

## Active versus Conservative Management of Pre labor Rupture of Membranes at Term Pregnancies and Nursing Implications

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### Abstract:

**Background:** Pre- labor rupture of membranes is a spontaneous rupture of the membranes at/or after 37 weeks gestation and before the onset of labor. The **aims** of the present study were, to compare the clinical effectiveness and safety of active management versus conservative management in women with pre-labor rupture of membranes. Also to compare the maternal and neonatal out comes of active management versus conservative management in women with pre-labor rupture of membranes. A Quasi experimental **design** was selected in carrying out this study. The **setting** of the study was the labor ward, at Zagazig University Hospital. A representative **sample** of 160 parturient women who had premature rupture of membranes and undergoing management according to the inclusion criteria were recruited for this study. They were categorized into: **Study group** (n=80) who received oral misoprostol 50-200ug and **Conservative group** (n=80) who were observed for 24 hours and received the normal management technique. **The tools** used for data collection were; an interview questionnaire, Clinical assessment form, Ultrasonography, Cardio-Tocography, Medication sheet, Partograph, and Summary of labor sheet. **The results** of the present study revealed that women in the study group had shorter total duration of labor than the conservative group (7.2±1.4hrs VS 10.1±2.5hrs respectively) and lower rate of cesarean section (6.2% &18.7% respectively). Only one fetal death in the study group was reported compared to 3 in the conservative group. **It can be concluded that**, active nursing management by using oral misoprostol resulting in reduction in the mean duration of labour, lower percentage cesarean section rate and better infant outcomes. **The study recommended** the active nursing management using of misoprostol for faster and safer labor.

**Key words:** misoprostol, conservative management

### Introduction:

Pre labor rupture of membranes (PROM) is defined as rupture of the amniotic sac surrounding the fetus before the onset of labor. The period between rupture of membrane and the onset of labor is called the latency period. It is called prolonged rupture of membranes when the latency period is extended beyond 24 hours.<sup>(1)</sup>

The etiology of PROM remains unclear, but a variety of factors are contributing to its occurrence as :increased intrauterine pressure with multiple gestation and

polyhydramnios, inflammatory process such as cervicitis and amnionitis, abnormalities of the internal cervical os and incompetent cervix, inherently weak fetal membranes, nutritional deficiency, cigarette smoking, and low socio economic status.<sup>(2)</sup> The diagnosis of PROM is commonly made by taking the patient history, visualization of vaginal pooling of amniotic fluid, identification of vaginal fluid microscopic (ferning) and finding of alkaline PH using nitrazine paper. Patient can be examined or evaluated

for decreased amniotic fluid with Ultrasonography and it may be helpful to determine the position of the fetus, placental location, estimated fetal weight, and presence of any anomalies.<sup>(3)</sup> The risks and complications of PROM that occur depend on the time of gestation as well as the duration of rupture of membranes, and the quality management provided during labor and delivery.<sup>(4)</sup>

The management of pre-labor rupture of membranes at term is still a matter of debate, and varies from centre to centre. The major question regarding management of women with PROM at term is whether to allow them to enter labor spontaneously or to induce labor.<sup>(5)</sup> Misoprostol is a prostaglandin E1 analogue which is rapidly absorbed after oral administration. Its utero-tonic and cervical-ripening properties have become increasingly well-known, and a wealth of information has emerged from studies investigating its potential use in obstetrics and gynecology.<sup>(6)</sup> Misoprostol, has been used effectively both orally and vaginally for labor induction with pre-labor rupture of membranes.<sup>(7)</sup>

#### **Aims of the study:**

To compare the clinical effectiveness and safety of active versus conservative management in women with pre-labor rupture of membranes. To compare the maternal and neonatal outcomes of active management versus conservative management in women with pre-labor rupture of membranes (PROM).

#### **Research Question:**

- What are the maternal and neonatal outcomes of women with Pre-labor Rupture of Membrane who received active management with oral misoprostol versus who received conservative

management?

