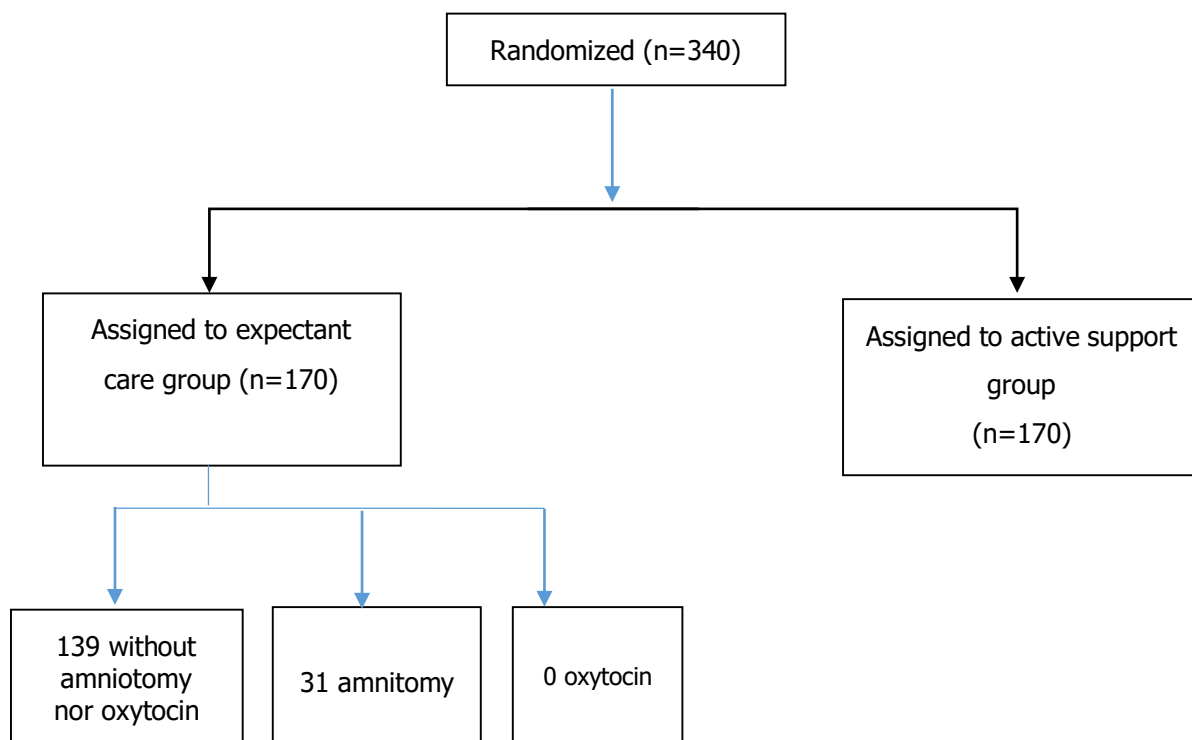


## 1-Results:

Our population was composed of 340 parturients randomized into two groups: a group of 170 who underwent the intervention: active management (amniotomy and oxytocin infusion) and a group of 170 parturients who underwent the intervention: expectant management. (Figure 1).



***figure1:Study Patient Flow Chart***

In the expectant management group, 31 parturients underwent amniotomy for pathological ERCF or stagnant dilation and no patient had oxytocin infusion. These patients were maintained in the same group for the intention-to-treat analysis.

### 1.1. Profile of parturients and characteristics of the newborn:

The general characteristics of our patients on inclusion in the study were comparable. The average age of parturients was 26 years with a BMI of 27.33 Kg/m<sup>2</sup>. All pregnancies were well monitored. We checked the comparability of the two groups according to the profile of the parturients; the population proved to be similar with regard to the criteria studied.

Concerning the characteristics of the newborn, the aspect of the amniotic fluid, the weight at birth as well as the funicular abnormalities were also similar between the two groups without significant difference.

### 1.2. Comparison of the two pipes:

Starting with the major comparison criterion, which was the rate of caesarean section, it was 35.6% in the total population: 27.6% for the GPE and 43.5% for the GPA with a significant difference between the two groups (  $P < 0.001$ ). The main indication for caesarean section was acute fetal distress. And it was more frequent in the GPA with a significant difference (  $p = 0.028$ ). The forceps delivery rate was 7.4%. It was significantly greater (  $P < 0.001$ ) in the active management group (10%), the main indication was acute fetal distress with no significant difference.

Concerning the secondary criteria, the immediate maternal complications were noted in 36 cases. They were more frequent in the GPA with a significant difference. (Table I). The most frequent maternal complication was postpartum hemorrhage (PPH) and it was more frequent in GPA with a significant difference between the two groups (table I).

The rate of late postpartum complications was similar in the two groups. And The average length of hospitalization was 38 hours, it was greater in the GPA with a significant difference.

