

ORIGINAL ARTICLE

Active management of labour *versus* expectant management of primiparous women with a prolonged latent phase: a randomized trial

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ABSTRACT

Background. The duration of the latent phase of labour is variable and can reach 20 hours. According to the World Health Organization (WHO), a prolonged latent phase is the absence of cervical dilation beyond four or six centimetres after eight hours of regular uterine contractions. In this situation, women are at higher risk of medical interventions with a higher rate of emergency caesarean sections. There is no consensus regarding the management of the prolonged latent phase. Thus, two attitudes are possible: Expectant management with spontaneous labour and active management with amniotomy and oxytocin infusion.

Our study aimed to compare the outcomes of expectant management to those of active management strategy in the case of a prolonged latent phase.

Patients and Methods. We undertook a prospective experimental randomized clinical trial, in the gynecology and obstetrics department of the university hospital Hédi Chaker, Sfax, Tunisia, between 1 July 2021, and 31 December 2021. We included in our study primiparous women with spontaneous labour beginning and with prolonged latent phase. Only single evolutive pregnancies with cephalic presentation were included. Patients were randomized into two groups. For Active Management Group (AMG), the intervention was an amniotomy followed by an oxytocin infusion. For the expectant management group (EMG), amniotomy and oxytocin infusion were not performed unless indicated. The primary outcome was the rate of caesarean sections.

Results. Our study population consisted of 340 primiparous parturients with spontaneous labour beginning and with a prolonged latent phase. The caesarean section rate was 27.6% for the EMG versus 43.5% for the AMG ($p < 0.001$). Immediate complications were found in 18.2% of patients for the AMG versus 2.9% for the EMG ($p < 0.001$). The most common complication was postpartum haemorrhage (PPH) and was more frequent for AMG (12.4%). At birth, 93.5% of newborns for the EMG had an Apgar score between 8 and 10 versus 84.7% for the AMG ($p = 0.01$). Medical reanimation was required for 25 newborns after AMG and for 10 cases with EMG ($p = 0.01$). Five newborns for EMG (2.9%) and 15 newborns for GPA (8.8%) were admitted to the neonatal intensive care unit ($p=0.03$). The average time between randomization and

vaginal delivery, for patients who had vaginal birth, was longer for the EMG (15 hours and 47 minutes versus 8 hours, $p=0.001$). The mean duration of the latent phase, for patients who had vaginal birth, in our study was 20 hours and 38 minutes for the EMG versus 13 hours and 19 minutes for the AMG ($p < 0.001$). The average duration of the active phase, for patients who had vaginal birth, was 5 hours and 14 minutes for the EMG versus 3 hours and 58 minutes for the AMG ($p < 0.001$). Concerning the satisfaction of the parturient, 68.2% of the AMG were satisfied for the labour progression versus 82.4% for the EMG; $p = 0.003$. For immediate postpartum satisfaction, the majority of patients were delighted with no significant difference.

Conclusions. The active attitude compared to the expectant attitude has shown several disadvantages: it gives a higher caesarean section rate, more maternal complications, less safety for the newborn, and a longer hospital stay with less satisfied parturient. At the end of this study, and in the wake of the results found in the literature, expectant management to manage the prolonged latent phase seems to be an effective alternative and we suggest its widespread use.

Key words

Caesarean; vaginal delivery; latent phase of labour; expectant management; patient satisfaction.

INTRODUCTION

Labor is defined by the association of painful, close, and regular uterine contractions. The first stage of labor begins with the first uterine contractions and ends with complete cervical dilation to 10 centimeters. This stage is divided into two phases: the latent phase and the active phase.

Labor is defined by the association of painful, close and regular uterine contractions, gradually increasing in frequency and duration, with changes in the cervix (the cervix shortens, centers, softens and opens to full dilation). There are 3 stages of labor:

*First stage of labor: begins with the first contacts until complete dilation of the cervix. This first stage itself comprises two phases: the latent phase and the active phase [1].

*The second stage of labor: begins at full dilation and ends with the birth of the baby.