#### **Significance of the study:**

Pre labor rupture of membranes is a great problem in obstetrics. At Zagazig, according to the registries of the University Hospitals PROM rate was 18% in 2010. It is considered as one of the major factors contributing to perinatal mortality and morbidity in normally formed babies.<sup>(8)</sup> The nurse has a major role in following up of patient with PROM and during preparation of the mother for administration of oxytocin and misoprostol for induction of labor. Her meticulous observation and monitoring of maternal and fetal condition during both conservative and active management can reduce the overwhelming effects of this condition on mother or her fetus. Effective implementation of evidence- based health care practices remains a significant challenge in nursing. Thus the present study was done to shed evidence based light on the effect of active and conservative management of labor for women with pre-labor rupture of membranes on labor outcome.

#### **Subjects and methods:**

##### **Research design:**

a Quasi-Experimental design is used in this study.

##### **Setting:**

Data were collected for pregnant women demonstrating PROM who presented to the labor ward of the Maternity and Neonate Hospital, Zagazig University Hospitals. Zagazig University Hospitals had high flow rate and available to researcher to collect the data.

##### **Sample:**

Representative sample of 160 (according to flow rate in Zagazig

University Hospitals) parturient women who have pre labor rupture of membranes were selected according to the following Inclusion criteria: The participants age ranged between 25 and 35 years, Multigravida (parity,  $\leq 5$ ), Gestational age ( $\geq 37$  weeks), Demonstrated PROM ( $< 4$  hours) at term, Single-fetus pregnancy with vertex presentation, Had a normal cardiotocogram and an adequate pelvis on clinical pelvimetry.

***Exclusion criteria included:***

Signs and symptoms suggestive of chorioamnionitis (maternal fever, tachycardia, uterine pain/tenderness, purulent vaginal discharge, fetal tachycardia), fetal distress, (meconium), malpresentation, postdate, pregnancy, cord prolapse. In addition, inadequate pelvis on clinical pelvimetry, previous C.S, sensitivity to misoprostol, and other medical problems were all excluded. Patients were initially seen by nurses on the labor ward when presenting with a history of leaking amniotic fluid. Women fulfilling the inclusion criteria were assigned to either the active or the conservative management groups until the required sample size was achieved (80 parturient each).

***Tools of data collection:*** Data collection was done using the following tools:

I) an interview questionnaire: The questionnaire was designed to collect data from parturient women in both groups regarding to: Personal data such as age, education and occupation

II) Clinical examination "on admission to labor room" which includes: General examination, abdominal examination Local examinations under complete aseptic precautions.

III) Ultrasonography: To evaluate fetal gestational age, fetal viability,

placental abnormalities, Amniotic Fluid Index (AFI), fetal weight, fetal presentation.

IV) Medication record.

V) Partograph: to evaluate labor progress.

VI) Follow up record: The sheet was used to record data related to women and fetal condition during their hospital stay and any problem that have arisen.

VII) Summary of labor record: It included data about the duration of labor, the mode of delivery, neonatal Apgar score at first and fifth minutes, neonatal condition and complications, as well as problems that may be encountered during the second, third or fourth stage of labor.

VIII) Neonatal Outcome record

X) Clinical Guidelines for Management of Prelabour Rupture of Membranes at Term.

Tools used after testing their validity through taking approval from three experts in the field of nursing and medicine.

***Field work:***

Data collection took a period of eight months from first of January 2011 to the end of August 2011. After getting the official permission the pilot testing of the study tools was done and analyzed. The researcher started the data collection for 3 days per week. Patients were initially seen on the labor ward by the researcher and the on-duty physician when presenting with a history of leaking amniotic fluid. Intervention phase:

Women were randomly assigned to two groups: Study group and Conservative group.

- (A) Women in the active study group received 50 µg of oral misoprostol, which is repeated every 6 hours up to a maximum of four doses (200 µg). If there were no uterine contractions or less than two mild contractions in 10 minutes. Before every dose, a fetal Cardiotocography was done. When uterine activity suggested the onset of labor, vaginal assessment was performed and the women were moved to the labor ward.
- (B) Women in the conservative control group (80) were kept under observation for 24 hours. Continuous maternal and fetal monitoring was performed.
- C) Implementation of the proposed nursing protocol:  
The implementation of the clinical guidelines or the nursing protocol was done during the assessment and management phases. Whereby, the researcher together with the assigned nurse midwives tailored such protocol (Appendix X) to meet each parturient and her fetus needs during the active and conservative management of PROM.

