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Effectiveness of Castor Oil in Preventing Formal Induction of Labour at a Tertiary Institution: A Randomized Controlled Trial.

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ABSTRACT

Objective: To evaluate the effectiveness of castor oil in the prevention of formal induction of labour amongst pregnant mothers with prolonged pregnancy.
Design: This was a randomized controlled trial
Setting: Antenatal ward, Alex Ekwueme Federal University Teaching Hospital Abakaliki (AEFUTHA), Ebonyi State Nigeria.
Participants: Clients aged 20-44 years at gestational ages from 41weeks and 41 weeks and 2 days.
Interventions: Group A received 30ml of castor oil and Group B received 30ml of water. These doses were repeated after 24 hours for participants that failed to enter spontaneous labour.
Main outcome measure: The proportion of participants who achieved spontaneous onset of labour and the proportion of women who have the need for formal induction of labour
Results: In group A (castor oil arm) 52% and 16% in group B (water arm) had spontaneous labour; while 41% in the castor oil group and 77% in the water arm had formal induction of labour. This difference was statistically significant (P value <0.001). The mean duration of drug ingestion –delivery interval was 15.69 hours ±6.94 and 17.92 hours ±6.78 for castor oil and water respectively. This was statistically significant (P value 0.025). There was no significant difference in the newborn side effects. However, there was significant difference in the maternal side effect with a P value <0.001
Conclusion: Castor oil compared to water was more effective in the prevention of formal induction of labour and reduction of duration of labour.

Keywords: Prolonged pregnancy, castor oil, induction of labour, water, tertiary

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INTRODUCTION

Pregnancy is said to be prolonged when it has gone beyond 42 weeks or 294 days from the first day of the last menstrual period.[1] Any pregnancy that has gone beyond the expected date of delivery (40 weeks from the first day of the last menstrual period) is termed a postdate pregnancy.[2,3] Prolonged pregnancy is a high-risk pregnancy associated with perinatal complications and it is the commonest indication for labour induction. [4] It is fraught with a higher likelihood of meconium aspiration syndrome, neonatal sepsis, postpartum haemorrhage, shoulder dystocia and birth traumas such as bone fracture.[1,5,6] There are also neurological complications such as, hypoxic ischaemic encephalopathy, neonatal convulsion, developmental deviation, cerebral palsy and epilepsy in childhood,[5] as such, no obstetrician will allow a patient get to 42 weeks before delivery.

Induction of labour for postdatism has been proven to have a better outcome in contrast to awaiting the spontaneous onset of labour.[6,7] National Institute of Clinical Excellence recommends induction of labour from 41+0 to 42+0 weeks, then expectant management and fetal monitoring commenced at 42 weeks.[8] At Alex Ekwueme Federal University Teaching Hospital Abakaliki, induction of labour is commenced from 41 weeks + 3 days to prevent post term pregnancy and its associated complications. Most women often still perceive induction of labor as an interference with the natural course of labor and evaluate it negatively on an emotional level. [9]

Various methods are used to induce labour including membrane sweeping, amniotomy, and pharmacological methods such as the use of prostaglandins and oxytocin. [7,10,11] However, women who have their labour initiated artificially have a tendency to be less fulfilled with the childbirth experience than women who did not undergo induction of labour[12] Irrespective of the agent used induction of labour seems to be a safer option when compared to Caesarean section.[13] Traditionally, people have tried various alternative therapies for induction of labour. They include; herbal remedies, castor oil, acupuncture, homeopathy and self-administered techniques like nipple stimulation.[7]