*The third stage of labor: delivery (expulsion of placenta and membranes).

The duration of the latent phase of labor is variable and can reach 20 hours [2]. According to the World Health Organization (WHO), a prolonged latent phase is the absence of cervical dilation beyond four or six centimeters after eight hours of regular uterine contraction [3]–[6]. In this situation, parturient women are more likely to be exposed to medical interventions with a higher rate of emergency cesarean sections. There is no consensus regarding the management of these patients [7].

Thus, face to this situation, two attitudes are possible: expectant management consisting of letting labor take place spontaneously, and active management with amniotomy and infusion of oxytocin.

The indications and the reported outcomes of these two management strategies by the different teams are different [7]. Thus, our study aimed to compare the outcomes of active and expectant management in the case of a prolonged latent phase.

PATIENTS AND METHODS

a) Study registration, ethical and methodological standards

We undertook a randomized comparative prospective study in the gynecology and obstetrics department of the Hedi Chaker University Hospital in Sfax, Tunisia, for six months between 1 July 2021 and 31 December 2021.

The study was registered in the Pan-African clinical trial on 07/08/2023 under the number PACTR202308714803965. (we started our work and at the same time registered in the panafrican clinical trial but the steps in the pan african trial take time. that's why the final registration comes after the start of the work. you will find enclosed the paper confirming the registration of our work.).

The study was approved by the ethics committee of PROTECTION OF PEOPLE SOUTH, SFAX.

Approval was granted by the ethics committee of PROTECTION OF PEOPLE SOUTH, SFAX (ID: 0371/2021) (Approval date: 22.12.2021).

All methods were performed according to the relevant guidelines and regulations set out by the Declaration of Helsinki.

Informed consent was obtained from all participants. Proof of consent to participate can be requested at any time.

The datasets generated and analyzed during the current study are not publicly available due to patient privacy but are available from the corresponding author.

b) Study population with selection criteria:

We included in our study:

- A prolonged latent phase of labor (the absence of cervical dilation beyond four centimeters after eight hours of regular uterine contractions (the contraction force must exceed 200 Montevideo within 10 minutes.)
- Primiparous women
- Women with a singleton evolutive pregnancy with cephalic presentation.
- Women with spontaneous beginning of labor
- Fetal weight between 2000 grams (g) and 4000g.
- Bishop score ≥ 6 .
- No contraindications to vaginal birth
- Term of pregnancy: ≥ 37 weeks.
- A first-trimester ultrasound done

We have not included in our study :

- Estimated fetal weight (EFW) ≥ 4000 g or ≤ 2000 g.
- Labour induction
- Contre indications to vaginal delivery.
- Scarred uterus (history of uterine surgery).
- Presence of notable pathological history contraindicating labor induction.
- Multiparity.
- Bishop score < 6 .
- Presentation other than vertex.
- Pathological ERCF.

- Unexplained placenta previa or metrorrhagia.
- Ruptured birth water bag .

c) *Statistical analysis*

All parturients were examined at admission. After obtaining the informed consent, we reported the participant's pieces of information using an investigation sheet.

Before starting this randomized prospective study, we obtained the agreement of the ethics committee. To determine the sample size, we developed a preliminary survey to estimate the number of cesarean sections among primiparous women in our population. Among 52 deliveries to primiparous patients, 18 had a cesarean delivery (34%).

To calculate the sample size, we used the following formula:

$$n = NZ^2pq / e^2$$

n= sample size; e= precision (0.05), Z= the statistic corresponding to level of confidence (1,96) ; P= estimated rate of cesarean section in primiparous women, q= 1-P ;

Thus, the estimated sample size was 345 patients, 170 patients per group, with a power of 80%, a risk of alpha error of 5%, $\Delta = 14\%$, and an increase of 10%.

