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Gynecology & Obstetrics

Study of Fetomaternal Outcome

Use of Immunoglobulin G Enriched

Highlights

Reproductive-Age Women in Brazil

Regional Difference in Symptoms Perception

Discovering Thoughts, Inventing Future

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Is There a Regional Difference in Symptoms Perception Associated with Pre-Menstrual Syndrome? Results from a National Study among Reproductive-Age Women in Brazil

By Adriana Orcesi Pedro, Samantha Belamarques de Oliveira Silva, Maura Gonzaga Lapa, Juliana Dineia Perez Brandao & Vivienne Carduz Castilho

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Abstract- Background: Evaluate the prevalence, intensity and regional distribution of premenstrual syndrome (PMS) symptoms reported by reproductive age Brazilian women.

Methods: An observational and retrospective study was conducted analyzing data of women from the five Brazilian regions. Women aged 20 to 49 years who consulted at private healthcare services filled up a self-reported questionnaire about the prevalence and intensity of somatic and psychoemotional pre-menstrual symptoms.

Results: A total of 23104 women stated to have premenstrual symptoms, of which 38.91% (n=8990) reported that these symptoms cause functional impairment.

Keywords: premenstrual syndrome, Brazilian women, regional study, premenstrual severity symptoms, premenstrual prevalence symptoms.

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Is There a Regional Difference in Symptoms Perception Associated with Pre-Menstrual Syndrome? Results from a National Study among Reproductive-Age Women in Brazil

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Methods: An observational and retrospective study was conducted analyzing data of women from the five Brazilian regions. Women aged 20 to 49 years who consulted at private healthcare services filled up a self-reported questionnaire about the prevalence and intensity of somatic and psychoemotional pre-menstrual symptoms.

Results: A total of 23104 women stated to have premenstrual symptoms, of which 38.91% (n=8990) reported that these symptoms cause functional impairment. Among the participants who accepted to answer the detailed symptoms questionnaire (n=5140) a total of 2475 respondents were randomized according to population proportions by Brazilian regions. Among psychoemotional symptoms, irritability was the most prevalent and severe symptom, with 98.5% prevalence and 61.7% severe intensity respectively. Headache was the most prevalent (86.2%) and severe (41%) physical symptom in Brazilian women. For symptom relief, 74.3% of affected women would be willing to take an oral contraceptive pill as a treatment option for PMS.

Conclusion: Our study shows a comprehensive overview of the perception of premenstrual symptoms among Brazilian women. Psycoemotional symptoms are more frequent and severe than somatic symptoms regardless of the Brazilian region studied. Also, most of these women would take an oral contraceptive to reduce their premenstrual symptoms and for this reason, health care professionals need to present this option for women suffering from PMS symptoms.

Keywords: premenstrual syndrome, Brazilian women, regional study, premenstrual severity symptoms, premenstrual prevalence symptoms.

I. Background

remenstrual syndrome (PMS) is a very common dysfunction among women of reproductive age. Approximately 20% to 25% of women experience moderate to severe premenstrual symptoms and about

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85% of women experience at least one premenstrual symptom[1]. However, few studies reveal the impact of PMS symptoms on quality-of-lifework, family, and social relationships.

There are several different psycho-emotional and physical symptoms associated with PMS as depression, angry outbursts, irritability, confusion, social withdrawal, breast tenderness, bloating, headache and swelling of extremities[2]. These symptoms are cyclic and recurrent and can change in extent and intensity during different menstrual cycles[2]. According to the World Health Organization, "Premenstrual Tension Syndrome" is characterized by certain environmental, metabolic, or behavioral symptoms that occur during the luteal phase of the menstrual cycle, and lead to cyclic emotional, physical, or behavioral symptoms that interfere with an individual's lifestyle[3]. The American College of Obstetrics and Gynecology and the Royal College of Obstetricians and Gynecologists' criteria describe PMS as any number of psychoemotional or physical symptoms and functional impairment is required[4].

Since PMS is a global problem, it has been studied worldwide to understand its effects on daily life[5, 6]. The first global meta-analysis reported the pooled prevalence of PMS at values around 47.8% worldwide, although most of the included studies were heterogeneous, involving several confounding factors within and between studies, and a limited sample size[7]. Some studies suggested that the prevalence of PMS is higher in Latin-American countries when compared to Europe[8].

In Brazil, there are few published studies on the prevalence, symptoms characteristics, and detailed information about the premenstrual syndrome in women of reproductive age. In addition, the correlation with socio-demographic, socioeconomic, and sociocultural conditions of the affected women is not established [9-12]. However, a study in the Brazilian population showed that when using criteria for the diagnosis of PMS, the prevalence of the syndrome was lower than the self-reported [9].

Therefore, nationwide studies looking at regional differences involving a large sample size among sufferers of PMS are scarce, and new data will contribute to demystifying PMS and help health professionals to assist affected women.

This study aimed to evaluate the prevalence, intensity and regional distribution of PMS symptoms reported by the Brazilian female population and the information generated may help to rethink mechanisms to improve the health and quality of life of PMS suffering women and offer decision-making tools related to the need for early and effective treatment of PMS.

II. **METHODS**

a) Study design and sample selection

It was an observational and retrospective study. All data were collected from a database with information stored by the Market Research Programs (MRP) and anonymized to ensure the data subjects' confidentiality and the study's security and confidentiality.

A self-reported questionnaire was answered by women aged 20 to 49 years from all Brazilian regions: South, Southeast, North, Northeast, and Midwest, between February 2019 and March 2020. The invitation to participate was made through an electronic device (cell phone or tablet). As soon as the woman requested access to the clinic's wireless network, she was invited to participate in the research and received information about the content and purpose of the research. This study was free from a consent form. The duration of the questionnaire filling out was around five to ten minutes.

Next, the participants were categorized as having PMS or not, according to the ACOG diagnostic criteria[2]. To evaluate functional impairment, the participants were asked how much the PMS symptoms disturbed their daily life (not at all, a little, or a lot) and those who answered "a lot" were considered as having a functional impairment.

Those who accepted to participate voluntarily were directed to the questionnaire adapted from the PSST - Premenstrual Symptoms Screening Tool -version validated in Brazil (Annex 1)[13].PSST is a retrospective questionnaire that can be completed during clinical consultation which is well established for PMS symptoms. It has demonstrated high sensitivity (79%) for PMS diagnosis and, in addition, identified women who suffer from severe PMS[14].

A 4-point Likert scale was used to measure the intensity of psychoemotional (irritability, anxiety and tension, decreased interest in routine activities, depression and sadness, overeating, concentration difficulties, emotional instability) and physical(headache, acne and oily skin, edema, weight gain, breast tenderness, exacerbation of immunoallergic conditions) symptoms according to intensity (0 = none; 1 = mild; 2)= moderate; 3 = severe). Also, demographic data of the participants were collected, and they were asked whether they would take oral contraceptives as a treatment option for PMS.

To have representativeness according to regional population, the respondent women were randomly selected according to the population proportions by region, based on the latest published demographic Census (2010)[15]. The study flow chart is represented in Figure 1.

The study protocol was submitted to the Research Ethics Committee under the registration number 33794520.1.0000.8098.

b) Sample Calculation

To calculate the sample size, an estimation formula was used for a descriptive study with a categorical qualitative variable[16-18]. In this case, the premenstrual syndrome (PMS) estimate was obtained from the literature[10]. The level of significance alpha or type I error was set at 5% (or 95% confidence interval) and the sampling error at 3% (d=0.03). According to the results, a minimum sample of n=1022 was obtained. The program used was SAS (Statistical Analysis System), version 9.4 (SAS Institute Inc, 2002-2012, Cary, NC, USA).

According to the 2010 Demographic Census data, [15] the Brazilian female population aged 20 to 49 years was distributed as follows: 42.4% in the Southeast, 26.9% in the Northeast, 14.1% in the South, 8.9% in the Midwest and 7.7% in the North region. A specific procedure was used for this selection that randomly shuffles and chooses lines among those available in each region, using the SAS statistical software.

c) Statistical methods

According to the variables under study, the sample characteristics are shown as frequency tables of categorical variables with absolute (n) and percentage (%) frequency values.

Comparisons among regions concerning the response of each question were analyzed using Pearson's Chi-Square test or Analysis of Variance (ANOVA). If a significant difference was found at 5% in the first test, multiple comparisons were performed so that each region was compared. Bonferroni's correction test was used for multiple comparisons.

The p-value was considered significant at 0.8%, resulting from the significance level of 5% divided by 6.We used Poisson Regression to compare regions regarding the number of moderate or severe symptoms, an appropriate statistical test for numerical data. All analyzes were performed using SAS software version 9.4 and Excel.

III. RESULTS

A total of 56,948 women responded to the initial questionnaire. Of these, 8,990 were aged between 20 and 49 years and met the diagnostic criteria for PMS (any number of psycho-emotional or physical symptoms with functional impairment). Among them, 5,121 participants agreed to answer a detailed anamnesis about their symptoms, characterizing the target population of the study.

After that, 2,475 respondents were randomized respecting the proportionality of the female population of each state, according to the 2010 census(Table 1).

The mean age of participants was 30.8 ± 7.4 years. Women between 20 and 29 years represented 47.8% of the sample, corresponding to the larger age group. The participants aged between 40 to 49 years represented the lowest proportion of respondents (14.4%). The mean age was higher in the southeast region (31.4, p=0.0003). Among the different Brazilian regions, the proportion of respondents in each age group was uniform (Table 2).

The profile of the participants who did not accept to respond to the questionnaire was similar to participants who accepted to respond, regarding the Brazilian regions and age group. Half of the participants in each profile agreed to answer the questionnaire.

By analyzing the total prevalence of symptoms and the distribution of severe physical symptoms, it was observed no significant differences between the regions of Brazil, except for the lower prevalence of weight gain in the northeast region (Table 3).

Headache was the most prevalent physical symptom (86.2%) in the Brazil average, as well as in the South and Midwest regions, and 41% of the women with headaches presented the symptom with severe intensity. The second most prevalent symptom in the Brazil average was acne and oily skin (85.8%), with 32.3% of severe intensity, followed by edema (85% prevalence, 25.5% with severe intensity). Acne and oily skin were also the most prevalent symptom in the Southeast and Northeast regions. In the North region, edema was the most prevalent physical symptom (Table 3).

Weight gain was the only physical symptom with a statistically significantly lower prevalence in the northeast region compared to other regions of the country (Table 3).

The least prevalent and severe symptom was an exacerbation of immunoallergic conditions (78.8% and 15.4%) respectively (Table 3).

When focusing on the psychoemotional symptoms, the most prevalent symptom in the country was irritability (98.5%) with 61.7% of women presenting the symptom in severe intensity. Anxiety and tension were the second most prevalent psychoemotional symptom in the Brazilian population (98.4%) and 54.2% of the participants presented it in severe intensity (average). The most prevalence of this symptom was observed in the south region. Regarding intensity, it was statistically significant in the northeast and southeast regions. In the South region, both symptoms (irritability / Anxiety and tension) showed the same higher prevalence (99.4%). The third most prevalent symptom in the country was decreased interest in routine activities (94.5%) and 39% of women considered it to be of severe intensity (Table 4).

Overeating was the only symptom was observed with a statistically significant difference between regions for prevalence and intensity.

On average, 74.3% of women with PMS stated they would take contraceptivesas an option for PMS symptoms treatment (Table 5).

Discussion IV.

Our investigation showed a high prevalence of physical and psychoemotional symptoms in all Brazilian regions, with the average prevalence of these symptoms in Brazil being 83.6% and 94.2%, respectively.