Castor oil has been used far and wide as a traditional method of initiation of labour by midwives and its use dates back to ancient Egypt. [1,6,7,11,14-16] Its function in initiation of labour is not well understood[15-17]. However in the uterus, it is thought to have a strong cathartic effect and this could probably be a prostaglandin mediated effect.[7,11] Ingestion of castor oil leads to the release of ricinoleic acid by intestinal lipases some of which are reabsorbed in the intestines and this leads to a strong laxative effect.[6,11,15,16] Studies in animals have shown that ricinoleic acid activates EP_3 prostanoid receptor and this leads to smooth muscle contractions[17] Castor oil has been used widely in obstetric practice to induce labour without recommendation. [11]A national survey conducted by American College of Nurses and Midwives showed that majority of the nurses recommended its use for induction of labour. [18] Okoro et al in Nigeria found that administration of 60ml oxytocin reduced the incidence of prolonged pregnancy and need for formal induction of labour.[19]Despite its widespread usage, there are limited studies on its safety and efficacy[1,15] especially in Nigeria. Untoward effects of castor oil include diarrhoea, nausea and vomiting. [10,11,15]

The widespread off label use of castor oil for labour induction in gravid women without adequate investigation into its proven efficacy, is not in keeping with best practices in medical practice. It is against this backdrop that this work is conceived to assess the effectiveness of castor oil in successfully initiating labour. If found efficacious it could confidently be recommended as a safe cost-effective alternative in labour induction, if not, then there will be no justification to subject women to it with its side effects.

MATERIALS AND METHODS

Study Site

This study was carried out at Alex Ekwueme Federal University Teaching Hospital Abakaliki (AE-FUTHA) with ethics approval number AEFUTHA/REC/VOL3/2020/015. AE-FUTHA came up as a merger of the former Ebonyi State University Teaching Hospital Abakaliki and former Federal Medical Centre Abakaliki in December 2011. It is the only tertiary health facility in the state.

Ebonyi state Nigeria with Abakaliki as its capital city had an estimated population of 438,700 in year 2015. However, it was estimated that as of 2019, the population of Abakaliki was about 775,604. The residents are an admixture of people from diverse ethnicity, predominantly Igbo.

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Majority of the inhabitants are traders and small-scale farmers while others are civil servants, artisans, and politicians with different level of health care facilities as well as private hospital and faith-based hospitals that deliver health care to the populace. Parturients in this locality strongly prefer vaginal deliveries and have an aversion for caesarean section.

AEFUTHA provides care for both primary and referred cases within Ebonyi and the neighbouring states. Both booked and unbooked cases are accepted for management. The Obstetrics and Gynaecology department has five units; each has at least five consultants with varying number of senior registrars, registrars and house officers. Patients are selected for induction of labour based on maternal or fetal indications but commonly due to postdatism. Induction of labour is often carried out in the morning in well selected patients with no contraindication to vaginal delivery. It is done with 10 i.u of oxytocin in 1 litre of dextrose saline. Incremental interval of the fluid is every 30 minutes or 45 minutes depending on whether the patient is less than para 5 or para 5 and above respectively. This incremental interval is continued until the patient attains 3 strong uterine contractions in 10 minutes. Patients on induction of labour are monitored with a cardiotocograph.

Study Design

This was a clinical superiority; open label randomized controlled trial on the effectiveness of castor oil in the prevention of formal induction of labour in the department of Obstetrics and Gynaecology of AEFUTHA.

Study Population

The research included all consenting pregnant mothers who met the inclusion criteria.

Study Duration

The study lasted for period of 10 months starting from 5th March, 2021 to 4th January, 2022.

Inclusion Criteria

1. Gestational age of 41weeks+0day to 41weeks+2days
2. Pregnancies with cephalic presenting fetuses
3. Pregnant women with singleton fetus
4. Absence of contraindications to vaginal delivery
5. Absence of uterine contraction
6. Bishop score ≤ 5
7. Ultrasound confirmed GA in early pregnancy

Exclusion Criteria

1. Pregnant women in latent phase of labour
2. Preterm or term premature rupture of membrane
3. Antepartum haemorrhage
4. Previous Caesarean section and myomectomy
5. Multiple gestation
6. Medical disorders of pregnancy
7. Unsure date

Sample Size

We used the formula by Zhong B for clinical superiority RCT. [20]

$$N = 2 \times \left(\frac{Z_{1-\alpha} + Z_{1-\beta}}{d - d_0}\right)^2 \times P \times (1-P)$$

N = sample size per group, Z = standard normal deviation for a one- or two-sided X, d =the real difference between two treatment group, d_0 =clinically acceptable margin, P =the response rate of standard treatment group

Substituting for,

$Z_{1-\alpha}$=1.645(where α=0.005), $Z_{1-\beta}$=0.845(where β=0.20), d =0.245 (from Okoro et al), d_0 = 0.10 (from Okoro et al),[19] P = 0.171 (from Okoro et al)[19]

$$N = 2 \times \left(\frac{(1.645 + 0.845)^2}{(0.245 - 0.10)^2}\right) \times 0.171 \times (1-0.171)$$

N= 100 per arm.

