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The effects of cryotherapy on perineal pain after childbirth: A systematic review and meta-analysis

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ABSTRACT

Background: Most women experience perineal pain after childbirth. Sustained perineal pain affects mother's daily living. Various methods have been used to relieve postpartum perineal pain, such as cold or warm therapy, but the pain-control effects of cryotherapy are still controversial.

Aims: The purpose of this study was to verify the effectiveness of cryotherapy in relieving perineal pain in women after childbirth.

Methods: The researchers searched the CINAHL, Cochrane, EMBASE, PubMed, Korea Education and Research Information Service, NDSL, KoreaMed, LILACS and SciELO databases for studies to include in this review, and selected studies using PICO criteria. Methodological quality was assessed based on Cochrane's risk of bias 2 for randomized controlled trials. Data were analyzed with the Comprehensive Meta-Analysis program.

Findings: Eleven published studies encompassing 1,492 participants were included. Cryotherapy significantly reduced pain two days postpartum. Ice packs and gel packs had similar pain-relieving effects. Cryotherapy did not differ significantly from Epifoam therapy (hydrocortisone-pramoxine) in its effects on perineal pain one day or five days after childbirth.

Conclusions: Cryotherapy can be an effective non-pharmacological nursing intervention to reduce pain after childbirth.

Introduction

Birth-related perineal trauma, which is sustained by spontaneous laceration, episiotomy or both, is frequently associated with vaginal birth (Silva et al., 2012). Perineal trauma can lead to short- and long-term complications for the mother, and the incidence of any perineal trauma with childbirth is up to 84.3 - 85% (Abedzadeh-Kalahroudi et al., 2018; Karaçam et al., 2012). Both vaginal laceration and perineal incision for episiotomy can cause pain for hours, days, or months after childbirth (East et al., 2012a). It is reported that 90% of new mothers are affected by perineal pain (East et al., 2012b; Erbaba and Pinar, 2016), although the intensity varies according to the severity of the perineal injury (de Souza Bosco Paiva et al., 2016). Immediate postpartum pain is typically the most severe (Hedayati et al., 2005), and more than a third of mothers are affected by severe postpartum pain while walking, sitting, and sleeping in postpartum period (East et al., 2012b; Erbaba and Pinar, 2016). Some studies reported that women continued experiencing pain until 10 days postpartum (Navvabi et al., 2009; Steen and Marchant, 2007). The other study reported that 20 to 25% of patients experienced pain for two weeks, while 10% of patients experienced pain for at least three months (Hedayati et al., 2005). A moderate degree of sustained, perineal pain affects feeding, child-rearing, and sexual life (East et al., 2012b; Erbaba and Pinar, 2016). Therefore, nurses or physiotherapists should provide interventions for mothers who ex-

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perience perineal pain after childbirth to help them perform the normal activities of daily living.

Various methods have been used to relieve postpartum perineal pain, including cold or warm therapy, topical analgesics, narcotic analgesics, anti-inflammatory agents, olive oil, and herbs (Amani et al., 2015; East et al., 2012b; Erbaba and Pinar, 2016; Sanders et al., 2005; Shahrahmani et al., 2016). In particular, cryotherapy has been used to regulate bleeding, edema, and pain immediately after child birth, because it can contract the blood vessels, reduce bleeding, and suppress the stimulation of nerve endings (East et al., 2012b; Navvabi et al., 2011; Hill, 1989; Oliveira et al., 2012). Cryotherapy does not require professional skills or special equipment, so mothers are commonly instructed to apply it at home after childbirth (de Souza Bosco Paiva et al., 2016). Prior studies reported that cold therapy was helpful for postpartum perineal pain control (East et al., 2012b; Lu et al., 2015; Thangaraju et al., 2006; Chiarelli and Cockburn, 1999). Thus, as a non-pharmacological nursing intervention, cold therapy could be a cost-effective and convenient approach to postpartum care.

On the other hand, a study reported that cold therapy was not superior to Epifoam or hamamelis water interventions (Moore and James, 1989), and another study reported that cold therapy was not effective for perineal edema or pain (Neto et al., 2015). Thus, the pain-control effects of cryotherapy remain controversial. One systematic review examined the effects of local cooling therapy after childbirth (East et al., 2012a); however, the study only included research published until 2011, and encompassed both randomized controlled trials (RCTs) and quasi-RCTs.

Therefore, the aim of the current study was to evaluate the effectiveness of cold therapy in treating perineal pain compared to no localized cooling, placebo, or other therapy after childbirth.

Methods

This study's systematic review and meta-analysis were conducted in accordance with the guidelines of the Cochrane Collaboration (Higgins and Green, 2011). The study selection criteria were based on the core question PICO (Participants, Intervention, Comparison, Outcomes) format of PRISMA (Preferential Reporting Items for Systematic Reviews and Meta-Analyses). The key question for the search was "Is cryotherapy effective for pain after childbirth compared to not applying cold therapy?" The participants (P) were patients who underwent child birth, the intervention (I) was cryotherapy including cold gel pack or ice pack, the comparative group (C) was the group receiving no localized cooling, placebo (water bag), pulsed electromagnetic therapy, warm sitz baths, or Epifoam therapy, and the outcome (O) was severity of perineal pain. The researchers searched for RCTs of human subjects published until May 20, 2020 and did not limit the study period or language.

Search strategy and study selection

The following English and Korean databases were searched: CINAHL, Cochrane, EMBASE, PubMed, Korea Education and Research Information Service (KERIS), National Digital Science Library (NDSL), KoreaMed, LILACS (Latin American and Caribbean Health Sciences Literature), and SciELO (Scientific Electronic Library Online). The first search was conducted by literature search experts (a librarian) and was complemented with a manual search. Duplicate studies were removed in EndNote X9. The study process was performed in accordance with the systematic review flow of PRISMA (Moher at al., 2015). Four reviewers (KHJ, AJW, LYY, and SYS) independently screened the titles and abstracts of studies for the first round of selection, and then also independently identified articles that met the selection criteria by checking their full texts in the second selection process.