In a study in southern Brazil 1395 women aged 15 to 49 years were evaluated. The main premenstrual physical symptoms found in this study were abdominal discomfort, headache and breast pain. Among the psychoemotional symptoms, the most prevalent were irritability, nervousness and fatigue.[9] In our study the most prevalent physical symptoms were headache (86.2%), acne and oily skin (85.8), and edema (85%) and the psychoemotional symptoms were irritability (98.5%), anxiety and tension (98.4%) and decreased interest in routine activities (94.5%).

In a multicenter Brazilian study that aimed to describe the perspectives and attitudes of Brazilian women toward premenstrual syndrome, 1053 women, separated by regions, between 18 and 40 years, lived in 6 Brazilian cities, 1 in each geographic region of the country and the Federal District were interviewed [10]. Results showed that most women (78.1%) stated that PMS is related to emotional symptoms, and 24.3% said that it is related to physical symptoms [10]. The emotional symptoms most frequently mentioned by the participants were nervousness/anxiety, irritability/anger/ aggressiveness and mood swings/crying, whereas the most common physical symptoms were headache, cramps and breast pain, swelling, and tenderness[10]. On the other hand, in our investigation we observed that irritability and anxiety/tension were the most prevalent psychoemotional symptoms.

When evaluating the prevalence of symptoms with severe intensity, our study showed a higher prevalence of psychoemotional symptoms over physical symptoms, reaching 60% for irritability versus 40% for headache, which was the most severe physical symptom.

In a study across several countries, including Brazil, with a total of 7226 women (400-500 women from each country) aged 15-49, it has been reported a higher frequency of physical symptoms, as assessed by severity and number of menstrual cycles affected[6]. In this global study, Brazil was characterized by the second-largest values of severity and duration of symptoms, staying only behind the UK. The high prevalence of severe symptoms observed in our study corroborates these findings. However, when evaluating the global population, among the 5 most prevalent symptoms, 4 were physical[6]. In our study, psychoemotional symptoms were a higher prevalence and severity. It is important to highlight that these data were collected before the pandemic of COVID-19, so these results were not influenced by the psychological effects seen during the pandemic. We continue to collect data during the pandemic, and it will be interesting to compare this issue.

The lower severity of overeating in the northeast region may be related to the lower severity of anxiety and tension during the premenstrual period.

Previously studies showed that among Brazilian women, 52.3% stated that physicians prescribed hormones as a strategy for dealing with premenstrual syndrome, [10] and PMS symptoms severity was inversely associated with oral contraceptive use (emotional symptoms) and better-perceived health (physical symptoms)[19].In our investigation, among respondents who met the diagnostic criteria for PMS 74.3% would take oral hormonal (n=2.475)contraceptives as a treatment option for PMS. This is an important finding since the combined oral contraception for women of reproductive age is one of the effective options used for the treatment of PMS, mainly for women who seek contraception counseling.[20]

The strength of this study includes the use of a questionnaire validated in Brazil that is commonly used for population studies, the large number of women included, and the national scope of the study. In addition, the participating women included in our study were selected in a private healthcare system to minimize bias-related the socioeconomic status of participants. A limitation of this study is that data such as education and family income of the participants were not collected.

Conclusion

Psychoemotional symptoms are more frequent and severe than somatic symptoms. There were a lot of similarities in women's experiences of these symptoms across Brazilian regions. Symptoms had a frequency and intensity regardless of the region, which makes many women states that would be willing to take a contraceptive that reduces TPM symptoms. It is important for healthcare professionals, to make screening symptoms associated with SPM during contraception counseling to choose the most proper

List of abbreviations

Premenstrual syndrome; MRP: Market Research Programs; PSST: Premenstrual Symptoms Screening Tool

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Authors contribution

Adriana O. Pedro contributed to the design, writing and revision of the manuscript; Samantha B. O. Silva contributed to the design, data analysis and wrote the manuscript: Maura G. Lapa contributed to data analysis; Juliana D. P. Brandao contributed to data analysis and wrote the manuscript and Vivienne C. Castilho contributed to the design and revision of the manuscript.

All authors discussed the results and contributed to the final manuscript.

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Availability of data and materials

The data generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

All procedures performed in this research were in accordance with the ethical standards and approved by Research Ethics Committee in all participating sites and was conducted following the ethical standards outlined in the Helsinki Declaration (1983).

Competing interests

Adriana O. Pedro has served on advisory boards or has been a consultant for Libbs Farmacêutica, Abott, Achè, Amgen, EMS, Eurofarma, Grumenthal, Mantecorp-Farmasa, and Sanofi. She has also served on the speaker's bureau for Libbs Farmacêutica, Abott, Achè, Amgen, EMS, Eurofarma, Grumenthal, Mantecorp-Farmasa, and Sanofi-Aventis.

Samantha B. de Oliveira, Maura G. Lapa, Juliana D. P. Brandao and Vivienne C. Castilho are employed at Libbs Farmacêutica, Medical Affairs Division.

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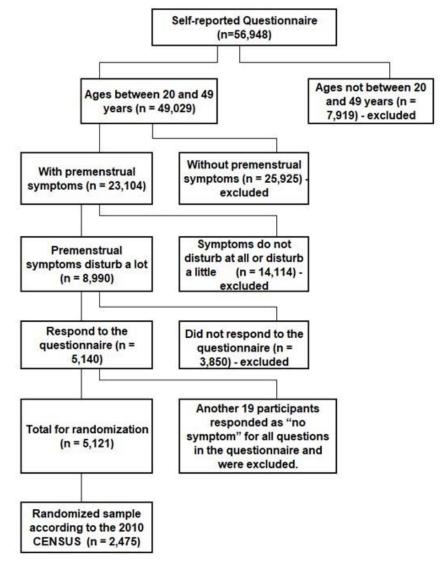


Figure 1: Flowchart of participants included in the study (n=2475).

Table 1: The number of responses from each region available in the database (Target Population) vs. the number of participants selected after randomization, respecting the proportionality of the female population of each state according to the 2010 Census (Random Selection).

	,				
Region	State	Target I	Target Population		n selection
Midwest	Distrito Federal	91	(35.3%)	79	(35.7%)
	Goiás	94	(36.4%)	79	(35.7%)
	Mato Grosso	54	(20.9%)	46	(20.8%)
	Mato Grosso do Sul	19	(7.4%)	17	(7.7%)
	Total	258	(100%)	221	(100%)
North	Amazonas	114	(57.6%)	108	(56.8%)
	Pará	41	(20.7%)	40	(21.1%)
	Tocantins	43	(21.7%)	42	(22.1%)
	Total	198	(100%)	190	(100%)

Northeast	Alagoas	7	(1.1%)	7	(1.1%)
	Bahia	98	(14.7%)	98	(14.7%)
	Ceará	124	(18.6%)	124	(18.6%)
	Maranhão	38	(5.7%)	38	(5.7%)
	Paraíba	31	(4.7%)	31	(4.7%)
	Pernambuco	218	(32.7%)	218	(32.7%)
	Piauí	124	(18.6%)	124	(18.6%)
	Rio Grande do Norte	20	(3.0%)	20	(3.0%)
	Sergipe	6	(0.9%)	6	(0.9%)
	Total	666	(100%)	666	(100%)
South	Paraná	191	(38.1%)	133	(38.2%)
	Rio Grande do Sul	196	(39.1%)	135	(38.8%)
	Santa Catarina	114	(22.8%)	80	(23%)
	Total	501	(100%)	348	(100%)
Southeast	Espírito Santo	154	(4.4%)	46	(4,4%)
	Minas Gerais	651	(18.6%)	196	(18.7%)
	Rio de Janeiro	805	(23%)	242	(23%)
	São Paulo	1888	(54%)	566	(53.9%)
	Total	3498	(100%)	1050	(100%)
Total		5121		2475	

Table 2: Brazilian region by age group in a random sample of the target population. (n=2475)

Region of Brazil		idwest n=221)		orth =190)		theast =666)		South =348)		theast 1050)		TAL 2475)
Profile - n (%)												
20 to 29 years	107	(48.4)	106	(55.8)	341	(51.2)	168	(48.3)	462	(44.0)*	1184	(47.8)
30 to 39 years	80	(36.2)	63	(33.2)	247	(37.1)	128	(36.8)	417	(39.7)	935	(37.8)
40 to 49 years	34	(15.4)	21	(11.1)	78	(11.7)	52	(14.9)	171	(16.3)	356	(14.4)
Total of participants	221	(100%)	190	(100%)	666	(100%)	348	(100%)	1050	(100%)	2475	(100%)
Mean (S.D.)	30	.7 (7.4)	29.	8 (7.2)	30.	2 (7.3)	30	.5 (7.5)	31.4	1 (7.4)	30.8	3 (7.4)
Median (Min - Max)	30 ((20 - 49)	28 (2	20 - 49)	29 (2	20 - 49)	30 ((20 - 49)	31 (2	20 - 49)	30 (2	0 - 49)
p (Anova Region * Age) = 0.0043	p =	0.9641	p =	0.0645	p =	0.0222	p =	0.4165	p = 0	0.0003		

Multiple comparisons: each region with the rest of country (α for Bonferroni correction = 0.008)

^{*} numbers means statistical significance compared with the others.

Table 3: The prevalence and severity of physical symptoms according to Brazilian regions (n=2475).

Region of Brazil		Midwest (n=221)	North (n=190)	Northeast (n=666)	South (n=348)	Southeast (n=1050)	TOTAL (n = 2475)	p-value
		Physic	al sympto	ms (%)				
Headache	Prevalence	86.8	86.3	85.7	87.6	85.9	86.2	p = 0,9253
пеацаспе	Severe intensity	43.2	39.6	41.3	41.0	40.6	41.0	p = 0.9615
Appa and aily akin	Prevalence	85.1	84.2	86.2	85.1	86.3	85.8	p = 0.9209
Acne and oily skin	Severe intensity	33.0	33.7	33.3	33.4	30.9	32.3	p = 0.8343
Edema	Prevalence	84.2	88.9	84.4	86.5	84.4	85.0	p = 0,4676
Edema	Severe intensity	23.1	29.6	22.2	24.3	27.7	25.5	p = 0.1077
\\/ - i - i - i - i - i - *	Prevalence	84.6	81.6	79.7*	85.3	85.3	83.5	p = 0.0267*
Weight gain *	Severe intensity	32.6	36.1	31.5	30.0	36.7	34.0	p = 0.1298
Breast tenderness	Prevalence	84.6	84.2	81.2	82.8	82.1	82.3	p = 0.7556
Dieast tenderness	Severe intensity	30.8	25.9	24.8	22.0	25.1	25.1	p = 0.3888
Exacerbation of	Prevalence	79.6	82.1	77.4	79.6	78.6	78.8	p = 0,6934
immunoallergic conditions	Severe intensity	19.9	10.3	15.5	14.8	15.5	15.4	p = 0.2006

^{*} numbers means statistical significance compared with the others.

Table 4: Psychoemotional symptoms according to prevalence and severity for different regions of Brazil (n=2475).

