

Platelet-Rich Plasma for Vulvovaginal Disorders: An Umbrella Review of Nineteen Systematic, Scoping and Narrative Reviews Published Since 2020

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Abstract

Background: Platelet-rich plasma (PRP) is offered increasingly widely for vulvar lichen sclerosus (VLS), the genitourinary syndrome of menopause (GSM), female sexual dysfunction (FSD) and stress urinary incontinence (SUI). The number of reviews summarising this practice has grown quickly, and their consistently favourable tone is now itself used as justification for clinical adoption.

Objective: To appraise, at the level of the secondary literature, what the post-2020 reviews of vulvovaginal PRP collectively establish; to reconstruct the primary-evidence layer beneath them after removing double-counted studies; and to define the minimum design and reporting standards that future trials in regenerative gynaecology must meet.

Methods: We conducted an umbrella review of systematic, scoping and structured narrative reviews published from 2020 onward that addressed PRP for vulvovaginal or lower genital tract indications. Ovarian, endometrial and infertility-only reviews were excluded. Twenty-seven candidate records were retrieved and read; every extracted value was bound to the specific source page that stated it, and values that could not be confirmed on a retrieved page were recorded as not available rather than inferred. For the subset of reviews publishing an included-study list, we constructed a primary-study overlap matrix and deduplicated participants and study designs.

Results: Nineteen reviews met eligibility. None reported a pooled effect estimate, confidence interval or heterogeneity statistic for any vulvovaginal PRP outcome. Four had a registered protocol, seven stated PRISMA adherence, three applied a named risk-of-bias instrument, and only eight published a retrievable included-study list. Reported participant totals in the six largest reviews summed to 2,529, but deduplication across the eight listable reviews yielded 55 unique primary studies and 1,704 participants — an inflation factor of approximately 1.5. Of those 55 studies, 24 were prospective single-arm or cohort designs, 12 were case reports or small series, nine were retrospective or otherwise uncontrolled, and only 10 were randomised. Just four were sham- or placebo-controlled, together enrolling 187 participants, and three of those four were null. Nine primary studies were assigned frankly discordant sample sizes or designs by different reviews. Whole-blood volume ranged from 5 to 100 mL, injected PRP from 1 to 10 mL, sessions from one to ten, and inter-session intervals from 15 days to three months; leukocyte content was addressed by a single review and standard PRP classifications were described as rarely applied. No review reported a median follow-up, one dedicated systematic review reported no adverse-event data at all, and no review specified a target sample size or minimal clinically important difference.

Conclusion: The apparent abundance of favourable secondary evidence for vulvovaginal PRP is an artefact of repeated summarisation of a small, largely uncontrolled and inconsistently characterised primary literature. Meta-analysis is not currently defensible. Progress requires adequately powered sham-controlled trials with prespecified minimal clinically important differences, full PRP characterisation, indication-specific core outcome sets, follow-up of at least 12 months, and structured graded harms ascertainment.

Keywords

Platelet-rich plasma; Vulvar lichen sclerosus; Genitourinary syndrome of menopause; Female sexual dysfunction; Regenerative gynecology; Umbrella review.

Abbreviations

ADSC, adipose-derived stem cells; AE, adverse event; CSS, clinical scoring system; CTCAE, Common Terminology Criteria for Adverse Events; DLQI, Dermatology Life Quality Index; FGM/C, female genital mutilation/cutting; FSD, female sexual dysfunction; FSDS-R, Female Sexual Distress Scale–Revised; FSFI, Female Sexual Function Index; GSM, genitourinary syndrome of menopause; HA, hyaluronic acid; ICIQ-SF, International Consultation on Incontinence Questionnaire–Short Form; IGA, Investigator Global Assessment; MCID, minimal clinically important difference; PFMT, pelvic floor muscle training; POP, pelvic organ prolapse; PRP, platelet-rich plasma; RCT, randomised controlled trial; SUI, stress urinary incontinence; UDI-6, Urogenital Distress Inventory–6; VHI, Vaginal Health Index; VLS, vulvar lichen sclerosus; VVA, vulvovaginal atrophy; VVF, vesicovaginal fistula.

Introduction

Autologous platelet-rich plasma (PRP) has moved from orthopaedic and dermatological practice into gynaecology with unusual speed. It is now offered, in office settings and often outside any regulatory pathway for a biological product, for vulvar lichen sclerosus (VLS), the genitourinary syndrome of menopause (GSM) and vulvovaginal atrophy (VVA), female sexual dysfunction (FSD), vaginal laxity, stress urinary incontinence (SUI), vesicovaginal fistula, perineal repair and reconstruction after female genital mutilation or cutting (FGM/C). The biological rationale is coherent: platelet alpha-granules release platelet-derived growth factor, transforming growth factor-beta, vascular endothelial growth factor, epidermal growth factor and insulin-like growth factor-1, which plausibly influence fibroblast activation, angiogenesis, extracellular matrix remodelling and epithelial regeneration in atrophic or sclerotic genital tissue [8,12,18].

Coherent rationale is not evidence of clinical benefit. Between 2020 and 2026 the secondary literature on vulvovaginal PRP expanded rapidly: systematic reviews restricted to lichen sclerosus [5, 12], to VVA of

menopause [7], to pelvic floor disorders [2], to FSD and SUI [9], and to gynaecology broadly [8,18], alongside narrative and commentary pieces that nonetheless carry the words "systematic review" in their titles [10,13]. Taken at face value, this body of work reads as a maturing, convergent and reassuring literature. Clinicians, marketing material and patient-facing content increasingly cite the sheer number of positive reviews as though it were an independent measure of certainty.

That inference is unsafe for a structural reason. Reviews of a young intervention rarely draw on independent evidence pools. When several reviews summarise the same small set of uncontrolled case series, the resulting impression of accumulation is an artefact of repetition. The corrective instrument is an umbrella review that does three things standard reviews do not: it appraises how the reviews themselves were conducted, it reconstructs which primary studies actually sit beneath them, and it reports what remains once double-counted studies are removed [1,8].

A second problem is specific to PRP. PRP is not a defined molecule but a procedural output whose composition depends on the volume of blood drawn, the centrifugation protocol, the resulting platelet concentration factor, the leukocyte content, whether and how the preparation is activated, the injected volume, the anatomical target and the number and spacing of sessions. Two interventions both labelled "PRP" may differ more from one another than either differs from saline. Without a standardised description of the product, apparently consistent efficacy claims across studies cannot be interpreted as replication, and pooling is not statistically meaningful [8,9].

A third problem is comparator rigour. In regenerative gynaecology, symptom scores in uncontrolled before–after designs are exceptionally vulnerable to regression to the mean, natural fluctuation of chronic vulvar conditions, concurrent topical therapy, the strong placebo response documented for genital and sexual outcomes, and the procedural expectation effects created by repeated intimate clinical contact. Only sham- or placebo-controlled designs can separate the biological effect of the injectate from the effect of being treated.

We therefore conducted an umbrella review with three objectives. First, to characterise the post-2020 review literature on vulvovaginal PRP and appraise its methodological conduct. Second, to reconstruct and deduplicate the primary-evidence layer beneath it, quantifying overlap, design distribution, comparator rigour and cross-review data-extraction discordance. Third, to convert the reviews' own recommendations, together with the gaps they leave unaddressed, into an explicit minimum design and reporting set for future standardised clinical trials in regenerative gynaecology.

Materials and Methods

Design and reporting

This is an umbrella review (overview of reviews) of secondary evidence on PRP for vulvovaginal and lower genital tract indications. It was conducted and is reported in accordance with the principles of the PRISMA 2020 statement as adapted for overviews of reviews. The protocol was not prospectively registered; this is stated explicitly as a limitation and is not presented as methodological equivalence to a registered review.

