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Abstract

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THE SAFEST METHOD OF INDUCING LABOUR WITH MISOPROSTOL

Relevance. Prolong pregnancy cause is unknown; some risk factors like obesity and the previous history has been outlined. The risk for bad outcomes increases with the increase in the time of delivery. Intrauterine fetal death, meconium aspiration, fetal distress, oligohydramnios increased rate of caesarian section are among the complications. Timely delivery with accurate dose of Misoprostol can reduce the bad outcomes.

Misoprostol is a prostaglandin, not expensive and easy to store but with different side effect once wrongly administered. It is not indicated for obstetrics and gynecology in some countries but currently it is widely used for induction of labour.

Objectives. To assess the effect of Oral miso juice and its outcomes for labour induction in postterm cases and in premature rupture of membrane (PROM) at term.

Methods and Results. Search of registered documented files of clients at Kivulini Maternity Center for the year 2020.

Out of 2399 deliveries per year, 67 received oral miso juice due to postterm and PROM. 61 participants aged 17 to 34 years and 6 females were above 35 years of age.

Conclusion. 44 (65.7%) started active phase of labour within 24 hours and delivered. 16 (23.9 %) delivered after 24 hours of oral miso juice administration. 7 (10.4%) took more than 48 hours and delivered safely.

57 (85%) of those who received oral miso juice had SVD and 10 (15%) underwent emergency caesarian section due to a complication of Misoprostol as well since the drug can course fetal distress, meconium stained and other complications. 66 (98.5%) of all deliveries had Apgar score of >7 in the 1st minute, while 1 (1.5%) had Apgar of <7.

Out of all deliveries, only 1 (1.5%) underwent caesarian section reason being non reassuring fetal status (NRFS).

Out of all deliveries, 14 (20%) were accompanied by perineum tear of I&II degree and in 14 (20%) cases episiotomy was applied.

The weight of the babies delivered after miso juice was distributed as follows: 2.5 to 3.5 kg – 54 cases and 3.6 to 4.5kg – 13 cases. No babies were delivered with weight above 4.5 kg. Among them, 33 (49%) were male babies and 34 (51%) were female babies.

Oral miso juice is effective to achieve a safe spontaneous vaginal delivery. It is more effective than other method of induction of labour

especially in developing country and in facility with limited human resources. It is possible to say that oral miso juice is the optimal regimen with less risk once in a right dose.

Keyword: postterm, induction of labour, premature rupture of membrane, Misoprostol.

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Резюме

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НАЙБЕЗПЕЧНІШИЙ МЕТОД ІНДУКЦІЇ ПОЛОГІВ ЗА ДОПОМОГОЮ МІЗОПРОСТОЛУ

Актуальність проблеми. Причина переношування вагітності невідома; деякі фактори ризику, такі як ожиріння, були в анамнезі. Ризик негативних результатів збільшується зі збільшенням часу переношування вагітності. Серед ускладнень – внутрішньоутробна смерть плода, аспірація меконію, дистрес плода, маловоддя, збільшення частоти кесаревого розтину. Своєчасні пологи із застосуванням точної дози мізопростолу можуть зменшити несприятливі наслідки.

Мізопростол – це простагландин невеликої вартості і легкий у зберіганні, але з різними побічними діями у випадку застосування не за призначенням. Його не призначають в акушерстві і гінекології у деяких країнах, але на сьогодні він широко застосовується для індукції пологів.

Мета роботи. Оцінити дію мізопростолу для перорального прийому і його вплив на індукцію пологів при переношуванні вагітності та у пацієнток із передчасним розривом навколоплідних оболонок при нормальній тривалості вагітності.

Матеріали і методи.

Проведено аналіз 2399 історій пологів у Пологовому будинку Ківуліні за 2020 р, 67 жінок отримали мізопростол для перорального прийому через переношування вагітності або передчасний розрив навколоплідних оболонок.

Вік 61 учасниці коливався у межах 17–34 років, а 6 учасницям було понад 35 років.