Region of Brazil		Midwest (n=221)	North (n=190)	Northeast (n=666)	South (n=348)	Southeast (n=1050)	TOTAL (n=2475)	p-value
		Psycho-em	otional syn	nptoms (%)				
Irritability	Prevalence	98.6	97.7	97.6	99.4	99.0	98.5	p = 0.0975
mitability	Severe intensity	64.7	64.5	58.9	58.7	63.3	61.7	p = 0.1935
Anxiety and tension*	Prevalence	97.7	96.3	98.0	99.4	98.8	98.4	p = 0.0501
	Severe intensity	58.3	50.8	50.4	50.0	57.66 *	54.2	p = 0.0085 *
Decreased interest in routine	Prevalence	95.5	93.2	94.9	94.0	94.6	94.5	p = 0.8327
	Severe intensity	39.8	35.6	39.6	38.5	39.2	39.0	p = 0.9027
Depression and sadness	Prevalence	96.4 45.5	92.6 38.1	93.7 41.5	95.1 44.7	94.6 45.6	94.4 43.8	p = 0.4339
Overeating *	Severe intensity Prevalence	91.0	89.5	41.5 89,2*	94.3 *	92.5	91.5	p = 0.2495 p = 0.0347 *
Overeating	Severe intensity	47.8	37.6 *	42.5 *	52.7 *	50.6 *	47.5	p < 0.001 *
Concentration difficulties	Prevalence	91.4	92.1	92.9	91.4	89.9	91.2	p = 0.2926
	Severe intensity	21.8	23.4	26.5	23.6	23.3	24.1	p = 0.5664
Emotional instability	Prevalence	93.2	93.2	90.4	90.8	90.7	91.0	p = 0.5801
, , , , , , , , , , , , , , , , , , , ,	Severe intensity	30.6	32.2	30.1	30.1	33.6	31.8	p = 0.5795

^{*} numbers means statistical significance compared with the others.

Table 5: Percentage of women willing to take an oral hormonal contraceptive as an option treatment of PMS treatment according to the regions (n=2475).

Region of Brazil	Midwest	North	Northeast	South	Southeast	TOTAL
negion of brazil	(n=221)	(n=190)	(n=666)	(n=348)	(n=1050)	(n=2475)
Willing to take the contraceptive - n (%)						
No	57 (25,8%)	41 (21,6%)	159 (23,9%)	99 (28,4%)	280 (26,7%)	636 (25,7%)
Yes	164 (74,2%)	149 (78,4%)	507 (76,1%)	249 (71,6%)	770 (73,3%)	1839 (74,3%)
Total responders	221 (100%)	190 (100%)	666 (100%)	348 (100%)	1050 (100%)	2475 (100%)

p (Chi-Square for Region*Willing) = 0.315



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Use of Immunoglobulin G Enriched with IGM+IGA in Primigestant with Septic Shock: Case Report

By Jaime A. Machado-Bernal, María C. Espinosa-González, Hernán L. Valle-Calderón & Belkis X. Quant-Vergara

University of Colombo

Abstract- Sepsis is a condition that occurs when the body produces an unbalanced immune response to an infection. Septic shock is the most serious manifestation of this infection, which increases with aggravation of maternal and perinatal morbidity and mortality. Within the pharmacological therapeutic options, the cornerstone of this entity is broad-spectrum antibiotic therapy; however, there are other drugs that can be used as adjuvants in the context of sepsis and among them are immunoglobulins. Currently there is little scientific evidence about the use of immunoglobulins in pregnant patients and in Colombia there is only one case report published so far. The objective of this patient report is to present the case of a primipregnant woman with a pregnancy of 16.3 weeks diagnosed with septic shock who was administered immunoglobulin G enriched with IgM + IgA, which had an excellent response to the established treatment and satisfactory evolution. without presenting maternal or fetal adverse effects to the drug.

Keywords: sepsis. septic shock. pregnancy. infectious complications of pregnancy. intensive care units. intravenous immunoglobulins.

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Use of Immunoglobulin G Enriched with IGM+IGA in Primigestant with Septic Shock: Case Report

Uso De Inmunoglobulina G Enriquecida Con IGM+IGA En Primigestante Con Choque Séptico: Reporte De Caso

Jaime A. Machado-Bernal a, María C. Espinosa-González , Hernán L. Valle-Calderón P & Belkis X. Quant-Vergara ^ω

Abstract- Sepsis is a condition that occurs when the body produces an unbalanced immune response to an infection. Septic shock is the most serious manifestation of this infection, which increases with aggravation of maternal and perinatal and mortality. Within the pharmacological therapeutic options, the cornerstone of this entity is broadspectrum antibiotic therapy; however, there are other drugs that can be used as adjuvants in the context of sepsis and among them are immunoglobulins. Currently there is little scientific evidence about the use of immunoglobulins in pregnant patients and in Colombia there is only one case report published so far. The objective of this patient report is to present the case of a primipregnant woman with a pregnancy of 16.3 weeks diagnosed with septic shock who was administered immunoglobulin G enriched with IgM + IgA, which had an excellent response to the established treatment and satisfactory evolution. without presenting maternal or fetal adverse effects to the drug. It is concluded that this drug could be used in pregnant patients as adjuvant therapy in this population.

Keywords: sepsis. septic shock. pregnancy. infectious complications of pregnancy. intensive care units. intravenous immunoglobulins.

Introduction I

epsis is defined as life-threatening organ dysfunction resulting from a dysregulated host response to infection according to the Third Internal Consensus Definitions for Sepsis and Septic Shock of the Task Force¹. Sepsis and septic shock are major health problems that affect millions of people worldwide each year².

Regarding sepsis in the obstetric population, its incidence is different in developed and underdeveloped countries, varying from 0.96 to 7.04 per 1,000 women aged between 15 and 49 years. As for the estimated global mortality rates, they ranged from 0.01 to 28.46

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per 100,000 women between 15 and 49 years of age^{3,4}. Regarding national figures and based on the report made in 2021 by the National Institute of Health of Colombia, sepsis related to pregnancy corresponded to 3%⁵. According to the World Health Organization, sepsis is the third leading cause of maternal death in the world⁶. The main non-obstetric conditions associated with sepsis in pregnant women are urinary tract infections; however, in countries like Colombia, it is important to consider tropical infectious diseases such as malaria, which could be a pathology to take into account originating from sepsis⁷.

The pathophysiology of maternal sepsis is based on an excessive inflammatory response which includes extravasation of albumin and fluid, with subsequent intravascular hypovolemia. Likewise, the release of cytokines leads to a decrease in systemic vascularization, resistance and an increase in cardiac output⁸. During normal pregnancy, the human decidua contains high numbers of immune cells such as macrophages, natural killer (NK) cells, and regulatory T (Treg) cells. Consequently, the presence of immune cells at the implantation site is not associated with a "foreign body" response (the fetus), on the contrary, they have been attracted to facilitate and protect pregnancy⁹.

Regarding immunoglobulins, immunoglobulin formulation enriched with IgM and IgA (12% IgM, 12% IgA and 76% IgG). Relevant mechanisms of action of IgM- and IgA-enriched include opsonization immunoglobulins phagocytosis of causative pathogens¹⁰, neutralization of virulence factors, including bacterial endotoxins and exotoxins, as well as immunomodulation through interaction with complement factors and prevention of proinflammatory responses. Immunoglobulins have also been shown to down-regulate IL-2 production, resulting in significant inhibition of the proliferative response of human T lymphocytes in vitro, as well as in peripheral blood mononuclear cells stimulated with IL-2. lectin, In addition, in vitro and in vivo models have shown an increase in IL-10 after administration of IgM- and IgAenriched immunoglobulins.

Regarding diagnosis, an obstetric modification of qSOFA was proposed by the Society of Obstetric Medicine of Australia and New Zealand (SOMANZ)11 and includes: systolic blood pressure ≤ 90 mm Hg, respiratory rate > 25/min, and altered mental status. These SOMANZ guidelines also include changes in laboratory values when applying the SOFA score in pregnancy, as shown in Table 1.

Table 1: Sequence for the evaluation of modified organ failure in obstetrics (omSOFA) 11

omSOFA variables.	Points	0	1	2	
PaO2/FiO2 respir	ation.	> 400	300-400	< 300	
Platelets		≥ 150.000/mm3	100.000 – 150.000/mm3	< 100.000/mm3	
Bilirrubins (mg/dL)		≤ 1.17	1.17 – 1.87	> 1.87	
Mean arterial (MAP)	pressure	PAM ≥ 70	< 70	Need for vasopressor to maintain MAP	
Consciousness state		Alert	Wake up to verbal encouragement	Arouses only to physical stimulation or pain	
Serum creatinine	Serum creatinine(mg/dL) < 1.0		1.0 – 1.36	> 1.36	

Sepsis in the pregnant population is a serious entity that has both short-term and long-term maternal and perinatal complications: such complications can even lead to maternal or neonatal death. Important neonatal complications include: preterm delivery, neonatal sepsis, chronic lung disease, brain injury secondary to maternal infection, and neurodevelopmental disorders¹².

Ideally, the indication of this medication is recommended up to 24 hours after the diagnosis of sepsis is made, however, it may be indicated when there has been no satisfactory evolution after 3 days of initial antibiotic therapy¹³. However, there is little evidence to support it.

Until now, only one published case report is known in Colombia in the context of an obstetric patient with a diagnosis of sepsis who was administered immunoglobulin G enriched with IgM and IgA with adequate clinical evolution, for which, taking into account the above, the objective of this report is to publicize and promote a new therapeutic option in obstetric patients with sepsis and inadequate response to conventional management.

CASE REPORTE II.

We present a 20-year-old patient, primiparous, with a pregnancy of 16.3 weeks by ultrasound between weeks 11-14, without significant pathological or surgical history, obstetric history: first pregnancy, without any prenatal control, or paraclinical tests to date, never cytology had been performed, she did not remember the date of her last period, menarche at 13 years of age; history of immunization single dose of vaccine for COVID-19 (Astrazeneca 1 dose - did not remember the date), who was admitted to the emergency department of a low-complexity center (Hospital PASO La Manga) due to clinical symptoms of approximately 3 days of evolution, sudden onset, characterized by abdominal pain 10/10 according to the visual analog scale, located in the hypogastrium, radiating to the bilateral lumbar region and the right thigh associated with dysuria, bladder tenesmus and dizziness and nausea, without emetic episodes. Refers outpatient treatment with cephradine 500mg, 1 tablet orally every 8 hours for 2 days without improvement. On admission physical examination, vital signs were stable but febrile (blood pressure 100/60mmHg, heart rate 86bpm, respiratory 18rpm. ambient oxygen saturation 99%, temperature 38°C); abdomen slightly painful on palpation in the hypogastrium and positive bilateral fist percussion, without vaginal leakage; It is managed in the emergency room with saline solution 500CC in bolus and continues at 80CC/hr. acetaminophen 2 tablets orally. Paraclinical tests were performed: normal blood cell count, urinalysis suggestive of urinary tract infection (bacteria ++, leukocytes 15xc, positive nitrites), negative acute phase reactants; Therefore, they consider that they have a urinary tract infection and initiate referral procedures to be managed and assessed by the gynecology and obstetrics service at Camino Universitario Distrital Adelita de Char. Upon admission to this center, vital signs were reported within normal parameters (blood pressure: 110/60 mmHg, heart rate 80 bpm, respiratory rate 18 rpm, oxygen saturation 98%, temperature 37°C), on physical examination there were no signs of dehydration, abdominal pain in the hypogastrium of lesser intensity, without signs of peritoneal irritation, in the gynecological examination abundant non-fetid leukorrhea was evidenced, closed cervix and pain on mobilization of the cervix and on mobilization of the adnexa. A diagnosis of pyelonephritis associated with bacterial vaginosis was considered clinically and intravenous management with cephalothin 1 gram IV every 6 hours was continued for 2 more days during said hospitalization. Subsequently, due to adequate clinical evolution and negative urine culture report at 48 hours (probably biased by antibiotic treatment previously received by the patient), she was discharged with cephradine 500mg, 1 tablet orally every 8 hours for urinary tract infection and metronidazole in ovules for the management of bacterial vaginosis, 1 ovule each day until completing 7 days with order of control urine culture 5 days after completion of antibiotic treatment.

