the field faces a fundamental challenge: a disconnect between theoretical potential and rigorous clinical evidence. Initial studies, while promising, often have significant methodological limitations, such as the lack of randomized controlled trials (RCTs), small patient cohorts, and considerable heterogeneity in treatment protocols and outcome measures (1). This situation has led to a dichotomy where the excitement of preliminary results clashes with a stance of caution from major medical societies and regulatory bodies. For example, while some studies report improvements in symptoms and quality of life with therapies like PRP (1), the American College of Obstetricians and Gynecologists (ACOG) strongly warns against procedures like "vaginal rejuvenation" due to the lack of data supporting their safety and efficacy (5). Similarly, the American Society for Reproductive Medicine (ASRM) and the European Society for Human Reproduction and Embryology (ESHRE)

have expressed concern about the commercialization of unproven fertility treatments, such as stem cell therapies, outside the framework of controlled clinical trials (2).

This apparent contradiction is due to the fact that the current level of evidence is not sufficient to justify the widespread clinical application of these therapies. The justification for this systematic review is, therefore, not only to consolidate existing data but also to critically analyze this gap and the reasons for the warnings issued by health authorities, providing a balanced and evidence-based view of the current state of regenerative gynecology. The main objective of this review is to conduct a comprehensive evaluation of the literature published between 2015 and 2025 to consolidate the evidence on the clinical applications of regenerative medicine in gynecology.

The specific objectives are:

- To evaluate the efficacy and safety of platelet-rich plasma (PRP) in the treatment of various gynecological conditions.
- To analyze the therapeutic potential and main challenges of stem cell therapies, with an emphasis on ovarian and endometrial regeneration.
- To review the use of scaffolds and biodegradable biomaterials in the repair of pelvic floor disorders.
- To examine the regulatory framework and ethical stances of key professional societies and regulatory bodies (ACOG, ASRM, ESHRE, IUGA, FDA, EMA).

Methodology

This systematic review was conducted following the guidelines of the systematic review manual and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement flowchart.

Search Strategy

The literature search was conducted in multiple international databases to ensure broad coverage of the topic. The databases consulted included PubMed, Scopus, Web of Science, Science Direct, Cochrane Library, ProQuest, and Google Scholar. The search was limited to publications from 2015 to 2025. The main search terms were combined using Boolean operators (AND, OR) and

included: ("regenerative medicine" OR "regenerative gynecology") AND ("platelet-rich plasma" OR "PRP") AND ("stem cells" OR "mesenchymal stem cells") AND ("biodegradable scaffolds" OR "biomaterials" OR "mesh") AND ("gynecology" OR "female reproductive disorders" OR "pelvic floor disorders"). The search also incorporated specific terms for the target pathologies, such as "sexual dysfunction," "lichen sclerosus," "ovarian insufficiency," "endometrial regeneration," "stress urinary incontinence," and "pelvic organ prolapse."

Inclusion and Exclusion Criteria

Rigorous criteria were established for the selection of studies, with the goal of including the most relevant and highest quality evidence available:

- **Inclusion Criteria:**
    - Human clinical studies, including randomized controlled trials (RCTs), prospective and retrospective studies, and systematic reviews.
    - Articles published in peer-reviewed scientific journals.
    - Studies that evaluated clinical applications of PRP, stem cells, or biomaterials in the treatment of gynecological conditions.
    - Publications in English or Spanish.
- **Exclusion Criteria:**
    - Isolated case reports or case series with fewer than 10 patients.
    - Preclinical studies, animal studies, or purely theoretical studies (unless necessary for contextualizing the discussion, such as in the mechanisms of action section).
    - Comments, editorials, letters to the editor, and opinion articles without original data.
    - Studies without explicit clinical results or that did not evaluate efficacy or safety.
    - Studies from time periods outside the 2015-2025 range.

Study Selection Process

The study selection process was carried out in two phases. In the first phase, two independent reviewers screened the titles and abstracts of all articles identified from the search strategy. Duplicates and articles that did not meet the preliminary inclusion criteria were removed. In the second phase, the reviewers evaluated the full text of the articles selected in the first phase. Any disagreement between the reviewers was resolved through discussion and consensus with a third senior reviewer. The studies that were ultimately included in the qualitative synthesis were those that met all inclusion criteria.

Study Selection Process and PRISMA Flow Diagram

The PRISMA flow diagram will visually represent the entire study selection process, from the initial number of records identified to the final number of studies included in the review. This diagram is a key component of systematic reviews, as it provides transparency and a clear overview of the selection process.