Informed Consent

At 40 weeks of gestation, pregnant women were counselled about the study and then followed up till 41 weeks. The researchers obtained written consent before enrolling the participants into the study. The study objectives were emphasized to the patients. The participants were told that castor oil or a placebo would be given to them to take orally, and this would neither harm them nor their babies. The participants were also informed that if at any time they felt uncomfortable with the study, they could withdraw their consent without any consequences and that the whole cost of the study would be borne by the researcher.

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Recruitment
All consenting pregnant women who met the inclusion criteria were recruited from the antenatal clinic through simple random sampling method.

Randomization And Concealment
We used a software randomizer® to randomly generate 100 numbers out of the two hundred numbers. Using a simple ballot, the first generated numbers was assigned group A (castor oil group) while the second numbers were assigned the group B (water group).
Group A, the study group received 30ml of castor oil (Bell, son & co (Druggists) Ltd Southport PR9.9AL England) in a plastic bottle from 41 weeks to 41 weeks and 2days. The castor oil was measured into transparent plastic bottle daily by the hospital pharmacist for ease of dispensing. Repeat dose of castor oil was given to any participant who failed to achieve spontaneous labour 24 hours after the first dose.

Group B received 30ml of water in a similar plastic bottle from 41weeks to 41 weeks and 2days. The water was measured into transparent plastic bottle daily by the hospital pharmacist for ease of dispensing and to reduce bias. A repeat dose of water was given to any participant who failed to achieve spontaneous labour 24 hours after the first dose.

Study Procedure
The serially numbered envelopes 1-200, released in batches were kept in a carton inside the antenatal clinic pharmacy. The hospital pharmacist at the antenatal clinic pharmacy prepared the castor oil and water in transparent plastic bottles daily to reduce bias and reaction of the castor oil with the plastic bottles. Participants in group A or B received either 30ml of castor oil or 30ml of water orally, directly observed by the research assistant or the researcher after initial assessment to ascertain that she was not in labour and her Bishop score documented at gestational ages of 41weeks to 41weeks and 2days. The date and time of the intake of castor oil or water were recorded and the participant's phone number and address documented. Patients were educated and counselled to present to the hospital immediately they noticed uterine contraction, rupture of membrane, vaginal bleeding, excessive vomiting and diarrhea or absence of labour after 24 hours of castor oil ingestion for further assessment. When participants presented, an astute examination was done by the researcher to determine if the participant was in labour. This was determined by the presence of painful, palpable uterine contractions with associated cervical dilation and effacement. Those in latent phase of labour were admitted into the antenatal ward for re-evalution later. Those in active phase of labour were managed as per institutional protocol.
A repeat dose of castor oil or water was administered to those who failed to achieve spontaneous labour in any of the groups after 24 hours. However, those who failed to achieve spontaneous labour after the repeat dose were followed up till 41 weeks and 3days when formal induction of labour according to the departmental was commenced.

Outcome Measures
The primary outcome measure is the proportion of women who had need for formal induction of labour and active phase of labour. The secondary outcome measures were, need for augmentation of labour, duration of active phase of labour, drug administration-delivery interval, gestational age at delivery**,** APGAR scores at first and fifth minute and maternal complications like nausea, vomiting diarrhea, need for AOL, gestational age and drug administration-delivery interval.

Follow Up
The participants and their newborns were followed up till 24 hours after delivery and at discharge there were no complications

Statistical Analysis
Data was analyzed with IBM SPSS, version 24.0 (2015, SPSS Inc., Chicago IL, USA) and by the concept of intention to treat to take care of participants who were non-adherent to the protocol during the study period. Absolute and relative frequencies of categorical variables, mean and standard deviation of continuous variables were calculated. X^2 test was used to analyze categorical variables while comparison of two means was done using the student T- test. P- value of 0.05 or less was taken as significant.

