

Effects of Yoga in High-Risk Pregnancy

Thesis

Submitted in partial fulfillment of

Doctor of Philosophy

By

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UNDER THE GUIDANCE OF

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Submitted to



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CERTIFICATE

This is to certify that Mr Abbas Rakhshani is a Ph.D. scholar bearing the university registration number of PhD/001/RES/2007 with effect from January 11, 2007 under the Division of Yoga and Life Sciences. He has successfully completed the prescribed course work and training in acquiring the relevant background knowledge related to the effect of yoga in high-risk pregnancy. This thesis entitled '**Effects of Yoga in High-Risk Pregnancy**' is based on the bonafide work carried out by him as per the regulations of the University.

Further it is declared that the subject matter of this thesis has not formed the basis for the award of any degree, diploma, associate-ship, fellowship or similar titles previously.

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DECLARATION

I hereby declare that this study was conducted by me at Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA), Bengaluru, under the guidance of Dr Raghuam Nagarathna, Dean, Division of Yoga and Life Sciences, Swami Vivekananda Yoga Anusandhana Samsthana, Deemed University, Bengaluru, India.

I also declare that the subject matter of my thesis entitled EFFECTS OF YOGA IN HIGH-RISK PREGNANCY has not formed the basis of the award of any degree, diploma, associate-ship, fellowship or similar titles previously.

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Date:

ABBAS RAKHSHANI

STANDARD INTERNATIONAL SANSKRIT TRANSLITERATION CODES

a	अ	ka	क	ḍa	ड	ma	म
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e	ए	cha	छ	dha	ध	śa	श
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K+a	क	K+ī	की	K+e	के	K+au	कौ
K+ā	का	K+u	कु	K+ai	कै	K+m	कं
K+i	कि	K+ū	कू	K+o	को	K+ḥ	कः

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Abstract

BACKGROUND

Both pregnancy and labor can be highly stressful events in any woman's life due to many physiological and psychological changes that may cause several problems. The psychological stress is magnified in high-risk pregnancies, where there are higher chances of complications. In spite of mounting evidence with strong correlation between maternal stress and pregnancy outcomes, the present conventional management of the pregnancy complications considers preterm delivery as the most viable treatment option, and this can substantially jeopardize the health of the newborn. Therefore, prevention of these serious pregnancy complications would have high public health and economic significance. In low-risk pregnancies, the effects of exercise and other complementary therapies have been investigated. In particular, there are a few trials, related to the present study, that have used yogic practices in their investigations. These studies have shown yoga to be an effective therapy for treatment of several lifestyle related diseases that are also known to be major risk factors for pregnancy complications including hypertension, diabetes mellitus, and obesity. Therefore, there is a need to look at traditional practices, which help in yogic lifestyle for positive health during pregnancy and offer a strong social acceptance for making pregnancy and childbirth a spiritual experience. Furthermore, yoga has been documented to improve pregnancy outcomes in part by reducing maternal stress. This randomized controlled trial investigated the effects of yoga in prevention of pregnancy complications in high-risk pregnancies for the first time.

METHODS

Aims: To assess the effects of yoga in high-risk pregnancy through a set of biological, psychological, and scientific parameters. Objectives: The objectives of this study was to investigate whether 16 weeks of yoga practice would: (i) be safe and feasible in hospital settings, (ii) reduce incidence of pregnancy complications in high-risk pregnant women, (iii) improve pregnancy outcomes in high-risk pregnant women as compared to standard care, and (iv) improve the blood flow to the uteroplacental and fetal arteries. Design: This was a single-blind prospective stratified randomized controlled clinical trial on 68 pregnant women at high risk of developing pregnancy complications. Sample size: The sample size was calculated using the data from a Japanese study that investigated simple yoga-like water exercises in prevention of preeclampsia. With α set at 0.05, probability of type I error at 0.01, and

powered at 0.8, a minimum sample size of 27 per group was obtained. Settings: The study was conducted at the obstetric unit of St. John's Medical College & Hospital (SJMCH) and Gunasheela Maternity Hospital (GMH) in Bengaluru, India. All subjects signed the informed-consent form approved by the ethical committee of SJMCH before recruitment. Interventions: The yoga group received standard care plus one-hour yoga session three times a week from the beginning of the 13th week to the end of the 28th week of gestation (a total of 28 sessions), while the control group received standard care plus advice for walking for half an hour mornings and evenings (the routine antenatal exercise offered by the hospital) during the period of the study. Measurements: Maternal and fetal measurements were assessed at the 12th week, 20th week, and 28th week gestation. Pregnancy outcomes and frequency of complications were recorded at the time of delivery. Timeline: The data collection began in February 2010 and continued till April 2011. Data analysis and preparation of the manuscripts started in May 2011.

RESULTS

Safety and Feasibility: No report of adverse events due to yoga interventions were recorded and the yoga practices were received well both by the subjects and the hospital staff. Conducting the yoga classes in the hospital premises was found to be quite feasible. Pregnancy Complications: There were 11 (36.7%) cases of pregnancy induced hypertension in the control group and 3 (10.3%) cases in the study group ($p=0.02$, chi2). The incidents of preeclampsia was also significantly less in the yoga group (0% in the yoga group versus 13.3% in the control, $p=0.04$, chi2). There were two cases of eclampsia in the control group and none in the yoga group. The yoga group had significantly fewer cases of intrauterine growth restriction ($p=0.05$, chi2) and preterm deliveries ($p=0.04$, chi2). There were also fewer occurrences of GDM in the yoga group ($p=0.05$, chi2). Fetal Outcomes: Significantly fewer babies born from the women in the yoga group had low APGAR scores after 1 and 5 minutes of delivery ($p=0.01$ and $p=0.04$ chi2, respectively). There were significantly lower small for gestational age newborns in the yoga group than in the control group ($p=0.03$, chi2). However, the number of large for gestational age and low birth weight babies were not significantly different between the groups ($p=0.12$ and 0.76 chi2, respectively). Ultrasound Fetal Measurements: RM-ANOVA results was significant for fetal biparietal diameter ($p<0.001$), femur length ($p=0.005$), fetal heart rate ($p=0.006$), and estimated fetal weight ($p=0.019$) but near significant in case of abdominal circumference ($p=0.099$). Doppler

Measurements: Right Uterine Artery- Systolic/Diastolic (S/D) ratio, Pulsatility Index (PI), and Resistance Index (RI) were significantly better in the yoga than the control group after 16 weeks of intervention ($p=0.001$, 0.01 , and 0.001 ANCOVA, respectively). Left Uterine Artery- only the RI was significantly better in the yoga group than the control group after 16 weeks of intervention ($p=0.013$ ANCOVA). Umbilical Artery- the S/D ratio was significantly better in the yoga than the control group after 8 ($p=0.001$ T-test) and 16 weeks ($p=0.031$ T-test) of intervention; the PI was highly significant at both measurements in time ($p=0.001$ Mann Whitney); but RI was only significant after 4 weeks of intervention ($p=0.011$ Mann Whitney). Fetal Middle Cerebral Artery - the S/D ratio, PI, and RI were significantly better in the yoga than control group after 16 weeks of intervention ($p=0.01$, 0.013 , and 0.045 Mann Whitney, respectively).

CONCLUSION

Yoga is an effective tool in the management of high-risk pregnancies and this module of yoga has proven to be safe and feasible. Furthermore, the yoga interventions used in this study has shown to improve the blood flow to the uterine and fetal arteries.

