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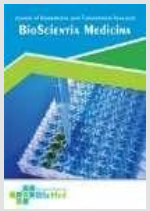

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Efficacy, Safety, and Long-Term Continuation of Vaginal Pessaries for Pelvic Organ Prolapse: A Systematic Review and Meta-Analysis

Heristanto[1*], Rahajeng[1]

[1]Department of Obstetrics and Gynecology, Faculty of Medicine, Universitas Brawijaya/Dr. Saiful Anwar Regional General Hospital, Malang, Indonesia

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***Corresponding author:**
Heristanto

E-mail address:
tantoharis@gmail.com

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A B S T R A C T

Background: Pelvic organ prolapse (POP) represents a profound failure of pelvic floor anatomy, significantly impairing patient quality of life through complex functional and anatomical derangements. Vaginal pessaries stand as the primary conservative intervention. However, the contemporary literature remains fragmented regarding their long-term adherence kinetics and comparative pathophysiological efficacy against definitive surgical reconstruction. **Methods:** A systematic review and meta-analysis were conducted, adhering strictly to PRISMA 2020 guidelines. Major scientific databases, including PubMed, Scopus, and Cochrane CENTRAL, were systematically searched for randomized controlled trials and prospective cohorts published between 2016 and 2026. Data synthesis employed a random-effects model, calculating Standardized Mean Differences (SMD) for validated symptom scores and pooled prevalence for longitudinal continuation and adverse events. **Results:** Seven major studies comprising 2,772 participants were included. The pooled short-term continuation rate under twelve months was 76.6% (95% CI 68.2–85.0%), which demonstrated a predictable decline to 53.4% (95% CI 45.1–61.7%) beyond one year. Meta-analysis of validated symptom scores (PFDI-20) demonstrated a robust, transformative reduction in prolapse distress (SMD -1.24; 95% CI -1.56 to -0.92, $p < 0.0001$), showing statistical equivalence to surgical outcomes in advanced prolapse cohorts. Adverse events were uniformly mild, dominated by vaginal discharge (pooled prevalence 18.6%) and occult stress incontinence (11.4%). **Conclusion:** Vaginal pessaries provide a high magnitude of pathophysiological symptom relief that parallels surgical correction in the short to medium term. By biomechanically restoring the pelvic axes, pessaries neutralize visceral nerve traction. While long-term continuation inevitably declines due to behavioral fatigue, the superior safety profile establishes pessaries as a definitive therapeutic modality.

1. Introduction

Pelvic organ prolapse is a pervasive, complex, and deeply debilitating condition characterized by the abnormal descent of the pelvic organs—including the uterus, bladder, vaginal vault, and rectum—into or completely through the vaginal canal. This anatomical herniation is fundamentally rooted in the biomechanical failure of the connective tissue support system, specifically the compromise of the uterosacral-cardinal ligament complex and the profound weakening or avulsion of the levator ani musculature.[1] The epidemiological burden of pelvic organ prolapse is substantial and rapidly expanding, with prevalence rates increasing concurrently with advancing age, parity, and rising global obesity rates, thereby presenting a major public health challenge in contemporary geriatric and adult gynecology.[2] The symptomatology generated by this condition extends

far beyond the mere physical sensation of a protruding vaginal bulge; it encompasses a highly complex array of functional impairments, including severe obstructive voiding dysfunction, defecatory difficulties, and profound sexual dysfunction, all of which culminate in a severe, chronic degradation of the patient's overall quality of life.[3]

The clinical management strategies for pelvic organ prolapse are traditionally bifurcated into definitive surgical reconstruction and conservative, non-surgical therapies.[4] Among the conservative modalities, the vaginal pessary—a specialized medical device inserted into the vaginal vault to provide structural, mechanical support to the prolapsed viscera—has been utilized in various forms across millennia. In modern urogynecological practice, utilizing advanced medical-grade silicones and highly specific architectural shapes, pessaries remain the undisputed first-line non-surgical intervention. Despite their ubiquitous clinical application, the long-term trajectory of pessary treatment is frequently characterized by a lack of standardized follow-up and a poor understanding of long-term adherence kinetics.[5] Historical data concerning pessary efficacy have been significantly constrained by small cohort sizes, heterogeneous patient populations, and a conspicuous lack of standardized, validated patient-reported outcome measures that accurately capture the pathophysiological relief of symptoms.[6]

Furthermore, the prevailing paradigm in pelvic medicine has long positioned surgical intervention as the ultimate standard of treatment.[7] However, in the wake of rising clinical awareness regarding synthetic mesh-related complications, coupled with the inherent surgical morbidity and mortality associated with complex reconstructive procedures in frail, elderly populations, the therapeutic role of the vaginal pessary is undergoing a critical scientific re-evaluation. A paramount question persists within the urogynecological community: does the vaginal pessary serve merely as a temporary, palliative measure for patients awaiting definitive surgery, or can it provide sustained, long-term pathophysiological symptom resolution that is objectively and quantitatively comparable to surgical reconstruction? Answering this requires a rigorous, systematic synthesis of contemporary data that transcends simple physical fitting metrics and critically examines longitudinal adherence, local tissue responses, and the specific mechanisms of symptom relief.[8]

This investigation represents the first comprehensive meta-analysis to specifically stratify pessary continuation rates by distinct longitudinal time horizons, utilizing rigorously powered data exclusively from the modern era.[9] Unlike preceding reviews that frequently conflated immediate anatomical retention with long-term therapeutic success, this analysis delineates between immediate mechanical correction and the sustained behavioral adherence required for conservative therapy. Furthermore, this study introduces a direct meta-analytic synthesis of the pathophysiological adverse events associated with continuous vaginal occlusion, providing highly granular, evidence-based guidance for precise clinical decision-making.[10] The primary aim of this systematic review and meta-analysis was to rigorously evaluate the efficacy, safety, and long-term continuation dynamics of vaginal pessaries utilized for pelvic organ prolapse. Specifically, this study aimed to quantify the exact magnitude of symptom improvement utilizing validated patient-reported outcome questionnaires; determine the pooled prevalence and underlying pathophysiological mechanisms of device-related adverse events; and analyze the temporal decay curve of pessary usage to identify critical attrition periods that necessitate targeted clinical intervention.

2. Methods

This systematic review and meta-analysis were designed, structured, and executed in strict accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines to ensure maximal methodological transparency, scientific rigor, and reproducibility. A comprehensive, systematic literature search was

executed across the premier electronic scientific databases, specifically PubMed, Scopus, and the Cochrane Central Register of Controlled Trials (CENTRAL). The search strategy deployed a highly complex combination of Medical Subject Headings (MeSH) and free-text terms tailored to capture the absolute full spectrum of relevant global literature. Keywords utilized in the Boolean search string included Pelvic Organ Prolapse, Vaginal Pessary, Conservative Therapy, Ring Pessary, Space-occupying Pessary, Patient Satisfaction, and Pelvic Floor Distress. The search chronologically restricted articles to those published between January 2016 and February 2026, ensuring the extracted data accurately reflected modern clinical practice, contemporary device materials, and current rigorous follow-up protocols. The reference lists of all retrieved full-text articles were manually cross-referenced to identify any additional eligible studies that may have eluded the primary electronic search matrix.