#### ***Pilot study:***

Before embarking on actual study, a pilot study was done for testing the tools and the study maneuvers. It was done on twenty women in the study setting who were included in the main study sample. Testing the tools was for identifying any ambiguous questions; it also aimed at estimating the time needed for filling out the forms. Modifications were done according to the pilot results.

#### ***Administrative and ethical considerations:***

An official approval was taken from the authorized personnel in the faculty and in the data collection

setting. An explanation of the aim of the study was given to every eligible woman before asking her to participate in this study, and written consent was obtained.

Each woman was instructed about her rights to refuse to participate, and to withdraw from the study at any time. Strict confidentiality of any obtained information was ensured. Professional help was provided to the participants. The study maneuvers are scientifically approved, and do not entail any harmful effect on subjects.

#### ***Statistical design:***

The data were recorded, categorized, tabulated and analyzed using computer software, SPSS version 13 using independent sample t test (Mean±SD) and chi-squared test (X<sup>2</sup>) with P< 0.05 is significant.

#### ***Results:***

**Table (1)** shows the absence of any significant difference between the study and conservative groups in their general characteristics. Where slightly less than two thirds (65.0%) of the conservative group were below 30 years old compared to more than half (53.8%) of the study group with approximately similar mean age of the two groups ( $28.9 \pm 2.8$  and  $28.8 \pm 2.9$  respectively). Meanwhile, almost two thirds of the study and conservative groups (65.0% & 66.3% respectively) were housewives and more than two fifth (43.8%) of the study group were illiterate or can read and write compared to 38.8% of the control group.

The past obstetrical history of the studied women is presented in **table (2)**, Regarding gravidity the table shows that more than one fourth (28.7%) of women in the conservative group were gravida 4 and more compared to 15.0% of the study group. As for parity, three fifth (60.0%) of

women in the conservative group were Para 3 and more compared to 21.4% of the study group, with statistical significant difference ( $X^2 = 23.3$ ,  $P = 0.000^*$ ). Previous history of abortion was evident in close proportion among the study and conservative groups (32.5% and 38.8% respectively). Meanwhile, the previous history of previous PROM among the study group was higher than that among the conservative group (31.3% and 23.3% respectively), but with no statistical significant difference.

**Table (3):** compares women condition upon admission to labor room in both study and conservative groups. It is evident that the two groups had close mean gestational age ( $38.2 \pm 1.4$  and  $39.3 \pm 1.7$  respectively), with no statistical significant difference. As regards the time elapsed from PROM until admission, it ranges between 1-4 hours with a similar mean in both study and conservative groups ( $3.1 \pm 1.7$  and  $3.1 \pm 1.9$  respectively). Conversely, fewer women in the conservative group had AFI < 6 compared to those in the study group (17.5% Vs 26.3% respectively).

Concerning the timing of events in labor after recruitment, according to type of management in the studied subjects, **table (4)** shows that the latency period and the total time between recruitment and delivery were significantly shorter in the study group ( $p < 0.000$ ). Thus the mean latency period and time between the onset of uterine contractions and delivery were significantly higher in the conservative group, compared to the study group ( $16.2 \pm 5.1$ ,  $9.4 \pm 2.4$  Vs  $10.1 \pm 4.1$ ,  $7.4 \pm 1.2$  hrs respectively).

**Figure (1) and (2)** compare the mode of delivery and indications of CS in the two groups. It is obvious that more women in the study group had normal vaginal delivery ( $X^2 = 4.6$ ,  $p = 0.031^*$ ). Conversely, more women

in the conservative group had CS (18.7%) compared to less than one tenth of the study group (6.2%). Fetal distress in the first stage was the most common indications among the study group with the highest percentage (80.0%) compared to only 26.7% in the conservative group. The difference observed is statistically significant ( $X^2 = 9.3$ ,  $p = 0.035^*$ ). On the other hand, more than half (53.3%) of the conservative group had their CS due to failure of labor progress, compared to none among the study group. Fetal distress in the first stage and cervical dystocia were also evident as indications of CS among the conservative group (26.7% and 20.0% respectively).

