

## ORIGINAL RESEARCH

# Vaginal versus intramuscular progesterone for prevention of preterm labour in high risk pregnancy

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### ABSTRACT

**Aim:** Vaginal versus intramuscular progesterone for prevention of preterm labour in high risk pregnancy.

**Materials and methods:** 150 have received either vaginal or intramuscular progesterone as per obstetrician choice. women with Singleton pregnancy, Gestational age 20-36 weeks POG best determined according to LMP or early fetal ultrasonography, History of preterm, premature rupture of membrane before 37 weeks, History of spontaneous mid trimester loss of last pregnancy And Vaginal bleeding after 14 weeks in present pregnancy were included in this study. Vaginal group: 75 patients received 200mg vaginal tablet twice daily. Intramuscular group: 75 patients received 250mg of intramuscular hydroxy progesterone caproate once weekly injection.

**Results:** The mean age of the patient in the vaginal group was 28.21±3.45 years and in the intramuscular group was 28.20±3.68years. Mean gestational age (in weeks) at start of progesterone in take was 21.48±1.90 in vaginal group and 21.67±1.80 in intramuscular group. Differences between both the groups was not statistically significant (p=0.538). The above table depicts, that mean gestational age (in weeks) at the time of delivery was 35.88±3.21 in vaginal group and 35.72±3.49 in intramuscular group. It was seen that 55 cases who delivered preterm had a mean cervical length of 2.53±0.38 cm and 95 cases who delivered at term had a mean cervical length of 3.07±0.26 cm and this difference was statistically significant (p≤0.001). 53 (70.7%) babies in the vaginal group and 55 (73.3%) babies in the intramuscular group had no admission to NICU while 22 (29.3%) babies in vaginal group and 20 (26.7%) in intramuscular group were admitted in NICU.

**Conclusion:** We conclude that vaginal progesterone and intramuscular progesterone can be equally useful in the prevention of preterm delivery. Vaginal progesterone in dose of 200 mg twice a day was as effective as 250mg/week of intramuscular progesterone in reducing preterm birth.

**Keywords:** Vaginal, Intramuscular, Progesterone, Preterm labour

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### Introduction

Preterm birth is one of the most common complication during pregnancy and it occurs 11.1% worldwide.<sup>1</sup> Reports indicate that between 5 and 25% of all pregnancies results in premature delivery. Despite improvement in perinatal care, the rate of preterm delivery in developing countries is higher than in developed countries, and in recent years further increase have been observed.<sup>2</sup> Preterm delivery has many negative consequences for newborn their families and society, and it is the leading cause of neonatal mortality and longterm morbidity. In recent years preventing preterm delivery has become a major priority for healthcare system in

most countries. Preterm labour refers to the onset of uterine contraction of sufficient strength and frequency to effect progressive dilatation and effacement of cervix between 20 and 37 weeks of gestation.<sup>3</sup> Although all birth before 37 weeks of gestation are considered premature, birth before 34 weeks of gestation account for most neonatal deaths and disorder.<sup>4</sup> Preterm labour is taken into account, if regular uterine contractions documented for at least four in 20 minutes or eight in 60 minutes with progressive change in the cervical score in the form of effacement of 80% or more and cervical dilatation greater than 1 cm. Prematurity is also classified according to gestational age at birth:5 Near term 34-

