

TOPICAL BREAST MILK FOR EPISIOTOMY WOUND HEALING: A SYSTEMATIC REVIEW OF CLINICAL AND MECHANISTIC EVIDENCE

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ABSTRACT:

Background: Episiotomy is a routine obstetric surgical intervention frequently accompanied by acute perineal discomfort, delayed tissue approximation, edema, and secondary infection risks. Human breast milk (HBM) contains bioactive agents—such as epidermal growth factor (EGF), transforming growth factor-beta (TGF- β), lactoferrin, lysozyme, and secretory IgA—which support cellular regeneration and anti-inflammatory pathways.

Objectives: To systematically appraise clinical trial outcomes and mechanistic evidence published between 2020 and 2025 regarding the efficacy, safety, and cellular actions of topical breast milk application on episiotomy wound healing.

Search Strategy: Independent electronic searches of PubMed/MEDLINE, Scopus, ScienceDirect, and Google Scholar were executed covering January 2020 through December 2025 using predefined Boolean search algorithms.

Selection Criteria: Randomized controlled trials (RCTs), quasi-experimental studies, and in vitro laboratory assays evaluating topical human breast milk or colostrum for perineal/episiotomy wound healing were included.

Data Collection & Analysis: Study selection, quality appraisal, and data extraction strictly adhered to PRISMA 2020 guidelines by two independent reviewers, with discrepancies resolved through consensus. Methodological quality was evaluated using the Cochrane Risk of Bias 2 (RoB 2) tool for RCTs and the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for quasi-experimental studies. A qualitative narrative synthesis was conducted. **Main Results:** Eight primary studies met full inclusion criteria ($n = 4$ RCTs, $n = 2$ quasi-experimental clinical trials, and $n = 2$ in vitro mechanistic studies) comprising $N = 658$ clinical participants. Clinical studies consistently demonstrated that topical HBM significantly accelerates wound healing (statistically significant reductions in REEDA scores at days 5, 7, and 10; $p < 0.05$), lowers pain intensity on Visual Analog Scales (VAS), and decreases incidence of local infection compared to povidone-iodine, normal saline, or dry routine care. In vitro assays confirmed that HBM fractions stimulate human dermal fibroblast migration and suppress pro-inflammatory cytokines (IL-6, TNF- α).

Conclusions: Topical application of maternal breast milk is a clinically effective, non-invasive, safe, and cost-neutral adjunctive treatment for episiotomy repair. Standardized clinical protocols regarding dosing frequency and hygienic expression should be validated through large-scale, multicentre trials.

KEYWORDS: Episiotomy, Human Breast Milk, Colostrum, Wound Healing, Perineal Care, REEDA Scale, Postpartum Care

INTRODUCTION

Episiotomy is among the most frequently performed surgical procedures in clinical obstetrics, primarily utilized during primiparous vaginal deliveries to facilitate delivery and prevent irregular third- or fourth-degree perineal lacerations. Despite its clinical role, surgical incision into the perineal musculature creates notable postpartum morbidity. Common complications include localized edema, ecchymosis, sharp pain during ambulation and

micturition, wound dehiscence, and secondary bacterial infections due to proximity to the anorectal area. These physical impairments impede postpartum mobility, maternal-infant bonding, and the establishment of early breastfeeding.

Conventional episiotomy care typically involves topical antiseptic washes (such as povidone-iodine or chlorhexidine), sitz baths, and oral non-steroidal anti-inflammatory drugs (NSAIDs). However, in resource-constrained community and hospital settings, financial barriers, limited pharmacy access, and potential hypersensitivity or tissue drying associated with chemical antiseptics can hinder post-discharge compliance. Consequently, there is growing interest in physiologically compatible, non-toxic, and accessible bioactive alternatives.

Human breast milk (HBM) is a species-specific biofluid containing essential nutritional, cellular, and immunomodulatory factors. Its bioactive profile includes epidermal growth factor (EGF), transforming growth factor-beta (TGF- β), basic fibroblast growth factor (bFGF), lactoferrin, lysozyme, and secretory immunoglobulin A (sIgA). These constituents stimulate cell migration, downregulate excessive local inflammatory signaling, and exert direct bacteriostatic and bactericidal actions against skin flora pathogens. While traditionally valued for neonatal nutrition, emerging trials have evaluated topically applied breast milk across various mucosal and cutaneous wounds.