Quality assessment

The quality of the selected studies was assessed with the risk of bias 2 (RoB 2) tool of the Cochrane Collaboration (Sterne et al., 2019) for randomized controlled trials. This tool evaluates risk of bias in five domains: randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Based on the RoB 2, the full text of each article was identified as exhibiting a "high risk," "some concerns," or "low risk." Four reviewers (KHJ, AJW, LYY, and SYS) independently evaluated the articles and discussed any differing opinions to reach a consensus.

Data collection and statistical analysis

The following data were extracted from the selected articles: author, year of publication, country, number of samples, method of cryotherapy (type, duration, starting point, and measurement time), intervention of the comparative group (no localized cooling, placebo, pulsed electromagnetic therapy, warm sitz baths and Epifoam therapy), outcome measurement tool, and results. The data were coded by two authors and then double-checked by two other authors, and mismatched data were reviewed and revised.

Statistical analyses of the effect size and heterogeneity were performed with the Comprehensive Meta-Analysis program (Version 3; Biostat, Englewood, NJ, USA). The effect size was determined by Hedges' g, a statistic that standardizes the results obtained by various measurement tools and assigns weights according to the number of samples in the studies (Hedges and Olkin, 1985). A random effects model was used in consideration of differences in the subjects, intervention methods, durations, and measurement tools of the included studies. Heterogeneity was evaluated with a Chi-square test. Higgin's I^2 test was conducted when significant heterogeneity was found. An I^2 value of 0.0% indicates that there is no heterogeneity, while 50.0% indicates medium heterogeneity and 75.0% or greater indicates substantial heterogeneity (Higgins and Green, 2011).

Results

Search findings

The search yielded 127 studies, of which 72 (67 selected from the search and five added by manual searching) were deemed appropriate for further assessment. The titles and abstracts were screened according to the defined criteria for eligibility, inclusion, and exclusion, and any duplicate articles were identified and removed (Fig. 1). In total, 14 RCTs were reviewed, and data were extracted from 11 of them for systematic review and 4 for meta-analysis. Three studies were excluded due to cross-over design (2 studies) and no control group (one study). Studies published by May 20, 2020 were included.

Study characteristics

The characteristics of the 11 RCTs selected for this systematic review are summarized in Table 1. Researchers analyzed the year of publication, country of the first author, research design, number of subjects, mean age, starting time and duration of cryotherapy, method of cryotherapy, and outcome measurement. Eight studies were published before 2011, and three after 2011. The countries of the first authors included the UK (Gallie et al., 2003; Moor and Hames, 1989; Steen et al., 2000; Steen and Marchant, 2007), Brazil

Table 1
Characteristics of articles analyzed in the study.

			Participants			Intervention				
Author (year)	Country	Study design	n	Mean age (years)	Treatment group	Type	Frequency and duration	Start time	Measurement time	Outcome measure
Bezela et al. (2017)	Brazil	RCT	Exp: 24 Con: 26	Not presented	Bag of crushed ice vs. No localized cooling	Plastic bag	20 min	From 6–24 h postpartum	Before intervention, immediately after cryotherapy, and 1 h after cryotherapy	NRS
Francisco et al. (2018)	Brazil	RCT	Exp:35 Con:34	Not presented	Ice pack(plastic pack) vs No localized cooling	Plastic pack	10 min	Within 6–24 h of delivery	Before intervention Immediately after and 2 h after the intervention	NRS
Gallie et al. (2003)	UK	RCT	Exp1: 50 Exp2: 50	Exp1: 27.2 Exp2: 27.9	Ice pack vs. Pulsed electromagnetic therapy	Instant cold pack	10–15 min,every 3–4 h	Within 24 h of delivery	Before intervention, and at 6, 12, 24, and 30 h after intervention	5-point Likert scale
Leventhal et al. (2011)	Brazil	RCT	Exp: 38 Con1: 38 Con2: 38	Exp: 21.8 Con1: 22.8 Con2: 22.0	Ice pack vs. Placebo (water pack) vs. No localized cooling	Frozen water pack	20 min	Within 2–48 h of delivery	Before intervention, and immediately, 20, 40, and 60 min after cryotherapy	NRS
Moore et al. (1989)	UK	RCT	Exp1: 86 Exp2: 93 Exp3: 87	Not presented	Epifoam vs.Hamamelis water vs.Ice	Ice	Not presented	Immediately after suturing in the delivery room	1, 3, and 5 days after delivery	4-point Likert scale
Morais et al. (2016)	Brazil	RCT	Exp: 40 Con: 40	Exp: 22.5 Con: 22.7	Ice pack vs. Water bag	Latex glove with crushed ice	20 min,6 times per day	2 h after vaginal delivery	Before and at the end of each application, and 24 h after delivery	VAS
Navvabi et al. (2009)	Iran	RCT	Exp1: 39 Exp2: 35 Con: 36	Not presented	Cold gel pack vs.Ice pack vs.No localized cooling	Gel pack or ice pack	Not presented	Within 4 h of episiotomy	4 h and 1, 2, 5 and 10 days after delivery	NRS
Sheikhan et al. (2011)	Iran	RCT	Exp: 30 Con: 30	Exp: 22.7 Con: 23.5	Cold gel pack vs.Warm sitz bath with povidone-iodine	Gel pack	20 min,according to their pain	First 4 h after episiotomy	4 h, 12 h, and 5 days after episiotomy	VAS
Steen et al. (2000)	UK	RCT	Exp1: 22 Exp2: 28 Con: 27	Not presented	Ice pack (frozen normal saline sachet) vs.Epifoam vs.Cold gel pack	Normal saline sachet or gel pack	Not presented	Within 4 h of delivery	Within 4 h, and 24 h, 48 h, and 5 days after suturing	VAS
Steen et al. (2007)	England	RCT	Exp1: 108 Exp2: 107 Con: 101	Exp1: 28.6 Exp2: 27.7 Con: 23.5	Cold gel pack vs.Ice pack (normal saline sachet) vs.No localized cooling	Gel pack or normal saline sachet	Not presented	Within half an hour of suturing	Within half an hour after suturing, daily from day one to five, at day ten and at day 14	4-point Likert scale
Yusamran et al. (2007)	Thailand	RCT	Exp: 125 Con: 125	Exp: 28.48 Con: 29.5	Cold gel pack vs.	Gel pack	Every 15 min until 2 h after delivery	Immediately perineorrhaphy	Before intervention and after treatment for 15, 30, 45, and 60 min, and before leaving labor room, and 48 h after delivery	VAS

Exp = experimental group; Con = control group; RCT = randomised controlled trial; NRS = numeric rating scale; VAS = visual analogue scale.

