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Review

Antenatal perineal massage - risk of perineal injuries, pain, urinary incontinence and dyspereunia - a systematic review

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ABSTRACT

Background: Natural childbirth is associated with the risk of damage to the perineum - a tears or a episiotomy. Adequate preparation of the woman for childbirth is essential to minimize the occurrence of perinatal injuries.
Aim: The aim of the review is to assess and analyze the impact of APM (antental perineal massage) on perinatal perineal injuries and the development of pelvic pain and other complications in postpartum women, such as dyspareunia, urinary (UI), gas (GI), and fecal incontinence (FI).
Methods: PubMed, Web of Science, Scopus and Embase were searched. Three authors independently searched databases and selected articles for inclusion and exclusion criteria. Next one author did Risk of Bias 2 and ROBINS 1 analyze.
Findings: Of 711 articles, 18 publications were left for the review. All 18 studies examined the risk of perineal injuries (tearing and episiotomy), 7 pain in postpartum period, 6 postpartum urinary, gas/fecal incontinence and 2 described dyspareunia. Most authors described APM from 34 weeks of pregnancy until delivery. There were different techniques and times for doing APM procedures.
Discussion: APM has many benefits for women during labor and the postpartum period (e.g. lower rate of perineal injuries and pain). However, it can be observed that individual publications differ from each other in the time of massage, the period and frequency of its performance, the form of obtaining instruction and control of patients. These components may affect the results obtained.
Conclusion: APM can protects the perineum from injuries during labor. It also reduces risk of fecal and gas incontinence in postpartum period.

Introduction

Intrapartum perineal tear, depending on the extent of the injury, has been divided into four degrees, with the 3rd and 4th including injury of anal sphincters complex and anorectal mucosa, respectively [1]. It is estimated that more than 85% of women have suffered perineal damage after vaginal childbirth, 3rd and 4th degree are 0.6–11% of them [2]. Risk factors for perineal injuries include: primogeniture [3], increasing maternal age [4], operative delivery - forceps, vacuum extraction [5], fetal macrosomia [6], prolonged duration of second stage of labor [7], position during labor [8].

Perinatal injuries can cause short- and long-term complications [9] such as: bleeding, pain, infections [10]. It may also result in problems with incontinence [11], pelvic organs prolapse [12], self-esteem disorders [13] and fear of pregnancy/delivery [14].

In order to reduce spontaneous injuries, were proposed surgical incisions of perineum [15]. The purpose of episiotomy is to enlarge the vaginal opening [16], protect tonus of perineum, prevent unwanted vaginal tears, facilitate delivery [17]. Nevertheless, a Cochrane analysis indicates that performing routine episiotomy to prevent severe trauma is not warranted and no benefit to mother or baby can be identified [18]. What is more there is an option to reduce rate of episiotomies by perineal massage during labor also [19]. Unfortunately, available data indicate the incidence of episiotomy can range from 100% (China) [20],

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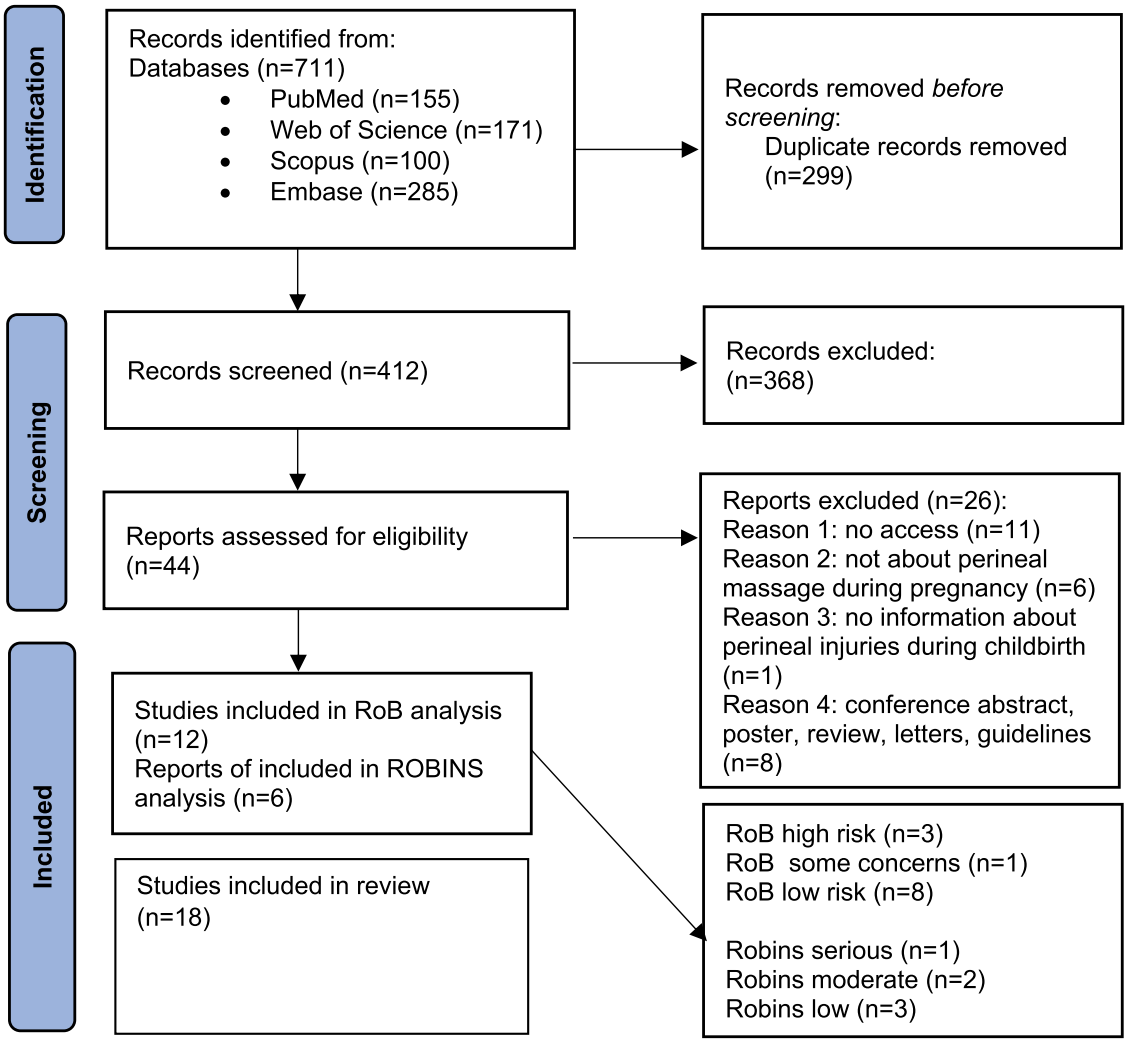

Fig. 1. PRISMA flow diagram of selection study.

94,5%−93,3 (Cambodia, Turkey) [21,22] to 4.9–8.4% (Denmark, Sweden, Iceland) [23].

The risk of injuries can be minimized by preparing pregnant woman for labor, e.g. learning to push, birthing positions, antepartum perineal massage (APM) [11,24]. APM relaxes the pelvic floor muscles (PFM) and improves blood flow. So as the APM can prepare tissues to labor, women who did it during pregnancy may have less perineal injuries, e.g. episiotomies [25]. It also reduces persistent perineal pain [25], leads to shortening second phase of labor, improve tissue regeneration and parameters of the newborn on APGAR scale [26]. If long-term consequences of delivery are considered, APM can minimize postpartum complications such as anal incontinence and can help in better wound healing also [26]. However, the prevention of perineal injuries can also include training of PFM during pregnancy [27] and instrumental techniques of stretching soft tissues, e.g. using the EPI-NO device [28]. In addition, research indicates that perineal flexibility can be increased during childbirth - the midwife performs an internal perineal massage or applies warm compresses [29]. Biana et al. [30] also recommend warm baths, electrostimulation, positions using balls, breathing techniques. They point out that appropriate actions preparing the body for childbirth should be implemented already during pregnancy, e.g. APM, pelvic floor muscle exercises (PFME), group classes for pregnant women [30].

In recent years, there has been a discussion on the necessity and consequences of perinatal episiotomy, which prompts reflection by many specialists, so we believe that it is necessary to update the state of knowledge in this area. The CNGOF guidelines established that perineal massage during pregnancy can minimize the rate of episiotomy, and postpartum perineal pain. This publication also underlined the need of encouraging all women who want to do the perineal massage in pregnancy [31]. The aim of the review is to assess and analyze the impact of APM on perinatal perineal injuries and the development of pelvic pain and other complications in postpartum women, such as dyspareunia. We also want to establish the effect of APM on UI, GI and FI.

Materials and methods

The review was conducted in the following databases: PubMed, Web of Science, Scopus and Embase. Only publications in English concerning APM in pregnancy were considered. Articles had to be published by June 2023, there was no lower limit for the publication date. All results were exported to an Excel file, duplicates were removed after searching all databases. The following keywords were used: „antenatal perineal massage OR perineal massage OR digital perineal massage OR perineum massage OR antepartum massage AND (muscle OR pelvic floor OR pelvic OR episiotomy OR tearing OR injury OR pregnancy OR quality of life OR trauma OR risk OR compliance OR pain OR postpartum OR VAS OR questionnaire OR urinary incontinence OR gas incontinence OR fecal incontinence OR dyspareunia OR sexual dysfunction)". The review was registered in PROSPERO database (protocol number CRD42023388949).

The inclusion criteria were: studies involving pregnant and/or postpartum women who performed APM and delivered vaginally, information about perineal tear/episiotomy, an assessment of pelvic pain/problems with incontinence/sexual dysfunctions. We qualified randomized, randomized, comparative and observational studies in English. The following elements were included in the exclusion criteria: not perform APM during pregnancy or despite APM, there was no information about perineal tears or episiotomy. Non-English articles, reviews, conference abstracts, letters to the editor, chapters in a book, dissertations were also rejected.

The inclusion criteria were based on the Participant-Intervention-Comparator-Outcomes-Study design (PICOS) format:

Participants: pregnant or postpartum women over 18 who gave birth vaginally. We excluded studies that did not involve pregnant or postpartum women, in which delivery was by cesarian section, or participants were under 18 years of age.

Intervention: APM performed independently/by a partner/specialist, APM combined with other procedures

Comparison: no intervention, comparison with another physiotherapeutic method, physical activity.

Outcomes: assessment of perinatal perineal injuries after APM - by medical personnel. Perineal pain - immediately after childbirth, during the postpartum period, VAS, VRS scale, verbal scale, e.g. no pain, medium, high, unbearable. Assessment of urinary/gas/fecal continence problems - proprietary questionnaire, standardized scales, e.g. KHQ, manometers, sonographic. Sexual dysfunctions - postpartum period, VAS scale, original questionnaires, ICIQ scales.

Study design: publications in English, no restrictions related to the type of study.

The review of the publication was conducted by three researchers. Searches were performed independently, then one researcher compared the results obtained and, if there were misunderstandings, consultations were carried out. After removing the duplicates, the first review of the articles was started. Publications were evaluated based on their titles and abstracts. Articles that met the inclusion criteria were left to be read in full. In the next step, using the Risk of Bias 2 tool available on the Cochrane platform, a Risk of Bias analysis was conducted. The answers obtained lead to the assessment of the publication: low risk of bias, some concerns, high risk of bias [32]. Non-randomized articles were evaluated using the ROBINS-I tool. The final results were classified as: low, moderate, serious, critical [33]. RoB-2 and ROBINS-I tool was performed by one researcher, however, doubts were consulted with other authors.

Results

The search identified 711 publications. After removing duplicates, 412 articles remained. 368 papers were rejected on the basis of titles and abstracts. After applying the inclusion and exclusion criteria, 18 publications were left for analysis. The reasons for rejection: lack of access to the full version ($n = 11$), publication did not concern APM during pregnancy ($n = 6$), lack of information on perineal injuries ($n = 1$), conference abstract, poster, review, recommendations ($n = 8$). 12 publications were finally qualified for the Risk of Bias analysis (Fig. A1), and 6 articles for the ROBINS-I analysis (Table A1). The exact characteristics of the analysis of publications in RoB-2 and ROBINS-I-tool can be found in Appendix A. We finally included all the analyzed papers in the review - PRISMA diagram (Fig. 1).

Antepartum perineal massage

APM is an element of physiotherapy that prepares a woman for natural childbirth [26]. In a study by Álvarez-González et al. [11] APM was performed from the 34th week of pregnancy until delivery. Pregnant women practiced it alone or with a physiotherapist. In the self-massage group, APM lasted about 10 min, at least twice a week. The group working with a physiotherapist received 6–10 sessions of 30 min each. Self-massage was divided into external (semicircular movement on both sides of the vaginal vestibule, pressing the central part of the perineum) and internal work. In the internal massage, sliding movements were performed on both sides of the vagina, especially pressing strongly tense points. The massage was completed by stretching the tissues with one finger placed in the vagina and the other outside. In the group working with a physiotherapist, APM looked similar, however, the number of movements performed was precisely defined: external work - semicircular drainage along the vestibule of the vagina, pumping - 5 repetitions in 3 series. In the internal massage, rubbing of the levator ani was performed (5 repetitions, 3 series) and compression of the pelvic diaphragm trigger points, ending with stretching of the places exposed to episiotomy. The EPI-NO device was then used. The work with the pregnant woman was completed by loosening the external tissues of the perineum - 3 sets of 5 repetitions [11]. Identical techniques were used in the second paper by this author [34]. Also Cabral et al. [35] suggested performing massage from the 34th week of pregnancy. The physiotherapist started APM with circular movements on the vulva and the middle of the perineum. Then, semicircular movements were performed on the inner walls of the vagina (4 times on each side, 30 s) and compressions (entering the vagina, down to the center of the perineum - 2 min). The work was finished by massaging the lower half of the vagina - the finger was moved along the shape of the letter "U". The whole lasted 10 min, sessions were held twice a week, a total of 8 sessions [35]. In turn, in a study by de Freitas et al. [28] women from the 33rd week of pregnancy participated in APM sessions with a physiotherapist twice a week for 4 weeks. In the first stage of APM, external tissues were developed - semicircular movements - the vulva, around the vagina, the tendon center of the perineum. In the second stage, the physiotherapist introduced his fingers into the patient's vagina to a depth of about 4 cm - movements along the side walls of the vagina and towards the anus - rubbing, pressure - four times on each side, pressure about 30 s. Compression of the vaginal entrance - 2 min. At the end, a massage of the vaginal walls was performed, moving in the shape of the letter "U" [28].