***Table I: Distribution of the population according to complications  
immediate postpartum***

	<i>Expectant care NOT (%)</i>	<i>Active support NOT (%)</i>	<i>P</i>
<b>Maternal complications</b>	<b>5 (2.9)</b>	<b>31 (18.2)</b>	<b>&lt; 0.001</b>
Immediate postpartum hemorrhage	4 (2.4)	21 (12.4)	< 0.001
Rupture of the collar	0 (0)	3 (1.8)	0.08
Soft tissue 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

On the neonatal level, for the apgar score at the first minute, 93.5% of the GPE newborns were in good adaptation to extrauterine life with an apgar score > 8 against 84.7 of the GPA, with significant difference between the two groups. At the 5th min the apgar score had improved for the whole population.

Medical resuscitation procedures were necessary in 10% of cases and hospitalization in the neonatology department in intoxicating 6% of cases. They were significantly more frequent in GPA. Similarly, complications dominated by acute respiratory distress were higher for this same group. (Table II).

***Table III: Distribution of the population according to neonatal outcomes***

	<b>Rate (%)</b>	<b>GPE</b>	<b>GPA</b>	<b>p</b>
Resuscitation	10.3	5.9	14.7	0.01
NN				
Neonatal transfer	5.91	2.9	8.8	0.03
NN	7	2.94	11.2	0.02
Complications				
D.Respiratory	20/340	2.4	9.4	0.03

For the duration of labor, the average duration between intervention and vaginal delivery was 15h and 47min for the GPE and 8h and 26min for the GPA. With significant difference, (p= 0.001).

The average duration of the latency phase was 20h and 38min for the GPE and 13H and 19min for the GPA with a very significant difference (p<0.001).

The average duration of the active phase was 5h and 14min for the GPE and 3h and 58min for the GPA with a significant difference (p<0.001).

Concerning the satisfaction of the parturients, 82.4% of the parturients of the GPE were satisfied for the course of labor against 68.2% of the GPA with a significant difference between the two groups (p<0.001). For immediate postpartum satisfaction, the majority of patients were very satisfied with no significant difference.

Table III below summarizes the different results of the two groups:

***Table III: Results of the two groups***

		<i>GPE(N=139)N</i> (%)	<i>GPA(N=170)N</i> (%)	<i>p</i>	
Delivery route	VB	114(67.6)	79 (46.5)	< 0.001	
	Forceps	8 (4.7)	17 (10)	< 0.001	
	caesarean section	47 (27.6)	74 (43.5)	< 0.001	
Immediate maternal complications	PPH	4 (2.4)	21 (12.4)	<0.001	
	Soft tissue tears	2 (1.2)	10 (5.9)	0.04	
	Rupture of the collar	0 (0)	3 (1.8)	0.08	
	Perineal hematoma	0 (0)	1 (0.6)	0.31	
Fetal complications	Apgar at M1	≤ 3	2 (1.2)	1 (0.6)	0.01
		Between 4 and 7	9 (5.3)	25 (14.7)	0.01
		≥ 8	159 (93.5)	144 (84.7)	0.01
	Neonatal resuscitation		10 (5.9)	25 (14.7)	0.01
	Neonatal transfer		5 (2.9)	15 (8.8)	0.03
	Average working time	Duration between operation and vaginal delivery		15.79 (SD=2.35)	8.44 (SD=1.79)
Active phase duration		5.24 (SD=0.68)	3.97 (SD=0.59)	< 0.001	
Latency phase duration		20.63 (SD=2.31)	13.32 (SD=1.72)	< 0.001	
Satisfaction	For the workflow		140 (82.4)	116 (68.2)	<0.001
	For immediate postpartum		163 (95.9)	155 (91.2)	> 0.05

### 1.3. Per-protocol analysis

The comparison of the GPE group with or without the 31 cases having had an amniotomy compared to the GPA did not show any change in the results and the differences remained significant between the two groups for the various endpoints studied. (Table IV).

***Table IV: Results of the two groups after exclusion of the 31 parturients who underwent a GPE amniotomy***

		<i>GPE(N=139)N</i> (%)	<i>GPA(N=170)N</i> (%)	<i>p</i>	
Delivery route	VB	100 (71.9)	79 (46.5)	< 0.0001	
	Forceps	8 (5.8)	17 (10)	< 0.001	
	caesarean section	31 (22.3)	74 (43.5)	< 0.001	
Immediate maternal complications	PPH	4 (2.9)	21 (12.4)	0.002	
	Soft tissue tears	2 (1.4)	10 (5.9)	0.04	
	Rupture of the collar	0 (0)	3 (1.8)	0.25	
	Perineal hematoma	0 (0)	1 (0.6)	1	
Fetal complications	Apgar at M1	≤ 3	2 (1.4)	1 (0.6)	0.03
		Between 4 and 7	8 (5.8)	25 (14.7)	0.03
		≥ 8	129 (92.8)	144 (84.7)	0.03
	Neonatal resuscitation		8 (5.8)	25 (14.7)	0.01
	Neonatal transfer		5 (3.6)	15 (8.8)	0.06
	Average working time	Duration between operation and vaginal delivery		15.53 (SD=2.2)	8.44 (SD=1.79)
Active phase duration		5.27 (SD=0.64)	3.97 (SD=0.59)	< 0.001	
Latency phase duration		20.6 (SD=2.3)	13.32 (SD=1.72)	< 0.001	
Satisfaction	For the workflow	117 (84.2)	116 (68.2)	0.01	

For immediate postpartum	132 (95)	155 (91.2)	> 0.05
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