Patient who is readmitted approximately 3 weeks later, with a pregnancy of 20.1 weeks, reporting the same symptoms of admission in the previous hospitalization, also comments that the outpatient treatment was not carried out adequately and the ordered control urine culture was not performed. He was admitted to the observation/emergency department with stable vital signs (blood pressure: 100/65 mmHg, heart rate 96 bpm, respiratory rate 18 bpm, oxygen saturation 98%, temperature 37.3°C, normal fetocardia 140 bpm), without omSOFA criteria in that moment; Management was started with bolus saline solution and after maintenance, hyoscine ampule 20mg intravenously in a single dose, analgesic treatment with acetaminophen 1 gram orally and laboratories were requested again: complete blood cell count, partial urine count and acute reactants, HIV and serology syphilis.Paraclinical tests were performed that same day, which were reported as follows (Table 2):

Table 2: Paraclinical

PATIENT VALUES	REFERENCE VALUES				
HIV: NEGATIVE.	HIV: NEGATIVE.				
TREPONEMIC TEST: NON-REACTIVE	TREPONEMIC TEST: NON-REACTIVE				
COMPLETE BLOOD COUNT: WBC: 13000, N: 78%, HB: 10, HTO: 33, PLT: 144.000.	COMPLETE BLOOD COUNT: WBC: 10.000- 15.000, N: 60% - 80%, HB: 12 - 15, HTO: 38 - 48, PLT: 150.000 - 450.000				
CRP: 1.34	CRP: 1 – 3.				
UROANALYSIS: NITRITOS NEGATIVOS, LEUCOCITOS INCONTABLES, BACTERIAS ++.	UROANALYSIS: NITRITOS: NEGATIVOS, LEUCOCITOS: 0-5XC, BACTERIAS ESCASAS.				

HIV: human immunodeficiency virus, WBC: White blood cells, N: neutrophils, HB: hemoglobin, HTO: hematocrit, PLT: platelets. CRP: C-reactive protein.

Pyelonephritis was again documented, for which the patient was hospitalized to start intravenous in-hospital antibiotic management (ampicillin/sulbactam, 3 g IV every 6 hours) and a urine culture was requested, renal and urinary tract ultrasound was performed, reporting a finding of bilateral hydronephrosis. grade II without findings of renal lithiasis or other alterations (figure 1). Patient who remained 4 days hospitalization under antibiotic treatment mentioned above with stable evolution, however, on the 5th day of hospitalization he presented abrupt torpid evolution of his clinical picture with blood pressure figures with a tendency to hypotension, tachypnea, tachycardia (blood pressure 80/50mmHq, respiratory rate 28rpm, heart rate 112lpm, wakes up to verbal stimulation) (omSOFA: 2pts), then considering a diagnosis of sepsis of urinary origin, for which it was indicated to stagger antibiotic treatment to piperacillin/tazobactam at a dose of 4.5gr IV every 8 hours, a bolus of 2000cc (30cc/kg) was administered and basal fluids were continued at 100cc/hr; extension laboratories for sepsis were requested (Table 3) and transfer to the intensive care unit for comprehensive management was indicated.

Table 3: Paraclinical

TP: 13. INR: 1.02. TPT: 29, 8. ALT: 13, 8. ASAT: 20, 9.
CR: 0,8. LDH. 196. BUN: 14. LACTATO: 1,9.
HEMOGRAMA: WBC: 13000, N: 78%, HB: 7.9, HTO: 24, PLT: 53.000
PCR: 0.04
CL: 105. K: 3,1. NA: 137.

PT: prothrombin time, INR: international normalized ratio, PTT: partial thromboplastin time, CR: creatinine, LDH: lactic dehydrogenase, BUN: urea nitrogen, WBC: White blood cells, N: neutrophils, HB: hemoglobin, HTO: hematocrit, PLT: platelets. CRP: C-reactive protein, CL: chlorine, K: potassium, NA: sodium

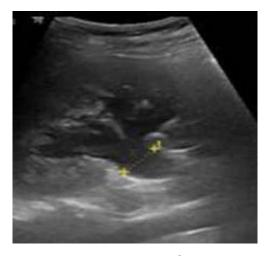


Figure 1: Renal and urinary tract ultrasound, coronal section. Grade II right hydronephrosis. Source: authors.

Based on platelet count findings, dengue with warning signs was considered as a differential diagnosis because it was located in an endemic area; but this diagnosis was later ruled out by both negative dengue IgG and IgM antibody tests. During her stay in the High Obstetric Risk Intensive Care Unit (seventh day of hospitalization and second day in the unit), she was assessed by the intensive medicine and critical care service, who, taking into account the intermittent fever, hypotension and systemic inflammatory response (tachycardia, tachypnea) despite management with broad-spectrum antibiotics (4 days of ampicillin/ sulbactam and two days of piperacillin/tazobactam at the doses described) and optimal fluid therapy, they consider a patient with septic shock and decide to start adjuvant therapy in the context of urinary focus shock

with immunoglobulin G enriched with IgM and IgA at a dose of (5ml/kg/day) for 3 days. The patient's clinical evolution was monitored and she had persistent tachycardia (102 bpm) without tachypnea and without new febrile episodes. She was assessed by the infectious disease service (eighth day of hospitalization and third day in the unit) who considered continuing antibiotic escalation to ertapenem 1gr IV every 24 hours for 7 days due to persistent tachycardia and continuing with the last dose of immunoglobulin G enriched with IgM and IgA. The patient continued with satisfactory evolution, with blood pressure figures at goals, without requiring vasopressor support, with a progressive increase in platelet levels and improvement in the blood cell count (Table 4).

Table 4: Paraclinical

WBC: 12.000
N: 76%
HB: 11 – HTO: 34
PLT: 180.000

On day 4 of intravenous antibiotic therapy with ertapenem (twelfth day of hospitalization, seventh day in the unit) the patient suddenly became tachypneic with saturations of 88%, for which a chest tomography was indicated (figure 2 and figure 3) where It showed a large left pleural effusion, which is why a thoracentesis was indicated, draining 620 cc of clear liquid without infectious characteristics in the bacterial culture cytology reading and a negative fungal test. Patient with immediate improvement after drainage of the pleural effusion; for which she was transferred to a general gynecological hospitalization receiving antibiotic treatment with stable vital signs, afebrile, without loss of fetal well-being evaluated by obstetric ultrasound, who

completed antibiotic treatment and proposed adjuvant immunotherapy scheme with immunoglobulin G enriched with IgM and IgA with adequate drug tolerance and favorable clinical course.

No adverse events were recorded during the hospitalization of the mother and the administration of immunoglobulin G enriched with IgM and IgA, nor were subsequent maternal and perinatal complications documented during the course of pregnancy.

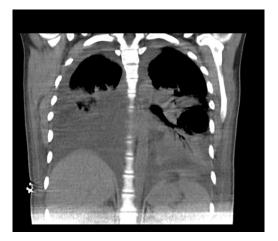


Figure 2: Chest tomography, coronal section. Bilateral pleural effusion. Source: authors.

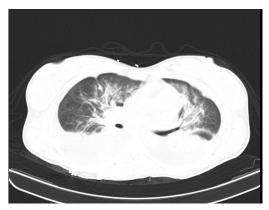


Figure 3: Chest tomography, axial slice. Bilateral pleural effusion. Source: authors.

III. Discussion

Maternal sepsis corresponds to an obstetric emergency, and a leading cause of maternal and perinatal morbidity and mortality¹⁴. Timely and targeted antibiotic treatment and intravenous fluid resuscitation are essential for the survival of patients with suspected maternal sepsis. If the patient presents with septic shock or does not respond to initial treatment, multidisciplinary management and therapeutic alternatives

necessary. **Among** these alternatives are immunoglobulins.

Specifying the management and treatment of this pathology, it is considered that it is generally similar in both the pregnant and non-pregnant population. The international guidelines for the management of sepsis and septic shock 2021 proposed by the campaign surviving sepsis¹⁵ establish some key points about what should be done when the diagnosis of sepsis is certain; these points are specified in table 5:

Table 5: Key points when sepsis is diagnosed

KFY	POI	INI	гς

- Measure the lactate level.
- Obtain blood and urine cultures before starting antibiotic therapy.
- 3. Administer broad-spectrum antibiotics.
- Administer 30 cc/kg of crystalloids to avoid hypotension.

The guide for sepsis care in pregnancy of the Royal College of the United Kingdom, and the Australian guide for sepsis in pregnancy consider that IgG enriched with IgM and IgA can be indicated as an alternative therapy in septic shock secondary to staphylococci and streptococci, recommending its use. use, but little evidence of its usefulness in sepsis due to gram-negative microorganisms has been reported; however, more studies and literature are expected to support the use of immunoglobulins in the context of obstetric sepsis of any origin^{16,17}.

Since 2012. the use of enriched immunoglobulins has been endorsed in the context of pregnant patients with sepsis who do not respond to initial management with antibiotics and intravenous fluids. According to the Sánchez-Padrón Guidelines for the care of severe sepsis in obstetric patients¹⁸, the currently recommended dose for the pregnant population is 5 ml/kg/day (250 mg/kg of body weight/day) for 3 consecutive days with an infusion rate of 0.4 ml/kg/h; Additional infusions may be required depending on the clinical course of each patient. However, it should be noted that this drug is not commonly prescribed, few institutions routinely use it for severe infections, and there are still no established guidelines for how and when to use it.

There are very few reports that support the use of this type of medication in pregnant patients. A case of a patient in Turkey with a 29-week pregnancy and sepsis secondary to resistant acinetobacter is described. After 7 days of starting antibiotic therapy, her condition worsened, so they decided to start enriched immunoglobulin G (20 mg/kg/hr initial dose and continue 10mg/kg/hr for 68hrs) with subsequent response to management with immunoglobulins without associated adverse effects¹⁹. In this case, even higher doses were used than those usually recommended in this type of population. Likewise, there is another case published in the United Kingdom²⁰ of a patient who had a preterm birth at 32 weeks of gestation, developed sepsis due to GBS (group B streptococcus) 12 hours postpartum and, in addition to antibiotic therapy, therapy with enriched immunoglobulin G (in said study no dose or duration is specified). Two days after the established treatment, it begins to stabilize, a fact that justifies that the earlier the medication is started, the better results in terms of clinical evolution are expected. In Colombia to date, there is only one reported case of a patient with a 36-week pregnancy, who presented septic shock secondary to a gastrointestinal infection and progressed to multisystem organ failure in whom adjuvant therapy with IgM-enriched immunoglobulin was started with a good outcome. response and no maternal-perinatal complications at a dose of 5ml/kg/day for 3 days²¹; As administered in this case report, the patient in question had an excellent response to the established treatment, reducing the systemic

inflammatory response in the context of septic shock of urinary origin.

IV. Conclusion

A case of a 20-year-old primipregnant woman, previously healthy, with pregnancy in the second trimester, who developed sepsis of urinary origin, was presented. Initially, it was treated as a urinary tract infection with antibiotic management, but the patient did not respond to said therapy. Subsequently, antibiotic treatment was staggered and enriched immunoglobulin G was used as adjuvant therapy. Despite the initial form of presentation, the patient responded favorably from the clinical and paraclinical point of view after receiving aforementioned treatment without presenting adverse effects or maternal-perinatal complications and continues her prenatal check-ups without documented sequelae. Among the strengths of this study, the use of a drug that can be used in pregnant women as adjuvant therapy in the context of sepsis and that could improve the maternal and perinatal prognosis should be highlighted. However, more studies and investigations should be carried out to evaluate the presence of adverse effects with the use of this drug in the short and long term, both in mothers and in newborns.