**Figure (3):** compare the duration of the various stages of labor among parturient women in the two studied groups. It is evident that the mean duration of the first stage of labor was significantly shorter among women in the study group ( $6.6 \pm 1.5$  hrs), compared to those in the conservative group ( $9.1 \pm 2.5$  hrs), the differences observed was statistically significant ( $P = 0.001$ ). The table also shows that mean duration of the second and third stage of labor were shorter in the study group ( $33 \pm 9.4$  &  $14.2 \pm 4.9$  minutes), compared to the conservative group ( $40.4 \pm 12.9$  &  $17.1 \pm 5.9$  minutes) and the difference was statistically significant. Moreover, the mean duration of the three stages of labor was significantly higher ( $X^2 = 38.5$ ,  $P = 0.000^*$ ) in the conservative group, compared to the study group ( $10.1 \pm 2.5$  and  $7.2 \pm 1.4$  minutes respectively).

#### Discussion:

Regarding socio-demographic data, the present study showed that the two groups were almost similar in their mean age which was less than 30 years and the difference observed was not statistically significant. These findings

were congruent with those reported by Ngai et al.,<sup>(9)</sup> in a study about "Active management of term pre labor rupture of membranes with oral misoprostol".

The present study showed that about two thirds of women in the two studied groups were house wives. This finding may clarify that house wives carry heavy house duties in addition to caring for children or other family member, so they are liable to have PROM. These data are in agreement with Shetty et al.,<sup>(10)</sup> who reported -in their studies about" Occupational fatigue and preterm premature rupture of membranes"- that occupational fatigue was independently associated with a significant increased risk of PROM.

Concerning parity, the present study showed that, more than three quarters of women in the study group were Para 1-2 and more than half of women in Conservative group were Para 3+. This finding means that PROM can happen for any pregnant women whether primiparous or multiparous. Similar findings were also reported by Tarik<sup>(11)</sup> in united state of America.

Other important factors related to induction of labor were women's gestational age and the time of membrane rupture. The results of the current study showed that, the range of gestational age at entry was 37-40 weeks and the mean was almost the same for the study and conservative groups ( $38.2 \pm 1.4$  and  $39.3 \pm 1.7$  respectively). These findings are in agreement with Manuck et al.,<sup>(12)</sup> in his study about " Pre labor rupture of membranes at term in low-risk women: induce or wait?" who mentioned that the mean of gestational age in the two studied groups were  $38.5 \pm 2.1$  &  $39.7 \pm 2.0$  respectively.

According to the assessment on admission, it is clear -in the current study- that, the mean fetal heart rates in the two studied groups were nearly similar  $142.2 \pm 5.4$  and  $142.7 \pm 4.4$  respectively. It is also clear that, the Bishop Score on women's admission was less than 7 in the two groups. This finding is in agreement with Dare et al.,<sup>(13)</sup> in their study about "Safety and efficacy of misoprostol in induction of labor in pre labor rupture of fetal membrane in Nigerian women". The researchers reported that the cervical score at commencement of induction were less than 6; its unfavorability placed the oxytocin arm at disadvantage since misoprostol is a cervical ripening agent. While misoprostol acts at both the cervical level and uterine level, Moreover, concerning to AFI the present study revealed that, most women in the Study and Conservative groups had AFI more than 6.

Concerning the time from management and the start of uterine contractions, the present study findings illustrated that, the latency period and the time from recruitment until delivery were significantly shorter in the study group than in the conservative group ( $10.1 \pm 4.1$  and  $16.2 \pm 5.1$  respectively). Meanwhile, women in the study group had shorter onset of contraction -to-delivery interval than the Conservative group ( $7.4 \pm 1.2$ hrs and  $9.4 \pm 2.4$ hrs respectively) with statistically significant difference. This finding could confirm the effectiveness of misoprostol to shorten the latency period and the efficiency of nurses' management skill of PROM.

These findings are supported by the findings of Ahmad et al.,<sup>(14)</sup> in Saudi Arabia in a study about "pre labor rupture of membranes at term in patient with unfavorable cervix: Active

versus conservative management". The researchers reported that, in their study group, almost all women showed significant uterine contractions within 24 hours of PROM, compared with 69% in conservative group.