Eligibility criteria

Eligible records were systematic reviews, scoping reviews, meta-analyses and structured narrative reviews published from 2020 onward, in any language with an accessible English abstract, that addressed PRP applied to vulvovaginal or lower genital tract targets. Eligible indications were VLS and genital lichen sclerosis, GSM and VVA, FSD and vaginal laxity, vesicovaginal fistula, vaginal mesh exposure, pelvic organ prolapse, perineal rupture and repair, reconstruction after FGM/C, and SUI when treated by vaginal or periurethral PRP administration. Reviews addressing only intraovarian or intrauterine PRP for infertility, and reviews of non-genital indications, were excluded. Records describing themselves as reviews but presenting original patient-level data were reclassified as primary studies and excluded from the review layer, while remaining available to the primary-evidence layer.

Information sources and search

We searched PubMed and PubMed Central together with publisher platforms (Oxford Academic, MDPI, Springer, SAGE, Taylor & Francis, Wiley, Cureus and open-access indexes) using eight indication-specific query sets combining platelet-rich plasma with lichen sclerosis, vulvovaginal atrophy, genitourinary syndrome of menopause, female sexual dysfunction, vaginal rejuvenation, pelvic floor disorders, stress urinary incontinence and regenerative gynaecology, each restricted to review publication types from 2020 onward. Searches were executed and all included pages retrieved on 7 September 2026. Reference lists of retrieved reviews were screened for further eligible records.

Data extraction and the grounding rule

Twenty-three records were profiled in full. For each, we extracted bibliographic details, review type, protocol registration, stated PRISMA adherence, risk-of-bias instrument, search end date and databases, number and design of included studies, participant totals, indications addressed, presence of any pooled effect estimate, follow-up statistics, adverse-event data, PRP preparation and administration parameters, every quantitative efficacy figure reported, stated limitations, and the review's own recommendations for future research.

A strict grounding rule was applied: every extracted value was bound to the specific retrieved page that stated it, and any field that could not be confirmed on a retrieved page was recorded as not available rather than inferred, imputed or supplied from background knowledge. This distinction matters, because "the review does not report this" and "we could not retrieve this" have different implications for appraisal. Two records were accessible only at abstract level because of publisher restrictions — De Ponte et al. [1] and Prodromidou et al. in *Surgical Innovation* [15] — and are flagged wherever this limits their contribution.

Overlap analysis and deduplication

Reviews publishing a retrievable included-study list were entered into a primary-study overlap matrix, with rows for each named primary study and columns for each review. Where reviews disagreed about the sample size or design of the same primary study, all reported values were retained and the discordance recorded separately rather than silently resolved. For the deduplicated denominator, each unique primary study was counted once; where sample sizes were discordant, the value most consistent with the majority of reviews and with the study's stated design was used, and the alternative retained in the discordance table. Studies of non-PRP regenerative interventions appearing inside the same reviews

(autologous fat grafting, stromal vascular fraction, hyaluronic acid or collagen mesotherapy) were tabulated but excluded from the PRP participant denominator. Reviews without a retrievable study list could not contribute to overlap analysis, which biases the deduplicated total downward and is reported as such.

Appraisal of review conduct

Rather than assigning a single composite quality score to heterogeneous review types, we appraised seven binary conduct criteria that are individually verifiable and individually consequential: protocol registration; stated PRISMA or PRISMA-ScR adherence; application of a named risk-of-bias instrument; publication of a retrievable included-study list; reporting of an aggregate follow-up statistic; structured reporting of harms; and presentation of any pooled effect estimate. Each criterion was judged solely on what the retrieved article stated.

Synthesis

Synthesis was structured and narrative. No new meta-analysis was attempted, and the reasons are themselves a finding of this review: no included review supplied a pooled estimate or the variance data required to construct one; overlap between reviews would have produced substantial double-counting; and the interventions summarised are too heterogeneously specified for a pooled estimate to correspond to any single treatment. Quantitative efficacy figures are therefore reported as study-level values with their comparator tier made explicit-uncontrolled before-after, active comparator, or sham/placebo control-because comparator rigour, not statistical significance, determines how each figure may be interpreted.

Results

Selection of reviews

Twenty-seven candidate secondary-evidence records were retrieved. One was excluded as addressing assisted reproduction and ovarian–endometrial indications only. Seven were reclassified: five were primary interventional trials, one a primary cohort study, and one a meta-analysis of PRP for skin ageing rather than a vulvovaginal indication. Nineteen review records met eligibility and form the analytic set (**Figure 1**). Ten were systematic reviews with a described formal method, two were scoping reviews, six were narrative or literature reviews, and one carried "systematic review" in its title while being labelled a commentary by its own publisher [10].

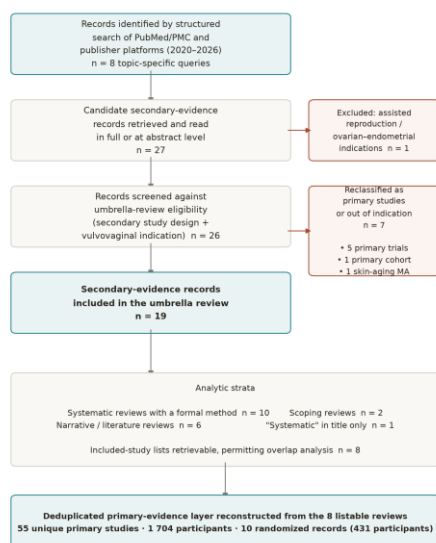


Figure 1: Selection of secondary-evidence records for the umbrella review, and reconstruction of the deduplicated primary-evidence layer beneath them.

Characteristics of the included reviews

Characteristics are summarised in (Table 1). The reviews were published between 2021 and 2026 in dermatology, plastic and aesthetic surgery, molecular science, reproductive medicine, urology and general gynaecology journals. Indication coverage was uneven and overlapping: six reviews addressed genital lichen sclerosus exclusively or predominantly [4,5,6,12], three addressed VVA or GSM [3,7], four addressed FSD [9,14], and six addressed pelvic floor disorders or SUI [2,11,15,16,17,19], with several spanning multiple domains [1,8,18].

Review [ref]	Type	Indications	Studies (design)	Patients	Reg.	RoB tool	List	Aggregate follow-up
De Ponte 2026 [1]	SR	VLS, FSD, VVA	18 (2 RCT, 10 single-arm, 1 retrospect., 5 case reports)	480 (401 PRP)	—	—	No	Not reported
Kurniawati 2024 [2]	SR	POP, SUI, FSD, perineal rupture, VVA, VVF	15 (2 RCT, 4 experimental, 4 cohort, 5 other)	600	PROSPERO	PEDro; JBI; CASP	Yes	Not reported
Waghe 2024 [3]	SR	GSM, VVA, LS, SUI	≥5 described (1 RCT, 1 case report, 3 pilots)	Not reported	—	—	Yes	≤6 months
Beutler 2025 [4]	SR	Vulvar lichen sclerosus	13 (1 RCT, 11 cohort, 1 case series); 7 PRP	360	—	—	Yes	3–24 months (study level)
Villalpando 2021 [5]	SR	Vulvar and penile LS	8 (1 randomised, 6 prospective uncontrolled, 1 case report)	Not reported	—	—	Yes	2–23.2 months; mean 9.9
El Attar 2026 [6]	NR	Genital lichen sclerosus	14 monotherapy + 4 combination	Not reported	—	—	No	Not reported
Moccia 2023 [7]	SR	VVA of menopause / GSM	8 (1 randomised, 7 observational)	236	—	—	No	Not reported
Willison 2025 [8]	ScR	13–16 conditions incl. VVA, VLS, FSD, FGM/C, SUI, VVF	43 vs 46 (internal conflict)	Median ≈48; range 5–200	OSF	—	Yes	4 weeks–12 months
Dankova 2023 [9]	SR	FSD (incl. VVA) and female SUI	12 (1 RCT, 10 prospective single-arm, 1 retrospect.)	327 (317 PRP)	PROSPERO	RoB-2; NOS	Yes	1–12 months