Ethical Clearance
Ethical approval was got from the Hospital Research and Ethics Committee of AEFUTHA with approval number- AEFUTHA/REC/VOL3/2020/015 and ClinicalTrials.gov Identifier: NCT06841939.

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Data Storage and Confidentiality
Data was stored as anonymized data. This is to be able to maintain patient's confidentiality

RESULT

A total of 235 patients were assessed for eligibility; 35 patients were excluded from the study; 13 of them did not meet inclusion criteria while 25 refused to give consent. Two hundred participants were randomized into castor oil and placebo as shown in **Fig 1**.

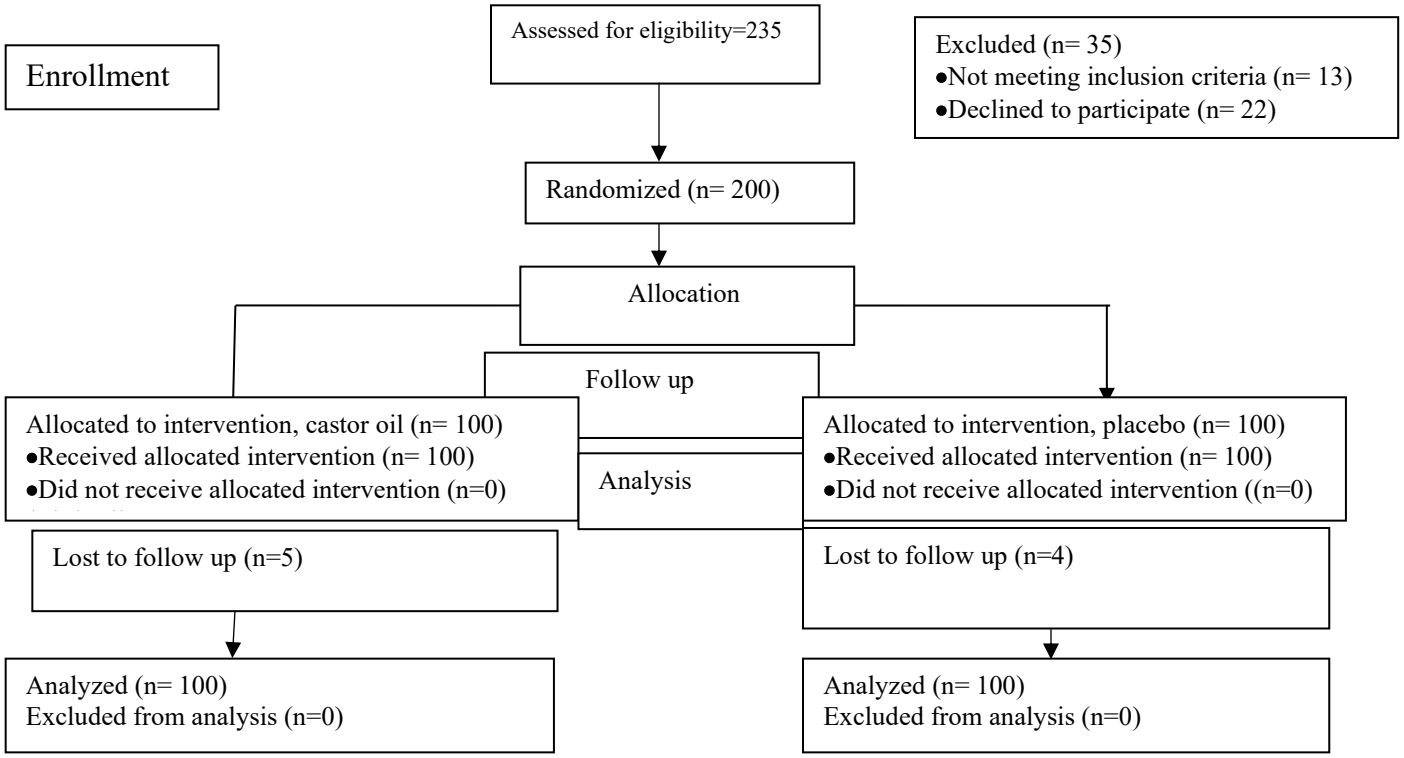

Fig 1: Consort Diagram of the study

Table 1: Sociodemographic Features OF Participants

Socio Demographic Variable	Group A (Castor oil group) N=100(%) Freq (%)	Group B (Water group) N=100(%) Freq (%)	χ2/Fisher's Exact	P-Value
AGE				
20-24	11(11%)	18(18%)	5.252	0.262
25-29	24(24%)	22(22%)		
30-34	31(31%)	36(36%)		
35-39	22(22%)	19(19%)		
40-44	12(12%)	5(5%)		
MARITAL STATUS				
Single	2(2%)	1(1%)		
Married	97(97%)	98(98%)	0.658*	1.000
Divorced	1(1%)	1(1%)		
OCCUPATION				
Housewife	19(19%)	31(31%)		
Farmer	4(4%)	6(6%)	6.591*	0.158

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Socio Demographic Variable	Group A (Castor oil group) N=100(%) Freq (%)	Group B (Water group) N=100(%) Freq (%)	χ2/Fisher's Exact	P-Value
Trader	29(29%)	25(25%)		
Artisan	9(9%)	12(12%)		
Civil Servants	39(39%)	26(26%)		
PARITY				
P0	19(19%)	21(21%)		
P1-P4	74(74%)	77(77%)	2.831*	0.275
>P4	7(7%)	2(2%)		
EDUCATIONALSTATUS				
None	1(1%)	1(1%)		
Primary	14(14%)	12(12%)	1.035*	0.855
Secondary	37(37%)	43(43%)		
Tertiary	48(48%)	44(44%)		
RESIDENCE				
Rural	8(8%)	11(11%)		
Semi Urban	8(8%)	10(10%)	0.849	0.689
Urban	84(84%)	79(79%)		