In other studies, APM was limited only to internal techniques. In the publication by Bodner-Adler et al. [36] massage was started 6 weeks before delivery. Pregnant women applied pressure with their fingers along the internal entrance to the vagina. The massage lasted 5–10 min, 3–4 times a week [36]. However, in the study by de la Cueva-Reguera et al. [37] APM was performed by pregnant women once a week for 20 min. The massage consisted of downward and sideways movements along the inner walls of the vagina [37]. In a study by Labrecque et al. [38–40] pregnant women performed APM independently from the 34th/35th week of pregnancy, for 5–10 min. Also, only internal techniques were used, which consisted of maintaining pressure for 2 min on each side of the vaginal entrance [38–40]. Also Kiremitli et al. [41] recommended practicing APM for pregnant women from the 34th week of pregnancy, every day, for 10 min. It consisted of the internal stretching of tissues in the shape of the letter 'U' (from 3 to 9 o'clock) [41]. Similarly, in the study by Mei-dan et al. [42] APM was performed by pregnant women from the 34th week, every day, for about 10 min. Nevertheless, the massage consisted of inserting the thumbs into the vagina (2–3 cm deep) and gently pressing down and moving both sides. Stretching was to be performed until a burning or tingling sensation was felt, then patients were to hold pressure for 1 min [42]. Similar techniques were used in the article by Monguilhott et al. [43]. APM was also practiced by women in the 34th week of pregnancy. It was recommended to massage the inside of the vagina for 5–10 min a day until delivery. During the massage, 1–2 fingers were inserted into the vagina to a depth of 3–4 cm, and compressions were made in the lower and lateral directions for 2 min each [43]. Also in the study by Takeuchi et al. [44] pregnant women (from 34 weeks) were asked to perform APM for 5–10 min, 3–4 times a week. In turn, Ugwu et al. [45] recommended practicing APM from 34/36 weeks of pregnancy until delivery. The massage was done by inserting two fingers into the vagina to a depth of 3–5 cm, the fingers were moved down and to the sides, until the feeling

Table 1
Characteristics of publications qualified for the review.

Author	Type of study	Participants	Intervention	Inclusion criteria	Exclusion criteria
Álvarez-González et al. (2021) Spain [11]	A Non Randomised Controlled Trial	90 women, Exp1: 30 Exp2: 30 Con: 30	In both groups - therapies from 34 wg to delivery Exp1: 6–10 APM sessions performed by a physiotherapist, each 30 min (weekly), EPI-NO practice after massage, external manual techniques Exp2: self-APM (10 min, min. 2x a week) Con: standard care	Age 18–40, 34 wg, term delivery (37 weeks or later), singleton pregnancy, cephalic position, no pregnancy complications, no other interventions, birth planning in Nuestra Señora de Sonsoles (Spain)	Contraindications to VD and APM, urogynecological dysfunctions before pregnancy, previous CS and perineal injuries, no consent to participate in the study, no attendance at therapeutic and assessment sessions
Álvarez-González et al. (2022) Spain [34]	Controlled Clinical Trial	81 women Exp1: 27 Exp2: 27 Con: 27	In both groups - therapies from 34 wg to delivery Exp1: 6–10 APM sessions with a physiotherapist (30 min, once a week), EPI-NO stretching, external manual techniques Exp2: self-APM (10 min, min. 2x a week) Con: standard care	Age 18–40, 34 wg, term delivery (37 weeks or later), singleton pregnancy, no pregnancy or delivery complications, no other interventions, consent to participate in the study, birth planning in Nuestra Señora de Sonsoles (Spain)	Contraindications to APM, pelvic and perineal dysfunctions before pregnancy, previous CS, UI before delivery (ICIQ-SF diagnosis)
Bodner-Adler et al. (2002) Austria [36]	Controlled Clinical Trial	531 women Exp: 121 Con: 410	Exp: APM - 6 weeks before the due date of delivery, 5–10 min, 3–4 times a week. Con: no intervention	Nulliparous women, VD planning, singleton pregnancy, cephalic fetal position	No information
Cabral et al. (2022) Brazil [35]	A Randomized Controlled Study	96 women Exp1: 24 Exp2: 24 Exp3: 24 Exp4: 24	Therapies performed twice a week from 34 wg, all techniques were performed by a physiotherapist Exp1: APM (10 mins) Exp2: Instrumental perineum stretch (15 min) Exp3: APM (10 min), Instrumental perineum stretch (15 min) Exp4: APM (10 min), instrumental stretching of the perineum (4 × 30 s each - 2 min total)	Women at 33 wg, 18 to 40 years of age, primiparas or women with previous pregnancies ending before 21 wg, ability to voluntarily contract PFM, force > 1 on the Oxford scale	No attendance at 2 consecutive therapies, intimate infection, termination of pregnancy before the last stage of the study
de Freitas et al. (2019) Brazil [28]	A Randomized Controlled Study	20 women Exp1: 10 Exp2: 10	In both groups, therapy: 2x a week, for 4 weeks (8 sessions), from 34 wg Exp1: APM performed by a physiotherapist, approx. 10 min Exp2: instrumental stretching of the perineum - EPI-NO, 15 min	Age 18–40, at 33 wg, nulliparous or termination of previous pregnancies before 21 wg, ability to activate MDM (MDM strength > 1 on the Oxford scale)	Absence from 2 consecutive sessions, urinary tract infections during pregnancy, termination of pregnancy before the last stage of the study
de la Cueva-Reguera et al. (2020) Spain [37]	A Randomized Controlled Study	49 women Exp1: 30 Exp2: 19	Exp1: APM (once a week, 20 min) Exp2: manual lymphatic drainage of the vagina (20 min), labia majora, suprapubic and inguinal areas (5 min), 1x a week Exp1 + Exp2: conventional therapy (from 25 wg to delivery, 5x a week, PFMT - 8–12x, 2 sets, tension 6–8 s; compression stockings 6 h a day)	Multiparous, from 18 years old, diagnosis of gestational edema in the 2nd trimester of pregnancy	Planned CS, pre-pregnancy genital prolapse, infection or disease, previous preterm or premature birth, neuromuscular disorder, epidural, instrumental delivery
Dieb et al. (2020) Egypt [46]	A Randomized Controlled Study	400 women Exp: 200 Con.: 200	Exp: educational program + APM (4 min, 3–4x a week or 10 min, 1x a week - from 34 weeks + PFMT (8–12x, 3 sets, tension max. 8 s, relaxation 8 s, holding the stream of urine during micturition) Con: Educational program (micturition, stimulants, diet, perineal control)	Pregnant women > 35 years of age, nulliparous or multiparous women	Problems with chronic constipation and cough, past or present UI/GI, pre-pregnancy prolapse, neuromuscular or connective tissue disorders, diseases, history of premature or premature birth, PROM, intimate infections, multiple pregnancy, previous CS, epidural anesthesia, instrumental delivery
Eogan et al. (2006) Ireland [48]	A Randomized Controlled Study	179 women Exp: 100 Con: 79	Exp: APM, from 34 weeks, 5 min, daily, massage performed alone or by a partner Con: no intervention	Nulliparous, 34 wg	No information
Kiremitli et al. (2022) Turkey [41]	A Randomized Controlled Study	173 women Exp1: 55 Exp2: 59 Con: 59	Exp1: APM, 10 min per day from 34 wg to birth Exp2: massage, when the cervical dilation was min. 4 cm - 4x, last time the cervix was fully dilated, approx. 10 min Con: no intervention	Nulliparas, age 20–35, delivery at 37–42 wg	No information

(*continued on next page*)

Table 1 (*continued*)

Author	Type of study	Participants	Intervention	Inclusion criteria	Exclusion criteria
Labrecque et al. (1999) Canada [38]	A Randomized Controlled Study	1034 pregnant women who have not given birth through VD before Exp1: 519 Con1: 515 493 women with previous VD Exp2: 246 Con2: 247	Exp1 + Exp2.: APM (daily, time 10 min, from 34/35 weeks to birth) Exp1 + Exp2 + Con1 + Con2: written and oral information on the prevention of perinatal perineal injuries	Pregnant women, patients of one of the five university hospitals in Canada, pregnant women who have previously given birth or not via VD, performed an USG or blood test in the 3rd trimester of pregnancy	High risk of CS, previous CS due to cephalopelvic disproportion, multiple pregnancy, placenta praevia, severe fetal growth restriction, non cephalic position, preeclampsia, non-participating physicians, genital herpes, other reasons including lack of French language skills or English, not understanding the instructions, already performing APM
Labrecque et al. (2000) Canada [39]	A Randomized Controlled Study	572 pregnant women who had not previously given birth via VD Exp1: 283 Con1: 289 377 women with previous VD delivery Exp2: 187 Con2: 190	Exp1 + Exp2: APM, 5–10 mins per day, from 34/35 by birth Exp1 + Exp2 + Con1 + Con2: written and oral information on the prevention of perinatal perineal injuries	A detailed description in the study by Labrecque et al. (1999) [43]	A detailed description in the study by Labrecque et al. (1999) [43]
Labrecque et al. (2001) Canada [40]	Observational Study	684 women rated the perineal massage during pregnancy (responders), 79 did not give such an assessment (non-responders)	APM from 34/35 wg until childbirth, 5–10 min a day	A detailed description in the study by Labrecque et al. (1999) [43]	A detailed description in the study by Labrecque et al. (1999) [43]
Leon-Larios et al. (2017) Spain [27]	A Randomized Controlled Study	466 women Exp: 254 Con: 212	Exp: leaflet with APM/PFE + instruction from a specialist. APM - by yourself/by your partner, from 32 pm until birth, 8 min, daily. PFE - 2x a day, from 32 g, 10–15 voluntary PFM contractions (5 s each) + relaxation, PFE with lift visualization, 10–15 min, 2x a day Con: no intervention	Single pregnancy, cephalic fetal position, planned delivery (without complications) in a public hospital, speaking and writing Spanish, consent to participate in the study	Probability of CS
Mei-dan et al. (2008) Israel [42]	Prospective Controlled Study	234 women Exp: 128 Con: 106	Exp: APM, 10 min, daily, from 34 weeks Con: no intervention Midwives, if necessary, could perform perineal massage during labor in both groups.	Primiparous women, 30–34 wg, planning VD in the indicated hospital	Previous perineal surgery, multiple pregnancies, use of other perineal massage oils, communication problems, CS delivery
Monguilhott et al. (2022) Brazil [43]	A Randomized Controlled Study	88 women Exp.: 44 Con.: 44	Exp.: APM (from 34 wg to the day of delivery, 5–10 min, daily) Con.: standard care	Single pregnancy with a physiological course, no age restrictions, pregnancy from $\leq$ 35 wg, decision VD, willingness to perform APM every day, speaking and writing Portuguese, understanding the instructions for APM	Fetal death, fetus weighing $\geq$ 4000 g or suspected cephalopelvic disproportion, CS planning, almond oil allergy, current APM
Shipman et al. (1997) United Kingdom [47]	A Randomized Controlled Study	681 women Exp.: 332 Con.: 349	Exp: APM (3–4 times a week, duration 4 min, from the 6th week before the planned birth) Exp + Con: PFE (4 exercises as instructed on the leaflet performed within an hour of waking up)	Nulliparous women, visit to the of midwife between 29 and 32 wg	Multiple pregnancy, planned CS, previously performed perineal massage, premature birth, medical conditions requiring hospitalization, allergy to nuts and products containing them, lack of knowledge of English in speech and writing
Takeuchi et al. (2016) Japan [44]	A Randomized Controlled Study	96 women Exp1: 47 Exp2: 49	In both groups: APM from 34 weeks, 5–10 min a day, 3–4 times a week Exp1: information about the massage technique, reminding about its performance, advantages, communication possibilities, were available on the smartphone website Exp2: information leaflet with instructions for perineal massage	30–33 wg, physiological pregnancy, primiparas, speaking and writing Japanese language, possession of a smartphone	No information
Ugwu et al. (2018) Nigeria [45]	A Randomized Controlled Study	108 primiparas Exp.: 53 Con.: 55	Exp.: APM (10 min, daily, from 34/36 weeks to delivery) Con.: no intervention	Primiparas at 34–36 wg, no pregnancy complications, fetal cephalic position, no uterine contractions	Uncertainty of the due date, contraindications to VD, diseases during pregnancy, genital herpes, thrush, PROM

APM, antepartum perineal massage; Con, control group; CS, cesarean section; Exp, experimental group; FI, fecal incontinence; GI, gas incontinence; h, hour; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; min, minutes; PFE, pelvic floor exercises; PFM, pelvic floor muscles; PFTM, pelvic floor muscle training; PROM, premature rupture of membranes; UI, urinary incontinence; USG, ultrasound examination; VD, vaginal delivery; wg, weeks gestation.

of burning, tingling, stinging. Then, at a given point, the pregnant woman applied pressure until the tissues became numb. It was performed daily for 10 min [45]. Dieb et al. [46] suggested starting APM 4 weeks before delivery. The massage focused only on internal techniques - movements up, down and sideways. A single session lasted 5 min, and pregnant women were encouraged to have 3 sessions a week [46].

In turn, Shipman et al. [47] combined APM with daily PFME. 6 weeks before delivery, pregnant women were to start practicing APM - 3–4 times a week for 4 min [47]. APM and PFME were also combined in a study by Leon-Larios et al. [27]. Women from the 32nd week of pregnancy were recommended to perform APM - fingers were inserted into the vagina to a depth of 3–4 cm, then pressure was applied to the vaginal tissues - pressure down and to the side. PFME were performed twice a day, with a combination of tensing and relaxing phases [27]. In Eogan et al. [48] massage was performed similarly to the articles [38, 47], its duration was 5 min daily, from the 34th week of pregnancy. The massage could also be performed by the woman's partner [48]. A brief description of the selected publications is shown in Table 1.

Perineal injuries

Labrecque et al. [38] compared primiparas and multiparous women. Significant differences in the intact perineum were observed only in primiparous women with APM compared to no APM (24.3% vs. 15.1%, $p = 0.01$). The lack of injuries correlated with the number of massages performed. The protective character of APM was also observed in multiparous women, but the obtained results were not significant (34.9% vs. 32.4%, $p = 0.92$) [38]. However, similar results were not obtained among primiparous women in the study by Mei-dan et al. [42]. Also, the study by Shipman et al. [47] showed no significant effect on the reduction of the percentage of perineal tears among primiparous women. Nevertheless, women who were over the age of 30 years and practicing APM were more likely to have a intact perineum during labor than those with no massage (30.7% vs. 18.6%, $p = 0.019$) [47].

Álvarez-González et al. [11] noted that APM reduces the risk of perinatal injuries, however, it is more effective to combine with EPI-NO stretching and manual techniques. This combination allowed to reduce the risk of mild tear by 4 times, moderate and medium by 2.94 times. Similar techniques were also used in the study by Cabral et al. [35]. They showed that APM combined with short stretching resulted in the highest percentage of non-perineal injuries (PMa: 9.09%, IStrLS: 22.22%, PM+IStrLS: 20%, PM+IStrSR 33.33%) [35]. In turn, in the study by de Freitas et al. [28] women subjected to APM more often experienced perineal injuries, mainly first degree tear (71.4% vs. 40.0%), however, no significance was obtained [28]. De la Cueva-Reguera et al. [37] showed that APM is more effective in reducing perineal injuries than manual lymphatic drainage, but the results were not statistically significant (51.8%% vs. 58.1%). Both procedures combined with PFME [39].In a study by Dieb et al. [46] reported that the combination of APM with PFME significantly reduces the incidence of perineal injuries compared to no such procedures during pregnancy (13.5% vs. 21.5%, $p = 0.034$). Nevertheless, it should be noted that the PFME proposal was to stop the urinary stream during voiding [46], which is an incorrect exercise regimen [49]. Also in the study by Leon-Larios et al. [27] reported that APM and PFME resulted in a lower rate of perineal injuries compared to women in the control group (17.61% vs. 6.85%, $p < 0.003$). In the intervention group, significantly fewer third and fourth degree tears were observed (5.18% vs. 13.12%, $p < 0.001$ and 0.52% vs. 2.5%, $p < 0.001$) [27]. By contrast, Kiremitli et al. [41] observed that APM, compared to massage during labor or no intervention, is the most effective in protecting the perineum from tearing (14.4%; 5.1%, 3.4%, respectively).