All data were analyzed using Statistical Package for the Social Sciences (SPSS) software, version 2022.

d) *Patient and public involvement*

Randomization was carried out after checking the inclusion and non-inclusion criteria. The participants were randomized into two groups using the Sealed Envelope method after drawing lots. Thus, two groups were defined:

-The Active Management Group (AMG): The intervention consisted of an amniotomy followed by an infusion of oxytocin. The time between amniotomy and oxytocin infusion is 1 hour if there is no good contractile regime.

patients with increased oxytocin levels were monitored by fetal heart rate recording and tocography.

The initial dose administered was 4 mIU per minute, with a dose increasing of 2 mIU every 20 minutes (without exceeding 30 mIU/min). To consider the uterine contraction as adequate, the contraction force must exceed 200 Montevideo within 10 minutes.

-The expectant management group (EMG): We defined the failure of the expectant management as the absence of more than 3 cm cervical dilation after 24 hours of adequate uterine contractions (To consider the uterine contraction as adequate, the contraction force must exceed 200 Montevideo within 10-minutes).

Active management (amniotomy and/or oxytocin infusion) could be required in case of stagnation of cervical dilation for more than 2 hours or an abnormal fetal heart rate. In this case; as part of the intention-to-treat analysis, these patients were maintained in the expectant management group.

e) *Outcomes*

- The primary outcome was the cesarean section rate.

-The secondary outcomes of management were:

*Maternal complications

* Neonatal outcomes

* Duration of labor for patients who have given birth vaginally

*Patient satisfaction on the Likert scale: before discharge, each patient was asked about her satisfaction with the labor progression and immediate postpartum outcomes:

- How satisfied are you with the progress of labor?

1. **Very satisfied**
2. **Somewhat satisfied**
3. **Somewhat dissatisfied**
4. **Very dissatisfied**

- How satisfied are you with the immediate post-partum?

1. **Very satisfied**
2. **Somewhat satisfied**
3. **Somewhat dissatisfied**
4. **Very dissatisfied**

RESULTS

In our study, 340 women were randomized into two groups. The AMG included 170 patients and the EMG was composed of 170 women (**Figure 1**).

In the EMG, 31 parturients underwent amniotomy for pathological fetal heart rate or protracted dilation and no patient had oxytocin infusion. These patients were maintained in the same group for the intention-to-treat analysis.

The average age of parturients was 26 years. BMI of 27.33 Kg/m². The average gestational age of the patients was 40 weeks. All pregnancies were well monitored. According to the baseline characteristics of the parturients, both groups were comparable as well as concerning the newborn characteristics (the aspect of the amniotic fluid, and birth weight). **Table 1**

The rate of cesarean section was 35.6% in the total study population. The AMG was associated with a more important cesarean section rate than the EMG with a statistically significant difference (respectively 43.5% versus 27.6%, $p < 0.001$). The main indication for cesarean section was abnormal fetal heart rate, which was more frequently reported in the AMG with a significant difference ($p = 0.028$). The total instrumental delivery rate was 7.4%. This rate was significantly higher in the active management group ($P < 0.001$). The main indication for instrumental delivery was abnormal fetal heart rate with no significant difference between both management groups. **Table 2, 3**

Immediate maternal complications were reported in 36 cases and were more frequent in the AMG with a significant difference. The most frequent maternal complication was postpartum hemorrhage (PPH), which was more frequent in AMG with a considerable difference between the two groups. The rate of late postpartum complications was similar in the two groups, **Table 4**.

The average hospital stay duration was 38 hours. This duration was higher in the AMG with a significant difference ($p = 0.0001$).

For neonatal outcomes, an Apgar score superior to 8 at the first minute was reported in 93.5% of cases in the EMG group versus 84.7% of cases in the AMG, with a significant difference between the two groups ($p = 0.01$). At the fifth minute, the Apgar score had improved for the entire population.

Medical resuscitation of the newborn was required in 10% of cases and admission to the neonatology department was necessary in 6% of cases. Those rates were significantly more frequent in the AMG (respectively $p = 0.01$ and $p = 0.03$). Similarly, neonatal complications dominated by acute respiratory distress were higher in the AMG, **Table 5**.

