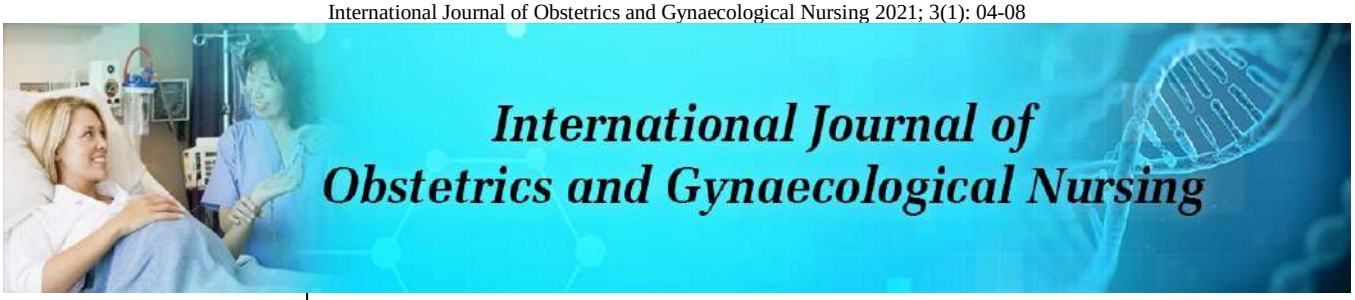

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Effectiveness of selected nursing strategies in managing anaemia during pregnancy through dietary supplementation and structured teaching: A randomised controlled trial in Andhra Pradesh India

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Abstract
Anemia during pregnancy leads to adverse maternal and infant mortality. IFA tablets are inadequate and needs supplementation by effective nursing strategies. After Ethical clearance and consent from the participants, a Randomized Double Blind Controlled trial was done on antenatal mothers with mild and moderate anemia at 24-26 weeks of gestation, during 2019 in Andhra Pradesh India, using Ragi and moringa leaves, with structured teaching on anemia as part of nursing care. Random allocation led to 53 antenatal mothers in the intervention group and 54 mothers as controls who received routine care. Baseline and post-intervention tests Structured Teaching along with IFA tablets provide safe, effective affordable management of anemia during pregnancy.

Keywords: Anemia, pregnancy, India, nursing interventions, RCT

Introduction
Anaemia during pregnancy is recognized as a global health problem especially in the developing nations (Stevens *et al.* 2013; Milman 2011) [10, 21]. The estimated prevalence of anaemia is 14% in developed countries as compared to 51% in developing countries and 65 - 75% in India (WHO 2012) [29]. Iron deficiency anaemia is responsible for 95% of the anaemia during pregnancy, due to inadequate nutritional intake. (Tandon *et al.* 2018; Parks *et al* 2019) [15, 25] resulting in deleterious complications and mortality in mothers and foetuses (Malhotra *et al.* 2004; Rahman *et al.* 2016; Smith *et al.* 2019) [11, 17, 20, 25]. Indian National Family Health Surveys 3 and 4 (NFHS 3,4, IIPS 2016) have also reported that the prevalence of anaemia to be 70% in pregnant women, because of low bio availability diet, defective absorption and chronic blood loss due to hook worm infestations and malaria and rapidly successive pregnancies. Pre-pregnancy counselling, dietary advice and therapy is very important for ensuring best pregnancy outcomes (Agbozo *et al.* 2018) [2]. How-ever this is not done in most developing countries like India, either due to lack of awareness, or negative attitudes and not recognized till pregnancy occurs (Murray-Kolb 2016) [12]. While Iron and Folate tablets are helpful, most women do not consume these tablets regularly and non-adherence is high (Yadav *et al.* 2019) [30]. Although iron supplementation is still a good intervention in developing countries, it is not sufficient to reduce overall prevalence of anaemia by the third trimester. There is a need to look beyond the approach and reinforce the importance of better feeding practices, food fortification and reduced frequency of pregnancies. Effective diet supplementation may be useful and more studies to prove this is needed (Samuel *et al.* 2013) [22]. Thus much research reveals that there is a great potential to treat anaemia through specific dietary management. Parenteral therapies are costly and mere consumption of iron and folate tablets may be inadequate. Suitable health education and a variety of low- cost foods as dietary supplements have the potential to be effective in managing anaemia during pregnancy, increasing haemoglobin levels and decreasing maternal and neonatal adverse outcomes. Such evidence- based nursing research is lacking and relevant publications are sparse, and not done comprehensively.