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Compendium and Phytochemicals of Selected Plants used for Dysmenorrhea Treatment in Ibadan Metropolis, Nigeria

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Abstract- A gynecological condition unique to women is dysmenorrhea. Dysmenorrhea makes women uncomfortable and lowers their quality of life. Non-steroidal anti-inflammatory medication (NSAID) use is nevertheless discouraged due to its negative side effects. Despite its frequency, dysmenorrhea gets little attention. As a result, there is a lack of knowledge about traditional medical treatments for dysmenorrhea. The study's main goal was to catalog the plants and phytochemicals found in the Ibadan metropolis in Nigeria that can be used to treat dysmenorrhea. Three (3) Local Government Areas (LGAs) within the city of Ibadan were purposefully chosen using a three-stage random selection technique, based on the presence of herb markets (Ibadan North, Ibadan South East, and Ibadan North East). In each LGA, three (3) important markets were chosen. The distribution of 90 structured questionnaires to herb vendors was done at random. Each market's socioeconomic data as well as documentation of medicinal plants were gathered. Chromatographic methods were used to identify the phytochemicals present in five herbs that should be prioritized.

Keywords: therapy, medicinal plants, phytochemicals, and dysmenorrheal.

GJMR-E Classification: DDC Code: 616.075 LCC Code: RC55



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Compendium and Phytochemicals of Selected Plants used for Dysmenorrhea Treatment in Ibadan Metropolis, Nigeria

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Abstract- A gynecological condition unique to women is dysmenorrhea. Dysmenorrhea makes women uncomfortable and lowers their quality of life. Non-steroidal anti-inflammatory medication (NSAID) use is nevertheless discouraged due to its negative side effects. Despite its frequency, dysmenorrhea gets little attention. As a result, there is a lack of knowledge about traditional medical treatments for dysmenorrhea. The study's main goal was to catalog the plants and phytochemicals found in the Ibadan metropolis in Nigeria that can be used to treat dysmenorrhea. Three (3) Local Government Areas (LGAs) within the city of Ibadan were purposefully chosen using a three-stage random selection technique, based on the presence of herb markets (Ibadan North, Ibadan South East, and Ibadan North East). In each LGA, three (3) important markets were chosen. The distribution of 90 structured questionnaires to herb vendors was done at random. Each market's socioeconomic data as well as documentation of medicinal plants were Chromatographic methods were used to identify the phytochemicals present in five herbs that should be prioritized. To evaluate the collected data, descriptive statistics were employed 42 herbs which were documented include: Bidensbipinnata, Aristolochiarepens, Gongronemalatifolium, and Oxytenantheraabyssinica, which were also the most often referenced herbs. Bark, leaf, root, seed, and flower bud were among the plant parts tested for efficacy. 96.7 percent of respondents used the maceration method, 2.2 percent used the squeezing method, and 1.1 percent boiled the herbs. All the botanicals contained steroids, cardiac glycosides, and herbs, with exception Gongronemalatifolium and Bidensbipinnata, contained phenol. All herbs, with the exception of Bidensbipinnata, contained saponins.

The analysis of the plants' roots and barks revealed that they contained phytochemicals that have anti-inflammatory properties and might be utilized to treat dysmenorrhea. The comments from the respondents demonstrated the efficacy of herbal treatments for dysmenorrhea.

Keywords: therapy, medicinal plants, phytochemicals, and dysmenorrheal.

Introduction

s unpleasant menstruation or uterine cramps, the most frequent gynecology ailment affecting women of reproductive age is dysmenorrhea (Coco, 1999). It is brought on by the overproduction of

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uterine prostaglandins, especially F2 prostaglandins, which cause the myometrium to contract excessively and the arteries to constrict (Dutta, 2014). A study done in a school of nursing in Spain revealed that other monthly symptoms of painful menstruation, like nausea, vomiting, diarrhea, dizziness, exhaustion, headaches, depression, and an inability to concentrate, are widespread among women, leading students to miss courses (Ana et al, 2020).

Dysmenorrhea comes in two main forms: primary and secondary (Proctor and Farguhar, 2006). Around the time of menarche (6 to 24 months into adolescence), primary dysmenorrhea typically develops (Dawood, 2006). Usually beginning just before or at the commencement of menstruation, a dinstict and foreseeable time pattern can be observed in primary dysmenorrheic pain (Harel, 2008). The pain, which can be felt in the back and thighs, often lasts 8 to 72 hours and may be worse on the first or second day of menstruation (Hofmeyr, 1996: Proctor et al., 2002: Ruoff and Lema, 2003). Inflammatory illness of the pelvis, endometriosis, adenomyosis, fibroids (myomas), and secondary dysmenorrhea are all potential causes of discomfort. secondary dysmenorrhea may occur at any time after menarche, usually two years after the start of the period, and may be accompanied by additional gynecological symptoms such as menorrhagia and inter menstrual hemorrhage depending on the underlying circumstances. In addition, secondary dysmenorrheic pain may manifest at any time during the menstrual cycle, may be chronic or diffuse and may not necessarily be accompanied with mensuration. (Hofmeyr, 1996; Proctor and Farguhar, 2006). The most frequent cause of secondary dysmenorrhea in teenagers is endometriosis, which is defined as the presence of endometrial tissue outside of the uterus (Janssen et al., 2013).

Herbs are renowned for their culinary and therapeutic uses (Oliver, 1960). Because the economics of plant use were passed down orally or without any written records from one generation to the next., they are extensively used throughout the world and there is a growing quantity of studies showing their usefulness in treating a wide range of maladies (Ekor, 2013). (Oliver, 1960). According to Sharaibi et al. (2017), several medicinal herbs, including Cuminum cyminum, Angelica sinensis, Cimicifuga racemosa, Coriandrum sativum,

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Foeniculum vulgare and Vitex agnus-castus, have been shown to be useful in the treatment of various gynecological problems.

Menstrual pain is commonly experienced by teenage girls and is therefore thought to be a normal part of the development that all women go through. As a result, it is frequently misdiagnosed and undertreated. Dysmenorrhea has masses of effects on females in several aspects of their lives, from their life's quality to its effect on their day to day activities and a lot of discomfort periods.

There are increasing suggestions for the use of herbs to eradicate the risk rather than the side-effectanti-inflammatory laden non-steroidal medicines (NSAIDS). Therefore, the main objective of the study was to document the plants that can be used in the treatment of dysmenorrhea in Ibadan metropolis and their phytochemicals constituents present in the plants

Materials and Methods II.

Study location: The study was carried out in Ibadan, the state capital of Oyo in southwest Nigeria. Latitude

7°22'39.22"N and longitude 3°54'21.28"E are its precise coordinates. The elevation of Ibadan city is 225 meters. In Ibadan, there are predominant tropical wet and dry weather, with a lengthy wet season and usually constant temperatures all year long. March through October is considered the rainy months, with august seeing some of the least amount of rain.

The rainy season is split into two distinct wet seasons as a result of this gap. Between November and February, Ibadan suffers the dry season, which is known as the harmatttan in West Africa. Ibadan experiences 1,230 mm of rainfall on average during the course of 123 days. The two highest rainfall months are June and September. The mean lowest temperature is 21.42°C while the mean daily temperature is 26.46°C and the relative humidity 74.55%.

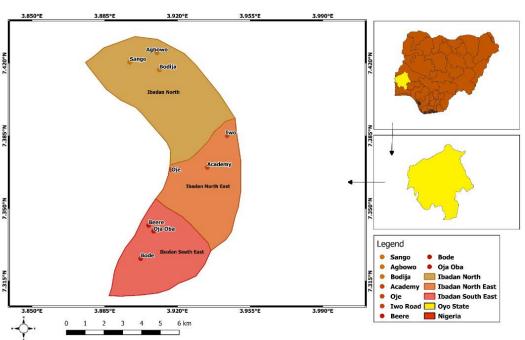


Figure 1: Map of Ibadan Metropolis showing the study area

Method of data collection: Three (3) Local Government Areas in the Ibadan Metropolis were purposefully chosen for the purpose of compiling a compendium of plants for the treatment of dysmenorrhea: Ibadan North, Ibadan North East, and Ibadan South East. Three (3) major markets were also identified in each Local Government Area. The respondents (local herb merchants) were surveyed using questionnaires to gather pertinent information about their understanding of menstruation pain therapy. In order to gather information about the respondents' demographics, the local names of the

plants used to treat menstrual pain, the plant parts used, whether other materials are added, the method of preparation, and other pertinent details pertaining to the study, the questionnaires for the herb sellers contained thirty-four (34) items.

Method of data analysis: The data generated from the questionnaires were collected, data analysis adopted was descriptive analysis using IBM SPSS software. Frequency of citation was also determined to help choose species with highest frequencies for further analysis.

Frequency of Citation (FC) = $\left(\frac{Np}{N}\right) * 100$

Where,

Np = number of times a species was mentioned N = total number of participants

Extraction of plant material

The chosen plants' barks were bought dry from Bode Market in Ibadan and powdered using a milling machine. The plant powder was placed in individual test tubes, each of which received distilled water after which the plant powder was thoroughly mixed and allow soaking. The solution was filtered after 48 hours using filter paper, and extracts were then taken out and used for further phytochemical investigation.

b) Botanical Chemical Screening

400 cc of each of the organic solvents were used to soak 200g of the powdered sample for 24 hours. Ethyl acetate, methanol and acetone, were different types of organic solvents employed. Whatman qualitative filter paper was then used to filter the resulting combination (Sigma-Aldrich, Germany). The colorimetric tests used as reported by (Alghasham et al., 2017; Sasidharan et al., 2011) are listed below.

Test for Saponins: the plant extracts were put to a test tube containing 5mm of distilled watter, vigorously shaken,, and then tested for saponins. For a positive test, a stable persistent effervescence was detected.

Test for Terpenoids: 1.5ml of concentrated H₂SO₄ solution was mixed with 1 ml of chloroform and 2.5 ml of each plant extract to test for terpenoids. Terpenoids were identified at the contact as a reddish-brown color development.

Test for Phlobatannins: Phlobatannins were checked for by adding 1 ml of a 1 percent HCl acid solution to each plant extract. When the mixture was cooked, the presence of a crimson precipitate indicated that the test was successful.

Test for Alkaloids: Two different tests were carried out to detect the presence of alkaloids:

Mayer's test: this was examined by adding 0.2ml of diluted HCL acid of 2ml of plant extracts in a test tube. Mayer's reagent was then added to the mixture at a volume of 1ml. alkaloids were detectable by a yellowish buff precipitate.

Test for Tannins: to check for tannins, 2-3 drops of a 1% lead acetate solution were added to 1 ml of the plant extract's each. The presence of tannins was confirmed by the emergence of dark blue or greenish grey color.

Test for Cardiac glycosides: to test for cardiac glycosides, dilute 1 ml of each plant extract of 1ml of chloroform, and the add 2-3 drop of the resulting solution to the side of the test tube to create a layer. The development of a brown ring during the inter phase was a sign that deoxy sugar, a property of cardiac glycosides was present.

Flavonoids: 1 ml methanol was added to 1 ml of 10 % lead acetate solution to conduct a flavonoid test. For a positive test, the emergence of a yellow colored precipitate extract was noted.

Phenols/Polyphenols: a 10% ethanolic ferric chloride solution was mixed with 0.5 cc of methanoloc extract. For a positive test, the development of blue green to dark blue color was seen.

Steroids: in attest tube, 1ml of the ethanolic extract and 1ml of sulfuric acid were added. Steroids were present because of the development of the red-colored solution

Alkaloids: Two tests were performed to identify the presence of alkaloids

Mayer's Test: Under this test, 2ml of the extract and 0.2ml of dilute hydrochloride acid was put in a test tube. Then, 1ml of Mayer's reagent was added. A yellowish buff precipitate is indicated of the presence alkaloids.