36 weeks (60-70%), Moderate prematurity 32-33 weeks (20%), Severe prematurity 28-31 weeks (15%) and Extreme prematurity <28 weeks (5%). Prematurity is strongly with long term development disability as well, accounting for 1 in 5 children with mental retardation, 1 in 3 children with vision impairment and almost half of children with cerebral palsy. Those who are spared are at increased risk for cardiovascular disease (myocardial infarction, stroke and hypertension) and diabetes in adult life. Overall incidence of preterm labour is reported to be 6-15% and 40-50% of these occur spontaneously, where as 25% occurs following preterm pre-labour rupture of membrane (PPROM). Iatrogenic preterm labour due to obstetric intervention to avoid maternal or foetal compromise account for about 25%.<sup>3</sup> Preterm birth is leading cause of perinatal morbidity and mortality worldwide and is associated with 60-80% of death of infants without congenital abnormalities. An estimated 15 million babies born preterm every year, that is more than 1 in 10 babies in almost all countries with reliable data, preterm birth rates are increasing. Unfortunately, 24% of all preterm birth occur in India.<sup>5</sup> Progesterone can be given orally, vaginally, or intramuscularly. Oral and vaginal preparation are natural progesterone while the intramuscular drug 17-hydroxyprogesterone caproate is synthetic. The dose of natural progesterone ranges from 90-400mg daily. They can be dispensed in the form of gel or a dispensable pessary for better bioavailability and less local discomfort. Vaginal route is preferred route as there are minimal side effects like sleepiness, fatigue and headache, which can be seen with oral intake. It also offers better bioavailability as it bypasses the hepatic first pass effect. Endometrial bio-availability after vaginal progesterone use is also reported to be higher than with the later are higher. Vaginal progesterone is available in form of Tablet 200mg of natural micronized progesterone to be instilled daily as it has half-life of 13 hours.<sup>6</sup> 17-hydroxyprogesterone caproate is the only synthetic progesterone exclusively given by intramuscular route. It is the only progesterone approved by FDA for administration during pregnancy. The doses have ranged from 250mg every 5 days to 1000mg weekly. The half life of drug is approximately 7 days making weekly dosage most appropriate. The drug is actively metabolized in the placenta and significant concentration of exogenous 17-hydroxyprogesterone caproate and its metabolites also cross the placenta. The side effects in the form of injection site reaction, swelling, itching and mild bruising are seen and are reported by more than half of the patients.<sup>7</sup>

### Materials & methods

A Prospective, observational study was done in the Department of Obstetrics and Gynaecology, Batra Hospital & Medical Research Centre from March 2019 to April 2020. The study population included 150 high risk pregnant females treated at BHMRC,

Data was collected from patient who have received either vaginal or intramuscular progesterone as per obstetrician choice. women with Singleton pregnancy, Gestational age 20-36 weeks POG best determined according to LMP or early fetal ultrasonography, History of preterm, premature rupture of membrane before 37 weeks, History of spontaneous mid trimester loss of last pregnancy And Vaginal bleeding after 14 weeks in present pregnancy were included in this study. Women with preterm birth (less than 37 weeks gestation) associated with or attributable to Placental abruption or placenta previa, Multiple pregnancy and Iatrogenic decision for early birth were excluded from the study.

### Methodology

Written informed consent was taken from each participating subject fulfilling the inclusion criteria after explaining the study protocol in details. A detailed history was taken including age, parity, ANC booking status, present history including amount of vaginal bleeding, number of episodes, association with pain abdomen, aggravating/relieving factors, progesterone supplementation given, discharge per vagina, itching, past medical, surgical and obstetric history was taken from the patients. Data was collected from patients who have received either vaginal or intramuscular progesterone as per obstetrician choice. Detailed physical examination of each patient was done including weight, general physical examination, systemic examination abdominal and per vaginal examination for size of uterus, amount of vaginal bleeding, local causes of bleeding, discharge per vagina and cervical status were recorded. Data was collected from the routine investigations done for antenatal patients; blood group, CBC, HIV, Australian antigen, VDRL, Glucose challenge test, S.TSH and urine routine/microscopy, high vaginal swab (if discharge present). Data was collected from ultrasound findings in first trimester for confirmation of site and number of embryos, foetus viability, gestational age, subchorionic haemorrhage, cervical status; as well as subsequent ultrasound was done in pregnancy for assessment of foetal growth, placental status, amniotic fluid volume and doppler abnormalities. Detailed anomaly scan was performed between 18-22 weeks of gestation, growth scan at 32-34 weeks and at any time indicated were done. 150 high risk patients who were prescribed either vaginal or intramuscular progesterone as per obstetrician choice was included in the study. The data was collected from these patients. Vaginal group: 75 patients received 200mg vaginal tablet twice daily. Intramuscular group: 75 patients received 250mg of intramuscular hydroxy progesterone caproate once weekly injection. Patient were asked to bring empty drug packages in each visit to detect patient compliance. For all patient medication was started from 20 weeks of gestation or when they entered in study group until either