In turn, in the study by Bodner-Adler et al. [36] it was observed that APM resulted in a lower risk of perineal tears, however, these differences were not statistically significant. The lack of a significant effect of APM compared to no intervention for perineal tears was also noted in the

Table 2
Perineal massage during pregnancy and the risk of perineal injuries: tearing and episiotomy.

Refs.	No. of perineal tears [n/%]	No. of episiotomy [n/%]
Álvarez-González et al. (2021) Spain [11]	Mild: Exp1.: 7 (23.3); Exp2: 7 (23.3); Con: 8 (26.7) Moderate/severe: Exp1: 1 (3.3); Exp2: 2 (6.7); Con: 4 (13.3)	Exp1: 3 (10.0); Exp2: 14 (46.7); Con: 20 (66.7)
Álvarez-González et al. (2022) Spain [34]	Mild: Exp1.: 4 (14.8); Exp2: 5 (18.5); Con: 8 (29.6) Moderate/severe: Exp1: 1 (3.7); Exp2: 2 (7.4); Con: 4 (14.8)	Exp1: 2 (7.4); Exp2: 14 (51.9); Con: 19 (70.4)
Bodner-Adler et al. (2002) Austria [36]	1st degree: Exp: 17 (14.1); Con: 64 (15.6) 2nd degree: Exp: 21 (17.4); Con: 70 (17.1) 3rd degree: Exp: 3 (2.5); Con: 22 (5.4)	Midline episiotomy: Exp: 20 (16.5); Con: 66 (16.1) Mediolateral episiotomy: Exp: 17 (14.1); Con: 45 (10.9)
Cabral et al. (2022) Brazil [35]	1st degree: Exp1: 7 (63.63); Exp2: 4 (44.44); Exp3: 1 (10.0); Exp4: 3 (12.0) 2nd degree: Exp1: 3 (27.27); Exp2: 3 (33.3); Exp3: 7 (70.0); Exp4: 5 (41.66)	No information
de Freitas et al. (2019) Brazil [28]	1st degree: Exp1: 6 (71.4); Exp2: 2 (40.0) 2nd degree: Exp1: 1 (28.6); Exp2: 1 (20.0)	No information
de la Cueva-Reguera et al. (2020) Spain [37]	Exp1: 14 (51.8); Exp2: 11 (58.1)	Exp1: 0 (0.0); Exp2: 3 (17.6)
Dieb et al. (2020) Egypt [46]	1st degree: Exp: 8 (4.0); Con: 4 (2.0) 2nd degree: Exp: 12 (6.0); Con: 19 (9.5) 3rd degree: Exp: 7 (3.5); Con: 15 (7.5) 4th degree: Exp: 0 (0.0); Con: 5 (1.3)	Exp: 59 (29.5); Con: 77 (38.5)
Eogan et al. (2006) Ireland [48]	1st degree: Exp: 12 (12.0); Con: 8 (10.1) 2nd degree: Exp: 13 (13.0); Con: 12 (15.2)	Exp: 38 (38.0); Con: 28 (35.4) Episiotomy + 3rd degree of perieal tear: Exp: 4 (4.0); Con: 1 (1.3)
Kiremitli et al. (2022) Turkey [41]	1st degree: Exp1: 5 (9.1); Exp2: 3 (5.1); Con: 1 (1.7) 2nd degree: Exp1: 1 (1.8); Exp2: 5 (8.5); Con: 3 (5.1) 3rd degree: Exp1: 1 (1.8); Exp2: 3 (5.1); Con: 7 (11.9)	Exp1: 41 (74.5); Exp2: 48 (81.4); Con: 54 (91.5)
Labrecque et al. (1999) Canada [38]	1st degree: Exp1: 60 (14.6); Con1: 77 (18.5); Exp2: 54 (23.0); Con2: 54 (22.4) 2nd degree: Exp1: 97 (23.6); Con1: 96 (23.0); Exp2: 63 (26.8); Con2: 66 (27.4) 3rd/4th degree: Exp1: 10 (2.4); Con1: 12 (2.9); Exp2: 1 (0.4); Con2: 1 (0.8)	Exp1: 111 (27.0); Con1: 129 (30.9); Exp2: 35 (14.9); Con2: 41 (17.0) 3rd/4th degree + episiotomy: Exp1: 33 (8.0); Con1: 40 (9.6); Exp2: 0 (0.0); Con2: 1 (0.8)
Labrecque et al. (2000) Canada [39]	1st degree: Exp1: 14.0; Con1: 18.4; Exp2: 23.8; Con2: 22.6 2nd degree: Exp1: 27.5; Con1: 25.9; Exp2: 26.5; Con2: 28.5 3rd/4th degree: Exp1: 8.7; Con1: 12.6; Exp2: 0.0; Con2: 0.5	Exp1: 25.3; Con1: 28.0; Exp2: 14.9; Con2: 16.7
Labrecque et al. (2001) Canada [40]	1st degree: R: 105 (17.9); NR: 9 (15.0) 2nd degree: R: 144 (24.6); NR: 16 (26.7) 3/4th degree: R: 41 (7.0); NR: 3 (5.0)	R: 135 (23.0); NR: 11 (18.3)

(*continued on next page*)

Table 2 (*continued*)

Refs.	No. of perineal tears [n/%]	No. of episiotomy [n/%]
Leon-Larios et al. (2017) Spain [27]	Severe perineal trauma: Exp: 11 (5.7); Con: 25 (15.62)	Exp: 97 (50.25); Con: 131 (81.8)
Mei-dan et al. (2008) Israel [42]	1st degree: Exp: 44 (73.3); Con: 45 (78.9) 2nd degree: Exp: 16 (26.7); Con: 11 (19.3) 3rd/4th degree: Exp: 0 (0.0); Con: 1 (1.8)	Exp: 23 (20.0); Con: 20 (18.9)
Monguilhott et al. (2022) Brazil [43]	1st degree without suture: Exp: 6 (14.0); Con: 6 (13.6) 1st degree with sututre: Exp: 9 (20.9); Con: 10 (22.7) 2nd degree: Exp: 12 (27.9); Con: 20 (45.5)	Exp: 1 (2.3); Con: 1 (2.3)
Shipman et al. (1997) United Kingdom [47]	Intact perineum, 1st degree of perineal tears, nonperineal lacerations: Exp: 87 (24.9); Con: 103 (31.0) 2nd/3rd degree of perineal tears + episiotomy: Exp: 263 (75.1); Con: 229 (69.0)	
Takeuchi et al. (2016) Japan [44]	1st degree: Exp1: 3 (7.3); Exp2: 9 (20.9) 2nd degree: Exp1: 10 (24.4); Exp2: 9 (20.9) 3rd degree: Exp1: 0 (0.0); Exp2: 0 (0.0)	Exp1: 24 (58.5); Exp2: 23 (53.5)
Ugwu et al. (2018) Nigeria [45]	1st degree: Exp: 6 (11.3); Con: 5 (9.1) 2nd degree: Exp: 0 (0.0); Con: 2 (3.6)	Exp: 20 (37.7); Con: 32 (58.2)

Con, control group; Exp, experimental group.

study by Eogan et al. [48]. Similarly, Monguilhott et al. [43] reported that APM resulted in perineal integrity during labor compared to controls (34.9% vs. 15.9%), but the differences were not significant. Results are presented in Table 2.

Pain in the postpartum period

In a study by Labrecque et al. [39] no pain was reported more often by multiparous than by primiparous women (93.6% vs. 83.2%), despite the fact that the same APM protocol was used in both groups. In turn, Eogan et al. [48] observed that no intervention resulted in singnificant increase severe pain (4.0% vs. 15.2%), while women who received APM reported mostly mild pain (50.0% vs. 34.2%). Monguilhott et al. [43] shown that APM differentiates level of pain immediately after childbirth (3.0 ± 2.9 vs. 4.1 ± 2.9) and on the 45th day of the postpartum period (1.4 ± 2.1 vs. 1.7 ± 2.5). In the 3rd month there were no differences in the level of symptoms. However, no significant differences were noted [43]. In turn, De la Cueva-Reguera et al. [37] showed that women who underwent perineal drainage procedures experienced less pain than the APM group (week 30 $p = 0.037$; week 36 $p = 0.000$; postpartum $p = 0.014$). APM and drainage was combined with PFME [37]. On the other hand, in the study by Dieb et al. [46], APM in combination with PFME and education, compared to education alone, results in significantly less pain in the perineum immediately after childbirth and almost 2 weeks later ($p = 0.001$ and $p = 0.013$, respectively). The effect of massage and PFME on pain reduction was also confirmed in a study by Leon-Larios et al. [27]. In APM group, pain was reported by 24.35% of patients, in the control group by 36.25% ($p < 0.001$) [27]. Also, Álvarez-González et al. [11] reported that self-massage and a combination of APM with mechanical stretching and manual therapy reduce pain in the puerperium. Detailed characteristics are presented in Table 3.

Table 3
Antenatal perineal massage for postpartum pain in women.

Reference	Assessment	Time of assessment	Result
Álvarez-González et al. (2021) Spain [11]	VAS	5/6 weeks postpartum	Exp1: 1.0 ± 1.5 Exp2: 2.3 ± 2.5 Con: 2.8 ± 3.0 *
de la Cueva-Reguera et al. (2020) Spain [37]	VAS (0-no pain, 10-unbearable pain)	At the beginning of the study, 30th, 36tth week of pregnancy and at the end of the postpartum period	Baseline: Exp1: 4.0 ± 2.42; Exp2: 5.0 ± 2.53 At 30 week: Exp1: 4.36 ± 2.37; Exp2: 2.84 ± 1.53* At 36 week: Exp1: 4.96 ± 2.00, Exp2: 2.58 ± 2.19* End of puerperium: Exp1: 2.00 ± 1.63; Exp2: 0.72 ± 1.01*
Dieb et al. (2020) Egypt [46]	Verbal rating score: no pain, mild, medium, severe	Assessment of pain in the first 24 h after delivery and on the 15th day of the postpartum period	24 h after delivery*: Mild: Exp: 179 (89.5); Con: 153 (76.5) Moderate: Exp: 10 (5.0); Con: 15 (7.5) Severe: Exp: 11 (5.5); Con: 32 (16.0) 15th days of puerperium*: Mild: Exp: 15 (7.5); Con: 18 (9.0) Moderate: Exp: 0 (0.0); Con: 5 (2.5) Severe: Exp: 0 (0.0); Con: 5 (2.5)
Eogan et al. (2006) Ireland [48]	Scale: no pain, mild, severe, severe, unbearable	3rd day of postpartum	No pain: Exp: 28 (28.0); Con: 24 (30.4) Mild: Exp: 50 (50.0); Con: 27 (34.2) Significant: Exp: 18 (18.0); Con: 16 (20.3) Severe: Exp: 4 (4.0); Con: (12 (15.2) *
Labrecque et al. (2000) Canada [39]	Scale: none, mild, moderate/ severe	3rd trimester, 3rd month postpartum	No pain: Exp1: 83.2; Con1: 78.3; Exp2: 93.6; Con2: 85.8 Mild: Exp1: 15.0; Con1: 19.6; Exp2: 5.9; Con2: 12.6 Moderate/severe: Exp1: 1.8; Con1: 2.1; Exp2: 0.5; Con2: 1.6 *only for women with a previous vaginal delivery (Exp2, Con2)
Leon-Larios et al. (2017) Spain [27]	Original questionnaire	48 h after delivery	Pain was felt by 47 women (24.35%) from the Exp group and 58 (36.25%) from the Con group*
Monguilhott et al. (2022) Brazil [43]	VAS (0-no pain, 10-unbearable pain)	Evaluation of perineal pain after childbirth, on the 45th and 90th day of the postpartum period	PP after delivery: Exp: 3.0 ± 2.9; Con: 4.1 ± 2.9 PP after 45 days: Exp: 1.4 ± 2.1; Con: 1.7 ± 2.5 PP after 90 days: Exp: 0.3 ± 1.0; Con: 0.3 ± 0.9

* statistical significant <0.05; Con, control group; Exp, experimental group; h, hours; PP, perineal pain; VAS, Visual Analogue Scale.

Table 4
Antepartum perineal massage and urinary, gas or fecal incontinence in postpartum women.

Refs.	Questionnaire/ device	Problem	Evaluation	Parameters of UI, GI or FI	Outcome
Álvarez-González et al. (2022) Spain [34]	KHQ, ICIQ-SF	UI	5/6 weeks postpartum	UI severity [n/%]: Lack: Exp1: 23/85.2; Exp2: 15/55.6; Con: 18/66.7 Low: Exp1: 4/14.8; Exp2: 12/44.8; Con: 8/29.6 Medium: Exp1: 0; Exp2: 0; Con: 1/3.7	No form of perineal massage had a significant effect on the frequency of UI. The severity of UI depended on the BMI of the woman and the weight of the child.
de la Cueva-Reguera et al. (2020) Spain [37]	KHQ	UI	1st and 5th meeting with therapists	KHQ UI impact: Exp1: 11.11 ± 18.96; Exp2: 10.71 ± 21.29	In both groups, a slight effect of UI on quality of life was demonstrated.
Eogan et al. (2006) Ireland [48]	Manometry, sonographic	FI, the activity of the sphincter mechanism	3rd month of postpartum	Median continence score: Exp: 0; Con: 0 Sonographic defect in external anal sphincter [n/%]: Exp: 25/37.3; Con: 18/38.3	No problems with stool continence were noted in the patients. External anal sphincter injury was diagnosed among 25 (37.3%) women performing perineal massage and 18 (38.3%) from the control group.
Labrecque et al. (2000) Canada [39]	Original questionnaire	UI, FI, GI	3rd trimester, 3rd month postpartum	Lack of UI [%]: ExpP: 73.5; ConP: 71.3; ExpW: 66.3; ConW: 61.1 Lack of GI [%]: ExpP: 73.4; ConP: 76.5; ExpW: 73.3; ConW: 74.2 Lack of FI [%]: ExpP: 96.8; ConP: 96.9; ExpW: 98.4; ConW: 95.8	There was no effect of perineal massage on UI, FI or GI dysfunctions in any of the postpartum groups.
Monguilhott et al. (2022) Brazil [43]	Original questionnaire	UI, FI, GI	Before the study, the 45th and 90th day of the puerperium	45 days postpartum [n/%]: UI: Exp: 13/30.2; Con: 17/40.5 GI: Exp: 9/20.9; Con: 20/47.6* FI: Exp: 4/9.3; Con: 3/7.1 90 days postpartum [n/%]: UI: Exp: 10/23.8; Con: 8/19.0 GI: Exp: 9/21.4; Con: 15/37.5 FI: Exp: 0; Con: 2/4.8	Perineal massage significantly reduced the percentage of women suffering from GI at 45 postpartum days. Similar relationships were not demonstrated in the later period of the study and for UI.
Ugwu et al. (2018) Nigeria [45]	ICIQ-UI-SF	UI, FI, GI	6th week, 3rd month postpartum	3rd month postpartum [n/%]: UI: Exp: 3/6.8; Con: 4/8.0 GI: Exp: 4/8.3; Con: 13/26.0* FI: Exp: 2/4.2; Con: 8/16.0	Women who performed perineal massage during pregnancy reported significantly less problems with FI and GI compared to no intervention. Similar differences were not shown in the UI.

