DIASTOLIC DYSFUNCTION IN PRE-ECLAMPTIC AND ECLAMPTIC WOMEN Vs NORMOTENSIVE PREGNANT WOMEN:A CASE CONTROL STUDY

By

REG.NO.BJ0114003

Dissertation

Submitted to the

KLE University, Belgaum, Karnataka

In partial fulfillment

of the requirements for the degree of

MASTER OF SURGERY
in
OBSTETRICS AND GYNAECOLOGY

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY,

JAWAHARLAL NEHRU MEDICAL COLLEGE,

BELGAUM, KARNATAKA

APRIL 2017

KLE UNIVERSITY, BELGAUM, KARNATAKA

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LIST OF ABBREVIATIONS USED

DDF-Diastolic dysfunction

HDP-Hypertensive disorders of pregnancy

PE-Pre-eclampsia

LV-Left ventricle

EF-Ejection fraction

E'-pulsed wave tissue doppler peak early diastolic velocity at the left side of mitral valve annulus

E-Peak early diastole transmitral wave velocity

A-Peak late diastole transmitral wave velocity

E/A-Early to late diastole peak transmitral velocity ratio

DT-Deceleration time of E wave

IVRT-Isovolumetric relaxation time

Adur-Mitral A wave duration

ARdur-AR duration

E-VTI -E wave time velocity integrals

A-VTI-A wave time velocity integrals

BMI-Body mass index

PR-Pulse rate

SBP-Systolic blood pressure

DBP-Diastolic blood pressure

MgSO4-Magnesium sulphate

PV_a-VTI-Pulmonary venous velocity time integral at the time of atrial contraction

dPVa -Duration of pulmonary venous flow at atrial contraction

dPVa-dA -Difference in duration btw pulmonary venous flow at atrial contraction and A wave

PVs% -Systolic fraction of pulmonary venous flow

ABSTRACT

Diastolic dysfunction in pre-eclamptic and eclamptic women Vs normotensive pregnant women:A case control study

Background: Pregnancy is associated with enormous changes in various organs, cardiovascular system being no exception to this. In normotensive pregnancy there is certain degree of diastolic dysfunction which is further modified in pre-eclampsia. There is also increased incidence of cardiopulmonary complication in pre-eclampsia and eclampsia. However very few studies were done on the prevalence of diastolic dysfunction in pre-eclampsia and no study was done to find out the same in eclampsia.

Objective:

- Primary objective:

  To find out the prevalence of the diastolic dysfunction among pre-eclamptic,eclamptic women and normotensive pregnant women by Doppler echocardiography

- Secondary objective:

  To find out correlation between diastolic dysfunction and cardiopulmonary complications

Methodology: Case-control study was done in department of Obstetrics and Gynaecology, at teaching hospital attached to KLE University's, J. N. medical college, Belagavi. Total sample size of 140 eligible women of which 70 cases were matched for gestational age (confirmed by 1^{st} or 2^{nd} trimester scan) with 70 controls. All the subjects underwent Doppler echocardiographic evaluation by a cardiology

resident experienced for 2yrs.All echocardiographies were done antepartum except in 20 eclamptics were it was done postpartum.

Results: As per the CONSORT flow diagram, 139 subjects were approached to participate in the study of which 91 were eligible.Of these 91 subjects, 70 consented. These 70subjects were matched with controls of same gestation age confirmed by 1st or 2nd trimester scan. Echo-cardiographic variables were collected from these 140 subjects.

From this study it was observed that there is a statistically significant increase in the prevalance of diastolic dysfunction in pre-eclamptics and eclamptics compared to normotensive pregnant women(p value=0.029).It was also observed increase in cardiopulmonary complications like pulmonary edema inpre-eclamptics and eclamptics(5 out of 70 cases) compared to normotensive pregnant women. All those who developed pulmonary edema had diastolic dysfunction.

Conclusion: From this study it was evident thatthere is an increase incidence of diastolic dysfunction in pre-eclampsia and eclampsia. This necessitates close and careful monitoring during the management of such cases especially with reference to cardiopulmonary complications.

Keywords: Diastolic dysfunction,Pre-eclampsia,Eclampsia

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INTRODUCTION

Pregnancy is associated with enormous changes in various organs, cardiovascular system being no exception to this. These changes are further modified by pathological states like hypertensive disorders of pregnancy. Though hypertensive disorders of pregnancy are one of the leading causes of maternal death, understanding of the haemodynamics and physiological changes in these disorders still remains a subject that needs to be elucidated, thus posing a challenge to the treating obstetrician.

Hypertensive disorders of pregnancy includes spectrum of disorders like gestational hypertension, pre-eclampsia, eclampsia and chronic hypertension with or without superimposed pre-eclampsia. Pre-eclampsia and eclampsia affects 5-10% of all the pregnancies and contributes to 18% of maternal deaths worldwide. Estimated case fatality rate due to eclampsia is 14 times higher in developing countries compared to developed countries.[1,2.]Thus hypertensive disorders of pregnancy contribute to significant maternal and perinatal morbidity and mortality in both developed and developing countries.

Preeclampsia is a multi-system disorder whose pathophysiology remains unclear. Preeclampsia is defined as a blood pressure of at least 140 mmHg systolic pressure and 90 mmHg diastolic pressure measured on two occasions 6 hours apart, accompanied by proteinuria of at least 300 mg per 24 hours, or at least 1+ on dipstick testing after 20 weeks.[3] It is a hypertensive disease specific to human pregnancy with a high risk of maternal and fetal morbidity and mortality. It is known to be associated with long-term cardiovascular risks to both the pregnant women and her child in the

later life.[4, 5] It is a precursor of a potentially serious eclampsia which is associated with increased maternal and perinatal morbidity and mortality.

Eclampsia refers to the onset of convulsions/coma in a woman with preeclampsia that cannot be attributed to other causes. The seizures are generalized tonic clonic seizures and may appear antepartum, intrapartum or postpartum. It's a serious manifestation that is associated with increased risk of mortality and morbidity in the pregnant women and poor perinatal outcomes.

In normotensive pregnant women there is certain degree of diastolic dysfunction as evidenced by Doppler echocardiographic parameters which is proven by various studies.[6] However there are very few studies that demonstrated a greater degree of diastolic dysfunction in pre-eclamptic women.[7,8] Certain studies also found an association between the diastolic dysfunction and the risk of having adverse cardiopulmonary event like congestive cardiac failure and pulmonary edema in the postpartum period.[7] Thus there is a limited data on the changes in left ventricular diastolic function in pre-eclamptics and no data regarding the same in eclamptic. This necessitates a study that addresses these questions .Therefore this study helps in assessing the diastolic function in pre-eclamptic and eclamptic women and finding an association if exists between the diastolic dysfunction and adverse cardiopulmonary complications.

AIMS AND OBJECTIVES

Primary objective:

To find out the prevalence of the diastolic dysfunction in pre-eclamptic, eclamptic women and in normotensive pregnant women by Doppler echocardiography

Secondary objective:

To find out correlation between diastolic dysfunction and cardiopulmonary complications

REVIEW OF LITERATURE

Preeclampsia is a hypertensive disorder of pregnancy whose pathophysiology remains unknown. It is a multi-system disorder causing multi organ failure which significantly contributed to maternal and fetal/neonatal morbidity and mortality.[3]It is often been labelled as "disease of theories "due to diverse school of thoughts that drives research into this complex disease.

What would be a millennium later pre-eclampsia and eclampsia was first described by Hippocrates around 400BC, who stated headache accompanied by heaviness and convulsions during pregnancy was considered bad. Since then until the later half of the 20th century, advancements to the understanding of pre eclampsia and eclampsia were limited. As recently as the late 1800s, the disease causation was shifted to theory of toxins. By the mid 1800s, the hallmark prodromal symptoms including headache, temporary loss of vision, severe abdominal pain, edema in the upper body, contributed to recognition that there was a pre eclamptic state that itself is a life threatening condition and the precursor of eclampsia. However, it was the introduction of Scipione Riva – Rocci's mercury manometer (1896) to measure blood pressure that led to the recognition that pre eclampsia was a hypertensive disorder.

Eclampsiawas first described by McMillen, where he noted that primigravida were at a greater risk for convulsions compared to multigravida.[9]Mauriceau described the cause of convulsions during pregnancy was due to lochial flow abnormality or intrauterine fetal death. When there is suppressed lochial flow it would cause inflammation, headache, convulsions, suffocation and death can occur. In a case wherein intrauterine fetal death had occurred a retained dead fetus caused foul-smell

and cadaverous humours in the womb which predisposed a woman to convulsions.[10]The word "eclampsia" first appeared in Varandaeus' treatise on gynaecology in 1619.[10]

Pregnancy is associated with enormous changes in various systems especially cardiovascular, renal, haematological, central nervous system.It is a chronic overload state that is associated with hemodynamic and hormonal changes that have an effect on cardiovascular system.[11] In cardiovascular system there are striking changes that assure adequate uterine blood flow, as well as appropriate oxygenation and nutrient delivery to the fetus. Further, these compensatory mechanisms allow the mother to function normally during altered physiological state of pregnancy.

Nearly 100 years ago, Lindhard reported on normal cardiovascular changes in pregnancy.[12]From the first trimester, there is an increase in cardiac output by 50% that places a volume overload on the heart. This increase in cardiac output is due to increase in heart rate and stroke volume. Hormonal changes include increased circulating estrogen and relaxin that cause decrease in peripheral vascular resistance. All these changes may directly or indirectly affect the heart.

Systolic and diastolic blood pressures decrease significantly as early as 5weeks of gestation. Decrements in diastolic levels exceed those in systolic levels, the former averaging 10mm Hg below the baseline value. Mean blood pressure nadirs at 16-20weeks, these changes persisting to the third trimester.[13] In mid-third trimester blood pressure gradually raises often approaching pre-pregnancy values.[14]

Cardiac output increases 35-50% during gestation, half or more of this increase established by 8 weeks of pregnancy and by 50% by 16-20wks, then increasing slowly or plateauing until term.[15,16] Stroke volume and heart rate, the two

determinants of cardiac output, appear to rise sequentially, with the increases apparent by 5-8 weeks gestation.[16,17]Stroke volume continues to increase until gestational week 16, plateauing thereafter, while heart rate continues to increase slowly into third trimester.[18,19]

Postural changes can impact heart rate, blood pressure, and cardiac output. Both heart rate and blood pressure are significantly lower in lateral recumbency, while cardiac output is increased in this position. There is a reduction in cardiac output upon standing, noted in first trimester, which becomes significantly attenuated in the second trimester and absent by the mid third trimester. Intravascular volume is progressively amplified up to 40 %, perhaps contributing to the aforementioned changes.

It appears that venous distensibility increases during pregnancy. However, there is limited information available regarding the changes in venous system in pregnancy.

The gestational increase in cardiac output and decrement in blood pressure have traditionally been ascribed to the marked decreased in total systemic vascular resistance that occurs in early gestation.[20,21] It should be recognised, however, that other changes may be involved. For example, both left ventricular and systemic arterial mechanical properties (ventricular after load) have a potential to alter systemic haemodynamics.

After load, or the arterial system load the heart experiences, is the mechanical opposition experienced by the blood ejected by the left ventricle. This opposition have two components, one steady, and the other pulsatile. The steady component is quantified in terms of total systemic vascular resistance. It is determined by the

properties of the small calibre resistance vessels and blood viscosity. Due to pulsatile nature of the cardiac ejection, oscillations in pressure and flow exist throughout the arterial tree and thus, the pulsatile component of the arterial load needs to be considered. Both steady and pulsatile arterial load decrease during normal pregnancy, indicating a state of peripheral vasodilatation and generalized vasorelaxation of both peripheral vessels and conduit vessels. The magnitude of the fall in systemic vascular resistance and the rise in cardiac output seem to be equivalent, which results in a very small change (fall) in mean arterial pressure.

Left ventricular mass increases in normal pregnancy ranging from 10-40%.[22,23] An increase in ventricular mass is contributed to the heart's ability to increase its total power as an adaptation to increase in plasma volume in first half of pregnancy and increase in after load in later gestation. This increase in left ventricular mass manifests as eccentric hypertrophy rather than concentric hypertrophy as seen in pathological conditions like hypertension. These changes in left ventricular mass begin in first trimester and peaks by 30-34weeks of gestation. However ventricular mass reverts to non pregnant values postpartum.

Left ventricular myocardial contractility as assessed by load independent indices is essentially unchanged in normal gestation. However some studies have shown a decrease in the contractility in third trimester secondary to decline in systolic function.

However in past decade, research has shown that abnormalities of diastolic function with preserved myocardial contractility in normal pregnancy.[6] Diastolic dysfunction in pregnancy is attributed as leading cause of congestive cardiac failure in pregnancy.[24]

From the mean pressure-flow perspective, the coupled left ventricle-arterial circulation system produces significantly higher cardiac output during normal gestation, with little change in mean blood pressure. This coupled equilibrium of mean pressure and flow is achieved by a significant peripheral vasodilatation(reduced systemic vascular resistance) and increases in heart rate, left ventricular preload(end-diastolic volume), and muscle mass, without any significant changes in left ventricular myocardial contractility.

Pulmonary capillary wedge pressure remains stable, reflecting a combination of decreased pulmonary vascular resistance and increased blood volume.

These changes in cardiovascular system are further modified in pre-eclamptic and eclamptic women. Normal pregnancy, as noted above, is accompanied by increased intravascular volume, high cardiac output and vasodilatation. With onset of pre-eclampsia there is a shift to a low output, high resistance state and intravascular volume is significantly lower than normotensive pregnant women. Cross-sectional studies of women with preeclampsia and eclampsia have revealed diverse hemodynamic findings such as reduced cardiac output, high vascular resistanceand reduced myocardial contractility. All these changes were due to increase in after load.

The increase in the arterial compliance seen in normal pregnancy is absent or significantly diminished in pre-eclampsia.[25]These changes in arterial compliance are secondary to endothelial dysfunction that persists postpartum.

Left ventricular structural changes in pre-eclamptics include left ventricular hypertrophy which is asymmetrical and involves predominantly basal anteroseptum.

Though adequate information is available regarding these changes in cardiovascular system, there is scant and conflicting information about the impact of preeclampsia and eclampsia on the function of the heart.[26-31] In left ventricular functional changes there might be isolated diastolic dysfunction with preserved systolic function and ejection fraction, some might also have systolic dysfunction

In pulmonary vasculature, endothelial damage leads to increase in capillary permeability leading to increased accumulation of fluid in interstitial space causing pulmonary edema.

Thus cardiopulmonary morbidity is seen in a significant proportion of preeclamptic and eclamptic women as demonstrated by autopsy data which showed that preeclamptic and eclamptic women have a 10-fold higher prevalence of myocardial contraction band necrosis than deaths in pregnancy from other causes.[8]They are also at risk of developing congestive cardiac failure and acute pulmonary edema.This is attributed to reduced functional capacity of heart.But even women with preserved ejection fraction developed pulmonary edema. This is attributed to subclinical diastolic dysfunction with preserved systolic function of heart.

Since many years understanding of the functional changes in heart that lead to these complications has been a field of extensive research. Invasive monitoring using Swan-Ganz catheter improved our knowledge of the hemodynamic changes in pathological states like pre-eclampsia and helped in planning effective therapeutic modalities in complications associated with pre-eclampsia like congestive cardiac failure and pulmonary edema.

Echocardiography has also been used traditionally for evaluation of these changes. In pre-eclamptics there were diverse hemodynamic changes like increased or normal cardiac output, increased or normal contractility, non dilated left ventricle, diastolic dysfunction and increased left ventricular mass on echocardiography. Echocardiography has been recommended as diagnostic and monitoring tool for acute hemodynamic complications of preeclampsia, such as pulmonary edema .Even in clinically asymptomatic patients, subtle echocardiographic changes in left ventricular (LV) function have been observed in preeclampsia.

Of the conventional echocardiographic indices, ejection fraction remained relatively preserved until later in the course of the disease process, making it less useful as a screening tool to follow patients over time.[31] For this reason Doppler echocardiography came into place that can identify functional abnormalities of heart including systolic and diastolic dysfunction even before changes in ejection fraction.

Till 1999 limited information was available regarding the changes in left ventricular diastolic function in pregnancy. Only within the past decade with advent of Doppler echocardiography have clinicians and researchers discovered that abnormalities of left ventricular diastolic function are important contributors to the cardiovascular complications in hypertensive disorders of pregnancy.