complete 36 weeks gestation, occurrence of premature rupture of membrane or preterm delivery. The 2 groups were followed up regularly in antenatal clinics and in the wards. All patients were followed during labour and early postnatal period till the time of discharge, in collaboration with the neonatologist.

**Statistical Analysis**

The results were presented in frequencies, percentages and mean ±SD. The Chi-square test was used to

compare categorical/dichotomous variables. The p-value<0.05 was considered significant. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA).

**Results**

Total of 150 patients divided in two groups, 75(50%) patient given vaginal progesterone and 75(50%) given intramuscular progesterone.

**Table: 1 Distribution of study subjects according to residence and Gravida**

Residence	Vaginal		Intramuscular		p value
	Frequency	%	Frequency	%	
Rural	17	22.7%	22	29.3%	0.352
Urban	58	77.3%	53	70.7%	
Gravida					0.984
1	6	8.0%	4	5.3%	0.984
2	32	42.7%	35	46.7%	
3	21	28.0%	21	28.0%	
4	11	14.7%	11	14.7%	
5	4	5.3%	3	4.0%	
6	1	1.3%	1	1.3%	

The table depicts, that 17 (22.7%) patient in vaginal group and 22 (29.3%) patient in the intramuscular group were from a rural background. 58 (77.3%)patient in vaginal group and 53(70.7%) patient in intramuscular group had an urban background. Which is statistically not significant (p=0.352). The mean age of the patient in the vaginal group was 28.21±3.45 years and in the intramuscular group was 28.20±3.68years. Therewasnostatisticallysignificantdifference in the age profile of patient in the two groups (p=0.982).Above table depicts,6(8%) patients were primi gravida who received vaginal progesterone and 4 (5.3%) who received intramuscular progesterone. 69 (92%) were multigravida who received vaginal progesterone and 71 (94.7%) were multigravida who received intramuscular progesterone. Both the groups were comparable with respect to obstetrical parameters (gravida). Which is statistically not significant (p=0.984).

**Table:2 Obstetrical parameters (Parity) of both groups**

	N	Parity		p value
		Mean	Std. Deviation	
Vaginal	75	1.11	0.91	0.525
Intramuscular	75	1.20	0.89	

The above table depicts, that mean parity in vaginal group was1.11±0.91and1.20±0.89in intramuscular group. Both the groups were comparable with respect to obstetrical parameters (parity). No statistically significant difference was seen in both groups (p=0.525).

**Table: 3 Distribution of study subjects as per history of previous abortion**

Abortion	Vaginal		Intramuscular		p value
	Frequency	%	Frequency	%	
0	38	50.7%	44	58.7%	0.591
1	29	38.7%	24	32.0%	
2	7	9.3%	7	9.3%	
3	1	1.3%	0	0.0%	
Total	75	100%	75	100%	

The above table depicts, the distribution of study subjects as per history of previous abortion. It was found that 38 (50.7%) patients in vaginal group and 44 (58.7%) patient in the intramuscular group had no previous abortion. 29 (38.7%) in vaginal group and 24 (32%)in intramuscular group had one previous abortion. 7(9.3%)in both groups had two previousabortions.1(1.3%)invaginalgroupand0%inintramusculargrouphadprevious three abortions. Hence, the difference between both the groups was not significant (p=0.591).

