

Maternal and Perinatal Prognosis of Artificial Induction of Labor with Misoprostol at the Reference Health Center of Commune 2 in Mali

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Abstract

Introduction: The artificial induction of labor is increasingly common. **Objective:** Evaluate the maternal-fetal prognosis of artificial induction with misoprostol at the referral health center of the commune II. **Methods:** This is a cross-sectional, prospective, descriptive and analytical study which took place from September 1, 2019 to December 31, 2020. Included in the study were pregnant women carrying an evolving or terminated single-fetal pregnancy of at least 28 WA in cephalic presentation on a healthy uterus. The trigger has been made with 50 µg misoprostol administered sublingually into the posterior vaginal fornix. The dose was renewed as needed every 6 hours, until sufficient uterine contractions were obtained without exceeding 200 µg. **Results:** The frequency of artificial induction of labor was 1.25%. Indications were dominated by premature rupture of membranes (29.8%), overdue (19.1%), high blood pressure (19.1%), suitability of pregnant women (14.9%) and terminated pregnancies (10.6%). The vaginal delivery rate was 85.1% The Apgar score was greater than or equal to 7 in 83.3% of cases at the 1st minute. Maternal morbidity was marked by postpartum hemorrhage due to uterine atony in 4.3% cases. No maternal and neonatal deaths were noted. **Conclusion:** Induction of labor with misoprostol is a safe and effective method if careful selection of patients is made.

Keywords

Childbirth, Induction, Artificial, Misoprostol, Prognosis

1. Introduction

The requirements of current obstetrical practice increasingly lead the obstetrician to induce labor earlier than nature would have done spontaneously. Thus the rate of artificial induction of labor has increased in many countries over the past two decades. It went from 10.4% in 1981 to 22% in 2016 in France [1] [2]. We find an overall similar rate in England (21%) and Germany (22.2%) and much lower rates in Italy (15.9%) and in the countries of Northern Europe (18.8% in Finland, 18% in Norway and 13.7% in Sweden) [2]. In Mali, the frequency of artificial triggering varied between 2.49% and 2.8% from 2001 to 2019 depending on the structures [3].

Artificial induction is defined as a medical intervention consisting of the induction of uterine contractions in order to achieve birth by natural means.

This artificial induction of labor can also, like any other intervention, have undesirable effects. For this, it should only be practiced if the expected outcome for the mother and/or the child brings more benefits than an expectant attitude.

When the cervix is unfavorable, maturation of the cervix may be necessary before initiating induction [4]. It allows at the end of pregnancy to prevent complications when the pregnant woman or the fetus is in danger. The reasons for the induction of labor include, among other things, the delay in its onset, the rupture of membranes before labor and high blood pressure. Induction of convenience refers to the induction of labor near term without any necessity related to a maternal or fetal indication. Its failure leads to cesarean section, the main indication of which is cervical dystocia defined by the non-progression of labor during its active phase [5].

Despite the practice of this intervention in our department, no study has been conducted to assess its frequency, specify its indications and determine the maternal-fetal prognosis. In order to gain our own experience with misoprostol, we began introducing it into our practice according to the recommendations of the Food and Drug Administration and as part of a prospective evaluation.

2. Methods

We carried out a cross-sectional, prospective descriptive and analytical study over a period of 16 months from September 1, 2019 to December 31, 2020 in the obstetrics gynecology department of the reference health center of the commune II of Bamako in Mali. This was an exhaustive sampling whose study population consisted of women who gave birth in the department during the study period. Included in the study were consenting pregnant women carrying an evolving or terminated single-fetal pregnancy of at least 28 WA in cephalic presentation on a

healthy uterus.

The variables studied were: the frequency of induction, the age of the pregnant women, the prenatal follow-up, the author of the prenatal follow-up, the term of the pregnancy, the evolution of the pregnancy, the pathologies associated with the pregnancy, the condition of membranes, time to rupture of membranes, Bishop Score, indications for induction, route of administration of misoprostol, a dose of misoprostol used, route of delivery, side effects of misoprostol, Apgar score, immediate postpartum.