RECOMMENDATIONS FOR FUTURE STUDIES

Independent RCTs investigating the impact of yoga on each of the risk factors could offer better insight on the mechanism of action of yoga. Also, a study that starts the yoga interventions much earlier in the first trimester, or even before conception, could provide more information on the role of yoga in placentation and oxidative stress.

CHAPTER 1

INTRODUCTION

CHAPTER CONTENTS:

- Background
- Definitions of Complications of Pregnancy
- Prevalence of Complications of Pregnancy
- Need for Mind-Body Interventions
- Need for This Study

Chapter 1: Introduction

Pregnancy and childbirth constitute significant events in the life of a woman. Advances in science, technology, and management have offered many tools to obstetric practices. Systematic implementation of these tools in the antenatal health programs have saved many lives with reduced maternal and infant mortality.¹ However, they have not been able to explain the root cause of pregnancy complications. As a result, the prevalence of many life style and stress related disorders of pregnancy are on the rise.²

Clearly, there is an urgent need for a holistic approach to the management of pregnancy complications. Not only does a pregnant woman during this phase of her life require a great deal of support from her family members, but she must also care for herself and follow a healthy regime to ensure the experience to be a rewarding one. The Vedic literature prescribes one such time-tested regiment. These guidelines contain various details related to ahara (nutrition), vihara (lifestyle), and vichara (thought process), which women have to follow at different stages of pregnancy. Diet also plays a major role. SVYASA University has conducted a couple of previous investigations on the effects of yoga in normal pregnancies that are reviewed in Chapter 3. This is the first randomized controlled trial that has investigated the effects of yoga in high-risk pregnancies.

The first three chapters of this manuscript are dedicated to providing general background information about pregnancy. The first chapter offers definitions of some terms frequently used in the rest of the manuscript. The second chapter describes the Vedic approach toward pregnancy and the third chapter reviews the scientific background on the subject. The remaining chapters provide information specific to this study and its results.

1.1 Background

Both pregnancy and labor can be highly stressful events in any woman's life due to many physiological and psychological changes that may cause several problems. These could be simple inconveniences, such as sleep disturbance³, some discomfort⁴, back pain⁴, edema⁵, heightened labor pain⁶, and anxiety due to the uncertainty of the outcome⁷. However, the problems could be serious, like pregnancy induced hypertension,⁸ preeclampsia,⁹ eclampsia,¹⁰

intrauterine growth restrictions,¹¹ HELLP Syndrome,¹² or gestational diabetes,¹³ which can be life-threatening. Stress has been shown to play a significant role in the etiology of many pregnancy complications; particularly in high-risk pregnancies.⁷

High-risk pregnancy is defined to be a pregnancy affected by complications that may affect the mother, the fetus, or both and may occur at different times during the pregnancy.¹⁴ American Pregnancy Association lists about 39 such pregnancy complications on their web site, which are presented in Table 1.1 (data from American Pregnancy Association, 2012, Pregnancy Complications, retrieved on 12-12-2012) The common pregnancy complications in the list include: Ectopic pregnancy, RH negative disease, group B strep, preterm delivery, gestational diabetes, and low birth weight. In our study, we only investigated the following conditions and the term ‘pregnancy complications’ in this context refers only to pregnancy-induced hypertension, preeclampsia, eclampsia, gestational diabetes, intrauterine growth restriction, small and large for gestational age babies, low birth weight babies, and preterm delivery.

Table 1.1: List of Major Pregnancy Complications

1	Bacterial Vaginosis	14	Fetal Growth Restriction	27	Molar Pregnancy
2	Bed Rest	15	Gestational Diabetes	28	Placenta Accreta
3	Bleeding During Pregnancy	16	Gestational Hypertension	29	Placenta Previa
4	Blighted Ovum	17	Group B Strep Infection	30	Placental Abruption
5	Cervical Cerclage	18	HELLP Syndrome	31	Preeclampsia
6	Chicken Pox	19	Incompetent Cervix	32	RH Factor
7	Common Pregnancy Complications	20	HIV/AIDS during Pregnancy	33	Concerns regarding Early Fetal Development
8	Cholestasis of Pregnancy	21	Hyperemesis Gravidarum	34	Yeast Infection
9	Small for Gestational Age	22	Urinary Tract Infection	35	Tipped Uterus
10	Cytomegalovirus Infection	23	Listeria	36	Toxoplasmosis
11	D&C procedure after a Miscarriage	24	Intrauterine Growth Restriction (IUGR)	37	High Amniotic Fluid Levels : Polyhydramnios
12	Ectopic Pregnancy	25	Miscarriage	38	Vanishing Twin Syndrome
13	Fetal Alcohol Spectrum Disorders	26	Low Amniotic Fluid Levels : Oligohydramnios	39	STD'S & STI'S During Pregnancy

1.2 Definitions of Complications of Pregnancy

1.2.1 HYPERTENSIVE DISORDERS OF PREGNANCY

Presence of hypertension during pregnancy can lead to many disorders, which are collectively referred to as hypertensive disorders of pregnancy.¹⁵ The National Heart, Lung, and Blood Institute (NHLBI) categorizes hypertensive disorders of pregnancy as follows: preeclampsia/eclampsia, pregnancy induced hypertension, the continued presence of chronic hypertension, and the superimposition of preeclampsia on chronic hypertension.¹⁵ In this study, we will only investigate pregnancy induced hypertension, preeclampsia, and eclampsia.

1.2.1.1 PREGNANCY INDUCED HYPERTENSION

Pregnancy induced hypertension (PIH) refers to the development of new arterial hypertension (BP systolic ≥ 140 mm Hg ; diastolic ≥ 90 mm Hg) after 20 weeks gestation without proteinuria represent clinical manifestation of PIH.

1.2.1.2 PREECLAMPSIA

Preeclampsia (PE) is a serious pregnancy disorder that can threaten the life of the mother and her infant.¹⁵⁻¹⁷ PE consists of PIH accompanied by new-onset proteinuria (defined as 24-hour urine protein ≥ 300 mg) that typically develops after 20-weeks of gestation¹⁸ and remits after delivery.¹⁹ In the mother, PE can cause placental abruption, renal and/or hepatic failure, cerebral hemorrhages, pulmonary edema, and stroke.²⁰ In the fetus, PE can result in intrauterine growth restriction, pre-term birth (about 15% of all pre-term births),²¹ and stillbirth.²² It is shown that PE increases the risk of cardiovascular diseases in both mother and the infant in later life; with maternal morbidity due to these complications increasing two folds.²³

1.2.1.3 ECLAMPSIA

Eclampsia is the advanced form of PE, which involves convulsion. Such convulsions, endangering the life of both the mother and the fetus, usually occur after mid-pregnancy or during delivery, but as many as one third of eclamptic convulsions occur during the first 48 hours of the immediate postpartum period.²⁴

1.2.2 GESTATIONAL DIABETES MELLITUS

Gestational Diabetes Mellitus (GDM) puts the woman and the fetus at higher risk of other complications during pregnancy, including: intrauterine growth restriction, and intrauterine fetal death.¹⁶ The Fourth International Workshop-Conference on Gestational Diabetes defined GDM as any degree of glucose intolerance with onset or first recognition during pregnancy.²⁵ More specifically, a fasting plasma glucose level in two consecutive days of greater than 126 mg/dl (7.0 mmol/l) or a non-fasting plasma glucose of greater than 200 mg/dl (11.1 mmol/l) meets the threshold for the diagnosis of GDM.²⁶