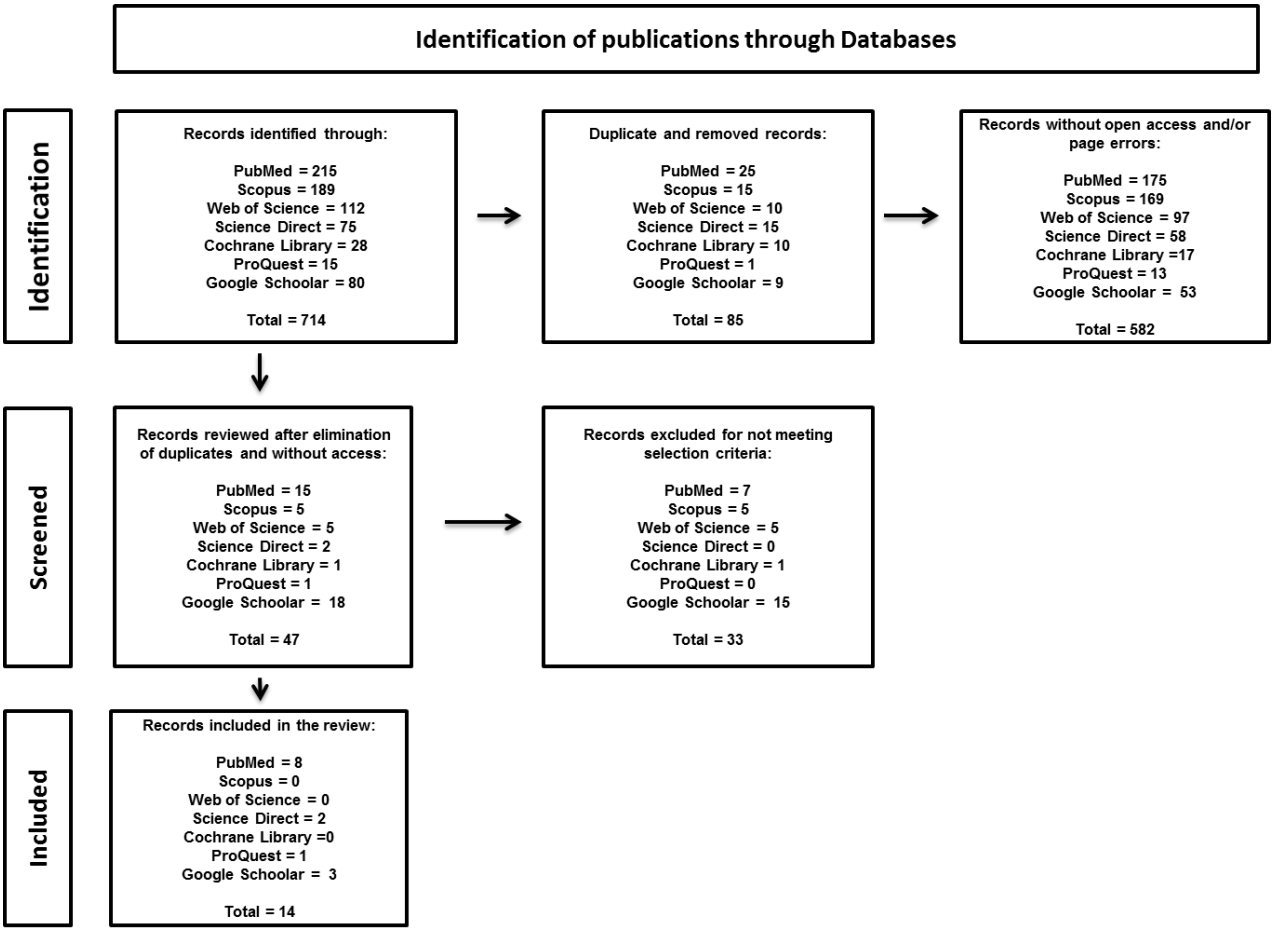
Table 1. *Study Selection by Database*

Database	Records Found	Records Selected (pre-screening)	Final Records Selected for Research
PubMed	215	185	8
Scopus	189	162	0
Web of Science	112	98	0
Science Direct	75	65	2
Cochrane Library	28	26	0
ProQuest	15	15	1
Google Scholar	80	78	3
Total	**714**	**629**	**14**

Of the total of 714 articles found, 629 were identified as unique after duplicates were removed. 582 articles were excluded for not meeting the inclusion and exclusion criteria, and 47 articles went to

the final review to assess their eligibility, with 15 articles being chosen that met all criteria for the research. Below is the PRISMA Flow Diagram of the two-phase screening process that led to the final study selection.