Review [ref]	Type	Indications	Studies (design)	Patients	Reg.	RoB tool	List	Aggregate follow-up
Wright 2025 [10]	NR †	Cosmetic gynaecology, VVA, FSD, SUI, LS	Not reported	Not reported	—	—	No	Not reported
Borislavski 2025 [11]	NR	Female SUI	Not reported	Not reported	—	—	No	Not reported
Paganelli 2023 [12]	NR	Genital (vulvar and penile) LS	≈20 studies	526 (272 PRP)	—	—	Yes	1–24 months in ≈half
Polo del Conoc. 2025 [13]	NR ‡	FSD, POP, ovarian insufficiency	Not reported	Not reported	—	—	No	Not reported
Ismail 2025 [14]	SR	FSD, VVA, laxity, GSM, LS, FGM/C	17 (4 RCT, 5 cohort, 6 case series/obs., 2 SRs)	Range 12–164	None stated	Cochrane; NOS; AMSTAR-2	Yes	"Generally short"
Prodromidou 2022a [15]	NR	VVA, POP, UI, fistula, mesh exposure	Not reported	Not reported	—	—	No	Not reported
Prodromidou 2022b [16]	NR	SUI, POP, fistula, GSM, mesh, genital LS	Not reported	Not reported	—	—	No	Not reported
Saputra 2024 [17]	ScR	Pelvic floor reconstruction surgery	5 articles	Not reported	OSF	—	No	Not reported
Streit-Ciećk. 2022 [18]	NR	Gynaecology and obstetrics incl. UI, sexual and aesthetic medicine	41 papers	Not reported	—	—	No	Not reported
Pourebrahimi 2025 [19]	NR	Female SUI	Not reported	Not reported	—	—	No	Not reported

Table 1: Characteristics and conduct of the 19 included reviews (2021–2026).

SR, systematic review; ScR, scoping review; NR, narrative or literature review. "Reg." indicates PROSPERO or Open Science Framework. "RoB tool" indicates a named risk-of-bias instrument. "List" indicates a retrievable included-study list. Blank cells indicate that the value could not be confirmed on the retrieved article page. No review reported a pooled effect estimate. † Self-labelled a commentary. ‡ Self-described as systematic without a reproducible search.

The largest reported evidence bases were Kurniawati et al. (15 studies, 600 patients across pelvic floor indications) [2], Paganelli et al. (approximately 20 studies, 526 patients with genital lichen sclerosus, including 106 males) [12], De Ponte et al. (18 studies, 480 patients, of whom 401 received PRP: 179 with VLS, 133 with FSD and 87 with VVA) [1], Beutler et al. (13 studies, 360 women with VLS) [4], Dankova et al. (12 studies, 327 patients of whom 317 received PRP: 172 with FSD and 155 with SUI) [9], and Moccia et al. (8 studies, 236 women with VVA) [7]. Willison et al. reported a sample-size range of 5 to 200 participants with a median of approximately 48 across its included studies [8].

Conduct and reporting of the reviews

(Figure 3) displays the seven conduct criteria across all 19 reviews. The single most consequential finding of this umbrella review is negative: no review reported a pooled effect estimate, confidence interval or heterogeneity statistic for any vulvovaginal PRP outcome. Despite the frequency with which this literature is described as meta-analysed, no meta-analysis of vulvovaginal PRP exists in the retrieved set. The only pooled estimates encountered anywhere during searching concerned PRP for facial skin ageing and are unrelated to genital indications.

Four reviews had a registered protocol: two in PROSPERO (CRD42022357561 [2]; CRD42022384473 [9]) and two on the Open Science Framework [8,17]. One review explicitly declared that it had not been registered [14]. Seven reviews stated adherence to PRISMA or PRISMA-ScR [2,3,4,8,9,13,14]. Only three applied a named risk-of-bias instrument: RoB-2 with the Newcastle–Ottawa Scale [9], PEDro with JBI and CASP checklists [2], and Cochrane RoB with the Newcastle–Ottawa Scale and AMSTAR 2 [14]. Sixteen of nineteen reviews therefore made claims about the quality of the underlying evidence without any formal instrument for assessing it.

Only eight reviews published an included-study list retrievable in sufficient detail to permit overlap analysis [2,3,4,5,8,9,12,14]. The remaining eleven, including several of those most frequently cited in support of clinical practice, cannot be audited against their own evidence base. One scoping review contained an internal contradiction, reporting 43 included studies in its abstract and strengths section and 46 in its results [8]. One systematic review presented two mutually exclusive "recommended protocols" for FSD within the same article — 2 mL into the distal anterior vaginal wall once monthly for three months in the abstract and discussion, and once weekly for three months in the text [9].

The deduplicated primary-evidence layer

Summing the reported totals of the six reviews that state a participant count yields 2,529 patients. Deduplication across the eight reviews with retrievable study lists yields 55 unique primary studies containing PRP arms and 1,704 participants — an inflation factor of approximately 1.5 between the apparent and the actual evidence base (**Figure 2, Table 2**). This is a conservative estimate of inflation, because the eleven reviews without retrievable lists could not be entered into the matrix; their inclusion would almost certainly raise the overlap and lower the unique total.

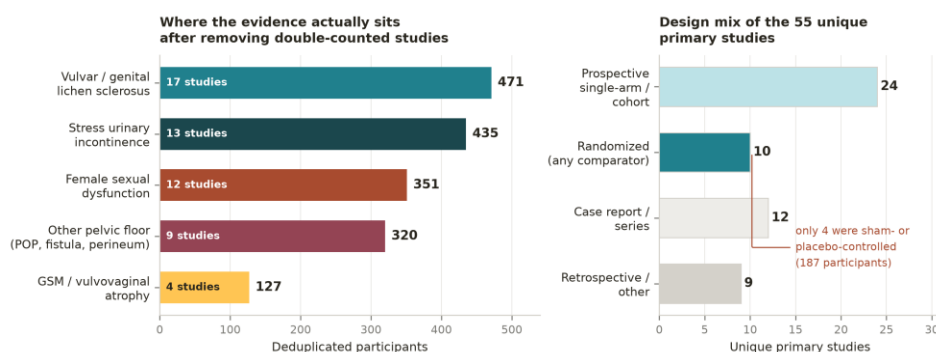


Figure 2: Left: deduplicated participants and unique primary studies by indication after removing studies double-counted across reviews. Right: study-design distribution of the 55 unique primary studies containing a PRP arm.

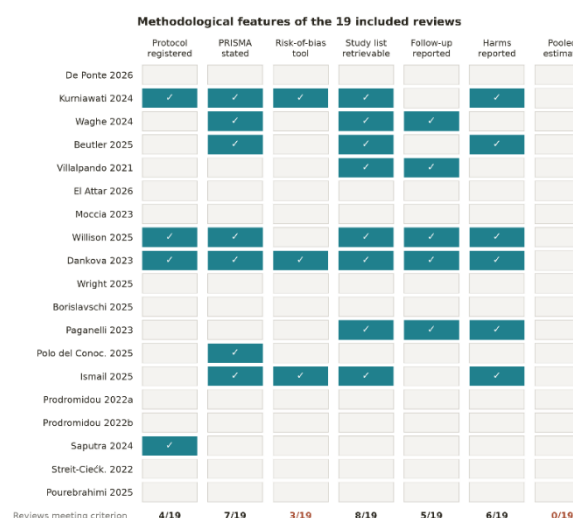


Figure 3: Seven conduct criteria across the 19 included reviews. Each criterion was judged solely on what the retrieved article stated. No review reported a pooled effect estimate for any vulvovaginal PRP outcome.

