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Preventive approaches to perineal trauma in vaginal delivery: Systematic Literature Review

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HIGHLIGHTS

• Pelvic physiotherapy strengthens pelvic muscles, aiding in childbirth preparation
• Vaginal dilator, perineal exercises and massage are indicated to preventing perineal trauma during vaginal delivery

ABBREVIATIONS

CG	Control group
Epi-No®	Epi-No® vaginal dilator
Elsevier	ScienceDirect database
GW	Gestational weeks
IG	Intervention group
LILACS	Latin American and Caribbean Health Sciences Literature
PICOC	Population, Intervention, Comparison, Outcome and Context
PEDro	Physiotherapy Evidence Database
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PubMed	National Institutes of Health
SLR	Systematic Literature Review

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BACKGROUND: The female pelvic floor plays a crucial role in supporting the pelvic organs during vaginal delivery and sexual practice. Often, the changes that occur during pregnancy do not prevent injuries during vaginal childbirth, contributing to the manifestation of dysfunctions such as urinary incontinence and prolapse. Studies highlight the importance of pelvic floor exercises as a preventative measure, with massage, specific exercises, and the use of vaginal dilator devices. However, there is a need to conduct additional research to validate the effectiveness of these approaches.
AIM: To conduct a Systematic Literature Review (SLR) to investigate the scientific evidence that addresses strategies aimed at preventing perineal injury in vaginal delivery.
METHOD: The search for studies was conducted on the PubMed, LILACS, Scopus, and Elsevier databases, following a PICOC protocol. The search strategy was developed in each database using MeSH terms and keywords, according to PRISMA guidelines.
RESULTS: Of the 96 titles initially found, 21 articles remained after evaluation according to the inclusion and exclusion criteria. Pelvic physiotherapy stands out in the preparation for childbirth by strengthening and increasing the resistance of the muscles in the pelvic region. There are physical and emotional benefits, resulting in more peaceful birth experiences. Vaginal dilator devices are effective in reducing episiotomies, perineal trauma, and lacerations.
CONCLUSION: The research points to the need for future studies to explore pregnant women's experiences in depth, including acceptability and comfort. The effectiveness of vaginal dilator devices, perineal exercises, and perineal massage in preventing perineal trauma during normal childbirth is highlighted.

KEYWORDS: Pelvic floor | Vaginal birth | Prevention | Perineal trauma

INTRODUCTION

The tissues of the pelvic floor consist of a complex combination of muscles, fascia, and ligaments, forming a net-like support within the abdominal-pelvic cavity and maintaining anatomical connections with the pelvic bones [1,2]. The pelvic floor serves a multifunctional role, primarily responsible for providing support to the pelvic organs – including the bladder, vagina, uterus, and rectum. In addition, this set of structures facilitates various physiological functions, such as sexual intercourse, vaginal childbirth, the storage of feces, and the processes of voluntary defecation and urination. Consequently, the support provided by the pelvic floor depends on the load the tissues receive and their biomechanical properties.

Maintaining the health and proper function of the pelvic floor is essential for a woman's overall well-being. During pregnancy, the female pelvic floor muscles undergo a series of adaptations in response to the pressure exerted by fetal growth and the increased weight in the abdominal region [3]. During this period, significant changes occur in the vaginal wall, including increased distensibility and reduced rigidity, along with a decrease in the maximum tension the tissues can support[4]. Pelvic floor disorders, such as urinary incontinence, pelvic organ prolapse, chronic pelvic pain, and sexual dysfunction, can arise due to weakness or damage to the muscles and connective tissues in the pelvic cavity [5,6]. Biomedical engineers collaborate closely with clinicians, physiotherapists, and biologists to understand the transformations inherent in pregnancy and vaginal delivery, as well as their impact on maternal and fetal health. Various imaging modalities, computational tools, and tissue engineering systems have been used to accurately quantify the evolutionary

