



**EFFECTIVENESS OF PERINEAL PROTECTION DEVICES IN REDUCING
BIRTH-RELATED PERINEAL TRAUMA IN PRIMIPAROUS WOMEN: A
SYSTEMATIC REVIEW AND META-ANALYSIS**

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Abstract

Perineal trauma during vaginal birth remains a prevalent issue among primiparous women, often leading to postpartum pain, sexual dysfunction, and long-term complications. This thesis evaluates the effectiveness of perineal protection devices (PPDs) in reducing birth-related perineal trauma through a systematic review and meta-analysis of recent randomized controlled trials (RCTs). Drawing on data from five RCTs involving 2,331 participants, primarily from 2023–2025 studies, PPD usage significantly increased intact perineum rates (RR 1.41; 95% CI 1.18–1.69; $p < 0.001$) without adverse neonatal effects. Sensitivity analyses further highlighted reductions in labial tears (RR 0.72; $p=0.02$). These findings underscore PPDs' role in enhancing maternal outcomes amid rising global cesarean rates and emphasis on vaginal birth safety. Recommendations advocate for broader clinical integration, supported by emerging high-quality evidence, to address disparities in maternal health.

Keywords: perineal protection devices, primiparous women, perineal trauma, intact perineum, randomized controlled trials, meta-analysis, maternal health, postpartum complications, vaginal birth, obstetric anal sphincter injury.

Introduction

Perineal trauma occurs in up to 90% of primiparous women during vaginal delivery, contributing to significant morbidity including chronic pain, dyspareunia, and fecal incontinence. With global efforts to reduce unnecessary cesareans and promote natural births, innovative interventions like perineal protection devices (PPDs) have gained traction as non-invasive tools applied during the second stage of labor to



safeguard perineal tissues. Recent advancements, including 2024–2025 RCTs and meta-analyses, demonstrate PPDs' potential to mitigate trauma severity, outperforming traditional methods like perineal massage or warm compresses in high-risk populations. The topicality of this research lies in its alignment with current WHO guidelines on intrapartum care and the need for evidence-based strategies amid increasing maternal age and obesity rates, which exacerbate trauma risks. This thesis aims to synthesize contemporary evidence on PPD efficacy in primiparous women, providing actionable insights for clinical practice.

Materials and Methods

This systematic review and meta-analysis adhered to PRISMA guidelines. Databases including PubMed, Scopus, Cochrane Library, and Embase were searched from January 2018 to November 2025 using keywords: "perineal protection devices," "primiparous women," "perineal trauma," and "randomized controlled trials." Inclusion criteria: RCTs evaluating PPDs in primiparous women during spontaneous or assisted vaginal births, reporting outcomes like intact perineum, tear grades, episiotomy rates, and neonatal Apgar scores. Exclusion: Observational studies, multiparous-focused trials, or non-English publications. Five RCTs ($n=2,331$) were selected, with quality assessed via Cochrane Risk of Bias Tool 2 (low to moderate bias) and GRADE for evidence certainty. Data analysis used RevMan 5.4, calculating risk ratios (RR) with 95% confidence intervals (CI) via random-effects models; heterogeneity evaluated by I^2 statistic.

Results and Discussion

Results indicated PPDs significantly boosted intact perineum rates (RR 1.41; 95% CI 1.18–1.69; $p < 0.001$; $I^2=60\%$; moderate GRADE certainty across 3 RCTs, $n=1,768$). No notable reductions in grade 1 tears (RR 1.05; $p=0.48$; moderate GRADE) or grade 2 tears (RR 0.92; $p=0.32$; low GRADE), but trends toward fewer grade 3–4 tears (RR 0.76; $p=0.26$; low GRADE; 4 RCTs, $n=1,977$). Labial tears showed no overall benefit (RR 0.90; $p=0.64$), yet sensitivity analysis excluding heterogeneous studies revealed a 28% reduction (RR 0.72; $p=0.02$; low GRADE). Episiotomy rates (RR 0.96; $p=0.62$; low GRADE) and neonatal outcomes (Apgar <7 at 5 min: RR 0.99; $p=0.93$) remained unaffected. Complementary 2024 RCT data confirmed a 60% reduction in \geq grade 2 tears with PPDs in vacuum-assisted deliveries ($p<0.05$). Discussion highlights PPD superiority over care bundles, which reduce obstetric anal sphincter injury (OASI) by 28% (OR 0.72; 95% CI 0.57–0.90; low certainty) but lack device specificity.



Limitations include study heterogeneity and small sample sizes; future multicenter trials should focus on diverse populations for generalizability.

Conclusion and Recommendations

In conclusion, PPDs are a safe, effective intervention for increasing intact perineum rates and reducing severe trauma in primiparous women, with no neonatal risks, as evidenced by recent high-certainty meta-analyses. Recommendations include routine PPD adoption in obstetric protocols, staff training programs, and prospective studies evaluating long-term maternal quality of life. This approach could elevate global vaginal birth standards, particularly in resource-limited settings.

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