Висновки. У 44 (65,7 %) із досліджуваних активна фаза пологів розпочалася протягом 24 годин і вони народили здорових дітей. 16 (23,9%) жінок народили через 24 години після перорального прийому мізопростолу. 7 (10,4 %) успішно народили пізніше, ніж через 48 годин.

57 (85 %) із тих, хто отримали мізопростол перорально, народили природнім шляхом, 10-м (15 %) було проведено екстрений кесарів розтин для попередження ускладнень від мізопростолу, а також через те, що препарат міг викликати дистрес плода, аспірацію меконію та інші ускладнення. 66 (98,5 %) новонароджених на першій хвилині життя отримали оцінку > 7 за шкалою Апгар, в той час як один новонароджений (1,5 %) мав оцінку < 7 за шкалою Апгар.

Із усіх пологів лише 1 (1,5 %) відбулися шляхом кесарева розтину через загрозливий стан для плода.

Серед породіль, 14 (20 %) мали розриви м'яких тканин пологових шляхів I і II ступеня, а 14 (20 %) жінкам було проведено епізіотомію.

Вага дітей, народжених після перорального прийому мізопростолу, коливалась від 2,5 до 3,5 кг у 54 випадках, та від 3,6 до 4,5 кг

у 13 випадках. Жодна дитина не народилася з вагою понад 4,5 кг. Серед них народилося 33 (49 %) хлопчики і 34 (51 %) дівчинки.

Таким чином, мізопростол для перорального прийому є ефективний для індукції самостійних пологів. Він є більш ефективним ніж інші методи індукції пологів, особливо у країнах, що розвиваються, та в установах з обмеженою кількістю персоналу. Можна сказати, що мізопростол для перорального прийому є оптимальним методом з невисоким ризиком при застосуванні у рекомендованій дозі.

Ключові слова: переношування вагітності, передчасний розрив плодових оболонок, індукція пологів, мізопростол,.

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Introduction

Pregnancy lasts for 280 days from the first day of the last menses [1]. Currently, pregnant women are recommended to deliver at least at 39 weeks if no complications. So a term pregnancy can be a time period between 39 and 42 weeks (+7) [2]. A woman can start labor a week either side of this period. Beyond this time, we call it postterm or overdue. Earlier, 3 weeks earlier or 2 weeks later after estimated date of delivery was considered a term pregnancy. Currently, as women are very keen with their due date and get agitated once the delivery time approaches, it makes it very difficult for medical personnel to keep them wait for a spontaneous vaginal delivery past 42 weeks. Different countries have different approaches to induce overdue pregnancy.

If labor will not start until 41 6/7 weeks, it termed as a late term and a plan for delivery has to be taken into consideration for the better outcomes.

The use of Misoprostol for induction of labour is not recommended in many countries.

When used, attention and close high-standard monitoring should be undertaken to avoid complication which may happen during the process. Some hospital facilities prohibited the use of Misoprostol for the induction of labour. Most research conducted regarding the induction of labour non-point out the exact dose and regimen. Some try to point out the best mode, which seems to be the best to induce pregnant women.

A recommendation comes from the World Health Organization (WHO), the International Federation of Gynecology and Obstetrics (FIGO), and the Society of Obstetricians and Gynaecologists of Canada. A systematic review suggests oral Misoprostol is safer than vaginal and demonstrate lesser caesarian rate [3].

According to different researches which studied Misoprostol, the required dose of Misoprostol is about 25 mcg to 50 mcg for the induction of labour [3, 4, 8]. The big concern right now is how to get the same dose since the drug is in tablet form and is made up of 100 mcg or 200 mcg. To divide the dose is an issue.

Most of the complications of labor induction by prostaglandins are uterus hyperstimulation and the development of tachysystole [5]. These complications are related to the dose given and the mode of administration of the particular dose. A study by Bolla et al., which compared misoprostol vaginal insertion (MVI) and misoprostol tablet insertion (MTI) showed that tachysystole was more prevalent for MTI [7].

Oral Miso Juice. The method which has been in practice by maternity African for administering Misoprostol for induction of labor for postterm pregnancies (41+5 days) and PROM at term for safety purpose of the mother and child at Kivulini Maternity Center, located in Arusha, Tanzania.