* statistical significant <0.05; ICIQ-SF - International Consultation on Incontinence Questionnaire-Short Form.

Problems with continence during postpartum period

In a study by Álvarez-González et al. [34] patients received 3 types of therapy: standard care, self-APM and APM performed by a physiotherapist combined with EPI-NO stretching. The analysis conducted in the 5th/6th week of the postpartum period showed that UI was most common among women practicing APM at home (Exp1: 14.8%; Exp2: 44.4%; Con: 33.33%). In contrast, Labrecque et al. [39] reported that APM from the 34th week of pregnancy resulted in a slightly lower incidence of UI problems compared to no intervention. Furthermore, multiparous women were more likely to experience UI than primiparous women (Exp2: 30.0%, Con2: 35.9% vs. Exp1: 24.0%, Con1: 26.3%). On the other hand, regardless of the number of births, the lack of GI was more frequently among participants from the control groups (Exp1: 73.4%, Con1: 76.5% vs. Exp2: 73.3%, Con2: 74.2%). Problems with FI occurred only in primiparous women [39]. A similar study was also conducted by Monguilhott et al. [43]. A 5–10 min APM, from 34 weeks of gestation, resulted in a lower percentage of women reporting UI (Exp: 30.2% vs. Con: 40.5%). Massage significantly reduced only the risk of GI - Exp: 20.9% vs. Con: 47.6% at 45th day of postpartum. By the 90th day of the postpartum, no woman practicing APM suffered from FI, in the controls this problem was present in 2 patients (4.8%) [43]. The impact of APM on the development of GI after childbirth was also confirmed in the studies of Ugwu et al. [45]. A 10 min APM from 34 to 36 weeks of gestation significantly reduced the proportion of women with GI compared to no intervention (Exp: 8.3% vs. Con: 26.0%). APM also had a positive effect on the incidence of UI (Exp: 6.3% vs. Con: 8.0%) and FI (Exp: 4.2% vs. Con: 16.0%) in women in the 3rd month of childbirth. In turn, in the observational study Eogan et al. [48] after 3 months postpartum, no problems with FI were reported. However, the ultrasound examination showed that 37.3% patients who performing APM had an external anal sphincter injury, in the control group this percentage was slightly higher (38.3%) [48]. Detailed characteristics are presented in Table 4.

Sexual dysfunctions in the postpartum period

The percentage of women suffering from dyspareunia may remain at a higher level than before pregnancy even a year after labor. Compared to women with no trauma/1st degree tear, 2nd/3rd/4th degree tears had a higher risk of developing dyspareunia [50]. Perineal injuries also negatively affects the level of arousal, pain and satisfaction during intercourse in women in the 6th month of the puerperium [51]. Unfortunately, despite this, most of the papers qualified for this review did not provide any data between APM and sexual dysfunctions.

In a study by Monguilhott et al. [43] it has been shown that a daily,

Table 5
Effect of antenatal perineal massage on dyspareunia.

Refs.	Questionnaire	Evaluation	SD	Outcome
Labrecque et al. (2000) Canada [39]	Original questionnaire	3rd trimester, 3rd month postpartum	3rd month of postpartum: Mild SD [%]: ExpP: 32.9; ConP: 34.8; ExpW: 23.5; ConW: 27.3 Moderate to severe SD [%]: ExpP: 29.2; ConP: 29.3; ExpW: 9.0; ConW: 8.1	Among primiparas, dyspareunia was not reported by 37.9% and 36.0% of women (Exp1 and Con). In turn, among multiparous women these percentages were higher (Exp2: 67.5, Con2: 64.5). However, there was no effect of massage on the level of sexual complaints.
Monguilhott et al. (2022) Brazil [43]	Original questionnaire, VAS	45th and 90th day of the postpartum period	After 45 days of confinement: Exp: 2.3 ± 2.2; Con: 3.1 ± 2.8 After 90 days of confinement: Exp: 1.3 ± 1.8; Con: 2.0 ± 2.5	Women who performed perineal massage returned to sexual activity earlier (34.9 vs. 36.1 days) and experienced less pain, but the differences were not significant

*statistical significant <0.05; SD, sexual dysfunction; VAS, Visual Analogue Scale.

5–10 min APM from the 34th week can eliminate problems of sexual life in the postpartum period. Women who received APM returned to sexual activity more quickly than patients receiving standard medical care (34.9 vs. 36.1 days). In addition, APM also reduced pain during intercourse, however, the results were not statistically significant: 45th day 2.3 ± 2.2 vs. 3.1 ± 2.8, 90th day 1.3 ± 1.8 vs. 2.0 ± 2.5 [43]. In turn, in the study by Labrecque et al. [39] the problem of sexual activity was analyzed in women in the 3rd month of the postpartum period. Sexual activity was then resumed by 88.0% of primiparous women and 90.9% of multiparous women who performed APM. Compared to the previous publication [43] massage was practiced for 10 min a day from 34/35 weeks of pregnancy. Unfortunately, about 1/3 of primiparas practicing APM had mild or moderate/severe dyspareunia. In the group of multiparous women, the percentage was lower (23.5% and 9.0%, respectively). The analyzed works [39,43] indicate that 5–10 min of daily APM may have a positive effect on the sexual life of postpartum women, however, results were not statistically significant (Table 5).

Discussion

The aim of the review is to assess and analyze the impact of APM on perinatal perineal injuries and the development of pelvic pain and other complications in postpartum women, such as dyspareunia and problems with incontinence (urinary, gas or fecal). Nearly 85% of women may experience perineal injuries during childbirth [2].

In our review, most authors recommended massage from 34 weeks of pregnancy until delivery [11,26,34,35,41–44,46,48]. Pregnant women also practiced APM from 6 weeks before delivery [36,47], 34/35 [38–40] and 34–36 weeks of pregnancy [45]. However, Leon-Larios et al. [27] showed that APM from the 32nd week of pregnancy is also effective and safe in protecting the perineum. Nevertheless, the studies differed in the technique of performing APM. In publications [11,28,34,35], APM was started with the preparation of the external tissues of the perineum, and then the internal walls of the vagina. In turn, in studies [27,36,37,46,41,38,47,45] pregnant women performed/received only internal vaginal massage.

Álvarez-González et al. [11] reported that patients in whom APM was performed by a specialist, combined with stretching using EPI-NO, had perinatal perineal injuries less often than women practicing APM alone or not performing it at all. However, it should be noted that the group was not randomized - patients were assigned to interventions according to their own preferences. In addition, women who massaged the perineum during pregnancy (by a specialist or independently) were less likely to deliver in the lithotomy position and more often in the sit/squat position (lithotomy: control: 90.1%, selfmassage: 80.0%, massage: 60%; sit/squat: 3.3%, 6.7%, 33.3% respectively). Moreover, APM during pregnancy resulted in significantly less perineal pain in the postpartum period, especially in women participating in APM with a physiotherapist [11]. In the continuation of this study [34], no differences in the severity of UI in young mothers were observed, regardless of the type of intervention during pregnancy. In a study by Cabral et al. [35] pregnant women were randomly assigned to one of four groups: APM, EPI-NO perineal stretching, APM combined with short (2 min) or long (15 min) EPI-NO stretching. There were no significant differences between the examined women in the frequency of perineal injuries during childbirth, however, it should be noted that in each group min. 50% of the deliveries were by cesarian section. The patients also gave birth in different hospitals, which could have influenced the monitoring and course of delivery [35]. De Freitas et al. [28] also assigned patients randomly in the morning to one of two groups: APM with a physiotherapist or stretching (15 min) with EPI-NO. In the APM group, every woman had a perineal tear, while in the EPI-NO group, 40.0% of the patients had an intact perineum. Nevertheless, in the massage group, 30% of women delivered by cesarian section, in the second group - 50.0% [28]. Also in the study by Bodner-Adler et al. [36], there were no significant differences in the occurrence of perineal injuries between women practicing APM or not. Women in the APM group more often used epidural analgesia (32.2% vs. 30.2%) and oxytocin stimulation (38.8% vs. 36.3%). However, when assessing the results, the number of people in the group should be taken into account: APM: 121, no intervention: 410, and no ranomization [36]. No significant effect of APM on the risk of perineal injuries during childbirth was also reported in the study by De la Cueva-Reguera et al. [37]. Nevertheless, pregnant women were to practice APM only once a week, for 20 min. The second group performed perineal manual lymphatic drainage (51.8% vs. 58.1%). However, regardless of the measurement point, a significant decrease in pain sensation was noted in the drainage group compared to APM. In the drainage group, the time of delivery was also shorter 30.29 ± 20.02 vs. 36.42 ± 27.29 min, but the difference was not significant. The patients were assigned to the groups on a radome basis [37]. In turn, Labrecque et al. [38] divided the patients into primiparas and multiparous women, who were then randomly assigned to APM or control (no intervention). An intact perineum was significantly more common in primiparas receiving APM than in controls (24.3% vs. 15.1%, $p = 0.01$), no similar differences were found in multiparous women (34.9% vs. 32.4%, respectively). Among primiparas, the second stage of labor was slightly longer than in controls (89.0 ± 63.4 vs. 85.9 ± 60.7 min), similarly in multiparous women (31.8 ± 38.2 vs. 26.2 ± 27.3 min). Regardless of the type of intervention, nearly 80% of primiparous women used epidural anesthesia, in the group of multiparous women, slightly more than 50%. It was noted that in total, women who performed APM of min. 2/3 of recommendations, significantly more often did not have perineal

injuries than women meeting less than 2/3 [38]. In another paper by Labrecque et al. [39], it was observed that regardless of the practice of APM or not, among primiparous women there were no significant differences in perineal pain, dyspareunia, sexual satisfaction and UI, GI, FI after 3 months of the postpartum period. Among multiparous women, the results were similar, with the exception of perineal pain - massage turned out to be a practice that significantly reduced pain compared to the control (93.6% vs. 85.8%; $p = 0.01$) [39]. In turn, Kiremitli et al. [41] showed that APM is significantly better at protecting the perineum from laceration than perineal massage during labor or no intervention. However, regardless of the type of massage performed, significantly shorter time in the second stage of labor was observed in both intervention groups (APM: 30.1 ± 14.8; massage during labor: 28.9 ± 15; control 36.8 ± 14.4 min) [41]. Meidan et al. [42] showed no significant effect of APM on perineal protection during labor compared to controls (intact perineum: 29.8% vs. 40.0%, respectively). However, women were assigned to groups based on their preferences. Participants were forbidden to inform the staff about their group assignment during labor, but midwives were allowed to perform perineal massage during the second stage of labor. Only 48.1% of women in the massage group performed APM more than two-thirds of the recommended time [42]. In a study by Monguilhott et al. [43] pregnant women were randomly assigned to the group of APM or control. Women in the intervention group were more likely to retain an intact perineum during labor, but the difference was not significant (34.9% vs. 15.9%). Nevertheless, after 10 days of puerperium, women from the control were diagnosed with edema significantly more often than women from the massage group (61.9% vs. 39.5%, $p = 0.032$). APM also significantly reduced the risk of developing GI (assessment after 45 days: 20.9% vs. 47.6%, $p = 0.009$). However, similar relationships were not found in the case of UI, FI, pain and dyspareunia [43]. In turn, Ugwu et al. [45] showed that women who practiced APM had significantly more intact perineum after delivery than controls (50.9% vs. 29.1%, $p = 0.02$). Moreover, similarly to the study [43], a significant effect of APM on reducing the risk of developing GI was observed (assessment 3 months after delivery: 8.3% vs. 26.0%, $p = 0.03$). Women were assigned to groups randomly [45]. In a study by Dieb et al. [46] examined only pregnant women over 35 years of age who were assigned to APM group combined with PFME and education or only education. It was noted that the combination of various techniques to prepare a woman for childbirth resulted in a significantly lower percentage of perineal injuries (13.5% vs. 21.5%, $p = 0.034$), and less pain on the 1st and 15th postpartum day ($p = 0.001$ and $p = 0.013$, respectively). Moreover, patients in the intervention group needed postpartum analgesia less frequently (10.5% vs. 24.5%, $p < 0.001$). No differences in the duration of the second stage of labor were observed [46]. Shipman et al. [47] also randomly divided the patients into a group performing APM and PFME or exercises alone. 24.9% of women practicing massage had an intact perineum, compared to 31.0% of the control group, but this difference is not significant. It was shown, that with the increase in age by one year, there was an increase in the risk of perineal injuries and instrumental delivery (in both cases $p = 0.0002$). Nevertheless, only 32.9% of pregnant women declared that they fully performed all APM sessions [47]. Also Leon-Larios et al. [27] combined APM with pelvic PFME. Participants were randomly assigned to an intervention or control group. APM combined with PFME resulted in a significantly higher percentage of intact perineum in young mothers (17.61% vs. 6.85%, $p < 0.003$). In addition, they had less postpartum pain (24.57% vs. 36.30%, $p < 0.001$) and required less epidural analgesia (83.46% vs. 94.81%, $p < 0.001$). Patients from the control more often gave birth in the lithotomy position, and less often in the semi-seated or lateral position ($p < 0.001$) [27]. In turn, in the study by Eogan et al. [48], there were no significant differences in the occurrence of perineal injuries between the massage group and the control group, but it was observed that the massage effectively reduced pain on the 3rd postpartum day ($p = 0.029$). However, none of the women in the intervention group completed all of their APM sessions. Moreover, the patients refused to be randomized into study groups [48]. Monguilhott et al. [43] reported the good acceptation of practicing APM by women and the willingness to do it again.