A studywas done on left ventricular diastolic function in normal pregnancy, where normotensive pregnant women were subjected to echocardiography at each trimester. They observed that diastolic function indices like peak mitral flow velocity in early diastole (E) increased 13.3% during the first trimester and remained at the high end of normal throughout pregnancy. Peak A-wave velocity (A) increased maximally in the third trimester. Pulmonary venous peak systolic forward flow

velocity increased, peaking in the second trimester, but returned to baseline levels postpartum. The pulmonary venous diastolic time-velocity integral decreased significantly from the first to the third trimester. Peak pulmonary venous reverse flow velocity at atrial contraction increased significantly, without being markedly changed in duration. This study has shown that chronic volume overload state like pregnancy is associated with alteration in hemodynamic and echocardiographic variables including the diastolic filling parameters.[6]

Study done on maternal diastolic dysfunction and left ventricular geometry in gestational hypertension concluded that left atrial and diastolic function evaluation with the analysisof DtE and IVRT might be useful in the evaluation of patientswith gestational hypertension with altered TVR.[7]In this study twenty-one consecutive pregnant women with gestational hypertension and 21 normotensive women matched for age and gestational age were enrolled in the third trimester of gestation. Echocardiographic and uterine colour Doppler evaluations were performed. Systolic, diastolic, and mean blood pressure, total vascular resistance (TVR), and uterine resistance index were higher in hypertensive women than in control subjects .Left atrial function and cardiac output were significantly lower in gestational hypertension. Patients with gestational hypertension had longer left ventricular isovolumetric relaxation time (IVRT), lower velocity-time integral of the A wave and of the diastolic pulmonary vein flow and higher velocity-time integral of the reverse pulmonary vein flow .Systolic fraction of the pulmonary vein flow was higher in women with gestational hypertension than in control subjects the difference in duration of pulmonary vein flow and A wave was closer to 0 in gestational hypertension. The results of this study showed that there are altered left ventricular geometric parameters in 100% of women with gestational hypertension. The altered

geometric pattern is associated in this study, with depressed systolic function, high total vascular resistance, altered diastolic function, and left atrial dysfunction.[7]

Another study was done on maternal cardiac dysfunction and remodelling in women with pre-eclampsia at term.[8]This study was designed to evaluate cardiac function and remodelling in preeclampsia occurring at term. This was a prospective case– control study of 50 term preeclampsia and 50 normal pregnancies assessed by echocardiography and tissue Doppler analysis. Global diastolic dysfunction was observed more frequently in preeclampsia versus control pregnancies (40% versus 14%, *P*_0.007).They observed that increased cardiac work and left ventricular mass indices that suggest left ventricular remodelling was an adaptive response to maintain myocardial contractility with preeclampsia at term. They also observed that approximately 20% of patients with preeclampsia at term had more evident myocardial damage. They concluded that diastolic dysfunction usually precedes systolic dysfunction in the evolution of ischemic or hypertensive cardiac diseases and is of prognostic value in the prediction of long-term cardiovascular morbidity This study has got significant clinical implications in peripartum intravascular volume management because they observed that women with global diastolic dysfunction are more likely to sustain acute cardiovascular morbidity from pulmonary edema.[8]

A study was conducted to assess maternal cardiovascular function in pre-eclamptic and normal pregnant women in third trimester of pregnancy.[32] 40 subjects, 20 with preeclampsia and 20 normotensive controls with 34 weeks gestation and singleton pregnancy were recruited. Systolic and diastolicparameters were assessed using echocardiography which showed significant systolic and diastolic dysfunction in pre-eclamptic women compared to normal pregnant women. This study concluded

that blood pressure monitoring alone is insufficient to identify effectively, risk of cardiovascular complications in these subjects.[32]

Study conducted on maternal diastolic dysfunction in women with pre-eclampsia where in one hundred and fifty nulliparous women of 20-35 years were recruited. Among these, 120 women with preeclampsia were taken as cases and 30 normotensive women were taken as controls. Doppler echocardiography was carried out between 28-36 weeks of gestation in both groups to assess and grade severity of diastolic dysfunction.This study concluded that cardiac diastolic dysfunction occurred in one-fifth of women with preeclampsia and grade of diastolic dysfunction correlated with the severity of preeclampsia.[33]

Though few studies were done on prevalence of diastolic dysfunction in hypertensive disorders of pregnancy, no study was done in South India. Therefore this study helps in assessing diastolic dysfunction in pre-eclamptics and eclamptics in this part of the country.

Methods

The present study was conducted in department of obstetrics and gynaecology at teaching hospital attached to KLE University`s J.N.Medical College, Belagavi.

Study design: A hospital based prospective case control study

Timeline of study:

PHASE	TIME PERIOD	OUTLINE
I	June 2014 to October 2014	1.Identification of problem 2.Review of Literature 3.Development of data collection instrument 4.Submission of Synopsis
II	September 2015 to April 2016	1.Enrolment 2.Data Collection
III	May 2016 to August 2016	1.Analysis of collection data 2.Discussion
IV	September & October 2016	1.Submission of dissertation

Source of data:

- Cases: All pregnant women with singleton pregnancy admitted in labour room with diagnosis of pre-eclampsia and eclampsia and willing to participate in study that is conducted in the department of obstetrics and gynaecology at teaching hospital attached to KLE University`s J.N.Medical College,Belagavi

- Controls: All normotensive pregnant women with singleton pregnancy without known medical disease matched for gestational age admitted in labour room, wards and OPD and willing to participate in the study conducted at teaching hospital attached to KLE University`s J. N. Medical College.

Selection criteria:

- Inclusion criteria:
  - Cases: All pre-eclamptic and eclamptic women.
  - Controls: All normotensive pregnant women with confirmed gestational age by 1^{st} or 2^{nd} trimester ultrasound.
- Exclusion criteria :
  - Women with known cardiac disease,
  - Haemoglobin ≤ 8gm%,
  - In active phase of labour(≥4cm dilatation of cervix),
  - not willing to participate in the study

Study period: Until sample size is met.

Sample size:

$$n = \frac{2(\text{alpha error} + \text{beta error})\, pq}{(p1-p2)^2}$$

n=sample size

p1=prevalence among exposed

p2=prevalence among unexposed

$$p = \frac{p1+p2}{2}$$

q = 100-p

$$n = \frac{2(1.96-0.84) \times 73}{(40-14)2}$$

= 45.7

Cases=50, Controls=50

Method of collection of data

Ethical clearance:

The ethical clearance was obtained from institutional Review Board of KLE University's teaching hospital attached to Jawaharlal Nehru Medical College, Belgaum. (MDC/DOME/17) dated on 30/11/2015 (Annexure I). This study is registered with Clinical trial registry of IndiaCTRI Number-Trial REF/2015/05/005788.

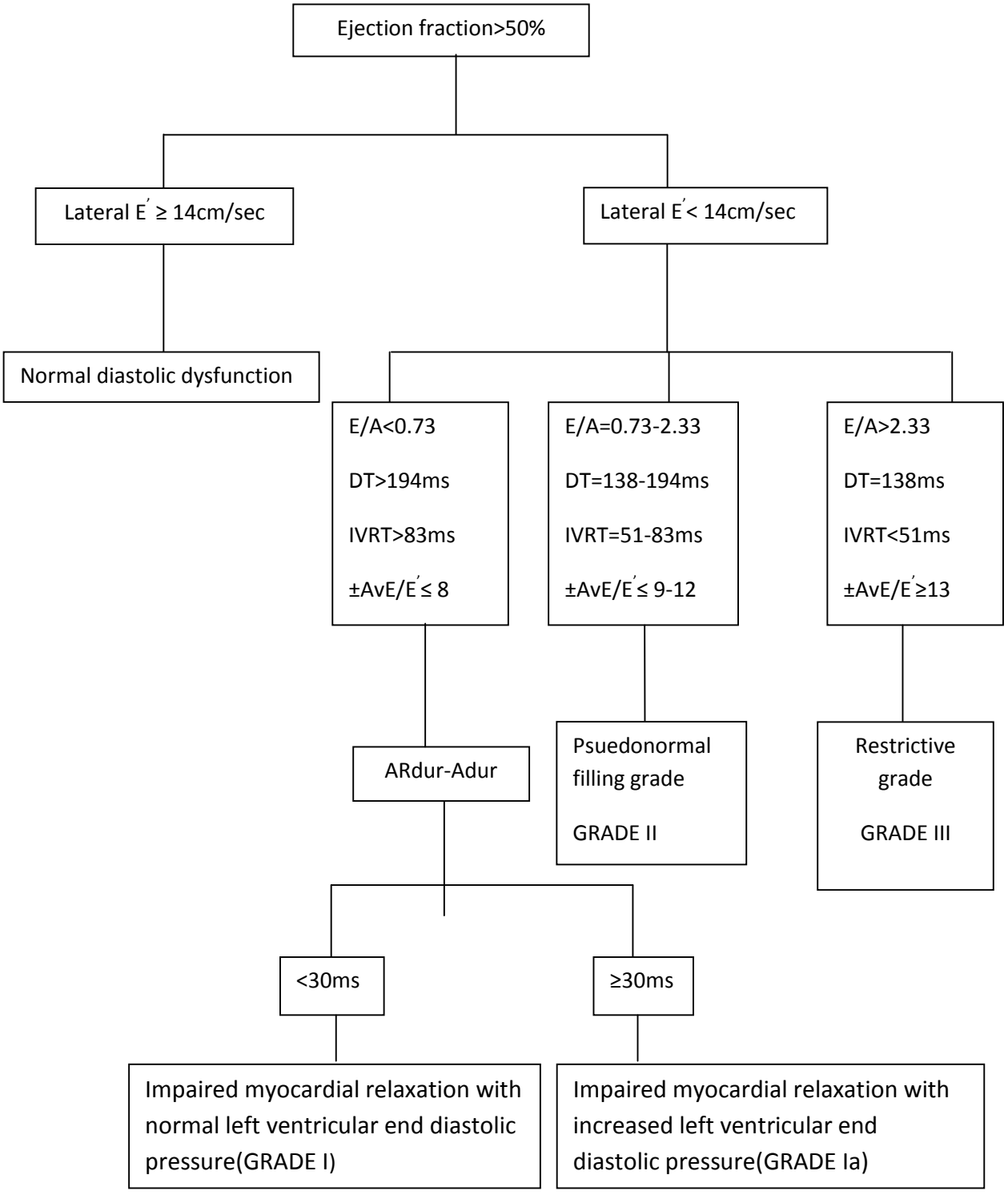
Screening and enrollment:

All the cases who were admitted to the labour room were screened for eligibility based on selection criteria.All the controls who were matched for gestational age that was confirmed by 1^{st} or 2^{nd} trimester scan were screened for eligibility based on selection criteria. Informed consent was obtained at the time of enrolment into the study from the eligible cases and controls. The informed consent form was provided by the investigator to the patient to be enrolled. The investigator obtained a signature or left hand thumb impression from the consented participant. Adequate time was provided for describing the study and fielding questions from the participant and immediate family members/witnesses. Fair balance was maintained while explaining the risks and benefits of participation in the study. No undue pressure was placed on the patient to enrol in the study.

It was further explained that lack of participation will not affect the usual and anticipated standard of care. The women were enrolled in the study only after taking

their signature or left hand thumb impression along with signature from the witness on informed consent form (Annexure II).

Diastolic dysfunction is assessed with the following algorithm:



EF indicates ejection fraction: Lateral $E^{'}$, pulsed wave tissue doppler peak early diastolic velocity at the left side of mitral valve annulus; E, peak early diastole transmitral wave velocity; A, peak late diastole transmitral wave velocity; E/A, early to late diastole peak transmitral velocity ratio; DT, deceleration time of E wave; IVRT,isovolumetric relaxation time; Adur, mitral A wave duration; Av $E/E^{'}$, E to average of lateral and septal $E^{'}$ velocities; AR, peak retrograde late diastolic pulmonary wave velocity; ARdur,AR duration.

Blood pressure was measured from the brachial artery using a manual cuff in supine position and recording is confirmed by re-checking blood pressure again after 10min.

Women with systolic blood pressure of ≥140mmHg or diastolic blood pressure of ≥ 90mmHg with proteinuria of ≥+1 or with signs of end organ damage are labelled as pre-eclamptics and those with superimposed generalized tonic clonic seizures are labelled as eclamptics.

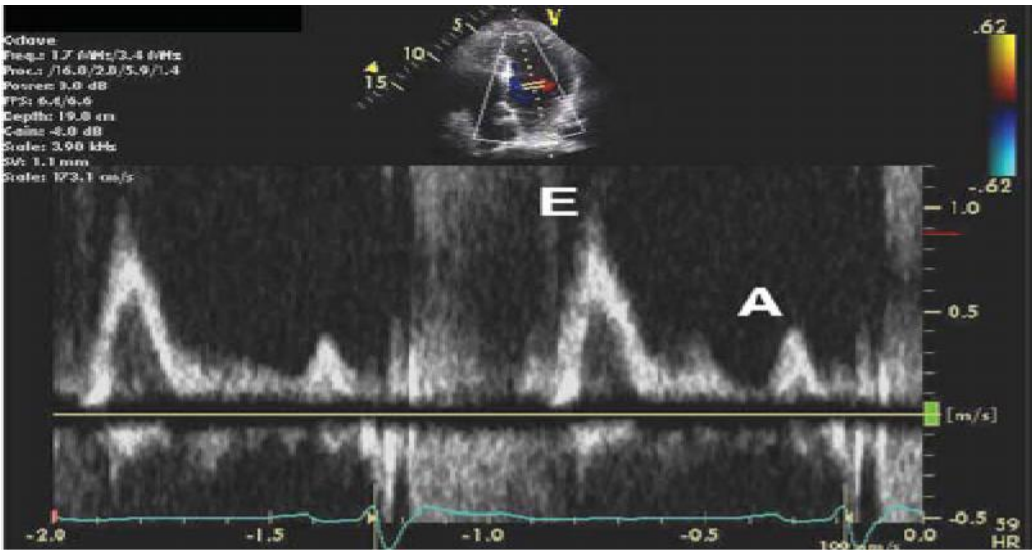
Gestational age matched normotensive pregnant women are taken as controls. Gestational age is confirmed by the first trimester scan. Pre-eclamptic cases and normotensive controls are accompanied by resident obstetrician to the cardiology OPD where doppler echocardiographic evaluation was done using Philips IE 33 echocardiographic machine with S4-2 probe. In eclamptics bedside doppler echocardiography was done using Philips CS120 with S3 probe. All data were recorded with patients in the left lateral position during end expiration apnea and recorded on videotape. All the echocardiographic values are recorded by a single person experienced for 2years to avoid interobserver variability

Doppler Indexes of Diastolic Function:

Assessment of diastolic function was obtained by pulsed-wave doppler of both transmitral and pulmonary venous flow patterns recorded in the apical 4-chamber view.Mitral flow velocities were detected by placing the sample volumebetween the tips of the mitral leaflets.

The following variables were measured:

- Peak flow velocity in early diastole (E wave) and during atrial contraction (A wave)
- Peak E/A ratio
- E- and A-wave time velocity integrals (E-VTI, A-VTI)
- Deceleration time of the E wave(DtE)
- Duration of the A wave (Adur).
- Left ventricular Isovolumetric relaxation time (IVRT) was also measured.



The normal transmitral flow has two peaks-an E wave and A wave

- E wave is the velocity across the mitral valve in early diastole.
- A wave is the velocity across the mitral valve during atrial systole.
- E/A ratio is the marker of the function of the left ventricle.
- Velocity time integral of a valve is the integral of all the velocities during the time of flow across a valve.
- DtE is the time taken from the maximum E point to baseline.
- IVRT defined as the interval between the aortic valve closure click and the start of mitral flow.

Pulmonary venous flow velocities were detected by placing a 3- to 5mm sample volume 1 to 2 cm at the right superior pulmonary vein.

The following variables were measured:

- Peak pulmonary venous flow velocity during ventricular systole (PVs) and its time-velocity integral (PVs-VTI)
- Peak pulmonary venous flow velocity during ventricular diastole (PVd) and its time-velocity integral (PVd-VTI);
- Peak pulmonary venous flow velocity at atrial contraction (PVa) and its time-velocity integral (PVa-VTI)

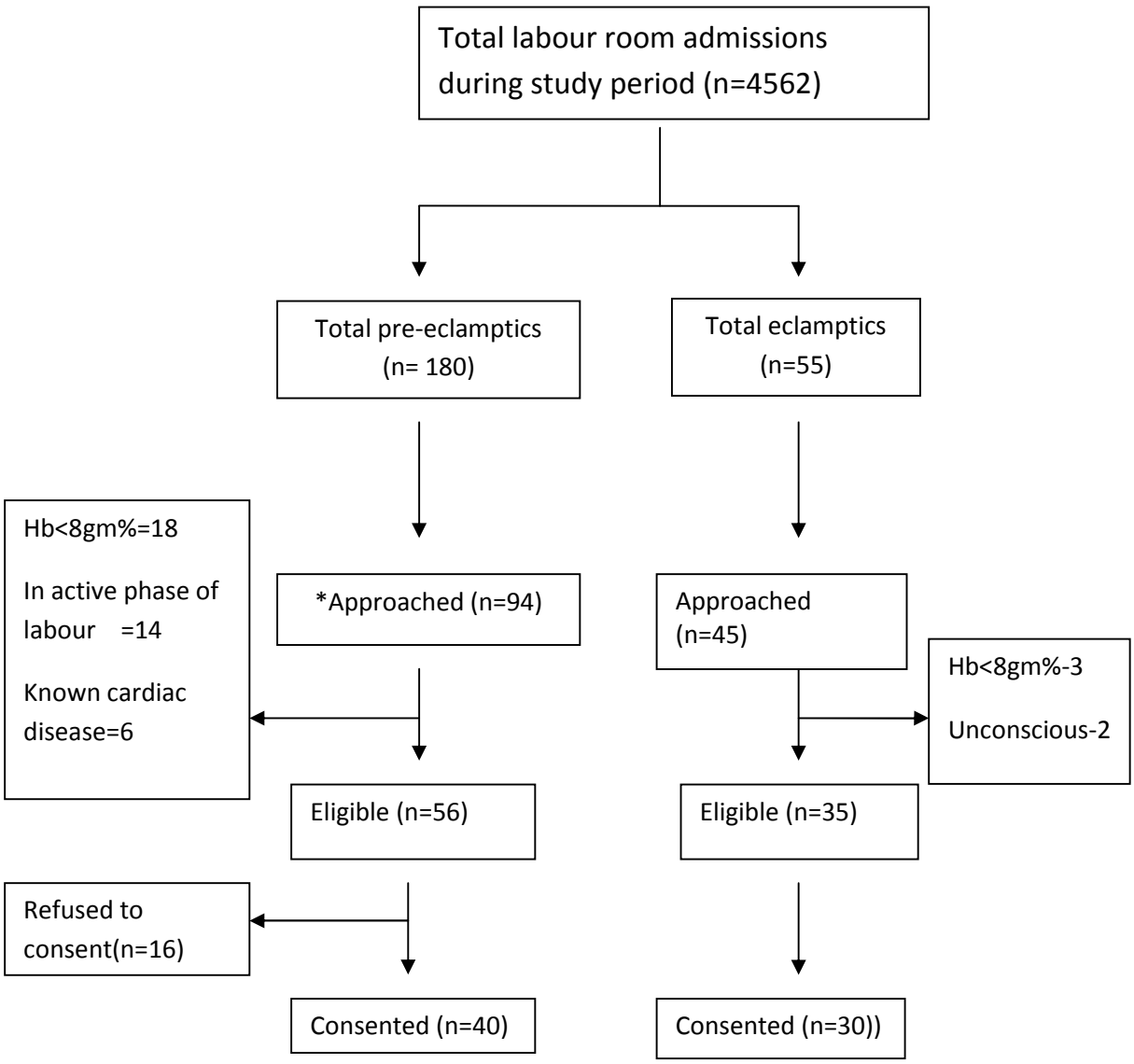
Data Analysis:

Demographic characteristics between the two groups were expressed as Mean±SD.Comparison between the normal and hypertensive women was done by two sample t test according to gestational age. Diastolic dysfunction is assessed by mean of proportions and Z test. Significance level of statistical test kept at 0.05 level of probability.