dynamics of the reproductive organs and surrounding structures during pregnancy [7]. Although vaginal delivery is associated with a shorter recovery period and potential benefits for maternal health, such as a reduced incidence of surgical complications, cesarean section are often indicated in situations of gestational or obstetric risk to ensure the safety of both mother and newborn [8]. Vaginal delivery is one of the main etiological factors contributing to pelvic floor dysfunction, which can ultimately result in organ prolapse. Injuries to the pelvic floor tissues, which affect approximately one-third of women during vaginal delivery, can result in a decline in muscle strength, triggering dysfunctions such as urinary and fecal incontinence [9,10]. Women who undergo vaginal delivery are 5.5 times more likely to experience prolapse and 2.9 times more likely to develop urinary incontinence compared to those who undergo cesarean delivery [11].

One of the causes of dysfunction after vaginal delivery is episiotomy, a surgical procedure used when it is necessary to widen the vaginal and perineal opening to facilitate the passage of the newborn and prevent serious lacerations. Commonly performed in Brazil in the lower portion of the vaginal opening, in a diagonal direction towards the buttocks, the determination and appropriate timing of episiotomy lack consensus, and the procedure is reserved for situations of clinical complications during vaginal childbirth [12]. However, when performed inappropriately, episiotomy can be interpreted as a form of obstetric violence [13,14]. Episiotomy is correlated with an increased long-term risk of urinary and fecal incontinence, possibly due to the damage caused to the pelvic floor muscles [15]. In this context, obstetricians should avoid performing episiotomy whenever possible to preserve the integrity of the pelvic floor and reduce the likelihood of postpartum sexual dysfunction [16,17]. Strengthening the pelvic floor muscles plays a significant preventative role in reducing the onset of perineal dysfunctions, such as incontinence and organ prolapse, during pregnancy, childbirth, and the postpartum period [18]. Childbirth training exercises or pelvic floor strengthening routines consist of repetitive movements that promote relaxation of the local muscles and increase the elasticity of the pelvic musculature [19,20,21]. A specialist should guide these exercises, as many women cannot initially contract pelvic floor muscles or may contract adjacent muscles, creating an additional overload on the pelvic floor.

Vaginal dilators are devices designed to promote dilation and enhance understanding of the muscles in the female pelvic region[22]. The Epi-No® (Starnerg Medical, Tecsana, Munich, Germany) is a vaginal dilator created in 2001 to train pregnant women's pelvic muscles before childbirth and prevent postpartum trauma to the perineum. It consists of a silicone balloon which, when inserted into the vagina, can be inflated under controlled pressure, triggering a stretching effect on the local muscles [23]. In 2015, Brito et al. [24] conducted a systematic literature review (SLR) that analyzed five studies published between 2001 and 2014, involving 1,369 pregnant women using the Epi-No® device. The SRL aimed to assess the effectiveness of pelvic floor muscle exercises in preventing perineal trauma during childbirth. According to the findings, the use of the device did not significantly impact reducing episiotomy rates, perineal tears, or increasing the percentage of women with an intact perineum after childbirth. In 2020, Sobhgol et al. [25] conducted another SRL to examine the effects of pelvic floor exercises during pregnancy and their impact on both vaginal and cesarean delivery, including the analysis of 16 randomized clinical trials published between 1988 and 2019. The authors concluded that prenatal pelvic floor muscle exercises and perineal massage effectively reduced the duration of the second stage of labor (expulsive period) and the incidence of severe perineal tears. However, there is still a lack of studies corroborating the effectiveness of vaginal dilator devices, perineal exercises, and other techniques implemented during pregnancy to prevent episiotomies or perineal trauma during vaginal delivery. The present SLR was conducted to evaluate the benefits of pelvic floor muscle training during pregnancy using vaginal dilator devices and physiotherapy exercises. The analysis concluded with a comparison between these techniques, incorporating a biomechanical perspective, aiming to prevent perineal trauma and reduce the need for episiotomy during normal childbirth.