The juice is prepared by a combination of Misoprostol 200 mcg, into 100 ml of ringer lactate (RL) and gives the pregnant women a dose of 10 ml (20 mcg) once in two hours to make a total of twelve doses. If the contraction is not attained, then the client is given a break of 6 hours before the next cycle. This process helps to administer the lowest dose possible to overcome the complications. Studies show that administration in one hour or two hours has the same efficacy, but side effects are more favored in two-hour interval [4].

Pharmacokinetic features of Misoprostol in RL have not yet been studied as well as the degradation of it in a solution completely has never happened unless for a long time, but the assumption is that every 10 ml of the solution will at least contain 20 mcg of Misoprostol. Shaking well before use is important to make sure contents

are not all settled down and leave less concentration on top.

Search Method

Data collection

Analyze data from patient files who received oral Misoprostol in the form of a solution, miso juice which was prepared in the hospital for the past year from January 2020 to December 2020 in a maternity-based hospital.

Subjects

We studied 67 clients who came to the maternity center at the age of 17 to 40 years old, null para and multipara. The median age was 28. We scrutinized their antenatal visit cards, history taking to tally their gestation age by comparing the last menstruation period (LMP), first visit scanning, and the trend of the physical exams during Antenatal Care (ANC).

Inclusion/exclusion criteria

All pregnant women with gestation age of 41+5 days and beyond with single live fetus and without any complication like low insertion of placenta, previous scar, breech presentation, a ruptured membrane with meconium, severe oligohydramnios, bishop score of more than 6, calcified placenta grade three, non-reassuring fetal status and biophysical profile of less than 6, estimated fetal weight > 4500.

All pregnant women presented with premature rupture of membrane (PROM) in less than 12 hours with clear amniotic fluid, with no sign of infection and bishop score of < 6 were also included.

Body Mass Index was not considered.

A total of 67 who met inclusion criteria and 20 who didn't were excluded from the study.

Main Results and Discussion

Out of 2399 deliveries, 67 received oral miso juice due to postterm and PROM pregnancies. In 65.7% active phase of labour started within 24 hours and delivered. 23.9% delivered after 24 hours of oral miso juice administration. 10.4% took more than 48 hours and delivered safely.

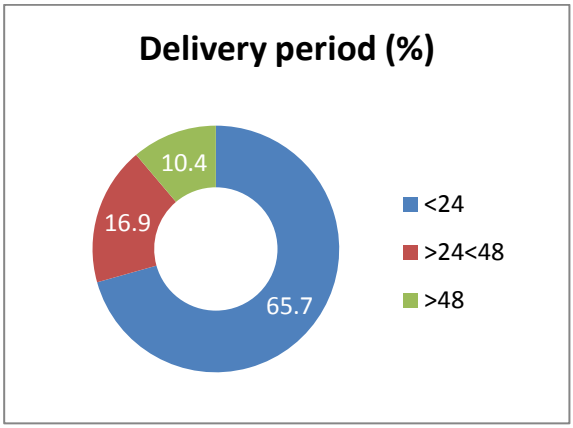

Figure 1 – Delivery period

85% of those who received oral miso juice had SVD, and 15% underwent emergency caesarian section due to different reason which does not directly relate to the effacement and cervical dilatation but might be the complication of Misoprostol. 98.5% of all deliveries had an Apgar score of >7 in the 1st minute, while 1.5% had an Apgar score of <7.

Table 1 – Data Results

Characters	Participant	%	<24 Hours	>24 <48 Hours	>48 Hour
Male	33	49%			
Female	34	51%			
Delivery time			65.7%	23.9%	10.4%
Clear amniotic fluid	59	88%			
Meconium	8	12%			
Score	1 <7	1.5.%		1	
	66 >7	98.5.%			
C-section	10	15%			
SVD	57	85%			
PPH	2	2.99.%			
Age >35	6				
Age <35	61				
Primigravida	28	41.8%			
Multipara	39	58.2%			

Out of all deliveries, only 1.5% underwent caesarian section reason being non-reassuring fetal status (NRFS) and probably the complication of Misoprostol.