Hence this research on the effectiveness of a planned teaching program, administration of locally available iron-rich foods along with consumption of iron and folic acid tablets daily, in improving haemoglobin levels, awareness and attitudes regarding anaemia and its control, and preventing adverse maternal, perinatal and neonatal outcomes, during labour and puerperium. It is hypothesized that compared to baseline, the Nursing Strategies will result in Increased Haemoglobin values, better Knowledge on Anaemia and will significantly reduce adverse maternal and neonatal outcomes.

Material and Methods

After a thorough critique of earlier research on this topic and discussion with experts, it was decided that an experimental approach following CONSORT guidelines (Schultz *et al*. 2010) will provide the best evidence of the effectiveness of the nursing strategies in managing anaemia during pregnancy. The study was conducted at the Department of Obstetrics and Gynaecology of PES Hospital in Kuppam, Andhra Pradesh state in South India. This is a well-established multispecialty hospital with daily attendance of 150-200 antenatal and postpartum mothers, from all socioeconomic strata.

As part of routine examination, haemoglobin (g/100ml), was measured using cyanmethemoglobin method and graded as: Severe: <7: Moderate: 7-8.99; Mild: 9-10,99; Normal 11 or more. The target population for the study included only the antenatal mothers with mild and moderate anaemia, who attended the antenatal outpatient department, at the Hospital. Booked mothers residing locally from similar socio-economic backgrounds, who were at 24-26 weeks of gestational age who planned to undergo delivery and postnatal care at PES hospital at Kuppam, who understand Telugu /or English and are willing to participate in the study were considered. Mothers with severe anaemia or medical and obstetrical complications receiving any other treatment for anaemia, with history of substance use, pre-existing psychiatric problem or non-residents were excluded. Assuming that 25% of mothers will experience an adverse outcome in general which will be significantly reduced to 5% through intervention, with a Type 1 or Alpha error: 5% Power of 80%, the minimum sample size in each of the 2 groups was estimated as 50. Allowing for possible losses, it was aimed to recruit 55 cases in each group. After explaining the project and receiving their consent, block randomization, 12 cases at a time, to randomly allocate the mothers to intervention or control group. An approval to conduct the study was obtained from the PESIMSR Ethical Committee. The ethical consideration criteria were based on the Indian council of medical research guidelines of biomedical research in human beings. Information essential for consent included description and purpose of the study, the research activities and the usefulness of the study outcome, assurance of privacy and confidentiality to answer any questions that a potential subject has and the option to withdraw themselves from the study at any time. Administration of Structured Teaching Program for Experimental Group Antenatal mothers, selected in the interventional group were given health education on management and prevention of anaemia, demonstration on Ragi Adai with Moringa leaves, administration of Amla, for iron absorption, importance of taking regular iron and folic acid were given individually and re-demonstration was taken from antenatal mothers with mild and moderate anaemia. Intervention was given for minimum 12 weeks and confined till delivery. Control group received routine care and follow-up. The mothers were seated in comfortable position to attend the structured teaching program and live demonstration of ragi adai preparation was done for1hour and re-demonstration from study participants, to repeat the procedure at home. After 7 days the post test was done regarding level of knowledge on anaemic antenatal mothers. The reinforcement was given through telephone twice a week and direct reinforcement was given to the women as they were coming for regular antenatal check-up and were insisted on the importance of daily consumption of amla, ragi Adai and iron and folic acid tablets. The control group anaemic antenatal mothers were requested to continue with their routine antenatal care and the researcher completed the assessment at the same time intervals as that of experimental group. A special research Proforma was developed to include all the baseline and post-intervention details including haemoglobin levels, general health, progression and outcome of labour and complications, adverse events if any in mother and child. Assessments were made blind to ensure objectivity and without bias.

Data were routinely transferred to Microsoft excel sheets, checked, edited and stored in a confidential manner. SPSS was used for data analyses.

Results

Two mothers in intervention group and one in the control were lost to follow-up due to migration and other reasons, so the analyses were done for 53 mothers in intervention group and 54 mothers in the control group, a total of 107 mothers.