In relation to mode of delivery, the current study showed that, the number and percentage of women who delivered normally were more in the study group than that in the conservative group. The majority of women in the study group had normal vaginal delivery (93.8%) compared to more than three quarters of women (81.3 %) in the Conservative group and the difference was statistically significant.

As regarding to cesarean section, the rate in the Conservative was higher (18.7%) than that in the Study group (6.2%) and the difference was statistically significant. This result means a preference for the active over the conservative management as regarding the mode of delivery.

This result is on the same line with that of Flenady et al.,<sup>(15)</sup> in Canada who reported that, caesarean section rates were higher in the conservative group than that of the group that received misoprostol. This means that the group that received misoprostol had better results with respect to the rate of vaginal delivery as a difference of 10% in these percentages cannot be considered negligible. Like wise, in San Francisco<sup>(6)</sup> reported that, the emergency CS rate due to failure of progress in the conservatively managed induction was almost twice than that in the misoprostol group.

In the mean time, Tarik<sup>(11)</sup> confirmed that, the normal vaginal delivery were higher in the misoprostol group (70%) compared to (67.5%) in the conservative group however, the difference was not statistically significant, and the cesarean section

rate, and instrumental deliveries were similar in both groups.

An important outcome of the present study was the overall duration of labor interval which was shorter ( $7.5 \pm 1.4$  hours) in the study group compared to  $10.1 \pm 2.5$  hours in the conservative group with statistical significant difference. This finding could indicate that nurses' active management of PROM with an unfavorable cervix using oral misoprostol was effective and results in a shorter interval between membrane rupture and delivery, and significantly more patients go into labor and deliver within 24 hours of PROM. The current finding is similar to those achieved by Manuck et al.,<sup>(12)</sup> in Canada who reported that the mean time of vaginal delivery with oral misoprostol group was  $501 \pm 389$  minutes compared to  $720 \pm 382$  minutes with conservative group. Also, the findings of the present study were in agreement with Ngai et al.,<sup>(9)</sup> who found in their study that, seventy-two percent of these women who delivered vaginally, did so within 24 hours of the pre labor rupture of membranes in the active group as compared with almost one quarter in the conservative group. The rupture of membranes to delivery time was significantly shorter in the active group (20.5 hours [SD 12] vs. 35.5 hours [SD 15], mean difference 15 hours, 95% CI 7.2 to 22.8).

### **Conclusion:**

Based on the study findings it can be concluded that:

Active management of PROM using oral misoprostol was responsible for shortening the latency period, the total time from recruitment until delivery and the time of maternal hospitalization. Active management using oral misoprostol at a dose of 50 µg was effective for cervical ripening and labor induction. The mean

duration of the second stage of labor was significantly shorter among women in the study group compared to those in the conservative group. Almost more women in the conservative group had significantly higher percentage of cesarean section compared to those in the study group.

#### Recommendations:

In the light of the study findings, the following recommendations are suggested:

- The active management of PROM using oral misoprostol at 50 µg at 6 h

interval is more effective than conservative management as it has less duration for labour, less incidence of C.S, better Neonatal outcome and less neonatal death and therefore, active management of PROM should be encouraged and advised.

- Proposed clinical nursing protocol for the management of PROM and using it in service training for training for nurse midwives.

**Table (1): Number and percent distribution of the study subjects according to their general characteristics**

General characteristics	Groups				X <sup>2</sup>	P
	Study (n=80)		Conservative (n=80)			
	No.	%	No.	%		
Age					2.1	0.147
▪ < 30	43	53.8	52	65.0		
▪ 30+	37	46.2	28	35.0		
Mean ± SD	28.9 ± 2.8		28.8 ± 2.9		t=0.41 <sup>@</sup>	0.683
Occupation					0.03	0.868
▪ House wife	52	65.0	53	66.2		
▪ Working	28	35.0	27	33.8		
Education					5.1	0.402
▪ Illiterate	30	37.5	22	27.5		
▪ Read and write	5	6.3	9	11.3		
▪ Primary school	3	3.8	2	2.5		
▪ preparatory school	11	13.7	8	10.0		
▪ Secondary school	25	31.2	35	43.7		
▪ University	6	7.5	4	5.0		

