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GALACTAGOGUE EXPERIMENTAL MODEL – AN APPROACH TOWARDS STANDARDISATION

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ABSTRACT

Mother's milk is the proved best and must food for proper development of infant. But in current scenario many mothers fail to feed their offspring because of insufficient production of milk. Need of the hour is for drug which can help in lactation, but there is no standard and full proof model for testing galactagogue property of drugs. Hence the model discussed in the paper was evaluated and proved with scientific evidence through assessing a hormonal assay and qualitative production of milk by weight gain and health of pups.

Keyword: Prolactin, Galactogogue, Hormonal assay.

INTRODUCTION

"*Matureva pibetstanyam tatparam deha vruddaye*"[1] envisages mother's milk as nectar. Galactogogues are medications which assists initiation, maintenance, or augmentation of milk production. Most galactagogues, exert their pharmacologic effects through interactions with dopamine receptors, resulting in increased prolactin levels and thereby increase milk supply.

WHO and UNICEF started World Breastfeeding Week (WBW) is started in the year 1992 in the month of August 1st to 7th, came up with the goal to promote exclusive Breastfeeding for the first six months of life which protects from deadly diseases like pneumonia, shigellosis and meningitis etc. Breast feeding is highly beneficial to both Mother and Child protected from diseases like ovarian cancer, pre-menopausal breast cancer, and reduction in hip fracture in post-menopausal period and gastroenteritis, lymphoma, pneumonia respectively.

Breast milk is widely accepted to be the optimal source of nutrition for the newborn infant, which is sterile, apt temperature for the child and whole some containing proteins, lipids, carbohydrates, micronutrients and trace elements required for growth and development. Colostrum and mature milk contain non-nutrient substances such as anti-bodies and bio-active factors important for the Growth.

Animal model standardization is tried here in this regard in order to get results that are reproducible.

MATERIALS

1.Animals

- The female Wistar Albino rats weighing 200-250g were procured from Acharya and B.M Reddy College of pharmacy, Bengaluru, were maintained under standard laboratory conditions with free access to

food and water ad libitum. Institutional Animal Ethics Committee's permission was obtained with reference no: IAEC/ABMRCP 2015-2016 /20.

- Dose was calculated to animal dose.

Human dose X Body surface area ratio convertibility factor (0.018) = 'x' gms/200gm of rat.

GROUPING AND METHODOLOGY

- Sixty four female wistar albino rats at age three months old with weight of 200-250 g were selected.
- Thirty two were taken for antenatal and thirty two for postnatal observation.
- Weight of the rats was recorded weekly and dose was changed according to the weight.
- Dose of Domperidone (Standard) drug and trial drugs were calculated based on previous article.[1,2]
- Methodology followed in phase II was based on previous article.[1]
- Administration of drug in Phase I from pregnancy till weaning period for 42 days and from Parturition till weaning period for 21 days Phase II.
- The wistar albino rats were divided into 8 Groups consisting of 4 rats in each group in both Phases I & II.
- After confirmation of pregnancy rats were isolated.
- After parturition body weight of mother rat and pups was recorded weekly and observed for mortality of pups of Phase I & II.
- To confirm the estrous phase vaginal smear was taken on every day for a week.
- After confirming estrus phase animals were grouped, 4 animals in each group and kept for mating with one male rat in a cage under standard laboratory condition with 12hr dark/light cycle.
- On 16thand 22nd day of parturition blood was collected, subjected for serum prolactin estimation and rats were sacrificed and mammary glands were removed, stored in 30% formalin and subjected for histopathology of phase I & II.

PARAMETERS OF THE STUDY:

- Histopathology of mammary tissue.
- Estimation of body weight of pups.
- Estimation of serum prolactin.

OBSERVATION & RESULT

Phase 1 –Antenatal

Observation of Mother Rats

There was gradual weight gain of rat up to parturition.

Lumps were observed on either side of abdomen after ten to twelve days of pregnancy.

In group 8th, the rats aborted on 18thday.

Observation of Pups

Weight gain of the pups was more in 4th and 7th groups.