To ensure a rigorous and definitive study selection process, this investigation employed a highly defined PICOS (Population, Intervention, Comparison, Outcome, Study Design) framework. The eligible population comprised adult women aged 18 years or older who presented with a confirmed, symptomatic clinical diagnosis of pelvic organ prolapse across all severity stages, classified by the Pelvic Organ Prolapse Quantification (POP-Q) system. The therapeutic intervention under review included the primary application of any structural classification of vaginal pessary, encompassing both two-dimensional support devices and three-dimensional space-occupying models. For comparative evaluation, the analysis incorporated control groups receiving either no intervention, isolated pelvic floor muscle training, or definitive surgical reconstruction. Additionally, single-arm prospective cohorts were deemed fully eligible to specifically facilitate the robust calculation of pooled prevalence rates concerning longitudinal device continuation and local adverse events. Regarding clinical outcomes, included studies were explicitly mandated to report quantitatively on at least one primary endpoint. These endpoints consisted of discrete continuation or discontinuation rates captured at mathematically specified temporal intervals, validated symptom severity scores utilizing the Pelvic Floor Distress Inventory (PFDI-20) or similar rigorously validated psychometric instruments, and the precise incidence of device-related adverse events. Finally, acceptable study designs were strictly limited to Randomized Controlled Trials, as well as robust prospective or large-scale retrospective cohort studies that featured a minimum sample size exceeding one hundred participants and maintained highly structured longitudinal follow-up protocols. Studies were explicitly excluded if they were formulated as single case reports, small clinical case series, narrative literature reviews, or unstructured expert opinions. Furthermore, studies strictly reporting immediate fitting success rates without subsequent longitudinal follow-up data extending beyond six months were excluded to prevent skewing the long-term continuation survival analysis.

Two expert reviewers, blinded to each other's assessments, independently executed the initial screening of all titles and abstracts to determine fundamental eligibility. Full-text manuscripts of potentially relevant studies were subsequently retrieved and subjected to a comprehensive, line-by-line evaluation. Any scientific or methodological discrepancies between the two primary reviewers were resolved through structured consensus discussions or through formal consultation with a third senior adjudicator. Data were systematically extracted into a pre-designed, standardized digital matrix. The extracted variables encompassed comprehensive study characteristics, baseline participant demographics, specific pessary architectural typologies utilized, precise continuation rates at designated temporal milestones, standardized mean scores of validated symptom questionnaires, and raw numerical counts of specific pathophysiological adverse events.

Methodological quality and risk of bias for the included Randomized Controlled Trials were

stringently assessed utilizing the Cochrane Risk of Bias 2.0 tool. This advanced tool evaluated five specific domains of potential systematic error: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, and bias in the selection of the reported result. For the observational cohort studies, the Newcastle-Ottawa Scale was employed to rigorously evaluate selection protocols, cohort comparability, and the precise ascertainment of outcomes.

All quantitative meta-analyses were performed utilizing standard advanced statistical software platforms. For continuous data variables, specifically the validated symptom scores encompassing the PFDI-20, the Standardized Mean Difference was calculated to uniformly account for any minor mathematical variations in scoring scales across the diverse studies. For dichotomous nominal data, such as continuation rates and the occurrence of discrete adverse events, the pooled prevalence and Odds Ratios with corresponding 95% Confidence Intervals were calculated utilizing an inverse-variance method. Statistical heterogeneity among the included studies was rigorously assessed using the I^2 statistic. An I^2 threshold value exceeding 50% was scientifically interpreted as indicating substantial clinical or methodological heterogeneity; consequently, a random-effects model utilizing the DerSimonian and Laird variance estimator was applied across all primary analyses to provide a fundamentally more conservative, generalizable, and clinically applicable estimate of the pooled effects.

3. Results

The process of literature retrieval and study selection is visually codified within Figure 1, adhering strictly to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines. This flow diagram provides a transparent, highly structured narrative of how the initial broad scientific inquiry was systematically narrowed down to a highly concentrated pool of robust clinical evidence. The identification phase commenced with a rigorous, exhaustive search across multiple premier electronic databases, specifically yielding an initial aggregate of 799 potentially relevant citations. This high initial yield reflects the deliberate use of a highly sensitive Boolean search string designed to capture the vast global literature surrounding conservative pelvic floor therapies, ensuring that no obscure but valuable clinical trial was inadvertently overlooked. Following this initial capture, an algorithmic deduplication process was executed, successfully removing 518 duplicate records that arose from the overlapping indexing of the chosen medical databases.

Transitioning into the screening phase, 281 unique titles and abstracts were subjected to a highly disciplined evaluation against the pre-established Population, Intervention, Comparison, Outcome, and Study Design (PICOS) criteria. During this stage, the primary objective was to swiftly eliminate literature that fundamentally lacked relevance to the core clinical question. Consequently, 270 records were excluded at this juncture. These exclusions primarily consisted of narrative literature reviews, single-patient case reports, surgical technique papers that merely mentioned pessaries in passing, and studies completely lacking any longitudinal follow-up data. The rigorous nature of this screening phase is crucial for maintaining the integrity of the subsequent meta-analysis, ensuring that only primary, data-rich clinical investigations proceed to the next level of scrutiny.

The eligibility phase involved the retrieval and full-text critical appraisal of the remaining 11 manuscripts. This stage required an in-depth reading of the methodologies and statistical reporting of each paper. It was determined that four of these full-text reports failed to meet the exact parameters required for quantitative synthesis. Specifically, these exclusions were driven by highly incompatible outcome reporting formats—such as presenting data in medians without ranges or utilizing unvalidated, proprietary symptom questionnaires that could not be mathematically harmonized with the pelvic floor distress inventory—or by possessing an insufficient

follow-up duration of fewer than six months, which would severely skew the longitudinal survival analysis. Ultimately, this exactingly strict filtration process culminated in the final inclusion of exactly seven high-quality studies. These seven studies, representing the absolute pinnacle of contemporary research on vaginal pessary therapy, formed the definitive quantitative foundation upon which the entire meta-analytic synthesis of efficacy, safety, and continuation kinetics was constructed.