1.2.3 INTRA-UTERINE GROWTH RESTRICTION

Intrauterine growth restriction (IUGR) refers to a condition that the fetal weight is below the 10th percentile for gestational age as determined through an ultrasound.²⁷ This can also be called small-for gestational age (SGA) or fetal growth restriction.²⁷ There are numerous causes for IUGR, including placental dysfunction.²⁸ IUGR is associated with sequelae during childhood that include both short stature and a higher incidence of learning and behavioral difficulties.²⁹

1.2.4 SMALL FOR GESTATIONAL AGE AND LARGE FOR GESTATIONAL AGE

Small for gestational age (SGA) is defined as infants with a birthweight lower than the 10th percentile for their gestational age; whereas, those that are above the 90th percentile are categorized as large for gestational age (LGA).³⁰ The term SGA should not be used as a synonym for IUGR. The term IUGR refers to insufficient growth of the fetus in the presence of at least 2 assessments of intrauterine growth, which show clearly that the fetus is not growing appropriately.³¹ In the absence of information about fetal growth, the term SGA can be used, which refers to body size that is of low weight and/or length for a known gestational age.³¹

1.2.5 LOWBIRTH WEIGHT

Low birthweight (LBW), as defined by the World Health Organization, is birth weight less than 2500 grams, irrespective of the duration of the gestational period.^{32, 33} LBW is prevalent in many countries and poses a significant public health problem contributing to a variety of

short- and long-term negative effects. While in the industrialized countries about half of LBW infants are born preterm (< 37 weeks' gestation), in the rest of the world, most of these LBW infants are born full-term.³⁴ In particular, India has a very high rate of LBW infants. The current estimate is that nearly one-third of all Indian infants weigh less than 2.5 Kg at birth (information from Nutrition Foundation of India, 2005, Twenty-Five years report 1980-2005). For a summary of the definitions of the pregnancy complications studied in this trial, please see Table 4.1 in chapter 4.

1.3 Prevalence of Pregnancy Complications

Nearly 25% of all pregnancies end up with some complications other than c-sections.²⁸ Hypertensive disorders of pregnancy, which affect an estimated 5 to 8% percent of pregnancies in the United States, contribute significantly to serious complications for both the fetus and the mother.¹⁵ Preeclampsia and eclampsia are recognized as a leading cause of maternal and perinatal morbidity and mortality throughout the world.¹⁶ World Health Organization (WHO) estimates that about 6 to 8% of the pregnancies in the US are affected by these disorders.¹⁷ The Preeclampsia Foundation approximates the financial cost of these complications at a staggering \$7 billion dollars to the United States alone and the human cost at about 18% of US maternal deaths.³⁵ Perhaps what is more troubling is that the incidents of preeclampsia have risen over 40% in the past few decades.³⁶

Approximately 4-8% of all infants born in developed countries and 6-30% in developing countries are classified as growth restricted.³⁷ This figure is dramatically increased to 12-47% of all twin pregnancies, making multiple pregnancy a major and most common cause of IUGR.³⁷ However, the figures vary depending on the population under examination (including its geographic location) and the standard growth curves used as reference.³⁸ The immediate neonatal mortality of infants affected by IUGR is about 6 times more than the normal newborn.²⁷ Perinatal asphyxia involving multiple organ systems is one of the most significant problems in growth-restricted infants.³⁹ Most of these babies die within 24 hours of birth.²⁷

It is not just the incidence of hypertensive disorders of pregnancies that have been rising. The American Diabetes Association has reported that GDM affects 1%–14% of all pregnancies globally, and that its incidence has been steadily increasing.⁴⁰ Women with GDM have increased risk of developing type 2 diabetes in the years following the pregnancy⁴¹ and their offsprings face increased risk of childhood obesity and early onset of type 2 diabetes mellitus⁴².

Preterm deliveries, which affected only 9.4% of live births in the United States in 1981, affected 12.5% of this population in 2004.⁴³ In fact, the United States' Institute of Medicine has reported that the incidence of preterm birth has increased markedly in the last two decades.⁴³ Other data has confirmed these figures, showing that, in 2006, 12.8% of births were preterm, which represented a 21% increase compared to 1990.⁴⁴ This increase is very alarming when you consider that excluding congenital malformations, about 75% of perinatal deaths and 50% of neurological abnormalities are directly attributed to preterm.⁴⁴

1.4 Need for Mind-Body Interventions

In the last section, we saw that the prevalence of pregnancy complications are on the rise. The reason for this increase is not clear yet. Some authors have hypothesized that the increase in obesity⁴¹ and decrease in physical activities⁴⁵ of women are the major causes. However, the majority have implicated the increase in maternal stress due to modern lifestyle for this rise.^{46,47} Psychological and social stress can cause an imbalance between the activities of the sympathetic and the parasympathetic nervous system in the mother.⁴⁷ Stress, in itself, is a natural and necessary reaction to demanding situations, which engages the sympathetic nervous system to handle the situation.⁴⁸ Once the source of stress has been removed, the parasympathetic nervous system gets activated to restore the body to its homeostasis.⁴⁸ However, today's stressful lifestyle doesn't include enough true relaxation for the body to restore its equilibrium.⁴⁸ Therefore the sympathetic nervous system continues to be active--flooding the body with stress related hormones with adverse side-effects to the health of the individuals.^{47,49} When this condition becomes chronic, the body remains in the state of sympathetic hyperactivity even when the individual is resting and having no active stress.⁴⁹ This can contribute to excessive vasoconstriction and elevated blood pressure.⁴⁷

1.5 Need for This Study

In spite of mounting evidence with strong correlation between maternal stress and pregnancy outcomes, the present conventional management of the pregnancy complications considers preterm delivery as the most viable treatment option,⁵⁰ and this can substantially jeopardize the health of the newborn.⁵¹ Therefore, prevention of these serious pregnancy complications would have high public health and economic significance.

In low-risk pregnancies, as we will see in chapter 3, the effects of exercise and other complementary therapies have been investigated. In particular, there are a few trials that have used yogic practices in their investigations, which are relevant to the present study. These studies have shown yoga to be an effective therapy for treatment of several lifestyle related diseases that are also known to be major risk factors for pregnancy complications; including hypertension⁵², diabetes mellitus⁵³, and obesity⁵³. Furthermore, yoga has been documented to improve pregnancy outcomes in part by reducing maternal stress.⁵⁴⁻⁵⁶

Surprisingly, except for supplementation^{57,58}, very few mind-body therapies have been studied in high-risk pregnancies. Hence, we have undertaken this study to investigate the effects of yoga practices on the outcome of high-risk pregnancies. In light of the results of the previous trials of yoga in low-risk pregnancies, we hypothesized that regular practice of yoga can prevent pregnancy complications and improve pregnancy outcomes in high-risk pregnancies when compared to a usual-care control group.

CHAPTER 2

VEDIC LITERATURE SEARCH

CHAPTER CONTENTS:

- Ancient Literature on Fetal Development
- Vedic Rituals in Pregnancy
- Vedic Basis for Yoga as a Mind-Body Therapy

Chapter 2: Vedic Literature Search

Several ancient texts, including that of yoga and Ayurveda, the two ancient medical sciences of India, have given detailed descriptions of the anatomical, physiological and spiritual aspects of pregnancy and fetal development. According to their views, the prescriptions for healthy progression of pregnancy and fetal development are based on the introspective understanding of the sages during deep meditation. This chapter on Vedic literature search has three sections: the first section covers the description of embryology found in *bhāgavata purāṇa*, a Vedic text. The second section, will describe the pregnancy related traditional rituals called *sanskāra* that were practiced in the ancient Indian society as described in different Vedic texts. The third section, will give a basic overview on the conceptual basis for the integrated yoga therapy for high risk pregnancy as portrayed in the *vedās* and used in this study.