It can be seen that the benefits of APM are not only during childbirth, but also during the postpartum period. Abdelhakim et al. [26] point to the potential impact of APM on shortening the duration of the second stage of labor. Their findings also as ours did not find evidence for positive aspects APM on UI. The difference about that and our review is that our data analysis was extended to June 2023 and we did not include any data about second stage of labor duration, wound healing, and Apgar score in our criteria [26]. In addition, Beckmann et al. [25], emphasizing the proven and potential benefits of performing APM,

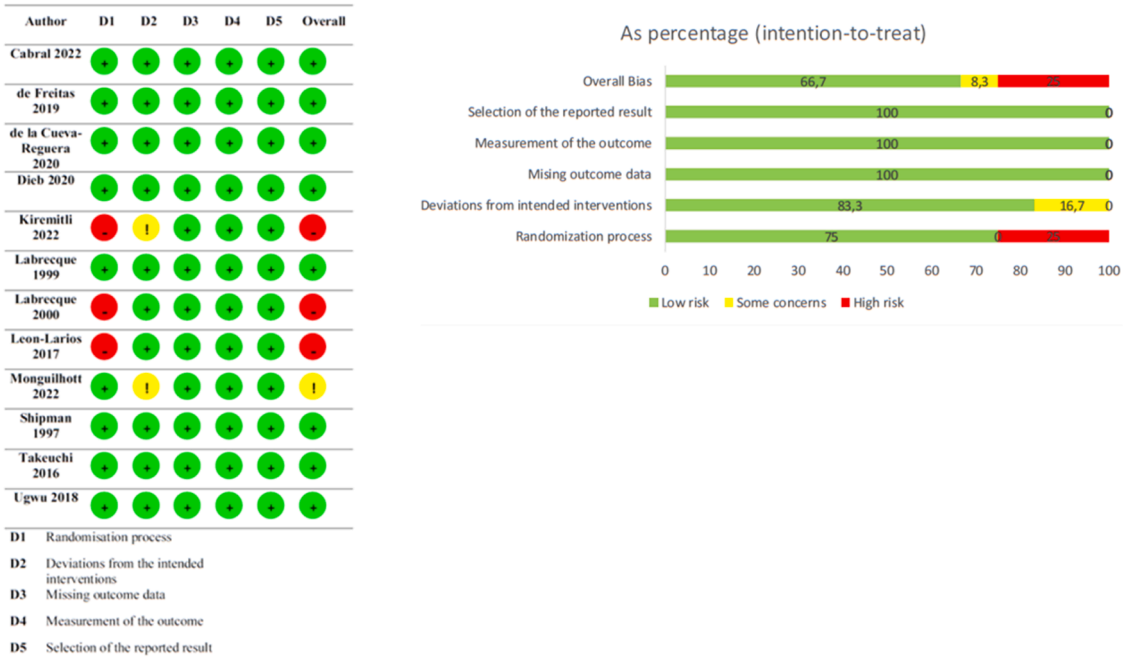

Fig. A1. RoB-2 analysis.

Table A1
Robins analysis.

Author	Type of study	Bias Due to Confounding	Bias in Selection of Participants into the Study	Bias in Classification of Interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall
Álvarez-González, 2021	Non-RCT	Moderate	Low	Low	Moderate	Low	Low	Low	Low
Álvarez-González, 2022	CCT	Moderate	Low	Low	Moderate	Low	Low	Low	Low
Bodner-Adler, 2002	CCT	Moderate	Low	Moderate	Moderate	Low	Moderate	Low	Moderate
Eogan, 2006	POS	Serious	Low	Low	Moderate	Moderate	Low	Low	Moderate
Mei-dan, 2008	PCT	Moderate	Moderate	Low	Serious	Low	Serious	Moderate	Serious
Labrecque, 2001	OS	Low	Low	Low	Moderate	Low	Low	Low	Low

A Non-RCT, A Non-Randomised Controlled Trial; CCT, Controlled Clinical Trial; OS, Observational study; PCT, A Prospective Controlled Trial; POS, Prospective Observational Study.

postulate that pregnant women should be informed about the benefits of this procedure and appropriate way of performing it.

Limitations and strengths

The main strength of our work is the lack of limitations related to the years of publication, which allows us to present studies performed in different periods. Unfortunately, no study has undertaken a comprehensive assessment of the psychophysical state in the postpartum period. The articles also differ in the follow-up period, so it was impossible to precisely compare results.

It should be noted that compared to the meta-analysis by Abdelhakim et al. [26] and Beckmann et al. [25], we not limit our review to RCT studies. The inclusion of all types of studies enabled a more accurate presentation of the relationship between APM and perineal injuries. However, in most articles, the massage was done at home. The authors noted that pregnant women were obliged to keep massage diaries, however, this is not an objective measure. In order to obtain the best publications, we performed the RoB-2 and ROBINS-I-tool analysis. However, due to the small number of papers meeting the inclusion and exclusion criteria (18), we decided to include also articles that scored high in risk of bias analyses.

Conclusions

APM performed in the second half of the third trimester of pregnancy is conducive to protecting the perineum during labor. Perineal massage during pregnancy reduces the risk of GI and FI in the puerperium. Unfortunately, a similar effect has not been demonstrated for UI. There are also no unequivocal reports on the impact of APM on sexual dysfunction.

Techniques of APM should be constantly improved. Current information on performing APM are insufficient. There are no recommendations that say unequivocally about the best time to start a massage, its duration and frequency. Some researchers recommended only internal vaginal massage, some also external. All these factors affect the effectiveness of massage, which should be taken into account when designing further research on its impact on the state of a woman during labor and the postpartum period.

Author contributions

All authors have read and agreed to the published version of the manuscript.

Declaration of Competing Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

Appendix A

12 publications were assessed in Rob-2 and 6 articles in ROBINS-I-Tool. Finally, all publications were included in the review.

References

[1] Royal College of Obstetricians and Gynaecologists. The management of third- and fourth-degree perineal tears. Green-top Guideline No. 29, 2015, pp. 5–6.
[2] Goh R, Goh D, Ellepola H. Perineal tears - A review. Aust J Gen Pract 2018;47(1–2):35–8. https://doi.org/10.31128/AFP-09-17-4333.
[3] Jansson MH, Franzén K, Hiyoshi A, Tegerstedt G, Dahlgren H, Nilsson K. Risk factors for perineal and vaginal tears in primiparous women - the prospective POPRACT-cohort study. BMC Pregnancy Childbirth 2020;20(1):749. https://doi.org/10.1186/s12884-020-03447-0.
[4] D'Souza JC, Monga A, Tincello DG. Risk factors for perineal trauma in the primiparous population during non-operative vaginal delivery. Int Urogynecol J 2020;31(3):621–5. https://doi.org/10.1007/s00192-019-03944-7.
[5] Abedzadeh-Kalahroudi M, Talebian A, Sadat Z, Mesdaghinia E. Perineal trauma: incidence and its risk factors. J Obstet Gynaecol 2019;39(2):206–11. https://doi.org/10.1080/01443615.2018.1476473.
[6] Worede DT, Alemu S, Tsegaye TB. Risk factors for severe perineal laceration among vaginally delivered mothers in public hospitals in ethiopia: unmatched case control study. Primary Health Care 2020;10(4):350.
[7] Sánchez-Ávila MT, Galván-Caudillo M, Cantú-Pompa JJ, Vázquez-Romero N, Martínez-López JP, Matías-Barrios VM, Avitia-Herrera AM, Morales-Garza LA, Hernández-Escobar CE, Soto-Fuenzalida G, González-Garza MT. Prevalence of high-grade perineal tear during labor in Mexican adolescents. Colomb Med 2018;49(4):261–4. https://doi.org/10.25100/cm.v49i4.3515 (Cali).
[8] Leon-Larios F, Corrales-Gutierrez I, Casado-Mejía R, Suarez-Serrano C. Influence of a pelvic floor training programme to prevent perineal trauma: a quasi-randomised controlled trial. Midwifery 2017;50:72–7. https://doi.org/10.1016/j.midw.2017.03.015.
[9] Domenighi LHH, Weinmann ARM, Haeffner LSB, Feltrin ML. Perineal lacerations: a retrospective study in a habitual-risk public maternity. Rev Bras Ginecol Obstet 2021;43(8):588–94. https://doi.org/10.1055/s-0041-1735227.
[10] Hartinah A, Usman AN, Sartini Jafar N, Arsyad MA, Yulianty R, Sirenden H, Nurung J. Care for perineal tears in vaginal delivery: an update for midwife. Gac Sanit 2021;35(S2):216–20. https://doi.org/10.1016/j.gaceta.2021.10.024.
[11] Álvarez-González M, Leirós-Rodríguez R, Álvarez-Barrio L, López-Rodríguez AF. Prevalence of perineal tear peripartum after two antepartum perineal massage techniques: a non-randomised controlled trial. J Clin Med 2021;10:4934. https://doi.org/10.3390/jcm10214934.
[12] Edqvist M, Hildingsson I, Mollberg M, Lundgren I, Lindgren H. Midwives' management during the second stage of labor in relation to second-degree tears-an experimental study. Birth 2017;44(1):86–94. https://doi.org/10.1111/birt.12267.
[13] Priddis H, Dahlen H, Schmied V. Women's experiences following severe perineal trauma: a meta-ethnographic synthesis. J Adv Nurs 2013;69(4):748–59. https://doi.org/10.1111/jan.12005.

[14] Wegnelius G, Hammarström M. Complete rupture of anal sphincter in primiparas: long-term effects and subsequent delivery. Acta Obstet Gynecol Scand 2011;90(3): 258–63. https://doi.org/10.1111/j.1600-0412.2010.01037.x.
[15] Barjon K., Mahdy H. Episiotomy. 2022 Sep 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: 31536281.
[16] Fodstad K, Laine K, Staff AC. Different episiotomy techniques, postpartum perineal pain, and blood loss: an observational study. Int Urogynecol J 2013;24(5):865–72. https://doi.org/10.1007/s00192-012-1960-3.
[17] Kartal B, Kızılırmak A, Calpbinici P, Demir G. Retrospective analysis of episiotomy prevalence. J Turk Ger Gynecol Assoc 2017;18(4):190–4. https://doi.org/10.4274/jtgga.2016.0238.
[18] Jiang H, Qian X, Carroli G, Garner P. Selective versus routine use of episiotomy for vaginal birth. Cochrane Database Syst Rev 2017;2(2):CD000081. https://doi.org/10.1002/14651858.CD000081.pub3.
[19] Demirel G, Golbasi Z. Effect of perineal massage on the rate of episiotomy and perineal tearing. Int J Gynecol Obstet 2015;131(2):183–6. https://doi.org/10.1016/j.ijgo.2015.04.048.
[20] Sangkomkamhang U, Kongwattanakul K, Kietpeerakool C, Thinkhamrop J, Wannasiri P, Khunpradit S, Thepsuthamarat K, Jampathong N, Lumbiganon P. Restrictive versus routine episiotomy among Southeast Asian term pregnancies: a multicentre randomised controlled trial. BJOG 2020;127(3):397–403. https://doi.org/10.1111/1471-0528.15982.
[21] Schantz C, Sim KL, Ly EK M, Barennes H, Sudaroth S, Goyet S. Reasons for routine episiotomy: a mixed-methods study in a large maternity hospital in Phnom Penh, Cambodia. Reprod Health Matters 2015;23(45):68–77. https://doi.org/10.1016/j.rhm.2015.06.012.
[22] Kartal B, Kızılırmak A, Calpbinici P, Demir G. Retrospective analysis of episiotomy prevalence. J Turk Ger Gynecol Assoc 2017;18(4):190–4. https://doi.org/10.4274/jtgga.2016.0238.
[23] Blondel B, Alexander S, Bjarnadóttir RI, Gissler M, Langhoff-Roos J, Novak-Antolič Ž, Prunet C, Zhang WH, Hindori-Mohangoo AD, Zeitlin J. Euro-Peristat Scientific Committee. Variations in rates of severe perineal tears and episiotomies in 20 European countries: a study based on routine national data in Euro-Peristat Project. Acta Obstet Gynecol Scand 2016;95(7):746–54. https://doi.org/10.1111/aogs.12894.
[24] Moraes JCM, de Assis LC. Role of physical therapy during pregnancy for childbirth preparation. Pediatr Dimens 2018;3(3). https://doi.org/10.15761/PD.1000172.
[25] Beckmann MM, Stock OM. Antenatal perineal massage for reducing perineal trauma. Cochrane Database Syst Rev 2013;4:CD005123. https://doi.org/10.1002/14651858.CD005123.pub3.
[26] Abdelhakim AM, Eldesouky E, Elmagd IA, Mohammed A, Farag EA, Mohammed AE, Hamam KM, Hussein AS, Ali AS, Keshta NHA, Hamza M, Samy A, Abdel-Latif AA. Antenatal perineal massage benefits in reducing perineal trauma and postpartum morbidities: a systematic review and meta-analysis of randomized controlled trials. Int Urogynecol J 2020;31(9):1735–45. https://doi.org/10.1007/s00192-020-04302-8.
[27] Leon-Larios F, Corrales-Gutierrez I, Casado-Mejía R, Suarez-Serrano C. Influence of a pelvic floor training programme to prevent perineal trauma: a quasi-randomised controlled trial. Midwifery 2017;50:72–80. https://doi.org/10.1016/j.midw.2017.03.015.
[28] de Freitas SS, Cabral AL, de Melo Costa Pinto R, Resende APM, Pereira Baldon VS. Effects of perineal preparation techniques on tissue extensibility and muscle strength: a pilot study. Int Urogynecol J 2019;30(6):951–7. https://doi.org/10.1007/s00192-018-3793-1.
[29] Aasheim V, Nilsen ABV, Reinar LM, Lukasse M. Perineal techniques during the second stage of labour for reducing perineal trauma. Cochrane Database Syst Rev 2017;6(6):CD006672. https://doi.org/10.1002/14651858.CD006672.pub3.
[30] Biana CB, Cecagno D, Porto AR, Cecagno S, Marques VA, Soares MC. Non-pharmacological therapies applied in pregnancy and labor: an integrative review. Rev Esc Enferm. USP 2021;55:e03681. https://doi.org/10.1590/S1980-220×2019019703681.
[31] Ducarme G, Pizzoferrato AC, de Tayrac R, Schantz C, Thubert T, Le Ray C, Riethmuller D, Verspyck E, Gachon B, Pierre F, Artzner F, Jacquetin B, Fritel X. Perineal prevention and protection in obstetrics: CNGOF clinical practice guidelines. J Gynecol Obstet Hum Reprod 2018;48(7):455–60. https://doi.org/10.1016/j.jogoh.2018.12.002.
[32] Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, Cates CJ, Cheng HY, Corbett MS, Eldridge SM, Emberson JR, Hernán MA, Hopewell S, Hróbjartsson A, Junqueira DR, Jüni P, Kirkham JJ, Lasserson T, Li T, McAleenan A, Reeves BC, Shepperd S, Shrier I, Stewart LA, Tilling K, White IR, Whiting PF, Higgins JPT. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019;366:l4898. https://doi.org/10.1136/bmj.l4898.
[33] Risk of bias info. Access on-line: https://www.riskofbias.info/welcome [20.02.2023].
[34] Álvarez-González M, Leirós-Rodríguez R, Álvarez-Barrio L, López-Rodríguez AF. Perineal massage during pregnancy for the prevention of postpartum urinary incontinence: controlled clinical trial. Medicina 2022;58(10):1485. https://doi.org/10.3390/medicina58101485 (Kaunas).
[35] Cabral AL, de Freitas SS, Pinto RMC, Resende APM, Pereira-Baldon VS. Are perineal massage and instrument-assisted perineal stretching with short protocol effective for increasing pelvic floor muscle extensibility? A randomized controlled trial. Phys Ther 2022;102(3):pzab305. https://doi.org/10.1093/ptj/pzab305.
[36] Bodner-Adler B, Bodner K, Mayerhofer K. Perineal massage during pregnancy in primiparous women. Int J Gynaecol Obstet 2002;78(1):51–3. https://doi.org/10.1016/s0020-7292(02)00065-6.
[37] de la Cueva-Reguera M, Rodríguez-Sanz D, Calvo-Lobo C, Fernández-Martínez S, Martínez-Pascual B, Robledo-Do-Nascimento Y, Blanco-Morales M, Romero-Morales C. Effectiveness of manual lymphatic drainage vs. perineal massage in secundigravida women with gestational oedema: a randomised clinical trial. Int Wound J 2020;17(5):1453–61. https://doi.org/10.1111/iwj.13427.
[38] Labrecque M, Eason E, Marcoux S, Lemieux F, Pinault JJ, Feldman P, Laperrière L. Randomized controlled trial of prevention of perineal trauma by perineal massage during pregnancy. Am J Obstet Gynecol 1999;180(3 Pt 1):593–600. https://doi.org/10.1016/s0002-9378(99)70260-7.
[39] Labrecque M, Eason E, Marcoux S. Randomized trial of perineal massage during pregnancy: perineal symptoms three months after delivery. Am J Obstet Gynecol 2000;182(1 Pt 1):76–80. https://doi.org/10.1016/s0002-9378(00)70493-5.
[40] Labrecque M, Eason E, Marcoux S. Women's views on the practice of prenatal perineal massage. BJOG 2001;108(5):499–504. https://doi.org/10.1111/j.1471-0528.2001.00111.x.
[41] Kiremitli S, Kiremitli T, Uluğ P, Yilmaz N. Comparison of obstetric outcomes and morbidity in nulliparous pregnant women who received antenatal and intrapartum perineal massage. Pelviperineology 2022;41(1):17–22. https://doi.org/10.34057/PPj.2022.41.01.2022-2-1.
[42] Mei-dan E, Walfisch A, Raz I, Levy A, Hallak M. Perineal massage during pregnancy: a prospective controlled trial. Isr Med Assoc J 2008;10(7):499–502. PMID: 18751626.
[43] Monguilhott JJ, Bruggemann OM, Velho MB, Knobel R, Costa R. Antenatal perineal massage for trauma prevention: a pilot randomized clinical trial. Acta Paul Enferm 2022;35:eAPE0381345. https://doi.org/10.37689/acta-ape/2022AO03813459.
[44] Takeuchi S, Horiuchi S. Randomised controlled trial using smartphone website vs leaflet to support antenatal perineal massage practice for pregnant women. Women Birth 2016;29(5):430–5. https://doi.org/10.1016/j.wombi.2016.01.010.
[45] Ugwu EO, Iferikigwe ES, Obi SN, Eleje GU, Ozumba BC. Effectiveness of antenatal perineal massage in reducing perineal trauma and post-partum morbidities: a randomized controlled trial. J Obstet Gynaecol Res 2018;44(7):1252–8. https://doi.org/10.1111/jog.13640.
[46] Dieb AS, Shoab AY, Nabil H, Gabr A, Abdallah AA, Shaban MM, Attia AH. Perineal massage and training reduce perineal trauma in pregnant women older than 35 years: a randomized controlled trial. Int Urogynecol J 2020;31(3):613–9. https://doi.org/10.1007/s00192-019-03937-6.
[47] Shipman MK, Boniface DR, Tefft ME, McCloghry F. Antenatal perineal massage and subsequent perineal outcomes: a randomised controlled trial. Br J Obstet Gynaecol 1997;104(7):787–91. https://doi.org/10.1111/j.1471-0528.1997.tb12021.x.
[48] Eogan M, Daly L, O'Herlihy C. The effect of regular antenatal perineal massage on postnatal pain and anal sphincter injury: a prospective observational study. J Matern Fetal Neonatal Med 2006;19(4):225–9. https://doi.org/10.1080/14767050600593155.
[49] Marques A, Stothers L, Macnab A. The status of pelvic floor muscle training for women. Can Urol Assoc J 2010;4(6):419–24. https://doi.org/10.5489/cuaj.10026.
[50] Leeman L, Rogers R, Borders N, Teaf D, Qualls C. The effect of perineal lacerations on pelvic floor function and anatomy at 6 months postpartum in a prospective cohort of nulliparous women. Birth. 2016;43(4):293–302. https://doi.org/10.1111/birt.12258.
[51] Gommesen D, Nøhr E, Qvist N, Rasch V. Obstetric perineal tears, sexual function and dyspareunia among primiparous women 12 months postpartum: a prospective cohort study. BMJ Open 2019;9(12):e032368. https://doi.org/10.1136/bmjopen-2019-0323.