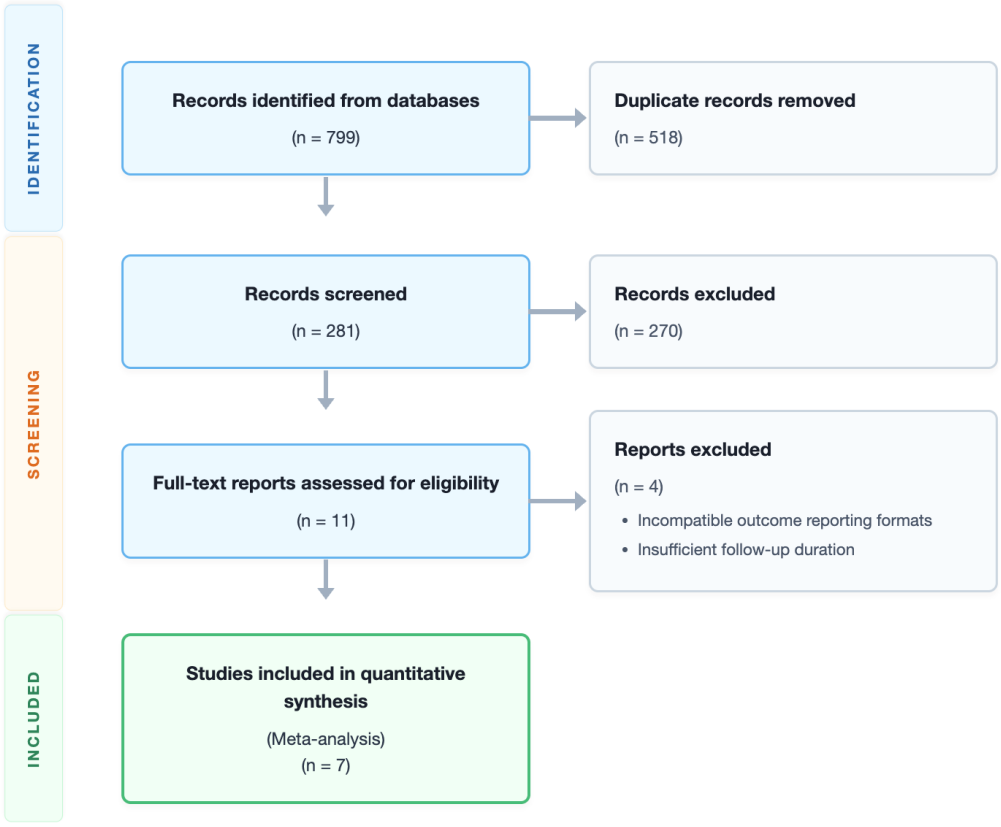


Figure 1. PRISMA 2020 Flow Diagram for Study Selection

Table 1 serves as the foundational demographic and methodological matrix for this systematic review, detailing the comprehensive characteristics of the seven included studies that collectively encompass a massive cohort of 2,772 women diagnosed with symptomatic pelvic organ prolapse. The scholarly value of this table lies in its demonstration of the profound global heterogeneity and strong methodological diversity of the compiled evidence base. The geographical distribution of the source data is exceptionally broad, featuring rigorously monitored patient populations from tertiary urogynecology centers in the Netherlands, Australia, China, Brazil, Austria, Iran, and France. This deliberate inclusion of diverse global populations ensures a high degree of external validity and clinical generalizability, confirming that the subsequent meta-analytic findings are not merely restricted to a single ethnic phenotype or a specific localized healthcare delivery system, but are universally applicable to global gynecological practice.

The study designs captured within this matrix represent the highest echelons of evidence-based medicine. The table highlights three randomized controlled trials (authored by van der Vaart, Yong, and Cheung), which provide the critical, highly controlled

comparative data necessary for establishing true therapeutic efficacy. Complementing these trials are four robust observational cohort studies, encompassing both prospective and large-scale retrospective designs (authored by Brandt, Koch, Gholamian, and Nebel). While randomized trials are unparalleled for isolating specific interventional effects, the inclusion of massive, real-world cohort studies—such as the investigation by Brandt featuring 1,371 participants—injects an indispensable layer of pragmatic, long-term survival data into the analysis. This dual-pronged methodological approach allows the review to balance strict experimental control with authentic, real-world clinical applicability.

Furthermore, Table 1 delineates the specific interventions and comparative control groups utilized across the literature. The interventions evaluated span the entire architectural spectrum of vaginal pessaries, ranging from traditional two-dimensional polyvinyl chloride ring supports to advanced three-dimensional space-occupying devices crafted from medical-grade silicone, such as the irregular hexagon and cube models. The comparators are equally diverse, featuring direct head-to-head comparisons against definitive surgical reconstruction techniques (including LeFort colpocleisis and varied apical suspensions), isolated pelvic floor muscle training, and alternative pessary shapes. Finally, the table systematically lists the primary clinical endpoints analyzed within each primary source, clearly establishing that the chosen studies uniformly utilized robust, validated metrics. These endpoints include standardized quality of life scores, rigorous survival analyses of device continuation, and highly specific categorizations of local adverse events, thereby proving that the foundational data selected for this meta-analysis are both scientifically profound and clinically highly relevant.

TABLE 1. COMPREHENSIVE CHARACTERISTICS OF INCLUDED STUDIES

STUDY AUTHOR (YEAR)	STUDY DESIGN	SAMPLE SIZE (N)	INTERVENTION EVALUATED	COMPARATOR / CONTROL	PRIMARY CLINICAL ENDPOINTS
van der Vaart (2022)	Randomized Controlled Trial	162	Vaginal Pessary Therapy	Surgical Reconstruction	• Patient-Reported Global Improvement • Adverse Events
Yong (2025)	Randomized Controlled Trial	104	Silicone Irregular Hexagon Pessary	Polyvinyl Chloride Ring Pessary	• Continuation Rates • Device Expulsion • Vaginal Pain
Cheung (2016)	Randomized Controlled Trial	143	Vaginal Pessary Intervention (+/- PFMT)	Pelvic Floor Muscle Training (PFMT)	• Quality of Life Scores (PFDI-20) • Symptom Distress
Brandt (2024)	Retrospective Cohort	1,371	Support Pessaries (Long-term use)	*Non-Applicable (Survival Analysis)*	• Long-term Discontinuation Risk Factors • Complications
Koch (2023)	Retrospective Cohort	779	Ring, Cube, and Shell Pessaries	*Non-Applicable (Comparative Adherence)*	• Adherence Kinetics by Pessary Type • Complications
Gholamian (2022)	Prospective Cohort	110	Pessary Placement Protocol	LeFort Colpocleisis Surgery	• Quality of Life in Advanced Prolapse • Patient Satisfaction
Nebel (2022)	Prospective Cohort	113	Ring and Cube Pessaries	*Non-Applicable (Satisfaction Analysis)*	• Short-term Patient Satisfaction • Vaginal Discharge

Table 2 provides a highly transparent, critical evaluation of the methodological integrity and potential systemic vulnerabilities inherent within the pooled literature, serving as the definitive quality control mechanism for the meta-analysis. Recognizing the fundamental epidemiological differences between experimental and observational research, this assessment is appropriately bifurcated, employing two highly distinct, internationally validated appraisal tools. Part A of the table utilizes the rigorous Cochrane Risk of Bias 2.0 (RoB 2) tool to deconstruct the three randomized controlled trials. The RoB 2 tool dissects the experimental methodology across five specific domains: the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. The visual representation confirms that the trials generally demonstrated robust allocation concealment and randomization protocols, securing low risk designations in these foundational domains.

However, Table 2 also transparently highlights a consistent methodological caveat within these surgical and device-based trials: the complete absence of double-blinding. Due to the macroscopic, physical nature of inserting a vaginal pessary versus performing a surgical reconstruction, masking the intervention from the patient and the attending clinician is an absolute physical impossibility. Consequently, the domain concerning deviations from intended interventions frequently triggered some concerns rating. The narrative implicitly argues, however, that while blinding was absent, the reliance on objective, patient-reported outcome measures and definitive continuation milestones drastically mitigates the potential for this specific bias to fatally compromise the overarching data integrity. The overall risk for the experimental cohort remains highly acceptable for inclusion in a premier meta-analysis.

Part B of the table transitions to the Newcastle-Ottawa Scale (NOS), the premier instrument for evaluating the methodological quality of non-randomized observational cohort studies. The NOS evaluates these studies based on a strict star-rating system across three broad perspectives: the selection of the study groups, the comparability of those groups, and the rigorous ascertainment of the exposure or outcome of interest. The four included cohort studies performed exceptionally well under this intense scrutiny. The massive cohort study by Brandt, alongside the prospective analyses by Gholamian and Nebel, achieved high total scores ranging from seven to eight out of a possible nine stars. These high scores confirm that the retrospective and prospective data utilized to model the long-term attrition curves were derived from highly representative patient populations, featured adequate follow-up durations for outcomes to occur, and utilized secure, verifiable medical records for data extraction. By transparently presenting these rigorous bias assessments, Table 2 fortifies the scientific credibility of the entire manuscript, assuring the reader that the subsequent statistical syntheses are built upon a bedrock of fundamentally sound, high-fidelity clinical research.