2.1 Ancient Literature on Fetal Development

Yoga believes that every aspect of life is sacred. That is why each significant stage, from conception to cremation, is celebrated as a reminder that life is a gift from God, which should be duly respected and lived with full awareness as a grace from the divine and offerings to the divine. The marriage is particularly sacred in the Indian tradition and is highly revered by the Vedic literature. From the social point of view, a baby is the product of that sacred union; and therefore, considered a divine gift. It is not then surprising that there are numerous rituals centered around marriage and pregnancy in the Indian traditions. Yet from the Vedic vantage point, a baby in the womb symbolizes the human bondage in the material world and birth is the beginning of a life long suffering unless self-realization has been achieved. In this chapter, we will study the different aspects of pregnancy stated in the Vedic literature.

Also known as *Śrīmad Bhāgavatam* or *Bhāgavata*, it is one of the major *Purāṇika* texts covering mainly the life of *Lord Kṛṣṇa*.⁵⁹ Its actual date of origin is unclear but many experts speculate that it was written around the ninth or tenth century CE.⁶⁰ The text contains about twelve cantos (books),⁶¹ out of which the first few chapters of the third book are relevant to this study, which are reviewed in details. This book could be considered as a great Vedic source for embryology.

The translation for each chapter has been borrowed from vedabase.net (<http://vedabase.net/sb/en3>). The transliteration has been used to generate the Sanskrit text using webdunia transliteration software (<http://utilities.webdunia.com/hindi/transliteration.html>). The discussion is the interpretations and personal opinions of the author from the translation. When appropriate, graphs have been borrowed giving credit to the source at the footnote of each graph. Each chapter is identified by the abbreviation SB (for *śrīmad bhāgavatam*) followed by the canto number, the chapter number and the verse number. The verses discussed here are instructions on the movements of living entities by sage *kapila*, son of *deevahuti*, who is widely credited as being one of the founders of the *sāṅkhya* school of philosophy.

2.1.1 ŚRĪMAD BHĀGAVATAM

2.1.1.1 CANTO 3 CHAPTER 31 VERSE 1

श्रीभगवानुवाच
कर्मणा दैवनेत्रेण जन्तुर्देहोपपत्तये ।
स्त्रियाः प्रविष्ट उदरं पुंसो रेतःकणाश्रयः ॥

Śrībhagavānuvāca
Karmaṇā daivanetreṇa janturdehopapattaye ।
Striyāḥ praviṣṭa udaram puṁso retaḥkaṇāśrayaḥ ॥

Sri-bhagavān uvāca {the Supreme Personality of Godhead said;} karmaṇā {by the result of work;} deva-netreṇa {under the supervision of the Lord;} jantuḥ {the living entity} dehaḥ {a body;} upapattaye {for obtaining} striyāḥ {of a woman;} praviṣṭaḥ {enters} udaram {the womb;} puṁsaḥ {of a man;} retaḥ {of semen;} kaṇa {a particle;} āśrayaḥ {dwelling in}.

TRANSLATION: The Personality of Godhead said: Under the supervision of the Supreme Lord and according to the result of his work, the living entity, the soul is made to enter into the womb of a woman through the particle of male semen to assume a particular type of body.

DISCUSSION: The concept of fertilization in Vedas is elaborated here. Similar to the science's view, the spermatozoon joins the oocyte in the uterine tube to form a zygote.

However, the passage also suggest that the soul is transferred to the fetus 1) at the time of conception and 2) through the male semen. So, it appears that this tradition believed that the father is the medium in giving the soul to the child. Yet it is the karmic forces of the individual (the result of his actions), that compels the soul to take a particular body form.

2.1.1.2 CANTO 3 CHAPTER 31 VERSE 2

कललं त्वेकरात्रेण पञ्चरात्रेण बुद्बुदम् ।
दशाहेन तु कर्कन्धूः पेश्यण्डं वा ततः परम् ॥

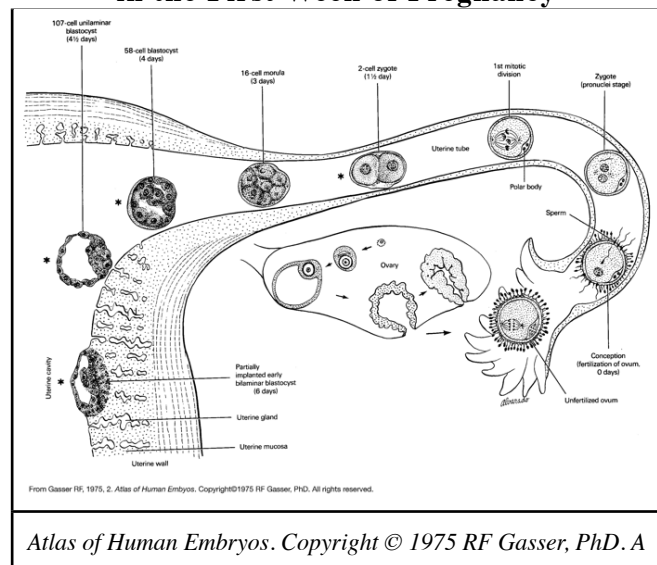
*Kalalaṁ tvekarātreṇa pañcarātreṇa budbudam ।
Daśāhena tu karkandhūḥ peśyaṇḍam vā tataḥ param ॥*

Kalalaṁ {mixing of the sperm and ovum;} tu {then;} eka-rātreṇa {on the first night;} pañcarātreṇa {by the fifth night;} budbudam {bubble;} daśāhena {ten days;} tu {then;} karkandhūḥ {like a plum;} peśy {lump of flesh;} aṇḍam {egg;} vā {or;} tataḥ {thence;} param {afterwards}.

TRANSLATION: On the first night, the sperm and ovum mix, and on the fifth night the mixture ferments into a bubble. On the tenth night, it develops into a form like a plum, and after that, it gradually turns into a lump of flesh or an egg, as the case may be.

DISCUSSION: Now an unprecedented description of mitosis is followed. The zygote becomes a morula (of 12 to 16 cells) after five nights, and then develops into a blastocyst with a fluid-filled center (just like a bubble) in ten days.⁶² The accuracy of this development is uncanny and clearly shows the ability of the seers to visualize the process through meditation since there were no other means at that time. A graphic illustration of the human embryo development in the first week points out this accuracy even better (see figure 2.1).

