

## ABSTRACT

Preterm birth accounts for most newborn deaths. Progesterone is responsible for the implantation of blastocyte and maintenance of pregnancy. Progesterone concentration rises till the end of pregnancy (upto 200ng/ml in plasma). Low progesterone concentration in plasma can result in early uterine contractions and hence, responsible for preterm birth.

Progesterone also occurs in free form in plasma, which as a lipophilic molecule can enter saliva easily via diffusion. Salivary progesterone correlates well with free progesterone in plasma and can be used to monitor progesterone concentrations. Salivary progesterone levels will help in monitoring the outcome of pregnancy.

The objectives of this study included the development of ELISA for salivary progesterone and applying assay on primigravida women to correlate outcome of pregnancy with salivary progesterone.

For the development of ELISA, 96-well format MTP was coated with sheep anti-mouse (SAM) IgG at 1:1000 diluted in borate buffer (pH 8.5) and mouse monoclonal anti-progesterone was coated at 1:10,000 diluted in PBS (pH 7.4) and 0.1% BSA. Progesterone CDI HRP conjugate was used at 1:150,000 diluted in borate buffer (pH 10.0) and 0.2% NaCl. Reaction time was optimized 4 hours before and overnight after the addition of conjugate. TMB was used as substrate for HRP and 1M H<sub>2</sub>SO<sub>4</sub> was used as a stopping agent in the reaction.

60 primigravida women who fulfilled the inclusion criteria were recruited and they provided pre-prandial salivary samples from 24 weeks of gestation until delivery. 29 women provided adequate salivary samples for estimation of salivary progesterone. It was seen that among women who delivered at <37 weeks of gestation (n = 1) i.e. 34 weeks had a drop in her salivary progesterone levels where as salivary progesterone of women who delivered between gestation age >37 and ≤39 weeks of gestation (n = 19) was lower than women delivered at >39 weeks of gestation (n = 9) who had significantly higher concentration of salivary progesterone.

**Conclusion:** Salivary progesterone concentrations can be used as a marker for preterm labor for women in their third trimester. It could also help in selecting women who are most likely to respond to progesterone therapy.