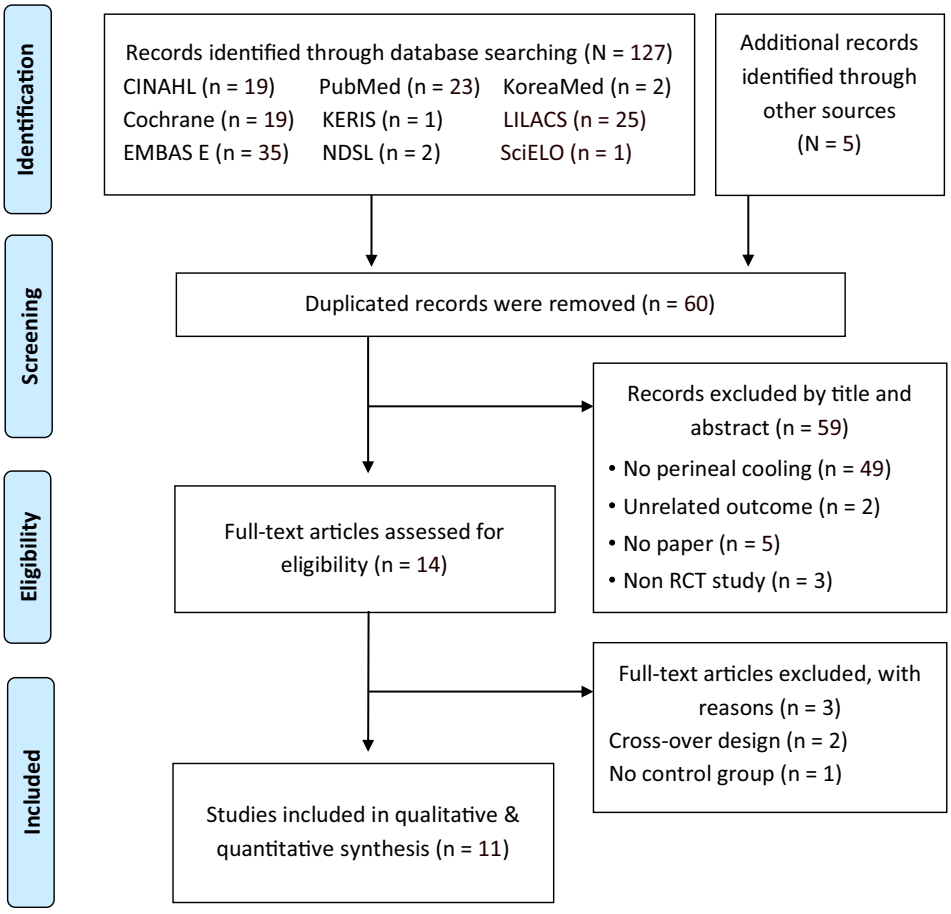

Fig. 1. Flow diagram.

(Beleza et al., 2017; Francisco et al., 2018; Leventhal et al., 2011; Morais et al., 2016), Iran (Navvabi et al., 2009; Sheikhan et al., 2011), and Thailand (Yusamran et al., 2007). In total, 1492 participants were examined in the RCTs. The number of participants in each study ranged from 50 to 316, and the mean age in each study ranged from 21.8 to 29.5 years. Patients were nulliparous or multiparous and had term child birth with or without episiotomies.

The types of cryotherapy varied, and included cold gel packs (Navvabi et al., 2009; Sheikhan et al., 2011; Steen et al., 2000; Steen and Marchant, 2007; Yusamran et al., 2007), ice packs (Beleza et al., 2017; Francisco et al., 2018; Gallie et al., 2003; Leventhal et al., 2011; Moore and James, 1989; Navvabi et al., 2009), frozen normal saline sachets (Beleza et al., 2017; de Souza Bosco Paiva et al., 2016; Steen et al., 2000; Steen and Marchant, 2007), and crushed ice in a latex glove (Morais et al., 2016). Six studies used cold gel packs or ice packs wrapped with sterile gauze or cotton tissue (Beleza et al., 2017; Francisco et al., 2018; Leventhal et al., 2011; Morais et al., 2016; Steen et al., 2000; Steen and Marchant, 2007; Yusamran et al., 2007), while the other studies did not mention these details. Five studies described the size or shape of the cold pack: an 8 × 22-cm pack (Francisco et al., 2018), 15-cm plastic bag (Leventhal et al., 2011), an 8 × 16-cm pack (Leventhal et al., 2011), a 10 × 9-cm pack (Yusamran et al., 2007), and a pack shaped like a slender sanitary towel (Steen et al., 2000). Only two studies (Beleza et al., 2017; Francisco et al., 2018) described the body position that participants were asked to maintain during the cryotherapy (the dorsal recumbent position).

The start times of cryotherapy ranged from immediately after suturing in the delivery room to 24 h after birth, immediately after suturing in three studies (Moore and James,1989; Steen and Marchant, 2007; Yusamran et al., 2007), within four hours after birth in five studies (Leventhal et al., 2011; Morais et al., 2016; Navvabi et al., 2009; Sheikhan et al., 2011; Steen et al., 2000), and from six to 24 h after birth in three studies (Beleza et al., 2017; Francisco et al., 2018; Gallie et al., 2003). Regarding the application duration, seven studies (Beleza et al., 2017; Francisco et al., 2018; Gallie et al., 2003; Leventhal et al., 2011; Morais et al., 2016; Sheikhan et al., 2011; Yusamran et al., 2007) employed cold application from 10 to 20 min, while four studies (Navvabi et al., 2009; Moore and James, 1989; Steen et al., 2000; Steen and Marchant, 2007) did not mention the duration.

None of the studies assessed the adverse effects of the cryotherapy, although four studies (Beleza et al., 2017; Francisco et al., 2018; Leventhal et al., 2011; Morais et al., 2016) measured the women's skin temperatures after cold application. Pain was measured with a visual analogue scale (VAS) in four studies (Morais et al., 2016; Sheikhan et al., 2011; Steen et al., 2000; Yusamran et al., 2007), with an numeric rating scale (NRS) in four studies (Beleza et al., 2017; Francisco et al., 2018; Leventhal et al., 2011; Navvabi et al., 2009) and with a Likert scale in three studies (Gallie et al., 2003; Moore and James, 1989; Steen and Marchant, 2007).