The mean (SD) age of mothers was 22.93 (3.27) years, with a Mean (SD) BMI of 20.26 (0.33), and the baseline haemoglobin level ranging from 7.4 to 10.2 g/100ml. About 70% had only primary education or less and were housewives, and another 10% were daily wage workers. Roughly half belong to each type of nuclear or joint family. Majority were Hindus (65%), a quarter were Muslims and 9% were Christians. Majority of the mothers (70%) had less than 5 years of marital life, and 3 (2.7%) mothers had more than 10 years marital life.

As a first step before comparing the outcomes in the two groups, it was necessary to determine if they are comparable. Analyses by all socio-demographic, reproductive and personal information showed no statistically significant differences between the two groups. In terms of baseline haemoglobin (g/100ml), the mean (SD) in the intervention group of 53 mothers was 8.59 (0.71) and in the control group of 54 mothers, the mean (SD) was 8.590 (0.65), the difference not statistically significant.

Paired difference in the Haemoglobin levels for each woman in the experimental and control groups was calculated and the Paired t-test showed highly statistical significance increase ($p< 0.01$) in the intervention group compared to the controls. The findings are shown in Table 1.

Table 1: Paired differences of haemoglobin values in the two groups

Difference (g/100 ml)	Group			
	Experimental		Control	
	No.	Percent	No.	Percent
<1.00	0	0.0	5	9.3
1.0-1.4	0	0.0	17	31.5
1.5-1.9	4	7.5	17	31.5
2.0-2,4	7	13.2	9	16.6
2.5-2.9	16	30.2	6	11.1
3.0-3.4	23	43.4	0	0.0
3.5-3.8	3	5.7	0	0.0
Total	53	100.0	54	100.0
Mean (SD)	53	2.83 (0.56)	54	1.64 (0.57)

The paired t- test within each group was also statistically significant, $p < 0.01$. The comparison of adverse maternal outcomes in the two groups are shown in Table 2.

Table 2: Comparison of maternal outcomes in the intervention and control groups

Adverse maternal outcome	Intervention		Control		Statistical significance	
	No.	%	No.	%	Chi square *P*	
1. Maternal Weight	5	9.4	22	40.7	22.67	<0.001 ***
2. Maternal Hypertension	6	11.3	10	18.5	1.09	0.297
3. Oxygen Saturation	2	3.8	5	9.3	1.32	0.251
4. Low Hemoglobin	0	0.0	19	35.2	22.67	<0.001 ***
5. Gestation < 37 weeks	6	11.3	20	37.0	9.62	<0.01 **
6. History of Bleeding	4	7.5	2	3.7	0.75	0.388
7. Prolonged I stage	15	28.3	19	35.2	0.59	0.445
8. Prolonged II stage	14	26.4	17	31.5	0.33	0.564
9. Sepsis	5	9.4	17	31.5		
10. PPH	5	9.4	17	31.5	7.9	<0.01**

As seen from the Table, Intervention groups have shown statistically better results in terms of lower adverse maternal outcomes in terms of Maternal weight, Haemoglobin level, Preterm delivery, Sepsis and Post-Partum Haemorrhage (PPH).

Similar comparisons were done for adverse neonatal outcomes in the two groups and the findings displayed in Table 3

Table 3: Comparison of neonatal outcomes in the intervention and control groups

Adverse neonatal outcome	Intervention		Control		Statistical significance	
	No.	%	No.	%	Chi-square	*p*
1. Low Birth Weight <2000g	3	5.7	14	25.9	8.22	<0.01**
2. Short Length <45 cm	3	5.7	17	31.5	11.73	<0.01**
3. Small Head circumference <32cm	4	7.5	18	33.3	10.89	<0.01**
4. Apgar score <6	6	11.3	16	29.6	5.49	<0.05*
5. Preterm Labor	6	11.3	20	37.0	9.6	<0.05*
6. IUGR	4	7.5	21	38.9	14.67	<0.01**
7. IUD	0	0.0	0	0.0	---	------
8. SGA	3	5.7	18	33.3	12.99	<0.01**
9. Still Birth	0	0.0	0	0.0	-----	-----
10. Asphyxia	9	17.0	19	35.2	4.59	< 0.05*
11. MAS	8	15.1	21	38.9	7.67	< 0.05*
12. Congenital Malformations	0	0.0	0	0.0	-----	-----

All the neonatal outcome variables show that the Intervention group is superior in terms of all the neonatal outcomes as compared to the Placebo or Control group.