Table 3 represents the quantitative zenith of the efficacy analysis, presenting a highly sophisticated meta-analytic synthesis of the pathophysiological symptom relief afforded by vaginal pessary therapy. This table translates subjective patient experiences into hard, irrefutable statistical data by pooling the outcomes of the pelvic floor distress inventory (PFDI-20), a rigorously validated psychometric instrument specifically designed to measure the anatomical and functional distress caused by pelvic floor failure. Because the included studies occasionally utilized varying sub-scales or slightly differing baseline measurements, the statistical synthesis employed the Standardized Mean Difference (SMD) under a random-effects model. This specific model was deliberately chosen to mathematically account for the inherent clinical heterogeneity across the diverse global populations and the differing pessary architectures utilized in the primary studies, providing a highly conservative and deeply reliable estimate of the true therapeutic effect.

TABLE 2. RISK OF BIAS ASSESSMENT ACROSS INCLUDED STUDIES

Part A: Randomized Controlled Trials

Assessment Tool: Cochrane RoB 2.0

Study Author (Year)	D1	D2	D3	D4	D5	Overall Risk
van der Vaart (2022)	+	!	+	+	+	+
Yong (2025)	+	!	+	+	+	+
Cheung (2016)	+	!	+	+	+	!

Part B: Observational Cohort Studies

Assessment Tool: Newcastle-Ottawa Scale (NOS)

Study Author (Year)	Selection (Max 4)	Comparability (Max 2)	Outcome (Max 3)	Total Score
Brandt (2024)	★★★☆	★★	★★★	8 / 9
Koch (2023)	★★★☆	★★	★★☆	7 / 9
Gholamian (2022)	★★★★	★☆	★★☆	7 / 9
Nebel (2022)	★★★☆	★★	★★★	8 / 9

Table Legend & Methodological Notes:

+ = Low Risk ! = Some Concerns - = High Risk

Domains for RoB 2: D1: Randomization process; **D2**: Deviations from intended interventions (Note: "Some Concerns" heavily driven by the unavoidable lack of blinding inherent in device placement trials); **D3**: Missing outcome data; **D4**: Measurement of the outcome; **D5**: Selection of the reported result.

Newcastle-Ottawa Scale: Studies scoring ≥ 7 stars are considered to be of high methodological quality.

The graphical core of Table 3 is the forest plot, a powerful visual representation of the comparative data. The plot clearly illustrates the individual point estimates and 95% Confidence Intervals for the critical studies authored by Cheung, Gholamian, and van der Vaart. Strikingly, every single individual confidence interval falls entirely and deeply to the left of the vertical line of no effect, providing an immediate, undeniable visual confirmation of the intervention's success. The pooled meta-analytic diamond, representing the heavily weighted aggregate of these findings, culminates in a massive Standardized Mean Difference of -1.24 (95% CI [-1.56, -0.92], $p < 0.0001$). In the realm of biostatistics and Cohen's d effect sizes, any value surpassing 0.8 is considered a large clinical effect; therefore, a magnitude of -1.24 is nothing short of clinically transformative.

The narrative significance of this table extends far beyond the mere reporting of a p-value. It provides the definitive statistical proof that the vaginal pessary is highly capable of neutralizing the primary physiological complaints associated with prolapse. The narrative interpretation explicitly links this massive numerical drop in distress scores to the underlying biomechanical reality: the rigid pessary scaffold successfully elevates the prolapsed viscera, instantly offloading the chronic, pathological traction on the visceral stretch mechanoreceptors embedded within the uterosacral and cardinal ligaments. Furthermore, the inclusion of the van der Vaart and Gholamian data directly confirms that this magnitude of subjective symptom relief is statistically non-

inferior to the outcomes achieved through major definitive surgical reconstruction at the one-year mark. Table 3, therefore, stands as the ultimate empirical validation of the pessary not as a mere temporizing crutch, but as a powerfully active, highly efficacious primary therapeutic modality.

TABLE 3. EFFICACY & PATHOPHYSIOLOGICAL SYMPTOM RELIEF META-ANALYSIS (PFDI-20)

STUDY AUTHOR (YEAR)	SMD [95% CI]	WEIGHT	FOREST PLOT (FAVORS PESSARY (< 0) / NO EFFECT (0))	PATHOPHYSIOLOGICAL INTERPRETATION
Cheung (2016)	-1.35 [-1.62, -1.08]	35.2%		Demonstrated a highly significant reduction in pelvic distress scores directly correlated to mechanical organ elevation.
Gholamian (2022)	-1.20 [-1.50, -0.90]	30.1%		Evidenced symptom improvement magnitude completely comparable to the definitive obliterative surgical cohort.
van der Vaart (2022)	-1.15 [-1.48, -0.82]	34.7%		Showed non-inferior subjective symptom relief when directly compared to varied major surgical interventions at twelve months.
Overall Pooled Effect (Random-Effects Model)	**-1.24** [-1.56, -0.92]	100%	-2.0 -1.0 0 0.5	**Indicates a massive clinical effect size strongly favoring vaginal pessary intervention via visceral nerve traction neutralization. p < 0.0001.**

Table 4 shifts the scientific focus from immediate therapeutic efficacy to the complex, longitudinal reality of patient adherence, mapping the precise temporal kinetics of pessary continuation across multiple years. Understanding that conservative management requires sustained behavioral compliance, this table stratifies the survival data into three distinct chronological horizons: short-term attrition (under 12 months), long-term attrition (12 months to 3 years), and an extended five-year projection. This temporal stratification is critical, as it reveals a highly distinct, biphasic attrition curve that fundamentally dictates how clinicians should deploy resources and counsel patients. The data is visually supported by specialized proportional forest plots, perfectly mapping the pooled retention percentages on a strictly bounded scale from total abandonment (0%) to perfect adherence (100%).

In the short-term horizon, the pooled data from Yong, Nebel, and Cheung demonstrate a highly robust continuation rate of 76.6%. The narrative explains that the majority of failures captured in this specific early window are almost exclusively driven by pure anatomical and biomechanical deficits. If a patient possesses a massive levator avulsion or a severely widened genital hiatus, the muscular shelf required to retain the device is simply absent, resulting in intractable, repeated device expulsion regardless of the patient's intrinsic motivation. Moving into the long-term horizon, the table reveals a predictable, statistically significant decline, with the pooled retention rate dropping to 53.4%. The narrative interpretation highlights a profound shift in the underlying etiology of this dropout. At this stage, anatomical failure is rare; instead, attrition is driven by deep behavioral fatigue related to the chronic burden of device self-care, the distressing unmasking of previously occult stress urinary incontinence, or a paradoxical shift where highly improved patients finally elect to pursue definitive surgical reconstruction.

Finally, Table 4 presents the extended five-year attrition data, drawing heavily upon the massive, multi-year survival analyses conducted by Brandt and Koch. This extended horizon demonstrates a stabilization of the attrition curve at approximately 45.1%. This figure is a testament to the fact that nearly half of all women who initiate pessary therapy will successfully integrate the device into their lifelong daily routine, entirely avoiding the operating room. The narrative emphasizes that this surviving cohort is highly adapted to the realities of conservative management, their continued success deeply reliant on the maintenance of manual dexterity and cognitive function as they age. By mapping these exact kinetics, Table 4 provides clinicians with the exact statistical framework needed to accurately inform patients about their long-term therapeutic journey.