Risk of bias in the included studies

Fig. 2 provides a summary of the methodological domain assessment for each included study. The random sequence and allocation concealment were specifically described in three studies (Francisco et al., 2018; Leventhal et al., 2011; Yusamran et al., 2007), and assessed with low risk of bias arising from the random-

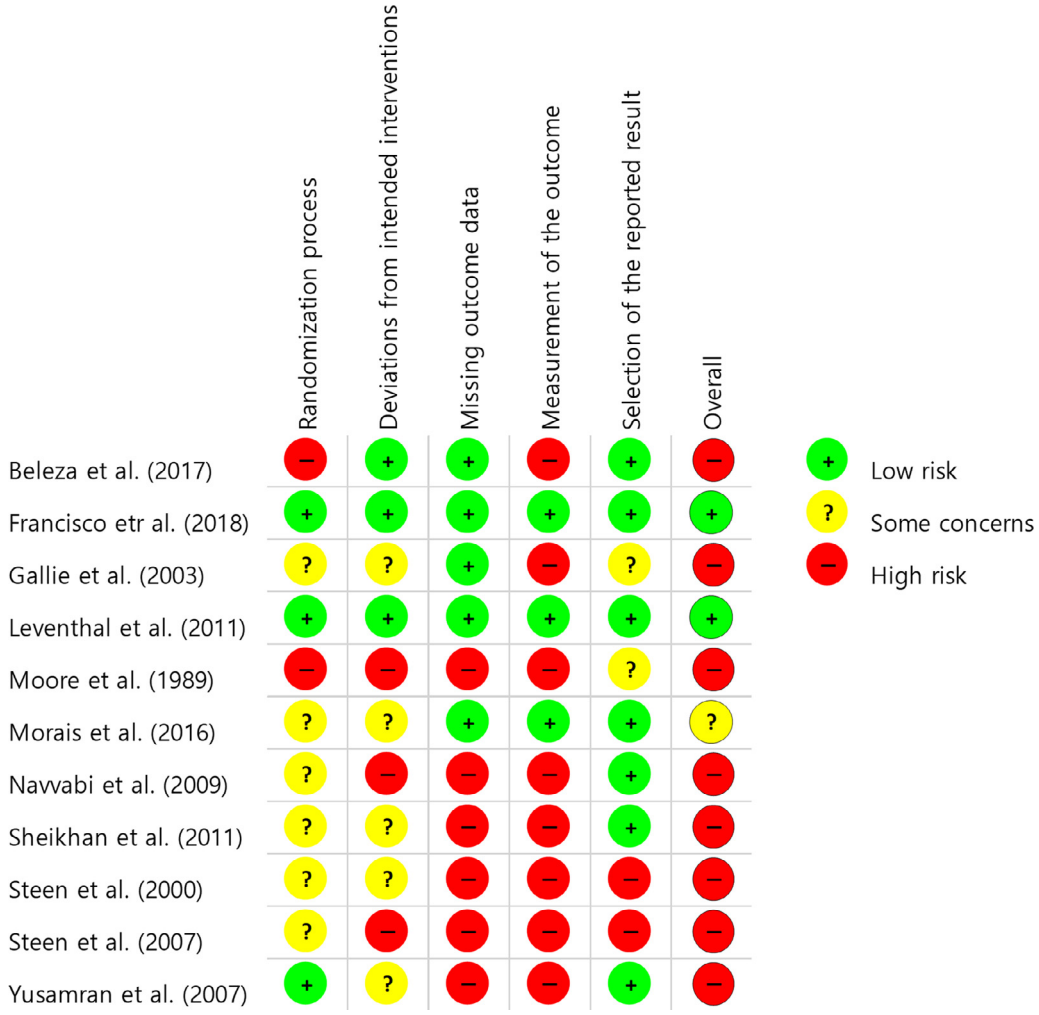

Fig. 2. Risk of bias summary: review author's judgements about each risk of bias item for each included study.

ization process while six studies were some concern or risk of bias. Three studies (Bezela et al., 2017; Leventhal et al., 2011) were assessed to have a low risk of bias due to deviations from the intended intervention. Regarding missing outcome data, five studies (Bezela et al., 2017; Francisco et al., 2018; Gallie et al., 2003; Leventhal et al., 2017; Morais et al., 2016) were low risk of bias. Three studies (Francisco et al., 2018; Leventhal et al., 2017; Morais et al., 2016) were assessed to have a low risk of bias in measurement of the outcome. The risk of bias in selection of the reported result were low in seven studies (Bezela et al., 2017; Francisco et al., 2018; Leventhal et al., 2017; Morais et al., 2016; Navvabi et al., 2009; Sheikhan et al., 2022; Yusamran et al., 2007) . An overall risk of bias judgement for each study was assessed based on domain-level judgement was generated by an algorithm. Out of a total 11 study, eight studies were high risk of bias, two were low risk of bias and one was judged to raise some concerns.

Effects of cryotherapy: cryotherapy (cold gel pack or ice pack) versus no localized cooling

Given the lack of data and the researchers' unsuccessful attempts to contact the trial authors, outcome data for pooling in the meta-analysis from only two studies that measured perineal pain at the same time were obtained (Navvabi et al., 2009; Steen and Marchant, 2007). In these two studies, the perineal application of ice packs or cold gel packs ($n = 289$) was compared with no localized cooling ($n = 137$). Perineal pain one day after childbirth did not differ significantly between the groups with and without cooling (Hedges' $g = -0.05$, 95% CI $= -0.13$ to 0.22, $p = 0.610$), and the effect size was not heterogeneous ($Q = 0.04$, $p = 0.840$, $I^2 = 0.0\%$, Fig. 3a). Two days after childbirth, the group receiving cryotherapy reported significantly less perineal pain than the group receiving no cryotherapy (Hedges' $g = -0.36$, 95% CI $= -0.54$ to 0.18, $p < 0.001$), and the effect size was not heterogeneous ($Q = 0.44$, $p = 0.51$, $I^2 = 0.0\%$, Fig. 3b). Perineal pain five days after childbirth did not differ between the cryotherapy and no-cooling groups (Hedges' $g = -0.18$, 95% CI $= -0.67$ to 0.32, $p = 0.484$). The effect size was highly heterogeneous ($Q = 5.87$, $p = 0.020$, $I^2 = 83.0\%$, Fig. 3c).