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Original Article

Intracytoplasmic sperm injection does not improve the outcome of IVF treatments in patients with advanced maternal age or low oocyte number: A randomized controlled trial

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ABSTRACT

Introduction: Intracytoplasmic sperm injection (ICSI) was introduced to achieve fertilization in cases of severe male factor infertility. However, ICSI is often used in cases of non-male factor infertility, such as advanced maternal age or low oocyte number, but the clinical benefit of the method in these indications has not been proven.
Material and Methods: A prospective randomized study was conducted in a university clinic between 2018 and 2020. Patients with ≥40 years of age and/or ≤4 oocytes with non-sever male factor infertility were randomized into conventional IVF or ICSI groups. Fertilization rate, embryo quality, implantation, clinical pregnancy and live birth rates were compared.
Results: A total of 336 IVF cycles (169 conventional IVF and 167 ICSI) were involved in the study. The fertilization rate was higher in the conventional IVF group compared to the ICSI group (IVF: 61.7%, ICSI: 53.4%, P=0.001). Embryo development and morphology did not show considerable difference between groups. Implantation, clinical pregnancy and live birth rate were 13.1%, 24.3% and 11.4% in the conventional IVF and 10.4%, 19.0%, 12.0% in the ICSI group. The differences were not significant. Subgroup analysis showed a significantly better clinical outcome following conventional IVF when advanced maternal age was accompanied by low oocyte number (Implantation: 11.7% vs 2.6%, P=0.027; Clinical pregnancy: 18.5% vs 4%, P=0.020).
Discussion: A significantly higher fertilization rate, a tendency for higher clinical pregnancy rate was found in conventional IVF treatments compared to ICSI. When advanced maternal age was associated with low oocyte number, ICSI resulted in a substantially lower chance of fertilization and clinical pregnancy. These data suggest that ICSI offers no advantage over conventional IVF in terms of fertilization, embryo quality, implantation and pregnancy rates for couples with advanced maternal age or with low oocyte number.

Introduction

Intracytoplasmic sperm injection (ICSI) was introduced to achieve fertilization in cases of severe male factor infertility. Over the past 30 years, it has become the most commonly used method in assisted reproduction. The frequency of ICSI was 45% in 1997 and increased up to 70% in Europe in 2007; however, it shows a large variation worldwide [1,2]. Besides male factor infertility it is also used for fertilizing frozen-thawed, *in vitro* matured oocytes or in preimplantation genetic testing cycles [3] as well as following total fertilization failure (TFF) in a previous conventional IVF (c-IVF) treatment [4,5]. Several studies were published, which compared the efficacy of ICSI and c-IVF in cases of slightly reduced sperm parameters [6,7], low oocyte number [8,9], advanced maternal age [10,11] or unexplained infertility [12] but these results are controversial.

The use of ICSI or c-IVF in case of non-male factor infertility has been a controversial issue in the past two decades. The main reason to use ICSI in this population is to prevent TFF. A significantly higher fertilization rate and a higher number of good-quality embryos were reported when oocytes were fertilized by ICSI compared to c-IVF in non-male factor infertility patients [13,14]. However, others could not confirm the superiority of ICSI, and its positive effect on fertilization rate, embryo quality, pregnancy rate and live birth rate [6,15,16].

Several authors draw our attention to the unnecessary overuse of ICSI and the lack of proven benefits in the case of non-male factor infertility [17,18].

Abbreviations: c-IVF, Conventional *in vitro* fertilization; ET, Embryo transfer; IVF, *In vitro* fertilization; ICSI, Intracytoplasmic sperm injection; TFF, Total fertilization failure; GnRH, Gonadotropin-releasing hormone; hCG, Human chorion gonadotrophin

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The aim of this study was to evaluate the efficacy of c-IVF and ICSI fertilization in patients with advanced maternal age or with low oocyte number. Our hypothesis was that ICSI is not superior over c-IVF in non-male factor infertility.

Material and methods

Study population

This prospective, randomized, controlled, non-inferiority clinical trial was performed at the Division of Assisted Reproduction, Department of Obstetrics and Gynaecology, Semmelweis University, Budapest, Hungary between January 2018 and December 2020. We compared c-IVF and ICSI fertilization methods in patients with advanced maternal age and/or low oocyte number when the male partner had normal or only slightly reduced semen parameters.

The study was approved by the national ethical review board (14055-8/2017/EÜIG) and was registered in the ClinicalTrials.gov database (NCT03513913). All participants provided their written informed consent after having been informed about all aspects of the treatment.

Eligible couples were awaiting IVF treatment at our department for an indication other than severe male factor infertility. All patients underwent a detailed andrological examination before establishing the indication for IVF treatment. Diagnostic semen analysis was performed using the same methods in the same laboratory where the IVF treatment was done.

Inclusion criteria were ≥40 years of female age or ≤4 oocytes collected. Furthermore, patients with normal semen parameter or nonsever male factor was included in the study. Non-severe male factor was defined as semen parameters, which were below the reference values according to WHO V. criteria [19] but at least 1 million progressive motile sperm and ≥75% progressive motility was observed after sperm preparation on the day of oocyte collection.

Couples were excluded from the study if the fertilization rate in a previous IVF treatment was <50%. Cycles with surgical sperm retrieval, sperm or oocyte donation and preimplantation genetic testing were also excluded.

Eligible couples were randomised into the c-IVF Group or the ICSI Group using a computer generated randomisation script by the embryologist after oocyte collection and sperm preparation. The randomization was done in batches of 10 to ensure equal distribution among the two groups. Randomized sequences were generated upfront and stored in a hidden and inaccessible backup table. Neither the number of oocytes nor any other cycle parameter had influence on the fertilization method.

Ovarian stimulation

The gonadotropin-releasing hormone-agonist (GnRH) “long protocol” or multiple dose flexible GnRH-antagonist regimens were used for ovarian stimulation. Transvaginal ultrasound-guided aspiration of follicles was performed 36 hours after hCG administration.

IVF procedure and embryo culture

Oocyte collection, fertilization, embryo culture and embryo transfer were performed using the standard laboratory protocol by experienced embryologists. Oocyte and embryo culture was performed in a culture media product line called “G-series” produced by Vitrolife (Göteborg, Sweden).

The same laboratory procedures were used for sperm preparation in c-IVF and in ICSI treatment groups. Progressive motile sperm was isolated by a combined method of density gradient centrifugation and swim-up technique. A two-layer SpermGrad (Vitrolife) density gradient centrifugation, according to the manufacturer’s instructions was used. Swim-up technique was applied following density gradient centrifugation to obtain a sample with high progressive motility. Those cycles, where total progressive motile sperm count was <1 million and progressive motility was <75% following sperm preparation, were excluded from the study.

Fertilization was performed 4-6 hours following oocyte collection using c-IVF or intracytoplasmic sperm injection (ICSI) according to the randomisation.

In the case of c-IVF treatment oocytes were co-incubated with 3×10^5 progressive motile sperm / ml of culture media in groups of 1-6 for 16-18 hours.

ICSI treatment was performed by embryologists with at least two years of micromanipulation experience. Oocytes were injected following enzymatic denudation. All oocytes were checked once for the presence of 2 pronuclei 16-18 hours post insemination. Only normally fertilized oocytes showing 2 pronuclei were used for further embryo culture, embryotransfer or cryopreservation. TFF was determined when none of the oocytes showed normal fertilization after multiple observations between 16 and 24 hours post insemination. Embryos which developed from abnormally fertilized (1 or 3 pronuclei) oocytes or which cleaved without any sign of pronuclear formation was not used for ET or cryopreservation.

Embryos were cultured in a benchtop incubator at 37°C, 6% CO_2 and 5% O_2 level. Embryo development and morphology were assessed each day according to the standard protocol [20]. Morphology score from 1 to 4 was given to cleavage stage embryos regarding to their quality.

Embryo transfer (ET) was performed at cleavage stage or at blastocyst stage according to our ET strategy which takes in account the number of embryos available, the age of the patient and the outcome of previous IVF treatments. Embryos with optimal developmental stage and with highest morphology grade were selected for transfer. More than one embryo was transferred if the patient was ≥40 years of age, or if she failed to conceive after two previous embryo transfer. Embryos were cultured until blastocyst stage when more embryo were available than we planned to transfer. In all other case embryos were transferred at cleavage stage.

Outcome measures

Primary outcome measure was the fertilization rate which was calculated by dividing the number of normally fertilized (2PN) zygotes by the total number of oocytes collected.

Secondary endpoints were embryo quality, implantation rate, clinical pregnancy rate and live birth rate. Cell number, morphology score and the rate of good quality embryos were compared on days 2 and 3 of embryo development. Blastocyst formation rate was defined as the number of embryos with clearly visible blastocoel divided by the number of embryos cultured to day 5. Embryo utilization rate was calculated as the number of embryos transferred or cryopreserved, divided by the number of normally fertilized oocytes.

Implantation rate was defined as the number of gestational sacs divided by the number of embryos transferred. Clinical pregnancy rate (the number of clinical pregnancies diagnosed by ultrasonographic visualization of one or more gestational sacs divided by the number of ETs) and live birth rate (the number of deliveries that resulted in at least one live newborn divided by the number of ETs) was also calculated. Multiple pregnancies was counted as one clinical pregnancy and deliveries of multiple pregnancies were counted as one live birth.

Subgroup analysis

Treatment cycles were further divided as follows:
Subgroup A): Cycles with low oocyte number (≤ 4 oocytes)
Subgroup B): Cycles with advanced maternal age (≥40 years)

Subgroup C): Cycles with low oocyte number and advanced maternal age (≤ 4 oocytes and ≥40 years together)

Fertilization, implantation and pregnancy data were also compared between c-IVF and ICSI treatments in the three subgroups.

Statistical analysis

At the design of this study we set the margin of inferiority 10% and assumed 55% fertilization rate with ICSI. On the basis of these numbers we estimated that 388 normal fertilizations by treatment arms were needed to show with 95% confidence that the fertilization rate with c-IVF was maximum 10% worse than that of ICSI.

Statistical analysis was performed using Statistica 12 software (StatSoft Inc., USA). Student's t-test was used to compare mean values, and the Chi2 test was used to compare proportional values. The time needed for morphology assessment was compared using a paired t-test. Statistical significance was set at P<0.05.

Results

A total of 336 IVF cycles were involved in the study. The number of cycles was 169 in the c-IVF Group and 167 in the ICSI Group. There was no significant difference between the groups regarding patient age, cause of infertility and cycle characteristics (Table 1); however, a slightly higher number of embryos were transferred in the c-IVF group. Sperm concentration, progressive motility and total progressive motile sperm count in native semen and in prepared sperm samples were also similar in both groups (Table 1.).

Fertilization rate was significantly higher in the c-IVF group compared to the ICSI group (IVF: 61.7%, ICSI: 53.4%, P=0.001) (Table 2). Total fertilization failure was observed in 12.4 % of c-IVF and 11.4% of ICSI groups. The difference was not significant (P=0.767) (Table 1).

All embryos were cryopreserved in 6 IVF and 2 ICSI cycles due to the elevated risk of ovarian hyperstimulation syndrome or because of other medical indication (c-IVF: 3.6%, ICSI: 1.2%, P=0.146). A total of 140 ET (82.8%) was performed in c-IVF and 142 ET (85%) in ICSI groups (Table 1).