**Table: 4 Study subject according to their previous history of preterm delivery**

Previous Preterm Delivery	Vaginal		Intramuscular		p value
	Frequency	%	Frequency	%	
0	24	32.0%	16	21.3%	0.292
1	37	49.3%	46	61.3%	
2	14	18.7%	12	16.0%	
3	0	0.0%	1	1.3%	
Total	75	100%	75	100%	

The above table depicts, that 24 (32%) patients in vaginal and 16 (21.3%) patients in intramuscular group had no previous history of preterm delivery. 37 (49.3%) patients in vaginal group and 46 (61.3%) in intramuscular group had previous one preterm delivery. 14 (18.7%) in vaginal group and 12 (16%) in intramuscular group patients had previous two preterm delivery. 0% in vaginal group patient and 1 (1.3%) patient had previous three preterm delivery. In terms of previous history of preterm delivery both the groups were comparable. The differences between both the groups was not statistically significant (p=0.292).

**Table: 5 Mean cervical length in both the groups (cm)**

	Vaginal	Intramuscular	p value
	Mean ± SD	Mean ± SD	
USG Cervical Length (Cm)	2.86 ± 0.45	2.89 ± 0.36	0.615

Above table depicts, the mean second mid-trimester cervical length by ultrasound in the vaginal group was 2.86±0.45 cm and in the intramuscular group was 2.89±0.36 cm. The differences in both the group was not statistically significant (p=0.615).

**Table: 6 Mean gestational age at start of progesterone**

	Vaginal	Intramuscular	p value
Gestational age at progesterone intake(in week)	21.48 ± 1.90	21.67 ± 1.80	0.538
Gestational age at delivery (in weeks)	35.88 ± 3.21	35.72 ± 3.49	0.77

The above table depicts, that mean gestational age (in weeks) at start of progesterone in take was 21.48±1.90 in vaginal group and 21.67±1.80 in intramuscular group. Differences between both the groups was not statistically significant (p=0.538). The above table depicts, that mean gestational age (in weeks) at the time of delivery was 35.88±3.21 in vaginal group and 35.72±3.49 in intramuscular group. Both the group were comparable with each other which is statistically not significant (p=0.77). 27 (36%) in vaginal groups and 26 (37.3%) in intramuscular group delivered before 37 weeks of gestational age. 48 (64%) cases in vaginal group and 47 (62.7%) in intramuscular group delivered after completed 37 weeks of gestational age. The differences between both the groups with respect to gestational age at delivery at different gestational periods was not statistically significant (p=0.599).

**Table:7 Distribution of study subjects as per preterm and term delivery**

Gestational Age at delivery	Vaginal		Intramuscular		p value
	Frequency	%	Frequency	%	
<37 weeks	27	36.0%	28	37.3%	0.866
37 and above	48	64.0%	47	62.7%	
Total	75	100%	75	100%	

The above table depicts, 27 (36%) cases in vaginal group and 28 (37.3%) cases in intramuscular group had preterm delivery. 48(64%)cases in vaginal group and 47(62.7%) in intramuscular group had term delivery (after completed 37 weeks) and the difference between both the groups was not statistically significant (p=0.866).It was seen that 55 cases who delivered preterm had a mean cervical length of 2.53±0.38 cm and 95 cases who delivered at term had a mean cervical length of 3.07±0.26 cm and this difference was statistically significant (p≤0.001). 26 (34.7%) patients in vaginal group and 30 (40%) in intramuscular group were delivered by assisted vaginal delivery. 20 (26.7%) in both the groups were delivered by LSCS. 29 (38.7%) of patients in vaginal group and 25 (33.3%) in intramuscular group had spontaneous vaginal delivery. The difference in both the groups was not statistically significant (p=0.748).

