Ethnobotanical practices in Antenatal and Postpartum Indian women and its evaluation

Synopsis for PhD thesis

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Synopsis of the thesis to be submitted to

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Synopsis

Title of the thesis

Ethnobotanical practices in Antenatal and Postpartum Indian women and its evaluation.

Introduction

All living forms evolutionary has identified the disorders and their remedies from natural resources as survival instinct. Humans indeed have gathered this knowledge of medicines and surgery through long experience and organized research. Traditionally many practices of plants and plants derived medicines are passed on for generations, makes the fundamental basis of ethnobotany. Although many ethnobotanical practices have been validated by systematic clinical trials and data analysis, a lot more is still lacking. Concerns over safety and efficacy of untested ethnical practices are always raised as the reports of worldwide usage of herbal medicines soars high. Major factors that lead to high demand of herbal medicines are its accessibility, low cost, range of therapeutic actions and believed safety and efficacy(Nyeko et al., 2016).

The use of herbal medicines during pregnancy is common worldwide due to physiological changes that lead to pregnancy related problems. With the increasing market for herbal medicines, the concerns of safety and efficacy is raised. Use of herbal medicine may also be associated with social and cultural influences, perceived efficacy, beliefs about safety, and general ease of access(Fennell et al., 2004). Patients with general access to Western medicine may use herbal medicine concomitantly, and often without the knowledge of a healthcare professional(Akour et al., 2016). In both developing and developed countries, study of the use of herbal medicine (and other traditional, complementary, and alternative medicines) broadens the scope of the public health perspective on not only factors that influence

maternal health outcomes, but also the health system and possible areas for intervention. As per a study conducted on Norweign population, 36% women had used average 1.7 herbal products. Within the medical establishment, a few herbal medicines are considered safe for use in pregnancy, although this belief is poorly grounded in hard evidence(Nordeng & Havnen, 2004). Most herbal medicines used during pregnancy and childbirth have not been subjected to rigorous clinical testing. Although anecdotal evidence may support their use, but clinical evidence of safety and efficacy is generally lacking(Akour et al., 2016; de Wet & Ngubane, 2014). Nonetheless, North American women continue to rely on locally available plants, often learning of these herbs by word of mouth or from books about natural childbirth. High prevalence of herbal medicines used in pregnancy and the lack of information on their safety is a public concern. Despite this, accurate and systematic data are less available regarding potential adverse effects of using herbal medicines during pregnancy, especially among developing Asian countries(Ahmed et al., 2017). Several medicines taken by pregnant women are identified as potentially harmful or unsafe, however substantive evidence regarding their safety in pregnancy is missing(Nordeng & Havnen, 2004). In India, with the knowledge of cultural and traditionally delivered information on ethnobotanical use of plants, many women practice different remedies for curing minor problems and recovery after maternity(Kaushik & Mathew, 1988; Malik et al., 2015). However, the documentation and validation of such practices is largely lacking.

A systematic study on ethnobotanical documentation and their clinical evaluation would pave a way for better understanding of the herbs and its efficacy. Such an objective would also create more research dimensions and interest of pharma industries. The population would be better catered with their need of treatments and a new knowledge of herbal medicines would be added. With these objectives this study was planned and executed during research period.

Objectives

1. Documentation of ethnobotanical practices in antenatal and postpartum women.
2. Correlation of the clinical outcomes for selected ethnobotanical practices in pregnant women - antenatal and postpartum period.
3. Evaluation of the selected ethnobotanical practices (herbal product) in an animal model.

Methodology

The Study was approved by Following Ethical Committees:

1. Institutional ethics committee for Human Research: No. IECHR/2018/20
2. Institutional Animal Ethical Committee: No. MSU-Z/IAEC04/16-2020 (revalidation)

For Objective 1, a cross-sectional questionnaire-based survey study was conducted using random sampling in Vadodara City area. The study was approved by Institutional ethics committee for Human Research with No. IECHR/2018/20. The participants were informed about the research conducted and their consent was registered in consent form. A detailed questionnaire was prepared and validated with pilot study. The modifications required were included and final questionnaire was generated. The participants were recruited from study area using locations like Maternity clinics and Anganwadis. The participants were interviewed in a single stretch of about 15 minutes. Participants of age 20 to 50 years who has delivered a baby at any age before the date of interview was included for the study. Participants with history of systemic diseases were excluded.