Figure 1. *PRISMA Flow Diagram of the Screening Process*



Results

Characteristics and Outcomes of Included Studies

Table 2. *Characteristics and Outcomes of Included Studies*

Study Reference	Condition Treated	Therapy Type	Study Type (N)	Main Results	Conclusions
Willison et al (1)	Sexual dysfunction	PRP	Systematic Review	Improvement in symptoms	PRP shows potential, but

	(SD), Lichen sclerosus (LS), Asherman's syndrome (AS), Vulvovaginal atrophy			and quality of life (QoL) in SD and LS. Potential in AS to increase endometrial thickness.	evidence is limited, and there is heterogeneity in protocols and outcomes.
Dankova et al (6)	Female sexual dysfunction (FSD), Stress urinary incontinence (SUI)	PRP	Systematic Review (327 women)	Significant improvement in sexual function indices (FSFI) and urinary symptom indices (ICIQ-SF, UDI-6).	Initial promising results, but the level of evidence is low due to methodological issues.
Sanoulis et al (7)	Pelvic floor disorders (PFDs), Urinary infection, Prolapse	PRP	Review (600 women)	Positive impact on FSD, perineal trauma, vulvovaginal atrophy, SUI, and POP.	PRP can be used for PFDs, but standardization of dosage and technique is needed.
Kurniadi et al (8)	Various gynecological pathologies	Adult stem cells	Scoping Review (42 articles)	Most studies are preclinical, with promising results in degenerative gynecological diseases.	Adult stem cell therapy is a candidate for various gynecological pathologies.
Nair et al (3)	Ovarian insufficiency, Endometrial regeneration, Endometriosis	Stem cells (MSCs)	Comprehensive Review	MSCs have considerable potential to regenerate tissues through paracrine factors (VEGF, TGF-β).	Massive clinical implementation is limited by reliance on preclinical data and the need to standardize protocols.

Silva et al. (4)	Pelvic organ prolapse (POP)	PCL scaffolds	Preclinical and simulation study	PCL threads significantly reduce the deformation of the vaginal wall under pressure, with results comparable to healthy tissue.	Biodegradable PCL threads are a promising and minimally invasive alternative for POP repair.
Isali et al (9)	Stress urinary incontinence (SUI)	Polymeric scaffolds	Narrative Review	Materials such as SIS, PLA, and PGA are explored. The main obstacle is premature degradation and insufficient tensile strength.	More research is required to overcome obstacles and ensure the safety and efficacy of biodegradable scaffolds.

Results

Platelet-Rich Plasma (PRP)

Available evidence suggests that PRP is a promising therapy due to its autologous nature and low risk of adverse effects. Its mechanism of action focuses on the release of growth factors and bioactive molecules that promote cell migration, proliferation, angiogenesis, and tissue regeneration (1). The studies reviewed show that PRP has been used with positive results in multiple conditions. In non-reproductive gynecology, it has improved symptoms and quality of life (QoL) in patients with sexual dysfunction (SD) and vulvar lichen sclerosus (LS), and has been explored for the treatment of vulvovaginal atrophy and stress urinary incontinence (SUI) (1). Furthermore, PRP has demonstrated promising potential in the management of female sexual dysfunction (FSD) and other vaginal conditions. It has been used to treat vulvovaginal atrophy, alleviating symptoms such as burning, pain, and vaginal dryness. Studies show that PRP improves

sexual function by reducing dryness, atrophy, and vaginal laxity (1). In fact, PRP injections have been found to significantly improve female sexual function indices (FSFI) and urinary symptoms (ICIQ-SF and UDI-6) in patients with FSD and stress urinary incontinence. The effectiveness of PRP in these conditions is attributed to its ability to promote new collagen formation and neovascularization in the anterior vaginal wall (6). PRP has also been reported to have a positive impact on perineal trauma and pelvic organ prolapse (7).

In the reproductive field, PRP has shown potential to increase endometrial thickness in patients with thin endometrium and to improve outcomes in assisted reproduction cycles. However, despite the encouraging results, systematic reviews conclude that the current level of evidence is low, mainly due to the variability in PRP preparation, doses, and injection technique (7).