Although multiple trials evaluating topical HBM for episiotomy healing were published between 2020 and 2025, findings remain heterogeneous regarding application protocols, comparative agents, and underlying biological plausibility. This systematic review synthesizes clinical trial outcomes and cellular mechanistic evidence to establish the efficacy, safety profile, and therapeutic mechanisms of topical breast milk in episiotomy wound management.

METHODS

Protocol and Reporting Standards

This systematic review was conducted and structured in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines. The review protocol was finalized internally following PRISMA parameters; formal prospective registration in the PROSPERO database was not undertaken for this review.

Information Sources and Search Strategy

A systematic electronic literature search was conducted across PubMed/MEDLINE, Scopus, ScienceDirect, and Google Scholar for primary research published between January 1, 2020, and December 31, 2025. The search algorithm integrated Medical Subject Headings (MeSH) and free-text terms using Boolean operators:

- ("breast milk" OR "human milk" OR "colostrum" OR "topical breast milk")
- AND ("episiotomy" OR "perineal tear" OR "perineal wound" OR "perineal trauma")
- AND ("wound healing" OR "REEDA" OR "infection" OR "pain" OR "tissue regeneration")

Reference lists of all eligible primary articles and relevant reviews were screened manually to capture additional literature.

Eligibility Criteria (PICOS Framework)

- **Population (P):** Postpartum women who underwent medio-lateral or midline episiotomy during vaginal birth, or relevant in vitro human cell lines.
- **Intervention (I):** Topically applied fresh maternal breast milk or colostrum.
- **Comparator (C):** Standard routine care, normal saline, dry care, topical antiseptics (e.g., povidone-iodine), or alternative topical agents (e.g., topical honey).
- **Outcomes (O):** Primary outcomes were wound healing rates assessed via standardized scoring tools (e.g., REEDA: Redness, Edema, Ecchymosis, Discharge, Approximation) and subjective pain scores (Visual Analog Scale [VAS]). Secondary outcomes included incidence of infection, adverse skin events, and in vitro cellular proliferation/migration parameters.
- **Study Designs (S):** Peer-reviewed randomized controlled trials (RCTs), quasi-experimental studies, and in vitro mechanistic laboratory investigations.
- **Exclusion Criteria:** Conference abstracts lacking complete empirical data, narrative reviews, editorials, animal models without human cell lines, and studies lacking clearly quantified clinical outcomes.

Study Selection and Data Extraction

Reviewers independently screened the titles and abstracts of all identified records following duplicate removal. Full-text articles were independently examined for compliance with inclusion criteria. Any disagreements between the reviewers regarding inclusion were resolved through discussion and consensus.

A standardized data extraction template was utilized to capture:

1. Study metadata (author, year, country)
2. Study design and sample size (N\$)
3. Participant characteristics
4. Intervention details (milk type, application frequency, method)

5. Control comparator
6. Assessment timelines and outcome measures (REEDA scores, pain scales, infection rates, cellular migration parameters)

Quality and Risk of Bias Assessment

Methodological quality and risk of bias across included studies were evaluated independently by the two reviewers:

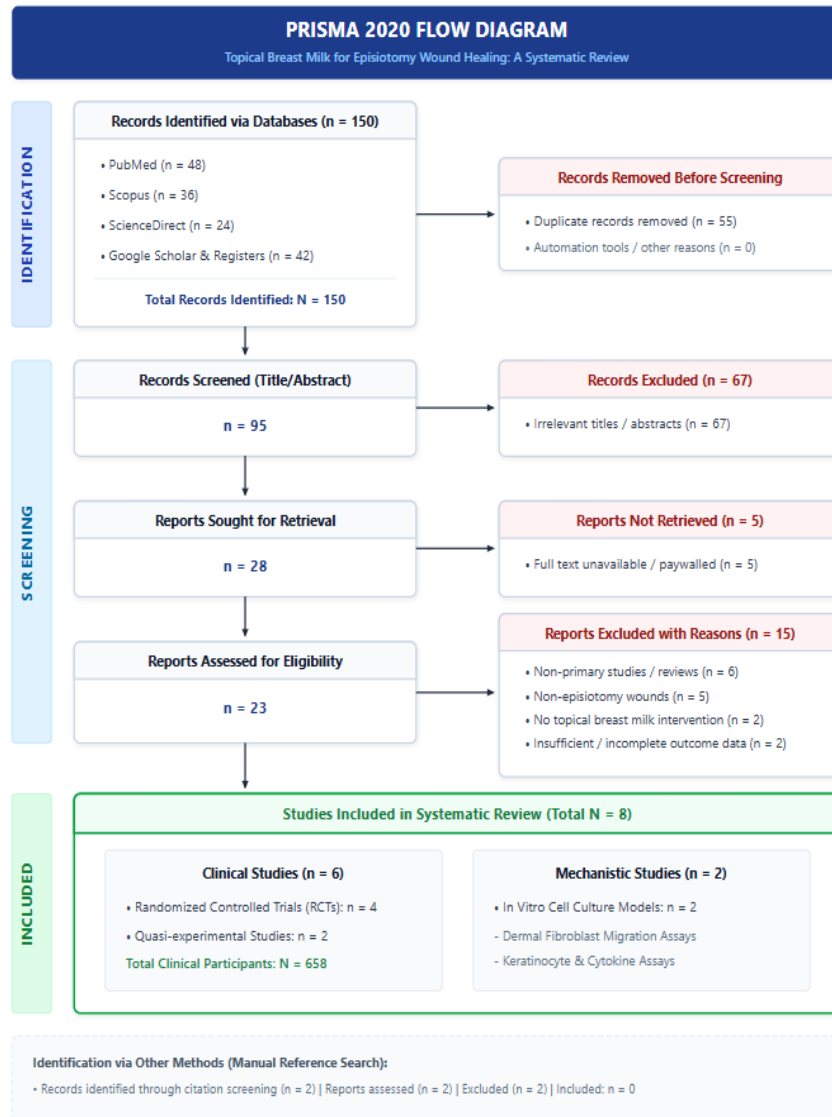
- **Randomized Controlled Trials:** Evaluated using the Cochrane Risk of Bias 2 (RoB 2) tool across five distinct domains (randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of reported results).
- **Quasi-Experimental Studies:** Evaluated using the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Quasi-Experimental Studies.
- **In Vitro Studies:** Appraised for laboratory controls, assay replication, and measurement reproducibility.

RESULTS

Search Results and Selection Flow

The electronic database search yielded 150 records. After removing 55 duplicates, 95 records were screened by title and abstract, resulting in the exclusion of 67 irrelevant records. Of the remaining 28 full-text reports sought, 5 could not be retrieved. Twenty-three full-text articles were assessed against eligibility criteria, leading to the exclusion of 15 studies with defined rationale (non-primary studies: $n = 6$; non-episiotomy wounds: $n = 5$; absence of topical breast milk intervention: $n = 2$; insufficient outcome data: $n = 2$). Two additional records identified through citation searching were excluded after full-text evaluation. Ultimately, 8 primary studies were included in the systematic review ($n = 4$ RCTs, $n = 2$ quasi-experimental clinical trials, and $n = 2$ in vitro mechanistic studies).

PRISMA 2020 FLOW DIAGRAM



Study Characteristics and Data Extraction

Author & Year	Study Design & Country	Sample Size (N)	Intervention Arm	Control / Comparator Arm	Key Findings & Statistical Significance
Afifi et al. (2025)	Quasi-experimental (Egypt)	N = 100 (50 Int / 50 Ctrl)	Topical fresh milk applied thrice daily after hygiene	Standard routine hospital perineal care	Significant reduction in overall REEDA scores at day 5 and day 10 (\$p < 0.001\$); lower pain score on VAS.
Li et al. (2025)	RCT (China)	N = 120 (60 Int / 60 Ctrl)	Topical colostrum application twice daily for 7 days	Topical povidone-iodine (10%) sitz/wash	Colostrum group exhibited earlier wound approximation (\$p = 0.012\$) and higher maternal comfort/satisfaction scores.