Figure 2.1: The Human Embryo Development in the First Week of Pregnancy



Atlas of Human Embryos. Copyright © 1975 RF Gasser, PhD. A

2.1.1.3 CANTO 3 CHAPTER 31 VERSE 3

मासेन तु शिरो द्वाभ्यां बाह्वङ्घ्र्याद्यङ्गविग्रहः ।
नखलोमास्थिचर्माणि लिङ्गच्छिद्रोद्भवस्त्रिभिः ॥

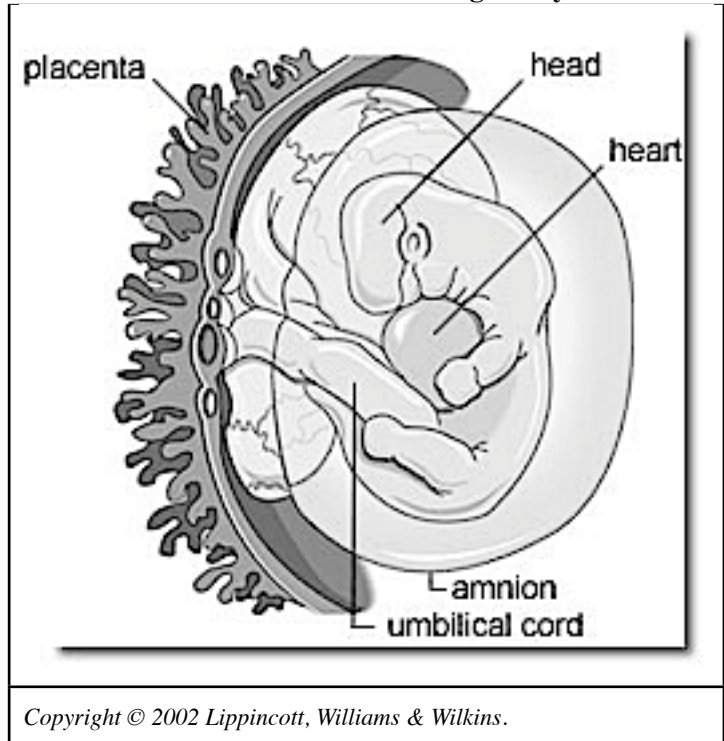
*Māsena tu śiro dvābhyāṁ bāhvāṅghryādyāṅgavigrahaḥ |
Nakhalomāsthicarmāṇi liṅgacchidrodभवastribhiḥ |*

Māsena {within a month;} tu {then;} śiro {head;} dvābhyāṁ {two months;} bāhu {arms;} aṅghri {feet;} ādi {and so on;} aṅga {limbs;} vigrahaḥ {form;} nakha {nails;} loma {body hair;} asthi {bones;} carmaṇi {and skin;} liṅga {organ of generation;} chidra {apertures;} udbhavaḥ {appearance;} tribhiḥ {within three months}.

TRANSLATION: In the course of a month, a head is formed; at the end of two months the hands, feet and other organs take shape. By the end of three months, the nails, fingers, toes, body hair, bones and skin appear, as do the organ of generation and the other apertures in the body, namely the eyes, nostrils, ears, mouth and anus.

DISCUSSION: The process of organ development is depicted in this passage, again with an amazing accuracy. Indeed, the formation of brain starts at the very early stages of embryo development. Between the 4th and 5th weeks of pregnancy, the head has developed to a much larger size compared to the rest of the body (see figure 2.2), giving the embryo the look of a tadpole.⁶² Notice that in the fifth week, the limbs are also formed.

Figure 2.2: The Human Embryo Development in the Fifth Week of Pregnancy



2.1.1.4 CANTO 3 CHAPTER 31 VERSE 4

चतुर्भिर्धातवः सप्त पञ्चभिः क्षुत्तृदुद्भवः ।
षड्भिर्जरायुणा वीतः कुक्षौ भ्राम्यति दक्षिणे ॥

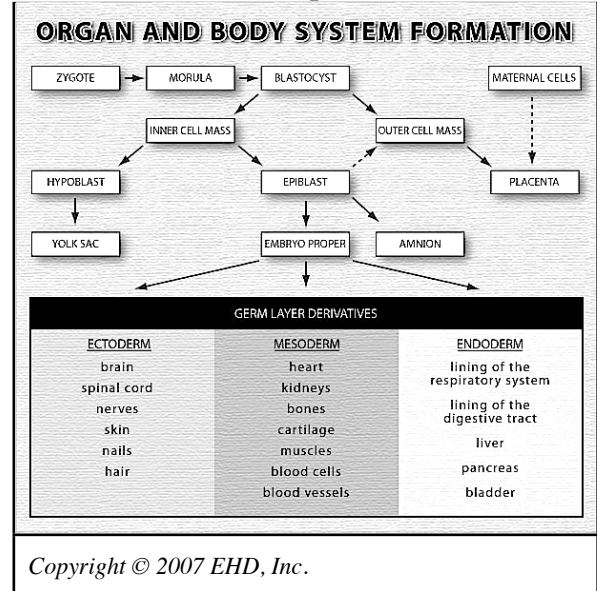
Caturbhirdhātavaḥ sapta pañcabhiḥ kṣuttr̥dudbhavaḥ |
Ṣaḍbhirjarāyuṇā vītaḥ kukṣau bhrāmyati dakṣiṇe ||

Caturbhiḥ {within four months;} dhātavaḥ {ingredients;} sapta {seven;} pañcabhiḥ {within five months;} kṣut-trit {of hunger and thirst;} udbhavaḥ {appearance;} ṣaḍbhi {within six months;} jarāyuṇā {by the amnion;} vītaḥ {enclosed;} kukṣau {in the abdomen;} bhrāmyati {moves;} dakṣiṇe {on the right side}.

TRANSLATION: Within four months from the date of conception, the seven essential ingredients of the body, namely chyle, blood, flesh, fat, bone, marrow and semen, come into existence. At the end of five months, hunger and thirst make themselves felt, and at the end of six months, the fetus, enclosed by the amnion, begins to move on the right side of the abdomen.

DISCUSSION: By the end of the first trimester, most body organs are partially developed through three layers of ectoderm, mesoderm, and endoderm (see figure 2.3). The circulation system is the first to function by the end of the third week.⁶² By the end of five month, the structure of the fetal gastrointestinal tract has developed to approximate that of the newborn and excessive fetal swallowing may lead to loss of amniotic fluid. By the end of six months, the fetus performs somersaults through a series of step-like leg motions similar to walking.⁶³

Figure 2.3- The Early Human Embryo Development



2.1.1.5 Canto 3 Chapter 31 Verse 5

मातुर्जग्धान्नपानाद्यैरेधद्वातुरसम्मते ।
शेते विण्मूत्रयोगर्ते स जन्तुर्जन्तुसम्भवे ॥

Māturjagdhānnapānādyairedhaddhāturasammate |

Śete viṇamutrāyorgarte sa janturjantusambhave ||

Mātuḥ {of the mother;} jagdha {taken;} anna-pāna {by the food and drink;} ādyaiḥ {and so on;} edhat {increasing;} dhātuḥ {the ingredients of his body;} asammate {abominable;} śete {remains;} vit-mūtrayoh {of stools and urine;} garte {in a hollow;} saḥ {that;} jantuḥ {fetus;} jantu {of worms;} sambhave {the breeding place}.

TRANSLATION: Deriving its nutrition from the food and drink taken by the mother, the fetus grows and remains in that abominable residence of stools and urine, which is the breeding place of all kinds of germs.

DISCUSSION: Here comes the first mention of placenta corridor and exchange of blood and nutrients between the mother and the fetus. After the second trimester, most organs are fully developed and the fetus uses the majority of the nutrients it gets from her mother to gain weight. Referring to the amniotic fluid as stools and urine and breeding place for germs may sound shocking at first. However, the seers could describe what they visioned in meditation. It is indeed a fact that the fetus frequently urinates and sometimes defecates in the amniotic fluid. Also, viewing the womb as a place of bondage, resembling the sufferings of the physical world may have contributed to exaggeration of this condition, as the description becomes more horrific in the next canto: “Bitten repeatedly all over the body by the hungry germs in the abdomen itself, the child suffers terrible agony because of his tenderness. He thus becomes unconscious moment after moment because of the terrible pain” Some experts have suggested that this is a graphic analogy of the disturbance that is inflicted on the fetus due to improper diet of the mother; described in the next cantos.