Stem Cells

Stem cells, especially mesenchymal stem cells (MSCs), have emerged as one of the most researched therapies in the gynecological and reproductive fields. These cells can be derived from various sources such as the endometrium, umbilical cord, adipose tissue, and bone marrow, and their main mechanism of action is through paracrine activity. They release a secretome rich in growth factors, cytokines, and immunomodulators (IL-10, TGF-β, VEGF) that promote angiogenesis, tissue repair, and inflammation suppression (3).

The application of MSCs has shown considerable potential in the regeneration of ovarian function in cases of premature ovarian insufficiency and in endometrial regeneration, restoring function through the modulation of molecular pathways and cell proliferation. However, an analysis of the literature reveals that most of the available studies are preclinical in nature, which means that the translation to clinical practice in humans is still at a very early stage. Challenges for clinical implementation include the optimization of administration methods, the standardization of protocols, and the need for long-term safety data (3).

Scaffolds and Biodegradable Biomaterials

In the repair of pelvic floor disorders, such as POP and SUI, the use of biodegradable biomaterials has been explored as an alternative to permanent synthetic meshes, which have been associated with complications such as mesh extrusion and chronic pain (10). Various polymeric materials

have been investigated, including poly(ϵ-caprolactone) (PCL), porcine intestinal submucosa (SIS), polylactic acid (PLA), and polyglycolic acid (PGA) (4).

Findings from simulations and preclinical studies suggest that new designs, such as 3D-printed PCL threads, can provide mechanical support comparable to that of healthy tissues, which reduces deformation in prolapse models (4). However, the research has also identified significant obstacles. A major challenge is that biomaterials can degrade prematurely before the native tissue has had enough time to integrate and provide the necessary support. Furthermore, the tensile strength of these materials may be insufficient to withstand the dynamic nature of the pelvic environment, and there is a need to minimize inflammatory responses (9).

The analysis of the literature suggests that the combination of therapies could be the future of the field. For example, scaffolds could be designed not only to provide a physical framework but also to be "loaded" with stem cells or growth factors that actively promote regeneration and vascularization (9). This would represent a synergistic approach that would address both the need for immediate physical support and long-term tissue regeneration, overcoming the inherent limitations of each therapy separately.

Regulatory and Ethical Aspects

Regulatory Framework (FDA and EMA)

The rapid evolution of regenerative medicine has generated significant scrutiny from regulatory bodies. The U.S. Food and Drug Administration (FDA) has issued clear warnings about the commercialization of unapproved regenerative medicine products, such as stem cell and PRP therapies, that are illegally offered to consumers. The FDA has reported cases of serious adverse events, including blindness, tumor formation, and infections, associated with the use of these products outside a supervised clinical trial setting. The agency emphasizes that most of these products have not been proven safe or effective for the conditions they advertise and require an Investigational New Drug (IND) application to be legally administered (11). However, the FDA has also established a framework for innovation through the Regenerative Medicine Advanced Therapy (RMAT) designation, which accelerates the development and review of therapies that have the potential to treat serious or life-threatening diseases (12).

For its part, the European Medicines Agency (EMA) has consolidated its guidelines for Advanced Therapy Medicinal Products (ATMPs), which include cell, tissue engineering, and gene therapies (13). These guidelines establish rigorous requirements for quality, non-clinical development, and clinical trials, with a special emphasis on detailed documentation and long-term patient follow-up (13). Unlike the FDA, the EMA tends to have more generalized requirements for determining donor eligibility, which can lead to regulatory divergences and hinder the global development of products (15). Both regulatory frameworks, however, share the fundamental premise that safety and efficacy must be rigorously demonstrated in a clinical trial setting before a therapy can be approved for widespread use.

Guidelines from Professional Societies (ACOG, ASRM, ESHRE, IUGA)

An analysis of the stances of key professional societies in gynecology and reproductive medicine reveals a unified position of caution regarding unproven therapies. The American College of Obstetricians and Gynecologists (ACOG) issued a strong opinion against vaginal cosmetic procedures such as "vaginal rejuvenation," stating that they lack a medical indication and that their safety and efficacy have not been documented (5).

The American Society for Reproductive Medicine (ASRM) has been particularly vocal in its criticism of "Restorative Reproductive Medicine" (RRM), a term often used to describe alternatives to in vitro fertilization (IVF). The ASRM warns that RRM is an ideology without a scientific basis that spreads misinformation and delays evidence-based clinical care (2). Similarly, the European Society for Human Reproduction and Embryology (ESHRE) has alerted patients and physicians about the risks of stem cell treatments offered outside a framework of rigorous scientific research and regulated clinical trials (14).

