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Castor oil for induction of labor in post-date pregnancies: A randomized controlled trial

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ABSTRACT

Background: Castor oil is a substance used for labor induction in an inpatient setting. However, its efficacy as an agent for the induction of labor, for post-date pregnancies in an outpatient setup is unknown.
Objective: Efficacy of castor oil as an agent for the induction of labor, for post-date pregnancies in outpatient settings.
Methods: Eighty-one women with a low-risk post-date singleton pregnancy with a Bishop score ≤ 7, without effective uterine contractions were randomized to the intervention, 60 ml of castor oil, or the control, 60 ml of sun-flower oil. The primary outcome was proportion of women entering the active phase of labor 24, 36, 48 h after ingestion. Secondary outcomes included meconium stained amniotic fluid, abnormal fetal heart rate tracing, cesarean section rate, instrumental deliveries, birth weight, 5 min Apgar score, chorioamnionitis, hypertensive complications, retained placenta, and post-partum hemorrhage.
Findings: Intervention and control groups included 38 and 43 women, respectively. No differences in baseline characteristics, except for age were noted. The observed interaction between castor oil and parity was significant ($p_{interaction} = 0.02$). Multiparous women in the intervention group exhibited a significant beneficial effect on entering active labor within 24, 36 and 48 h after castor oil consumption compared with the placebo (Hazard Ratio = 2.93, p = 0.048; Hazard Ratio = 3.29, p = 0.026; Hazard Ratio = 2.78, p = 0.042 respectively). This effect was not noted among primiparous women. No differences in rate of obstetric complications or adverse neonatal outcomes were noted.
Conclusion: Castor oil is effective for labor induction, in post-date multiparous women in outpatient settings.

Statement of significance

Problem or issue

Is castor oil a safe and effective substance for labor induction in the outpatient setting?

What is already known

Castor oil is a substance used for labor induction in an inpatient setting.

What this paper adds

Castor oil is effective for labor induction, in post-date multiparous women in outpatient settings.

1. Introduction

Post-term pregnancy refers to a pregnancy that has reached or extended beyond 42 + 0 weeks' gestation, and late-term pregnancy is defined as a pregnancy between 41 + 0 and 41 + 6 weeks

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gestation.[1,2] Both late- and post-term pregnancies are referred to as post-date pregnancies. Five to ten percent of pregnancies will not end spontaneously even after 42 weeks gestation.[2,3] Post-date pregnancy is a risk factor for fetal distress, meconium staining of amniotic fluid, cesarean section (CS) Intra-uterine Fetal Demise, and neonatal death.[2,4] The standard of care in our facility for women who present with postdate pregnancies is expectant management with bi-weekly fetal assessment including a biophysical profile (BPP) and a non-stress test (NST) until week 42. Labor is induced in cases of an abnormal BPP and\ or a non-reassuring NST or at gestational week 42 + 0.

In several studies, labor induction for post-date pregnancies was shown to improve outcomes when compared to awaiting the onset of spontaneous labor.[5–7] The Cochrane Review summarized 22 trials including 9383 women. This meta-analysis showed that labor induction at 41 + 0 weeks gestation was associated with fewer perinatal deaths as compared with follow-up only. There was no statistically significant difference in the risk of CS for women induced at 41 + 0 weeks when compared to women induced at 42 + 0 weeks. However, in the latter group, neonates were more likely to have meconium aspiration syndrome. The Cochrane Review concluded that labor induction at 41 + 0 weeks gestation should be offered to low-risk women as it is associated with fewer cases Intra-uterine Fetal Demise, no increase in assisted vaginal or CS rates and is preferable over continued follow-up until spontaneous labor occurs or later induction of labor.[3]

Castor oil, a naturally produced oil from the *Ricinus communis* plant, has been traditionally used by midwives as an agent for the induction of labor. McFarlin et al. showed that castor oil was the most widely used natural substance for induction of labor among 500 surveyed midwives.[8] Davis' retrospective non-randomized study of 196 women demonstrated that castor oil can be used safely and effectively to stimulate labor in uncomplicated, singleton, term pregnancies with premature rupture of membranes (PROM).[9] In a prospective trial, Garry et al. showed its efficacy to be better than non-treatment for labor induction in 80 post-date pregnancies[10] and Beiranvand et al. in 47 post term women.[11] In contrast, Kahnamoyiagdam et al. recently published a non-randomized and non-placebo controlled clinical trial of 100 women that demonstrated inefficiency of castor oil as an agent for the induction of labor.[12] However, the effects of castor oil on induction of labor in post-date pregnancies have not been assessed in a randomized placebo controlled trial in an outpatient setting. The aim of our study was to test the efficacy and safety of castor oil to induce labor in low-risk post-date pregnancies in the outpatient setting.