Effects of cryotherapy: comparison of two cooling treatments (cold gel pack versus ice pack)

Three studies (Navvabi et al., 2009; Steen et al., 2000; Steen and Marchant, 2007) compared the use of cold gel packs ($n = 174$) with the use of ice packs ($n = 164$). Perineal pain one day after childbirth did not differ significantly between the cold gel pack and ice pack groups (Hedges' $g = -0.05$, 95% CI $= -0.27$ to 0.18, $p = 0.700$). The effect size was not heterogeneous ($Q = 1.59$, $p = 0.450$, $I^2 = 0.0\%$, Fig. 4a). Two days after childbirth, perineal

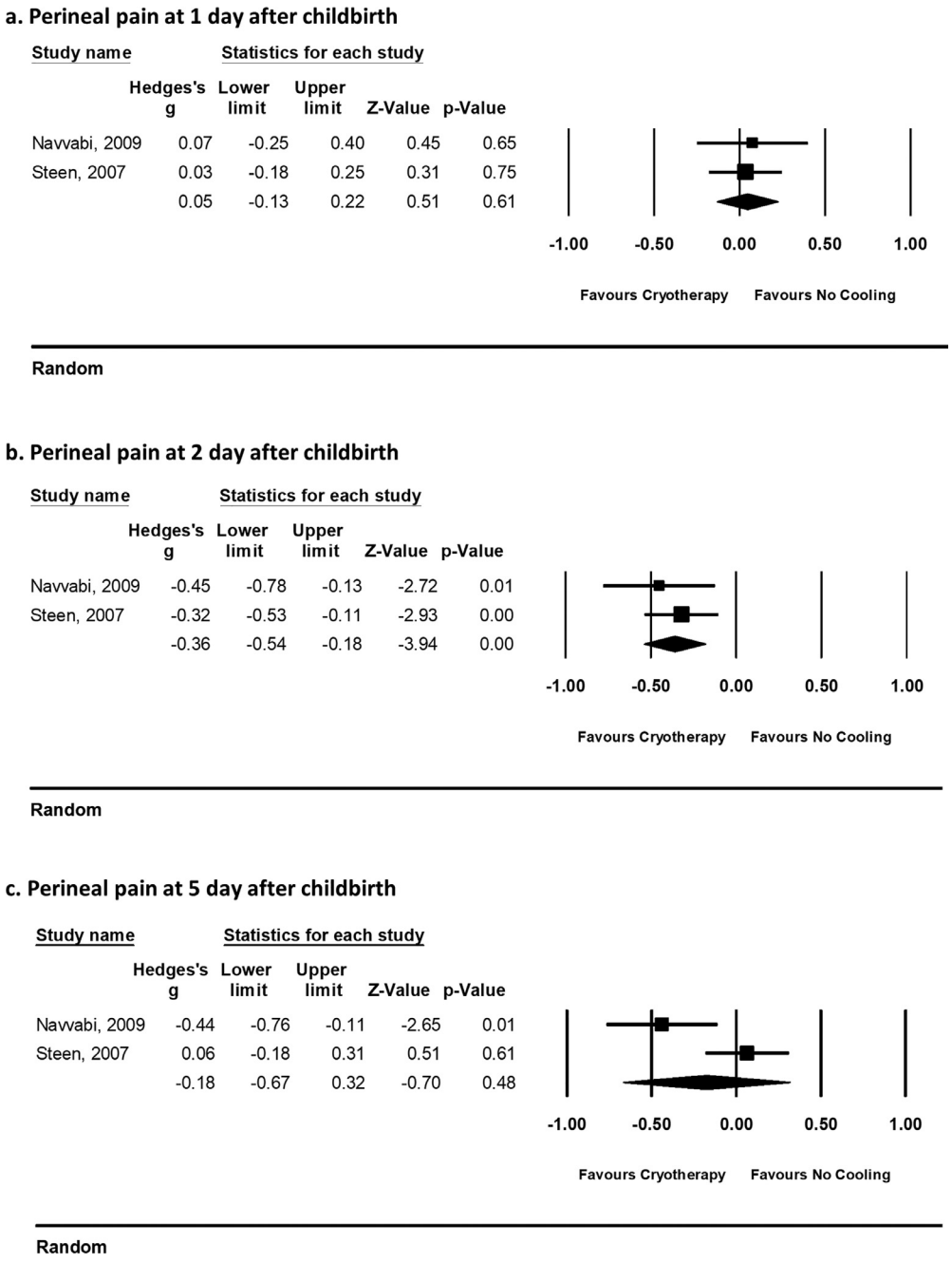

Fig. 3. Forest plot for perineal pain after childbirth, comparing any cryotherapy versus no localized cooling.

pain did not differ between the groups (Hedges' $g = -0.23$, 95% CI $= -0.47$ to 0.01, $p = 0.052$), and the effect size was not heterogeneous ($Q = 1.00$, $p = 0.610$, $I^2 = 0.0\%$, Fig. 4b). Pooling of the results indicated that the severity of pain in the cold gel pack group was significantly lower than the ice pack group five days after childbirth (Hedges' $g = -0.41$, 95% CI $= -0.66$ to -0.16, $p = 0.002$). The effect size was not heterogeneous ($Q = 1.22$, $p = 0.540$, $I^2 = 0.0\%$, Fig. 4c).

Effects of cryotherapy: comparison of cryotherapy (cold gel pack or ice pack) versus other therapy (Epifoam)

Four studies (Gallie et al., 2003; Moore and James, 1989; Steen et al., 2000; Sheikhan et al., 2011) compared cryotherapy with other treatments such as pulsed electromagnetic therapy (PEMG), warm sitz baths, and Epifoam (hydrocortisone acetate foam) treatment. One study comparing ice packs with PEMG indicated that megapulse therapy was more effective in reducing perineal pain than local ice pack application (Gallie et al., 2003). In a study comparing cold gel packs with warm sitz baths, women who received cold gel packs reported lower pain levels four hours, 12 h and five days after episiotomy (Sheikhan et al., 2011).