Out of all deliveries, 14 (20%) females got perineum tear I&II degree, and in 14 (20%) cases, episiotomy was applied.

The weight for the babies delivered after miso juice, from 2.5 to 3.5kg were 54 and from 3.6 to 4.5 kg were 13. No baby delivered with weight above 4.5 kg. Among them, 33 (49%) were male babies, and 34 (51%) was female babies

61 participants aged 17 to 34 years, and 6 were above 35 years of age. The median age was 28.

Table 2 – Amount of oral miso juice given until delivery

Amount of oral miso juice given until delivery

Frequency of Miso juice given	ML (mcg)	Total Patient	%	PPH
1–5	10-50	14	22.6	
6–10	60-100	30	48.4	1
11–20	110-200	16	25.8	1
21–30	210-300	2	3.2	

Discussion

The purpose of this study is to assess the safest method and outcome of the miso juice to a postterm and PROM pregnancies.

The study shows that participants receive Misoprostol in the form of juice every two hours, with a circle of 12 doses, and then a break of 6 hours in case of not responding well from the previous doses then resumed to the next circle. This means that after a circle, a woman receives 240 mcg of Misoprostol in 24 hours for a maximum of 3 circles.

Data shows that the dose didn't affect the outcome of the fetus. No matter how many circles the women received before delivery, the outcomes were excellent.

44 clients delivered in less than 24 hours which made 65.7% of all participants. 16 clients (23.9%) delivered in >24 h, while 7 (10.4%) clients delivered in more than 2 days. Regardless of the time, taking miso before delivery presented with bad outcomes post-delivery in very few cases.

A study by Alfirevic Z, Aflaifel N shows that in nine trials comparing oral Misoprostol with placebo, women using oral Misoprostol were more likely to give birth vaginally within 24 hours which supports the findings [5].

Uterine hyperstimulation was not well documented during miso juice administration which is something that has to be considered in other scientific research but the fetal heart rate were within the normal range though.

Other studies by Bolla et al. show that there was a significant change in uterine contraction when he compares MVI and MVT. Tachysystole was more evidently increased in MVI [7].

A study by Lenita Wannmacher reported no significant differences were found for uterine hyperstimulation with fetal heart rate changes and no severe neonatal or maternal morbidity was reported [8].

The dose will be discontinued if the cervix effaced and or the dilatation of > 3 cm with contractions of at least 2–3/10 minutes, which is > 30 seconds.

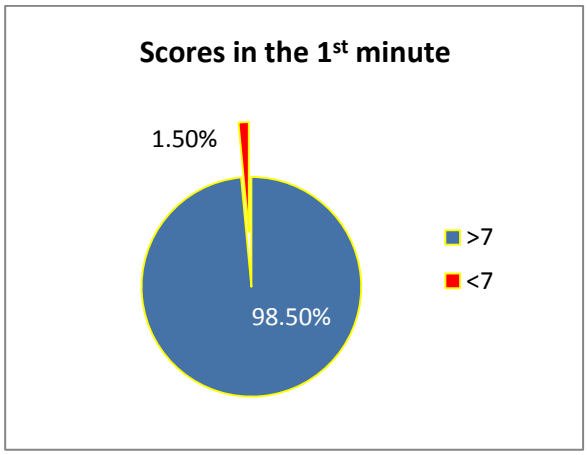

Figure 1 – Scores in the 1st minute

98.5% of all deliveries post miso juice score > 7 in the first minutes and only 1.5 % scored < 7 in first minutes, but the reason was not related to Misoprostol.

25.8 % received up to 400 mcg of miso juice before they delivered. From the data collected, the maximum doses given were 600 mcg which was 3.2% of Misoprostol given. In this group in which clients received up to 600 mcg – 3.2%, 1.6% underwent a caesarian section and the other half SVD. Both babes scored 9^{1} and 10^{5} and during

delivery, the amniotic fluid was clear. 48.4% delivered after 6th to 10th dose of Misoprostol which was the majority of all participants. From this small observation, no matter the amount of dose given, since it is in a small proportion, the outcome will still be good.