Indication	Unique studies	Participants	Randomised studies	Sham/placebo-controlled	Studies appearing in ≥3 reviews
Vulvar and genital lichen sclerosus	17	471	2	1 (null)	7
Stress urinary incontinence	13	435	5	3 (2 null, 1 positive)	2
Female sexual dysfunction (incl. FGM/C)	12	351	2	0	3
Other pelvic floor (POP, fistula, mesh, perineum)	9	320	1	1 (null)	0
GSM / vulvovaginal atrophy	4	127	2	0	3
Total	55	1,704	10 (431 participants)	4 (187 participants)	15

Deduplicated across reviews [2,3,4,5,8,9,12,14]. Studies of non-PRP regenerative interventions appearing within the same reviews (six studies, 138 participants: autologous fat grafting, stromal vascular fraction, hyaluronic acid and collagen mesotherapy) are excluded from these denominators. The eleven reviews without retrievable study lists could not be entered into the matrix, so overlap is underestimated.

Fifteen primary studies appeared in three or more reviews: Behnia-Willison 2016, Tedesco 2020/2022 [21], Sukgen 2019, Long 2021, Goldstein 2017, Goldstein 2019, Tedesco 2021, Medina Garrido 2023, Casabona 2023, Franić 2018, Hersant 2018, Saleh 2022, Daneshpajoo 2021, Dardeer 2022 and Kim 2017. Conversely, approximately 40 of the named studies appeared in exactly one review, so no single review substitutes for the set and the reviews are simultaneously redundant and incomplete. In the lichen sclerosus domain, four reviews with retrievable lists cover substantially the same core studies, which is best understood as one evidence base counted four times [4,5,8,12]. In the urogynaecological domain the pattern differs: two systematic reviews addressing overlapping questions shared only five studies [2,9], while a later scoping review subsumed much of both and added four randomised trials from 2023–2024

that appear in no other in-scope review [8].

The design distribution of the 55 unique studies is the decisive result. Twenty-four were prospective single-arm or cohort studies, twelve were case reports or small case series, nine were retrospective or otherwise uncontrolled, and ten were randomised, together enrolling 431 participants. Of those ten randomised records, only four were sham- or placebo-controlled, enrolling 187 participants in total. Deduplicated participants by indication were: genital lichen sclerosus 471 across 17 studies; SUI 435 across 13 studies; FSD including FGM/C 351 across 12 studies; other pelvic floor indications 320 across 9 studies; and GSM or VVA 127 across 4 studies. The indication with the strongest commercial promotion — vaginal rejuvenation for atrophy and sexual function — rests on the smallest deduplicated denominator.

Discordant data extraction between reviews

Nine instances were identified in which different reviews assigned frankly incompatible sample sizes, designs or interventions to the same primary study (Table 3). Medina Garrido 2023 was reported with N = 23, N = 20 and N = 28 by three reviews, and described variously as a cohort, a prospective study and a pilot study. Boero 2024 was reported by one review as a 9-patient study of umbilical cord-blood PRP and by another as a 50-patient self-controlled pilot of autologous PRP — a discrepancy that concerns the identity of the biological product, not merely its sample size, and the two renderings also report different efficacy figures (a 55.5% reduction in maintenance-steroid requirement in nine patients versus a 42% reduction with universal satisfaction at six months). Saleh 2022 appeared as N = 47 and N = 37; Daneshpajooch 2021 as N = 20 and N = 40; Dardeer 2022 as N = 45 and N = 30; and what appears to be a single Goldstein single-arm study was cited as Goldstein 2016 with N = 15 and Goldstein 2017 with N = 12.

Primary study	Discordant values reported	Reviews reporting each value
Medina Garrido 2023	N = 23 vs 20 vs 28; design described as cohort, prospective study and pilot study	[4] / [8] / [12]
Boero 2024	N = 9, umbilical cord-blood PRP vs N = 50, autologous PRP self-controlled pilot; steroid reduction 55.5% vs 42%	[4] / [8]
Saleh 2022	N = 47 vs N = 37	[3,8] / [9]
Daneshpajooch 2021	N = 20 vs N = 40	[2,9] / [8]
Dardeer 2022	N = 45 vs N = 30	[2,8] / [14]
Sukgen 2019/2023	Retrospective cohort vs cross-sectional vs retrospective single-arm vs prospective study	[2] / [8] / [9] / [14]
Goldstein 2016 vs 2017	N = 15 vs N = 12 for what appears to be the same single-arm study	[12] / [4,5]
Tedesco 2020	Same label used for a 94-patient PRP lichen sclerosus cohort and a 40-patient adipose-SVF ± PRP randomised comparison	[5] / [12]
Goldstein 2019 (interpretation)	"No benefit of PRP compared with placebo" vs "PRP was more effective than saline injection"	[5] / [12]

Table 3: Cross-review data-extraction discordance for the same primary study.

Each row records incompatible values reported by different reviews for a single primary study. These discordances must be resolved against the primary sources before any pooling is attempted.

Interpretive discordance was equally serious. The Goldstein 2019 randomised sham-controlled trial was summarised by one review as demonstrating that "the only double-blinded controlled study found no

benefit of PRP compared with placebo" [5], and by another as showing that "PRP was more effective than saline injection" [12]. Both statements describe the same trial, in which histopathological inflammation change did not differ between arms ($p = 0.542$) and the patient-domain clinical scoring system change was -7.74 with PRP versus -9.44 with placebo ($p = 0.654$) — a numerically larger improvement in the placebo arm. A reader relying on the second rendering would form a materially incorrect view of the pivotal controlled evidence in this field.

Efficacy signals by indication and comparator tier

(Table 4) presents representative quantitative figures grouped by comparator tier. The pattern is consistent across all four indications: uncontrolled before–after studies report large, highly significant improvements, while controlled designs attenuate or eliminate the effect.