Since the above two studies used different control groups, only the two studies comparing the effects of cold therapy and Epifoam therapy (Moore and James, 1989; Steen et al., 2000) were included in the meta-analysis. Moore and James (1989) reported that there were no significant differences in pain relief among Epifoam, hamamelis water, and ice pack groups. In this study, only the Epifoam group was selected and analyzed as a control group. Steen et al. (2000) found no differences among ice packs, cold gel

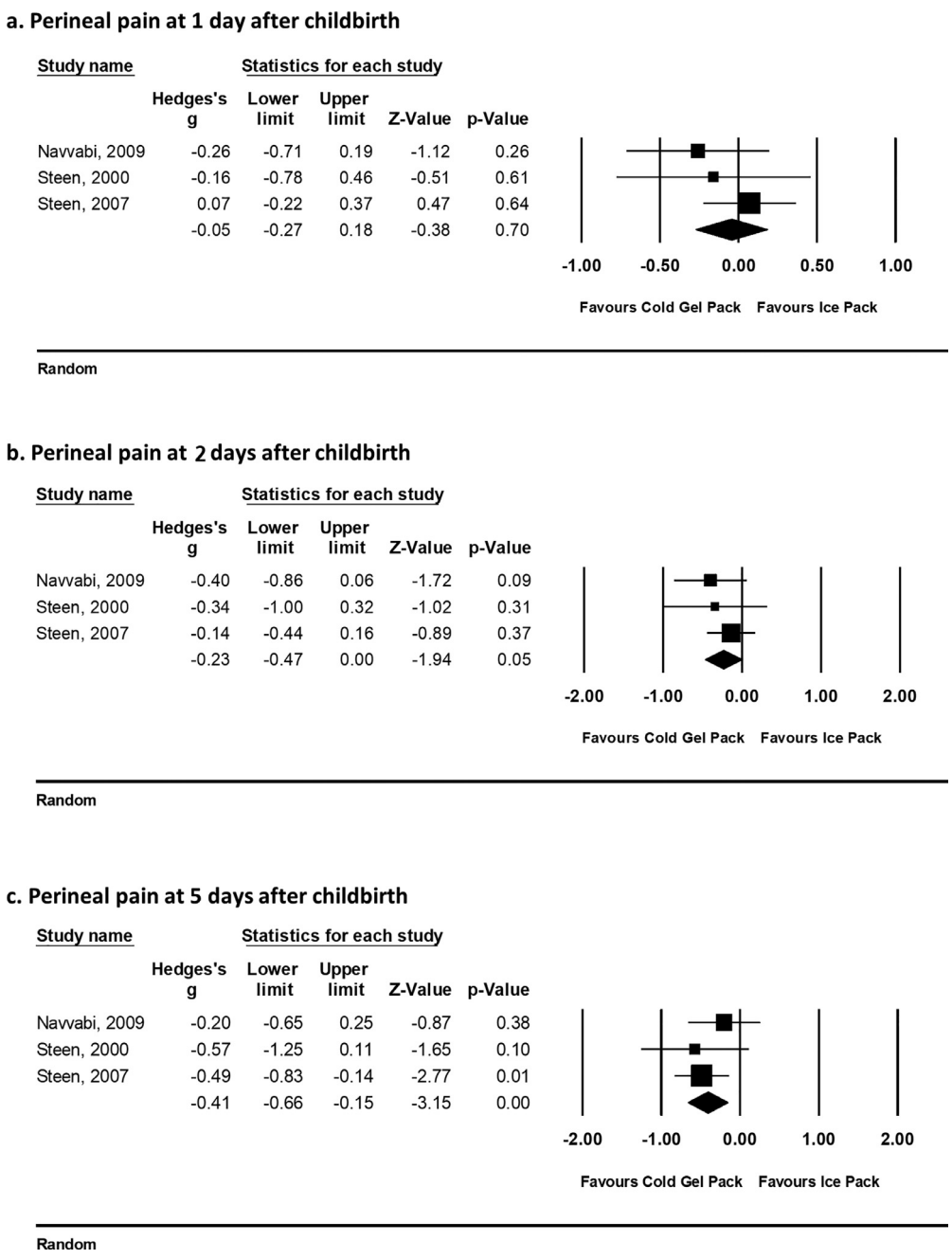

Fig. 4. Forest plot for perineal pain after childbirth, comparing gel pack versus ice bag.

packs, and Epifoam, and indicated that gel packs significantly reduced the reported pain at 48 h in women who initially demonstrated moderate or severe pain. For purposes of the study, cold gel packs and ice packs were regarded as the same type of cryotherapy and used the mean effect size of the two groups as the effect size of the intervention group.

The common time points of pain measurement in both studies were one and five days after childbirth. In the meta-analysis, perineal pain one day after childbirth did not differ significantly between the cryotherapy and Epifoam groups (OR = 0.88, 95% CI = 0.49 to 1.57, $p = 0.664$), and there was no heterogeneity ($Q = 0.03$, $p = 0.860$, $I^2 = 0.0\%$, Fig. 5a). Perineal pain five days after childbirth also did not differ significantly between the groups (OR = 0.70, 95% CI = 0.32 to 1.52, $p = 0.366$) or exhibit heterogeneity ($Q = 0.19$, $p = 0.660$, $I^2 = 0.0\%$, Fig. 5b).

Discussion

This study attempted to confirm the effects of cryotherapy on perineal pain after childbirth by conducting a meta-analysis after a systematic review. Unlike previously published reviews have included both randomized and quasi-randomized trials; this review selected only 11 RCTs.