METHOD

The SLR was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline [26]. This review focuses on investigations into physiotherapeutic exercises aimed at reducing perineal injuries during vaginal childbirth in pregnant women.

Search protocol

A research protocol was established to identify, select, and evaluate the studies used in the SLR, utilizing the Parsif.al electronic platform, which allows for the consolidation of information extracted from studies in a single environment (Table 1). The research process was structured in five stages: defining the research problem, conducting a literature search for evidence, categorizing the studies, evaluating the results, and, finally, presenting the findings. The research protocol followed the PICOC criteria (Population, Intervention, Comparison, Outcome, and Context) (Table 2). The search for studies was conducted across several databases, including the National Institutes of Health (PubMed), Latin American and Caribbean Health Sciences Literature (LILACS), SciVerse Scopus, and ScienceDirect (Elsevier). The search strings were carefully crafted using specific keywords to accurately identify articles related to the topic (Table 3). The validation of the selected articles was performed using a descriptive approach, focusing on studies involving pregnant women who engaged in pelvic floor muscles exercises, either using vaginal dilator devices or physiotherapy sessions. The review examined the incidence of perineal trauma or episiotomies during normal childbirth in these women. A comparison between the studies was made based on the evaluation of the reduction in episiotomy and perineal trauma rates during childbirth, considering the quality criteria of the studies.

Table 1. Research protocol used to plan the RSL.

Identification of studies	
Keywords	Pelvic floor, pregnant women, vaginal birth, pelvic floor deformities, laceration prevention, vaginal dilator devices.
Search strings	Selection of keywords associated with Boolean operators to obtain results geared towards the research objective (Table 3).
Search base selection criteria	Search tool that allows you to look for studies in national and international literature in the field of medicine and biomedical engineering.
Search bases	PUBMED, LILACS, Scopus and Elsevier
Search strategy	Use pre-established search strings and combine the logical operator "AND" and "OR" with the keywords in each database.
Selection and evaluation of studies	
Inclusion criteria	a) Articles published between 2000 and 2023; b) Full text available in English; c) Studies on vaginal dilator devices to exercise pelvic floor muscle distensibility and prevent tears during childbirth, and studies on pelvic muscle injuries during childbirth due to muscle stiffness; e) Studies that fully or partially answer the research questions.
Exclusion criteria	a) Redundant articles by the same author; b) Duplicate articles, c) Short articles of less than 3 pages; d) Studies not published in full; e) Conference abstracts.
Data summaries and presentation of results	
Data extraction strategy	Completion of the "data extraction table" with the studies selected from the SLR, read in full, with bibliographic data, publication date, abstract, database and analysis (inclusion or exclusion).
Strategy for summarizing results	Use of the Parsif.al platform to analyze the studies found from the strings and evaluate them using a study quality analysis form.
Strategy for publishing the results	Searching for a reputable journal or forum of interest on the research topic.

Table 2. PICOC (Population, Intervention, Comparison, Outcome e Context) protocol used to conduct the research.

Population	Pregnant and parturient women (vaginal delivery)
Intervention	Use of exercises, manual procedures, or vaginal dilator devices for pelvic floor muscle distension
Comparison	No use of vaginal dilators
Outcome	Intact perineum and measurement of muscle distensibility
Context	Topics related to studies on devices used in perineal exercises during pregnancy

Table 3. Search strings used to create the RSL separated by research base.

