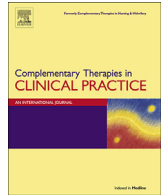




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Birth ball or heat therapy? A randomized controlled trial to compare the effectiveness of birth ball usage with sacrum-perineal heat therapy in labor pain management



Simin Taavoni ^a, Fatemeh Sheikhan ^b, Somayeh Abdollahian ^{c,*}, Fatemeh Ghavi ^d

^a Iran University of Medical Sciences, Research Institute for Islamic & Complementary Medicine (RICM, IUMS), Tehran, Iran

^b Department of Midwifery, Faculty of Midwifery, Khalkhal Branch, Islamic Azad University, Khalkhal, Iran

^c Department of Midwifery, Firoozabad Branch, Islamic Azad University, Firoozabad, Iran

^d Department of Nursing and Midwifery, Jahrom University of Medical Sciences, Jahrom, Iran

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ABSTRACT

Objective: Labor pain and its management is a major concern for childbearing women, their families and health care providers. This study aimed to investigate the effects of two non-pharmacological methods such as birth ball and heat therapy on labor pain relief.

Material & methods: This randomized control trial was undertaken on 90 primiparous women aged 18–35 years old who were randomly assigned to two intervention (birth ball and heat) and control groups. The pain score was recorded by using Visual Analogue Scale (VAS) before the intervention and every 30 min in three groups until cervical dilatation reached 8 cm.

Results: The mean pain severity score in the heat therapy group was less than that of in control group at 60 and 90 min after intervention ($p < 0.05$). In addition there were significant differences between the pain scores in the birth ball group after all three investigated times in comparison to control group.

Conclusion: Both heat therapy and birth ball can use as inexpensive complementary and low risk treatment for labor pain.

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1. Introduction

Pain has been promoted as the fifth vital sign for a decade, but there is little empirical evidence to suggest that doing so has affected the care of individuals suffering pain [1]. Labor pain is unique and complex and an improved understanding of labor pain will assist in informing and enhancing pain management approaches [2]. The use of complementary and alternative medicine (CAM) and complementary and alternative therapies (CAT) during pregnancy is increasing. Scientific evidence for CAM and CAT in the field of obstetrics mainly covers pain relief in labor. Midwives are responsible for labor and delivery care: hence, their knowledge of CAM and CAT is important [3]. There is evidence of high use of complementary and alternative medicine (CAM) by pregnant women but despite debate and controversy regarding CAM use in pregnancy there has been little research focus upon the impacts of

CAM use on birth outcomes [4]. The documentation of pain in the labor and delivery setting is one of the essential tasks of all health care providers who care for women in labor [5]. Another 20th-century theory was gate control theory, introduced by Ronald Melzack and Patrick Wall [6]. The authors stated that the more large fiber activity (touch, pressure, vibration) relative to thin fiber activity (pain) at the inhibitory cell, the less pain is felt [7]. It means that inhibiting the transmission of noxious stimuli can be done by stimulating large nerve fibers that have been shown to alter pain perception [8]. This theory helps to explain the effectiveness of various labor pain relief methods such as dry needling, acupuncture, intense cold, intense heat, breathing, listening to music, verbal coaching, and back massage [9,10]. One of the popular non-pharmacological techniques is heat therapy applied to the sacral-perineal area during labor [11]. Heat therapy got its usage during ancient civilizations. Heat therapy often finds it is most wide range appeal in it is relatively low expense and also being easy to apply [12]. From last decades heat therapy has been used for pain relief during labor and it can be applied on different parts of pregnant women [13]. Ganji et al. and also Dahlen et al. showed that heat

* Corresponding author.

E-mail address: s.abdollahian59@gmail.com (S. Abdollahian).

therapy is an effective method for reducing labor pain in various phases to our knowledge no study has been evaluated the effects of perineal heat therapy on labor pain management in first stage of labor. Another popular non pharmacologic technique is movement and change of position during the first stage of labor [14,15]. Upright position during labor has several potential mechanical advantages, including the effect of gravity and increased pelvic dimensions, which might decrease the need for instrumental births [16]. Sitting on birth ball and pelvic movement is one kind of upright position. In the literature there is no comparison between the heat therapy and birth ball in reducing labor pain. Therefore our research group decided to compare the effectiveness of the use of birth ball and sacral-perineal heat therapy on labor pain and duration of the active phase of physiologic labor.