Dragendroff's Test: in the case of this test, 2ml of the extract and 0.2ml of dilute hydrochloride acid was put in a test tube. Then, 1ml of dangendroff reagent was added. Observation of an orange-brown precipitate indicated the presence of alkaloids,

Results and Discussions III.

Social and demographic data of respondents

The most responders (42.2 percent of all respondents) are from Ibadan South East, next Ibadan North (33.3% of all respondents), and finally Ibadan North East (24.4 percent of the total respondents). Because it featured the most well-known herb markets, including Bode, Oje, and Beere, Ibadan South East had the biggest population. Only 18.9 percent of respondents were men, making up the majority of respondents (81.1%). Because the work requires less physical strength than other types of work, there are more women than men who do it.

Most respondents had primary education (77.8%) while thirteen percent had secondary school education and those with tertiary education were 8.9%. Most respondents were married while least (1.0%) were single, this is because the business is a veritable source of income for married person that need to cater for their own family. The age range of 20-30, 31-40 and 41-50 years old had 14.4%, 81.1% and 4.4% of the respondents respectively.

b) Knowledge on treatment of menstrual pain

Most of the respondents indicated that the use of herbs for the treatment of menstrual pain is very effective (97.8%) while other respondents indicated that herbs is only effective (2.2%). Moreover, most of the respondents indicated that they add other supplements during the preparation of the herbs (96.7%) while other respondents indicated that they do not add any other supplements during the preparation of the herbs (3.3%). The addition of other supplements for the preparation of herbs is believed to enhance efficiency of the herbs rather than being used alone without supplements.

Furthermore, most of the respondents (96.7%) indicated that the maceration of the plants was the method used for preparation, while others indicated squeezing (2.2%) and boiling (1.1%), the use of maceration in the preparation of herbs is the most effective because maceration prevents evaporation of the active ingredients in the leaves compare to other herb preparation methods.

Most of the respondents (98.9%) indicated that refrigeration was used in the preservation of the herbs and others (1.1%) indicated the boiling of the herbs as a means of preservation.

c) Relative Frequency of Citation of the Medicinal Plants used in the Traditional Treatment of Menstrual Pain

More than forty (40) medicinal plants which were used for the treatment of menstrual pain were recorded from the respondents which are presented in the appendix and the five which had the highest frequency were chosen for further study for the phytochemical constituents. This relative frequency of citation was calculated using the formula: (RFC) = $\left(\frac{Np}{N}\right) * 100$ Where.

Np = number of times a species was mentioned N = total number of participants

d) Medicinal plants used for the treatment of Menstrual Pain and other information acquired

Most of the respondents (48.9%) indicated that the availability of the plant materials used were the same,

while others indicated that the availability was decreasing (36.7%) and increasing (14.4%). Most of the respondents (93.3%) got their knowledge from their ancestors, while the rest of them got their knowledge from training (3.3%) and from both ancestors and training (3.3%).

Furthermore, most of the respondents (36.7%) had over 30 years of experience, followed by those with over 40 years of experience (35.6%), then those with over 60 years of experience (8.9%), then those with over 50 years of experience (7.8%), followed by those with over 20 years of experience (6.7%), then those with over 35 years of experience (3.3%) and the least of them with over 15 years of experience (1.1%). Most of the respondents (97.8%) has an association while others (2.2%) had no association. Moreover, majority (97.8%) of the respondents were registered herb sellers, while others (2.2%) were not registered. On the respondents' knowledge on conservation, most (57.8%) did not have the knowledge of the conservation of indigenous knowledge, while others (42.2%) had knowledge on it.

Detailed responses for ways of conserving indigenous knowledge and plant diversity

Most of the respondents (57.8%) had no knowledge on the conservation of indigenous knowledge, followed by some of them (13.3%) who kept records, then some who taught persons and kept records (6.7%) and some others who taught their offspring. The rest of the respondents, trained people (6.7%) and documented and taught persons (4.4%).

Detailed responses for ways of conserving indigenous knowledge and plant diversity

Question	Items	Frequency	Percentage (%)
Detailed	Documentation and teaching	4	4.4
	Keeping records	12	13.3
	None	52	57.8
	Teaching	6	6.7
	Teaching and recording	3	3.3
	Teaching offspring	3	3.3
	Teaching offspring	4	4.4
	Training	6	6.7
	Total	90	100

Phytochemical Screening of the Selected Medicinal **Plants**

Five prioritized, carefully chosen therapeutic plants were the subject of а phytochemicals which revealed their investigation, phytochemical contents i.e., saponin, tannin, flavonoid, alkaloid, cardiac glycosides, phlobatanin, steroids, terpenoids,

anthraguinones and phenols are either present or absent in these plants and the results are summarized. In this study it was investigated that most of aforementioned phytochemicals are present in the five selected plants. Saponins are glycosides of both tritepenes and sterols that typically include five sugar units as well as gluconic units. More than 70 families of higher plants have been documented to contain saponins. They work by preventing the body's reabsorption of cholesterol to lower it. Insectisides, emulsifiers and foamy extinguishers are other products where they are used. (Narayanasamy and Ragavan, 2012). The data shows that saponin is absent in Bidensbipinnata and Gongronemalatifolium but present in the rest of the plants.

Tannins are polyphenolic compounds that are naturally present in almost all plants, including their leaves, bark and stems. Their abundance in nature has influenced their historical use in a variety of ways (Fraga-Corral et al., 2020). Herbs that contain tannins are used to tighten tissues (varicose veins), dry up excessive watery discharges (diarrhea), protect damaged tissue (skin), aid in stopping bleeding (heavy menstrual flow) and control infection. In addition to acting as anti inflammatory, anti-microbial and keratolytic agents, they also function to inhibit enzymes such as 5-lipoxygenase & hyaluronidase, (Lufuluabo et al., 2018). In the result shown in Figure 4, tannins were only present in Gongronemalatifolium and the Oxytenanthera species but were absent in the rest of the plants.

Alkaloids are well known nitrogen-containing natural bioactive compounds. From this study, two types of tests were carried out to evaluate the presence of alkaloids in the samples under study which were; Dragendoff's test and Meyer's test. Alkaloids are shown present Gongronemalatifolium in Oxytenanthera species but absent in Aristolochiarepens and Bidensbipinnata, from the data presented.

Terpenoids were found to be present in all of the samples except Gongronemalatifolium. Terpenoids signifies anti-inflammatory, antiviral, antihyperglycemic and anticancer activities.

Steroids were found to be present in all of the samples except Gongronemalatifolium.

According to the table presenting the results, cardiac glycosides were present in all the plant samples tested except one of the Oxytenanthera species (Paranfunfun).

Although many essential oils are terpenes and some phenolic compounds, phenols undoubtedly make up the biggest group of plant secondary metabolites. They range in size from simple structures containing an aromatic ring complicated ones, like lignin (Aldred, 2008). It was present in all plant samples except Bidensbipinnata.

As a result of its anti-inflammatory analgesic and anti-oxidant qualities, pholabataninhas been noted for its ability to speed up the healing of wounds (Wadood et al., 2013). It is observed that phlobotannin is present in Gongronemalatifolium and Oxytenanthera species but absent in Aristolochiarepens and Bidensbipinnata.

In addition to their function as flavoring agents, flavonoids are also expressed in plants in response to microbial infection, which suggests that they have antimicrobial properties. (Awotedu et al., 2019). In addition, flavonoids have been linked to anti-oxidant activity in both healthy and pathological conditions. Flavonoid was found to be present in Bidensbipinnata and an Oxytenanthera species (Paran pupa) and not present in other plants.

h) Phytochemical qualitative analysis of the five prioritized plants

	Phytochemical Screening				
Phytochemicals	Bidensbipi	Aristolochiar	Gongronemalatifol	Oxytenantheraabyss	Oxytenantheraabys
	nnata	epens	ium	<i>inica</i>	sinica
Saponins	-	+	-	+	+
Tannins	-	-	+	+	+
Flavonoids	+	-	-	-	+
Steroids	+	+	-	+	+
Phlobatannins	-	-	+	+	+
Cardiac glycosides	+	+	+	-	+
Terpenoids	+	+	-	+	+
Phenol	-	+	+	+	+
Alkaloid	-	-	+	+	+

Where; + Implies the presence of the phytochemicals

Conclusion

This study provides clear insight on the medicinal plants used in curing dysmenorrhea in three selected local governments in Ibadan and a qualitative analysis was done on five prioritized plants. The presence of phytochemicals in the root and barks of the plants analyzed shows that, they can be used for the treatment of dysmenorrhoea. The responses the respondents gave as given in the results, also showed the effectiveness of herbal remedies for the treatment of dysmenorrhea.

RECOMMENDATION

This study sturdily recommends that further work to isolate, identify, characterize, and standardize the bioactive elements in charge for the medicinal properties of future promising medicinal plants be looked into and studies to regulate satisfying dosages, adverse reactions and effects. This would not only help the country develop, but it will also encourage the use of locally made herbal treatments and the exportation of our abundant herbal medicines.

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Study of Fetomaternal Outcome in Cases of Pre-Eclampsia By Amsaveni M

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Aims: This study investigated the various risk factors, fetal and maternal outcome in cases of preeclampsia.

Study Design: This was a cross sectional study conducted over a period from January 2019 and June 2020. This study enrolled 100 cases of non severe preeclampsia and 100 cases of severe preeclampsia.

Methods and Materials: Participants were selected by consecutive sampling and baseline data were collected by using a predesigned and pretested structured questionnaire.

Data Analysis: Data were entered and analysed by using SPSS version 20.

Keywords: preeclampsia, hypertensive disorders, fetomaternal outcome.

GJMR-E Classification: DDC Code: 618.2 LCC Code: RG524



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Study of Fetomaternal Outcome in Cases of Pre-Eclampsia

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Results: It was observed that preeclampsia was more common in the age group of 21 to 30 years (68%), women living in rural area (71.5%), low socioeconomic class, unbooked antenatal history (70%). Maximum number of patients were Primigravida (52.5%). 79.5% were anemic. 50% patients had vaginal delivery, 50% had Caesarean section. 73.5% babies born were full term alive babies, preterm were 20.5% (41), 4% (8) IUD and 2% (4) stillbirth. Early neonatal death occurred in 4.5% babies (9), 26% (52) babies were low birth weight, 18.5% were Growth restricted, 5.5% babies had Neonatal jaundice and 18.5% babies were admitted in Neonatal Intensive Care Unit. The most common maternal complication was Post Partum Haemorrhage (7.5%), which was observed in 15 cases, the next common complication was Abruption, which occurred in 10 cases (5%). Maternal mortality occurred in 2 cases (1%).

Conclusion: This study concludes that fetal and maternal outcome were markedly affected by preeclampsia and also the grave complications were more common in severe preeclampsia cases than in non severe preeclampsia cases. So proper Antenatal care, early diagnosis of preeclampsia and timely intervention will decrease perinatal morbidity and mortality.

preeclampsia, Keywords: hypertensive disorders. fetomaternal outcome.

Introduction I.

ypertensive disorders are among the most common medical disorders during pregnancy and continue to be a serious challenge in obstetric practice. About 10% of pregnancies are complicated by hypertensive diseases [1]. They are one of the deadly triad along with haemorrhage and infection [2].

These disorders comprise of spectrum of diseases that include pre-existing hypertension (i.e., hypertension, Hypertension), gestational preeclampsia, chronic hypertension with superimposed preeclampsia, eclampsia, and HELLP syndrome. Among these, preeclampsia syndrome either alone or superimposed on chronic hypertension, is the most dangerous.