Indication	Tier	Reported result	Direction	Source review [ref]
VLS	A	Behnia-Willison 2016 (N = 28): lesions absent 28.6%, smaller 60.7%; 82.1% off topical steroids at ≥ 12 months ($p < 0.001$)	Favourable	[4]
VLS	A	Tedesco 2022 (N = 51): itching 80.4% $\rightarrow$ 21.6% ($p < 0.0001$); asymptomatic 14.9% $\rightarrow$ 52.1%; median DLQI 6 $\rightarrow$ 4	Favourable	[4]
VLS	A	Goldstein 2017 (N = 12): biopsy inflammation reduced in 58% ($p = 0.024$); IGA 2.67 $\rightarrow$ 1.83 ($p = 0.0054$); VAS pruritus/burning not significant	Mixed	[4]
VLS	A	Posey 2019 (N = 38): none of the observed outcomes statistically significant	Null	[5]
VLS	C	Goldstein 2019 RCT (N = 29): histological inflammation change $p = 0.542$; patient CSS change -7.74 (PRP) vs -9.44 (placebo), $p = 0.654$	Null	[4,5]
GSM/VVA	A	Hersant 2018 (N = 20, PRP + HA): VHI 11 $\pm$ 2.1 $\rightarrow$ 21 $\pm$ 4.8; FSIDS 36 $\pm$ 2.5 $\rightarrow$ 30 $\pm$ 2.5 at 6 months (both $p < 0.001$)	Favourable	[9]
GSM/VVA	A	Saleh 2022: VHI 12 $\pm$ 2.7 $\rightarrow$ 17 $\pm$ 3.9 at 1 month ($p < 0.001$)	Favourable	[9]
GSM/VVA	B	Sacarin 2025 RCT (N = 90): FSFI gain $+10.1 \pm 3.4$ (PRP) vs $+9.3 \pm 3.7$ (estriol), $p = 0.19$; VHI gain $+6.2$ vs $+5.6$, $p = 0.199$	No difference	[20]
FSD	A	Sukgen 2019 (N = 52): FSFI 14 $\pm$ 3.8 $\rightarrow$ 28 $\pm$ 4.8 at 6 months ($p < 0.001$); 50% reached FSFI ≥ 26	Favourable	[8,9]
FSD	A	Runels 2014 (N = 11): mean FSFI increase 5.5 points ($p = 0.01$); FSIDS-R 17 $\rightarrow$ 7.3	Favourable	[9]
FSD	B	Al-Hamadani 2019 (N = 20): both groups improved; no significant difference in satisfaction, orgasm ability or perceived importance of sex	Partly null	[8]
SUI	A	Athanasίου 2021 (N = 20): ICIQ-FLUTS 18 $\pm$ 9.5 $\rightarrow$ 12 $\pm$ 8.2; 1-h pad test 15 $\pm$ 7.9 g $\rightarrow$ 6.2 $\pm$ 3.8 g (both $p < 0.001$)	Favourable	[9]
SUI	A	Long 2021 (N = 20): ICIQ-SF 12 $\pm$ 3 $\rightarrow$ 7.3 $\pm$ 4.3; UDI-6 39 $\pm$ 14 $\rightarrow$ 28 $\pm$ 17 at 6 months (both $p < 0.01$)	Favourable	[9]
SUI	B	Daneshpajoo 2021: at 3 months ICIQ-SF 8 $\pm$ 6.8 (PRP) vs 2.2 $\pm$ 3.5 (midurethral sling), $p = 0.02$; UDI-6 6.6 $\pm$ 5.7 vs 1.3 $\pm$ 1.7, $p = 0.007$	PRP inferior	[9]
SUI	C	Ashton 2024 (N = 50): 6-month composite success 16% (PRP) vs 4.5% (placebo), not significant	Null	[8]
SUI	C	Grigoriadis 2024 (N = 50): significant symptom reduction vs placebo; $\approx$ one-third with little or no leakage at 6 months	Favourable	[8]
Pelvic floor dysfunction	C	Moegni 2022 (58 completed of 240 enrolled): no significant difference vs placebo in levator ani strength or hiatal area	Null	[8]

Table 4: Representative quantitative efficacy figures by indication and comparator tier.

Parameter	Documented range or state of reporting	Sources [ref]
Whole blood drawn	5–100 mL overall; 8–9 mL to 150–180 mL in pelvic floor studies; 20 mL per session in one comparator RCT	[2,8,20]

Parameter	Documented range or state of reporting	Sources [ref]
PRP yield / injected volume	1–10 mL overall; 2–10 mL per treatment in LS; 2–12 mL in FSD and SUI; 4–5 mL in VLS; 7 mL over 35 sites in one GSM trial	[4,5,8,9,14,22]
Centrifugation	Single spins 1500–6000 rpm for 5–15 min or 1500 g for 5 min; double spins 2500 then 4000 rpm, 800 then 3500 rpm, 200 then 2000 × g; one review records speed, duration and spin number as not reported	[2,5,8,9]
Platelet concentration	Stated variously as 1.6–6× baseline, 1.6–9× baseline, or >1 million/μL per 5 cc plasma; only 4 studies in one review reported standardised counts; not stated for every study in three reviews	[3,4,5,8,9,12,14]
Leukocyte content	Addressed as a conceptual distinction by one review only; not stated in six others	[2,3,4,5,8,9,12]
Activation	Calcium chloride, calcium gluconate, thrombin-rich serum, or deliberate in vivo clotting without exogenous activation; one review asserts activation is not required for soft-tissue injection; not stated for any study in two reviews	[2,4,5,8,9,12]
PRP classification (PAW, Mishra, Dohan Ehrenfest)	"Rarely applied" across the gynaecological literature	[8]
Sessions	1 to 10; mean 2.98 per participant in LS; 1–5 in FSD and SUI; median of four injections over three years in one series	[5,8,9]
Intervals	15 days, 2, 3, 4, 4–6, 6 and 8 weeks, and 3 months	[4,5,8,12]
Anaesthesia	Reported in 4 of 8 LS studies; "commonly topical lidocaine" in one review; not stated at all in six reviews	[2,3,4,5,8,9,12,14]
Injection targets	Labia majora and minora, clitoris and clitoral hood, posterior fourchette, vestibule and first 3 cm of vagina, anterior and posterior vaginal walls, periurethral region and urethral sphincter, perineum, peri-fistula points, intravesical instillation	[2,5,8,9]
Co-interventions	Hyaluronic acid, autologous fat or nanofat, fractional CO2 laser, photodynamic therapy with physiotherapy, pelvic floor muscle training, platelet-rich fibrin glue	[3,8,9,12]

Table 5: Reported ranges of PRP preparation and administration parameters across the included reviews.

Ranges are as reported inside the reviews. "Not stated" indicates that the review explicitly recorded the parameter as unreported by its included studies.

Recommendation	As stated by the reviews	Reviews making it [ref]
Sham- or placebo-controlled RCTs	"Further high-quality randomized controlled trials are required"; "conduct additional double-blind controlled studies"; "large-scale, multicenter randomized controlled trials"	[1,4,5,9,12]
Standardised PRP preparation and reporting	Standardise blood collection, centrifugation, platelet concentration, leukocyte content, activation, dose, frequency and site; apply PAW, Mishra or Dohan Ehrenfest classifications; "shared protocols and official guidelines are urgently needed"	[5,8,12,14]
Validated and objective core outcomes	CSS, DLQI and FSFI for wider use in LS research; "consistent" and "objective outcome measures"; validated FSD questionnaires used by only 2 of 7 studies and pad testing "rarely reported"	[4,9,12,14]
Extended, standardised follow-up	Determine durability and sustainability of benefit and clarify long-term safety, particularly in chronic VLS and SUI	[3,8]
Standalone-PRP designs and stratification	Study PRP as a standalone treatment against other modalities; stratify and analyse outcomes by menopausal status	[3,8]
Target sample size and MCID	Not recommended by any review. The only prespecified anchor in the retrieved literature is a 4-point FSFI difference, SD 5.5, 80% power, alpha 0.05, n = 90	None [20]
Prospective protocol registration	Not recommended by any review, although only 4 of 19 are themselves registered	None

Table 6: Research recommendations made by the included reviews, and the gaps they leave unaddressed.

Domain	Minimum requirement	Rationale from this review
Registration	Prospective registration of the trial protocol, with the statistical analysis plan deposited before recruitment closes	Only 4 of 19 reviews and a minority of primary studies are registered
Comparator	Sham control using an identical injection procedure with saline; blinding of participants, injectors where feasible, and all outcome assessors	Effects attenuate or disappear across the comparator gradient; only 4 sham- or placebo-controlled studies exist (187 participants)
Product characterisation	Whole-blood volume and anticoagulant; centrifugation in g and minutes with spin number; final platelet concentration per μL and as a factor of baseline; absolute leukocyte and erythrocyte content; activation method and agent; classification under a named framework	Blood volume 5–100 mL, injected volume 1–10 mL, concentration variously 1.6–9 $\times$ baseline, leukocyte content addressed by one review only
Dose and administration	Injected volume, needle or cannula gauge, anatomical targets with depth, number of sessions, inter-session interval, and anaesthesia	Sessions 1–10, intervals 15 days to 3 months, anaesthesia not stated in six reviews
Population	Explicit diagnostic criteria, menopausal status, prior and concurrent therapy including topical corticosteroids and local oestrogen, with prespecified stratification	Concurrent therapy is the principal confounder in LS and GSM; stratification by menopausal status is recommended but not practised
Outcomes	Indication-specific core outcome set combining one validated patient-reported instrument with one objective measure, prespecified as primary	Validated instruments used inconsistently; objective measures such as pad testing rarely reported
Effect size	Prespecified MCID with sample size powered against it, not against a nil hypothesis	No review specifies a target sample size or MCID for any vulvovaginal outcome
Follow-up	Minimum 12 months with prespecified assessment points; retreatment frequency reported as an outcome	No review reports a median follow-up; several report none at all
Harms	Prospective ascertainment with a graded instrument (e.g. CTCAE v5.0); prespecified events of interest including vulvodynia, fibrosis, sensory change and injection-site complications; reporting by arm regardless of attribution	Harms are not systematically ascertained in any review; one dedicated systematic review reports no adverse-event data at all
Reporting	CONSORT with the harms extension for trials; PRISMA with a published included-study list for reviews	11 of 19 reviews publish no retrievable included-study list, preventing audit and overlap analysis

Table 7: Proposed minimum design and reporting set for future trials of PRP in regenerative gynaecology.