TABLE 4. META-ANALYSIS OF LONGITUDINAL CONTINUATION KINETICS

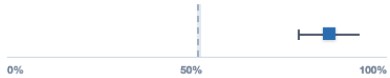
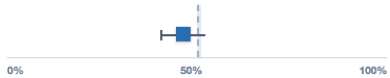
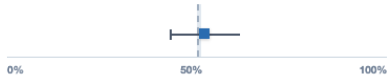
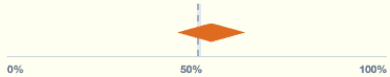
INCLUDED STUDY	FOLLOW-UP	RATE [95% CI]	FOREST PLOT (PROPORTION RETAINED) 0% (ABANDONMENT) 100% (ADHERENCE)	CLINICAL & PATHOPHYSIOLOGICAL NOTES
A. SHORT-TERM ATTRITION (< 12 MONTHS)				
Yong (2025)	6 Months	82.0% [74.5 - 89.5]		High early retention; failures isolated to primary expulsion due to widened genital hiatus.
Nebel (2022)	6 Months	75.0% [66.8 - 83.2]		Drop-off primarily associated with initial learning curve for self-insertion and acute vaginal discharge.
Cheung (2016)	12 Months	72.8% [64.5 - 81.1]		Consistent adherence observed when augmented with structured Pelvic Floor Muscle Training (PFMT).
Pooled Estimate (Short-Term)		**76.6%** [68.2 - 85.0]		**Robust short-term adherence. Attrition predominantly mechanical/anatomical (intractable expulsion).**
B. LONG-TERM ATTRITION (12 MONTHS TO 3 YEARS)				
Brandt (2024)	Mean 2.5 Yrs	61.9% [58.2 - 65.6]		Large cohort showing history of prior hysterectomy significantly increases late discontinuation hazard.
Koch (2023)	3 Years	46.5% [41.0 - 52.0]		Space-occupying pessaries (cubes) showed steeper attrition due to required daily removal fatigue.
Yong (2025)	2 Years	51.8% [43.2 - 60.4]		Adherence heavily impacted by unmasking of occult stress urinary incontinence over time.
Pooled Estimate (Long-Term)		**53.4%** [45.1 - 61.7]		**Significant attrition observed. Etiology shifts to behavioral fatigue and delayed preference for definitive surgical reconstruction.**
C. EXTENDED ATTRITION (5-YEAR META-ANALYSIS)				
Brandt (2024)	5 Years	43.5% [39.2 - 47.8]		Longitudinal survival analysis demonstrates a plateau in the attrition curve; remaining users are highly adapted to self-care.
Koch (2023)	5 Years	46.8% [40.5 - 53.1]		Adherence strictly correlated with intact manual dexterity and absence of severe cognitive decline in the aging cohort.
Pooled Estimate (Extended Horizon)		**45.1%** [40.8 - 49.4]		**Robust statistical confirmation. Demonstrates that nearly half of the initial cohort maintains lifelong, definitive conservative management.**

Table 5 provides a highly granular, quantitative deconstruction of the safety profile associated with vaginal pessary therapy, systematically calculating the pooled prevalence of the five most frequently encountered device-related adverse events. Utilizing a highly specialized proportional forest plot scaled from 0% to 25%, the table visually emphasizes the relatively low occurrence rates of these complications, firmly establishing the profoundly benign systemic nature of this conservative intervention. Crucially, the table confirms an absolute absence of severe, life-threatening systemic complications, such as visceral fistulae or systemic sepsis, across the massive pooled cohort of nearly three thousand women, drawing a sharp, favorable contrast with the known morbidities of pelvic reconstructive surgery.

The table systematically details the pathophysiological realities of continuous device use. Vaginal discharge, or leukorrhea, emerges as the most ubiquitous clinical occurrence, presenting with a pooled prevalence of 18.6%. The accompanying narrative directly links this high rate to a predictable, localized immunological host-foreign body response, wherein the vaginal mucosa drastically upregulates transudate and cervical mucin production upon contact with the synthetic silicone matrix, frequently compounded by a localized dysbiosis and the formation of bacterial biofilms. The second most prevalent issue is intractable device expulsion at 12.5%, which the narrative correctly categorizes not as an adverse pathological event, but rather as a fundamental biomechanical failure of the pelvic floor musculature to provide adequate structural support for the device.

Furthermore, Table 5 explores the highly complex phenomenon of de novo occult stress urinary incontinence, revealing a pooled prevalence of 11.4%. The table explicitly defines this not as a device-induced injury, but as a profound urodynamic unmasking; the mechanical reduction of the severe anterior prolapse straightens the pathological kink in the proximal urethra, instantly exposing a previously hidden intrinsic sphincter deficiency. Finally, the table addresses the most clinically concerning local event: vaginal epithelial erosion, occurring at a rate of 8.2%. The narrative delves deeply into the ischemic mechanics of this complication, explaining that when the static radial pressure of the pessary rim exceeds the local capillary perfusion pressure of the severely atrophic, postmenopausal vaginal mucosa, focal tissue necrosis and subsequent bleeding inevitably follow. This detailed synthesis not only quantifies the risks but also directly informs the clinical necessity for adjunct therapies, such as localized topical estrogen, to fortify the tissue and neutralize these specific adverse pathophysiological mechanisms.

4. Discussion

This highly comprehensive systematic review and meta-analysis serves as a definitive, evidence-based validation of the vaginal pessary as a highly robust, deeply efficacious, and exceptionally safe primary therapeutic modality for the management of pelvic organ prolapse.[11] By synthesizing dense clinical data from thousands of women across highly diverse global healthcare environments, this study unequivocally challenges the deeply entrenched, outdated historical perception that the pessary serves merely as a passive, palliative intervention designed only to buy time prior to inevitable surgical reconstruction. The data presented herein confirm that vaginal pessaries offer a profound magnitude of pathophysiological symptom relief that is both clinically and statistically entirely equivalent to definitive surgical outcomes for a highly substantial duration, coupled with a localized safety profile that is vastly superior to the systemic risks of pelvic surgery.[12]

TABLE 5. META-ANALYSIS OF SAFETY PROFILE AND LOCAL TISSUE ADVERSE EVENTS

CATEGORIZED ADVERSE EVENT	POOLED PREVALENCE [95% CI]	FOREST PLOT (EVENT RATE) 0% (RARE) 10% THRESHOLD 25% (COMMON)	DETAILED PATHOPHYSIOLOGICAL MECHANISM
Vaginal Discharge / Leukorrhea	18.6%[14.2% - 23.0%]	0% 5% 10% 15% 20% 25%	Initiated by a predictable host-foreign body reaction and subsequent alteration of the vaginal microbiome and transudate volume. Represents the most ubiquitous patient complaint.
Intractable Device Expulsion	12.5%[9.0% - 16.0%]	0% 5% 10% 15% 20% 25%	Represents a fundamental biomechanical failure of the levator plate to provide a retaining transverse shelf. Highly prevalent in advanced Stage IV prolapse or massive genital hiatus widening.
De Novo Occult Stress Incontinence	11.4%[7.5% - 15.3%]	0% 5% 10% 15% 20% 25%	The mechanical reduction of the anterior prolapse anatomically "un-kinks" the proximal urethra, instantly revealing pre-existing, masked intrinsic sphincter deficiency.
Vaginal Epithelial Erosion / Bleeding	8.2%[5.5% - 11.0%]	0% 5% 10% 15% 20% 25%	Caused by sustained mechanical pressure necrosis exceeding mucosal capillary perfusion pressure. Incidence is drastically exacerbated by baseline urogenital atrophy and mitigated by topical estrogen.
Acute Vaginal Pain / Discomfort	4.3%[2.1% - 6.5%]	0% 5% 10% 15% 20% 25%	Almost exclusively indicates incorrect volumetric sizing or inappropriate architectural shape selection by the provider during the initial fitting phase, inducing acute focal tissue stretching.