Table 1 showed that most of the participants were between the ages of 30-34 years. Majority were married with 97% and 98% in the castor oil and placebo group respectively. Most of the women who participated were multiparous; 74% and 77% for castor oil and placebo groups respectively. 2most of them had tertiary education, were traders and were urban settlers. There were no statistically significant differences in the sociodemographic variables of these participants

Table 2: WOMEN WHO HAD LABOUR INDUCTION IN BOTH GROUPS

Variable	Group A (Castor oil group) Freq (%)	Group B (Water group) Freq (%)	Chi-square	P value
Formal induction of labour	41(41%)	77(77%)	27.875	<0.001
Need for AOL	9(17%)	11(68%)	40.102	<0.001

In table 2, 41% of participants who were given castor oil had need for formal induction of labour as against 77% of participants who received water. Also, 17% of participants in the castor oil arm and 68% of participants in the water group had need for Augmentation of labour. These findings were statistically significant, P<0.001.

Table 3: Comparison of mean duration of drug ingestion –delivery interval, duration of active phase of labour and gestational age at delivery

Variable	Group A (Castor oil group) N=100(%) Mean ± SD	Group B (Water group) N=100(%) Mean ± SD	t- test	P value	Confidence interval (CI)
Ingestion delivery interval (in hours)	15.69±6.94	17.92±6.78	2.258	0.025	0.281- 4.198

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Mean GA at delivery (in weeks)	41.29±0.14	41.40±0.09	6.599	<0.001	0.077-0.143
Active Phase labour duration	4.71±2.12	5.67±2.59	2.436	0.016	0.181-1.745

In table 3, the mean duration of drug ingestion –delivery interval following ingestion of castor oil was 15.69 hours ±6.94 while ingestion of water was 17.92 hours ±6.78. This was statistically significant, p=0.025. The mean gestational age at delivery was 41.40 weeks ±0.09 in the water group and 41.29 weeks ±0.14 in the castor oil group. The duration of active phase of labour was 4.71±2.12 and 5.67±2.59 in the castor oil and placebo group respectively. These differences were statistically significant (P value <0.05).