Vulvar and genital lichen sclerosis

Uncontrolled series report substantial benefit. Behnia-Willison 2016 reported lesions absent in 8 of 28 women (28.6%) and smaller in 17 (60.7%), with 23 of 28 (82.1%) discontinuing topical steroids at 12 months or more ($p < 0.001$) [4]. Tedesco 2022 ($N = 51$) reported reductions in pain from 33.3% to 7.8% ($p < 0.0001$), burning from 51% to 15.7% ($p = 0.0001$) and itching from 80.4% to 21.6% ($p < 0.0001$), with the proportion asymptomatic rising from 14.9% to 52.1% [4]. Casabona 2023, combining PRP with fat grafting in 72 women, reported a median Skindex-29 change of -31.8 , an FSFI gain of $+7.6$ and a DLQI change of -9 (all $p < 0.001$) [4]. Goldstein 2017 ($N = 12$) reported reduced biopsy inflammation in 7 of 12 (58%, $p = 0.024$) and an Investigator Global Assessment fall from 2.67 ± 0.49 to 1.83 ± 0.83 ($p = 0.0054$), while visual analogue scores for pruritus and burning did not change significantly [4].

The single randomised sham-controlled trial in this indication is null on both its histological and its patient-reported endpoints, as described above [4,5]. A further uncontrolled series of 38 patients also reported no statistically significant outcomes [5]. The claim that PRP modifies the natural history of lichen sclerosis

therefore rests entirely on uncontrolled designs, in a condition characterised by spontaneous symptomatic fluctuation and near-universal background topical corticosteroid use.

Genitourinary syndrome of menopause and vulvovaginal atrophy

Hersant 2018 (N = 20, PRP with hyaluronic acid in breast cancer survivors) reported a Vaginal Health Index rise from 11 ± 2.1 to 21 ± 4.8 and a Female Sexual Distress Scale fall from 36 ± 2.5 to 30 ± 2.5 at six months (both $p < 0.001$) [9]. Saleh 2022 reported a VHI rise from 12 ± 2.7 to 17 ± 3.9 at one month ($p < 0.001$) [9]. Omar 2023, a randomised trial in 45 cancer survivors, found that PRP and PRP-plus-hyaluronic-acid arms improved vaginal pH, fluid volume and VHI, but reported no numerical effect sizes retrievable through the reviews [8]. Moccia et al. summarised the field as a significance map rather than an effect-size synthesis: PRP with hyaluronic acid significantly improved VHI, sexual function and SF-12; PRP alone significantly improved VHI and the Vaginal Symptom Questionnaire; microfat or nanofat with PRP improved VHI and FSDS-R; and micro-fragmented adipose tissue alone produced no significant improvement [7].

The most quantitatively complete dataset in this indication is a randomised trial that postdates most of the reviews and appears in none of them: 90 postmenopausal women randomised to intravaginal PRP or vaginal estriol, in which the FSFI gain was $+10.1 \pm 3.4$ with PRP versus $+9.3 \pm 3.7$ with estriol ($p = 0.19$) and the VHI gain was $+6.2 \pm 2.1$ versus $+5.6 \pm 2.3$ ($p = 0.199$) [20]. PRP was neither superior nor formally non-inferior to a cheap, widely available topical hormone; the trial had no placebo arm and 12 weeks of follow-up.

Female sexual dysfunction

Sukgen 2019 reported an FSFI rise from 14 ± 3.8 to 28 ± 4.8 at six months ($p < 0.001$) [9], rendered elsewhere as 13.61 to 27.88 with 50% of participants reaching an FSFI of 26 or above [8]. Runels 2014 (N = 11) reported a mean FSFI increase of 5.5 points ($p = 0.01$) [9]. Romashchenko 2022 reported increases in clitoral peak systolic velocity at rest from 1.6–2.3 to 3.7–5.8 cm/s [9]. Across studies, one review estimated lubrication improvements of 20–60% from baseline in nine studies, FSFI orgasm-domain gains of 25–70% in eight studies and dyspareunia visual analogue reductions of 30–80% in six studies, while desire results were mixed with three positive and two null studies [14]. A case report of a woman with lichen sclerosus recorded an FSFI change from 3.6 to 32.6 on a 2–36 scale — a figure that illustrates how single-patient anecdotes enter and inflate this literature [5].

Comparator-controlled data are sparse and less impressive. Al-Hamadani 2019 found that PRP and non-PRP groups both improved significantly, with PRP enhancing interest, activity and pleasure but showing no significant difference in satisfaction, orgasm ability or the perceived importance of sex [8].

Stress urinary incontinence and other pelvic floor indications

Uncontrolled series again report strong effects: Amirzargar 2016, an incontinence score fall from 17 ± 1.8 to 5.9 ± 2.5 ; Apolikhina 2018, a negative cough stress test in 18 of 19 patients at 12 months; Athanasiou 2021, ICIQ-FLUTS 18 ± 9.5 to 12 ± 8.2 and a one-hour pad test 15 ± 7.9 g to 6.2 ± 3.8 g (both $p < 0.001$); Long 2021, ICIQ-SF 12 ± 3 to 7.3 ± 4.3 ($p < 0.01$); and Tahooun 2022, ICIQ-SF 12 ± 2.9 to 5 ± 1.4 ($p < 0.01$) [9].

Controlled data invert this impression in two distinct ways. First, against an active surgical comparator, PRP is inferior: at three months, ICIQ-SF was 8 ± 6.8 with PRP versus 2.2 ± 3.5 with a midurethral sling (p

= 0.02) and UDI-6 was 6.6 ± 5.7 versus 1.3 ± 1.7 ($p = 0.007$) [9]. Second, against placebo, the largest reported effect is not statistically significant: Ashton 2024 reported six-month composite success, defined as subjective improvement with a negative cough stress test, in 16% with PRP versus 4.5% with placebo, a difference that did not reach significance [8].

A randomised trial in pelvic floor dysfunction found no significant difference from placebo in levator ani muscle strength or levator hiatal area [8]. Against this, Grigoriadis 2024 ($N = 50$) reported significantly reduced symptoms versus placebo with approximately one-third of participants reporting little or no leakage at six months, and Saraluck 2024 reported that 90% of participants achieved at least 50% symptom reduction with two PRP injections plus pelvic floor muscle training, significantly better than training alone [8]. The controlled SUI evidence is thus genuinely mixed rather than uniformly negative — and its total randomised, placebo-controlled enrolment across the whole indication is under 200 participants.

Heterogeneity of the intervention itself

Table 5 summarises the reported ranges. Whole-blood volumes ranged from 5 to 100 mL [8], with pelvic floor studies drawing between 8–9 mL and 150–180 mL [2]. PRP yield or injected volume ranged from 1 to 10 mL [8], reported as 2–10 mL per treatment in lichen sclerosis [5], 2–12 mL in FSD and SUI [9] and 4–5 mL in VLS [4]. Centrifugation protocols were reported included single spins at 3200 rpm for 8 minutes, 6000 rpm for 6 minutes, 1500 rpm for 8 minutes, 5000 rpm for 5 minutes, 1500 g for 5 minutes and 3400 rpm for 15 minutes, and double spins at 2500 then 4000 rpm, 800 then 3500 rpm, and 200 then $2000 \times g$ [2,5,8]; one systematic review recorded that exact speed, duration and number of spins were not reported by its included studies [9].