RESULTS

This case –control study was conducted in Department of Obstetrics and Gynaecology at teaching hospital attached to KLE University's J.N.Medical College. During the study period a total 235 subjects were admitted with diagnosis of pre-eclampsia and eclampsia. Of these 139 subjects were approached because of need for experienced personnel to shift subjects to cardiology OPD for echocardiography. Of these 70 were eligible and consented. These 70subjects were matched with controls of same gestation age confirmed by 1^{st} or 2^{nd}trimester ultrasound. Echo-cardiographic variables were collected from these 140 subjects

CONSORT diagram:



*Cases were approached personally by the investigator of the study.

Maternal characteristics:

Table 1

Parameter	Hypertensive(n=70)	Normal (n=70)	P value
Age	24.2	23.8	0.5074
BMI	26.2	25.8	0.2825
Gestational age	34w1d	33w3d	0.1418

The demographic characteristics are shown in the table. Both the groups are well matched.

Comparison of vitals

Table 2

Parameter	Hypertensive(n=70)	Normal (n=70)	P value
SBP	168.1	117.9	<0.0001
DBP	107.4	73.5	<0.0001
Pulse rate	90+5.4	82+4.9	0.002

The mean systolic blood pressure is 168mmHg in cases whereas it is 117.9 mmHg in controls. (P value < 0.0001).

The mean diastolic blood pressure is 107.4mmHg in cases whereas it is 73.5mmHg in controls. (P value < 0.0001).

The mean pulse rate in cases is 90bpm whereas it is 82bpm in controls.

Diastolic function parameters in cases Vs controls:

Table-3

Parameter	Cases (n=70)	Controls (n=70)	P value
E wave velocity time integral	13.2±3	14.5±2	NS
Deceleration time of E wave	196±20	210±18	NS
IVRT	94±10	72±5	<0.0001
A wave	62±12	63±8	NS
A wave velocity time integral	6.2±1	8.4±0.5	0.04
Duration of A wave	126±22	143±5	0.01
Peak E/Peak A ratio	1.24±0.22	1.31±0.4	NS
Peak pulmonary venous systolic flow	58±13	57±9	NS
Pulmonary venous systolic time velocity integral	15±3	13.2±2	NS
Peak pulmonary venous diastolic flow	49±10	52±9	NS
Pulmonary venous diastolic velocity time integral	11±3	12±3	0.03
Peak pulmonary venous flow at time of atrial contraction	25±4	22±5	NS

The diastolic function parameters which were clinically significant include IVRT, A wave velocity time integral, duration of A wave, pulmonary venous diastolic velocity time integral.

Diastolic function parameters in cases Vs controls:

Table-4

Parameter	Cases (n=70)	Controls (n=70)	P value
Pulmonary venous velocity time integral at the time of atrial contraction	3.4±0.8	1.7±0.5	0.04
Duration of pulmonary venous flow at atrial contraction	128±24	94±18	0.001
Difference in duration between pulmonary venous flow at atrial contraction and A wave	5±20	53±17	0.0001
Systolic fraction of pulmonary venous flow	63.4±3.3	53.9±5.3	0.001

The diastolic function parameters at pulmonary vein which were clinically significant include

- pulmonary venous velocity time integral at atrial contraction,
- duration of pulmonary venous flow at atrial contraction,
- difference in duration between pulmonary venous flow at atrial contraction and A wave,
- systolic fraction of pulmonary venous flow.

Diastolic function parameters in pre-eclamptic cases Vs controls:

Table-5

Parameter	Pre-eclamptic cases (n=40)	Controls (n=40)	P value
E wave velocity time integral	13±3	14±2	NS
Deceleration time of E wave	194±30	207±18	NS
IVRT	95±10	70±4	0.002
A wave	63±12	64±8	NS
A wave velocity time integral	6.3±1	8.2±0.5	0.03
Duration of A wave	124±23	142±6	0.001
Peak E/Peak A ratio	1.30±0.32	1.32±0.4	NS
Peak pulmonary venous systolic flow	57±12	56±10	NS
Pulmonary venous systolic time velocity integral	14±2	13±3	NS
Peak pulmonary venous diastolic flow	48±10	51±9	NS
Pulmonary venous diastolic velocity time integral	10±2	13±2	0.04
Peak pulmonary venous flow at time of atrial contraction	24±4	23±5	NS

The diastolic function parameters which were clinically significant include IVRT, A wave velocity time integral, duration of A wave, pulmonary venous diastolic velocity time integral.

Diastolic function parameters in pre-eclamptics cases Vs controls:

Table-6

Parameter	Pre-eclamptic cases (n=40)	Controls (n=40)	P value
Pulmonary venous velocity time integral at the time of atrial contraction	3.1±0.9	1.6±0.8	0.003
Duration of pulmonary venous flow at atrial contraction	124±26	96±17	0.01
Difference in duration between pulmonary venous flow at atrial contraction and A wave	3±14	52±17	0.002
Systolic fraction of pulmonary venous flow	62.3±2.7	53.8±7.3	0.003

The diastolic function parameters at pulmonary vein which were clinically significant include

- pulmonary venous velocity time integral at atrial contraction,
- duration of pulmonary venous flow at atrial contraction,
- difference in duration between pulmonary venous flow at atrial contraction and A wave,
- systolic fraction of pulmonary venous flow.

Diastolic function parameters between eclamptic cases Vs controls

Table-7

Parameter	Eclamptics (n=30)	Normal (n=30)	P value
E wave velocity time integral	12.8±3	14±3.2	NS
Deceleration time of E wave	197.8±30	204.2±18	NS
IVRT	97.3±10	77.8±4	0.001
A wave	61±10	67±7	NS
A wave velocity time integral	6.0±1	7.9±0.5	0.05
Duration of A wave	125±22	144±3	0.01
Peak E/Peak A ratio	1.34±0.24	1.42±0.3	NS
Peak pulmonary venous systolic flow	57±13	54±10	NS
Pulmonary venous systolic time velocity integral	14±1	12±2	NS
Peak pulmonary venous diastolic flow	48±3	52±8	NS
Pulmonary venous diastolic velocity time integral	11±1.5	14±3	0.05
Peak pulmonary venous flow at time of atrial contraction	26±4	24±3	NS

The diastolic function parameters which were clinically significant include IVRT, A wave velocity time integral, duration of A wave, pulmonary venous diastolic velocity time integral.

Diastolic function parameters between eclamptic cases Vs controls:

Table-8

Parameter	Eclamptics (n=30)	Normal (n=30)	P value
Pulmonary venous velocity time integral at the time of atrial contraction	3.2±0.7	1.3±0.9	0.03
Duration of pulmonary venous flow at atrial contraction	128±24	94±13	<0.001
Difference in duration btw pulmonary venous flow at atrial contraction and A wave	4±21	54±17	<0.0001
Systolic fraction of pulmonary venous flow	64.8±2.6	52.6±6.3	<0.001

*Note- Of these 30 eclampsia cases, echocardiographic evaluation is done 24hrs following delivery in 20 eclamptics, remaining were evaluated before delivery.

The diastolic function parameters at pulmonary vein which were clinically significant include

- pulmonary venous velocity time integral at atrial contraction,
- duration of pulmonary venous flow at atrial contraction,
- difference in duration between pulmonary venous flow at atrial contraction and A wave,
- systolic fraction of pulmonary venous flow.

Diastolic function parameters between pre-eclamptic cases Vs eclamptic cases:

Table-9

Parameter	Pre-eclamptic (n=40)	Eclamptics (n=30)	P value
E wave velocity time integral	13±3	12.8±3	NS
Deceleration time of E wave	194±30	197.8±30	NS
IVRT	95±10	97.3±12	0.38
A wave	63±12	61±10	0.46
A wave velocity time integral	6.3±1	6.0±1	0.28
Duration of A wave	124±23	125±22	0.85
Peak E/Peak A ratio	1.30±0.32	1.34±0.24	NS
Peak pulmonary venous systolic flow	57±12	57±13	NS
Pulmonary venous systolic time velocity integral	14±2	14±1	NS
Peak pulmonary venous diastolic flow	48±10	48±3	NS
Pulmonary venous diastolic velocity time integral	10±2	11±1.5	0.024
Peak pulmonary venous flow at time of atrial contraction	24±4	26±4	NS

The clinically significant diastolic function parameter was pulmonary venous diastolic velocity time integral.

Diastolic function parameters between pre-eclamptic cases Vs eclamptic cases:

Table-10

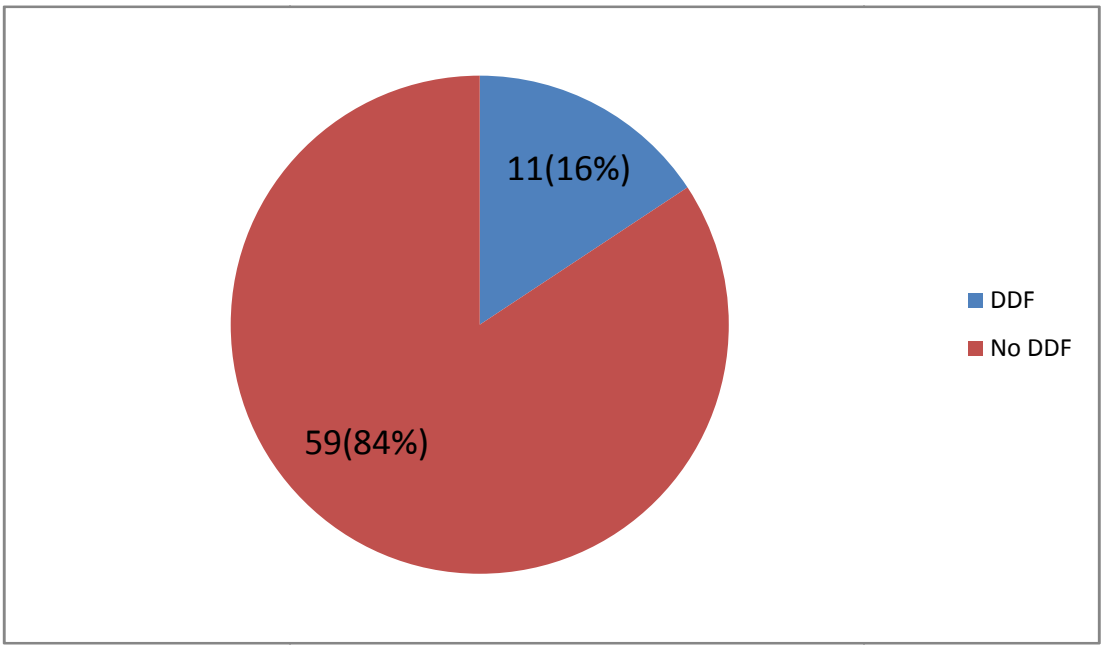
Parameter	Pre-eclamptics (n=40)	Eclamptics (n=30)	P value
Pulmonary venous velocity time integral at the time of atrial contraction	3.1±0.9	3.2±0.7	NS
Duration of pulmonary venous flow at atrial contraction	124±26	128±24	NS
Difference in duration btw pulmonary venous flow at atrial contraction and A wave	3±14	4±21	NS
Systolic fraction of pulmonary venous flow	62.3±2.7	64.8±2.6	0.0002

*Note- Of these 30 eclampsia cases, echocardiographic evaluation is done 24hrs following delivery in 20 eclamptics, remaining were evaluated before delivery.

The clinically significant diastolic function parameter at pulmonary vein was systolic fraction of pulmonary venous flow.

Diastolic dysfunction(DDF) in normal subjects

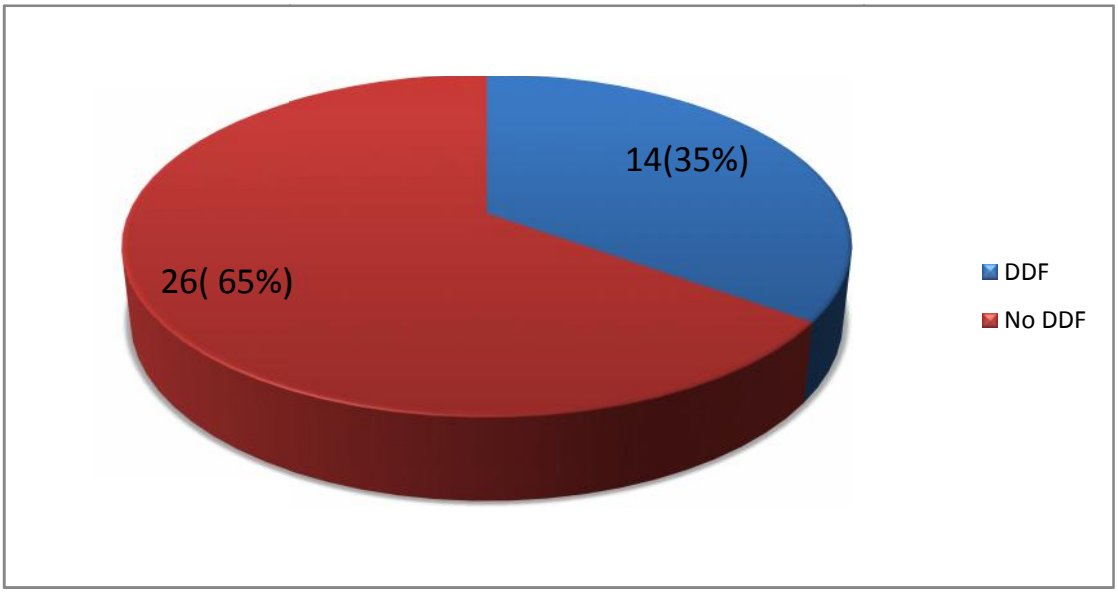
Graph-1



Diastolic dysfunction is observed in 16% of controls.

Diastolic dysfunction in pre-eclampsia:

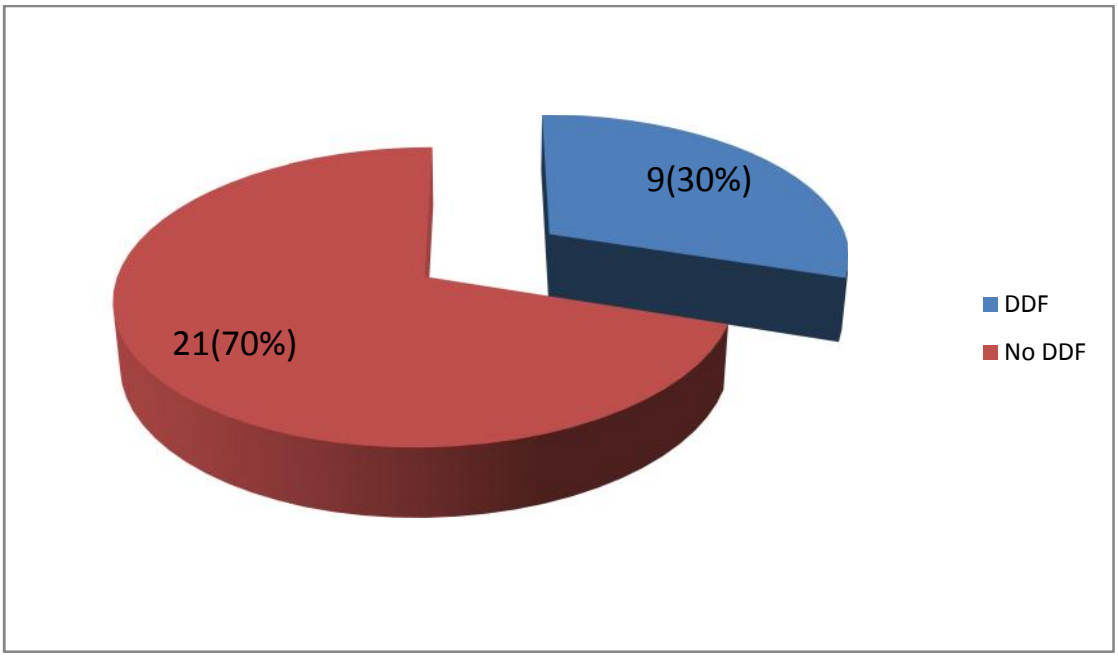
Graph-2



Diastolic dysfunction is observed in 35% of pre-eclamptic cases.