PubMed	(“Training d e v i c e s ”) OR (“training delivery”) AND ("Pregnant women") AND (”prevention”) AND (“pelvic floor deformations") OR ("pelvic floor disorders") OR ("Perineal injury")
LILACS	(“Training devices”) AND ("Pregnant women") AND (” prevention”) AND (“pelvic floor deformations")
Scopus	(“training delivery”) AND ("Pregnant women") AND (” prevention”) AND (“pelvic floor deformations") OR ("pelvic floor disorders")
ScienceDirect Elsevier	(“training delivery”) AND (” prevention”) AND (“pelvic floor deformations")

RESULTS

Selection of studies

A total of 96 articles were initially identified using the Parsif.al platform, following the established search protocol. After analyzing and removing duplicate articles from the PubMed and Elsevier databases, 37 articles were excluded. In the next stage, which involved evaluating the titles and abstracts of the remaining 59 articles, based on the inclusion and exclusion criteria, an additional 38 studies were removed as they did not align with the objectives of the SLR. Among these, eleven articles were identified as integrative reviews and were also discarded. This process resulted in 21 articles that were deemed eligible for the SLR, having met the protocol criteria. These articles are presented in Figure 1, following the Preferred Reporting Items for Systematic Reviews and MetaAnalyses (PRISMA).

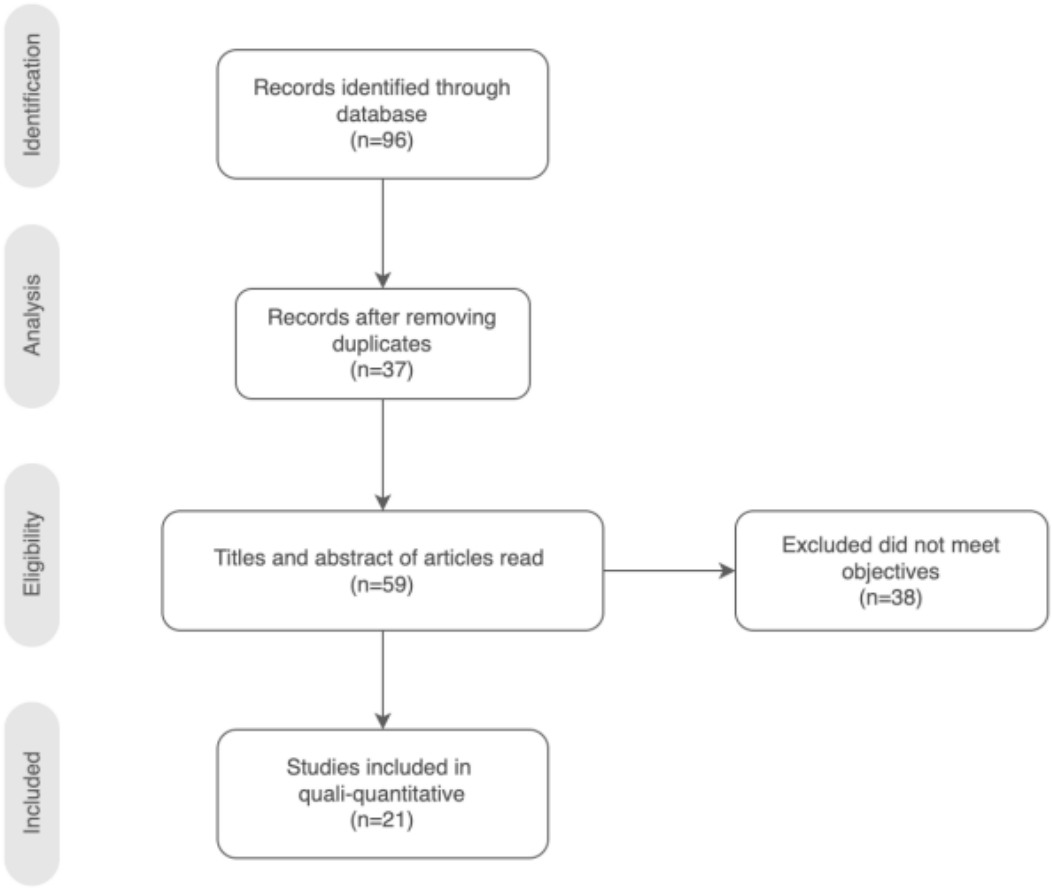

Figure 1. Flowchart of the study search and selection process based on the PRISMA 2020 guidelines.