Table 1
Cycle characteristics in conventional IVF (c-IVF) and ICSI treatment groups.

	c-IVF		ICSI		P-value
Number of cycles	169		167		
Age (year)	40.4	±3.5	40.1	±4.0	0.484
Cause of infertility					0.085
Tubal factor	27	16,0%	38	22,8%	
Other female factor	23	13,6%	14	8,4%	
Male factor	21	12,4%	10	6,0%	
Multiple factor	3	1,8%	3	1,8%	
Idiopathic	95	56,2%	102	61,1%	
Sperm parameters in the native sample					
Sperm concentration (M)	57,3	±40,6	58,3	±37,5	0,815
Total motility (%)	54,3	±16,2	57,2	±13,1	0,070
Progressive motility (%)	49,2	±16,3	52,0	±13,6	0,094
Total progressive motile sperm count (M)	81,3	±58,1	85,8	±61,1	0,496
Sperm parameters in the prepared sample					
Total progressive motile sperm count (M)	4,9	±5,8	5,5	±5,4	0,373
Progressive motility (%)	87,7	±8,1	88,4	±8,6	0,444
Number of previous IVF cycles	1.1	±1.4	1.3	±1.5	0.374
Length of stimulation (day)	11.6	±1.3	11.4	±1.3	0.445
Number of oocytes collected	4.3	±3.0	4.4	±3.0	0.792
Total fertilization failure	21	12.4%	19	11.4%	0.767
Number of embryo transfers	140	82.8%	142	85.0%	0.585
Number of embryos transferred (/ET cycles)	2.2	±1.0	2.0	±0.9	0.044

Table 2
Fertilization and embryo development in conventional IVF (c-IVF) and ICSI treatment groups.

	c-IVF		ICSI		P-value
Number of oocytes	721		727		
Normal fertilization	445	61.7%	388	53.4%	0.001
Cleavage	427	96.0%	379	97.9%	0.102
D2 embryo development	Mean	±SD	Mean	±SD	
N	427		379		
Cell number	4.0	±1.2	4.0	±1.1	0.138
Morphology score	2.3	±0.8	2.3	±0.8	0.753
Good quality embryos (Grade A and B)	139	31.2%	120	31.0%	0.944
D3 embryo development	Mean	±SD	Mean	±SD	
N	257		233		
Cell number	7.6	±2.6	7.8	±2.8	0.204
Morphology score	2.3	±0.8	2.3	±0.7	0.326
Good quality embryos (Grade A and B)	75	16.9%	70	18.1%	0.640
Morula and blastocyst development	N	%	N	%	
Embryos cultured to D5	171		166		
Number of morula	142	83.0%	133	80.1%	0.489
Number of blastocyst	112	65.5%	97	58.4%	0.182

Cell number, morphology score and the amount of good quality embryos were similar in both groups on days 2 and 3. Sign of compaction and blastocyst formation rates were comparable in the two groups (Table 2).

Embryos were transferred at cleavage stage or blastocyst stage according to our transfer policy. Proportion of blastocyst stage transfer were similar in the two groups (18.6% vs 21.8%; P=0.496). Number of transferred embryos was similar in c-IVF and ICSI group eider in case of cleavage stage ET (2.2±1.0 vs 2.0±0.9; P=0.085) or blastocyst stage ET (2.2±0.8 vs 1.9±0.7; P=0.295).

Cryopreservation was performed in 15.0% of the c-IVF (21/140) and in 12% of the ICSI group (17/142) following embryo transfer, which did not differ significantly between both groups (P=0.457). The embryo utilization rate was similar in both groups (81.8% vs. 83.8%; P=0.454). However, a significantly higher rate of the collected oocytes were used for ET or cryopreservation in the c-IVF group compared to the ICSI group (50.5% vs. 44.7%. P= 0.028).

Implantation rate was 13.1% in the c-IVF group and 10.4% in the ICSI group (P=0.326). Clinical pregnancy rate (/ET) was 24.3% in the c-IVF group and 19.0% in the ICSI group (P=0.282). Multiple pregnancies, live birth and abortion rates were also similar in both groups (Table 3).

Results of the subgroup analysis are indicated in Table 4. The number of cycles with TFF was comparable between the c-IVF and the ICSI treatment in all subgroups.

Fertilization rate was significantly higher when c-IVF was used compared to ICSI in the case of low oocyte number (subgroup A: 62.7% vs 51.5%, P<0.001), and when low oocyte number and advanced maternal age occurred together (subgroup C: 61.5% vs 47.8%, P=0.014). Implantation and clinical pregnancy rates did not

Table 3
Implantation, pregnancy and delivery in conventional IVF (c-IVF) and ICSI treatment groups.

	c-IVF		ICSI		P-value
Pregnancy outcomes					
Implantation rate	40/306	13.1%	29/278	10.4%	0.326
Clinical pregnancy (/ET)	34	24.3%	27	19.0%	0.282
Multiple pregnancy (/ET)	5	3.6%	2	1.4%	0.218
Abortion (/ET)	18	12.9%	10	7.0%	0.887
Live birth (/ET)	16	11.4%	17	12.0%	0.887
Number of newborns	19		17		

Table 4
Fertilization, implantation and pregnancy in subgroups.

	Subgroup A					Subgroup B					Subgroup C				
	≤4 oocytes					≥40 years					≤4 oocyte and ≥40 years				
	c-IVF		ICSI		P-value	c-IVF		ICSI		P- value	c-IVF		ICSI		P- value
Number of cycles (total)	119		118			114		110			64		61		
Total fertilization failure	10	8.4%	14	11.9%	0.377	20	17.5%	21	19.1%	0.765	9	14.1%	11	18.0%	0.545
Fertilization (%)	368/587	62.7%	308/598	51,5%	<0.001	173/290	59.7%	155/286	54.2%	0.186	96/156	61.5%	75/157	47.8%	0.014
Implantation (%)	27/250	10.8%	15/208	7.2%	0.186	24/150	16.0%	16/146	11.0%	0.205	11/94	11.7%	2/76	2.6%	0.027
Clinical pregnancy (/ET)	23/106	21.7%	13/101	12.9%	0.094	21/88	23.9%	16/91	17.6%	0.300	10/54	18.5%	2/50	4.0%	0.020
Live birth (/ET)	9/106	8.5%	6/101	5.9%	0.479	11/88	12.5%	12/91	13.2%	0.890	4/54	7.4%	1/50	2.0%	0.206

Subgroup A): Cycles with low oocyte number (≤ 4 oocytes)
Subgroup B): Cycles with advanced maternal age (≥40 years)
Subgroup C): Cycles with low oocyte number and advanced maternal age (≤ 4 oocytes and ≥40 years together)

differ significantly between c-IVF and ICSI in subgroups A and B. However, c-IVF was superior compared to the ICSI method in subgroup C (Implantation: 11.7% vs 2.6%, P=0.027; Clinical pregnancy rate: 18.5% vs 4%, P=0.020). Live birth rate did not differ significantly between the c-IVF and the ICSI groups in all subgroups.

Discussion

The original goal of using intracytoplasmic sperm injection was to achieve fertilization in the case of severe male factor infertility, but the frequency of ICSI in assisted reproductive treatments reaches 70% worldwide [2]. Such a high ICSI rate cannot be explained by the frequency of severe andrological factor or TFF. There is some evidence that ICSI can improve fertilization rate when the patient has a history of TFF [4,5]. However, ICSI is also used as a preferred method of fertilization in many other indications, e.g. advanced maternal age or poor ovarian response. Recent systematic literature analyses showed that the use of ICSI in non-male factor infertility does not increase pregnancy or live birth rates [21,22] and several authors draw the attention to the overuse of ICSI despite the lack of evidence of improvement in clinical outcomes [17,18].

In this study we compared the effect of the c-IVF and the ICSI fertilization methods on IVF outcome in case of advanced maternal age and/or low oocyte numbers which are common indications of ICSI treatment. Fertilization, embryo development and clinical outcome of IVF treatments were studied. The primary goal of ICSI is to achieve fertilization in a well-defined patient population. On the other hand, several authors pointed that c-IVF and ICSI results similar development and quality of the normally fertilized embryos [6,10]. Therefore, the primary endpoint in this study was the fertilization rate and the second endpoint was to determine the clinical outcomes, like pregnancy and live birth rate.

One of the inclusion criteria in our study was advanced maternal age. It have been theorized that oocytes obtained from older women may have structural defects of the zona pellucida or the cytoplasm which may reduce the chance of fertilization with c-IVF. This hypothesis was not confirmed by a recent meta- analysis where the fertilization rate was similar between c-IVF and ICSI cycles in advanced maternal age [23].

The usage of ICSI in case of low oocyte number based on the theory that ICSI is a more effective method, which improve the number of embryos in this patient population. However, the higher fertilization rate followed by ICSI compare to conventional insemination was not confirmed by several authors [8,9,24].

The frequency of TFF in our study was about 12%, and it was similar in both groups. TFF should be below 5% both in IVF and ICSI cycles according to international standards [25]. The higher amount of TFF may be related to a decreased oocyte quality in this study population. The similar TFF rate in both groups indicates that neither ICSI nor IVF can prevent TFF in this patient population.

The main reason of offering ICSI to patients with non-male factor infertility is to increase the fertilization rate using micromanipulation techniques. Several authors found higher fertilization rate in ICSI cycles compared to c-IVF [13,14,26]; however, other studies showed that conventional IVF resulted in equal or even higher fertilization rate compared to ICSI [9–11,24,27]. The heterogeneity in these results may be due to the different inclusion criteria of the reviewed studies. In order to obtain comparable data, the fertilization rate was calculated based on total number of collected oocytes in case of both c-IVF and ICSI treatment in our study. The ICSI fertilization rate based on the number of injected metaphase II oocytes in our study was 64.3% (data not shown). The Vienna Consensus Report [25] determined the competence value for ICSI fertilization rate ≥65% per injected oocytes, however, this key performance indicator were derived relative to cycles that met the criteria for a 'reference population', where female age was <40 years. The inclusion criteria in our study was advanced maternal age (≥40 years) and/or low oocyte number (≤4) which refer to a poor responder patient population with lower oocyte quality. This may caused the relatively lower fertilization rate in ICSI treatment group.

We found 8% higher fertilization rate in the c-IVF group compared to the ICSI group. This difference in fertilization rate may result in higher number of embryos available for transfer and cryopreservation, which could be beneficial for patients receiving conventional IVF.

Embryo morphology is a good indicator of viability and it may be influenced by the fertilization process. Cell number, morphology score and the number of good quality embryos were similar between both groups on days 2 and 3 in our study which is in agreement with previous findings [6,24,28]. However, better embryo morphology was also reported after ICSI [5,14].

Sign of compaction during extended culture was similar between the groups in our study, however, our data showed a tendency of higher blastocyst formation rate following c-IVF. This result is in contrast with the observation of Chamayou and colleagues [26] who found more blastocyst formation after ICSI treatment.

Implantation rate, clinical pregnancy rate and live birth rate was compared in c-IVF group and in ICSI group. These data are in consonance with other publications which conclude that ICSI does not increase the clinical outcome of assisted reproductive treatments [5,15,16,24,29]. Furthermore, recent meta-analysis reported a significantly higher clinical pregnancy rate [21,22], live birth rate and implantation rate [22] following c-IVF.

We also analysed the subgroup of patients with low oocyte number, advanced maternal age and cycles where both factor appeared together. In the case of low oocyte number, ICSI had lower fertilization rate compared to c-IVF. It is in congruence with previous findings that low oocyte number is not an indication to perform ICSI [9,11,24]. The use of ICSI in advanced maternal age is rather controversial [10,11,14]. However, our finding also suggests that ICSI may not improve reproductive outcomes in this patient population.

In the third subgroup, where advanced maternal age and low oocyte number occurred together, we observed significantly lower fertilization, implantation and clinical pregnancy rates when oocytes were fertilized by ICSI. We believe that oocytes in this poor responder patient population have a lower viability and are rather sensitive for invasive interventions like mechanical and enzymatic denudation and sperm microinjection. The result of this subgroup analysis draws our attention to the potential negative effect of ICSI when it is used without a valid indication.

The strength of this study is that we randomized IVF-ET cycles into c-IVF or ICSI group instead of sibling oocyte study. Thus, the efficacy of conventional IVF and ICSI in a particular female population (advanced maternal age and/or low oocyte number) could be analysed. However, the relatively low number of cycles in each group, especially in subgroup analysis is the limitation of this study.

In conclusion, based on our study, conventional IVF can result a higher fertilization rate, a tendency of higher clinical pregnancy rate and similar live-birth rate compared to ICSI in non-male factor infertility patients. When advanced maternal age was associated with low oocyte number, ICSI is expected to result in lower chance of fertilization and clinical pregnancy. These data may suggest that ICSI offers no advantage over IVF in terms of fertilization rate, embryo quality, implantation and pregnancy rates for couples with advanced maternal age or low oocyte number, where the male partner had normal or only slightly reduced semen parameters.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