2.1.1.6 CANTO 3 CHAPTER 31 VERSE 7

कटुतीक्ष्णोष्णलवणरूक्षाम्लादिभिरुल्बणैः ।
मातृभुक्तैरुपस्पृष्टः सर्वाङ्गोत्थितवेदनः ॥

*Kaṭutīkṣṇoṣṇalavaṇarūkṣāmlādibhirulbaṇaiḥ |
Mātrbhuktairupasprṣṭaḥ sarvāṅgotthitavedanaḥ ||*

Kaṭu {bitter;} tīkṣṇa {pungent;} uṣṇa {hot;} lavaṇa {salty;} rūkṣa {dry;} āmla {sour;} ādibhiḥ {and so on;} ulbaṇaiḥ {excessive;} mātrbhuktaiḥ {by foods eaten by the mother;} upasprṣṭaḥ {affected;} sarvāṅga {all over the body;} utthita {arisen;} vedanaḥ {pain}.

TRANSLATION: Owing to the mother's eating bitter, pungent foodstuffs, or food which is too salty or too sour, the body of the child incessantly suffers pains which are almost intolerable.

DISCUSSION: Indeed, the food consumed by the mother can reach the fetus very quickly. For instance, amniotic fluid takes the odor of garlic within 45 minutes of ingestion by the mother.⁶⁴ The fetus reacts to these tastes and odors by making facial expressions accordingly.^{65, 66} Studies have shown that the fetus does not like bitter, pungent, salty, or very sour foods, while it reacts pleasantly to sweet foods.⁶⁷ Interestingly, The Bhagavad Gita classify the bitter, pungent, salty, or sour foods as rajasic, or those that promote motion and activity.⁶⁸

2.1.1.7 CANTO 3 CHAPTER 31 VERSE 8

उल्बेन संवृतस्तस्मिन्नन्त्रैश्च बहिरावृतः ॥
आस्ते कृत्वा शिरः कुक्षौ भुग्नपृष्ठशिरोधरः ।

*Ulbena saṁvṛtastasminnantraishca bahirāvṛtaḥ ||
Āste kṛtvā śiraḥ kuṅṣau bhugnapṛṣṭhaśirodharah ||*

Ulbena {by the amnion;} saṁvṛtaḥ {enclosed;} tasmin {in that place;} antraiḥ {by the intestines;} ca {and;} bahiḥ {outside;} āvṛtaḥ {covered;} āste {he lies;} kṛtvā {having}

put}; *śiraḥ* {the head}; *kukṣau* {towards the belly}; *bhugna* {bent}; *pr̥ṣṭha* {back}; *śiraḥ-dharaḥ* {neck}.

TRANSLATION: Placed within the amnion and covered outside by the intestines, the child remains lying on one side of the abdomen, his head turned towards his belly and his back and neck arched like a bow.

DISCUSSION: This and the next canto describe the increasingly limited space for movement of the fetus in the uterus at later stages of the pregnancy: “Placed within the amnion and covered outside by the intestines, the child remains lying on one side of the abdomen, his head turned towards his belly and his back and neck arched like a bow.” and “The child thus remains just like a bird in a cage, without freedom of movement. At that time, if the child is fortunate, he can remember all the troubles of his past one hundred births, and he grieves wretchedly. What is the possibility of peace of mind in that condition?”

From here onward, *Lord Kalpa* paints a grim picture of the material life starting from the womb and uses these agonizing illustrations to embed dispassion in the reader through a series of lessons of wisdom. It is interesting to point out that the 10th canto indicates that only the human embryo is able to develop consciousness after 7 months of gestation. Another canto that relates to this study is canto 3.17.18, which talks about multiple pregnancies and is discussed next.

2.1.1.8 CANTO 3 CHAPTER 17 VERSE 18

प्रजापतिर्नाम तयोरकार्षीद्यः प्राक्स्वदेहाद्यमयोरजायत ।
तं वै हिरण्यकशिपुं विदुः प्रजा यं तं हिरण्याक्षमसूत साग्रतः ॥

*prajāpatirnāma tayorakārṣīdyaḥ prākṣvadehādyamayorajāyata |
taṁ vai hiraṇyakaśipuṁ viduḥ prajā yaṁ taṁ hiraṇyākṣamasūta sāgrataḥ ||*

prajāpatiḥ {Kāśyapa;} *nāma* {names;} *tayoḥ* {of the two;} *akārṣīd* {gave;} *yaḥ* {who;} *prāk* {first;} *sva-dehāt* {from his body;} *yamayoh* {of the twins;} *ajāyata* {was delivered;} *taṁ* {him;} *vai* {indeed;} *hiraṇyakaśipuṁ* {Hiranyakaśipu;} *viduḥ* {know;}

prajāḥ {people;} yaṁ {whom;} taṁ {him;} hiraṇyakaśipuṁ {Hiranyāksha;} asūta {gave birth to;} sū {she (Diti);} agrataḥ {first}.

TRANSLATION: Kaśyapa, Prajāpati, the creator of the living entities, gave his twin sons their names; the one who was born first he named Hiraṇyāksha, and the one who was first conceived by Diti he named Hiraṇyakaśipu.

DISCUSSION: This is a reiteration of the Vedic literature, Piṇḍa-siddhi, it is stated that when the male semen enters the uterus, the female may develop two embryos in her womb, and she brings forth twins in a reverse order to that in which they were first conceived. The child conceived first is born later, and the one conceived later is brought forth first. But that is not necessarily the case scientifically. However, it does illustrate here why Hiraṇyāksha, the second child conceived, was delivered first, whereas Hiraṇyakaśipu, the child who was behind him, having been conceived first, was born second.

2.2 Vedic Rituals in Pregnancy

Saṁskārā are ritual that are performed throughout the life of a Hindu. These rituals have both social and spiritual aspects to them. The purpose of *saṁskārā* can include: 1) physical, mental, spiritual, and karmic purification, 2) providing inner balance in this lifetime, 3) offering the rite of passage through different stages of life, 4) removing hostile influences, and 5) attracting favorable influences.

There are in total about 40 *saṁskārās*, out which 16 of them, listed in Table 2.1, are very important and must be observed by a Hindu through his/her lifetime.⁶⁹ Here, we shall describe the first four *saṁskārās* that are meant to be performed prior to conception, during pregnancy and at birth.

The life of a Hindu, from conception (*nīśakrāmato*) to cremation (*śmaśānam*) rotates around these series of milestones along his/her journey through life. The general meaning of the word ‘*saṁskārā*’ is impression, which in this context, refers to life impressions. The literal meaning of the word is ‘*saṁ*’ meaning betterment and ‘*karma*’ meaning actions - or ‘improving one’s actions’. The Vedas advise the Hindu that observance of these *saṁskārās* will cleanse the body and the mind and lead to the betterment of one’s life quality.⁶⁹

From a spiritual point of view, the practice of the *saṃskārās* will lead to development of the eight auspicious *guṇas*, also known as *ātma guṇas*, which are: 1) *dayā* or universal compassion and love for all living beings, 2) *kānti* or development of patience, 3) *anasuyā* or absence of jealousy or rancor, 4) *śauca* or purification, 5) *anāyāsa* or absence of anxiety, 6) *maṅgala* or development of inner happiness, 7) *akarpaṇyā* or generosity of spirit and time, and 8) *āśaphā* or dispassion.⁷⁰