Was done with 50 µg of misoprostol administered in the posterior vaginal fornix when the membranes were intact and sublingually when they were ruptured. The dose was renewed as needed every 6 hours, until sufficient uterine contractions were obtained without exceeding 4 doses, *i.e.* 200 µg. Induction was interrupted and considered as failure in the absence of labor after three days of induction, in the event of anomalies of the fetal heart rate, uterine hyperkinesia or stationary dilation during labour. Labor monitoring was done using the WHO partograph.

Data was entered into Word, Excel and analyzed on SPSS20. The statistical test used was Pearson's Chi² with a significance level set at 5%.

3. Results

3.1. Frequency

From September 1, 2019 to December 31, 2020, we performed 47 artificial inductions of labor with misoprostol out of 3754 deliveries. The frequency of induction of labor over this period was 1.25%.

3.2. Sociodemographic and Clinical Characteristics

The average age of pregnant women was 26 ± 5 years with extremes of 17 and 42 years. The average parity was 4.6. They were multiparous in 53.2% of cases and nulliparous in 21.3% of cases. Pregnancy was at term in 38 pregnant women (80.8%) including 11 cases of overterm. Pregnancy was monitored in 46 pregnant women (98%) with a number of prenatal consultations greater than or equal to 4 in 68.1% of cases. Consultations for all pregnant women were carried out by qualified service providers, 55.3% of whom were obstetrician-gynaecologists, 36.2% by midwives and 8.5% by general practitioners. These were ongoing pregnancies in 89.4% of cases and 10.6% of patients had an aborted pregnancy. Regarding pathologies associated with pregnancy, diabetes and arterial hypertension were found in 2.2% and 19.1% of cases. The induction was carried out on a pregnancy with intact membranes in 70.2% of pregnant women against 29.8% of pregnant women with ruptured membranes whose average duration of the rupture time was 8.76 hours with extremes of 2 and 15 hours. The Score Bishop score was 5 to 6 in 74.4% of pregnant women. The indications for induction were dominated by the rupture of the membranes (9.8%), the exceeding of the term (19.1%), arterial hypertension (19.1%), the suitability of the pregnant

woman (14.9%) and terminated pregnancies (10.6%). The route of administration of misoprostol was the vaginal cul-de-sac in 74.4% of pregnant women against 25.6% sublingually. During the onset, no side effects occurred in 57.4% of pregnant women compared to 42.6% who presented a side effect, including 23.5% chills, 12.7% fever and 12.7% vomiting.

3.3. Maternal-Fetal Prognosis

Seven parturients underwent caesarean section after induction, the indications of which were acute fetal distress with 4 cases (57.14%) and stationary dilation with 3 cases (42.56%) of the cases.

The average time between induction and delivery after administration of the first dose of misoprostol was 8.76 hours with extremes of 4 and 26 hours. The delivery rate within 24 hours was 45/47 cases (95.74%) including 85.1% vaginally.

It should be noted out of 47 pregnant women five are admitted with absent fetal heart sounds. No neonatal deaths were recorded.

Of a total of 42 live neonates, 7 had an Apgar score below 7 at the first minute. They were resuscitated and the Apgar score was good, above 7 at the 5th minute in all newborns.

No case of uterine rupture or maternal death was recorded, however, two cases (4.3%) of immediate postpartum hemorrhage due to atony were noted.

$\text{Chi}^2 = 1.184$; $\text{dof} = 3$ $\alpha = 0.05$ $P = 0.333$ In our study, the majority of pregnant women, *i.e.* 28/47 patients (59.57%) required only a single dose for induction of labour. There was no statistically significant relationship between the dose of misoprostol received and maternal prognosis.

4. Discussion

The modern practice of obstetrics is based on various indicators, including the rate of artificial induction, which is undoubtedly associated with quality of care [2]. Although the onset of labor is spontaneous in the majority of full-term pregnant women, a few require artificial initiation of labor for medical, obstetrical or social reasons [6]. This is why during our study 47 births out of 3754 were subject to artificial induction, a frequency of 1.25%. Our frequency is much lower than in developed countries where artificial triggering is one of most common obstetrical procedures concerning at least one in five women in most developed countries with rates that have stabilized in France since 2010 (22.1% in 2010, 22% in 2016 and 20% in 2020). We find an overall similar rate in England (21%) and Germany (22.2%) and much lower rates in Italy (15.9%) and in the countries of Northern Europe (18.8% in Finland, 18% in Norway and 13.7% in Sweden) [2] [7]. It rose from 9.5% in 1990 to 22.1% in 2004 in the United States [1]. In Canada, the induction rate grew, peaking at 23.7% in 2001-2002, then declining slightly (21.8%) in 2004-2005; it has remained stable since [8]. In Mali, the frequency of artificial triggering has increased from 2.49% to 2.8% from 2001 to 2019 depending on the structures [3].