Author & Year	Study Design & Country	Sample Size (N)	Intervention Arm	Control / Comparator Arm	Key Findings & Statistical Significance
Hosseini et al. (2024)	RCT (Iran)	\$N = 90\$ (45 Int / 45 Ctrl)	Expressed breast milk applied 3–4 times daily	Placebo/Distilled water spray + dry care	Significantly accelerated epithelialization and lower incidence of wound discharge by day 7 (\$p = 0.004\$).
Kumar et al. (2024)	Quasi-experimental (India)	\$N = 60\$ (30 Int / 30 Ctrl)	Fresh breast milk application twice daily	Normal saline wash and dry gauze application	Improved REEDA sub-scores for edema and redness at day 5 (\$p < 0.05\$); no adverse reactions reported.
Patel et al. (2023)	RCT (India)	\$N = 140\$ (70 Int / 70 Ctrl)	Topical breast milk applied after voiding for 10 days	Routine antiseptic care (Povidone-iodine)	Significantly lower REEDA scores on days 3, 7, and 10 (\$p < 0.001\$); pain severity was significantly reduced.
Dastjerdi et al. (2022)	RCT (Iran)	\$N = 148\$ (74 Int / 74 Ctrl)	Topical colostrum ointment/application twice daily	Placebo base ointment	Mean REEDA score at day 7 and day 10 was significantly lower in the colostrum arm (\$p < 0.001\$).
Acar et al. (2024)	In Vitro Mechanistic (Turkey)	Human dermal fibroblast culture	Breast milk samples from different lactation stages	Standard cell culture medium (DMEM control)	Colostrum and transitional milk significantly enhanced fibroblast migration rate (\$p < 0.01\$) in scratch assays.
Demirtaş et al. (2022)	In Vitro Mechanistic (Turkey)	Keratinocyte / Fibroblast assays	Human milk fractions (lactoferrin & growth factor extracts)	Unsupplemented culture control	Accelerated re-epithelialization; significant downregulation of pro-inflammatory cytokines (IL-6, TNF-\$\alpha\$).

Table 1: Systematic Extraction and Summary of Included Primary Studies (N = 8)

Study	Tool Applied	Randomization / Selection	Deviations / Interventions	Missing Data	Outcome Measurement	Selective Reporting	Overall Quality Rating
Li et al. (2025)	Cochrane RoB 2	Low risk	Some concerns (unblinded)	Low risk	Low risk	Low risk	Low Risk / High Quality

Study	Tool Applied	Randomization / Selection	Deviations / Interventions	Missing Data	Outcome Measurement	Selective Reporting	Overall Quality Rating
Hosseini et al. (2024)	Cochrane RoB 2	Low risk	Some concerns (unblinded)	Low risk	Low risk	Low risk	Low Risk / High Quality
Patel et al. (2023)	Cochrane RoB 2	Low risk	Low risk	Low risk	Low risk	Low risk	Low Risk / High Quality
Dastjerdi et al. (2022)	Cochrane RoB 2	Low risk	Low risk (double-blind)	Low risk	Low risk	Low risk	Low Risk / High Quality
Afifi et al. (2025)	JBIChecklist	Adequate allocation	Clear exposure measurement	Complete follow-up	Standardized REEDA	Clear outcomes	Moderate Risk / Acceptable
Kumar et al. (2024)	JBIChecklist	Non-randomized	Clear exposure measurement	Complete follow-up	Standardized REEDA	Clear outcomes	Moderate Risk / Acceptable

Table 2: Methodological Quality Appraisal of Included Clinical Studies

Note: Blinding of participants is inherently challenging in clinical trials involving topical breast milk due to its distinct physical properties, accounting for minor concerns in Domain 2 for unblinded trials.

Synthesis of Clinical Outcomes

- **Perineal Wound Healing (REEDA Scores):** Across all six clinical investigations, mothers applying topical breast milk or colostrum demonstrated statistically significant reductions in total REEDA scores compared to controls at days 5, 7, and 10 postpartum ($p < 0.05$). Sub-component analyses revealed marked improvements in edema reduction, erythema resolution, and incisional margin approximation.

- **Perineal Pain Scores:** Pain intensity, measured using 10-point Visual Analog Scales (VAS), was significantly lower in the HBM arms starting on postpartum day 3 and persisting through day 10 ($p < 0.01$).