Towards achieving Objective 2, a questionnaire-based study was conducted using stratified random sampling as Prospective cohort study. The study was conducted with women visiting for routine check-up at maternity clinics during last trimester of the pregnancy. The participants were informed about the study and a written consent was obtained. The participants were interviewed for their demographic details and herbal practices and their clinical proforma was registered with the help of a medical practitioner. The subjects were followed-up to 6 months postpartum. For the study, reproductive aged group –women (20-

35years) belonging to any socio-economic strata, and is a primi-gravida was included. Women with history of any major systemic diseases were excluded from the study.

To attain Objective 3, animal studies protocol was approved by Institutional Animal Ethical Committee with No. MSU-Z/IAEC04/16-2020 (revalidation). In brief, the nulliparous 12 female Wistar rats were housed in an animal house with controlled lighting (12:12 h L:D) and temperature of 25degree Celsius along with ad libitum access to food and water. After a week of acquaintance period, animals were grouped as Control, Treatment group 1 and Treatment group 2. Animals were given the herbal preparation of Batrisu vasanu in their standard chow diet as per calculated human dose equivalent to 1g/day. Next group was treated with 10g/day human dose equivalent and labelled as Treatment group 2. Control animals were fed the standard diet. In brief, animals were given 200gm of diet daily and the left over was weighed and replaced with same diet each evening. The water intake was also calculated each day. Every third day, animals were weighed and its fecal material was collected and weighed from the cage. After 3 weeks of dosing, animals were sacrificed, and blood was collected for haematological and serological parameters.

Limitations:

For objective 3: The animal studies were proposed with Pregnant rats and to observe the development of pups. However, due to limitations of time and procurement during pandemic the effect of Batrisu vasanu was tested in nulliparous female rats.

Results

For objective 1, From the questionnaire collected, data was entered and decoded using Microsoft excel. The data was analysed using appropriate statistical tools. Data was subjected to avail Median, frequency, ANOVA, Odds ratio and Multiple logistic regression. The data obtained were first presented as demographic details of the respondents. Participants' age, state of residence, religion, caste and birthplace was analysed. Total participants were 387, of these, 96.6% respondents were found to be married and living with their partners, rest were divorced or widowed. Size of the family, their domicile of the state and education, occupation and income group were analysed. Modified Kuppuswamy scale (Saleem & Jan, 2021) was used to classify the participants. Single parity was observed with 64.3% participants in this survey. Their present health status and diet was also analysed, where 10.3%

participants were found to have followed diet restrictions during their pregnancy. Respondents following traditional practices of various kinds were recorded and respective individual groups were formed for further data analysis. Further, it was observed that, 13.1% female had not used any traditional practices throughout pregnancy and postpartum period. These subjects' questionnaires were excluded for further analysis. Types of traditional and ethnobotanical herbal products usage, its form, its purchase location and period of usage were analysed. According to purpose of the traditional practices, herbal products and data were segregated and analysed for plants usage. Plants used, part of plant used, its family and botanical name etc were analysed. The details of the herbal practices and its preparation were recorded. It was found that 83.1% respondents were very satisfied with traditional medicines usage followed by 5.7% neutral. The analysed data paved way for appropriate documentation of various traditional herbal practices existing in the community.

For objective 2, demographic details and ethnobotanical practices followed during gestation was recorded from the mother on her first visit to the clinic. A clinical proforma was filled up in consultation with the medical practitioner. The respondents who agreed to participate were included on basis of their response of usage of traditional practices.