The average duration between randomization and vaginal delivery was 15 hours and 47 minutes for the EMG versus 8 hours and 26 minutes for the AMG ($p= 0.001$), for patients who have given birth vaginally. The average duration of the latent phase was 20 hours and 38 minutes for the EMG and 13 hours and 19 minutes for the AMG with a very significant difference ($p<0.001$) for patients who have given birth vaginally.

The average duration of the active phase was 5 hours and 14 minutes for the EMG and 3 hours and 58 minutes for the AMG with a significant difference ($p<0.001$) for patients who have given birth vaginally.

Concerning the parturients' satisfaction, 68.2% of the AMG were satisfied for the labor progression versus 82.4% for the EMG; $p=0.003$. For immediate postpartum satisfaction, the majority of patients were delighted with no significant difference.

Table 6 summarizes the different outcomes for the two management groups.

DISCUSSION

a) *Main findings*

The increase in the rate of cesarean section remains a major concern in Tunisia and even throughout the world. The prolonged latent phase of labor is a common indication for active management by amniotomy and oxytocin infusion to shorten the labor duration.

We present here the first Tunisian study comparing the results of expectant management with those of active management in the event of a prolonged latent phase.

Our study showed that expectant management reduced the rate of cesarean sections and could avoid both maternal and fetal complications and similar results were reported by several studies.

b) *Strengths and Limitations*

This study was the first prospective randomized study carried out in Tunisia with a size calculated from the data of a pre-survey, which allows high scientific-level results. In addition, sociodemographic characteristics, medical history, and examination at admission were comparable between the two groups permitting pertinent statistical analyses. The sample size may also seem limited compared to the international literature data, but it is a large size compared to the Tunisian studies. However, after randomization, the follow-up of the patients was ensured by several contributors (resident on call, midwife) which can be a source of bias, even if the investigating doctor was the same. In our series, no patient benefited from epidural analgesia. Knowing the contribution of the epidural in obstetrical dynamics, the non-installation of the epidural in all patients could constitute a bias in our study. Finally, the monocentric nature of the study can limit the possibility of generalizing the outcomes, which suggests prospects for a multicenter study to conclude with definitive results.

c) *Interpretation and comparison with other literature*

Our study showed that expectant management reduced the rate of cesarean sections and could avoid both maternal and fetal complications and similar results were reported by several studies.

Janne Rossen and al undertook a cohort study including 20227 women with singleton pregnancies ≥ 37 weeks, cephalic presentation, spontaneous labor, and no history of cesarean section. Before the protocol's implementation, oxytocin was used if the progress of labor was perceived as slow. After initiation, oxytocin can only be administered if there is an indication to accelerate delivery. The overall rate of emergency cesarean sections decreased from 6.9% to 5.3% ($p < 0.05$) and the rate of emergency cesarean sections performed due to fetal distress was reduced from 3.2% to 2.0% ($p = 0.01$). [8]

In a study reported by Van Royen Laura at the medical-surgical and obstetrical center in Schiltigheim concerning the use of oxytocin in the latent phase, 193 patients were included. The authors concluded that the use of oxytocin significantly increased the rate of cesarean sections ($p=0.02$) as well as the rate of instrumental delivery ($p=0.01$) [9].

In addition, Piotr Baran and al reported that cesarean deliveries were noted in 16.97% of women in the AMG (16.97%) versus 8.85% in the control group ($p < 0.001$) [10].

Other studies have also shown an increase in the rate of caesareans for women in the latent phase who underwent labor management. [11]–[13]. Jennifer L. Ballit and al [11], evaluated all low-risk women with full-term pregnancies. The authors concluded that women admitted in the latent phase had more cesarean deliveries (14.2% versus 6.7%) and this can be explained by an active attitude using oxytocin and the use of amniotomy to accelerate labor.

In the same context, P Holmes and al concluded that women presented with a cervical dilation less than 3 cm were more likely to undergo amniotomy and oxytocin infusion than those who present at more advanced labor and that the cesarean section rate of these women is also significantly more increased (10.3% versus 4.2%) [12].