Platelet concentration was described in three mutually inconsistent ways across reviews: 1.6 to 6 times baseline [9], 1.6 to 9 times baseline [8], and a definitional threshold of more than one million platelets per microlitre per 5 cc of plasma [3]. One review found that only four of its included studies reported standardised platelet counts [14], and three reviews recorded platelet concentration as not stated for every included study [4,5,12]. Leukocyte content — the parameter that distinguishes leukocyte-rich from pure PRP and plausibly determines the local inflammatory response in mucosal tissue — was addressed as a conceptual distinction by exactly one review [8] and recorded as not stated by six others [2,3,4,5,9,12]. The same review noted that the standard PRP classification frameworks (PAW, Mishra, Dohan Ehrenfest) are "rarely applied" across the gynaecological literature [8].

Activation was non-standardised and actively contested: calcium chloride in some studies, calcium gluconate or thrombin-rich serum in others, deliberate in vivo clotting without exogenous activation in another, and an explicit assertion in one systematic review that "PRP activation is not required when injected into soft tissue" [2,8,9]. Sessions ranged from one to ten, averaging 2.98 per participant in lichen sclerosis [5], with one series reporting a median of four injections over three years [8]. Inter-session intervals of 15 days, 2, 3, 4, 4–6, 6 and 8 weeks and 3 months were all documented [4,5,8,12]. Anaesthesia was reported in four of eight lichen sclerosis studies [5] and not stated at all in six reviews [2,3,4,8,9,12]. Injection targets ranged across labia majora and minora, clitoris and clitoral hood, posterior fourchette, vestibule and the first 3 cm of the vagina, anterior and posterior vaginal walls, the periurethral region and urethral sphincter at multiple clock positions, the perineum, transvaginal peri-fistula points and

intravesical instillation.

Co-intervention further confounds attribution. PRP was combined with hyaluronic acid, autologous fat or nanofat, fractional CO2 laser, photodynamic therapy with physiotherapy, pelvic floor muscle training and platelet-rich fibrin glue across the included studies. One review named this as the field's central gap, stating that "the predominant focus on combining PRP with other therapeutic modalities leaves a notable gap in evidence regarding the standalone efficacy of PRP" [3].

Follow-up

No review reported a median follow-up for its included studies. Only two reported an aggregate range: 2 to 23.2 months with a mean of 9.9 months in lichen sclerosis, with three of eight studies reporting no follow-up at all [5]; and 1 to 12 months in FSD and SUI, with four of twelve studies listed as having no follow-up [9]. A third reported follow-up as available in just over half of cases and ranging from 1 to 24 months [12]. A fourth contained an internal contradiction, stating a range of 4 weeks to 12 months in one section while reporting relief maintained up to two years in another [8]. Eight reviews gave no aggregate follow-up figure whatsoever [1,2,6,7,10,11,13,19]. The reviews are candid that this matters: durability "remains uncertain" [8], long-term efficacy "remains unclear... largely attributed to the limited duration of follow-up in existing studies" [11], and "the absence of comprehensive long-term follow-up data across several studies hinders assessment of the sustainability of treatment effects and identification of delayed complications" [3].

Safety

Harms ascertainment was not systematic in any included review. The dedicated systematic review of PRP for lichen sclerosis reported no adverse-event data and no separate safety analysis at all [5]; the systematic review of injection treatments for VVA likewise reported none [7]. In the FSD and SUI review, only 2 of 12 included studies provided any adverse-event evidence, and the frequently quoted figure of minor events in 3 of 317 PRP recipients (under 1%) therefore derives from an ascertainment base of two studies; the events were extreme sexual arousal in two patients and urinary retention requiring several days of self-catheterisation in one [9]. Another review stated plainly that "most studies did not report side effects", while noting adverse effects in 3.8% in one SUI report and mild haematuria or painful urination in 10 patients (28.6%) in another [2].

Where study-level harms were reported in lichen sclerosis, they included infection, bleeding and haematoma with day-one pain scores of 2–3 in 26 of 28 patients in one series, a mean numerical rating scale of 4.4 at needle insertion and 7.3 for burning during cord-blood PRP injection in another, and transient discomfort and bruising in others [4]; one case of balanitis was reported in a male series [12]. A theoretically serious harm — vascular embolism from material injected into the vaginal wall — has been flagged but never systematically studied [3].

The most reassuring statements in this literature rest on the weakest ascertainment. Adverse events were described as "few and mild" with a "favorable safety profile" without frequencies, severity grading or an ascertainment method [1]; the safety profile "appears favorable" without specifics [6]; and PRP was described as "non-allergenic" with "minimal risk of adverse reactions" without supporting data [10]. Only one review self-policed this reasoning, cautioning that the absence of serious adverse events "should be

interpreted cautiously because follow-up was largely short-term" [14]. Across the entire retrieved set, only one record used a structured graded harms instrument — CTCAE version 5.0 with structured interviews — and it is a randomised trial rather than a review, reporting any adverse event in 4 of 45 (8.9%) PRP recipients versus 7 of 45 (15.6%) hormonal-therapy recipients ($p = 0.521$) with no serious events in either arm [20]. The correct summary of vulvovaginal PRP safety is not that it is safe, but that its safety has not been measured.

What the reviews recommend

The reviews are internally consistent about what is missing, and Table 6 maps their recommendations. Five call for high-quality, double-blind, sham- or placebo-controlled and preferably multicentre randomised trials [1,4,5,9,12]. Four call for standardisation of PRP preparation and reporting, including blood collection, centrifugation, platelet concentration, leukocyte content, activation, dose, frequency and administration site, with explicit application of the PAW, Mishra or Dohan Ehrenfest classifications [5,8,12,14]. Four call for consistent, validated and objective outcome measures, with one proposing the clinical scoring system, DLQI and FSFI for wider use in lichen sclerosis research [12], and one noting that validated FSD questionnaires were used by only two of seven studies and objective measures such as the pad test were rarely reported [9]. Two calls for extended, standardised follow-up sufficient to establish durability and detect delayed complications [3,8]. Two calls for designs that isolate PRP as a standalone treatment and stratify outcomes by menopausal status [3,8].

Two gaps are notable for being absent from the reviews' own recommendations. First, no review in this set specifies a target sample size or a minimal clinically important difference for any vulvovaginal outcome. The only prespecified MCID anchor identified anywhere in the retrieved literature is a randomised trial's a priori four-point clinically meaningful FSFI difference, with an assumed standard deviation of 5.5, 80% power and alpha 0.05, yielding $n = 90$ [20]. Second, no review recommends prospective protocol registration, although only four of nineteen carry a registration number themselves.

Discussion

Principal findings

Nineteen reviews published since 2020 present vulvovaginal PRP as a promising and safe regenerative option. Beneath them lie 55 unique primary studies and 1,704 participants, of whom fewer than 200 have ever been randomised to a sham or placebo comparison. No pooled effect estimate exists for any vulvovaginal PRP outcome. Fifteen primary studies are counted three or more times across the review layer. Nine primary studies are described with incompatible sample sizes or interventions by different reviews, and the pivotal sham-controlled lichen sclerosis trial is reported by one review as null and by another as positive. The intervention is specified so variably — blood volume 5 to 100 mL, injected volume 1 to 10 mL, one to ten sessions, intervals from 15 days to three months, leukocyte content essentially never reported — that the noun "PRP" does not denote a single treatment across this literature.