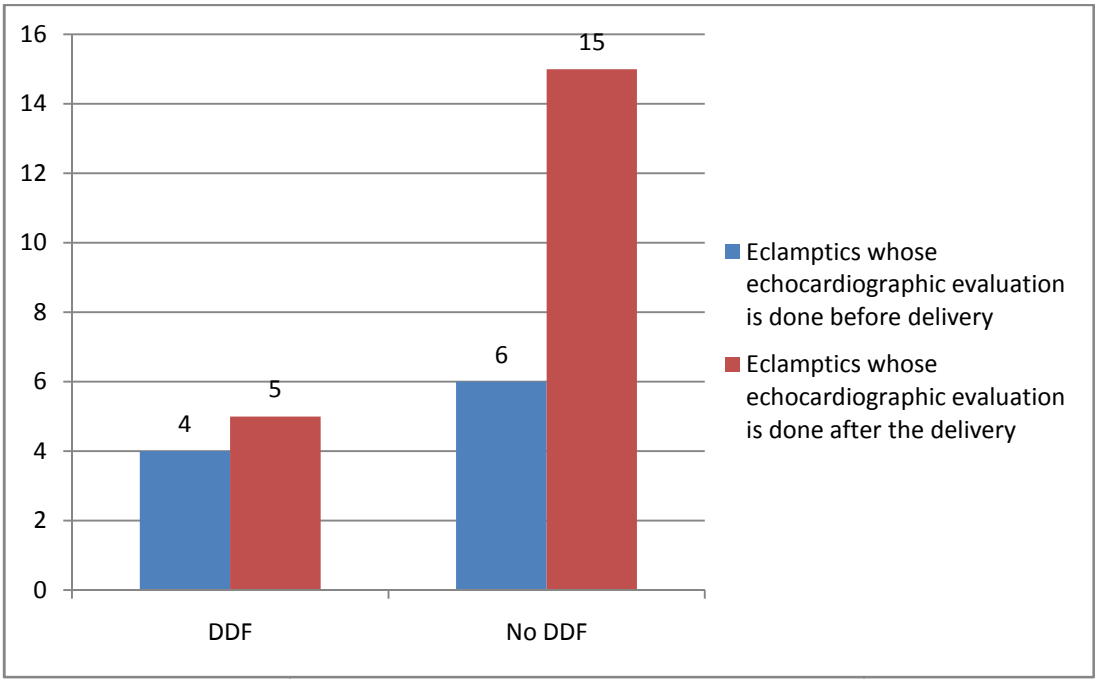
Diastolic dysfunction in eclampsia:

Graph-3



Diastolic dysfunction in eclampsia cases evaluated antepartum and postpartum

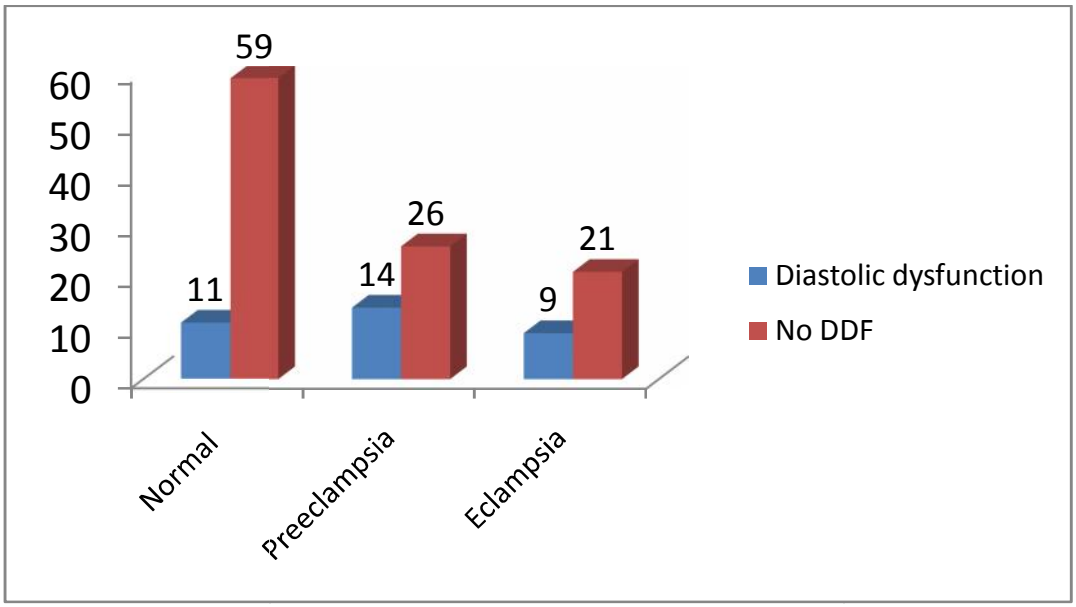
Graph-4



Diastolic dysfunction is observed in 30% of eclampsia cases.

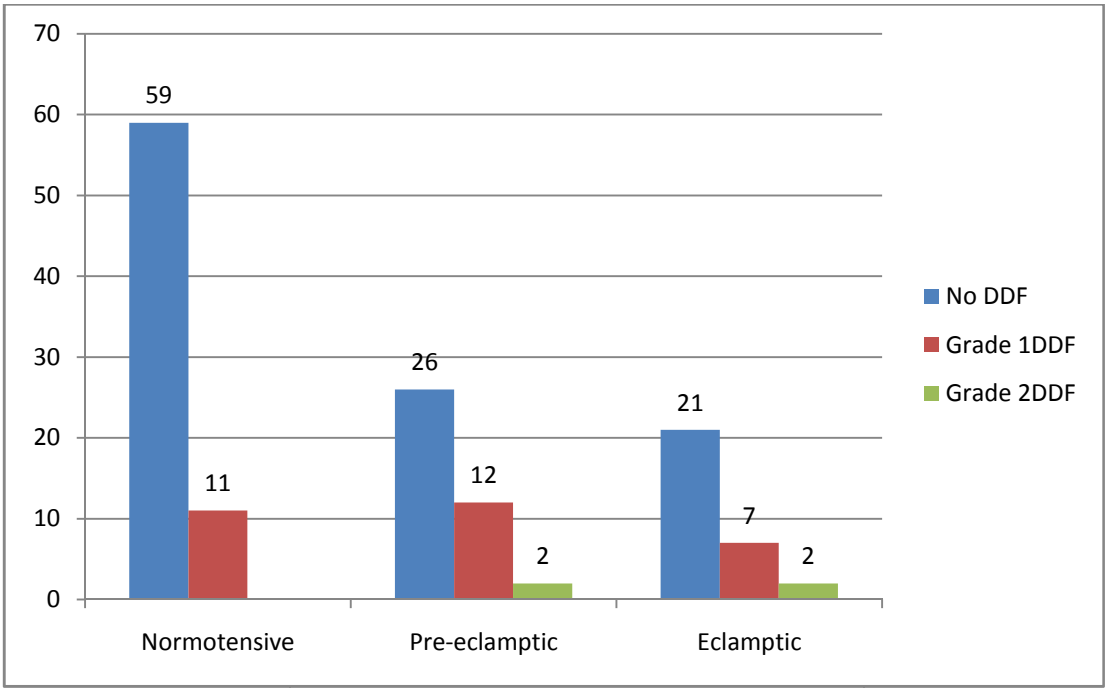
Diastolic dysfunction in normotensive, pre-eclamptic and eclamptic subjects:

Graph-5



Grading of diastolic dysfunction

Graph-6



- Grade I Diastolic dysfunction was present in 12 pre-eclamptics and 7 eclamptics
- Grade II Diastolic dysfunction was present in 2 pre-eclamptics and 2 eclamptic

Association between blood pressure and diastolic dysfunction

Table-11

Subjects	With diastolic Dysfunction	Without diastolic Dysfunction
Preeclamptic and eclamptic women (n=70)	23	47
Normal pregnant women (n=70)	11	58

P value=0.029(statistically significant)

Incidence of diastolic dysfunction was more in pre-eclamptic and eclamptic women than normotensive women

Relative risk ratio:

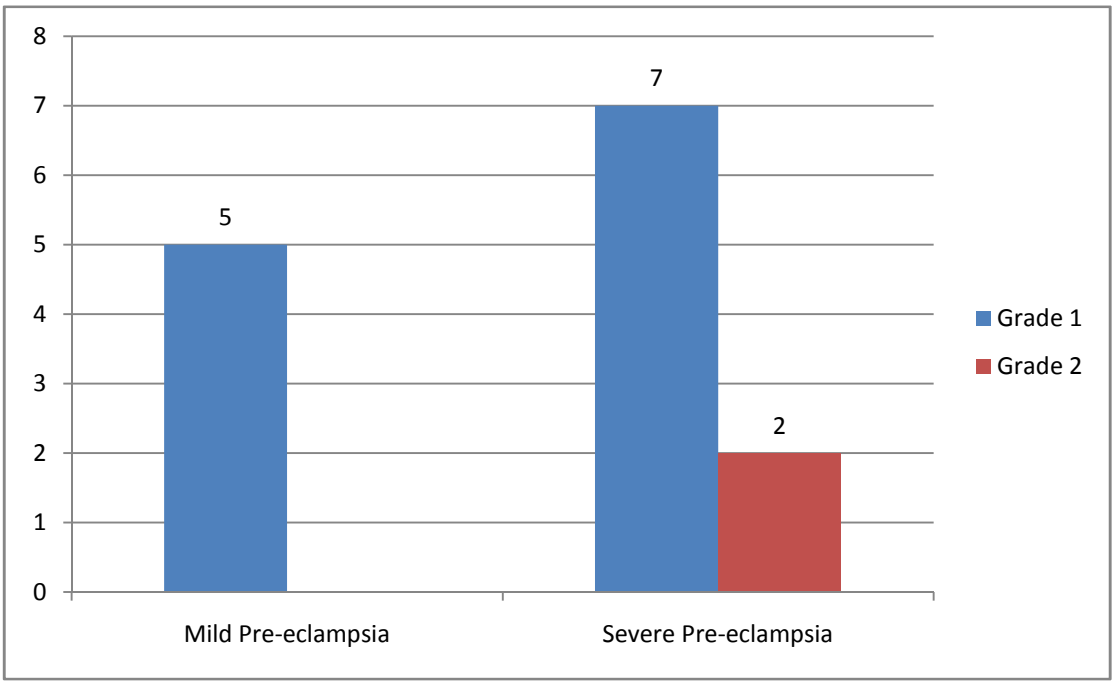
Table-12

Incidence of diastolic dysfunction in pre-eclamptic and eclamptic women	23/70 X 100	32.8%
Incidence of diastolic dysfunction in normal pregnant women	11/70 X 100	15.7%
Relative risk	32.8/15.7	2.08

Relative risk of having Diastolic dysfunction is 2.08 times more in pre-eclamptics and eclamptics compared to normotensive women

Diastolic dysfunction in mild Vs severe pre-eclamptics

Graph-7

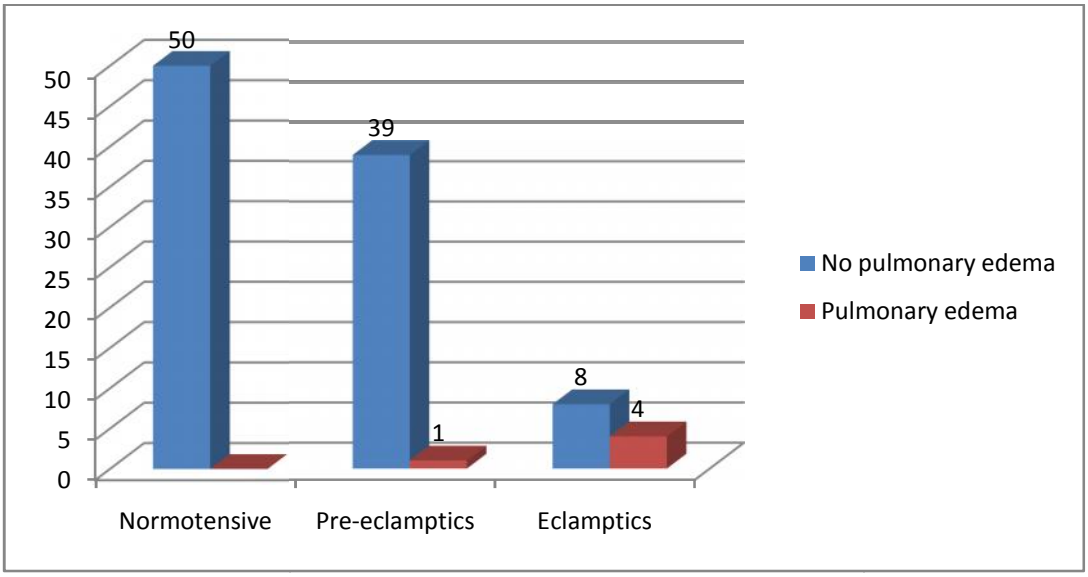


- All mild pre-eclamptics had Grade I Diastolic dysfunction.

- Amongst severe pre-eclamptics 7 had Grade I Diastolic dysfunction,2 had Grade II Diastolic dysfunction

Pulmonary edema in normotensive subjects Vs pre-eclamptics Vs eclamptics

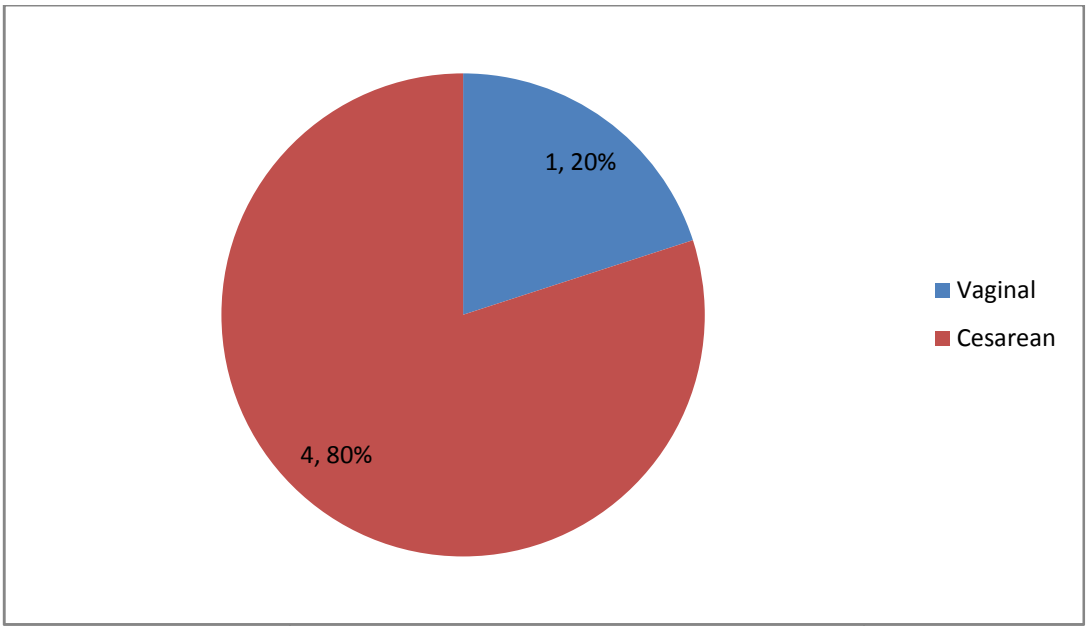
Graph-8



Pulmonary edema was observed in 5 cases of which 1 was pre-eclamptic and 4 were eclamptics.

Mode of delivery in cases with pulmonary edema:

Graph-9



Of the cases with pulmonary edema 1 delivered vaginally and 4 by caesarean section.

Cases of pulmonary edema

Table-13

Cases of pulmonary edema	Blood pressure (mmHg)	Onset of pulmonary edema	Mode of delivery	Intravenous fluid therapy	MgSO4	Grade of DDF
Case1	170/110	Post delivery	Vaginal	1000ml	Given	Grade II
Case 2	180/110	Post delivery	LSCS	1500ml	Given	Grade II
Case 3	190/120	Post delivery	LSCS	1500ml	Given	Grade I
Case 4	160/100	Post delivery	LSCS	1700ml	Given	Grade I
Case 5	160/110	Post delivery	LSCS	1500ml	Given	Grade II

All the cases that developed pulmonary edema had diastolic dysfunction on Doppler echocardiography.