The socio-demographic profile of our pregnant women was that of a young woman aged 26 ± 5 years with extremes of 17 and 42 years, multiparous in 53.2% of cases, carrier of pregnancy followed in 98% of cases with a number of prenatal consultations greater than or equal to 4 in 68.1% of cases. Consultations were provided by qualified service providers, of which 55.3% were by obstetrician-gynecologists, 36.2% by midwives and 8.5% by general practitioners. These pregnancies were at term in 80.8% of cases and in 11 cases (23.40%), it was overterm. Pregnancies were ongoing in 89.4% of cases and terminated in 10.6% of cases. In Benin in the study by Denakpo JL *et al.* [1], the mean age was 28.68 ± 7.15 years, it was paucigestes in 44.23% of cases and 50.6% of pregnant women had carried out their pregnancy follow-ups with qualified providers (gynecologists and midwives). In a randomization study of vaginal and sublingual misoprostol for cervical ripening and induction of labor carried out in Nigeria the same profile of young women with respective average ages of 29.4 ± 3.5 years and 29.3 ± 3.9 years ($P = 0.161$) for the sublingual and vaginal groups were reported by Ifarinola D *et al.* [6]. In France, in the study by Gams J [4], the mean age was 31.3 years and nulliparae were the most represented with 63.9% of cases. In Egypt, multiparas were the most frequent in the study by Abdel-Aal *et al.* [9]. With regard to pathologies associated with pregnancy, diabetes and arterial hypertension (HTA) were found in 2.2% and 19.1% of cases. The pathologies found by Denakpo JL *et al.* [1] were HIV infection (1.28%) and diabetes (0.64%).

The indications for induction were dominated by the premature rupture of the membranes (29.8%), the passing of the term (19.1%), arterial hypertension (19.1%), the suitability of the pregnant woman (14.9%) and terminated pregnancies (10.6%). The same indications have been reported in other studies. In Benin, premature rupture of membranes (33.33%) and prolonged pregnancies (32.05%) were the main indications reported by Denakpo JL *et al.* [1]. In the study by Ouerdiane N *et al.* [9] in Tunisia, the indications for induction included prolonged pregnancy (48%), gestational diabetes (22.7%), oligohydramnios (18%) and hypertension (11.4%). In France in the study of Gams J [3], overdue and premature rupture of the membranes were the main indications of onset with 30.7% and 12.2% respectively. In the study by Delaney T [6], gestational age greater than 41 weeks (49.9%) and hypertensive disorders (22.5%) were the most common indications. The same trend has been reported in the USA where prolonged pregnancy with 29% of cases was the first indication of artificial induction [10]. In our study, the main route of administration of misoprostol was the vaginal fornix in 74.4% of pregnant women against 25.6% sublingually. While in some studies, induction was exclusively oral [4] [5] [9], in the studies by Haas DM *et al.* [11] and by Acharya I *et al.* [12], the sublingual and vaginal routes were used. In Tunisia [9], misoprostol was administered only in the vaginal fornix. Even though misoprostol has so many benefits in the field of obstetrics and gynecology, it has many side effects. Several case studies of misoprostol side effects have been reported by researchers around the world. It can cause fever and