The clinical trials included in this review were evaluated using the Physiotherapy Evidence Database (PEDdro) Scale, with the results presented in Table 4.

Table 4. PEDro Scale items and scores from clinical trials with at least two groups (n = 15).

Reference	Allocation randomized	Blind allocation	Comparability initial	Participants blind	Therapists blind	Assessors blind	<15% of sample loss	Intention-to treat analysis	Comparison between groups	Variability of result key	Total (0 - 10)
Stamp et al. (2001)[28]	Y	Y	Y	N	N	N	Y	N	Y	Y	6/10
Geranmayeh et al. (2012) [29]	Y	N	Y	N	N	N	N	N	Y	Y	4/10
Demirel and Golbasi (2015) [30]	Y	Y	Y	N	N	N	Y	N	Y	Y	5/10
Ugwu et al. (2018) [31]	Y	N	Y	N	N	Y	Y	Y	Y	Y	9/10
Dieb et al. (2020) [32]	Y	N	Y	N	N	N	Y	N	Y	N	4/10
Monguilhott et al. (2022) [33]	Y	N	Y	N	Y	Y	N	N	Y	Y	6/10
Leon- Larios et al. (2017) [27]	N	N	Y	N	Y	Y	Y	Y	Y	N	6/10
Feira-Ramírez et al. (2021) [34]	N	N	Y	N	N	N	Y	N	Y	Y	4/10
Kovacs et al. (2004) [23]	N	N	N	N	N	N	Y	N	Y	N	2/10
Ruckhäberle et al. (2009) [40]	Y	Y	Y	N	N	N	Y	Y	Y	Y	7/10
Shek et al. (2011) [8]	Y	Y	Y	N	N	N	Y	Y	Y	Y	7/10
Kamisan Atan et al. (2016) [42]	Y	Y	Y	Y	N	N	Y	Y	Y	Y	8/10
Orejuela et al. (2018) [11]	N	N	N	N	N	N	Y	Y	Y	N	3/10
De Freitas Et al. (2018) [43]	Y	Y	Y	N	N	Y	N	N	Y	Y	6/10
Cabral et al. (2022) [44]	Y	Y	Y	N	N	N	Y	Y	Y	Y	7/10

Y = Yes; N = No

Study characteristics

How effective is perineal massage in the birth process?

Several studies have examined the effects of perineal massage in preventing trauma during childbirth, specifically focused on the rate of episiotomy and perineal tears. The findings suggest that perineal massage is an effective method for preserving the perineum during labor. For instance, the study conducted by Leo-Larios et al. [27] demonstrated a significant decrease in frequency of episiotomy, better preservation of perineum integrity, and a substantial reduction in third- and fourth-degree tears among pregnant women who practiced perineal massage and exercises. Additionally, participants in the massage program reported a significant reduction in postpartum pain and a decreased need for analgesics. These results suggest that perineal massage should be considered a recommended practice to prevent pelvic floor injuries during childbirth, especially when started around the 32nd gestational weeks (GW) (Table 5).

Table 5. Description of the studies that presented the effect of perineal massage in preventing perineal injuries during vaginal delivery.