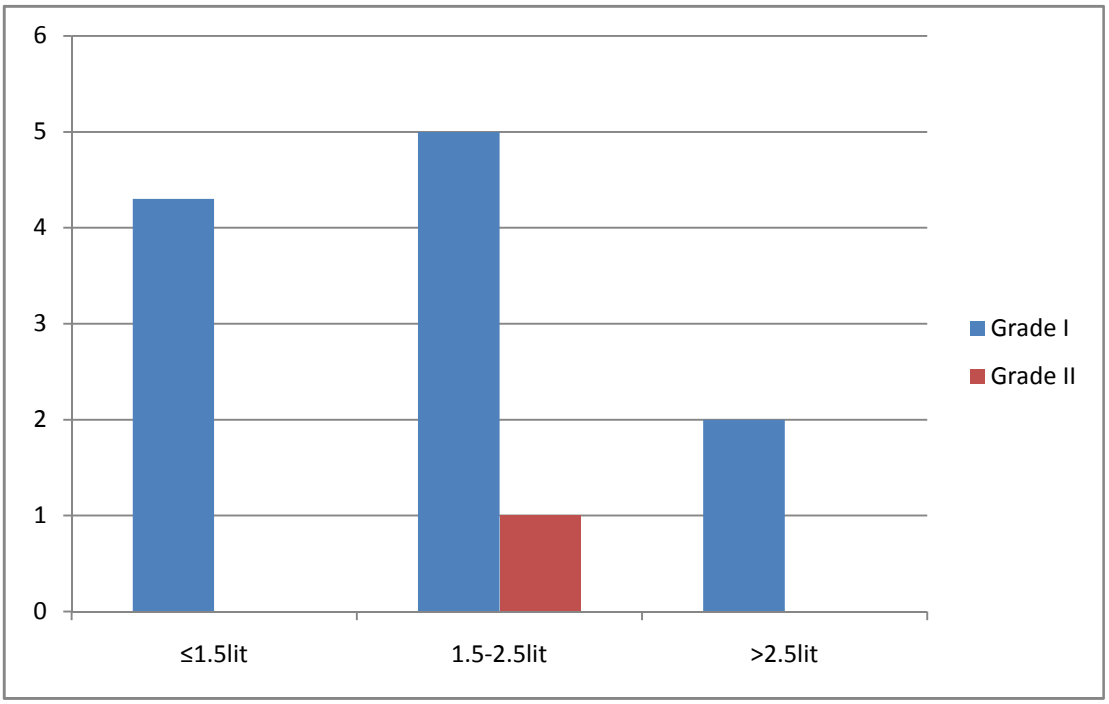
Cases with diastolic dysfunction without pulmonary edema:

Table-14

Cases with DDF	Grade of DDF	Blood pressure (mmHg)	Mode of delivery	Intravenous fluid therapy	MgSO4
Case1	Grade I	170/120	Vaginal	500ml	Given
Case 2	Grade I	140/100	Vaginal	500ml	Not given
Case 3	Grade I	154/100	LSCS	1500ml	Not given
Case 4	Grade I	140/100	Vaginal	500ml	Not given
Case 5	Grade I	180/120	LSCS	1500ml	Given
Case 6	Grade I	170/110	LSCS	2000ml	Given
Case 7	Grade I	140/100	Vaginal	1000ml	Not given
Case 8	Grade I	180/120	LSCS	1500ml	Given
Case 9	Grade I	170/110	LSCS	2000ml	Given
Case 10	Grade I	200/120	LSCS	3000ml	Given
Case 11	Grade I	180/100	LSCS	1500ml	Given
Case 12	Grade I	160/110	Vaginal	1000ml	Given
Case 13	Grade II	160/110	LSCS	1500ml	Given
Case 14	Grade I	180/110	LSCS	2500ml	Given
Case 15	Grade I	160/110	LSCS	3000ml	Given
Case 16	Grade I	190/100	LSCS	1500ml	Given
Case 17	Grade I	180/120	LSCS	2500ml	Given
Case 18	Grade I	170/110	LSCS	2000ml	Given

Intravenous fluid therapy in cases with diastolic dysfunction without pulmonary edema:

Graph-10



Grade I & II DDF was observed in women who received intravenous fluid ranging from <1.5lit to >2.5lit irrespective of the intravenous fluid load.

DISCUSSION

Pregnancy is associated with enormous changes in various organs, cardiovascular system being no exception to this. Pregnancy a hyper-dynamic state is associated with both structural & functional changes in the heart. In cardiovascular system there is a decrease in preload, decrease in cardiac output and increase in afterload.There is also certain degree of diastolic dysfunction in normal pregnancy. These changes are further modified in women with hypertensive disorders of pregnancy. Incidence of diastolic dysfunction is more in women with hypertensive disorders of pregnancy, which has been linked to development of pulmonary edema. Thus this study was aimed to know the diastolic dysfunction in pre-eclamptic, eclamptic women and normotensive pregnant women and to see how many of these subjects had cardiopulmonary event like pulmonary edema and congestive cardiac failure.

As per the CONSORT flow diagram, 139 women were approached of which 91 women were eligible, of these 70 consented and participated. Amongst these 40 were pre-eclamptics and 30 were eclamptics. These cases were matched with casesfor gestational age confirmed by first or second trimester ultrasound.All the cases and controls underwent Doppler echocardiography.

The two groups selected were representative of two different hemodynamic states as can be evaluated from significant difference in the systolic and diastolic blood pressure. The mean systolic blood pressure amongst the cases was 168.1mmHg as compared to the control group which was 117.9mmHg(p value <0.0001).The mean

diastolic blood pressure amongst the cases was 107.4mmHg as compared to control group which was 73.5mmHg(p value <0.0001).

In this study diastolic function parameters described by Doppler echocardiography at mitral area and pulmonary area which were statistically significant between the cases and controls were

- IVRT,
- A wave velocity time integral,
- duration of A wave,
- pulmonary venous diastolic velocity time integral,
- pulmonary venous velocity time integral at atrial contraction,
- duration of pulmonary venous flow at atrial contraction,
- difference in duration between pulmonary venous flow at atrial contraction and A wave,
- systolic fraction of pulmonary venous flow.

Diastolic dysfunction was evidenced by prolongation of IVRT in cases compared to controls (p value < 0.0001) which can be explained by the elevated after load in cases that is co-relating with other study.[8,33]

It was observed that A wave velocity time interval and duration of A wave were significantly lower in cases compared to controls (p value= 0.04 & =0.01 respectively) which can be explained by increased diastolic ventricular pressures in cases that affect left atrial emptying.Similar observations were made in other studies.[7,8]

It was observed that pulmonary venous diastolic filling velocity time integral was significantly lower in cases than controls(p value=0.03) which might be due to impaired left atrial filling secondary to impaired ventricular filling as a result of increase in afterload. This observation was consistent with other study.[8]

It was also observed that pulmonary venous velocity time integral at the time of atrial contraction was significantly higher in cases compared to controls

(p value=0.03) indicating increase in pulmonary pressure secondary to impaired left atrial filling,that is observed in other studies.[7,8]

It was observed that duration of pulmonary venous flow at atrial contraction was significantly higher in cases compared to controls (p value=0.001) indicating an impaired left atrial filling, which is co-relating with other study.[7,8]

It was observed that difference in duration between pulmonary venous flow at atrial contraction and A wave was significantly lower in cases compared to controls (p value=0.0001).It was also observed that systolic fraction of the pulmonary venous flow was significantly(p value=0.001)higher in cases compared to controls indicating a reduced left atrial filling during diastole. Similar observations were made in other studies.[7,8]

On analysis of diastolic function parameters between the pre-eclamptic cases Vs controls and eclamptic cases Vs controls, similar findings were observed but level of significance being more in eclamptics Vs controls than pre-eclamptics Vs controls indicating a greater degree of hemodynamic adaptation in eclamptics than pre-eclamptics.

However clinically significant diastolic parameters between the pre-eclamptics and eclamptics were pulmonary venous diastolic velocity time integral and systolic fraction of pulmonary venous flow (p value=0.02 and 0.0002 respectively) indicating that there is an increasing severity of DDF among the eclamptics than pre-eclamptics.

There was a statistically significant difference in the incidence of diastolic dysfunction between the cases and controls (p value=0.029) which is co-relating with other studies.[7,32]

Amongst the cases 35% of pre-eclamptics and 30% of eclamptics had diastolic dysfunction compared to 16% in control group which is consistent with other study.[8]

Amongst the pre-eclamptic cases 12 subjects (85.7%) had grade I diastolic dysfunction as compared to another study where the incidence was 85%[8] indicating most of those with diastolic dysfunction had Grade I type.

Among the pre-eclamptic cases 14% had grade II diastolic dysfunction as compared to eclamptics where it was 22% indicating higher incidence of Grade II diastolic dysfunction in eclamptics and need for careful intravenous fluid therapy in eclamptics.

A positive co-relation was observed between the severity of hypertension and grade of diastolic dysfunction as Grade II DDF was noted in severe pre-eclamptics and eclamptics whereas none of the mild pre-eclamptics had it..Similar findings were observed in another study.[33]

Pulmonary edema was noted in 5 cases whereas none in the control group had it. Of these subjects 4 were eclamptics and 1 was severe pre-eclamptic. All the 5 subjects developed pulmonary edema post delivery. All 5 subjects had diastolic

dysfunction noted on Doppler echocardiography. Of these, 2 had Grade I DDF whereas 3 had Grade II DDF indicating possibility of diastolic dysfunction in the pathogenesis of pulmonary edema. None of these subjects had a fluid overload,though all the subjects received magnesium sulphate that might have had an additive effect on development of pulmonary edema. Oxytocin,by its water retention property might have played a role in development of pulmonary edema.However information regarding the same was missing.

In cases where >2.5lit of fluids were administrated there was a diastolic dysfunction, but none of them had pulmonary edema. This may be because of use of other drugs like diuretics which might have altered the hemodynamics involved in the development of pulmonary edema. However data regarding the usage of these drugs was missing.

None of the cases and controls had congestive cardiac failure indicating effective management and watchful expectancy of these cases.

Based on this study we observed that women with pre-eclampsia and eclampsia had higher incidence of diastolic dysfunction compared to normotensive pregnant women. We also noticed 5 out of 50 women with pre-eclampsia and eclampsia developed pulmonary edema. Surprisingly all the women with pulmonary edema had diastolic dysfunction on echocardiography indicating that functional cardiac abnormalities like diastolic filling abnormalities might be involved in pathogenesis of pulmonary edema. All the subjects with pulmonary edema had optimal intravenous fluid therapy indicating none had excess intravenous fluids that might to contribute to pulmonary edema. However more studies are required to identify a causal relationship between diastolic dysfunction and pulmonary edema.

Strengths of the study:

- This was the one of the few studies with large sample size of 70 cases that included both pre-eclamptics and eclamptics.
- All the Doppler echocardiographies were done by a single person trained for two years in cardiology to avoid interobserver variability.
- All the Doppler echocardiographies in pre-eclamptics and stable eclamptics were done using Philips IE 33 echocardiographic machine with S4-2 probe. In eclamptics bedside doppler echocardiography was done using Philips CS120 with S3 probe.

Limitations of the study:

- Cases were stabilized before shifting them for echocardiographic evaluation that might have modified haemodynamics and thus might have affected Doppler echocardiographic variables.
- Only conscious eclamptics were taken in this study as it was an ethical issue.
- Data regarding the usage of diuretics, oxytocin and antihypertensives that might have altered the hemodynamics in these cases was missing

Recommendations:

The findings of this study can be endorsed by a large multicentric trial incorporating on admission bedside echocardiography of pre-clamptics and eclamptics in labour room which will probably detect more of these cases with diastolic dysfunction and thus answer the question whether Doppler echocardiography of the mother is essential in every case pre-eclampsia and eclampsia.

SUMMARY

A case control study was performed on 140 consenting women fulfilling the eligibility criteria of whom 70 were cases thatwere matched for gestational age by 1st or 2nd trimester ultrasound with 70 controls in Department of Obstetrics and Gynaecology, at teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belgaum.

In this study, of the139 women screened, 91 were eligible to participate in the study of which 70 women consented. These 70 subjects were matched with controls of same gestation age confirmed by 1st trimester or 2nd trimester scan. Echo-cardiographic variables were collected from these 140 subjects and final results were analysed. Of these 70 cases, 40 were pre-eclamptics and 30 were eclamptics.

There was no statistically significant difference in the demographic characteristics between the two groups i.e., both the groups were well matched.

It was observed that statistically significant Doppler echocardiographic variables were IVRT(p value < 0.0001), A wave velocity time integral(p value= 0.04), duration of A wave(p value =0.01), pulmonary venous diastolic velocity time integral(p value=0.03), pulmonary venous velocity time integral at atrial contraction(p value=0.03), duration of pulmonary venous flow at atrial contraction(p value=0.001), difference in duration between pulmonary venous flow at atrial contraction and A wave(p value=0.0001), systolic fraction of pulmonary venous flow(p value=0.001).

In this study there was a statistically significant increase in the prevalence of diastolic dysfunction in cases compared to controls (p value=0.029).Majority of the

cases had Grade I diastolic dysfunction ,however the prevalence of Grade II diastolic dysfunction was more in eclamptics compared to pre-eclamptics.

It was also observed that all cases of pulmonary edema had diastolic dysfunction on Doppler echocardiography.

From this study it is evident that there is an increased prevalence of diastolic dysfunction in pre-eclamptics and eclamptics and possibility of this diastolic dysfunction in pathogenesis of pulmonary edema which needs to be confirmed by large multicentric study.

CONCLUSION

From this study it is evident that there is increased prevalence of diastolic dysfunction in pre-eclamptics and eclamptics. This necessitates close and careful monitoring during the management of such cases especially with reference to cardiopulmonary complications. Fluid therapy must be monitored closely in cases with diastolic dysfunction, as these in the absence of other medication may increase the maternal morbidity and mortality.

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ANNEXURE I –ETHICAL CLEARANCE LETTER

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K.L.E.UNIVERSITY'S

JAWAHARLAL NEHRU MEDICAL COLLEGE,

NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

(Accredited 'A' Grade by NAAC)

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Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/170 **Date: 14/11/2014**

To,

PG student in OBG,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"DIASTOLIC DYSFUNCTION BY 2D-ECHOCARDIGRAPHY IN PRE-ECLAMPTIC & ECLAMPTIC WOMEN VS NORMAL PREGNANT WOMEN: A HOSPITAL BASED CASE CONTROL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr.Hema Dhumale)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr.Ganga Pilli)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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ANNEXURE II –CONSENT FORM

INFORMATION SHEET FOR WOMEN PARTICIPATING IN RESEARCH STUDY

Diastolic dysfunction by 2D-Echocardiography in pre-eclamptic and eclamptic women vs normal pregnant women

A Hospital based Case control study

Nameof Principal Investigator: Professor,Department of Obstetrics and Gynaecology, KLE's University's Jawaharlal Nehru Medical College,Belagavi

Namesof Co-Investigators: Postgraduate in Department of Obstetrics and Gynaecology, KLE University's Jawaharlal Nehru Medical College, Belagavi

Name of the Institution:KLE University's Jawaharlal Nehru Medical College, Women's & Children's Health Research Unit, Belgavi

You are hereby requested to participate in study which we are conducting to find out Heart dysfunction in pre-eclamptic and eclamptic women compared to normal pregnant women conducted by Dr.Jahnavi.Atluri, PostGraduate in Obstetrics and Gynaecology under the guidance of Dr.M.B.Bellad ,M.S.(OBG), Professor, DepartmentofObstetrics and Gynaecology ,J.N.Medical College, Belagavi under KLE University , Belagavi. This helps in reducing morbidity and mortality associated with high blood pressure

We request you to enroll yourself to participate in our study as you are eligible for participating in the study.During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary.Your decision whether or not to participate in the study will not affect your relationship with J. N.MedicalCollege.If you decide not to participate in the study,you are free to withdraw at any time

Purpose of the study:

The purpose of the study is to assess Heart dysfunction in pre-eclamptic and eclamptic women compared to normal pregnant women

Procedure Involved:

Once you consent to participate in the study some information will be collected from you and will perform a procedure called 2D-Echocardiography(Evaluation of Heart by ultrasound)

Benefits and risks:

This study may or may not directly benefit you,but if you are the case the findings of 2D-Echocardiography may help in your management and also help in managing pregnant women with these complications in future.There are no risks to you or your baby due to this study.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary.You may choose not to enroll yourself in this study.Your decision will not change present or future health care services offered to you at K.L.E.S Hospital

Alternatives:

Even if you decline the participation in the study,you will get the same standard of care as any other pregnant women of the hospital

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team which include .We will be providing you the identity card which will be kept confidential and we alone will have access to identity card.No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1.In emergency to protect your rights and welfare
2.If required by law

Authorization to Publish Results:

When the results of research are published or discussed, in a conference no information will be displayed that would disclose your identity.Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for Participation:

No financial incentives are being offered to enrolled patients.Its is purely being done with the idea of research.

Questions:

In case you have any questions related to the study in future or in case of study related injury or illness,you can contact .Department of Obstetrics and Gynaecology,KLES Hospital and MRC,Ph. No ,Professor,Department of Obstetrics and Gynaecology,KLES Hospital and MRC,Belgavi,

If you have any queries about your rights as a study subject, you may call Dr. Ganga Pilli, Professor, Department of Pathology and Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number- , or extension at J.N. Medical College, Belgavi.

Consent Statement

I, _____ voluntarily agree for the participation as a subject of study.By signing this consent form I am giving up any of my legal rights.I may withdraw from the study anytime.I am signing the consent form after having read or been read form in vernacular language,including the risks and the benefitsand having all my questions answered

Subject Name: _____

Signature or the Left thumb print of Subject: _____

Witness Name: _____ Signature: _____

Investigators Name: _____ Signature: _____

Place:

Date:

ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ ಪತ್ರ

ಶ್ರೀಮತಿ _____

ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ವ್ಯಾಸಂಗ ಮಾಡುತ್ತಿರುವ ಡಾ॥ ಇವರು , ಪ್ರಾಧ್ಯಾಪಕರು, ಕೆ.ಎಲ್.ಇ. ವಿಶ್ವವಿದ್ಯಾಲಯದ ಜೆ.ಎನ್. ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯ ಅವರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ಮಾಡಿರುವ **"ಪ್ರಸವಾಸ್ಮಾರದ ಮುನ್ನ ಮತ್ತು ಪ್ರಸವಾಪಸ್ಮಾರದ ಮಹಿಳೆಯರಲ್ಲಿ ಅಗುವ ವ್ಯಾಕೋಚನದ ನಿಷ್ಕ್ರಿಯತೆಯನ್ನು ಸಾಮಾನ್ಯ ಗರ್ಭಿಣಿ ಮಹಿಳೆಯೊಂದಿಗೆ ಹೋಲಿಸಿ ಮಾಡಿರುವ ಒಂದು ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ"** (Diastolic dysfunction in preeclamptic and eclamptic women compared to normal subjects) ದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಆಮಂತ್ರಿಸುತ್ತಿದ್ದೇವೆ.