WHO reported the incidence of preeclampsia to be in the range of 2-15% in India, and India has an average of 4.5% [3]. Eastern and north eastern states of India were reported to have highest incidence of preeclampsia [4].

Criteria for hypertension- During pregnancy, hypertension is defined as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure≥ 90 mmHg. Severe hypertension is defined as systolic blood pressure ≥ 160 mmHg and / or diastolic blood pressure ≥ 110 mmHg.

Preeclampsia refers to the new onset of hypertension and proteinuria or the new onset of hypertension and significant end-organ dysfunction with or without proteinuria after 20 weeks of gestation or postpartum in a previously normotensive woman [5, 6, 7, 8].

The diagnosis of preeclampsia with severe features is made when the women with preeclampsia who have severe hypertension and/or specific signs or symptoms of significant end organ dysfunction. The specific criteria are following [9].

- Severe BP elevation- Systolic BP ≥ 160 mmHg and Diastolic BP≥ 110 mmHg on two occasions at least 4 hours apart.
- Symptom of CNS dysfunction-1. New onset cerebral or visual disturbances such as Photophobia. scotomata. cortical blindness and retinal vasospasm 2.severe headache.
- Hepatic abnormality- Impaired liver functions characterised by serum transaminase concentration more than two times the upper limit of normal range or severe persistent right upper quadrant or epigastric pain unresponsive to medications.
- Thrombocytopenia $< 100000 \text{ platelets/}\mu\text{L}$.
- Renal abnormality- Serum creatinine > 1.1 mg/dL or a doubling of serum creatinine concentration in the absence of other renal disease.
- 6. Pulmonary edema.

7. Uteroplacental dysfunction- fetal growth restriction changes in doppler velocimetry studies of the umbilical artery especially if combined with uterine arteries.

The study was undertaken to study the management of preeclampsia, fetal and maternal outcome in preeclampsia and to correlate outcome to various responsible factors so as to include clinical knowledge of preeclampsia among the various group of patients and draw out a policy for management to improve maternal and fetal morbidity & mortality.

- a) Aims and Objectives of the Study
- To Study various risk factors responsible for increased fetomaternal morbidity and mortality.
- To study the maternal outcome in terms of severity, complications of preeclampsia and maternal mortality.
- To study the fetal outcome in terms of morbidity and perinatal mortality.

Materials and Methods П.

Study Design and study population

This was a hospital based cross-sectional observational study, conducted between January 2019 and June 2020. 100 cases of non severe preeclampsia and 100 cases of severe preeclampsia admitted in Department of Obstetrics & Gynaecology in our institute. The study was approved by institutional ethical committee memo no 62, IEC RIMS, Ranchi.

- b) Inclusion Criteria
- All cases of severe preeclampsia.
- All cases of non severe preeclampsia.
- All cases of preeclampsia with complications related to preeclampsia.
- c) Exclusion Criteria
- Patients with BP ≤140/90mmHg.
- Patients who presented with convulsions.
- Cases of Preeclampsia with medical complications which affect fetomaternal outcome. e.g.: Heart disease, Chronic hypertension, Diabetes, Haemoglobinopathies, connective tissue disorders, primary renal disorder.
- Cases with obstetric complications not related to Preeclampsia e.g.: Placenta previa, Polyhydramnios.
- Cases with Multifetal gestation.

Ethical consideration

The study was approved by the institutional ethics committee before commencing the study.

e) Data collection procedure

Data on socio-demographic variables and obstetric characteristics were collected by using predesigned and pretested structured questionnaire. After admission in the antenatal ward, the patients were monitored for blood pressure, any imminent symptoms, proteinuria, fetal heart rate tracings. Details of labour, spontaneous or induced, and mode of delivery were recorded. Maternal complications were Newborn's birth weight and condition at birth were recorded. All newborns were followed up to 7 days of their birth to determine the perinatal outcome. At the end of the study, the data was compiled and analyzed.

Data analysis

Data were entered and analysed by using SPSS version 20. Significance of statistical association were tested at P-value < 0.05.

III. RESULTS

Socio Demographic Factors

It was observed that preeclampsia was most common in the age group of 21 to 30 years, women living in rural area, low socioeconomic class and in women with unbooked antenatal history. There was significant association of preeclampsia with above socio-demographic variables (Table No: 1).

Maximum number of patients in the study were Primigravida (52.5%). 43.5% cases belonged to second, third and fourth gravida. 4% of cases in the study were grand multigravida (Gravida ≥5).

Among the 200 patients with pre-eclampsia 8 % patients presented in gestational age of 28 to ≤34 weeks, 13.5% were in the group of >34 to ≤ 37 weeks, 78.5% were in >37 weeks.

Maximum number of patients were in gestational age >37 weeks.

b) Anemia

Most of the preeclampsia patients had anemia. Presence of anemia was statistically significant with the severity of preeclampsia. (Table No:2) 159 patients (79.5%) were anemic according to WHO definition of anemia (<11 gm%).

c) Antihypertensive drugs

All the patients of severe pre-eclampsia (100%) needed Antihypertensive drugs and 50% of non severe pre-eclampsia needed Antihypertensive drugs.

d) Ini. MaSO4

Inj. MgSO4 was used in 79% of severe preeclampsia for eclampsia prophylaxis in those cases where BP couldn't be controlled with antihypertensive drugs. Out of 79 patients who received Inj.MgSO4, only one patient developed convulsions and 21 patients didn't receive any eclampsia prophylaxis, of these 3 patients developed convulsions.

e) Mode of delivery

50% patients had vaginal delivery, 50% had Caesarean section (Table No: 3).

Maternal outcome

Out of 200 cases of preeclampsia 134 patients (67%) had uneventful maternal outcome and in 66 patients (33%) the maternal outcome was eventful.

Although there was no statistical association between maternal outcome and severity preeclampsia, the grave complications were more common in severe preeclampsia cases than in non severe preeclampsia cases.

The most common complication in the cases of preeclampsia was Post Partum Haemorrhage, which was observed in 15 cases (7.5%), the next common complication was Abruption, which occurred in 10 cases (5%).

HELLP Syndrome occurred in 7 cases of severe preeclampsia, Eclampsia in 4 cases, Pulmonary edema in 3 cases, Renal failure in 3 cases, Sepsis in 6 patients, Cerebrovascular Accident in 1 case and 11 patients needed ICU care.(Table No:4). Maternal mortality occurred in 2 cases (1%).

g) Fetal Outcome

Of the 200 babies 73.5% (81 from non severe and 66 from severe pre-eclampsia) were full term alive babies, preterm were 20.5% (41 babies), 4% (8 babies) IUD and 2% (4 babies) stillbirth. Early neonatal death occurred in 4.5% babies (9), 26% (52) babies were low birth weight, 18.5% were Growth restricted, 5.5% babies had Neonatal jaundice and 18.5% babies were admitted in Neonatal Intensive Care Unit. (Table No: 5)

IV. Discussion

In our study majority of patients (68%) belonged to the age group of 21 to 30 years. Similar result was obtained by Kari Annapurna et al [22], Singh et al [23], Neha Kumari et al [16] and Dr. J B Sharma et al [24]. This is because most of the patients in our country get pregnant at this age group only.

There was preponderance of primigravida in preeclampsia cases (52.5%) i.e., 56% in non severe cases and 52.5% in severe cases. This was comparable with the results observed by various authors by Rakesh Gadsa et al [24] (66.6%), Parveen M. Aabidha et al [18] (61.2%) and Kishwara et al [14] (63.3%). In most of the literature on preeclampsia, this has been reported that preeclampsia is common among the primigravida [10, 11]. The maximum number of patients (78.5%) were in the gestational age≥37 weeks, which is almost similar to study by Dr Ashok Kumar Kumawat et al (72%) [23].

In our study anemia was present in 79.5% patients. In another study 55.9% were anaemic [41]. Awol Yamane Legesse et al [30] (2019) reported only 19.6% anemia. This is because the prevalence of anemia in Jharkhand is 78.45% among pregnant women [31] and anemia itself is a risk factor for developing preeclampsia.

In our study 73.5% patients had spontaneous labour, only 22% had induced labour which is similar to the study by Al Mulhim A.-A et al [12] (22.8%) and elective caesarean section was done in 4.5%.

In our study 50% (100 patients) delivered vaginally and 50% (100 patients) underwent Caesarean section. Similar to Aabidha et al [18] study in which 48.3% patients delivered by Caesarean section. Kari Annapurna et al [22] observed 57.6% Caesarean section. In another study 43% delivered by Caesarean section [26]. It is more when compared with other studies by Singh et al (21.4%) [19] and Rathore R, Butt NF et al [27] (15%).

It is also observed that there was no significant statistical association between the number of Caesarean sections and severity of preeclampsia. This is similar to the study by Juhi Patel et al [17]. The incidence of caesarean section was higher in our study because, in our institute most of the cases were referred complicated and previous caesarean section cases.

Prematurity was the most common complication associated with pre-eclampsia, which was seen in 20.5% cases. Similar results have also been observed by Aabidha et al [22] (23.65%). This is less when compared to the studies by Shaila Khan et al [13] (2013) and Muhammad Ashfaq et al. [21] (2018). In both studies prematurity was present in 52% cases. Prematurity as a complication of preeclampsia is either due to spontaneous preterm onset of labour or due to preterm induction of labour [14].

In the present study 16% babies had birth asphyxia. This is close to the study by Singh et al [23] (21.4). Aslam et al. [29] at Karachi (2014). Incidence of MSL and Fetal Distress were high in these cases.

In the present study 18.5% babies born to preeclampsia cases were growth restricted. This observation is similar to the study by Juhi Patel et al [17] (2015), in which 21% had IUGR babies. While Shaila Khan et al [13] and Vajira HW Dissanayake et al [32] observed 50% and 48% respectively.

The perinatal mortality was observed in 10.5% cases, similar result was also observed by Singh et al [23] (12.5%). Rakesh P.Gadsa et al [20] and Parveen M. Aabidha et al [18] observed perinatal mortality 17.4% and 15% cases respectively. However lower perinatal mortality was observed by Al Mulhim A.-A et al [12] (3.36%). This variability could be due to differences in availability of medical facilities. Main causes of fetal mortality were birth asphyxia, prematurity and IUGR.

a) Maternal outcome

The most common complication in the present study was post partum haemorrhage, which was observed in 7.5% cases. This is similar to the study by Dr Ashok Kumar Kumawat et al [23] (7%) and Aabidha et al [18] (10.75%). Preeclampsia patients lack normal pregnancy hypervolemia, are much less tolerant of even normal blood loss than are normotensive pregnant women [2].

The next most common complication in our study was Abruption, which was present in 5% cases. Almost similar incidences (5.6%) were noted by Baha M Sibai et al. [28] and Rathore R, Butt et al at Lahore [27] (4%). Hypertension in pregnancy is a most important risk factor for Abruption (10-50%) [10].

HELLP syndrome is a form of severe preeclampsia and is the most serious haematologic complications of preeclampsia [28]. In the present study 7% cases of severe preeclampsia developed HELLP Syndrome. It is comparable to the study by Vithal Kuchake et al [25] and Baba M Sibai et al [28] where HELLP syndrome developed in 8% and 8.6% patients respectively.

In our study, 2% cases developed convulsions. It is comparable to the study by Ashok Kumar kumawat et al (3%) [23] This is less when compared with studies by Juhi Patel et al [17] (36%), Rathore R, Butt et al [27] (26%), Vithal Kuchake et al [25] (10%) and Allilaj Minire et al [15] (3.25%). Less number of preeclampsia cases was attributed to the proper selection of cases for eclampsia prophylaxis and timely administration of MgSO₄.