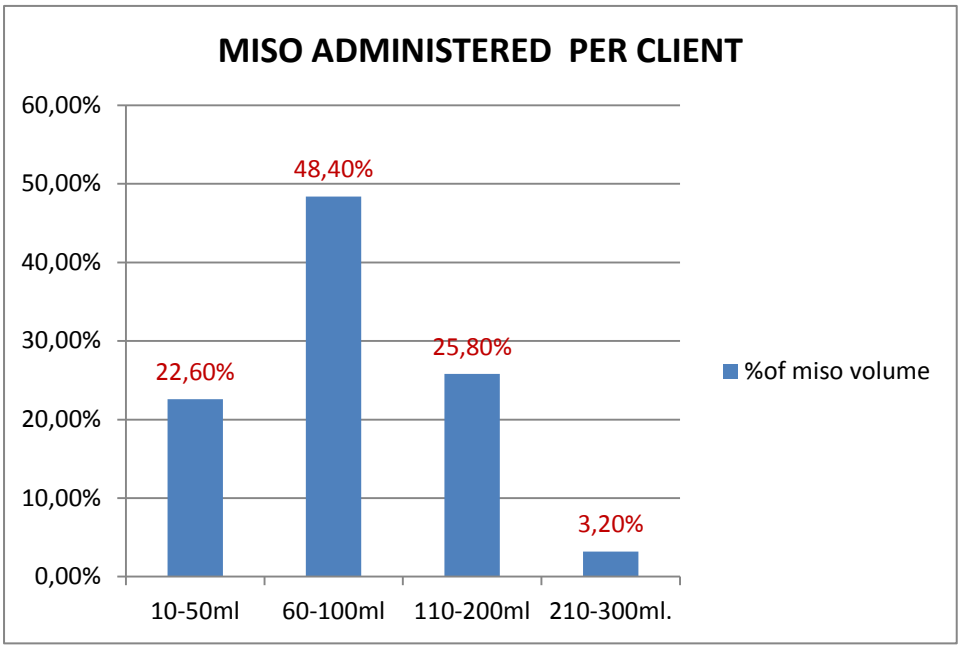

Figure 3 – Miso Administered Per Client

Spontaneous vaginal deliveries (SVD) were 85% and Caesarian section (C/S) 15%. Compared to other studies, the rate of c/s is lower than other methods of induction of labor. Cochrane review shows vaginal Misoprostol the rate of c/s is 21.7% (Hofmeyr) [5].

41.8% were primigravida and 58.2% were multipara women. More c/s was from primigravida group (9%) and 4% of c/s was from multipara group. The reason for all this operation was not directly related to the miso juice but can be the complication of Misoprostol as well since the drug can course fetal distress, meconium staining and other complications.

PPH is one of the complications that arise after the use of Misoprostol. From this study, two participants (2.99%) developed PPH post SVD. More precaution should be taken once more than one circle of miso juice is administered. Further studies should be done to relate the dose and course of PPH.

As a sign of the maturation of the gastrointestinal tract, meconium can be a good sign but once presented while the fetus is still intrauterine, this can be a worrisome sign since it indicated the sign of fetal compromise. Meconium intrauterine can increase the rate of c section [10]. Different factors can cause meconium, including postterm delivery and misoprostol use. Meconium stained amniotic fluid was as well observed. 12% had meconium stained amniotic fluid during the time of delivery, while 88 % had clear amniotic fluid.

Neither ruptured uterus, nor mortality were reported after miso juice administration [10].

Conclusions

Miso juice is very effective to achieve a safe spontaneous vaginal delivery. It is more effective than any other method of induction of labour. It is possible to say that miso juice is the optimal regimen with lesser risk. Even though misoprostol is not recommended in many African countries, miso juice can be of great help especially for the developing countries where the number of deliveries is very high and the rate of caesarian sections are still increasing day by day with limited human resources. More studies are needed for more trial in a large group.

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Conflict of interest

The authors declare no conflict of interest.

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Ethics approval and consent to participate

The study was approved by the Kivulini Medical Center Ethics Committee.

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