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅರ್ಹರಾಗಿರುವುದರಿಂದ ನಿಮ್ಮ ಹೆಸರನ್ನು ನೊಂದಾಯಿಸಲು ನಿಮ್ಮನ್ನು ವಿನಂತಿಸುತ್ತೇವೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸದ್ಯ ನೀವು ಅನುಭವಿಸತ್ತಿರುವ ತೊಂದರೆಗಳ ಬಗ್ಗೆ ಕೆಲವು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲಾಗುವುದು, ಅವುಗಳಿಗೆ ನೀವು ನಿಮ್ಮ ಗೊತ್ತಿರುವ ಮಾಹಿತಿಯ ಮೇರೆಗೆ ಉತ್ತರಿಸಬಹುದು. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವುದು ವೈಯಕ್ತಿಕವಾಗಿದ್ದು, ನೀವು ಇದರಲ್ಲಿ ಭಾಗವಹಿಸಿದರೂ ಅಥವಾ ಭಾಗವಹಿಸದಿದ್ದರೂ ಜೆ.ಎನ್. ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯದ ಜೊತೆಗಿರುವ ನಿಮ್ಮ ಸಂಬಂಧ ಮೇಲೆ ಯಾವುದೇ ಪರಿಣಾಮ ಉಂಟಾಗುವುದಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ಇಚ್ಛಿಸಿದರೂ ಸಹ, ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಇದರಿಂದ ಹೊರಹೋಗಬಹುದು. **ಪ್ರಸವಾಸ್ಮಾರದ ಮುನ್ನ ಮತ್ತು ಪ್ರಸವಾಪಸ್ಮಾರದ ಮಹಿಳೆಯರಲ್ಲಿ ಅಗುವ ವ್ಯಾಕೋಚನದ ನಿಷ್ಕ್ರಿಯತೆಯನ್ನು ಸಾಮಾನ್ಯ ಗರ್ಭಿಣಿ ಮಹಿಳೆಯೊಂದಿಗೆ ಹೋಲಿಸಿ, ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ ಮಾಡುವುದು ನಮ್ಮ ಈ ಅಧ್ಯಯನದ ಮುಖ್ಯ ಉದ್ದೇಶವಾಗಿರುತ್ತದೆ.**

ಅಧ್ಯಯನವು ಒಳಗೊಂಡಿರುವ ವಿಧಾನ:

ನೀವು ಸದರಿ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೊಂದಾಯಿಸಲು ಒಪ್ಪಿಕೊಂಡರೆ, ನಿಮ್ಮ ಈಗಿನ ಮತ್ತು ಹಿಂದಿನ ಕುಟುಂಬದ ಇತಿಹಾಸ ಗಳ ಬಗ್ಗೆ ಒಂದು ಸಂದರ್ಶನ

ನಡೆಸಲಾಗುವುದು ಮತ್ತು ವೈದ್ಯಕೀಯ ಪರೀಕ್ಷೆಗೆ 2ಡಿ ಎಕೊಕಾರ್ಡಿಯೋಗ್ರಫಿಯ ಮೂಲಕ ಪರೀಕ್ಷಿಸಲಾಗುವುದು.

ಅಪಾಯ ಮತ್ತು ಪ್ರಯೋಜನಗಳು:

ಈ ಅಧ್ಯಯನದಿಂದ ಪ್ರಸವಾಸ್ಥಾರದ ಮುನ್ನ ಮತ್ತು ಪ್ರಸವಾಪಸ್ಥಾರದ ಮಹಿಳೆಯರಲ್ಲಿ ಅಗುವ ವ್ಯಾಕೋಚನದ ನಿಷ್ಕ್ರಿಯತೆಯನ್ನು ಸಾಮಾನ್ಯ ಗರ್ಭಣಿ ಮಹಿಳೆಯೊಂದಿಗೆ ಹೋಲಿಸಿ ಅದರಲ್ಲಿ ಗಮನಾರ್ಹ ವ್ಯತ್ಯಾಸಗಳನ್ನು ಕಂಡುಹಿಡಿಯುವುದಾಗಿದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ಗಮನೀಯ ಅಪಾಯಗಳಿರುವುದಿಲ್ಲ.

ಸ್ವಯಂ ಪ್ರೇರಿತ ಭಾಗವಹಿಸುವಿಕೆ/ಹೊರ ಹೋಗುವುದು:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದು ಸಂಪೂರ್ಣ ವೈಯಕ್ತಿಕವಾಗಿರುತ್ತದೆ. ನೀವು ಇದರಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೊಂದಾಯಿಸದಿದ್ದರೂ ಸಹ ನೀವು ಇದರಲ್ಲಿ ಭಾಗವಹಿಸಿದರೂ ಅಥವಾ ಭಾಗವಹಿಸದಿದ್ದರೂ ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆಯ ಜೊತೆಗಿರುವ ನಿಮ್ಮ ಸಂಬಂಧ ಮೇಲೆ ಯಾವುದೇ ಪರಿಣಾಮ ಉಂಟಾಗುವುದಿಲ್ಲ.

ಪರ್ಯಾಯ/ಬದಲಿ:

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸದಿದ್ದರೂ, ನಮ್ಮ ದಿನ ನಿತ್ಯದ ನಿರ್ವಹಣೆಯಲ್ಲಿ ಯಾವುದೇ ವ್ಯತ್ಯಾಸವಾಗುವುದಿಲ್ಲ.

ಗೌಪ್ಯತೆಯ ರಕ್ಷಣೆ:

ನಿಮ್ಮ ಬಗೆಗಿನ ವಿವರಗಳು ಸಂಶೋಧನಾ ತಂಡದವರಿಗೆ ಮಾತ್ರ ತಿಳಿದಿರುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನೀವು ಒದಗಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು (ಈ ಕೆಳಗಿನ ಸಂದರ್ಭಗಳನ್ನು ಬಿಟ್ಟು) ನಿಮ್ಮ ಲಿಖಿತ ಪರವಾನಿಗೆ ಇಲ್ಲದೇ ಬೇರೆಯವರಿಗೆ ಕೊಡಲಾಗುವುದಿಲ್ಲ.

1) ನಿಮ್ಮ ಹಕ್ಕು ಮತ್ತು ಹಿತರಕ್ಷಣೆ ಸಲುವಾಗಿ ತುರ್ತು ಸಂದರ್ಭಗಳಲ್ಲಿ
2) ಯಾವುದೇ ಕಾನೂನಿನ ಪ್ರಕಾರ ಒದಗಿಸಬೇಕಾದ ಸಂದರ್ಭದಲ್ಲಿ

ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸುವ ಅಧಿಕಾರ:

ಈ ಸಂಶೋಧನೆಯ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸಿದಾಗ ಅಥವಾ ಚರ್ಚಿಸುವಾಗ ನಿಮ್ಮ ಯಾವುದೇ ವೈಯಕ್ತಿಕ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಕೊಡಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗುವುದು.

ಭಾಗವಹಿಸುವುದರಿಂದ ಆರ್ಥಿಕ ಪ್ರೋತ್ಸಾಹಗಳು:

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೊಂದಾಯಿಸಿದರೆ ನಿಮಗೆ ಯಾವುದೇ ಆರ್ಥಿಕ ಪ್ರೋತ್ಸಾಹಗಳನ್ನು ಕೊಡಲಾಗುವುದಿಲ್ಲ. ಇದನ್ನು ಕೇವಲ ಸಂಶೋಧನೆಗಾಗಿ ಮಾಡಲಾಗುವುದು ಮತ್ತು ಇದರ ಎಲ್ಲ ಖರ್ಚುವೆಚ್ಚಗಳನ್ನು ಸಂಶೋಧಕರೇ ಭರಿಸುತ್ತಾರೆ.

ಪರಿಹಾರ:

ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಪಟ್ಟಂತೆ ನಿಮಗೆ ಯಾವುದೇ ಗಾಯಗಳಾದರೆ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ. ವತಿಯಿಂದ ಚಿಕಿತ್ಸೆ ನೀಡಲಾಗುವುದು. ಈ ರೀತಿಯ ವೈದ್ಯಕೀಯ ಚಿಕಿತ್ಸೆಗೆ ಯಾವುದೇ ಪರಿಹಾರಧನ ಕೊಡಲಾಗುವುದಿಲ್ಲ. ನಿಮಗೆ ಯಾವುದೇ ಗಾಯವಾದ ಸಂದರ್ಭದಲ್ಲಿ ನೀವು ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ.,
ಇವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಪ್ರಶ್ನೆಗಳು:

ಈ ಅಧ್ಯಯನದಿಂದಾಗಿ ಉಂಟಾಗಿರುವ ಯಾವುದೇ ಗಾಯ ಅಥವಾ ಅನಾರೋಗ್ಯಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ, ನೀವು ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ.,
ಅಥವಾ ಅಥವಾ , ಪ್ರಾಧ್ಯಾಪಕರು, ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ.,
ಅಥವಾ ಇವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು,

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪ್ರಯೋಗಾರ್ಥಿಯಾಗಿ ನಿಮ್ಮ ಹಕ್ಕುಗಳ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ, ನೀವು . ಪ್ರಾಧ್ಯಾಪಕರು ಮತ್ತು ಪೆಥಾಲಾಜಿ ವಿಭಾಗದ ಮುಖ್ಯಸ್ಥರು, ಜೆ.ಎನ್. ಮೆಡಿಕಲ್ ಕಾಲೇಜ್ ಇನ್ಸಸ್ಟಿಟ್ಯೂಷನಲ್ ಎಥಿಕ್ಸ್ ಕಮೀಟಿ ಆನ್ ಹ್ಯುಮನ್ ಸಬ್ಜೆಕ್ಟ್ಸ್ ರಿಸರ್ಚ್, ಮೆಡಿಕಲ್ ಕಾಲೇಜು ಬೆಳಗಾವಿ ಅಥವಾ ಇವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಈ ಸಂಶೋಧನಾ ಪ್ರಯೋಗದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ

ಈ ಕೆಳಗೆ ಸಹಿ ಮಾಡಿದ _____

ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಂಡಿರುತ್ತೇನೆ. ಈ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಮಾಡುವುದರಿಂದ ನಾನು ನನ್ನ ಯಾವುದೇ ಕಾಯದೆಬದ್ಧ ಹಕ್ಕುಗಳನ್ನು ಬಿಟ್ಟುಕೊಟ್ಟಿರುವುದಿಲ್ಲ. ನಾನು ಯಾವುದೇ ಸಂದರ್ಭದಲ್ಲಿ ಈ ಅಧ್ಯಯನದಿಂದ ಹೊರಹೋಗಬಹುದು. ನಾನು ಈ ಅಧ್ಯಯನವು ಒಳಗೊಳ್ಳುವ ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳು ಹಾಗೂ ಪ್ರಶ್ನೆಗಳಿಗೆ ನಾನು ಕೊಟ್ಟಿರುವ ಉತ್ತರಗಳನ್ನು ನನ್ನ ಮಾತೃಭಾಷೆಯಲ್ಲಿ ಓದಿ, ತಿಳಿದುಕೊಂಡು ನನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು ಕೊಟ್ಟಿರುತ್ತೇನೆ.

ಪ್ರಯೋಗಾರ್ಥಿ ಹೆಸರು : _____

ಪ್ರಯೋಗಾರ್ಥಿಯ ಸಹಿ: _____ ದಿನಾಂಕ: _____

ಸಾಕ್ಷಿಯ ಹೆಸರು: _____ ಸಹಿ:_____ ದಿನಾಂಕ: _____

ಸಂಶೋಧಕರ ಹೆಸರು: _____ ಸಹಿ: _____ ದಿನಾಂಕ:_____

ಸ್ಥಳ: _____

महिलांचे अध्ययनात सहभागी होण्यासंबंधीचे माहिती पत्र

प्री.एक्लॅम्प्टीक आणि एक्लॅम्टीक महिला आणि सामान्य गरोदर महिला यांच्यामध्ये २ डी एकाकार्डीओग्राफी ने होणारे डीस्टॉलिक डी सफंक्शन

हॉस्पीटलस्थीने केस कंट्रोल अभ्यास

मुख्य संशोधकाचे नांव : प्राध्यापक, (प्रस्तुती विभाग आणि स्त्रीरोग विभाग) के एल ई विद्यापिठाचे जवाहरलाल नेहरु मेडिकल कॉलेज, बेळगाव.

सह संशोधकाचे नांव : प्रसुती विभाग आणि स्त्रीरोग विभागाचे पोस्ट ग्रॅज्युएट के एल ई विद्यापिठाचे जवाहरलाल नेहरु मेडिकल कॉलेज

संस्थेचे नांव : के एल ई युनिव्हर्सिटीजचे जवाहरलाल नेहरु मेडिकल कॉलेजचे , महिला आणि मुलांचे आरोग्य संदर्भात शोध करणारे युनिट

तुम्हाला विनंती करण्यात येत आहे कि, आम्ही प्री प्री.एक्लॅम्प्टीक आणि एक्लॅम्टीक महिला यांच्यात आणि सामान्य गरोदर महिला यांच्यात होणारा हदयाच्या बिघाडांचा तुलनात्मकरित्या अभ्यास करत आहोत. त्यामध्ये सहभागी होण्याचा. हा अभ्यास डॉ. जान्हवी अटलूरी ज्या प्रस्तुतीशास्त्र आणि स्त्रीरोग या विषयावरच्या पोस्ट ग्रॅज्युएट आहेत त्या प्राध्यापक प्रस्तुती आणि स्त्रीरोग विभाग जे.एन मेडिकल कॉलेज बेळगावी के एल ई युनिव्हर्सिटी या संस्थेअंगर्गत आहे त्यांच्या मार्गदर्शनाखाली हा अभ्यास करत आहेत. या अभ्यासामूळे हायब्लडप्रेशर मुळे रोग आणि होणारे जीवितहानी टाळण्यास मदत होईल.

आम्ही अशी विनंती करतो की तुम्ही आमच्या या अभ्यासात सहभागी होण्याकरता आपले नांव नोंदवावे. जसे की तुम्ही या अभ्यासात सहभागी होण्याकरीता लायक असाल. या अभ्यासा दरम्यान तुमच्या सद्यस्थितीतील तक्रारीविषयी काही प्रश्न विचारले जातील. आणि तुम्ही त्या प्रश्नांचे उत्तर तुमच्य माहितीप्रमाणे योग्य ते उत्तर देणे आहे.

या अध्ययनामध्ये सहभागी होण्याचा निर्णय ऐच्छिक आहे. या अध्ययनामध्ये सहभागी होण्याचा अथवा न होण्याच्या तुमच्या निर्णयामुळे तुमच्या जे. एन मेडिकल कॉलेजबरोबर असलेल्या संबंधामध्ये कोणताहि फरक पड़णार नाही. जर तुम्हाला या अभ्यासामध्ये सहभागी व्हायचे नसेल तर कोणत्याही क्षणी तुम्ही माघार घेऊ शकता.

* **अध्ययनाचे उद्देश :** सामान्य गरोदर महिलामध्ये आणि प्री.एक्लॅम्प्टीक आणि एक्लॅम्टीक महिला मध्ये असणाऱ्या हदयाच्या बिघाडांचा तुलनात्मक रित्या अभ्यास करणे.

* **कार्यपध्दती :** तुम्ही जर अध्ययनामध्ये सहभागी होण्यास होकार दर्शविला की तुमच्याकडून काही माहिती जमा केली जाईल. आणि तुमच्यावर एक २ डी एकाकॉर्डीयोग्राफी (अल्ट्रासाओंडद्वारे हदयाचे मोजमाप) नावाची पध्दत अवलंबीली जाईल.

* **फायदे आणि नुकसान :** हा अभ्यास तुम्हाला थेट असा फायदा पोहोचवू शकेल अथवा नाही. जर तुमची २ डी एकोकॉडीयोफी केस असेल तर तुमच्या व्यवस्थापनाकरिता ती उपयोगी पडू शकेल तसेच ती भविष्यात गरोदर महिलामधील गुंतागुंतीची व्यवस्था करण्यास मदत करु शकते. या अभ्यासामुळे तुम्हाला अथवा तुमच्या बाळाला कोणतीही धोका नाही.

* **ऐच्छिक सहभाग /माघार :** या अध्ययनात भाग घेणे ऐच्छीक आहे तुम्ही तुम्हाला या अध्ययनामध्ये नाव नोंदवण्यास नका देवू शकता. तुमच्या निर्णयामुळे तुमच्या सद्यस्थितीमधील अथवा भविष्यामधील के.एल ई एस हॉस्पीटलमधील आरोग्य सुविधावर कोणताही परिणाम होणार नाही.

* **इतर मार्ग:** तुम्ही अध्ययनात भाग घेण्यास नकार दिला तरी तुम्हाला हॉस्पीटलमध्ये इतर गरोदर महिलाप्रमाणेच उपचार केले जातील.

***खासगी व गोपनियता:** तुम्ही एका शोधाचा विषय आहात हे फक्त शोधकर्त्याच्या गटालाच माहित असेल जे

हे असतील तुम्ही आम्हाला एक ओळखपत्र देवू जे की गोपनिय असेल आणि फक्त आमचीच त्या ओळखपत्रापर्यंत पोहोच असेल. तुमच्या बद्दलची कोणतीही माहिती, तसेच तुम्ही आम्हाला या अध्ययना दरम्यान पुरवलेला तुमची माहिती तुमच्या लिखित परवानगी शिवाय दुसऱ्याला देणार नाही. फक्त काही कारणे सोडून

१) आणीबाणीमध्ये तुमचे आधिकार आणि तुमचे स्वास्थ जपण्याकरीता

२) कायद्यानुसार गरज भासल्यास

* **अभ्यासाचे परिणाम प्रकाशीत करण्यासंबंधीचे हक्क :**

जेव्हा या अभ्यासाचे परिणाम प्रकाशीत केले जातील अथवा त्यावर चर्चा होईल. त्यावेळी अशी कोणतीही माहिती मांडली जाणार नाही. त्याद्वारे तुमची ओळख स्पष्ट होईल. अशी कोणतीही माहिती या अभ्यासादरम्यान घेतलेली नसेल त्या माहितीनुसार तुमची ओळख पटविली जाऊ शकते. ती गोपनिय राखली जाईल.