1.1. Subjects and methods

In this randomized control trial design, a convenience sample of 90 volunteer primiparous women was recruited from one of the largest general public hospital of Iran University of Medical Sciences, Tehran- Iran. To provide an acceptable sample size, the following formula was used with a significance level of 0.05, a power level of 0.80 with an anticipated effect size $d = \text{difference of means/standard deviation} = 2.5$. The minimum sample size for this study was estimated 26 in each group. The study protocol was approved by the ethics committee of Iran University of Medical Sciences, Tehran- Iran. Inclusion criteria were 18- to 35-year-old primiparous women with one pregnancy, cephalic presentation of infant, 38–40 weeks of gestation, anticipating a normal birth and without a history of infertility. If there was a need for analgesic medication or if obstetric complications occurred, the participant was immediately referred to an obstetrician and other professionals as needed, and then removed from the study. First the investigator, MSc midwifery student, described the aim of study for participants and they were informed that heat therapy and birth ball usage is being studied for its effects on their labor pain and whether it provides a satisfactory childbirth experience. Then consent forms were signed by the subjects and those in the first stage of active phase with cervix dilatation between 4 and 8 cm were randomly allocated into two intervention (heat therapy and birth ball) and control groups, while the pregnant women in latent phase were observed till their active phase started. Randomization was assigned by the investigator using a randomization table.

In heat therapy group, the participants were in reclining position during the study and the investigator applied warm packs to the participants' sacral and perineal area. A warm moist towel soaked in boiled tap water at a temperature of roughly 45 °C was used as a warm pack. Subjects were asked to hold and fix the pack with their closed thighs for at least 30 min. The subjects were asked to check the towel's heat by their hands to avoid burning or discomfort. Pain scores were recorded by the investigator every 30 min till the dilation has reached 8 cm. During these periods, the subjects were asked to inform the investigator to replace the towel when it became cold.

In the birth ball group, women were instructed to sit on the ball and rock their hips for a minimum of 30 min. The participants were instructed to sit on the ball while their arms rested extending to their sides and then start to rock their hips back and forth or around in a circle. Although participants should have been able to maintain their balance on the ball during these exercises, the professional attending the session gave the women support.

Because there are not enough complementary therapy devices in the most Iranian hospitals, women usually do not receive any facility for pain management. Therefore, to simulate routine labor process, in the control group, the subjects received customary care

during labor. No pain management intervention was provided to the control group. In the routine labor care in Iran, patients are in a reclining position without ambulating or any other intervention. Accessible intravenous line is provided at the bedside and usual clinical examinations, i.e., station, dilatation, effacement measurement, are performed every 2 h, and fetal heart rate is monitored every 30 min throughout the active phase of labor. All stages of labor in 3 groups were completed in a labor room with equal environmental conditions such as room temperature, light, sound, and equipment in a similar time of the day.

In three groups, demographic characteristics such as age, education level, gestational age, and occupation were collected from the medical records of participants. Clinical examination was performed by the investigator to record dilatation, effacement, station, position, duration and interval of uterine contraction, and fetal heart rate. During the study, the investigator was supervised by an experienced midwife (MSc Midwife, Senior Lecturer). Before the study, the supervisor evaluated and confirmed the investigator through taking cervical dilation measurements, and the intra-examiner reliability had been considered acceptable.

The pain score was recorded using visual analog scale (VAS). In this method, pain is quantitatively scored charted on an analog linear horizontal 0- to 10-cm scale (0 = no pain, 10 = intolerable pain). Pain scores were measured in three groups before the intervention and then recorded every 30 min in three groups until cervical dilation reached 8 cm.

To reduce the potential for bias, investigators were instructed not to give verbal information about the possible effects of intervention before and during the subjects' participation in the study. Also, the individual responsible for data analysis was masked to the study purposes to minimize any bias that might arise from knowledge about the study. This ensured us that, as far as possible, differences came only from the effect of two interventions.

The demographic characteristics were analyzed by *t*-test and chi-square. *P* values less than 0.05 were considered significant.

2. Results

Ninety primiparous women were enrolled in this study. Two participants from the heat therapy group and one from the control group were excluded because they needed a cesarean section caused by the lack of fetal head descent and fetal heart rate deceleration. Demographic characteristics of subjects (mean age, educational level, occupation) which are shown in Table 1 were not significantly different between groups. ($P > 0.05$). The majority of the participants were aged 18–24 years and were housekeepers, and had finished high school education. Mean pain scores in control and intervention groups showed in Table 2. There was no significant difference between the pain scores of the women before intervention in three groups. There was no significant difference between the pain scores of the women in heat therapy and control groups after 30 min ($p = 0.056$), but the mean pain severity score of the heat therapy group was significantly less than the score in the control group in other periods (60 and 90 min after intervention). There were significant differences between the pain scores of the women in the birth ball group after 30-min ($P = 0.001$), 60-min ($P = 0.001$), and 90-min interventions ($P = 0.001$) when compared with the pain scores of the women in the control group. The mean score of pain severity in the birth ball group was significantly less than that of the control group (Table 3).

Mean duration of active phase of labor in the intervention groups and the control group showed in Table 4. There was no significant difference between the mean duration of active phase of labor of the women in three groups.

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