Numbers of pups delivered are less in 6th and 8th group compared to other groups.

Mortality of pups was observed in 6thgroup.

Phase 2 – Postnatal

Observation of Pups

Progressive weight gain of the pups was observed more in 8thgroup compared to other groups.

In postnatal groups, the numbers of pups delivered are less compared to antenatal phase.

DISCUSSION

Administration of drugs in Phase I antenatal and puerperal period and in Phase II only Puerperal period

New model developed which has 2 Phases has following a feature which gives a clue regarding its full proof quality.

1. Vaginal smear - Monitored here tells us the exact date of ovulation.
2. Weight of off springs - weight gain response was more encouraging in phase I when compared to Phase II.
3. Devouring of pups - None of the pups were devoured by mother rats in Phase I which is an indicator of health of pups.
4. Prolactin hormonal assay - No much difference between two Phases.

CONCLUSION

1. Phase I study takes care of health of pups.

2. Thus trial drugs administration during antenatal phase helps in forming a platform for processing of milk.

3. Qualitative production and adequacy of lactation till weaning period.

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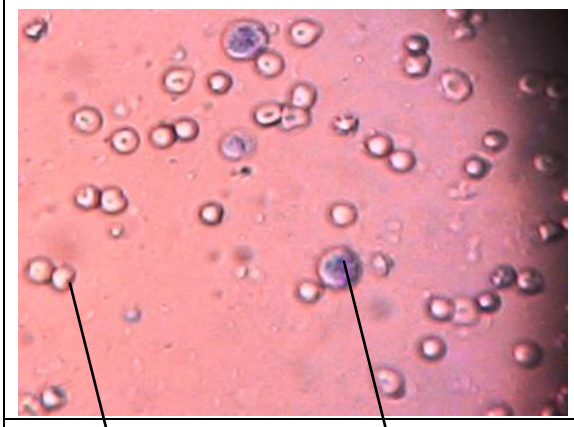
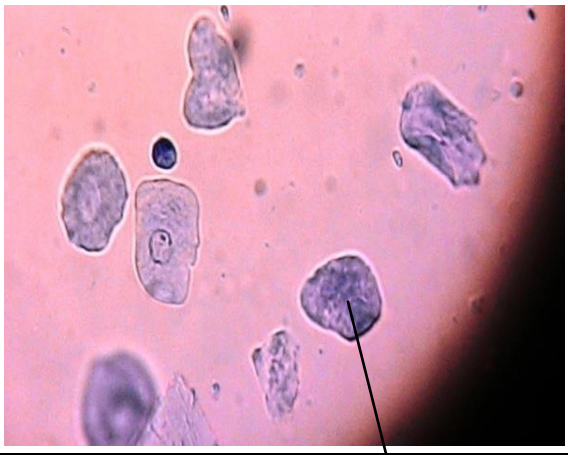
OBSERVATION OF VAGINAL SMEAR IN DIFFERENT PHASES



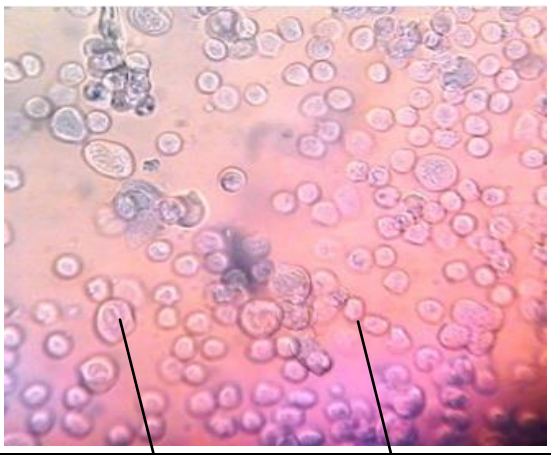
1 DIESTRUS 2

3 PROESTRUS



ESTRUS

4



METESTRUS

5 6

1. Leukocytes.
2. Small cornified epithelial cells.
3. Rounded nucleated epithelial cells.
4. Cornified epithelial cells.
5. Non- nucleated epithelial cells.
6. Large number of leukocytes.

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