[1] Wyns C, De Geyter C, Calhaz-Jorge C, Kupka MS, Motrenko T, Smeenk J, et al. ART in Europe, 2017: results generated from European registries by ESHRE†. Hum Reprod Open 2021;2021(3) Jun 1hoab026.
[2] Adamson GD. O-043 International committee for monitoring assisted reproductive technologies (ICMART) preliminary world report on ART, 2017. Hum Reprod 2021;36(Supplement_1) Jul 1deab126.042.
[3] O'Neill CL, Chow S, Rosenwaks Z, Palermo GD. Development of ICSI. Reprod Camb Engl. 2018;156(1):F51–8 Jul.
[4] van der Westerlaken L, Helmerhorst F, Dieben S, Naaktgeboren N. Intracytoplasmic sperm injection as a treatment for unexplained total fertilization failure or low fertilization after conventional *in vitro* fertilization. Fertil Steril 2005;83(3):612–7 Mar.
[5] Kim JY, Kim JH, Jee BC, Lee JR, Suh CS, Kim SH. Can intracytoplasmic sperm injection prevent total fertilization failure and enhance embryo quality in patients with non-male factor infertility? Eur J Obstet Gynecol Reprod Biol 2014;178:188–91 Jul 1.
[6] Plachot M, Belaisch-Allart J, Mayenga JM, Chouraqui A, Tesquier L, Serkine AM. Outcome of conventional IVF and ICSI on sibling oocytes in mild male factor infertility. Hum Reprod 2002;17(2):362–9 Feb 1.
[7] van der Westerlaken L, Naaktgeboren N, Verburg H, Dieben S, Helmerhorst FM. Conventional *in vitro* fertilization versus intracytoplasmic sperm injection in patients with borderline semen: a randomized study using sibling oocytes. Fertil Steril 2006;85(2):395–400 Feb 1.
[8] Borini A, Gambardella A, Bonu MA, Dal Prato L, Sciajno R, Bianchi L, et al. Comparison of IVF and ICSI when only few oocytes are available for insemination. Reprod Biomed Online 2009;19(2):270–5.
[9] Luna M, Bigelow C, Duke M, Ruman J, Sandler B, Grunfeld L, et al. Should ICSI be recommended routinely in patients with four or fewer oocytes retrieved? J Assist Reprod Genet 2011;28(10):911–5 Sep.
[10] Haas J, Miller TE, Nahum R, Aizer A, Kirshenbaum M, Zilberberg E, et al. The role of ICSI vs. conventional IVF for patients with advanced maternal age—a randomized controlled trial. J Assist Reprod Genet 2021;38(1):95–100 Jan 1.
[11] Tannus S, Son WY, Gilman A, Younes G, Shavit T, Dahan MH. The role of intracytoplasmic sperm injection in non-male factor infertility in advanced maternal age. Hum Reprod 2017;32(1):119–24 Jan 1.
[12] Shveiky D, Simon A, Gino H, Safran A, Lewin A, Reubinoff B, et al. Sibling oocyte submission to IVF and ICSI in unexplained infertility patients: a potential assay for gamete quality. Reprod Biomed Online 2006;12(3):371–4 Jan 1.
[13] Khamsi F, Yavas Y, Roberge S, Wong JC, Lacanna IC, Endman M. Intracytoplasmic sperm injection increased fertilization and good-quality embryo formation in patients with non−male factor indications for *in vitro* fertilization: a prospective randomized study11Presented at the 46th Annual Meeting of the Canadian Fertility and Andrology Society, St. John's, Newfoundland, Canada, September 13−16, 2000. Fertil Steril 2001;75(2):342–7 Feb 1.
[14] Farhi J, Cohen K, Mizrachi Y, Weissman A, Raziel A, Orvieto R. Should ICSI be implemented during IVF to all advanced-age patients with non-male factor subfertility? Reprod Biol Endocrinol 2019;17(1):30. Mar 7.
[15] Li Z, Wang AY, Bowman M, Hammarberg K, Farquhar C, Johnson L, et al. ICSI does not increase the cumulative live birth rate in non-male factor infertility. Hum Reprod 2018;33(7):1322–30 Jul 1.
[16] Bhattacharya S, Hamilton M, Shaaban M, Khalaf Y, Seddler M, Ghobara T, et al. Conventional in-vitro fertilisation versus intracytoplasmic sperm injection for the treatment of non-male-factor infertility: a randomised controlled trial. Lancet 2001;357(9274):2075–9 Jun 30.
[17] Evers J. Santa Claus in the fertility clinic. Hum Reprod Oxf Engl 2016;31(7):1381–2 Jul.
[18] Glenn TL, Kotlyar AM, Seifer DB. The impact of intracytoplasmic sperm injection in non-male factor infertility—a critical review. J Clin Med 2021;10(12) Jan2616.
[19] World Health Organization. WHO laboratory manual for the examination and processing of human semen. 5th edition World Health Organization; 2010 https://apps.who.int/iris/handle/10665/44261.
[20] Alpha Scientists in Reproductive Medicine and ESHRE Special Interest Group of Embryology. The Istanbul consensus workshop on embryo assessment: proceedings of an expert meeting. Hum Reprod 2011;26(6):1270–83. doi: 10.1093/humrep/der037.
[21] Abbas AM, Hussein RS, Elsenity MA, Samaha II El, Etriby KA, Abd El-Ghany MF, et al. Higher clinical pregnancy rate with in-vitro fertilization versus intracytoplasmic sperm injection in treatment of non-male factor infertility: Systematic review and meta-analysis. J Gynecol Obstet Hum Reprod 2020;49(6):101706 Jun.
[22] Geng T, Cheng L, Ge C, Zhang Y. The effect of ICSI in infertility couples with non-male factor: a systematic review and meta-analysis. J Assist Reprod Genet 2020;37(12):2929–45 Dec 1.
[23] Sunderam S, Boulet SL, Kawwass JF, Kissin DM. Comparing fertilization rates from intracytoplasmic sperm injection to conventional *in vitro* fertilization among women of advanced age with non-male factor infertility: a meta-analysis. Fertil Steril 2020;113(2):354–63 Febe1.
[24] Drakopoulos P, Garcia-Velasco J, Bosch E, Blockeel C, de Vos M, Santos-Ribeiro S, et al. ICSI does not offer any benefit over conventional IVF across different ovarian response categories in non-male factor infertility: a European multicenter analysis. J Assist Reprod Genet 2019;36(10):2067–76 Oct 1.
[25] ESHRE Special Interest Group of Embryology, Alpha Scientists in Reproductive Medicine. The Vienna consensus: report of an expert meeting on the development of art laboratory performance indicators††. Hum Reprod Open. 2017 Jul 12;2017(2):hox011.
[26] Chamayou S, Ragolia C, Alecci C, Storaci G, Romano S, Sapienza R, et al. More blastocysts are produced from fewer oocytes in ICSI compared to IVF – results from a sibling oocytes study and definition of a new key performance indicator. Reprod Biol Endocrinol 2021 Jul 26;19(1):116.
[27] Dang VQ, Vuong LN, Luu TM, Pham TD, Ho TM, Ha AN, et al. Intracytoplasmic sperm injection versus conventional in-vitro fertilisation in couples with infertility in whom the male partner has normal total sperm count and motility: an open-label, randomised controlled trial. The Lancet 2021;397(10284):1554–63 Apr 24.
[28] Fishel S, Aslam I, Lisi F, Rinaldi L, Timson J, Jacobson M, et al. Should ICSI be the treatment of choice for all cases of in-vitro conception? Hum Reprod 2000;15(6):1278–83 Jun 1.
[29] Foong SC, Fleetham JA, O'Keane JA, Scott SG, Tough SC, Greene CA. A prospective randomized trial of conventional *in vitro* fertilization versus intracytoplasmic sperm injection in unexplained infertility. J Assist Reprod Genet 2006;23(3):137–40 Mar 1.

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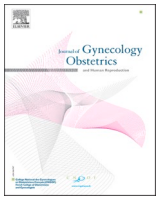

Technical Note

Old meets new: vNOTES retroperitoneal promontory fixation in conjunction with the uterus preserving Manchester procedure☆,☆☆☆,☆☆

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ABSTRACT

Introduction and Hypothesis: The Manchester procedure is a classic native tissue prolapse technique with low recurrence and low complication rate. vNOTES (vaginal natural orifice transluminal endoscopic surgery) is a vaginal approach to enter the intra or retroperitoneal space, with the guidance of endoscopic visualization. Different studies have shown women to prefer uterus-preserving correction of prolapse over hysterectomy, as they worry about complications, impact on sexual function and self- sense. At the same time, an increasing caution and awareness of mesh related complications has evolved, giving a need for the development of additional non-mesh uterus preserving surgical techniques for prolapse. The aim with the video is to show a new surgical technique for prolapse, combining the Manchester procedure with vNOTES retroperitoneal non-mesh promontory hysteropexy.

Aim of the video/Introduction

Pelvic organ prolapse affects 3–6% of women and the life time incidence of prolapse surgery is 13% [1]. The surgical pendulum swings, and concerns regarding mesh related complications are growing, giving a renewed interest in the conventional native tissue prolapse repairs.

Korbly et al. [2] investigated patient preference regarding surgical correction of prolapse, given equal surgical efficiency; 36% of women preferred uterine preservation versus 20% preferring hysterectomy. If hysterectomy was considered to give superior surgical results over uterus sparing surgery, 21% of women still preferred uterus preservation despite surgical inferiority. The authors concluded that patient preference of uterus conservation should be taken into account in the surgical decision making.

A recent study [3] included 10 000 patients that underwent surgery for apical prolapse comparing the Manchester procedure (MP) with sacrocolpopexy and sacrohysteropexy. The Manchester procedure was associated with a lower rate of recurrent prolapse surgery, lower rate of symptomatic recurrence and lower surgical morbidity. In analogy, Tolstrup et al. [4] summarized in a review that MP showed lower rate of anatomical recurrence of the middle compartment, lower re-operation rate, lower rate of postoperative complications, and shorter duration of surgery than vaginal hysterectomy. Despite that the Manchester procedure seems to be associated the lowest risk of recurrence, as many as 5–7% [3] are re-operated after MP for recurrent prolapse, which raises the question if additional apical support can reduce the risk of recurrence.

Scarless vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) [5] has taken vaginal surgery to the next step by combining the vaginal approach and adding the benefits of endoscopic visualisation of the abdominal cavity or the retroperitoneal space. vNOTES is most commonly used for hysterectomy [5] or adnexectomy [6] as two RCTs showed benefits with vNOTES over gold standard laparoscopic hysterectomy or adnexectomy; with less pain, less postoperative complications, shorter duration of surgery, and more patients being operated in day surgery. Within prolapse surgery vNOTES [7] has developed the traditional vaginal high uterosacral ligament suspension, permitting full visualization of ureters and uterosacral ligaments. Further benefits of vNOTES surgery is the possibility of a completely vaginal endoscopic correction of prolapse, without any complications to the abdominal wall.

The aim with the video is to show the synergetic surgical effects of a

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uterus preserving approach by combining the MP with a retroperitoneal, non-mesh vNOTES promontory fixation.

Method

Firstly, a classical MP was performed [8]; circumferential cervical incision, dissection of the vaginal epitelium and the cervix skeletonised to the uterovesical fold, transection and ligating the cardinal complex over clamp, plication of cardinal ligaments to the ventral/anterior aspect of the cervical isthmus by Fothergills suture using PDS 2–0, an extra PDS suture is placed approximating the left to the right cardinal ligament over the anterior aspect of the isthmus, and amputation of the cervix with monopolar diathermy.

Secondly, the vaginal mucosa was carefully dissected from the posterior side of the cervix entering the pararectal space, taking care not to enter the pouch of Douglas. After initial sharp dissection the pararectal space was opened further using blunt dissection.

A Gelpoint vPath ® (7 cm) (Applied Medical) was inserted and CO_2 was insufflated to 10 mmHg in the retroperitoneum. Dissection was made pararectally, retroperitoneally, and the sacrum was dissected cranially to identify and free the promontory. The iliac vessels were identified and dissected for safe placement of the sutures. An Ethibond 2–0 suture was sutured to the anterior longitudinal ligament over the promontory taking care not to place the suture at the level of the intravertebral disk. A second suture was placed just cranially to the first one. To the surgeon's preference these sutures can also be placed to the anterior sacral longitudinal ligament at the level of the upper third of the sacrum. The gas was exsufflated, and the Ethibond sutures were attached to the posterior aspect of the isthmus, but not brought under tension yet.

Thirdly, the re-adaptation of the mucosa over the cervix was performed with a Sturmdorf suture, and anterior and posterior colporaphy and perineorraphy was performed.

Finally the Ethibond sutures are tied and the uterus was lifted cranially towards the promontory to −8 cm from the hymen.

Conclusion

We here show a novel approach of combining an effective, low risk classical native repair for prolapse (MP) together with a fully retroperitoneal non-mesh fixation of the isthmus with sutures to the promontory. In contrast to a sacrocolpopexy the abdomen was never entered. vNOTES retroperitoneal promontofixation is a new approach requiring further validation, and could theoretically also be used for a vault suspension in post-hysterectomy patients.

DeLancey described in 1992 the three levels of vaginal connective tissue support [9,10]; with the cardinal and uterosacral ligaments being the most cephaled supporting structures (level 3). A classical Manchester Fothergill procedure offers 3 levels of support: level 1 the perineoraphy, level 2 the anterior and posterior repair and level 3 the plication of cardinal and uterosacral ligaments with Fothergills suture. In patients with advanced middle compartment prolapse, a classical Manchester Fothergill procedure doesn't create as high an apical suspension as a sacrocolpopexy of the high uterosacral ligament suspensions does.

We now take the uterus to new heights by adding a fourth level of support, with the attachment of the isthmus with permanent sutures to the promontory.

Consent: 'Written informed consent was obtained from the patient for publication of this video article and any accompanying images

Declaration of Competing Interest

The authors have no conflict of interest. Jan Baekelandt and Andrea Stuart declares consultancy/ teaching for Applied Medical.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jogoh.2023.102628.

References

[1] Wu JM, Vaughan CP, Goode PS, Redden DT, Burgio KL, Richter HE, Markland AD. Prevalence and trends of symptomatic pelvic floor disorders in U.S. women. Obstet Gynecol 2014;123(1):141–8.

[2] Korbly NB, Kassis NC, Good MM, Richardson ML, Book NM, Yip S, Saguan D, Gross C, Evans J, Lopes VV, Harvie HS, Sung VW. Patient preferences for uterine preservation and hysterectomy in women with pelvic organ prolapse. Am J Obstet Gynecol 2013;209(5). https://doi.org/10.1016/j.ajog.2013.08.003. 470.e1-6Epub 2013 Aug 3. PMID: 23921090.

[3] Brunes M, Johannesson U, Drca A, Bergman I, Söderberg M, Warnqvist A, Ek M. Recurrent surgery in uterine prolapse: a nationwide register study. Acta Obstet Gynecol Scand 2022;101(5):532–41. https://doi.org/10.1111/aogs.14340. Epub 2022 Mar 7. PMID: 35257371; PMCID: PMC9564727.

[4] Tolstrup CK, Lose G, Klarskov N. The Manchester procedure versus vaginal hysterectomy in the treatment of uterine prolapse: a review. Int Urogynecol J 2017; 28(1):33–40. https://doi.org/10.1007/s00192-016-3100-y. Epub 2016 Aug 2. PMID: 27485234.

[5] Baekelandt JF, De Mulder PA, Le Roy I, et al. Hysterectomy by transvaginal natural orifice transluminal endoscopic surgery versus laparoscopy as a day-care procedure: a randomised controlled trial. BJOG 2019;126:105–13.

[6] Baekelandt J, De Mulder PA, Le Roy I, Mathieu C, Laenen A, Enzlin P, Morlion B, Weyers S, Mol B, Bosteels J. Adnexectomy by vaginal Natural Orifice Transluminal Endoscopic Surgery versus laparoscopy: results of a first randomised controlled trial (NOTABLE trial). BJOG 2021;128(11):1782–91. https://doi.org/10.1111/1471-0528.16838. Epub 2021 Jul 27. PMID: 34246198.

[7] Lowenstein L, Matanes E, Lauterbach R, Mor O, Burke YZ, Weiner Z, Baekelandt J. Feasibility and learning curve of transvaginal natural orifice transluminal endoscopic surgery for hysterectomy and uterosacral ligament suspension in apical compartment prolapse. Female Pelvic Med Reconstr Surg 2021;27(1):e171–6. https://doi.org/10.1097/SPV.0000000000000875. PMID: 32520745.

[8] Oversand SH, Staff AC, Borstad E, Svenningsen R. The Manchester procedure: anatomical, subjective and sexual outcomes. Int Urogynecol J 2018;29(8): 1193–201. https://doi.org/10.1007/s00192-018-3622-6. Epub 2018 Mar 12. PMID: 29532126.

[9] DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy. Am J Obstet Gynecol 1992;166:1717–24.

[10] Lamblin G, Delorme E, Cosson M, Rubod C. Cystocele and functional anatomy of the pelvic floor: review and update of the various theories. Int Urogynecol J 2016; 27(9):1297–305. https://doi.org/10.1007/s00192-015-2832-4. Epub 2015 Sep 4. PMID: 26337427.