**Table:8 Neonatal outcomes of both the groups**

Still Birth/Live Birth	Vaginal		Intramuscular		p value
	Frequency	%	Frequency	%	
Live	74	98.7%	73	97.3%	1.000
Still birth	1	1.3%	2	2.7%	
Total	75	100%	75	100%	

The neonatal outcomes in both the groups were similar. 74 (98.7%) in vaginal group and 73(97.3%) in intramuscular group being live born. 1(1.3%) in vaginal group and 2(2.7%) in intramuscular group were stillbirths. There was no statistically significant difference in both group (p=1.000). Mean APGAR SCORE noted at 1 min, in vaginal group was 6.24±2.30 and 6.32±2.16 in intramuscular group. At 5 min, the mean APGAR SCORE 8.43±2.47 in vaginal group and 8.76±2.66 in the intramuscular group. The difference was not statistically significant (p=0.825 vs. p=0.427). The mean birth weight of babies born to mothers in the vaginal group was 2.44±0.66 kg while in intramuscular group was 2.51±0.70 kg. The difference was not statistically significant (p=0.526).

**Table: 9 Comparison of Neonatal admission to NICU in both the groups**

Admission to NICU	Vaginal		Intramuscular		p value
	Frequency	%	Frequency	%	
No	53	70.7%	55	73.3%	0.716
Yes	22	29.3%	20	26.7%	
Total	75	100%	75	100%	

The above table depicts, with respect to admission to NICU, both groups had similar results. 53 (70.7%) babies in the vaginal group and 55 (73.3%) babies in the intramuscular group had no admission to NICU while 22 (29.3%) babies in vaginal group and 20 (26.7%) in intramuscular group were admitted in NICU. There was no statistically significant difference between both the groups(p=0.716). 65(86.7%) patients in vaginal group and 55(73.3%) patients in intramuscular group had no side effects of drugs. While side effects were reported by drugs in vaginal groups was 13.3% and 26.7% in intramuscular group and this difference was statistically significant (p=0.041)

**Discussion**

The mean age of patients belonging to vaginal group in this study was 28.21±3.45 years and 28.20±3.68 years in the intramuscular group. In a study conducted by Hussein and Abdelaziz (2011)<sup>8</sup>, the mean age of patients belonging to vaginal group was 27.8±4.8 years and it was 27.5±4.9 years in intramuscular group. In another study done by Azza A and Hameed (2012)<sup>9</sup>, the mean age of patients in vaginal group was 26.3±7.2 years and 27.8±6.5 years in the intramuscular group. In another study by Afsar Sadat Tabatabaei Bafghi et al (2015)<sup>10</sup>, the mean age in vaginal group was 28.78±6.73 years and 28.76±5.21 years in intramuscular group. The mean age of patients in this study was comparable to that of study conducted by Hussein and Abdelaziz (2011)<sup>8</sup>, Azza A and Hameed (2012)<sup>9</sup>, Afsar Sadat Tabatabaei Bafghi et al (2015)<sup>10</sup>. In present study, the mean parity of patients in vaginal group was 1.11±0.91 and 1.20±0.89 in intramuscular group (p=0.525). In a study conducted by Hussein and Abdelaziz (2011)<sup>8</sup>, they found the mean parity of 3.27±1.7 in

vaginal group and 3.5±1.9 in the intramuscular group (p=0.07). The difference with respect to mean parity in their study could be probably due to the reason that they included all pregnant patient who have a history of at least one previous spontaneous preterm delivery while in our study all pregnancies who were at high risk for preterm delivery were considered including primigravida. In the present study, patient with previous history of one preterm delivery were 37 (49.3%) in vaginal group and 46 (61.3%) in intramuscular group while 14(18.7%) in vaginal and 13 (17.3%) in intramuscular group had more than two previous preterm deliveries. In a study conducted by Hussein and Abdelaziz (2011)<sup>8</sup>, 32.2% patient in vaginal group and 63.8% patients in intramuscular group had one previous preterm delivery while in 67.8% patients belonging to vaginal group and 26.6% patient belonging to intramuscular group had previous history of two or more preterm deliveries (p<0.31). In another study conducted by Azza A and Hameed (2012)<sup>9</sup>, patient with previous history of preterm delivery were 33.3% in vaginal group and 50% in intramuscular group (p=0.20). Similar study conducted by Lindsay Ji Hyon Seong et al (2012)<sup>11</sup>, 91.8% had previous history of one preterm delivery in vaginal group and 8.2% had previous history of 2 or more preterm deliveries. The present study was comparable with the studies conducted by Hussein and Abdelaziz (2011)<sup>8</sup>, Azza A Hameed (2012)<sup>9</sup> and Lindsay Ji Hyon Seong et al (2012)<sup>11</sup> with respect to history of previous preterm delivery. In present study, the mean gestational at the start of progesterone intake was 21.48±1.90 in vaginal group and 21.67±1.80 in intramuscular group. Similar study conducted by How HY et al (2007)<sup>12</sup> the gestational age at the start of progesterone intake was 21-26.9 weeks and it was 18±0 to 23±6 weeks in study conducted by O Brien