Reference	Participants	Intervention	Results
Stamp et al. (2001) [28]	IG - 670 pregnant women CG - 670 pregnant women	IG received a perineal massage during the second period of labor. CG did not receive a massage.	Massage during this period was not effective against perineal injuries, and there was no difference between the groups in terms of perineal integrity.
Geranmayeh et al. (2012) [29]	IG e CG constituted. 90 pregnant women primiparous (first birth), aged between 18 and 30 years old, and from 38 to 42 gestational weeks	IG received a perineal massage with Vaseline during the second stage of labor. CG received only routine delivery care.	IG had a shorter second stage of labor and a lower episiotomy rate, as well as an intact perineum in more cases than CG.
Demirel and Golbasi (2015) [30]	IG - 142 pregnant women CG - 142 pregnant women	IG received 10 min of perineal massage during the first period of labor. CG received only routine birth care.	In IG there were fewer episiotomies (31%) than in CG (69.7%). There was no difference in lacerations between the groups.
Ugwu et al. (2018) [31]	IG - 53 pregnant women CG - 55 pregnant women	IG received daily perineal massage for 10 min. CG Did not receive a perineal massage.	IG had higher rates of intact perineum than CG (50.9% vs. 29.1%). IG had fewer episiotomies than CG (37.7% vs. 58.2%).
Dieb et al. (2020) [32]	IG - 200 pregnant women CG - 200 pregnant women.	IG received massage and pelvic floor training exercises. CG only received prevention education.	IG deliveries had fewer complications such as perineal injuries and episiotomy than CG deliveries ($p<0.05$).
Monguilhott et al. (2022) [33]	IG - 78 pregnant women CG - 75 pregnant women	IG received a perineal massage. CG did not receive.	The women well accepted the massage. It did not protect against perineal injuries, but it did prevent perineal edema after childbirth.

IG – Intervention group; CG – control group

Are physiotherapy exercise methods for strengthening the pelvic floor effective in preventing perineal trauma?

In their investigation, Feria-Ramírez et al. [34] found that women who participated in Pilates exercises during pregnancy experienced a significant reduction in the incidence of perineal trauma during vaginal deliveries compared to those in the control group. These results suggest that Pilates training is effective in both preventing and treating pelvic floor injuries during pregnancy. Notably, only two studies focused on pelvic floor strengthening were included in this review (Table 6).

Table 6. Description of the studies included on pelvic floor strengthening for preventing perineal injuries during vaginal delivery.

Reference	Participants	Intervention	Results
Leon- Larios et al. (2017) [27]	IG - 254 pregnant women CG - 212 pregnant women	Perineal massage and pelvic floor strengthening exercises	The occurrence of episiotomy in the IG was 50.56% and in the CG 82.19% ($p<0.001$)
Feira-Ramírez et al. (2021) [34]	IG - 48 pregnant women CG - 24 pregnant women	IG received weeks of Pilates sessions in the intervention group and outcome measurement	IG had fewer perineal lesions (9.7%) than CG (65.9%). Prolapse symptoms decreased and colorectal-anal symptoms by 76.5 and 86.1%, urinary incontinence by 76.5 and 72.2% and sexual dysfunction symptoms by 55.9 and 69.4%.

IG – Intervention group; CG – control group

Does the use of vaginal dilating devices during pregnancy prevent perineal trauma or episiotomy?

The Epi-No® vaginal dilator is designed to stretch the local muscles and is used during pregnancy to facilitate distension of the pelvic floor muscles [23]. The use of this device has been associated with a reduction in perineal trauma and the need for episiotomy during childbirth. In a 2019 study conducted by Paschoal et al. [35], the reliability of the Epi-No® in measuring pelvic floor distensibility was investigated. The researchers introduced the Epi-No® to participants, inflating and removing the device, and measuring the maximum circumference achieved. Through interobserver analysis, they found good reliability across two evaluation days, with a ICC of 0.76 on the first day and 0.82 on the second. They concluded that the Epi-no® is a reliable tool for physiotherapists to measure pelvic floor distensibility during pregnancy. However, research by Nakamura et al. [36] raised concerns about the discomfort associated with using the device. After quantifying the pain experienced by women who used the device (on a scale of 0 to 10), it was observed that the discomfort was mild and tolerable. Additionally, women who trained with the device showed a reduction in the duration of the second stage of labor and a decreased need for analgesics, as reported by Hillebrenner et al. [37].