<sup>@</sup> Independent sample t test



**Table (2): Number and percent distribution of the study subjects according to their obstetrical history**

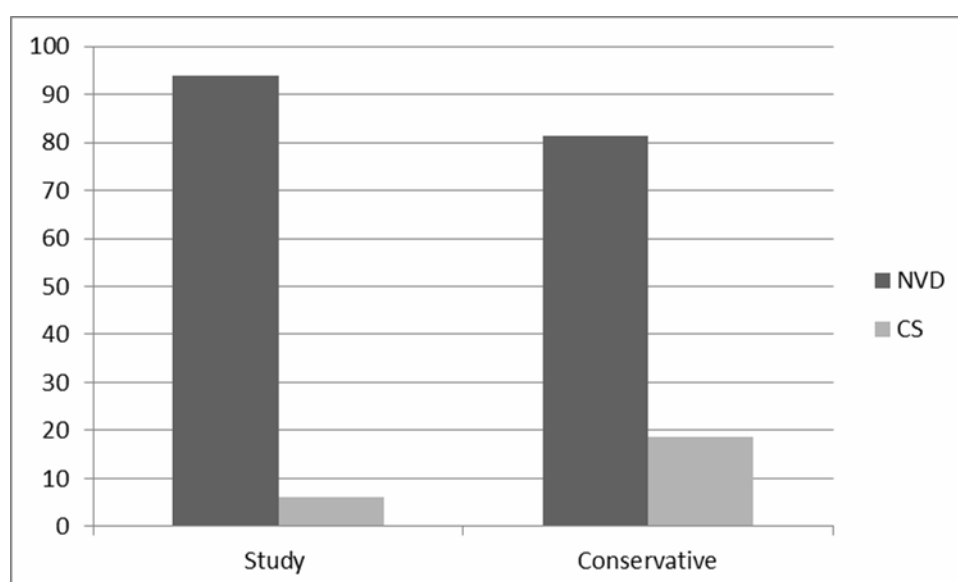
Obstetrical history	Groups				X <sup>2</sup>	P
	Study (n=80)		Conservative (n=80)			
	No.	%	No.	%		
Gravidity					3.7	0.055
▪ 2-3	68	85.0	57	71.3		
▪ 4+	12	15.0	23	28.7		
Parity					23.3	0.000*
▪ 1-2	63	78.6	32	40.0		
▪ 3+	17	21.4	48	60.0		
Mean ± SD	2.2 ± 0.9		2.4 ± 0.9			
Previous abortion					0.44	0.509
▪ No	54	67.5	49	61.2		
▪ Yes	26	32.5	31	38.8		
PROM in previous deliveries					1.1	0.284
▪ No	59	68.7	63	76.7		
▪ Yes	21	31.3	17	23.3		

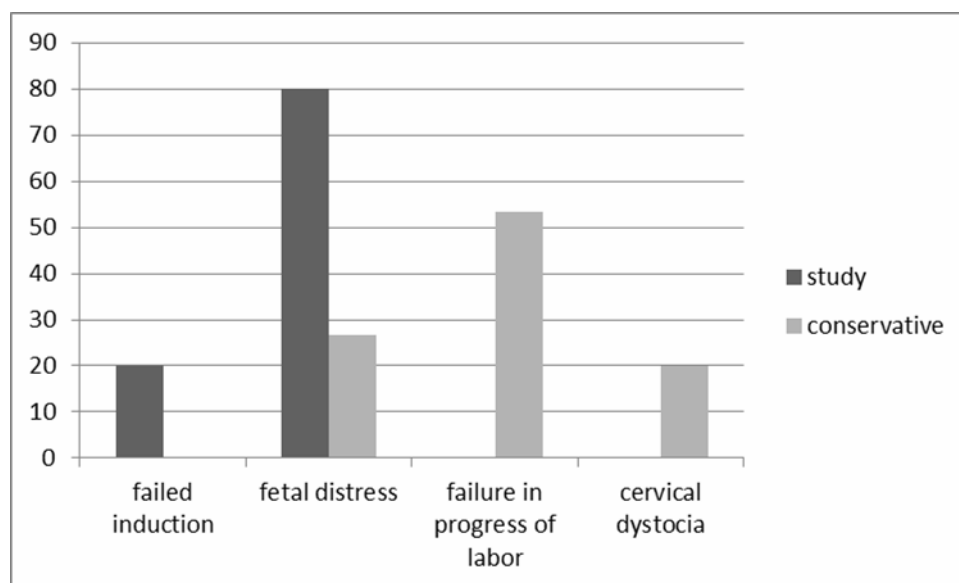
**Table (3): Number and percent distribution of the study subjects according to the current labor data**