Seven papers (Beleza et al., 2017; Francisco et al., 2018; Leventhal et al., 2011; Moore and James, 1989; Navvabi et al., 2009; Sheikhan et al., 2011; Steen and Marchant, 2007) reported that cryotherapy effectively reduced perineal pain. The time to achieve effective pain reduction by applying local cold therapy was reported as 10 min, 20 min, 1 h, 2 h, 4 h, 12 h, 2 days, 3 days, 5 days, or 10 days after childbirth, respectively. Because the studies included in this review used different cryotherapy application

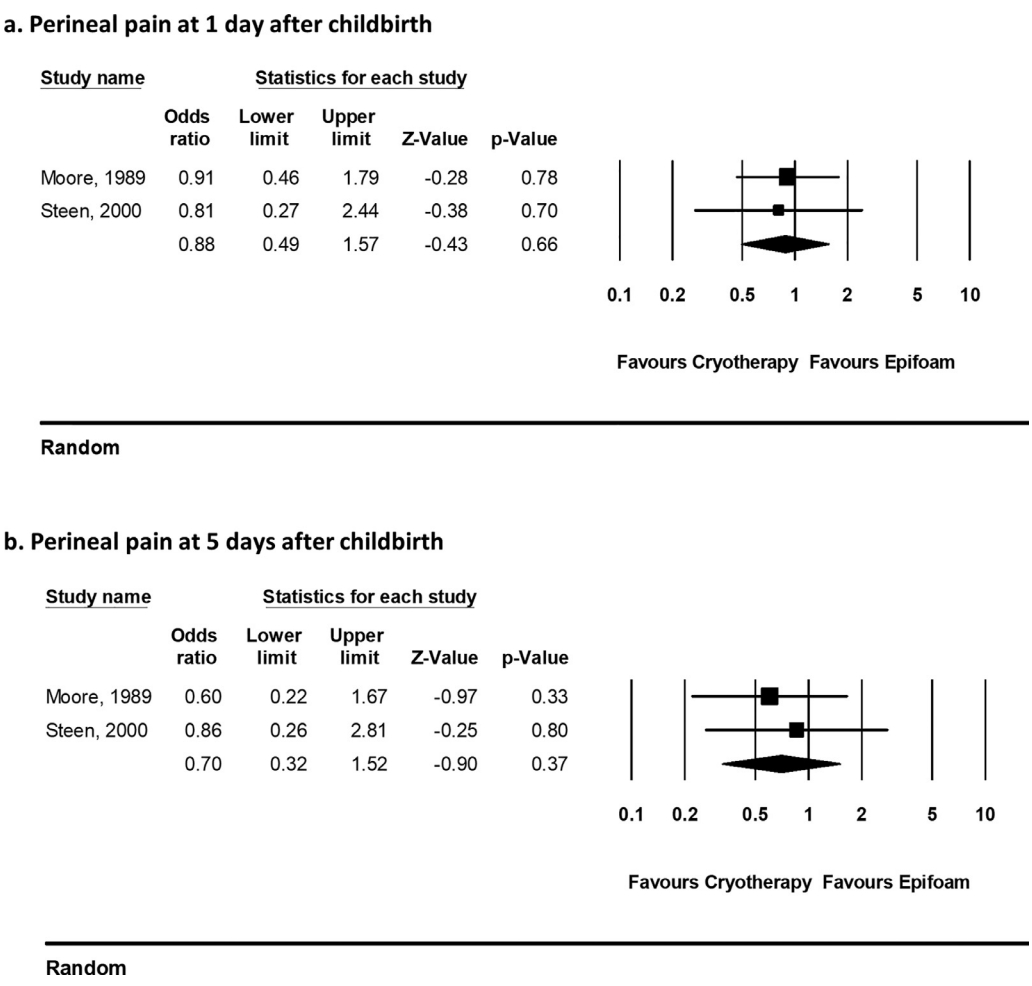

Fig. 5. Forest plot for perineal pain after childbirth, comparing cryotherapy versus Epifoam.

methods and the pain was assessed at different times, each study showed different effective times.

The overall effect size was significantly different, and a low heterogeneity was observed only on the second postpartum day. Similarly, a prior systematic review reported that women who received cryotherapy between 24 and 72 h postpartum exhibited a significant reduction in pain (East et al. (2007). In the two studies included in the analysis, researchers mentioned they applied the cooling within half an hour of suturing or four hours after childbirth, but the time when the actual application of the cooling treatment to each subject was not specified, suggesting that there might have been differences. In addition, each study showed pain reduction effects on the second postpartum day, as the assessment time of the perineal pain varied from minutes to hours after childbirth.

Episiotomy may be a major risk factor for perineal pain. However, among 11 RCTs included in this review, women who had received episiotomy were included all in 5 studies, partially included in 5 studies, and no included in 2 studies. Because the number of studies included in the meta-analysis in this study is very small, it is difficult to quantitatively evaluate the sensitivity analysis.

Most of all, it is unclear whether the intended cryotherapy has been completed because the studies included in the meta-analysis did not provide the frequency and duration of cold application. Therefore, there is little evidence to determine the effects of cryotherapy. In the future, it is necessary to accumulate RCTs with specific protocols of the cryotherapy and similar pain measurement plans, based on which the overall effect of the cryotherapy on perineal pain needs to be accurately evaluated.

The most commonly used tools for cryotherapy were gel packs and ice packs. When the effects of gel packs and ice packs on pain were compared, the overall effect size did not differ significantly. This was interpreted as a meaningful result when considering the process of preparing cryotherapy. When an intervention tool is prepared with ice, water must be frozen or crushed ice must be placed in a bag or glove, whereas a gel pack can be applied immediately if it is frozen. Thus, gel pack therapy may be more convenient in view of the need for efficiency in nursing work. However, since the included studies did not address the issue of cost, it will be necessary to evaluate the cost effectiveness of different forms of cryotherapy in future research. According to a study about cost of cryotherapy tools, commercialized gel packs cost $2.06 apiece, whereas commercialized cold packs cost $1.79 apiece, and latex gloves cost $0.03 apiece (Peterson, 2011). Thus, it is expected that greater costs will be incurred when relatively commodified products are used. Nurses and other health professionals should consider the both the convenience and cost of cryotherapy.

In this comparison of the pain reduction effects of cold therapy and other interventions, it was difficult to draw conclusions because the results were as diverse as the compared interventions. However, cold therapy did not differ significantly from topical Epifoam treatment in its pain-reducing effects. Epifoam is an alternative form of treatment in which anti-inflammatory steroid-based foam is applied directly to the perineal injury (Steen et al., 2000). Although only two papers were included in this portion of the

analysis; study results indicated that cryotherapy was as effective as Epifoam treatment for pain reduction.