Furthermore, some authors have suggested that the Epi-no® may not be as effective in preventing certain types of perineal injuries, such as avulsion of the levator ani muscle, highlighting the need for further research to fully understand the devices'impact no preventing perineal injuries during childbirth [24]. In the context of labor, Orejuela et al. [11] demonstrate that the use of the Materna vaginal dilator was both safe and effective in preventing muscle injuries, with a significantly lower injury rate compared to the control group. The results indicate that the Epi-no® is reliable for assessing pelvic floor distension during pregnancy and that the other devices examined may also contribute to preventing perineal trauma. The studies involving the use of vaginal dilators in the prevention of perineal injuries are summarized in Table 7.

DISCUSSION

The SLR aimed to conduct a comparative analysis of various approaches, such as the use of vaginal dilator devices, physiotherapy exercises, and perineal massage, in the context of preventing perineal trauma during vaginal childbirth. The research provides a comprehensive perspective on the intervention strategies. The literature reviewed emphasizes the benefits of physiotherapy exercises, particularly in preparing the birth canal and enhancing the strength and endurance of the pelvic floor muscles. This approach, centered on pelvic physiotherapy, offers a comprehensive solution designed to improve muscle elasticity and promote greater awareness and active control of these muscles among pregnant women. Empowering women through pelvic physiotherapy not only prepares them physically, but also emotionally for the birthing process, leading to a healthier and more satisfying experience.

When analyzing the included studies, it was observed that the Epi-no® device is widely used. However, its effectiveness in reducing perineal trauma is not well established due to the limited number of studies. On the other hand, as highlighted by Orejuela et al. [11], the Materna device demonstrated a significantly lower rate of episiotomy (20% vs. 40%) and a reduced need for analgesia during childbirth. Therefore, there is a notable convergence in the findings regarding the effectiveness of these devices.

The primary purpose of vaginal dilator devices is to gradually expand the vaginal canal until it reaches its maximum diameter. This practice is intended to facilitate perineal distension during normal childbirth, similar to the principle behind perineal massage, which aims to stretch the vaginal muscles and the birth canal. However, data on the average diameter of perineal distension achieved during these exercises, whether with or without devices, has not yet been established. Each study selected for review contributed uniquely to understanding the role of these devices in preventing perineal trauma. For instance, Kovacs et al. [23] highlighted a higher rate of intact perineum in the study group, while Shek et al. [8] reported a significant reduction in the risk of avulsion and perineal trauma. These findings underscore the consistent effectiveness of these devices across different contexts.

The studies presented have significant practical implications for health professionals. Confirming the effectiveness of these devices could influence clinical practice, encouraging their integration as a standard component of prenatal care to reduce the incidence of episiotomies and perineal trauma. This review is notable for its comprehensive coverage of various strategies aimed at preventing perineal trauma. However, there are limitations to consider, including the heterogeneity of the studies, which varied in methods, populations, and interventions. While the studies shared common objectives, their evaluations were primarily based on outcomes such as episiotomy rate and third- and fourth-degree perineal tears. Additionally, the diversity of the populations studied, including both primiparous and multiparous women, adds to the complexity. This multiplicity of approaches does not diminish the study's validity but rather highlight the need for a comprehensive and contextualized analysis of the results.

Table 7. Studies included in the SRL involving the use of vaginal dilators in the prevention of perineal injuries during vaginal delivery.