* **भाग घेण्यास आर्थिक लाभ :** या अध्ययनामध्ये भाग घेतलेल्यांना कुठलेही आर्थिक लाभ मिळनार नाही.

* **प्रश्ने :** तुम्ही अध्ययनासम्बधी कोणताही प्रश्न विचारणार असाल तर

डॉ जान्हवी अटलुरी प्रसुती विभाग आणि स्त्रीरोग विभागाचे पोस्ट ग्रॅज्युएट के एल ई विद्यापिठाचे जवाहरलाल नेहरु मेडिकल कॉलेज बेळगांवी फोन नं.

तुम्ही संशोधनात भाग घेऊन हक्काकरीता कुठलाही प्रश्न विचारणार असाल तर, डॉ. (श्रीमती) गंगा एस. पिल्ली, कार्याध्यक्ष संस्थिक नैतिक समिती, मानव संशोधन विभाग, जे.एन.एम.सी, बेळगावी किंवा एक्सटेन

सम्मति पत्र

मी ----------

स्वखुशीने या अध्ययनात भाग घेणेस संमती दिलेली आहे. पण माझ्या कायदेशिर हक्क सोडलेले नाही. मी मला नको झालेतर या अध्ययनातून बाहेर पडतो. हे संमती पत्र वाचून घेऊन मला माझी मात्र भाषामध्ये वाचून समजल्यानंतर ऐकून जबाबदारी आणि प्रयोजन वगैरे ला उत्तर दिल्यानंतर या खालील सही केलेली आहे.

विषयाचे नाव (अभ्यर्थी) : ----------

सही:/ डाव्या हाताचा निशान : ----------

साक्षी : नांव : ----------सही ----------

इनव्हेस्टीगेटर्स नांव ----------सही ----------

दिनांक :

स्थळ :

ANNEXURE III – SCREENING FORM

DIASTOLIC DYSFUNCTION BY 2D-ECHOCARDIOGRAPHY IN PRE-ECLAMTIC & ECLAMPTIC WOMEN VS NORMAL PERGNENT WOMEN : A HOSPITAL BASED CASE CONTROL STUDY

ELIGIBILITY FORM

Date:-

Name of the pregnant women :- Idno

Addresss Tel No:

Age

IP No-

OP No-

LMP- DD MM YYYY

EDD- DD MM YYYY

Gestational age- Weeks Days

Gravida

Para

Living

Haemoglobin gm

Dose she have any cardiac disease 1.Yes 2.No

Does she have any exclusion criteria 1.Yes 2.No

Has she consented 1.Yes 2.No

Eligible and consented

Eligible and not Consented

ANNEXURE IV– DATA COLLECTION INSTRUMENT

"DIASTOLIC DYSFUNCTION BY 2D-ECHOCARDIOGRAPY IN PRE-ECLAMPSIA & ECLAMPSIA WOMEN V/S NORMAL PREGNANT WOMEN: A HOSPITAL BASE CASE CONTROL STUDY"

Data Collection Instrument

Id no ☐☐☐

Gestational Age- ☐☐ weeks ☐ Days

Height ☐☐☐ cm Weight ☐☐ kg

BMI ☐☐ kg/m^2

Pulse ☐☐ bpm

B.P. Systolic in mmHg ☐☐☐

Diastolic inmmHg ☐☐☐

Proteinuria- 1+ ☐ 2++ ☐ 3+++ ☐ 4 ++++ ☐

Jaundice- 1.Yes ☐ 2.No ☐

USG

Gestational Age- ☐☐ weeks ☐ Days

AFI- ☐☐ cm

Liver function Tests

Total Bilirubin-

Direct Bilirubin-

Total protein-

Sr.Albumin-

AST-

ALT-

Alkaline phosphatase-

LDH

Platelet count

Fundoscopy findings

Echocardiodiographic variables:

E wave velocity time integral-

Deceleration time of E wave-

Isovolumetric ventricular relaxation time-

A wave-

A wave velocity time integral-

Duration of A wave-

Peak E/Peak A Ratio-

Peak pulmonary venous systolic flow-

Pulmonary venous systolic time velocity integral-

Peak Pulmonary Venous diastolic flow-

Pulmonary venous diastolic velocity time integral –

Peak Pulmonary venous flow at time of atrial contraction-

Pulmonary venous velocity time integral at atrial at atrial contraction-

Duration of pulmonary venous flow at atrial contraction –

Difference in duration between pulmonary venous flow at atrial -

Systolic fraction of pulmonary vein flow –

Maternaloutcome: ☐

Congestive cardiac failure- 1.Yes

2.No ☐

Pulmonary edema- 1.Yes ☐

2.No ☐

ANNEXURE I –ETHICAL CLEARANCE LETTER

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K.L.E.UNIVERSITY'S

JAWAHARLAL NEHRU MEDICAL COLLEGE,

NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/170 **Date: 14/11/2014**

To,

Dr. Jahnavi Atluri,
PG student in OBG,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"DIASTOLIC DYSFUNCTION BY 2D-ECHOCARDIGRAPHY IN PRE-ECLAMPTIC & ECLAMPTIC WOMEN VS NORMAL PREGNANT WOMEN: A HOSPITAL BASED CASE CONTROL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr.Hema Dhumale)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr.Ganga Pilli)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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ANNEXURE II –CONSENT FORM

INFORMATION SHEET FOR WOMEN PARTICIPATING IN RESEARCH STUDY

Diastolic dysfunction by 2D-Echocardiography in pre-eclamptic and eclamptic women vs normal pregnant women

A Hospital based Case control study

Nameof Principal Investigator:Dr.M.B.Bellad,M.S.(OBG)Professor,Department of Obstetrics and Gynaecology, KLE's University's Jawaharlal Nehru Medical College,Belagavi

Namesof Co-Investigators: Dr Jahnavi.Atluri,Postgraduate in Department of Obstetrics and Gynaecology, KLE University's Jawaharlal Nehru Medical College, Belagavi

Name of the Institution:KLE University's Jawaharlal Nehru Medical College, Women's & Children's Health Research Unit, Belgavi

You are hereby requested to participate in study which we are conducting to find out Heart dysfunction in pre-eclamptic and eclamptic women compared to normal pregnant women conducted by Dr.Jahnavi.Atluri, PostGraduate in Obstetrics and Gynaecology under the guidance of Dr.M.B.Bellad ,M.S.(OBG), Professor, DepartmentofObstetrics and Gynaecology ,J.N.Medical College, Belagavi under KLE University , Belagavi. This helps in reducing morbidity and mortality associated with high blood pressure

We request you to enroll yourself to participate in our study as you are eligible for participating in the study.During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary.Your decision whether or not to participate in the study will not affect your relationship with J. N.MedicalCollege.If you decide not to participate in the study,you are free to withdraw at any time

Purpose of the study:

The purpose of the study is to assess Heart dysfunction in pre-eclamptic and eclamptic women compared to normal pregnant women

Procedure Involved:

Once you consent to participate in the study some information will be collected from you and will perform a procedure called 2D-Echocardiography(Evaluation of Heart by ultrasound)

Benefits and risks:

This study may or may not directly benefit you,but if you are the case the findings of 2D-Echocardiography may help in your management and also help in managing pregnant women with these complications in future.There are no risks to you or your baby due to this study.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary.You may choose not to enroll yourself in this study.Your decision will not change present or future health care services offered to you at K.L.E.S Hospital

Alternatives:

Even if you decline the participation in the study,you will get the same standard of care as any other pregnant women of the hospital

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team which include Dr.M.B.Bellad,Dr.SureshPatted,Dr.AnkurBatra,Dr.Jahnavi and Ms.Rashmi.We will be providing you the identity card which will be kept confidential and we alone will have access to identity card.No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1.In emergency to protect your rights and welfare
2.If required by law

Authorization to Publish Results:

When the results of research are published or discussed, in a conference no information will be displayed that would disclose your identity.Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for Participation:

No financial incentives are being offered to enrolled patients.Its is purely being done with the idea of research.

Questions:

In case you have any questions related to the study in future or in case of study related injury or illness,you can contact Dr.Jahnavi.Atluri,Department of Obstetrics and Gynaecology,KLES Hospital and MRC,Ph. No.0831-2551292 or 9844953099 or Dr.M.B.Bellad,Professor,Department of Obstetrics and Gynaecology,KLES Hospital and MRC,Belgavi,Ph.no-9448124893

If you have any queries about your rights as a study subject, you may call Dr. Ganga Pilli, Professor, Department of Pathology and Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number- 9480275601, or extension 0831-2474052 at J.N. Medical College, Belgavi.

Consent Statement

I, _____ voluntarily agree for the participation as a subject of study.By signing this consent form I am giving up any of my legal rights.I may withdraw from the study anytime.I am signing the consent form after having read or been read form in vernacular language,including the risks and the benefitsand having all my questions answered

Subject Name: _____

Signature or the Left thumb print of Subject: _____

Witness Name: _____ Signature: _____

Investigators Name: _____ Signature: _____

Place:

Date:

ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ ಪತ್ರ

ಶ್ರೀಮತಿ _____

ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ವ್ಯಾಸಂಗ ಮಾಡುತ್ತಿರುವ ಡಾ॥ ಜಾಹ್ನವಿ ಅಟ್ಲೂರಿ, ಇವರು ಡಾ॥ ಎಮ್. ಬಿ. ಬೆಲ್ಲದ (ಎಮ್.ಎಸ್.(ಓಬಿಜಿ), ಪ್ರಾಧ್ಯಾಪಕರು, ಕೆ.ಎಲ್.ಇ. ವಿಶ್ವವಿದ್ಯಾಲಯದ ಜೆ.ಎನ್. ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯ ಅವರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ಮಾಡಿರುವ **"ಪ್ರಸವಾಸ್ಮಾರದ ಮುನ್ನ ಮತ್ತು ಪ್ರಸವಾಪಸ್ಮಾರದ ಮಹಿಳೆಯರಲ್ಲಿ ಅಗುವ ವ್ಯಾಕೋಚನದ ನಿಷ್ಕ್ರಿಯತೆಯನ್ನು ಸಾಮಾನ್ಯ ಗರ್ಭಿಣಿ ಮಹಿಳೆಯೊಂದಿಗೆ ಹೋಲಿಸಿ ಮಾಡಿರುವ ಒಂದು ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ"** (Diastolic dysfunction in preeclamptic and eclamptic women compared to normal subjects) ದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಆಮಂತ್ರಿಸುತ್ತಿದ್ದೇವೆ.

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅರ್ಹರಾಗಿರುವುದರಿಂದ ನಿಮ್ಮ ಹೆಸರನ್ನು ನೊಂದಾಯಿಸಲು ನಿಮ್ಮನ್ನು ವಿನಂತಿಸುತ್ತೇವೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸದ್ಯ ನೀವು ಅನುಭವಿಸತ್ತಿರುವ ತೊಂದರೆಗಳ ಬಗ್ಗೆ ಕೆಲವು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲಾಗುವುದು, ಅವುಗಳಿಗೆ ನೀವು ನಿಮ್ಮ ಗೊತ್ತಿರುವ ಮಾಹಿತಿಯ ಮೇರೆಗೆ ಉತ್ತರಿಸಬಹುದು. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವುದು ವೈಯಕ್ತಿಕವಾಗಿದ್ದು, ನೀವು ಇದರಲ್ಲಿ ಭಾಗವಹಿಸಿದರೂ ಅಥವಾ ಭಾಗವಹಿಸದಿದ್ದರೂ ಜೆ.ಎನ್. ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯದ ಜೊತೆಗಿರುವ ನಿಮ್ಮ ಸಂಬಂಧ ಮೇಲೆ ಯಾವುದೇ ಪರಿಣಾಮ ಉಂಟಾಗುವುದಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ಇಚ್ಛಿಸಿದರೂ ಸಹ, ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಇದರಿಂದ ಹೊರಹೋಗಬಹುದು. **ಪ್ರಸವಾಸ್ಮಾರದ ಮುನ್ನ ಮತ್ತು ಪ್ರಸವಾಪಸ್ಮಾರದ ಮಹಿಳೆಯರಲ್ಲಿ ಅಗುವ ವ್ಯಾಕೋಚನದ ನಿಷ್ಕ್ರಿಯತೆಯನ್ನು ಸಾಮಾನ್ಯ ಗರ್ಭಿಣಿ ಮಹಿಳೆಯೊಂದಿಗೆ ಹೋಲಿಸಿ, ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ ಮಾಡುವುದು ನಮ್ಮ ಈ ಅಧ್ಯಯನದ ಮುಖ್ಯ ಉದ್ದೇಶವಾಗಿರುತ್ತದೆ.**

ಅಧ್ಯಯನವು ಒಳಗೊಂಡಿರುವ ವಿಧಾನ:

ನೀವು ಸದರಿ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೊಂದಾಯಿಸಲು ಒಪ್ಪಿಕೊಂಡರೆ, ನಿಮ್ಮ ಈಗಿನ ಮತ್ತು ಹಿಂದಿನ ಕುಟುಂಬದ ಇತಿಹಾಸ ಗಳ ಬಗ್ಗೆ ಒಂದು ಸಂದರ್ಶನ

ನಡೆಸಲಾಗುವುದು ಮತ್ತು ವೈದ್ಯಕೀಯ ಪರೀಕ್ಷೆಗೆ 2ಡಿ ಎಕೊಕಾರ್ಡಿಯೋಗ್ರಫಿಯ ಮೂಲಕ ಪರೀಕ್ಷಿಸಲಾಗುವುದು.

ಅಪಾಯ ಮತ್ತು ಪ್ರಯೋಜನಗಳು:

ಈ ಅಧ್ಯಯನದಿಂದ ಪ್ರಸವಾಸ್ಥಾರದ ಮುನ್ನ ಮತ್ತು ಪ್ರಸವಾಪಸ್ಥಾರದ ಮಹಿಳೆಯರಲ್ಲಿ ಅಗುವ ವ್ಯಾಕೋಚನದ ನಿಷ್ಕ್ರಿಯತೆಯನ್ನು ಸಾಮಾನ್ಯ ಗರ್ಭಣಿ ಮಹಿಳೆಯೊಂದಿಗೆ ಹೋಲಿಸಿ ಅದರಲ್ಲಿ ಗಮನಾರ್ಹ ವ್ಯತ್ಯಾಸಗಳನ್ನು ಕಂಡುಹಿಡಿಯುವುದಾಗಿದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ಗಮನೀಯ ಅಪಾಯಗಳಿರುವುದಿಲ್ಲ.

ಸ್ವಯಂ ಪ್ರೇರಿತ ಭಾಗವಹಿಸುವಿಕೆ/ಹೊರ ಹೋಗುವುದು:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದು ಸಂಪೂರ್ಣ ವೈಯಕ್ತಿಕವಾಗಿರುತ್ತದೆ. ನೀವು ಇದರಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೊಂದಾಯಿಸದಿದ್ದರೂ ಸಹ ನೀವು ಇದರಲ್ಲಿ ಭಾಗವಹಿಸಿದರೂ ಅಥವಾ ಭಾಗವಹಿಸದಿದ್ದರೂ ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆಯ ಜೊತೆಗಿರುವ ನಿಮ್ಮ ಸಂಬಂಧ ಮೇಲೆ ಯಾವುದೇ ಪರಿಣಾಮ ಉಂಟಾಗುವುದಿಲ್ಲ.

ಪರ್ಯಾಯ/ಬದಲಿ:

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸದಿದ್ದರೂ, ನಮ್ಮ ದಿನ ನಿತ್ಯದ ನಿರ್ವಹಣೆಯಲ್ಲಿ ಯಾವುದೇ ವ್ಯತ್ಯಾಸವಾಗುವುದಿಲ್ಲ.

ಗೌಪ್ಯತೆಯ ರಕ್ಷಣೆ:

ನಿಮ್ಮ ಬಗೆಗಿನ ವಿವರಗಳು ಸಂಶೋಧನಾ ತಂಡದವರಿಗೆ ಮಾತ್ರ ತಿಳಿದಿರುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನೀವು ಒದಗಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು (ಈ ಕೆಳಗಿನ ಸಂದರ್ಭಗಳನ್ನು ಬಿಟ್ಟು) ನಿಮ್ಮ ಲಿಖಿತ ಪರವಾನಿಗೆ ಇಲ್ಲದೇ ಬೇರೆಯವರಿಗೆ ಕೊಡಲಾಗುವುದಿಲ್ಲ.

1) ನಿಮ್ಮ ಹಕ್ಕು ಮತ್ತು ಹಿತರಕ್ಷಣೆ ಸಲುವಾಗಿ ತುರ್ತು ಸಂದರ್ಭಗಳಲ್ಲಿ
2) ಯಾವುದೇ ಕಾನೂನಿನ ಪ್ರಕಾರ ಒದಗಿಸಬೇಕಾದ ಸಂದರ್ಭದಲ್ಲಿ

ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸುವ ಅಧಿಕಾರ:

ಈ ಸಂಶೋಧನೆಯ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸಿದಾಗ ಅಥವಾ ಚರ್ಚಿಸುವಾಗ ನಿಮ್ಮ ಯಾವುದೇ ವೈಯಕ್ತಿಕ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಕೊಡಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗುವುದು.

ಭಾಗವಹಿಸುವುದರಿಂದ ಆರ್ಥಿಕ ಪ್ರೋತ್ಸಾಹಗಳು:

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೊಂದಾಯಿಸಿದರೆ ನಿಮಗೆ ಯಾವುದೇ ಆರ್ಥಿಕ ಪ್ರೋತ್ಸಾಹಗಳನ್ನು ಕೊಡಲಾಗುವುದಿಲ್ಲ. ಇದನ್ನು ಕೇವಲ ಸಂಶೋಧನೆಗಾಗಿ ಮಾಡಲಾಗುವುದು ಮತ್ತು ಇದರ ಎಲ್ಲ ಖರ್ಚುವೆಚ್ಚಗಳನ್ನು ಸಂಶೋಧಕರೇ ಭರಿಸುತ್ತಾರೆ.