Thus, the research conclusively demonstrates that the Nursing strategies as planned and implemented improves haemoglobin levels, reduces anaemia and reduces adverse labour outcomes in mother and child.

Discussion

Experiences during the recruitment and follow up of antenatal women in this research has confirmed the wide prevalence of anaemia during pregnancy and the urgent need for its management. Despite intensive efforts taken by the governments in reducing the burden through several health actions including provision of iron and folate tablets (WHO 2012) [29], mothers still suffer from the scourges of anaemia during labour and childbirth. Socioeconomic and cultural factors, ignorance, and environmental settings continue to affect large numbers of women in low and middle income countries, poor and indigenous populations, with varying degrees of anaemia contributing to the high maternal and infant mortality and morbidity (Murray-Kolb 2016; Lone *et al*., 2004) [12]. Thus the international and national guidelines strongly advocate early registration of pregnancy and baseline testing of haemoglobin level identifying the need for appropriate treatment (WHO 2018) [29]. Findings from this research confirm the seriousness of the problem, and has therefore planned this research with

involvement of nurses in a more practical manner as part of active and meaningful nursing care.

Manisha Nair *et al*, (2016) reported on retrospective cohort study done to examine the association between maternal anaemia and adverse maternal and infant outcomes, the author concluded that maternal iron deficiency anaemia is a major public health problem in Assam, and was associated with increased risks of Post-Partum Haemorrhage, low birth-weight, small-for-gestational age babies and perinatal death. While the best approach is prevention, a large number of women present with severe anaemia in third trimester and there is no clear guidance on how these women should be managed during labour and delivery. Shashi Kant *et al*., (2018) reported a record-based study from secondary care hospital, Haryana that there was increased incidence of preterm (10.2%) in the anaemic group compared to 6.8% in non-anemic group. Since anaemia is more common among women who did not receive adequate antenatal care, strengthening and utilization of antenatal services are essential to control anaemia at the time of delivery.

Several excellent studies have confirmed that iron deficiency anaemia (IDA) is most common (Tandon *et al.* 2018) [25]. Nursing strategies in this research, therefore, focussed on structured teaching and supplementing the diets with locally available iron-rich foods, while other investigators report successful interventions with fortified wheat or maize, and use of leafy proteins (Magon *et al*., 2014) [1], a more practical approach was used in this research using a local staple cereal Ragi, a millet, and drumstick (Moringa) leaves and the Indian gooseberry, Amla. The strategy involved continuous reinforcement, developing skills and changing attitudes apart from just providing knowledge, and this resulted in significant results in the intervention group. Rosen *et al.* (2018) [6] explored 4 primary themes: (a) perceptions of ideal diet during pregnancy, (b) barriers to consuming the ideal diet, (c) coping strategies including dietary responses related to pregnancy illnesses, and (d) changes in perceptions from early to late pregnancy, and thorough longitudinal data collection using repeated interviews reported that although awareness of optimal foods for supporting healthy pregnancies was moderately high, some misconceptions were observed and multilevel barriers to food security restricted opportunities for consuming these foods. In the present research, therefore the nursing strategy required combining strong structured teaching to encourage anaemic antenatal women to regularly consume iron -rich foods, which paid rich dividends in terms of much benefit to the mother and child. Among all the health professionals, the nurses play a leadership role and spend the maximum time with the mothers gaining their confidence and trust. Most developing countries have to deal with food taboos, stigma and negative attitudes, and the present research setting is no exception. Nurses will have to continue to address the health problems such as anaemia during pregnancy, combining education and development of skills to identify and process iron-rich foods that are locally available, affordable and acceptable. This place great responsibilities on the education and training of nurses, developing their leadership and communication skills. In this connection, the CONSORT guidelines (Schulz *et al.* 2010) [23] provide the best advice which was strictly followed in this research, which strengthens the evidence base of managing anaemia during pregnancy.

Conclusion

Suitable dietary supplements and structured teaching program as part of Nursing Strategies for antenatal care of anaemic pregnant mothers along with routine IFA tablets provide a safe, effective, affordable and acceptable method for management of anaemia, increasing haemoglobin to normal levels and preventing adverse maternal and neonatal outcomes

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