Table 4: Route of delivery

Maternal /Neonatal side effects	**Group A** (Castor oil group) N=100(%) Freq (%)	**Group B** (Water group) N=100(%) Freq (%)	**χ^2*Fisher's Exact**	**P value**
Vaginal Delivery	86(86)	80(80)	2.288	0.319
Caesarean Section	9(9)	16(16)		

Table 4 showed that there was no statistically significant difference in the route of delivery between the two groups. Eighty-six percent (86%) of participants in the castor oil group had vaginal delivery as against 80% in the water group.

Table 5: Maternal and neonatal side effects

Maternal /Neonatal side effects	**Group A** (Castor oil group) N=100(%) Freq (%)	**Group B** (Water group) N=100(%) Freq (%)	**χ^2*Fisher's Exact**	**P value**
Nausea	54(54)	3(3)	63.820	<0.001
Vomiting	15(15)	0(0)	16.216	<0.001
Diarrhoea	69(69)	1(1)	101.626	<0.001
1st minute APGAR mean ± SD	9.07±0.85	9.06±0.83	-0.092	0.927
5th minute APGAR mean ± SD	9.72±0.48	9.70±0.53	-0.246	0.806
Meconium-stained liquor	5(5)	6(6)	0.202	0.904
NICU admission	5(5)	3(3)	0.713	0.747

Table 5: Diarrhea, nausea and vomiting were significantly more common among women who received castor oil than water group for initiation of labour; 69% versus 1%, 54% versus 3%, 15% versus 0 respectively with P value of <0.001. The first, fifth minute APGAR score and proportion of women admitted into NICU were not statistically significant.

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DISCUSSION

Prolonged pregnancy is a high risk pregnancy and the most common indication for induction of labour. Different agents have been used for induction of labour but the procedure is not without maternal and fetal side effects. From this study, the sociodemographic characteristics of the participants were not statistically significant in both groups. This was similar to the studies by Okoro et al, [19] Saberi et al[21]and Neri et al[15]as they also reported no difference in the sociodemographic characteristics of the participants in their study. However, in the study by Gilad et al, [6] there was statistical difference in the sociodemographic characteristics of the participants in terms of the age in both groups. This conflicting result may be due to the method of recruitment which was not stated in their study. However, this study used simple random sampling method.

In this study, the proportion of women who had spontaneous labour following the ingestion of castor oil (52%) was greater than those who ingested water (16%) and the difference was statistically significant. This shows that castor oil is effective in initiation of labour thereby preventing the need for formal induction of labour and its attendant consequences. The above findings may be attributed to the strong laxative effect of the ricinoleic acid released by the intestinal lipases from the intestinal lumen which activates EP_3 prostanoid receptor leading to smooth muscle contractions following castor oil ingestion.[14,16] This finding was comparable to the finding in the study by Azhari et al[1] and Azarkish et al. [22]The findings by Gilad et al[6] were in contrast to our finding as no difference was found between the study and the control population in the proportion of women who achieved spontaneous labour at various hours. The differences in the findings could be because Gilad et al[6] used sunflower oil as placebo which may have had effect on the uterine contraction as was against our study where water was used.

Table 2 showed that the proportion of participants who had formal induction of labour were more in the water group (77%) than the castor oil group (41%) and this was statistically significant (P value <0.001). The above finding shows that castor oil is effective in preventing formal induction of labour and at such prevents post term pregnancy. These findings may also be attributed to the mechanism of action of castor oil. This was similar to the findings in Neri et al[15] where 90% of the control group had medical induction of labour. This was also in keeping with the findings by Okoro et al. [19] Within the limit of our search, no study compared the need for augmentation labour between castor oil and placebo.