In the field of urogynecology, the International Urogynecological Association (IUGA) has collaborated on the creation of a standardized terminology and classification for complications of meshes and grafts used in pelvic floor surgery. Although it does not discourage the use of meshes in specific procedures such as sacrocolpopexy, the existence of this classification system underscores the inherent risks of biomaterials and the need for continuous vigilance and structured complication reporting (10).

Critical Discussion

Comparison of Efficacy and Safety

When comparing the three therapeutic modalities, there is a difference in the maturity of the evidence. PRP, due to its autologous nature and generally favorable safety profile, has been the most widely studied in the clinical setting and has shown promising results in a variety of conditions (1). However, the lack of standardization in its preparation and dosage remains a significant barrier to its widespread adoption (7).

Stem cell therapies, while showing enormous potential at the preclinical level, are at a more nascent stage of clinical translation (3). Their greater complexity and potential risks, such as tumorigenicity or cell migration, require much stricter supervision (11).

Scaffolds and biomaterials offer a mechanical solution to structural problems, but the experience with synthetic meshes has taught the critical importance of biocompatibility and long-term degradation resistance. The new biodegradable biomaterials are designed to mitigate these risks, but the clinical evidence is not yet robust (4).

The relationship between PRP and stem cells is fundamental to understanding the field. PRP not only provides growth factors but is also believed to attract and activate endogenous stem cells, thus promoting tissue regeneration (1). Therefore, PRP can be considered a therapy that leverages the body's intrinsic regenerative potential, while stem cell therapy introduces a new biological material that may have a more potent action but also more complex risks.

Limitations of Current Evidence

The main limitations identified in the current literature are methodological. Despite the existence of some systematic reviews, most of the original studies are cohort or case-control, which reduces the strength of conclusions about causality. The heterogeneity in treatment protocols, especially with PRP, prevents direct comparison between studies. For example, the platelet concentration, the use of activators, the injection technique, and the number of sessions vary widely.

Additionally, there is a lack of standardized outcome measures, which makes it difficult to synthesize findings and determine true clinical efficacy. The lack of long-term follow-up in many

of the existing studies is also a critical limitation, as the durability of results and the appearance of late adverse effects, as seen with surgical meshes, remain unanswered questions.

Research Gaps and Future Directions

For the field of regenerative gynecology to advance responsibly, a significant investment in high-quality research is required. It is imperative that future studies focus on:

- **Standardization of protocols:** Trials must be conducted to determine the optimal PRP preparation protocol, as well as the most effective dose and administration method for each pathology.
- **Rigorous Clinical Trials:** The focus should shift from observational studies to randomized controlled trials (RCTs) to establish the true efficacy and safety of therapies.
- **Long-term safety evaluation:** Long-term follow-up studies are needed to monitor for late side effects and the durability of results.
- **Investigation of combined therapies:** The future of regenerative gynecology likely does not lie in a single therapy but in a combination of them. Research should explore the synergy between scaffolds, stem cells, and PRP to create complete solutions that offer structural support, modulate the inflammatory response, and promote sustained tissue regeneration. This combined approach could address the limitations of each individual therapy, such as the premature degradation of biomaterials or the lack of a framework for cells.

Conclusions

Regenerative gynecology is a field with transformative potential for treating gynecological conditions that have traditionally had limited treatment options. The evidence analyzed in this systematic review suggests that therapies with PRP, stem cells, and biomaterials are promising in tissue repair and function restoration. In particular, PRP has shown encouraging results in the treatment of sexual dysfunction and vulvovaginal atrophy, while stem cells and scaffolds are opening new avenues for ovarian regeneration and pelvic floor repair, respectively.

However, the field is at a nascent stage. The gap between the initial promise of research and high-quality clinical evidence is notable. The heterogeneity in protocols and the preponderance of preclinical or low-quality clinical studies limit the ability to generalize findings. The cautious stance of regulatory agencies and professional societies is necessary and appropriate to protect patients from unproven therapies with potential risks. The way forward requires a commitment to standardization, the conduct of rigorous and large-scale clinical trials, and a greater exploration of combined therapies. Only through solid and responsible research can the gap between innovation and evidence-based clinical practice be closed, making regenerative gynecology a safe and effective reality.

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