In our study, we noted immediate postpartum hemorrhage in 7.4% of cases. The literature reported similar rates varying from 5 to 10% [14]. Our results showed a low postpartum hemorrhage rate for EMG. Prolonged exposure to oxytocin during labor is associated with uterine atony and can increase the risk of postpartum hemorrhage due to desensitization of oxytocin receptors [15].

Tran and al performed a retrospective study including 490 and concluded that an increased oxytocin recovery interval was associated with a decrease in blood loss during cesarean section among women with directed labor [15]. Furthermore, A study carried out in the Port Royal maternity reported a significant association ($p = 0.015$) between compliance with the latent phase and the reduction in the rate of hemorrhage during delivery. [16].

Concerning the neonatal outcomes, we reported a lower rate of resuscitation in the delivery room and admission to neonatology in the EMG. Similarly, the study carried out by Pedro Hidalgo-Lopezosa and al showed a significant difference in the pH of umbilical cord blood in primiparae, but no significant differences were found concerning either 5-minute Apgar scores or neonatal resuscitation rates [17]. The neonatal results of this study are comparable with those of previous studies, in which oxytocin use was associated with lower umbilical cord pH values compared to unexposed mothers (16.17).

According to a study carried out in the Port Royal maternity hospital [16], a significant association was found between expectant management and a lower rate of neonatal resuscitation (12.8% for the AMG and 5.3% for the EMG). A significant difference was reported for the 5-minute Apgar score, the umbilical cord pH, and the immediate admission to neonatal intensive care ($p < 0.05$).

However, the active management of the prolonged latent phase allowed to shorten the duration of labor, saving occupation time in the delivery room at the expense of a longer hospital stay, with a very significant difference.

The study carried out by [Zohar Nachum](#) and al compared amniotomy, oxytocin, or both for the acceleration of labor in the prolonged latent phase [7]. The duration between the intervention and delivery was shorter in the case of active management (7 hours versus 12.33 hours in the control group, $p < 0.001$).

In addition, according to [Heather C Brown](#) and al, the duration between intervention and delivery was significantly longer for the control group compared to the active management group ($p < 0.005$) [20]. In the study carried out by [Sargunam](#) and al in central Malaysia, the duration of the latent phase was 9.6 ± 10.2 for the AMG versus 29.6 ± 18.5 h for the EMG ($p < 0.001$) [21].

The EMG was associated with a higher satisfaction rate concerning the labor process (82.4% versus 68.2%). For immediate postpartum satisfaction, the majority of patients were delighted with no significant difference.

Some authors highlight specific indicators of satisfaction, such as women's active participation in the birth process, which increases childbirth satisfaction and positive long-term memory (20).

A systematic review showed that the factors involved in a woman's satisfaction were the consideration of her expectations, the support provided by health professionals, the quality of her relationship with them,

and her participation in decision (21). Indeed, the presence of pain does not necessarily reflect a negative childbirth experience, pain can coexist with satisfaction (22).

Furthermore, a Malaysian study on induction of labor demonstrated that maternal satisfaction is associated with a shorter interval between induction and delivery[25]. A recent study also reported that women's perception of the healthcare quality, childbirth experience, and feelings were associated with the latent phase duration [26].

However, [Sargunam](#) and al reported that, despite having a significantly shorter intervention until delivery, women who underwent expectant management showed better satisfaction with the delivery process and with the outcome of the baby but with no significant difference [21].

In our study, patients in the AMG were less satisfied with the childbirth experience despite the shorter labor duration. This can be explained by the high rate of emergency cesarean sections in this group, which causes a stressful situation for the patient and influences the quality of satisfaction.

CONCLUSIONS

The active attitude compared to the expectant attitude to manage the prolonged latent phase has shown several disadvantages. Active management is associated with more cesarean sections, more maternal complications, less safety for the newborn, and longer hospital stays with less satisfaction rate.

According to this study, as well as to the results reported in the literature, expectant management in the case of the prolonged latent phase seems to be an effective alternative and we suggest its generalization.