This systematic review of the application method of cryotherapy revealed that an insufficient number of studies mentioned detailed information about the diversity and size of the tools, the posture of the patients, and the application start time of cryotherapy. Only two studies mentioned that the cryotherapy was applied while the patients were in the dorsal recumbent position (Beleza et al., 2017; Francisco et al., 2018), and it was difficult to confirm whether the cryotherapy was applied while the patients were walking. In addition, the application time of cryotherapy varied from a short period of time to several days, making it difficult to determine the complete cold application time. The cold application tool was reported to be rectangular in four studies (Beleza et al., 2017; Francisco et al., 2018; Leventhal et al., 2011; Yusamran et al., 2007). It was difficult to draw conclusions on the optimum starting point for cryotherapy, since the starting point varied according to the postpartum condition of the subject. However, in the early postpartum period, other symptoms such as hemorrhaging and edema may be present, so cryotherapy should be applied with consideration of the subject's overall condition.

When cryotherapy is applied to the surface of the body, the epidermal tissue will lower the skin temperature within 2 to 5 min, resulting in immediate cooling. Twenty minutes later, the deep muscle tissue covered by about 2.5 cm of subcutaneous fat will decrease in temperature by about 5 °C (Palastanga, 1988). The studies included in this systematic review employed 15 to 20 min of cryotherapy to maintain a therapeutic temperature. A previous study suggested that patients receiving cryotherapy should be carefully observed for side effects such as cold allergies, chills, frostbite, headaches, and the hunting response, a cycle of vasoconstriction and vasodilation (Shin et al., 2018). The studies included in this review did not investigate adverse effects of cryotherapy aside from the therapeutic temperature, so caution is needed when providing cryotherapy.

When cryotherapy is applied directly or wrapped with gauze before being applied to the perineal wound after childbirth, attention must be given to the risk of infection (Petersen, 2011). When nurses or other professionals apply cryotherapy, they should use a new cold application tool each time, and nursing activities should be included to prevent infection if a tool is reused. Only two reports (Steen et al., 2000; Steen and Marchant, 2007) included in this review mentioned that the midwife cleaned the cold application tool with hot water or soap, dried it and reapplied it. When a saline bag was applied, it was discarded after use to prevent infection (Steen and Marchant, 2007).

The major countries in which studies included in this review were conducted were Brazil, Iran, and the UK, and no studies were conducted in East Asian countries such as Korea and Japan. This probably reflects differences in cultural perceptions of postpartum care. Some studies in Korea have confirmed the effectiveness of postpartum cold therapy (Nam and Park, 1991), but there is still a relatively negative perception of postpartum cold therapy in Korea due to the unique belief and practice system of postpartum care known as "Sanhujori" (Yoo, 1998). In view of one of the basic principles of "Sanhujori," Yoo (1998) recommended warming the body, avoiding cold or using alternatives to cold therapy after childbirth. Thus, cryotherapy research is rare in Korea due to the Korean custom of keeping the body warm after childbirth. As such, the research included in this study may reflect specific cultures, and a woman's cultural background should be considered when a postpartum care method is chosen.

The quality of the 11 RCTs included in this study was evaluated with the Cochrane RoB 2 tool. Most of the included studies were some concerns of risk of bias in the randomization process, but because of the nature of the intervention, the participants were difficult to blind. Most studies had a high risk of bias in measurement of the outcome. Thus, the results may have been affected by the assessments of evaluators who knew which interventions were applied to the subjects. Therefore, future studies should be designed not only to randomize the subjects, but also to blind the patients and the outcome assessment.

Only three studies had a low risk of bias due to deviation from the intended intervention. The deviation from the intended intervention is a domain that was not included in the existing RoB tool. In this review, each study was evaluated with the RoB 2 tool, including a domain of deviation from the intended intervention. Since the RoB 2 tool is a rigorous evaluation tool, it is believed that risk of bias of included RCTs in this review was higher than in a previous SR (East et al., 2012a).

The effects of cryotherapy were heterogeneous over time, and the type, application time, and application period of cryotherapy varied. The application tools of cryotherapy were mainly cold gel packs, ice packs, and saline packs. The start time of cryotherapy varied from immediately after childbirth to two, four, or 24 h after childbirth. The application time for cryotherapy was 15 to 20 min, like the general cryotherapy application time, but there was insufficient information about the total application time and application frequency. Repeated research and expanded studies will be needed to establish standardized guidelines for applying cryotherapy in clinical nursing practice.

The limitations of this study are as follows. First, it was difficult to obtain consistent results because the starting points, durations, and application frequencies of cryotherapy varied among the studies. Second, the internal validity of the meta-analysis was low due to the insufficient number of well-designed studies. Enough studies are needed if various analyses are to be performed in a meta-analysis.

Conclusion

The researchers conducted this study to determine the effects of cryotherapy on pain after child birth and to provide suggestions for cryotherapy interventions based on nursing practice. They found that cryotherapy was typically started within 24 h (immediate after to 24 h) after child birth and was effective in alleviating pain two days postpartum. Ice packs and gel packs had similar pain-relieving effects, allowing for the selection of the most convenient method for clinical nursing practice. Cryotherapy was as effective as Epifoam treatment for pain reduction after childbirth. Therefore, the cryotherapy can be optionally applied in consideration of the women's preference under the clinical judgment of health professionals for the reduction of perineal pain after childbirth. The results of this study should be applied with caution because of the small number of articles analyzing the cryotherapy intervention method. Further studies are needed to verify the effects of different tool types, application times, and durations of cold therapy after childbirth. In addition, as no studies monitored patients for adverse effects of cryotherapy, further studies are needed to evaluate such side effects.

Ethical approval

This systematic review was not considered by the Ethic Committee.

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The authors declare that they have no competing interests.

CRediT authorship contribution statement

Hyun-Jung Kim: Conceptualization, Writing - original draft, Software, Writing - review & editing. **Ji-Won An:** Data curation, Software, Validation, Visualization, Writing - original draft. **Yoonyoung Lee:** Methodology, Validation, Writing - original draft. **Yong-Soon Shin:** Conceptualization, Funding acquisition, Validation, Writing - original draft, Writing - review & editing.

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