V. Conclusion

This study highlights various risk factors for preeclampsia. Unbooked, young primigravida in advanced period of gestation are at greater risk for preeclampsia related morbidity and mortality.

Preeclampsia tends to threaten maternal health and fetal viability adding to maternal and neonatal morbidity & mortality. There is a high frequency of preeclampsia in our setting and consequences of preeclampsia for neonatal morbidity and mortality are alarmingly high. Treating and improving socioeconomic status will improve maternal and neonatal outcome in preeclampsia. Antenatal care and educating women on significance of symptoms will markedly improve perinatal morbidity and mortality.

Prematurity, growth restriction and Low birth weight are neonatal complications to be anticipated and dealt with, when the mother has preeclampsia. A good Neonatal Intensive Care Unit (NICU) will help to improve neonatal outcome. Prompt treatment and management of its complications will certainly improve maternal and fetal complications.

Reversing the present trend in maternal health seeking behaviour is therefore an issue that needs to be effectively addressed if significant improvement in maternal health is to be achieved.

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Table 1: Socio-Demographic Factors in cases of Preeclampsia (N=200)

S.No.	Variables		Frequency		
1.	Age in years	Non-severe preeclampsia	Severe preeclampsia	Total	Р
	<20	24	20	44 (22%)	P=>0.05
	21-30	65	71	136 (68%)	
	>30	11	9	21 (10.5%)	
2.	Residence				P=>0.05
	Rural	67	76	143 (71.5%)	
	Urban	33	24	57 (28.5%)	
3.	Socioeconomic status				P=>0.05
	Upper	0	0	0	
	Upper middle	3	2	5 (2.5%)	
	Lower middle	14	8	22 (11)	
	Upper lower	22	32	54 (27%)	
	Lower	61	58	119 (59.5%)	
4.	Booking History				P=>0.05
	Booked	38	22	60 (30%)	
	Unbooked	62	78	140 (70%)	
5.	Gravidity			Ì	P=>0.05
	1	56	49	105 (52.5%)	
	2,3,4	41	46	87 (43.5%)	1
	≥5	3	5	8 (4%)	

Table 2: Distribution of Anemia in Preeclampsia cases (N=200)

S.No.	Anemia (Hb<11 gm%)	Non-Severe preeclampsia	Severe preeclampsia	Total	
1	Not Anemic	33	18	51(25.5%)	
2	Anemic	67	82	149(74.5%)	
Chi square X ² =4.10					
P value=0.038					

Table 3: Observation of Mode of Delivery in Pre-Eclampsia Cases (N=200)

S.No.	Mode of delivery	Non Severe preeclampsia	Severe preeclampsia	Total	
1	Vaginal delivery	54	46	100(50%)	
2	Caesarean section	46	54	100(50%)	
Chi square X ² =1.28					
P value=0.254 P= >0.05					

Table 4: Observation of Maternal Complications in Preeclampsia cases (N=200)

S.No.	Maternal complications	Non Severe Preeclampsia (N/%)	Severe Preeclampsia (N/%)	Total
1	PPH	12	3	15 (7.5%)
2	Abruption	2	8	10 (5%)
3	HELLP syndrome	0	7	7 (3.5%)
4	Sepsis/Infection	3	3	6 (3%)
5	Pulmonary edema	0	3	3(1.5%)
6	Acute Renal Failure	0	3	3 (1.5%)
7	Eclampsia	0	4	4 (2%)
8	CVA	0	1	1(0.5%)
9	ICU Admission	0	11	11(5.5%)
10	Death	0	2	2(0.5%)

CVA- Cerebro Vascular Accident; ICU-Intensive Care Unit;

PPH- Post Partum Haemorrhage

Table 5: Observation of Fetal Outcome in Preeclampsia cases (N=200)

S.No.	Fetal Outcome	Non Severe Preeclampsia (N/%)	Severe Preeclampsia (N/%)	Total
1	Full term alive baby	66	81	147 (73.5%)
2	Preterm alive baby	26	15	41(20.5%)
3	Intrauterine death	5	3	8(4%)
4	Stillbirth	3	1	4(2%)
5	Birth Asphyxia	15	17	32(16%)
6	Early neonatal death	7	2	9(4.5%)
7	Low birth weight babies	33	19	52(26%)
8	Newborn jaundice	7	4	11(5.5%)
9	IUGR	22	15	37(18.5%)
10	NICU Admission	23	14	37(18.5%)

IUGR- Intra Uterine Growth Restriction; NICU- Newborn Intensive Care Unit

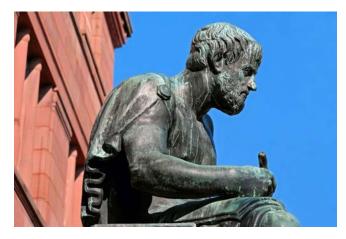
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- **16. Multitasking in research is not good:** Doing several things at the same time is a bad habit in the case of research activity. Research is an area where everything has a particular time slot. Divide your research work into parts, and do a particular part in a particular time slot.
- 17. Never copy others' work: Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.
- 18. Go to seminars: Attend seminars if the topic is relevant to your research area. Utilize all your resources.
- 19. Refresh your mind after intervals: Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.



- **20.** Think technically: Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.
- 21. Adding unnecessary information: Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.
- **22. Report concluded results:** Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.
- **23. Upon conclusion:** Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium though which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

INFORMAL GUIDELINES OF RESEARCH PAPER WRITING

Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

The introduction: This will be compiled from reference matter and reflect the design processes or outline of basis that directed you to make a study. As you carry out the process of study, the method and process section will be constructed like that. The results segment will show related statistics in nearly sequential order and direct reviewers to similar intellectual paths throughout the data that you gathered to carry out your study.

The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

Writing a research paper is not an easy job, no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record-keeping are the only means to make straightforward progression.

General style:

Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

To make a paper clear: Adhere to recommended page limits.



Mistakes to avoid:

- Insertion of a title at the foot of a page with subsequent text on the next page.
- Separating a table, chart, or figure—confine each to a single page.
- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

Title page:

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

Abstract: This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

Reason for writing the article—theory, overall issue, purpose.

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

Approach:

- Single section and succinct.
- An outline of the job done is always written in past tense.
- o Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

Introduction:

The introduction should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.



The following approach can create a valuable beginning:

- o Explain the value (significance) of the study.
- o Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
- Briefly explain the study's tentative purpose and how it meets the declared objectives.

Approach:

Use past tense except for when referring to recognized facts. After all, the manuscript will be submitted after the entire job is done. Sort out your thoughts; manufacture one key point for every section. If you make the four points listed above, you will need at least four paragraphs. Present surrounding information only when it is necessary to support a situation. The reviewer does not desire to read everything you know about a topic. Shape the theory specifically—do not take a broad view.

As always, give awareness to spelling, simplicity, and correctness of sentences and phrases.

Procedures (methods and materials):

This part is supposed to be the easiest to carve if you have good skills. A soundly written procedures segment allows a capable scientist to replicate your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order, but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt to give the least amount of information that would permit another capable scientist to replicate your outcome, but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section.

When a technique is used that has been well-described in another section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show all particular resources and broad procedures so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step-by-step report of the whole thing you did, nor is a methods section a set of orders.

Materials:

Materials may be reported in part of a section or else they may be recognized along with your measures.

Methods:

- Report the method and not the particulars of each process that engaged the same methodology.
- Describe the method entirely.
- o To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- Simplify—detail how procedures were completed, not how they were performed on a particular day.
- o If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

Approach:

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

What to keep away from:

- o Resources and methods are not a set of information.
- o Skip all descriptive information and surroundings—save it for the argument.
- o Leave out information that is immaterial to a third party.



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Results:

The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

Content:

- Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- o In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- o Present a background, such as by describing the question that was addressed by creation of an exacting study.
- Explain results of control experiments and give remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or manuscript.

What to stay away from:

- Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- Do not include raw data or intermediate calculations in a research manuscript.
- o Do not present similar data more than once.
- o A manuscript should complement any figures or tables, not duplicate information.
- Never confuse figures with tables—there is a difference.

Approach:

As always, use past tense when you submit your results, and put the whole thing in a reasonable order.

Put figures and tables, appropriately numbered, in order at the end of the report.

If you desire, you may place your figures and tables properly within the text of your results section.

Figures and tables:

If you put figures and tables at the end of some details, make certain that they are visibly distinguished from any attached appendix materials, such as raw facts. Whatever the position, each table must be titled, numbered one after the other, and include a heading. All figures and tables must be divided from the text.

Discussion:

The discussion is expected to be the trickiest segment to write. A lot of papers submitted to the journal are discarded based on problems with the discussion. There is no rule for how long an argument should be.

Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implications of the study. The purpose here is to offer an understanding of your results and support all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of results should be fully described.

Infer your data in the conversation in suitable depth. This means that when you clarify an observable fact, you must explain mechanisms that may account for the observation. If your results vary from your prospect, make clear why that may have happened. If your results agree, then explain the theory that the proof supported. It is never suitable to just state that the data approved the prospect, and let it drop at that. Make a decision as to whether each premise is supported or discarded or if you cannot make a conclusion with assurance. Do not just dismiss a study or part of a study as "uncertain."



Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work.

- o You may propose future guidelines, such as how an experiment might be personalized to accomplish a new idea.
- o Give details of all of your remarks as much as possible, focusing on mechanisms.
- o Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
- One piece of research will not counter an overall question, so maintain the large picture in mind. Where do you go next? The best studies unlock new avenues of study. What questions remain?
- o Recommendations for detailed papers will offer supplementary suggestions.

Approach:

When you refer to information, differentiate data generated by your own studies from other available information. Present work done by specific persons (including you) in past tense.

Describe generally acknowledged facts and main beliefs in present tense.

THE ADMINISTRATION RULES

Administration Rules to Be Strictly Followed before Submitting Your Research Paper to Global Journals Inc.

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Written material: You may discuss this with your guides and key sources. Do not copy anyone else's paper, even if this is only imitation, otherwise it will be rejected on the grounds of plagiarism, which is illegal. Various methods to avoid plagiarism are strictly applied by us to every paper, and, if found guilty, you may be blacklisted, which could affect your career adversely. To guard yourself and others from possible illegal use, please do not permit anyone to use or even read your paper and file.



CRITERION FOR GRADING A RESEARCH PAPER (COMPILATION) BY GLOBAL JOURNALS

Please note that following table is only a Grading of "Paper Compilation" and not on "Performed/Stated Research" whose grading solely depends on Individual Assigned Peer Reviewer and Editorial Board Member. These can be available only on request and after decision of Paper. This report will be the property of Global Journals.

Topics	Grades		
	A-B	C-D	E-F
Abstract	Clear and concise with appropriate content, Correct format. 200 words or below	Unclear summary and no specific data, Incorrect form Above 200 words	No specific data with ambiguous information Above 250 words
Introduction	Containing all background details with clear goal and appropriate details, flow specification, no grammar and spelling mistake, well organized sentence and paragraph, reference cited	Unclear and confusing data, appropriate format, grammar and spelling errors with unorganized matter	Out of place depth and content, hazy format
Methods and Procedures	Clear and to the point with well arranged paragraph, precision and accuracy of facts and figures, well organized subheads	Difficult to comprehend with embarrassed text, too much explanation but completed	Incorrect and unorganized structure with hazy meaning
Result	Well organized, Clear and specific, Correct units with precision, correct data, well structuring of paragraph, no grammar and spelling mistake	Complete and embarrassed text, difficult to comprehend	Irregular format with wrong facts and figures
Discussion	Well organized, meaningful specification, sound conclusion, logical and concise explanation, highly structured paragraph reference cited	Wordy, unclear conclusion, spurious	Conclusion is not cited, unorganized, difficult to comprehend
References	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring



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