Table 2.1- The 16 Saṃskāras

	SAMSKĀRĀ (संस्कारा)	PREGNANCY STAGE	DESCRIPTION
1	<i>ḡarbhādhāna</i> (गर्भाधान)	Prior to conception	The ritual of conception
2	<i>puṃsāvana</i> (पुंसवन)	During pregnancy	The ritual of seeking a male child
3	<i>sīmantonmayana</i> (सीमन्तोन्नयन)	During pregnancy	The ritual for safe delivery
4	<i>jaṭākarma</i> (जातकर्म)	At birth	The ritual to purify the newborn
5	<i>nāmakaraṇam</i> (नामकरणम्)	After birth	The naming ceremony
6	<i>niṣkramaṇam</i> (निष्क्रमणम्)	After birth	The first outing ceremony
7	<i>annaparasana</i> (अन्नप्राशनम्)	After birth	The first solid food feeding ceremony
8	<i>cūḍākaraṇam</i> (चूडाकरण)	After birth	The tonsure ceremony
9	<i>karnabhedhaḥ</i> (कर्णभेद)	After birth	The ear piercing ceremony
10	<i>vidyārambhaḥ</i> (वद्वारम्भ)	Childhood	The education ceremony
11	<i>upanayanam</i> (उपनयनम्)	Childhood	The sacred Thread wearing ceremony
12	<i>vedārambhaḥ</i> (वेदारम्भ)	Youth	The initiation into the Vedic studies
13	<i>keśāntah</i> (केशान्त)	Youth	The first shaving ceremony
14	<i>samāvartanam</i> (समावर्तनम्)	Adult	The school graduation ceremony
15	<i>vivāhah</i> (विवाह)	Adult	The marriage ceremony
16	<i>antyēṣṭi</i> (अन्त्येष्टि)	Adult	The funeral rites

2.2.1 Ġarbhādhāna

This *saṁskārā*, literally meaning ‘the gifting of the womb’⁷¹, is not merely about religious rituals and prayers for a healthy offspring. There is a rather scientific rationale behind the procedure. Looking at the rituals scientifically, it becomes clear that the seers understood the concept of gene expression and prescribed practices that produced the most favorable mindset for procreation.

Furthermore, in contrast to the Western approach to conception, where most often sensual pleasures overweight the procreation objectives of copulation, a hindu couple continue chanting mantras all through the act of intercourse as it is delineated in details in the *bṛhadāraṇyaka upaniṣad*.⁶⁹ The process is as follows: On the fourth night after menstruation, the wife take a bath to cleanse herself and then wears clean and new clothing.⁷² Meanwhile, the husband is advised to continue with the thought that her wife looks like the *Goddess lakṣmi*.⁷²

He then approach her and feed her *sāttvik* food, while chanting various mantras; one of which invites her to have intercourse: “I am the sky, you are the earth. Come, let us unite. Let me deposit my seed to get a child.”⁷² During the actual intercourse, the husband chants this hymn from *ṛig veda*, chapter 10.184.1: “Let *viṣṇu* prepare the womb; let *tvaṣṭṛ* shape the forms. Let *prajāpati* shed the seed; let *dhātṛ* place the embryo in you. Place the embryo, *sinvali*, place the embryo, *sarasvatī*. Let the twin *aśvins*, the lotus-garlanded gods, place the embryo in you. With golden kindling woods the *aśvins* churn out fire. We invoke that embryo for you to bring forth in the tenth month.”⁷⁴ This hymn identifies the different deities, during the Vedic era, involved in the procreation and their various roles.

From these verses, one can conclude that the main objective of *ġarbhādhāna saṁskāra* is to invoke the divine entities to participate in the act of procreation and at the same time, to make the process a *yajña* (sacrifice) to the Gods.

2.2.2 Puṁśavana

Puṁśavana literally means ‘the engendering a male’. Traditionally, a male offspring has been preferred because: 1) a son will ensure the continuation of the family lineage, and 2) a son is needed to perform the necessary cremation rituals that guarantee a safe sojourn for the father and mother after they pass away.⁷¹ This *saṁskārā* is performed in the third month of pregnancy, before the fetus’s movements are felt by the mother (*yājñavalkya smṛti* 1.11). The mother wears new clothing after a fresh bath and is adorned by jewelries.⁷¹ *atharva Veda* offers many rituals and mantras for this occasion. But the highlight of the event is when at night, the husband pours the juice of a banyan tree sprout into the right nostril of his wife, while chanting: “May a male embryo enter your womb, as an arrow into a quiver. May a son be born after ten months.” (*atharva veda* 3.23.4)⁷⁵

It is interesting to note that according to the Vedas and the ancient *āyurvedic* texts, the gender of the fetus is determined after the first trimester. Again, it is important to remember that the seers knowledge of embryology

was mostly based on what they observed through meditation. It is a fact that it is at this time that the gender of the fetus can be determined by external examinations. Moreover, according to *śusruta saṁhitā*, one of the principal texts of *āyurveda*, medicine can very effectively be administered through the nostrils and the banyan tree has properties that can help many pregnancy

complications. An earlier hymn to that, which was quoted above, actually explains the intentions of the ritual more clearly: “That which has caused thee to miscarry, do we drive away from thee, that very thing do we deposit outside of thee, away in a far place.” (*atharva veda* 3.23.4)⁷⁵

Figure 2.4- The Administration of Banyan Juice



Image borrowed from www.sadagopan.org

2.2.3 Sīmantakaranam

Also known as *Sīmantakaranam* or *Sīmanta saṁskārā*, literally means ‘hair parting’.⁶⁹ The main objective of this saṁskāra is to prevent complications of pregnancy.⁷² The *āśvalayan a ġrihya sutra* recommends this ritual to be performed in the 4th month of the gestation, although some conduct it in the 6th or even the 8th months.⁷² In this *saṁskārā*, the husband simply combs his wife’s hair, from front to back, while chanting mantras to the family deity.⁷⁵ The question would arise that how combing of hair could prevent pregnancy complications. Previous studies have shown that reduction in maternal stress and increased social support is directly correlated with reduction in unfavorable outcomes of pregnancy.⁷⁶⁻⁷⁹

The combing of the hair, could create an opportunity for the couple to bond,

provide social support to the mother, and reduce her psychological distress. Perhaps, such an interpretation is supported by *khaṇḍika* 13.7 of *ġrihya sutra*, where the husband addresses his wife after the ceremony by saying: “What is hidden, O thou whose hair is well parted, in thy heart, in *prajāpati*, that I know; such is my belief. May you not fall into distress...”⁸⁰

There are a number of hymns in the *atharva veda* intended to protect the fetus from disturbances. In hymn 4.17, it says: “As this great earth conceives the germs of the beings, thus shalt thy embryo be—held fast, to produce a child after pregnancy! As this great earth holds the mountains and the peaks, thus shall thy embryo be held fast, to produce a child after pregnancy! As this great earth holds the animals scattered far, thus shall thy embryo be held fast, to produce a child after pregnancy!”⁸¹