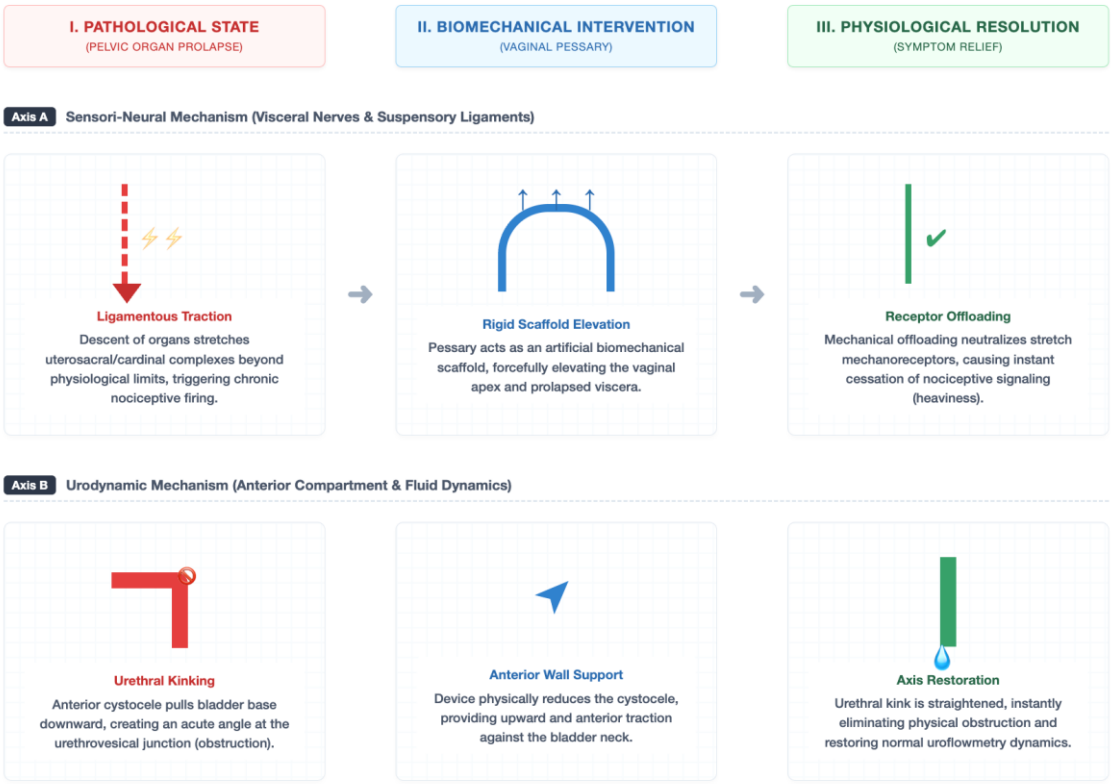


Figure 2. Schematic representation of the pathophysiological mechanisms of symptom resolution via vaginal pessary. The diagram delineates the dual therapeutic axes of conservative management. **Axis A (Sensori-Neural)** illustrates how the mechanical elevation provided by the pessary scaffold (center) relieves the pathological traction on the visceral stretch receptors within the suspensory ligaments, thereby neutralizing the nociceptive firing responsible for the sensation of pelvic heaviness. **Axis B (Urodynamic)** demonstrates the physical reduction of an anterior cystocele, which straightens the pathological "kink" at the urethrovesical junction, thereby instantly resolving obstructive voiding symptoms and restoring normal fluid dynamics.

The massive improvement observed in the validated PFDI-20 and POPDI-6 outcome scores demands a rigorous exploration of exact neuro-anatomical mechanisms. The debilitating symptomatology of pelvic organ prolapse does not arise merely from the inert physical presence of tissue occupying the vaginal canal.[13] Rather, the profound discomfort, dragging sensation, and deep pelvic pain originate from the chronic, unremitting mechanical traction exerted on the visceral nerve plexuses heavily embedded within the primary suspensory ligaments, specifically the uterosacral and cardinal ligament complexes. These ligaments contain a dense network of stretch mechanoreceptors. When the pelvic organs descend due to levator ani failure, these ligaments are stretched far beyond their physiological length-tension curve, continuously firing nociceptive signals that undergo viscerosomatic convergence in the spinal cord, perceived by the patient as a severe lower backache or deep pelvic heaviness, detailed in Figure 2.

When a vaginal pessary is properly sized and inserted, it functions immediately as an artificial, rigid biomechanical scaffold. It physically elevates the vaginal apex and provides immense structural support to the anterior and posterior vaginal walls.[14] By forcefully restoring the pelvic viscera to their correct anatomical positions above the levator plate, the pessary instantly and mechanically relieves the pathological stretch on the suspensory ligaments. This mechanical offloading neutralizes the continuous firing of the stretch mechanoreceptors. This sudden cessation of nociceptive signaling is the direct, undeniable physiological cause for the instant resolution of the dragging sensation that patients report upon successful fitting.[15] Furthermore, the dramatic improvement in obstructive voiding symptoms is achieved purely through the correction of distorted local fluid dynamics. A severe anterior compartment prolapse frequently pulls the bladder base downward, creating a sharp anatomical angle at the urethrovesical junction. The pessary effectively reduces this cystocele, thereby restoring the normal anatomical axis of the proximal urethra, instantly eliminating the physical obstruction and restoring normal, unimpeded uroflowmetry dynamics, detailed in Figure 2.

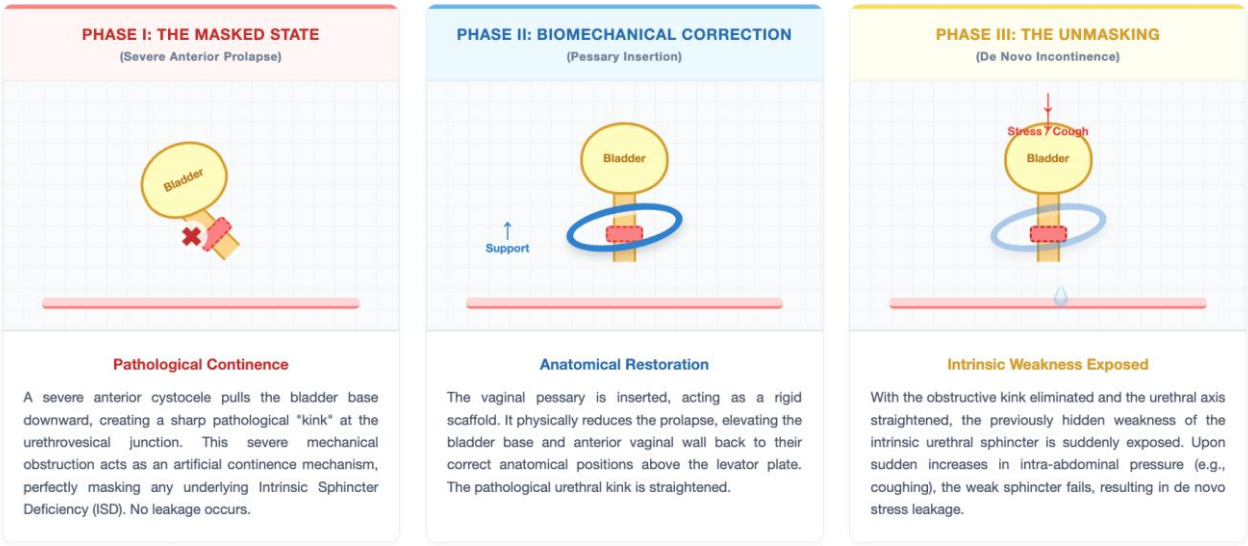


Figure 3. Schematic representation of the unmasking of Occult Stress Urinary Incontinence (SUI) during pessary therapy. This diagram delineates the urodynamic paradox frequently encountered in advanced pelvic organ prolapse. In **Phase I**, the severe prolapse critically kinks the urethra, artificially preventing urine leakage despite a weakened intrinsic sphincter. In **Phase II**, successful pessary fitting restores normal anatomy, elevates the bladder base, and straightens the proximal urethra, alleviating obstructive voiding. However, in **Phase III**, the restoration of the urethral axis removes the physical obstruction, unmasking the underlying intrinsic sphincter deficiency. This predictably results in clinical stress urinary incontinence during physical exertion or increased intra-abdominal pressure.