For further follow-up, the subjects were divided into three groups. The people who did not use the traditional foods were named as non-users formed (group 1), the ones who consumed Methi-laddu formed (group 2) and the ones who followed consumption of Batrisu vasanu were gathered as (group 3). Data for the participants in each group were recorded for the clinical information for more than one time upon their parturition and postpartum visit. The data were analysed as cohort study using R-studio statistical tool using Median, fraction, ANOVA, Odd's ration, Chi-square test and Multiple logistic regression analysis. For participants, their demographic details like age, place of birth, domicile of the state, religion, size of family and mother tongue were analysed as per cohort. Modified Kuppuswamy scale (Saleem & Jan, 2021) was used to analyse the socioeconomic status of the mothers. Their present parity and health status was also recorded. Their knowledge about herbal medicines and ethnical knowledge about plants were recorded. Past history of the participant for medical complications like diseases and surgeries were recorded. Personal history and physical examination of patients included in the study was found to be normal. Any abnormality during the pregnancy period reported like stillbirth and pre-mature delivery was

excluded from the study. Of the total participants-(n=50), 13.2% patients had shown abnormality during study and 9.2% had dropped from the study, thus with a total of n=38. Each group were recorded for the vitals of the mother and child which included pulse, BP, temperature, Respiration rate, edema over body parts and CVS, RS and CNS was found to be within normal range. Participants after parturition were recorded by us for their Obstetric parameters, physical examination and new-born examination was availed from medical records. During the study of the postnatal care visits, child weight, hematinic supplements prescribed, galactagogue prescribed and newborn parameters like weight-velocity and growth-velocity were significantly found different for each cohort under study.

Towards fulfilling the third objective, the Animal experimentation using Batrisu vasanu samples were carried out. The samples were collected from each region of Gujarat. The collected 16 samples were recorded for the plant used, and their botanical details. It was found that all 16 samples were having varied herbs added. Further, all samples were selected and its total phenols, flavonoids and flavonols as well as antioxidant properties were studied. For the animal studies, one of these samples were selected and animals were dosed in their food pellets for 21 days. For the parameters under study, haematological tests like Lymphocytes, HGB, Monocytes, WBC, RBC, Platelets, Neutrophil, MCV, MCHC, MCH and Eosinophils. Further, serological analysis like Total protein, Albumin, Creatinine, Bilirubin, ALT, AST, Urea, Uric acid, Glucose, Total cholesterol, Triglycerides, HDL, LDL, VLDL and ALP was carried out for each group and found to be altered among the three groups. Hormones like FSH, Prolactin, Progesterone, Insulin, Estrogen, Estradiol, serum Luteinizing hormone were analysed for statistical alterations among groups.

Conclusions

The present study performed for the ethnobotanical evaluation of traditional practices reports various ethnical practices performed by the Indian women during pregnancy and childcare. This study presents the details of the practices and purpose of the herbal usage as well as their knowledge and belief toward herbal medicines. Out of this study, documentation of ethnical herbal practices could be prepared. Further, among the clinical details, child health and mother health at various levels was found to be improved by using Batrisu vasanu and

Methi-laddu compared to other practices. The products however need further detailed study to understand about its clinical relevance and implications. Animal studies showed significant change in the female rats hematological and serological parameters. This indicates the clinical changes in rats can be further extrapolated to the health benefits , can be considered to be attributed in similar parameters in human subjects, as in this case is pregnant women. Further studies would pave way towards better understanding of the herbal medicine usage and their clinical pathways for better drug design.

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Research article published

1. Sanket Charola, Bhavesh Tadvi, Susy Albert, B. Suresh, Sirimavo Nair. (2021) Analysis of a polyherbal galactagogue Batrisu vasanu, an indigenous Indian ethnomedicine. Indian Journal of Natural Products and Resources 12(4) 610-616. (Scopus Indexed)

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1. Sanket Charola, B. Suresh, Sirimavo Nair, Susy Albert. (2019) Questionnaire based survey of ethnobotanical supplements' usage for maternal care in Indian women. Presented at 6th International congress of Society for Ethnopharmacology, India organised by MAHE, India.
2. Sanket Charola, Pathan, F., Bhudia, B., Susy Albert. (2022) An efficacy concern over varied contents of total phenols, flavonoids and flavonols in Batrisu vasanu samples. Presented at International seminar on "emerging trends in biological sciences" organised by Suri Vidyasagar College, India.