Amplification, not accumulation

The central epistemic problem is that the review layer has grown faster than the primary layer. A reader encountering six favourable systematic reviews of lichen sclerosis reasonably infers convergent independent evidence; in fact four of them summarise substantially the same studies, and the inflation factor between summed reported totals and deduplicated participants is approximately 1.5 in the

auditable subset and certainly higher across the full set. Each new review adds citations without adding patients. Where reviews disagree with one another, the disagreement is rarely visible to a reader of any single review, because eleven of nineteen do not publish a retrievable included-study list. An intervention can thus acquire the bibliometric signature of an established therapy without any corresponding growth in controlled evidence.

The comparator gradient

Reading the efficacy data by comparator tier produces a consistent and clinically decisive gradient. Uncontrolled before–after studies report large improvements with impressive p values across all four indications. Active-comparator studies show PRP performing similarly to vaginal estriol for GSM [20] and worse than a midurethral sling for SUI [9]. Sham- and placebo-controlled studies are few and mostly null: no benefit over saline for lichen sclerosus on either histology or symptoms [4,5], no significant difference in composite success for SUI [8], and no difference from placebo in levator ani strength or hiatal area in pelvic floor dysfunction [8], against one positive placebo-controlled SUI trial [8]. This is the classic signature of an intervention whose apparent effect is dominated by non-specific factors: natural history, regression to the mean, concurrent therapy, and the substantial placebo response characteristic of genital and sexual outcomes assessed by unblinded self-report. It does not prove PRP is inert, but it does mean that no uncontrolled improvement in this field can currently be attributed to the injectate.

Safety reassurance is unearned

The recurring claim that PRP is "safe because it is autologous" conflates biological plausibility with measurement. A dedicated systematic review reporting no adverse-event data cannot support a safety conclusion [5]; a sub-1% adverse-event rate derived from 2 of 12 studies is an ascertainment artefact, not an incidence [9]; and "most studies did not report side effects" [2] is a statement about reporting, not about risk. With no review reporting a median follow-up and follow-up frequently under six months, delayed harms — persistent vulvodynia, fibrosis or scarring at repeatedly injected sites, granuloma formation, altered sensation, and the theoretically flagged risk of vascular embolism [3] — could not have been detected even if they occurred. The one instance of graded, instrument-based ascertainment in the entire retrieved set is a single 90-patient trial [20]. Autologous origin removes immunogenic and transmissible risk; it does not remove procedural, mechanical or dose-related risk, and it says nothing about a product whose composition is unreported.

Why meta-analysis is not currently defensible

Three independent barriers prevent responsible pooling, and each is empirically documented above. First, no included review provides pooled estimates or the variance data required to compute them, and the primary studies feeding them are dominated by single-arm designs from which no between-group effect can be derived. Second, overlap across reviews would produce systematic double-counting of the same participants, in a set where 15 studies recur three or more times. Third, and most fundamentally, the interventions are not commensurable: pooling a 2 mL leukocyte-unspecified, unactivated preparation injected once into the anterior vaginal wall with a 10 mL calcium-chloride-activated preparation injected across the vulva in ten sessions would produce a number that corresponds to no treatment any clinician can deliver. A meta-analysis performed on this literature today would convert heterogeneity into a spuriously precise summary estimate and would accelerate, rather than correct, the amplification

problem described above.

A minimum set for the next generation of trials

Table 7 converts the reviews' recommendations, plus the gaps they do not name, into an operational minimum set. Five elements deserve emphasis. First, comparator: sham-controlled designs with an identical injection procedure using saline, and blinding of participants, injectors where feasible and all outcome assessors, since PRP is visually distinguishable from saline and unblinded injection cannot support a symptom endpoint. Second, product characterisation: mandatory reporting of whole-blood volume and anticoagulant, centrifugation protocol in g and minutes, final platelet concentration in platelets per microlitre and as a factor of baseline, absolute leukocyte and erythrocyte content, activation method, injected volume, needle or cannula gauge, anatomical target, session number and interval, with classification under a named framework. Third, outcomes: indication-specific core outcome sets combining a validated patient-reported instrument with an objective measure, with a prespecified MCID and powering against it rather than against a nil hypothesis — the four-point FSFI anchor is the only such precedent in this literature [20]. Fourth, duration: minimum 12-month follow-up with prespecified assessment points, and reporting of retreatment frequency as an outcome in its own right. Fifth, harms: prospective ascertainment with a graded instrument such as CTCAE version 5.0, prespecified events of interest including vulvodynia, fibrosis and sensory change, and reporting of harms by arm regardless of attribution. To this we add two elements the reviews omit: prospective registration of both trials and reviews, and publication of the included-study list in every review so that its evidence base can be audited.

Strengths and limitations

The strengths of this umbrella review are its grounding rule, under which every reported value is bound to the source page that states it and unconfirmable values are recorded as missing rather than inferred; its reconstruction and deduplication of the primary-evidence layer, which converts a qualitative impression of overlap into a quantified inflation factor; and its explicit stratification of efficacy figures by comparator tier rather than by statistical significance.

Several limitations apply. The protocol was not prospectively registered. Screening and extraction were performed without independent duplicate assessment, so extraction error cannot be excluded — a limitation whose salience is increased by the very discordances documented in Table 3. Two eligible reviews were accessible only at abstract level because of publisher restrictions [1,15], so their included-study lists could not enter the overlap matrix; obtaining them through institutional access would refine but, given their reported study counts and indications, is unlikely to reverse the deduplicated findings. Eleven of nineteen reviews published no retrievable study list, so the deduplicated total of 1,704 participants is a lower bound on overlap and an upper bound on unique evidence within the auditable subset. We did not apply AMSTAR 2 or ROBIS as composite instruments, preferring seven individually verifiable criteria, which limits comparability with umbrella reviews that report composite confidence ratings. Finally, the search was conducted in English-language sources and a Spanish-language record could be characterised only partially, so non-English regional literature may be under-represented.

Conclusion

Nineteen reviews published since 2020 create the impression of a substantial and consistently favourable evidence base for platelet-rich plasma in vulvovaginal disorders. Deduplication shows that impression to

be an artefact of repeated summarisation: 55 unique primary studies, 1,704 participants, 10 randomised records and just four sham- or placebo-controlled trials enrolling 187 participants in total, of which three are null. No pooled effect estimate exists for any vulvovaginal PRP outcome, three reviews applied a named risk-of-bias instrument, no review reported a median follow-up, and no review specified a target sample size or a minimal clinically important difference. The intervention itself is so variably prepared and so incompletely characterised that the same term denotes materially different products across studies.

Clinically, PRP for vulvovaginal indications should currently be positioned as an investigational option, offered with explicit disclosure that controlled evidence of benefit over placebo is absent for lichen sclerosus, mixed and underpowered for stress urinary incontinence, and limited to non-superiority against inexpensive topical hormone therapy for the genitourinary syndrome of menopause; and that its safety profile has not been systematically measured rather than having been shown to be favourable. Scientifically, the field does not need more reviews. It needs a small number of adequately powered, registered, sham-controlled trials that fully characterise the product, prespecify an indication-specific core outcome set and a minimal clinically important difference, follow participants for at least 12 months, and ascertain harms with a graded instrument. Until those trials exist, further syntheses of the present literature will continue to amplify uncertainty into apparent consensus.

Declarations

Ethical approval

Not applicable. This study is a review of previously published literature and involved no human participants, human material or human data collected by the authors.

Consent to participate for publication

Not applicable.

Availability of data

All data analysed in this review are contained within the published articles cited in the reference list. The full extraction table, the primary-study overlap matrix and the deduplication dataset are available from the corresponding author on reasonable request.

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Conflict of interest

The authors declare that they have no conflict of interest.

Author contributions

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Use of artificial intelligence

Figures 1–3 were generated programmatically by the authors from the extracted dataset using a plotting

library; they contain no AI-generated imagery.

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