COMPLIANCE WITH ETHICAL STANDARDS

Authors' contributions

OB, MD, contributed to the study design, data collection, and data analysis.

OB, MD, FC, and FK contributed to manuscript writing and review.

KC, critically revised the manuscript.

All authors read and approved the final manuscript.

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Study registration

We undertook a randomized comparative prospective study in the gynecology and obstetrics department of the Hedi Chaker University Hospital in Sfax, Tunisia, for six months between 1 July 2021 and 31 December 2021.

The study was registered in the Pan-African clinical trial on 07/08/2023 under the number PACTR202308714803965.

Approval was granted by the ethics committee of PROTECTION OF PEOPLE SOUTH, SFAX (ID: 0371/2021) (Approval date: 22.12.2021).

Disclosure of Interests:

The authors declare that they have no competing interests.

Ethical Approval

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Informed consent

Informed consent was obtained from all participants. Proof of consent to participate can be requested at any time.

Data sharing

The datasets generated and analyzed during the current study are not publicly available due to patient privacy but are available from the corresponding author.

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Table 1: Comparison of patients' characteristics in the EMG versus AMG

	EMG (N=170)	AMG (N=170)	P
Age (average in years)	26.11	26.87	0.13
BMI (Kg/m2)	26.98	27.68	0.41
Gestational age	39 weeks + 5 days	40 weeks + 2 days	0.45
Pregnancy monitoring (>5 prenatal consultations)	83.5%	86.5%	0.44
BISHOP score = 8	69.4%	68.2%	0.67
clear amniotic fluid	85.3%	75.9%	0.08
Weight of the newborn at birth	3188.24	3273.53	0.38
Funicular abnormalities	15.88%	12.94%	0.7

*EMG: expectant management group

*AMG: Active management Group

* BMI: body mass index

Table 2: Distribution of the population according to mode of delivery.

		EMG (N=170) N (%)	AMG (N=170) N (%)	p
Type of delivery	Vaginal	115(67.6)	79 (46.5)	< 0.001
	Instrumental	8 (4.7)	17 (10)	< 0.001
	cesarean section	47 (27.6)	74 (43.5)	< 0.001

*EMG: expectant management group

*AMG: Active management Group

Table 3: Distribution of the population according to the indication for cesarean sections.

	EMG (N=170) N (%)	AMG (N=170) N (%)	P
Abnormal foetal heart rate	23 (48.9)	51 (68.9)	0.028
Prolonged latent phase	7 (14.9)	9 (12.2)	0.66
Protracted dilation	7 (14.9)	4 (5.4)	0.077
Protracted fetal head descent	9 (19.1)	6 (8.1)	0.072
Intrauterine infection	1 (2.1)	4 (5.4)	0.64

*EMG: expectant management group

*AMG: Active management Group

Table 4: Repartition of patients according to postpartum immediate complications.

	EMG (N=170) N (%)	AMG (N=170) N (%)	P
Maternal complications	5 (2.9)	31 (18.2)	< 0.001
Immediate postpartum hemorrhage	4 (2.4)	21 (12.4)	< 0.001
Cervical laceration	0 (0)	3 (1.8)	0.08
Perineal tears	2 (1.2)	10 (5.9)	0.019
Perineal hematoma	0 (0)	1 (0.6)	0.31
Other complications	0 (0)	1 (0.6)	0.31

*EMG: expectant management group

*AMG: Active management Group

Table 5: Repartition of patients according to neonatal outcomes

	EMG (%)	AMG (%)	p
Neonatal Resuscitation	5.9	14.7	0.01
Admission to the neonatology department	2.9	8.8	0.03
Neonatal complications	2.94	11.2	0.02
Respiratory acute syndrome	2.4	9.4	0.03