there is some evidence that genetic susceptibility may play a role in misoprostol-induced fever [13]. The side effects encountered in our study were chills (23.5%), fever (12.7%) and vomiting (2.7%). According to Shaheen *et al.* [14], side effects depend on the route, dose, and indications for which misoprostol is used. This is how they reported vaginal bleeding during misoprostol-induced abortion, fever and/or chills when the interval between doses is shorter or with oral or sublingual administration, contraction abnormalities like hypertonia in 10.7% of cases and hyperstimulation syndrome in 13.8% of cases. The average time between induction and delivery in our study was 8.76 h with extremes of 4 and 26 h. Our deadline was close to that of Gabon [15] with 10.80 h but lower than that of Tunisia [10] which was 17 h with extremes varying from 4 to 40 h. the delivery rate within 24 hours was 45/47 cases (95.74%) in our study, of which 85.1% vaginally (Table 1). The same trend has been reported in Tunisia [10] with a vaginal delivery rate of 70.4% within 24 hours as well as in Nepal and Pakistan [12] [16], where the frequency of vaginal delivery is vaginal route was 84% when misoprostol was administered vaginally versus 74% and 92% respectively when misoprostol was administered sublingually. We recorded 7/47 cases (14.9%) of failure after induction which were the subject of a caesarean whose indications were acute fetal distress with four cases (57.14%) and stationary dilation. with three cases (42.56%). Our failure rate was higher than that of Benin with 3% [1]. Like our study, in Tunisia [10], the indication of the Caesarean section was dominated by acute fetal distress in 22.7%. The same indications (acute fetal distress, stagnation of dilation) have been reported in Gabon [15] with a caesarean section rate of 7.4%. The maternal-fetal prognosis was good in our study. The condition of newborns at birth was assessed by scoring the Apgar score (Table 2). Whatever the delivery route, out of a total of 42 live neonates, 7 had an Apgar score below 7 at the first minute. They were resuscitated and the Apgar score was good, above 7 at the 5th minute in all newborns. Our result was similar to that of Benin [1] where 6 newborns had an Apgar score of less than 7

Table 1. Distribution of patients according to delivery route.

Triggering	Number	Frequency. (%)
low way	40	85.1
caesarean section	7	14.9
Total	47	100

Table 2. Distribution of newborns according to the Apgar score at the 1st minute.

Apgar	Number	Frequency. (%)
4 - 6	7	16.7
≥7	35	83.3
Total	42	100

Table 3. Distribution of women giving birth according to immediate postpartum.

Immediate diaper suites	Number	Frequency. (%)
Simple	45	95.7
Hemorrhage due to uterine atony	2	4.3
Total	47	100

Table 4. Distribution of patients according to maternal prognosis in relation to the dose of misoprostol.

Maternal prognosis	Misoprostol dose				Total
	1/4cp	2/4cp	3/4cp	1pc	
Simple suites	28	13	2	2	45
Hemorrhage due to uterine atony	0	1	1	0	2
Total	28	14	3	2	47

at the first minute, but lower than that of Tunisia where 44 newborns (16%) [10] had an Apgar score of less than 7 at the 5th minute. In Morocco [17] ten newborns had an Apgar score below 7 at 1 min requiring resuscitation in the labor room, but none maintained a score below 7 after 5 min of life. We did not note any neonatal death during our study, as in the Moroccan series where no neonatal death was reported [17]. In Nepal in a study of sublingual versus vaginal misoprostol, Acharya I *et al.* [12] recorded three cases of neonatal deaths in the vaginal group (6%) and one case in the sublingual group (2%). Similarly, the mean Apgar score at five minutes was better in the sublingual group (8.04 ± 0.92) compared to the vaginal group (7.62 ± 1.17). We did not record any uterine rupture or maternal death, however, two cases (4.3%) of immediate postpartum hemorrhage due to atony were noted (Table 3). In Tunisia [10] a case of uterine rupture on a healthy uterus occurred in a 28-year-old primipara hospitalized for prolonged pregnancy. In Benin [1], perineal tear and postpartum hemorrhage were noted in 0.64% of cases. Contrary to our study, no case of postpartum hemorrhage was reported in Morocco [17]. In our study, the majority of pregnant women, *i.e.* 28/47 patients (59.57%) required only a single dose for induction of labour. There was no statistically significant relationship between the dose of misoprostol received and maternal prognosis (Table 4). The same trend was reported in the Moroccan series [17] where a single dose was sufficient for the induction of labor in 48% of pregnant women.

5. Conclusion

The use of misoprostol facilitates the management of pregnant women requiring artificial induction of labor regardless of the indication. It has proven to be very effective and well tolerated on the maternal-fetal and neonatal levels.

Limits of the Study

The small size of the sample did not allow us to have sufficiently significant results, the absence of PH metry to evaluate the fetal state explained the neonatal suffering.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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