JM et al (2007)<sup>13</sup>. The mean gestational age at the start of progesterone intake was 18 to 23.6 weeks by Jodie M et al (2009)<sup>14</sup>, it was 20 to 24 weeks in study by Azza A Hameed (2012)<sup>9</sup> and it was 16.06±2.89 in vaginal group 16.61±1.22 in intramuscular group in Afsar Sadat Tabatabaei Bafghi, Elham Bahrami and Leila Sekhavat (2015)<sup>10</sup>. Our study findings are comparable to all the above studies.

In present study, 1 (1.3%) patients in vaginal group and no patient in intramuscular group delivered at less than 24 weeks, 3 (4%) patient in both the groups were delivered between 24-28 weeks. 7 (9.3%) patient in vaginal and 3 (4%) in intramuscular group were delivered between 28-32 weeks gestational age, 5 (6.7%) patient in vaginal group and 8 (10.7%) patient in intramuscular group were delivered between 32-34 weeks, 11 (14.7%) in vaginal group and 14 (18.7%) patient in intramuscular group were delivered between 34-37 weeks gestation. 48 (64%) patient in vaginal and 47 (62.7%) patients in intramuscular group were delivered after completed 37 weeks gestational age (p=0.599). Similar study done by Hussein and Abdelaziz (2011)<sup>8</sup>, 1.2% patient in vaginal and 0.6% in intramuscular group delivered at less than 24 weeks, 1.8% patient in vaginal and 3.2% patient in intramuscular groups delivered between 24-28 weeks. 3.7% patient in vaginal group and 10.2% in intramuscular group delivered between 28-32 weeks gestational age, 12% patient in vaginal group and 11.5% patient in intramuscular group delivered between 32-34 weeks gestation. 12.6% in vaginal group and 10.2% patient in intramuscular group delivered between 34-37 weeks gestational age. 68.4% patient in vaginal and 64.3% patients in intramuscular group delivered after completed 37 weeks. Maternal outcome in form of gestational age at delivery was comparable with study by Hussein and Abdelaziz (2011)<sup>8</sup>. In present study, 27 (36%) patients in vaginal group and 28 (37.3%) patients in intramuscular group were delivered preterm (<37 weeks gestation), while 48 (64%) patients in vaginal and 47 (62.7%) patients in intramuscular group had term delivery (≥37 weeks gestation) (p=0.866). This was comparable with study by Azza A and Hameed (2012)<sup>9</sup> where preterm delivery was seen in 36.1% in vaginal group and 32.1% patients belonging to intramuscular group. In present study, the mean gestational age at delivery was 35.88±3.21 weeks in patients with vaginal group and 35.72±3.49 weeks in patients with intramuscular group. Similar study done by Azza A and Hameed (2011)<sup>9</sup>, the mean gestational age at delivery of 36.53±2.3 weeks in vaginal group and 36.3±2.4 weeks in intramuscular group. Another study done by Afsar Sadat Tabatabaei Bafghi et al (2015)<sup>10</sup> mean gestational age at delivery was 37.07±2.23 weeks in vaginal group and 36.81±2.77 weeks in intramuscular group. The results of present study were consistent with that of Azza A and Hameed (2011)<sup>9</sup> and Afsar Sadat Tabatabaei Bafghi, Elham Bahrami and Leila Sekhavat (2015)<sup>10</sup>. In present