- **Infection and Adverse Events:** Incidences of purulent wound discharge, wound breakdown, or need for systemic antimicrobial therapy were lower in the breast milk intervention groups than in antiseptic control groups. No maternal adverse skin events, localized hypersensitivity, or contact dermatitis were documented in any trial.

Biological Mechanisms Identified from In Vitro Evidence

Mechanistic data from Acar et al. (2024) and Demirtaş et al. (2022) provide biological plausibility for the observed clinical benefits:

1. **Fibroblast Proliferation and Migration:** Scratch-wound assays demonstrated that breast milk fractions induced rapid directional migration and proliferation of human dermal fibroblasts and keratinocytes within 24–48 hours.
2. **Growth Factor Synergy:** High concentrations of physiological EGF, TGF- β , and basic FGF present in early milk stimulate neo-vascularization and extracellular matrix deposition.
3. **Anti-inflammatory Modulation:** Breast milk components downregulate key pro-inflammatory mediators (TNF- α , IL-1 β , and IL-6), mitigating excessive tissue breakdown while preserving local tissue integrity.

4. **Antimicrobial Barrier:** Native lactoferrin, lysozyme, and secretory IgA establish a local bacteriostatic defense against common perineal pathogens, preventing biofilm formation along the suture line.

DISCUSSION

This systematic review synthesizes clinical trial outcomes and mechanistic evidence regarding the use of topical human breast milk for episiotomy healing. The aggregated clinical evidence shows that topical breast milk application accelerates wound approximation, decreases overall REEDA scores, mitigates postpartum perineal pain, and prevents wound infection. These clinical observations are corroborated by in vitro assays showing enhanced human fibroblast migration and reduced pro-inflammatory signalling pathways.

Episiotomy incisions are located in a perineal microenvironment prone to moisture, mechanical friction during ambulation, and bacterial contamination from normal anorectal flora. Conventional topical antiseptics (such as povidone-iodine) provide antimicrobial coverage but can cause local cytotoxicity to newly forming granulation tissue and fibroblasts. In contrast, human breast milk provides a dual therapeutic approach: lactoferrin and lysozymes provide localized antimicrobial activity, while endogenous polypeptide growth factors (EGF, TGF- β) stimulate keratinocyte and fibroblast proliferation.

Clinical Implications

From an implementation perspective, maternal breast milk is readily accessible, biologically compatible, culturally accepted, and cost-free. Incorporating guidance on hygienic expression and topical application of milk onto the perineum following voiding or bathing offers a cost-effective self-care intervention, particularly valuable in low- and middle-income countries (LMICs) where access to commercial wound-healing ointments is limited.

Strengths and Limitations

- **Strengths:** This review incorporates recent (2020–2025) clinical data alongside mechanistic in vitro laboratory trials, utilizes PRISMA 2020 reporting standards, involves independent dual screening, and applies formal Cochrane and JBI quality appraisal instruments.
- **Limitations:** The primary clinical trials showed heterogeneity in intervention protocols (varying from application twice daily to after every void), milk types (colostrum versus mature milk), and sample sizes. Additionally, performance blinding of participants was largely impossible due to the nature of the intervention.

CONCLUSION

Topical human breast milk is an effective, biologically plausible, safe, and cost-neutral physiological intervention that accelerates episiotomy wound healing, reduces postpartum perineal pain, and protects against wound infection. Healthcare providers and postpartum nursing teams can consider recommending topical breast milk application as a supportive self-care measure for episiotomy care. Future research should focus on large-scale, multicenter double-blind trials using standardized delivery formulations to establish optimal application frequencies.

DECLARATIONS

- **Author Contributions:** Author and Co-Authors contributed equally to study conceptualization, literature search execution, independent screening, data extraction, risk-of-bias assessment, and manuscript drafting. Both authors reviewed and approved the final manuscript.
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- **Ethical Approval:** Not applicable -systematic review of previously published literature.
- **Patient Consent for Publication:** Not applicable (systematic review of previously published literature).
- **Data Availability Statement:** All data generated and analyzed during this systematic review are included within this article and its referenced primary sources.

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