Reference	Participants	Training	Results
Hillebrenner et al. (2001) [37]	IG - 50 pregnant women CG- 50 pregnant women	Epi-no® vaginal dilator	IG significantly reduced episiotomies compared to CG (49% vs. 82%) and 1st and 2nd perineal ruptures (4% vs. 2%) in IG. The average time of the second stage of labor was reduced in IG (29 min vs. 54 min). Reduced use of analgesics.
Kok et al. (2004) [38]	IG - 31 pregnant women 37 GW	Epi-no® vaginal dilator	IG with a lower rate of perineal trauma (90% vs. 96.6%). Significantly lower episiotomy rate (50% vs. 93.3%) and less perineal trauma in the IG.
Cohain et al. (2004) [39]	209 women after childbirth	Epi-no® vaginal dilator	86% of women in the IG had an episiotomy but reported a more positive experience during childbirth. Suggestion of possible effects on the elasticity of perineal tissues and the decision to avoid episiotomies.
Kovacs et al. (2004) [23]	IG - 48 pregnant women 37 GW	Epi-no® vaginal dilator	Higher rate of intact perineum in the IG (46% vs. 17%). Lower rate of episiotomy and perineal laceration in the IG.
Ruckhäberle et al. (2009) [40]	IG - 138 pregnant women CG - 138 pregnant women	Epi-no® vaginal dilator	A higher percentage of intact perineum and a trend towards less episiotomy in the IG.
Shek et al. (2011) [8]	IG - 100 pregnant women CG- 100 pregnant women	Epi-no® vaginal dilator	Reduced risk of avulsion and perineal trauma in the IG. 42% reduction in perineal trauma or microtraumas in the IG.
Nakamura et al. (2014) [36]	227 pregnant women	Epi-no® vaginal dilator	Mild discomfort was reported by Epi-No® users, but perineal extensibility was successful.
Pereira et al. (2015) [41]	IG - 13 pregnant women CG- 14 pregnant women	Epi-no® vaginal dilator IG compared to perineal massage (CG)	Epi-No® and perineal massage were equally effective in increasing perineal extensibility during pregnancy.
Kamisan Atan et al. (2016) [42]	IG - 330 pregnant women CG - 330 pregnant women	Epi-no® vaginal dilator	Use of Epi-no® may not be effective in preventing certain types of perineal trauma, such as avulsion of the elevator ani muscle.
Orejuela et al. (2018) [11]	61 pregnant women	Materna vaginal dilator	No related lesions in the IG. Average dilation of the vaginal canal: 7.4 cm in 27 min. Injury rate: 7% in IG vs 22% in CG.
De Freitas et al. (2018) [43]	Instrument-assisted stretching group - 27 women Perineal massage group - 14	Epi-no® vaginal dilator and perineal massage	Increased muscle extensibility in both groups. Perineal massage group: 17.6 cm to 20.2 cm. Instrument assistance group: 19.9 cm to 22.9 cm. No difference in muscle strength.
Paschoal et al. (2019) [35]	28 pregnant women, 29° - 37° GW	Epi-no® vaginal dilator	The average circumference tolerance was 20.4 cm, ranging from 15 cm to 26.5 cm..
Cabral et al. (2022) [44]	Groups with 24 pregnant women in each: Pn IStrLS PnM + IStrLS PnM + IStrSR	PnM received a perineal massage for 10 min IStrLS- used the Epi-no for 15 min PnM + IStrLS used to massage and Epi- no ® PnM + IStrSR received massage + Epi-no for 4 sessions of 30 s each	Women in the groups who underwent combined massage and Epi-no therapy had greater perineal extensibility than massage alone or Epi-no® alone.

IG - Intervention group; CG - Control group; GW – Gestational weeks; PnM perineal massage group; IStrLSinstrument- assisted stretching group with long protocol; PnM+ IStrLS- both techniques applied in previous groups; PnM + IStrSR- same techniques with a short, repeated protocol.

CONCLUSION

The SLR opens space for future research to explore the experiences of pregnant women more deeply, particularly in terms of acceptability and comfort. Additionally, longitudinal studies are needed to provide insights into the long-term effects of these interventions on women's health. The prevention of perineal trauma must take into account not only biological factors but also ethical considerations. Women have the right to make informed decisions about their bodies and childbirth, and they should be fully aware of the risks and the alternatives available to prevent perineal trauma. The SLR highlights the importance of communication and dissemination of knowledge regarding perineal trauma prevention, emphasizing the need for an open and informed dialog between health professionals and pregnant women.

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