2. Materials and methods

This prospective, randomized, double-blind, placebo-controlled clinical trial was approved by the Ethics Committee (0280-08-HMO), and registered at clinicaltrials.gov (NCT00244738). All participants provided informed consent and were randomly assigned to either castor oil or sunflower oil (placebo). Sunflower oil was chosen as the placebo since it is commonly used in the food industry. The study was conducted at a major tertiary care facility in a large urban center. The study population included Christian, Muslim and Jewish women.

The standard of care in our facility for women who present with postdate pregnancies is expectant management with bi-weekly fetal assessment including a biophysical profile (BPP) and a non-stress test (NST) until week 42. Labor is induced in cases of an abnormal BPP and\or a non- reassuring NST or at gestational week 42 + 0.

Inclusion criteria were: gestational age of 40 +0 to 41 +6 weeks; singleton pregnancy; cephalic presentation; Bishop score ≤ 7; absence of regular uterine contractions; BPP of 8/8; and NST.

Exclusion criteria included: previous CS or myomectomy; oligohydramnion (amniotic fluid index < 50 mm) or polyhydramnion (amniotic fluid index > 240 mm); hypertension (including pregnancy induced); ruptured membranes; suspected intrauterine growth restriction; suspected macrosomia (>4000 gm); fetal genetic or structural malformations; or any contraindication for vaginal delivery.

Women who fulfilled the eligibility criteria at between the years 2006–2011 were approached for participation. The effect of castor oil was evaluated by comparing women who received castor oil (intervention group) with those who received sunflower oil (control group).

Allocation sequence was generated by the hospital's pharmacy via a computer generated random list. The pharmacist filled sequentially numbered identical dark plastic bottles with either castor oil or sunflower oil. Women were assigned a sequential study number ranging from 1 to 82. After randomization, each woman was given a bottle with her study number. The allocation list was kept securely in the pharmacy department until trial completion.

Sunflower oil is quite similar to castor oil in terms of color, taste and consistency. We conducted a blinded pilot taste and smell study to verify that the two oils were indistinguishable once admixed with orange juice. Therefore, it was impossible for both care providers and women to distinguish between the two oils. The intervention group received 60 ml of castor oil orally and the control group received 60 ml of placebo (sunflower oil). The oils were admixed with orange juice and were ingested in the presence of a midwife. Participants remained in the delivery room for 30 min to ascertain that there was no vomiting.

Participants were instructed to return to the delivery room for the following indications: regular contractions, ruptured membranes, decreased fetal movements, vaginal bleeding, or after 24 h from drinking the oil in the absence of any of the aforementioned events.

Follow-up examinations included BPP, NST and vaginal examination to determine the Bishop score. In cases of an abnormal BPP, non-reassuring NST or the presence of any other indication the patient was immediately admitted for labor induction.

Women who were not in labor and their follow-up was reassuring, were asked to return to the study walk-in clinic every 24 h. Follow up examination included measurement of BPP and NST until delivery. Women who reached 42 + 0 week gestation were referred to the delivery room for formal induction of labor, per standard clinical protocol.

The primary outcome was time to the spontaneous, active phase of labor, defined as cervical dilation of 3 cm or more, or cervical effacement of 80% or more, and regular uterine contractions of at least 2 contractions in 10 min. Secondary outcomes included meconium staining of amniotic fluid, abnormal fetal heart rate tracing, mode of delivery, indications for CS, birth weight, 5 min Apgar score, maternal febrile and hypertensive complications, retained placenta and post-partum hemorrhage (PPH).

Given a spontaneous delivery rate of 4.2% within 24 h in the control group[10], we calculated a sample size of 82 women (41 in each group), based on a two-tailed test with $\alpha = 0.05$, 80% statistical power and an expected increase of approximately 20% in the percentage of women entering labor within 24 h following castor oil administration. This effect size was conservatively estimated as less than half of the effect shown by Garry et al. where the effect of castor oil was compared to no treatment.[10]

A total number of 205 eligible women were approached. Of the 82 recruited women, 38 were randomly assigned to the intervention (castor oil), and 44 were randomly assigned to the control

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