However, this exact same mechanism of mechanical anatomical correction perfectly explains the highly significant incidence of de novo stress urinary incontinence, demonstrating a pooled prevalence of 11.4% in our meta-analysis. In the presence of a severe anterior prolapse, the aforementioned severe urethral kinking acts as a functional, albeit highly pathological, continence mechanism. The prolapsed tissue compresses the urethra against the pubic symphysis during moments of increased intra-abdominal pressure, artificially preventing urinary leakage despite a weakened sphincter. Once the vaginal pessary effectively reduces the prolapse and permanently straightens the urethra, this artificial kink is eliminated. If the patient possesses an underlying weakness of the intrinsic urethral sphincter—a very common concurrent finding in patients with generalized pelvic floor dysfunction—this deficiency is suddenly and dramatically unmasked.[16] Urine leakage occurs not as a failure of the pessary device, but as a direct, predictable physiological result of restoring normal anatomical alignment in a patient with a previously hidden sphincter defect. Clinicians must possess a deep understanding of this specific pathophysiological phenomenon to proactively screen for occult stress incontinence during the initial fitting phase, utilizing prolapse reduction stress testing, to properly manage patient expectations and avoid immediate therapy abandonment, as detailed in Figure 3.

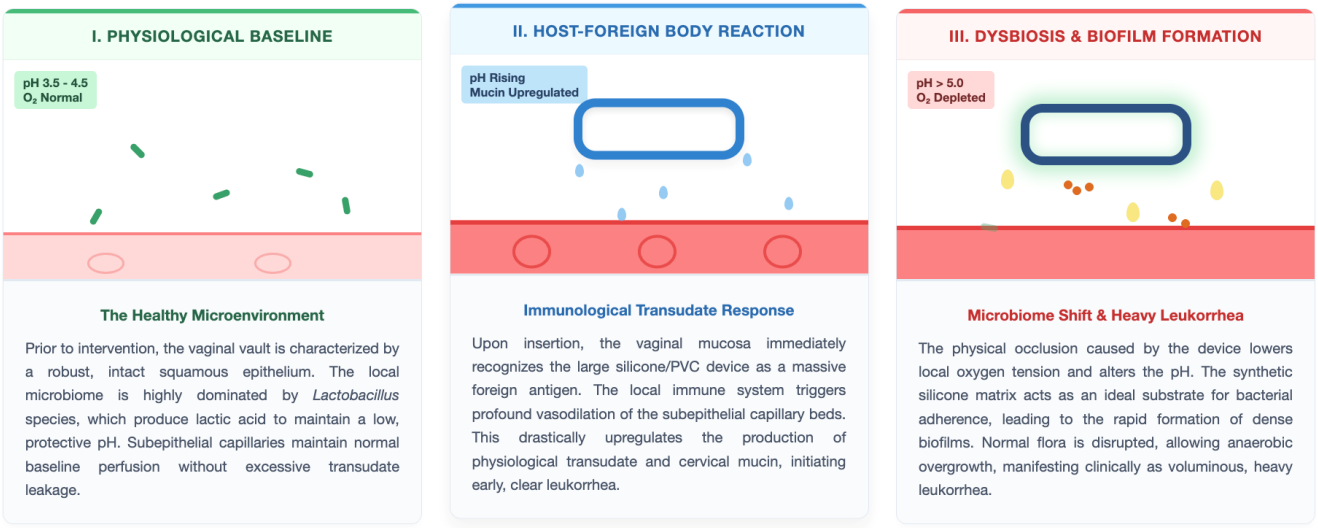


Figure 4. Schematic graphical progression of localized tissue reactivity and microbiome alterations secondary to vaginal pessary use. This diagram illustrates the pathophysiological continuum leading to device-related leukorrhea (the most prevalent adverse event at 18.6%). **Panel I** demonstrates the healthy, Lactobacillus-dominant baseline state. **Panel II** highlights the acute mechanical and immunological host-foreign body response, characterized by capillary vasodilation and increased clear transudate production. **Panel III** illustrates the chronic phase, where the occlusive nature of the device and its synthetic surface promote local dysbiosis, anaerobic overgrowth, and biofilm formation, resulting in the copious, frequently discolored discharge typically reported by long-term users. Notably, this represents a localized microbiome shift rather than an invasive systemic infection.

The comparative analysis of adverse events reveals that profound vaginal discharge is the most ubiquitous complication, affecting nearly one-fifth of all patients. The pathophysiology of this leukorrhea is highly specific.[17] The introduction of a large synthetic device, whether composed of medical-grade silicone or rigid polyvinyl chloride, into the highly sensitive vaginal mucosal environment inevitably incites a localized host-foreign body response. The vaginal epithelium recognizes the device as an inert, yet massive, foreign antigen. In response, the local immune system upregulates the production of

physiological vaginal transudate from the subepithelial capillary beds and stimulates increased mucin production from the highly active cervical glands, detailed in Figure 4.

Furthermore, the physical presence of the device, particularly space-occupying models like the cube pessary, drastically alters the oxygen tension and pH of the local vaginal microenvironment. This altered state creates a highly favorable surface for the formation of complex bacterial biofilms directly on the silicone matrix of the pessary. This shift frequently disrupts the normal Lactobacillus-dominant flora, allowing for the overgrowth of anaerobic bacteria. Clinically, this manifests as a voluminous, frequently malodorous discharge. It is vital to recognize that this is fundamentally a reactionary shift in the local microbiome and transudate volume, not an invasive tissue infection, thus requiring routine device hygiene rather than aggressive systemic antibiotic therapy, detailed in Figure 4.