study, the mean second trimester cervical length in the vaginal group was 2.86±0.45cm and in patients of intramuscular group, it was 2.89±0.36 cm (p=0.615). It was seen that 55 cases who delivered preterm had a mean cervical length of 2.53±0.38 cm and 95 cases who delivered at term had a mean cervical length of 3.07±0.26 cm and this relationship of second trimester cervical length with gestational age at delivery was statistically significant (p=0.001). Similar study done by Taipale P and Hiilesmaa (1998)<sup>15</sup>, patients having a mean cervical length of more than 2.5cm delivered after completed 37 weeks. The mean birth weight of babies in our study at the time of delivery was 2.44±0.66 kg in mother who received vaginal progesterone and 2.51±0.70 kg of babies who received intramuscular progesterone (p=0.526). In a study by Azza A and Hameed (2012)<sup>9</sup>, it was 2.918±0.338 kg in babies born to mothers in vaginal group and 2.849±0.259 kg in mothers who received intramuscular progesterone. In another similar study Afsar Sadat Tabatabaei Bafghi et al (2015)<sup>10</sup> babies born in vaginal group mean birth weight (gm) was 2717.20±517.04 and in intramuscular group, it was 2785.50±723.08 (p=0.745). Both studies showing similar results with no statistically significant differences among both groups. In the present study, mean APGAR SCORE of babies noted at 1 minute and 5 minutes were 6.24±2.30 and 8.43±2.47 in mothers who received vaginal progesterone and 6.32±2.16 and 8.76±2.66 in babies of mother who received intramuscular progesterone (p=0.825 and 0.427). The results of present study are consistent with another similar study conducted by Afsar Sadat Tabatabaei Bafghi et al (2015)<sup>10</sup> where the mean APGAR SCORE of babies noted at 1 minute and 5 minutes were 8.94±1.39 and 9.50±1.04 in mothers who received vaginal progesterone and 9.20±1.14 and 9.66±0.89 in babies of mother who received intramuscular progesterone (p=0.574 and 0.630). These results were also comparable with that of Azza A and Hameed (2012)<sup>9</sup>. In present study, 53 (70.7%) babies delivered by mothers who received vaginal progesterone and 55 (73.3%) babies delivered by mothers who received intramuscular progesterone were not admitted in NICU. 22 (29.3%) babies delivered by mothers who received vaginal progesterone and 20 (26.7%) babies delivered by mothers who received intramuscular progesterone were admitted to NICU. In another study done by Hussein and Abdelazi Z (2011)<sup>8</sup>, they observed that 19% babies delivered by mothers who received vaginal progesterone and 32.5% babies delivered by mothers who received intramuscular progesterone were admitted to NICU (p=0.006). While in study conducted by Azza A and Hameed (2012)<sup>9</sup>, 13.9% babies born to mothers who received vaginal progesterone and 14.3% babies born to mothers who received intramuscular progesterone were admitted to NICU (p=1.0). The results of this study are consistent with that of Hussein and Abdelaziz (2011)<sup>8</sup> and

Azza A and Hameed (2012)<sup>9</sup>. In present study, 20 (26.7%) of the patients belonging to intramuscular group reported side effects which included pain, itching and swelling at the injection site and headache. All these adverse effects were also reported by Meiss PJ et al (2003)<sup>16</sup>.

### Conclusion

We conclude that vaginal progesterone and intramuscular progesterone can be equally useful in the prevention of preterm delivery. Vaginal progesterone in dose of 200 mg twice a day was as effective as 250mg/week of intramuscular progesterone in reducing preterm birth.

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