The mean duration of drug ingestion- delivery interval was higher in the water group when compared to the castor oil group. This was statistically significant. This implies that castor oil is effective in reducing the duration of labour compared to water. This study further showed a decrease in the duration of labour in the castor oil group than the placebo group and the finding was significant with a p value=0.016. The finding is similar to a study by Anindra et al,[23] in which the average duration of labour in participants following castor oil ingestion was 5.88±3.82 while in the control group it was 12.5±3.29 and this was statistically significant at P value of 0.004. Also, in a study by lamadah et al,[24] the mean duration of labour was shorter in the castor oil group than the control group and this was also statistically significant. The similarity noted may be account for by the activity of castor oil, irrespective of dose. Different doses of castor oil were used in these studies, but the outcomes were similar. The mean gestational age at delivery was significantly shorter among women who received castor oil. This implies that the activity of castor oil induced spontaneous labour faster than water, laying credence to the effectiveness of castor oil.

Majority of the participants in both groups had vaginal delivery; 86% in the castor oil group and 80% in the water group as seen in Table 4, however, there was no statistically significant difference in both groups when vaginal delivery was compared with caesarean section. The finding of the study implies that castor oil ingestion had no effect on the route of delivery. The above finding could be as a result of formal induction of labour which the water group had. One of the most common indications for Caesarean section following induction of labour is failed induction of labour, either due to maternal or fetal reasons. Lamadah et al [24] and Saberi et al [21] reported similar findings. However, Iravani et al [25] reported three times as many caesarean sections in the control group (22%) compared to the castor oil group (7.5%), though this was not statistically significant.

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The participants who received castor oil had more significant side effects, such as diarrhoea, nausea and vomiting, than the placebo group. None of these side effects required intervention. The greater side effect seen in the castor oil group could be as a result of the gastrointestinal effect of the drug. The findings were similar to the findings in the study by Lamadah et al.[24] Again, the finding in the study by Gilad et al[6] was in contrast to the finding in this study as there was no statistical difference in the maternal side effect profile. This may be adduced to the type of placebo used in the study (sunflower oil).

The neonatal outcome was similar on both arms of the study as there was no statistically significant difference in the outcome. This was similar to the finding by Gilad et al[6] and Iravani et al.[25] Also, the study by Okoro et al[19] showed similar findings. However, in the study by Lamadah et al[24]; a statistically significant difference was found in the neonatal side effects among the two groups with 32% of the neonates in the castor oil group having meconium-stained liquor and compared to12% in the control group. The difference in the findings could be as a result of various doses used in their study (20ml, 50ml, 100ml and150ml) as participants who received 100ml of castor oil had more meconium-stained liquor. However, in our study 30ml of repeat doses of castor oil was used for all participants who received castor oil.

Limitation

Due to the design of the study, the long-term side effects of the drug on the participants could not be determined. It was a single-centre study.

Strength of the Study

The study was a randomized controlled trial and the power of the study was 90%. The agents were administered under direct observed therapy (DOT).

Implication of the Findings of the Study

The finding from this study showed that the use of castor oil in prevention of formal induction of labour is promising and more positive findings from local studies will enhance widespread use in other to prevent formal induction of labour.

CONCLUSION

This study demonstrated that castor oil was effective in reducing the need for formal induction of labour and the administration-delivery interval with minimal maternal side-effects. Multicentre centre studies can further increase its external validity.

Declarations

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Author Contributions: ICU and OA conceptualized and designed the study. ICU, OA, ANN, EO, UEO were involved in data collection/acquisition and statistical analysis; ICU, OA, ANN, COO, AI, AVN, COUE and OUJU were involved in the writing and revising the manuscript for intellectual content. All authors read and approved the final manuscript and agreed to be accountable for all aspects of the work.

Ethical Approval: The ethical approval for the study was obtained from the Health Research Ethics Committee of Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi State, Nigeria with ethical approval number: AEFUTHA/REC/VOL 3/2020/015.

Declaration of Patient's Consent: The authors certify that they have obtained all appropriate patient consent forms. The patients understand that their names and initials will not be published, and due efforts will be made to conceal their identity.

Declaration of Helsinki: The study was conducted in accordance with the ethical principles of Helsinki Declaration.

Availability of Research Data: Authors are available and ready to supply the data upon any requests through the corresponding author.

Financial Support and Sponsorship: Nil.

Conflicts of Interest: There are no conflicts of interest.

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