ಪರಿಹಾರ:

ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಪಟ್ಟಂತೆ ನಿಮಗೆ ಯಾವುದೇ ಗಾಯಗಳಾದರೆ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ. ವತಿಯಿಂದ ಚಿಕಿತ್ಸೆ ನೀಡಲಾಗುವುದು. ಈ ರೀತಿಯ ವೈದ್ಯಕೀಯ ಚಿಕಿತ್ಸೆಗೆ ಯಾವುದೇ ಪರಿಹಾರಧನ ಕೊಡಲಾಗುವುದಿಲ್ಲ. ನಿಮಗೆ ಯಾವುದೇ ಗಾಯವಾದ ಸಂದರ್ಭದಲ್ಲಿ ನೀವು ಡಾ॥ ಜಾಹ್ನವಿ, ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ., ಮೊಬೈಲ: 9844953099 ಇವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಪ್ರಶ್ನೆಗಳು:

ಈ ಅಧ್ಯಯನದಿಂದಾಗಿ ಉಂಟಾಗಿರುವ ಯಾವುದೇ ಗಾಯ ಅಥವಾ ಅನಾರೋಗ್ಯಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ, ನೀವು ಡಾ॥ ಜಾಹ್ನವಿ, ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ., ಫೋನ್: 0831-2551292 ಅಥವಾ ಮೊಬೈಲ: 9844953099, ಅಥವಾ ಡಾ॥ ಬೆಲ್ಲದ, ಪ್ರಾಧ್ಯಾಪಕರು, ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ., ಫೋನ್: 0831-2551292 ಅಥವಾ ಮೊಬೈಲ: 9448124893 ಇವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪ್ರಯೋಗಾರ್ಥಿಯಾಗಿ ನಿಮ್ಮ ಹಕ್ಕುಗಳ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ, ನೀವು ಡಾ॥ ಗಂಗಾ ಪಿಳ್ಳೈ, ಪ್ರಾಧ್ಯಾಪಕರು ಮತ್ತು ಪೆಥಾಲಾಜಿ ವಿಭಾಗದ ಮುಖ್ಯಸ್ಥರು, ಜೆ.ಎನ್. ಮೆಡಿಕಲ್ ಕಾಲೇಜ್ ಇನ್ಸಸ್ಟಿಟ್ಯೂಷನಲ್ ಎಥಿಕ್ಸ್ ಕಮೀಟಿ ಆನ್ ಹ್ಯುಮನ್ ಸಬ್ಜೆಕ್ಟ್ಸ್ ರಿಸರ್ಚ್, ಫೋನ: 0831-2473777 ext-1527, ಮೆಡಿಕಲ್ ಕಾಲೇಜು ಬೆಳಗಾವಿ ಅಥವಾ ಮೊಬೈಲ ನಂ. 9480275601 ಇವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಈ ಸಂಶೋಧನಾ ಪ್ರಯೋಗದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ

ಈ ಕೆಳಗೆ ಸಹಿ ಮಾಡಿದ _____

ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಂಡಿರುತ್ತೇನೆ. ಈ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಮಾಡುವುದರಿಂದ ನಾನು ನನ್ನ ಯಾವುದೇ ಕಾಯದೆಬದ್ಧ ಹಕ್ಕುಗಳನ್ನು ಬಿಟ್ಟುಕೊಟ್ಟಿರುವುದಿಲ್ಲ. ನಾನು ಯಾವುದೇ ಸಂದರ್ಭದಲ್ಲಿ ಈ ಅಧ್ಯಯನದಿಂದ ಹೊರಹೋಗಬಹುದು. ನಾನು ಈ ಅಧ್ಯಯನವು ಒಳಗೊಳ್ಳುವ ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳು ಹಾಗೂ ಪ್ರಶ್ನೆಗಳಿಗೆ ನಾನು ಕೊಟ್ಟಿರುವ ಉತ್ತರಗಳನ್ನು ನನ್ನ ಮಾತೃಭಾಷೆಯಲ್ಲಿ ಓದಿ, ತಿಳಿದುಕೊಂಡು ನನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು ಕೊಟ್ಟಿರುತ್ತೇನೆ.

ಪ್ರಯೋಗಾರ್ಥಿ ಹೆಸರು : _____

ಪ್ರಯೋಗಾರ್ಥಿಯ ಸಹಿ: _____ ದಿನಾಂಕ: _____

ಸಾಕ್ಷಿಯ ಹೆಸರು: _____ ಸಹಿ:_____ ದಿನಾಂಕ: _____

ಸಂಶೋಧಕರ ಹೆಸರು: _____ ಸಹಿ: _____ ದಿನಾಂಕ:_____

ಸ್ಥಳ: _____

महिलांचे अध्ययनात सहभागी होण्यासंबंधीचे माहिती पत्र

प्री.एक्लॅम्प्टीक आणि एक्लॅम्टीक महिला आणि सामान्य गरोदर महिला यांच्यामध्ये २ डी एकाकार्डीओग्राफी ने होणारे डीस्टॉलिक डी सफंक्शन

हॉस्पीटलस्थीने केस कंट्रोल अभ्यास

मुख्य संशोधकाचे नांव : डॉ. एम. बी. बेह्लद, एम एस. (obG) प्राध्यापक, (प्रस्तुती विभाग आणि स्त्रीरोग विभाग) के एल ई विद्यापिठाचे जवाहरलाल नेहरु मेडिकल कॉलेज, बेळगाव.

सह संशोधकाचे नांव : डॉ जान्हवी अटलुरी प्रसुती विभाग आणि स्त्रीरोग विभागाचे पोस्ट ग्रॅज्युएट के एल ई विद्यापिठाचे जवाहरलाल नेहरु मेडिकल कॉलेज

संस्थेचे नांव : के एल ई युनिव्हर्सिटीजचे जवाहरलाल नेहरु मेडिकल कॉलेजचे , महिला आणि मुलांचे आरोग्य संदर्भात शोध करणारे युनिट

तुम्हाला विनंती करण्यात येत आहे कि, आम्ही प्री प्री.एक्लॅम्प्टीक आणि एक्लॅम्टीक महिला यांच्यात आणि सामान्य गरोदर महिला यांच्यात होणारा हदयाच्या बिघाडांचा तुलनात्मकरित्या अभ्यास करत आहोत. त्यामध्ये सहभागी होण्याचा. हा अभ्यास डॉ. जान्हवी अटलुरी ज्या प्रस्तुतीशास्त्र आणि स्त्रीरोग या विषयावरच्या पोस्ट ग्रॅज्युएट आहेत त्या डॉ. एम बी बेह्लद एम एस (OBG) प्राध्यापक प्रस्तुती आणि स्त्रीरोग विभाग जे.एन मेडिकल कॉलेज बेळगावी के एल ई युनिव्हर्सिटी या संस्थेअंगर्गत आहे त्यांच्या मार्गदर्शनाखाली हा अभ्यास करत आहेत. या अभ्यासामूळे हायब्लडप्रेशर मुळे रोग आणि होणारे जीवितहानी टाळण्यास मदत होईल.

आम्ही अशी विनंती करतो की तुम्ही आमच्या या अभ्यासात सहभागी होण्याकरता आपले नांव नोंदवावे. जसे की तुम्ही या अभ्यासात सहभागी होण्याकरीता लायक असाल. या अभ्यासा दरम्यान तुमच्या सद्यस्थितीतील तक्रारीविषयी काही प्रश्न विचारले जातील. आणि तुम्ही त्या प्रश्नांचे उत्तर तुमच्य माहितीप्रमाणे योग्य ते उत्तर देणे आहे.

या अध्ययनामध्ये सहभागी होण्याचा निर्णय ऐच्छिक आहे. या अध्ययनामध्ये सहभागी होण्याचा अथवा न होण्याच्या तुमच्या निर्णयामुळे तुमच्या जे. एन मेडिकल कॉलेजबरोबर असलेल्या संबंधामध्ये कोणताहि फरक पड़णार नाही. जर तुम्हाला या अभ्यासामध्ये सहभागी व्हायचे नसेल तर कोणत्याही क्षणी तुम्ही माघार घेऊ शकता.

* **अध्ययनाचे उद्देश :** सामान्य गरोदर महिलामध्ये आणि प्री.एक्लॅम्प्टीक आणि एक्लॅम्टीक महिला मध्ये असणाऱ्या हदयाच्या बिघाडांचा तुलनात्मक रित्या अभ्यास करणे.

* **कार्यपध्दती :** तुम्ही जर अध्ययनामध्ये सहभागी होण्यास होकार दर्शविला की तुमच्याकडून काही माहिती जमा केली जाईल. आणि तुमच्यावर एक २ डी एकाकॉर्डीयोग्राफी (अल्ट्रासाओंडद्वारे हदयाचे मोजमाप) नावाची पध्दत अवलंबीली जाईल.

* **फायदे आणि नुकसान :** हा अभ्यास तुम्हाला थेट असा फायदा पोहोचवू शकेल अथवा नाही. जर तुमचो २ डी एकोकॉडीयोफी केस असेल तर तुमच्या व्यवस्थापनाकरिता ती उपयोगी पडू शकेल तसेच तो भविष्यात गरोदर महिलामधील गुंतागुंतीची व्यवस्था करण्यास मदत करु शकते. या अभ्यासामुळे तुम्हाला अथवा तुमच्या बाळाला कोणतीही धोका नाही.

* **ऐच्छिक सहभाग /माघार :** या अध्ययनात भाग घेणे ऐच्छीक आहे तुम्ही तुम्हाला या अध्ययनामध्ये नाव नोंदवण्यास नका देवू शकता. तुमच्या निर्णयमुळे तुमच्या सद्यस्थितीमधील अथवा भविष्यामधोल के.एल ई एस हॉस्पीटलमधील आरोग्य सुविधावर कोणताही परिणाम होणार नाही.

* **इतर मार्ग:** तुम्ही अध्ययनात भाग घेण्यास नकार दिला तरी तुम्हाला हॉस्पीटलमध्ये इतर गरोदर महिलाप्रमाणेच उपचार केले जातील.

***खासगी व गोपनियता:** तुम्ही एका शोधाचा विषय आहात हे फक्त शोधकर्त्याच्या गटालाच माहित असेल जे की डॉ. एम बी. बेह्नद, डॉ सुरेश पट्टेड, डॉ अंकूर बात्रा, डॉ जान्हवी आणि मिस रश्मी हे असतील तुम्ही आम्हाला एक ओळखपत्र देवू जे की गोपनिय असेल आणि फक्त आमचीच त्या ओळखपत्रापर्यंत पोहोच असेल. तुमच्या बद्दलची कोणतीही माहिती, तसेच तुम्ही आम्हाला या अध्ययना दरम्यान पुरवलेला तुमची माहिती तुमच्या लिखित परवानगी शिवाय दुसऱ्याला देणार नाही. फक्त काही कारणे सोडून

१) आणीबाणीमध्ये तुमचे आधिकार आणि तुमचे स्वास्थ जपण्याकरीता

२) कायद्यानुसार गरज भासल्यास

* **अभ्यासाचे परिणाम प्रकाशीत करण्यासंबंधीचे हक्क :**

जेव्हा या अभ्यासाचे परिणाम प्रकाशीत केले जातील अथवा त्यावर चर्चा होईल. त्यावेळी अशी कोणतीही माहिती मांडली जाणार नाही. त्याद्वारे तुमची ओळख स्पष्ट होईल. अशी कोणतीही माहिती या अभ्यासादरम्यान घेतलेली नसेल त्या माहितीनुसार तुमची ओळख पटविली जाऊ शकते. ती गोपनिय राखली जाईल.

* **भाग घेण्यास आर्थिक लाभ :** या अध्ययनामध्ये भाग घेतलेल्यांना कुठलेही आर्थिक लाभ मिळनार नाही.

* **प्रश्ने :** तुम्ही अध्ययनासम्बधी कोणताही प्रश्न विचारणार असाल तर

डॉ जान्हवी अटलुरी प्रसुती विभाग आणि स्त्रीरोग विभागाचे पोस्ट ग्रॅज्युएट के एल ई विद्यापिठाचे जवाहरलाल नेहरु मेडिकल कॉलेज बेळगांवी फोन नं. ९४४८१२४८९३

तुम्ही संशोधनात भाग घेऊन हक्काकरीता कुठलाही प्रश्न विचारणार असाल तर, डॉ. (श्रीमती) गंगा एस. पिल्ली, कार्याध्यक्ष संस्थिक नैतिक समिती, मानव संशोधन विभाग, जे.एन.एम.सी, बेळगावी ५९००१०. फोन नं. ९४८०२७५६०१ किंवा एक्सटेन ०८३१- २४७४०५२.

सम्मति पत्र

मी ----------

स्वखुशीने या अध्ययनात भाग घेणेस संमती दिलेली आहे. पण माझ्या कायदेशिर हक्क सोडलेले नाही. मी मला नको झालेतर या अध्ययनातून बाहेर पडतो. हे संमती पत्र वाचून घेऊन मला माझी मात्र भाषामध्ये वाचून समजल्यानंतर ऐकून जबाबदारी आणि प्रयोजन वगैरे ला उत्तर दिल्यानंतर या खालील सही केलेली आहे.

विषयाचे नाव (अभ्यर्थी) : ----------

सही:/ डाव्या हाताचा निशान : ----------

साक्षी : नांव : ----------सही ----------

इनव्हेस्टीगेटर्स नांव ----------सही ----------

दिनांक :

स्थळ :

ANNEXURE III – SCREENING FORM

DIASTOLIC DYSFUNCTION BY 2D-ECHOCARDIOGRAPHY IN PRE-ECLAMTIC & ECLAMPTIC WOMEN VS NORMAL PERGNENT WOMEN : A HOSPITAL BASED CASE CONTROL STUDY

ELIGIBILITY FORM

Date:-

Name of the pregnant women :- Idno

Addresss Tel No:

Age

IP No-

OP No-

LMP- DD MM YYYY

EDD- DD MM YYYY

Gestational age- Weeks Days

Gravida

Para

Living

Haemoglobin gm

Dose she have any cardiac disease 1.Yes 2.No

Does she have any exclusion criteria 1.Yes 2.No

Has she consented 1.Yes 2.No

Eligible and consented

Eligible and not Consented

ANNEXURE IV– DATA COLLECTION INSTRUMENT

"DIASTOLIC DYSFUNCTION BY 2D-ECHOCARDIOGRAPY IN PRE-ECLAMPSIA & ECLAMPSIA WOMEN V/S NORMAL PREGNANT WOMEN: A HOSPITAL BASE CASE CONTROL STUDY"

Data Collection Instrument

Id no ☐☐☐

Gestational Age- ☐☐ weeks ☐ Days

Height ☐☐☐ cm Weight ☐☐ kg

BMI ☐☐ kg/m^2

Pulse ☐☐ bpm

B.P. Systolic in mmHg ☐☐☐

Diastolic inmmHg ☐☐☐

Proteinuria- 1+ ☐ 2++ ☐ 3+++ ☐ 4 ++++ ☐

Jaundice- 1.Yes ☐ 2.No ☐

USG

Gestational Age- ☐☐ weeks ☐ Days

AFI- ☐☐ cm

Liver function Tests

Total Bilirubin-

Direct Bilirubin-

Total protein-

Sr.Albumin-

AST-

ALT-

Alkaline phosphatase-

LDH

Platelet count

Fundoscopy findings

Echocardiodiographic variables:

E wave velocity time integral-

Deceleration time of E wave-

Isovolumetric ventricular relaxation time-

A wave-

A wave velocity time integral-

Duration of A wave-

Peak E/Peak A Ratio-

Peak pulmonary venous systolic flow-

Pulmonary venous systolic time velocity integral-

Peak Pulmonary Venous diastolic flow-

Pulmonary venous diastolic velocity time integral –

Peak Pulmonary venous flow at time of atrial contraction-

Pulmonary venous velocity time integral at atrial at atrial contraction-

Duration of pulmonary venous flow at atrial contraction –

Difference in duration between pulmonary venous flow at atrial -

Systolic fraction of pulmonary vein flow –

Maternaloutcome: ☐

Congestive cardiac failure- 1.Yes

2.No ☐

Pulmonary edema- 1.Yes ☐

2.No ☐

ANNEXURE V

KEYWORDS FOR MASTER CHART

Y - yes

N - no

BMI - Body mass index

UAD - Umbilical artery doppler

LFT - Liver function tests

T.B - Total bilirubin

D.B - Direct bilirubin

T.P - Total proteins

AST- - Aspartate transaminase

ALT - Alanine transaminase

ALP - Alkaline phosphatase

LDH - Lactate dehydrogenase

E-VTI - E wave velocity time integral

DtE - Deceleration time of E wave

IVRT - Isovolumetric relaxation time

A-VTI - A wave velocity time integral

DurA - Duration of A wave

PPVSF - Peak pulmonary venous systolic flow

PVSVTI - Pulmonary venous systolic velocity time integral

PPVDF - Peak pulmonary venous diastolic flow

PVDVTI - Peak pulmonary venous diastolic flow velocity time integral

PPVF at atrial contraction - Peak pulmonary venous flow at atrial contraction

PVVTI - Pulmonary venous velocity time integral at the time of atrial contraction

DurPVF at AC- Duration of pulmonary venous flow at atrial contraction.

PVF at AC-Difference in duration between pulmonary venous flow at atrial contraction and A wave

Sys frac of PVF- Systolic fraction of pulmonary venous flow

CCF –Congestive cardiac failure