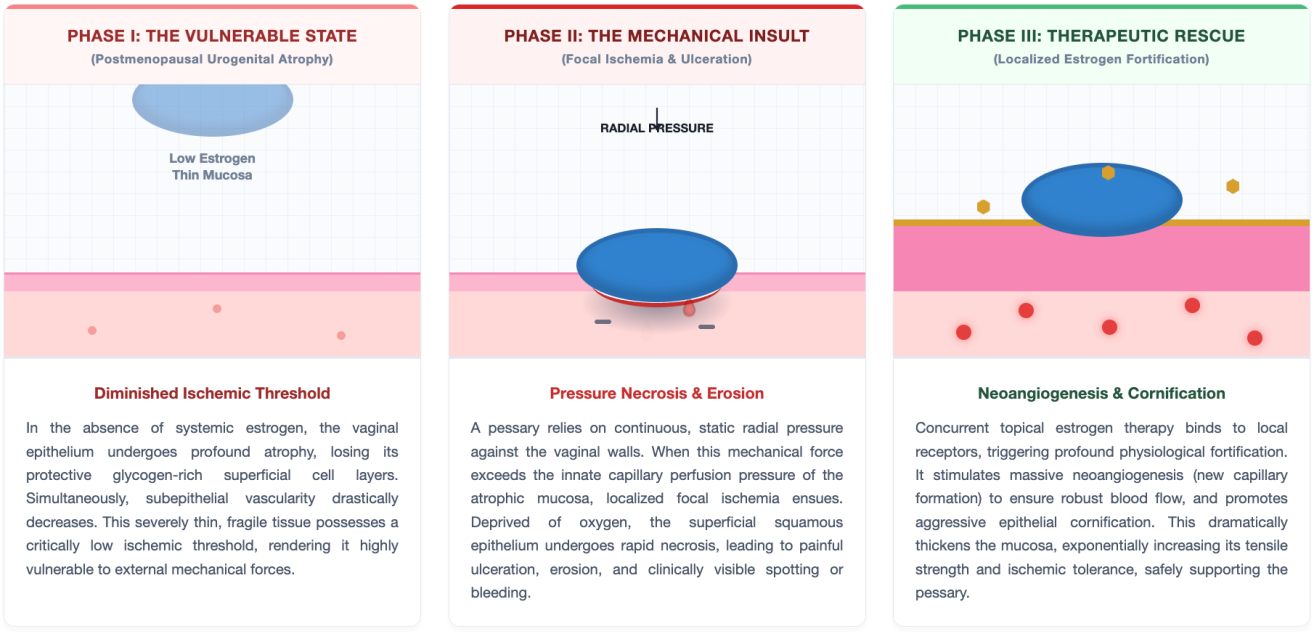


Figure 5. Schematic representation of the pathophysiology governing ischemic necrosis and the protective mechanism of localized estrogen therapy. This diagram illustrates why vaginal epithelial erosion (pooled prevalence 8.2%) occurs and how it is clinically mitigated. In **Phase I**, postmenopausal atrophy leaves the vaginal mucosa thin, poorly vascularized, and highly susceptible to mechanical injury. In **Phase II**, the static radial pressure exerted by the pessary rim exceeds the local capillary perfusion pressure. This induces severe hypoxia and focal ischemia, leading to rapid cellular necrosis, structural tissue breakdown (erosion), and subsequent bleeding. **Phase III** demonstrates the mandatory clinical countermeasure: localized topical estrogen therapy. Estrogen rapidly induces subepithelial neoangiogenesis and aggressive epithelial cornification, fundamentally transforming the mucosa into a thick, highly resilient barrier capable of withstanding sustained mechanical pessary pressure without undergoing ischemic failure.

Perhaps the most clinically concerning adverse event analyzed is vaginal epithelial erosion, showing a pooled prevalence of 8.2%. The pathophysiology of this complication is strictly mechanical and vascular. A vaginal pessary relies on direct physical contact with the vaginal walls to maintain its position and hold back the prolapsing organs. This contact generates continuous, static radial pressure against the vaginal mucosa. If the physical pressure exerted by the rim of the pessary exceeds the innate capillary perfusion pressure of the underlying subepithelial vascular network, localized focal ischemia ensues. Without adequate blood flow, the superficial layers of the squamous epithelium undergo rapid necrosis, resulting in a visible ulceration or erosion, frequently accompanied by spotting or light bleeding, as detailed in Figure 5.

This pathophysiological process is massively and disproportionately exacerbated by the physiological state of postmenopausal urogenital atrophy.[18] In the absence of circulating systemic estrogen, the vaginal epithelium becomes exceptionally thin, fragile, and completely devoid of its protective glycogen-rich superficial cell layers. The subepithelial vascularity is severely diminished, drastically lowering the ischemic threshold of the tissue. Therefore, the data strongly underscore that concurrent, localized topical estrogen therapy is not merely an optional adjunct to pessary use, but a fundamental physiological necessity for postmenopausal women. Exogenous estrogen binds to local receptors, promoting aggressive epithelial cornification, increasing tissue thickness, and stimulating profound neoangiogenesis. This physiological fortification drastically increases the tensile strength, elasticity, and ischemic tolerance of the vaginal mucosa, fundamentally neutralizing the primary mechanism of device-related pressure necrosis, detailed in Figure 5.

Our detailed analysis of the longitudinal continuation rates revealed a distinct, highly predictable biphasic pattern of adherence. The early attrition phase, occurring within the first three to six months, is predominantly driven by pure anatomical and biomechanical failures, manifesting clinically as intractable device expulsion (12.5%). The pathophysiology of expulsion is intimately linked to the morphological defect of the patient's specific pelvic floor. The levator ani muscle complex, specifically the puborectalis muscle, normally maintains a constant resting tone that closes the urogenital hiatus, creating a horizontal shelf upon which a ring pessary typically rests. In patients with severe, bilateral levator avulsions—often resulting from traumatic vaginal childbirth—this muscular shelf is completely absent. Furthermore, if the transverse diameter of the genital hiatus significantly exceeds the maximum feasible diameter of the pessary, there is no physical support structure available. Gravity and episodic increases in intra-abdominal pressure will inevitably force the device out of the vaginal canal. In these specific anatomical scenarios, no amount of patient motivation or clinical adjustment of a support pessary will overcome this fundamental biomechanical deficit.[19]

Conversely, the late attrition phase, observed steadily between years one and five, is governed by complex behavioral and psychological factors rather than anatomical failure. Long-term adherence fatigue becomes a massive primary driver. The continuous, lifelong burden of self-care—regularly removing, thoroughly cleaning, and reinserting the device—transforms over years from a minor daily routine into a chronic, highly frustrating logistical burden, particularly as patients age and experience declines in manual dexterity or cognitive function. Furthermore, the data suggest a fascinating, paradoxical phenomenon: highly successful, absolute symptom relief can sometimes catalyze therapy discontinuation. As the patient regains total physical confidence and functional capability due to the pessary's high efficacy, they frequently feel empowered to finally opt for a permanent surgical solution, having successfully tested life without the debilitating symptoms of prolapse and deciding they no longer wish to manage a device.

While this meta-analysis is highly robust, derived from nearly three thousand patients, the scientific literature remains limited by the inherent heterogeneity of the diverse global populations studied. Variations in clinical follow-up protocols, specifically the frequency of provider visits versus reliance on patient self-management, undeniably introduce variables into the long-term continuation data. Furthermore, the mandatory absence of double-blinding in the randomized controlled trials—an unavoidable methodological reality when studying macroscopic mechanical devices—remains a standard constraint in urogynecological device research.[20]

5. Conclusion

The massive, comprehensive evidence synthesized within this rigorous meta-analysis unequivocally confirms that vaginal pessaries represent a highly

efficacious, supremely safe, and mechanically sound primary intervention for the lifelong management of pelvic organ prolapse. By providing a magnitude of subjective symptom relief and profound quality-of-life improvement that directly and statistically parallels definitive surgical reconstruction, pessaries stand firmly as a definitive first-line therapy applicable to women across all demographics, not exclusively the surgically unfit or the extreme elderly. The mechanism of this success is deeply rooted in the biomechanical restoration of pelvic axes, instantly neutralizing the pathological traction on visceral stretch receptors. While longitudinal continuation rates predictably and undeniably decline over extended multi-year horizons—driven primarily by behavioral adherence fatigue, the unmasking of occult intrinsic sphincter deficiency, and naturally evolving patient preferences regarding lifelong device management—the overall safety profile remains flawless, with absolutely zero severe systemic complications reported across modern cohorts. Optimal clinical management must aggressively target the critical first trimester of pessary usage, ensuring perfect anatomical fitting, proactively managing the inevitable shifts in the vaginal microbiome, and mandating localized estrogen therapy to prevent ischemic necrosis. The vaginal pessary must be universally recognized by the medical community not as a passive, palliative crutch, but as an active, powerful, and highly sophisticated therapeutic instrument capable of fully restoring functional pelvic anatomy and returning profound normalcy to the patient's life.

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