Current labor data	Groups				X <sup>2</sup>	P
	Study (n=80)		Conservative (n=80)			
	No	%	No	%		
Gestational age(weeks)						
▪ 37	11	13.8	8	10.0	6.2	0.101
▪ 38	16	20.0	26	32.5		
▪ 39	48	60.0	36	45.0		
▪ 40	5	6.2	10	12.5		
Mean ± SD	38.2±1.4		39.3±1.7			
Duration of rupture of membranes						
▪ < 2	64	80.0	60	75.0	0.57	0.449
▪ 2+	16	20.0	20	25.0		
Mean ± SD	3.1 ± 1.7		3.1 ± 1.9		Z=0.02 <sub>m</sub>	0.978
AFI (ultrasound)						
▪ < 6	21	26.3	14	17.5	1.3	0.251
▪ 6 +	59	73.7	66	82.5		

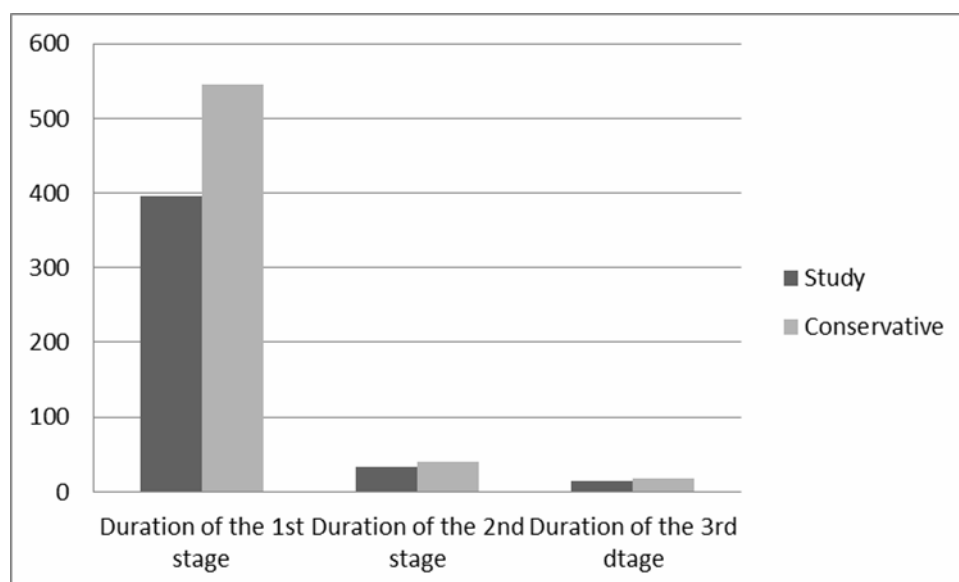
**Table (4): Number and percent distribution of the study subjects according to the latency and total period until delivery**

Time (hours)	Groups				FEP \$
	Study(n=80)		Conservative(n=80)		
	No.	%	No.	%	
Time Between recruitment and beginning of uterine contractions “latency period”					0.028*
▪ < 24 hrs	80	100.0	74	92.5	
▪ 24+	0	0.0	6	7.5	
Mean ± SD	10.1 ± 4.1		16.2 ± 5.1		0.000* <sup>m</sup>
Time Between onset of contraction and delivery					0.010*
▪ <6	3	3.8	1	1.3	
▪ 6-12	77	96.2	71	88.7	
▪ >12	0	0.0	8	10.0	
Mean ± SD	7.4 ± 1.2		9.4 ± 2.4		0.000* <sup>m</sup>

**Figure (1): Mode of delivery**



**Figure (2): Indications of C.S**



**Figure (3): The mean duration of the three stages of labor**

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