*EMG: expectant management group

*AMG: Active management Group

Table 6: Comparison of labor and delivery outcomes in the EMG versus AMG

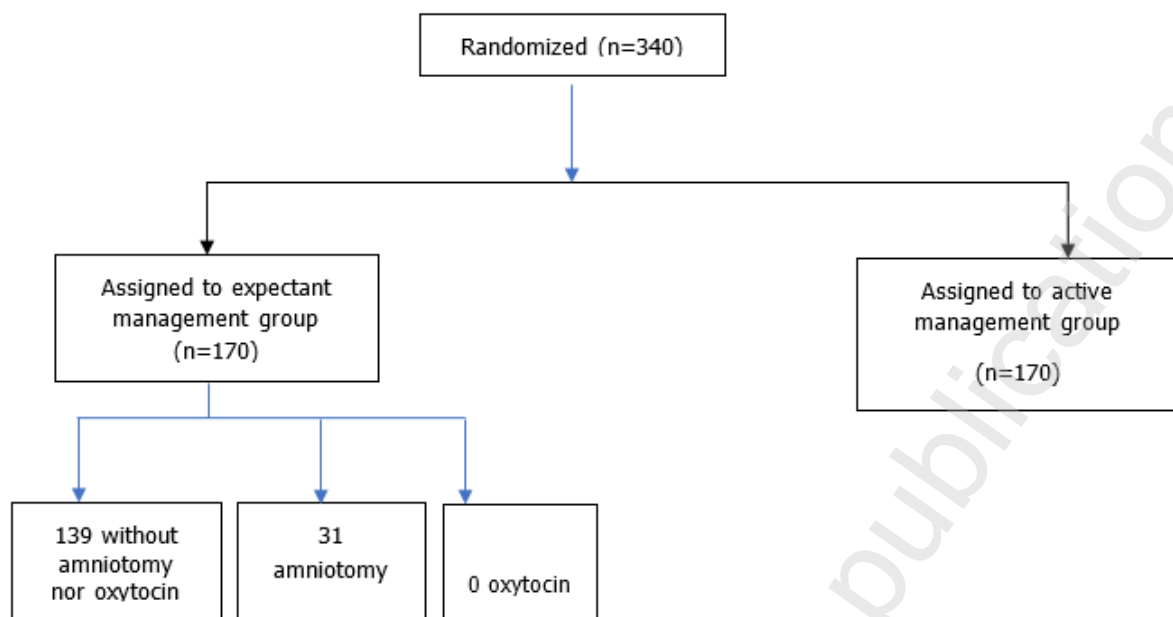
		EMG	AMG	p	
Type of delivery (N %)	Vaginal	115(67.6)	79 (46.5)	< 0.001	
	Instrumental	8 (4.7)	17 (10)	< 0.001	
	cesarean section	47 (27.6)	74 (43.5)	< 0.001	
Immediate maternal complications (N %)	Post Partum hemorrhage	4 (2.4)	21 (12.4)	<0.001	
	Perineal tears	2 (1.2)	10 (5.9)	0.04	
	Cervical laceration	0 (0)	3 (1.8)	0.08	
	Perineal hematoma	0 (0)	1 (0.6)	0.31	
Fetal complications (N %)	Apgar at 5 min	≤ 3	0 (0)	0 (0)	>0.05
		Between 4 and 7	1 (0.6)	1 (0.6)	>0.05
		≥ 8	169 (99.4)	169 (99.4)	>0.05
	Neonatal Resuscitation		10 (5.9)	25 (14.7)	0.01
	Neonatal hospitalization		5 (2.9)	15 (8.8)	0.03
Mean duration of labor for patients who had a vaginal birth. (Hours)	Duration between randomization and vaginal delivery.	15.79 (SD=2.35)	8.44 (SD=1.79)	0.0001	
	Active phase duration	5.24 (SD=0.68)	3.97 (SD=0.59)	< 0.001	
	Latent phase duration	20.63 (SD=2.31)	13.32 (SD=1.72)	< 0.001	
Satisfaction of parturients (N %)	For the labor progression	140 (82.4)	116 (68.2)	<0.001	
	For immediate postpartum	163 (95.9)	155 (91.2)	> 0.05	

*EMG: expectant management group

*AMG: Active management Group

* SD: standard deviation

Figure 1: Study Patient Flow Chart



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