Figure 2.5: Parting of the Hair by the Husband

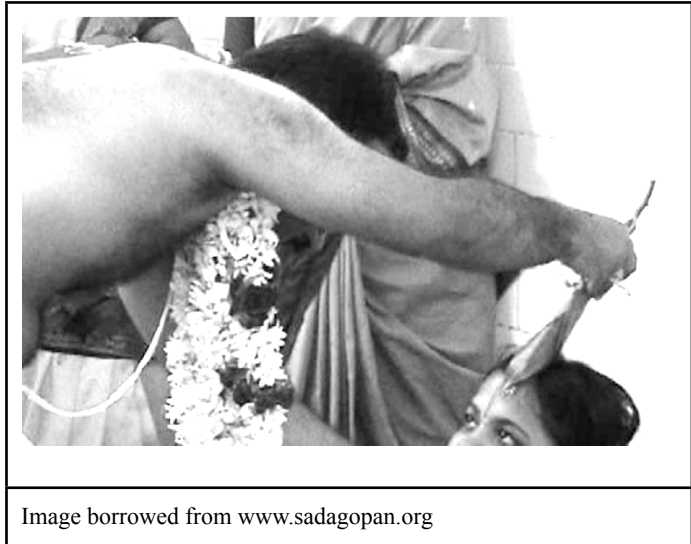


Image borrowed from www.sadagopan.org

2.2.4 Jātakarma

Jātakarma is performed to welcome the newborn child into the world reminding it of its divine nature on this journey of life.⁷⁵ The baby is first bathed and cleaned and then fed a small mixture of honey, ghee and gold by the father.⁶⁹ The father also whispers a mantra in the child's right ear reminding it of its divine nature.⁷⁵ This *samskāra* also seeks the blessings of intelligence, health and long life for the child.⁷⁵

Figure 2.6: Jatakarmam Ceremony



2.3 Vedic Basis for Yoga as a Mind-Body Therapy During Pregnancy

2.3.1 THE VEDIC VIEWS ON HEALTH

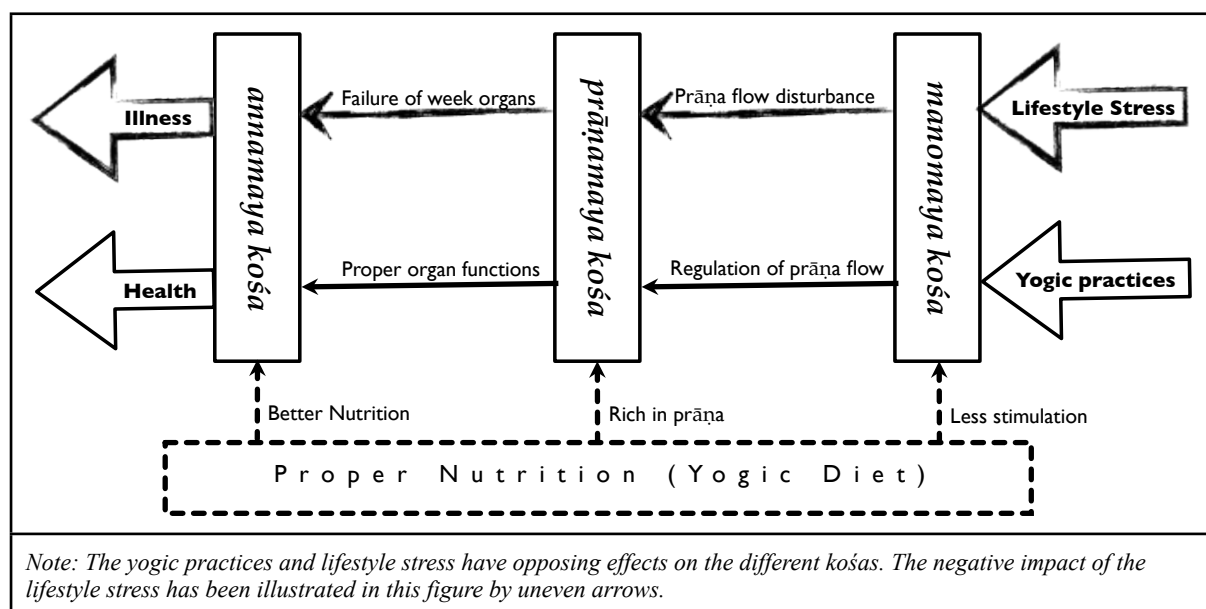
The concept of health according to Ayurveda can be summarized in this *śloka*: “*samadoṣa samāgniśca samadhātu malakriyāḥ | prasanna ātmendriya manāḥ svastha iti abhidhīyate*,” which means “health is defined as balanced functioning of all physiological functions of the body.” In Sanskrit, “*sama*” means “Balanced.” In the *śloka*, this balance is described as *sama-doṣa* (the proper balance of the three *doṣas*: *vāta pitta* and *kapha*), *sāma-agni* (balanced digestive capacity and balanced release of digestive hormones and enzymes), *sama-dhatva agni* (balanced metabolic activity), *sama-dhātu* (balanced functioning of the basic tissues), and *sama-malakriyā* (balanced process of excretion).

The concept of health according to yoga is also about balance. More specifically, yoga defines health as a state of complete harmony of five different aspects of our personality, also called *kośa* (कोश) or sheaths. The physical body is the grossest part of human existence. Other metaphorical bodies are more subtle than the physical body, and play important roles in our emotional, mental, and spiritual well-being. In fact, yoga seeks the root cause of life style illnesses within these subtle bodies, believing that the diseases of the physical body are manifestation of disturbances in these subtle *kośas*.⁴⁸ Table 2.2 outlines the different bodies and their primary functions.

2.3.2 YOGIC VIEWS ON ILLNESS

The first three bodies are very much interrelated. Daily lifestyle stresses (including traumas) disturbs the balance in the *manomaya kośa* (due to long standing suppressed emotional reactions to demanding situations of life) and causes instability. This disturbs the flow of *prāṇa* in the *prāṇamaya kośa* and may even result in blockages in the *nādis* that carry the *prāṇa*. This shows up as functional abnormalities, such as disturbed breathing and/or digestion, without any cellular or structural abnormalities in the body. This in turn settles

Figure 2.7: Effects of Lifestyle Stress Versus Yoga on Health



down as excessive activity (e.g. inflammation) in one of the organs (possibly due to genetic predisposition), a component of *annamaya kośa*. Thus, an erratic lifestyle disturbs the

balanced functioning of the mind (*manomaya*), manifests initially as functional abnormalities in the vital energy (*prāṇamaya*) and then shows up as structural abnormalities in an organ (*annamaya*). In contrast, yogic practices calm the mind and stabilizes the *manomaya kośa*,

Table 2.2- Kośas and Their Primary Characteristics

KOŚA	DESCRIPTION
<i>annamaya kośa</i> (अन्नमाया कोश)	This refers to the grossest form of the human existence, the physical body, which is made of chemicals (elements, atoms, subatomic particles, energy). According to yoga texts, <i>annamaya kośa</i> is made of five elements: solid (<i>prithvi</i>), liquid (<i>apah</i>), gaseous state (<i>vāyu</i>), heat (<i>agni</i>), and space (<i>ākāśa</i>). ‘Anna’ means food. This physical body needs food as its nourishment “<i>annadhyeva khalvimani bhutāni jayante</i>” (everything is born out of physical matter); “<i>annena jatāni jivanti</i>” (they live because of anna); “<i>annam prayanti abhisamvisanti</i>” (they merge into anna); and “<i>jātanyannena vardhante</i>” (they grow because of anna)². If this <i>kośa</i> is neglected, improvement in other <i>kośa</i> become difficult if not impossible.
<i>prāṇamaya kośa</i> (प्राणमाया कोश)	‘prāṇa’ means vital energy that is responsible for life activities in all living cells (physiology). Five sections of the main <i>prāṇa</i> manage the functions in five zones (प्राणो व्यानोअपान उदानः समानः 1)² <i>prāṇa</i> (respiration and special senses), <i>Apāna</i> (defecation, Micturition, menstruation etc), <i>samānā</i> (digestion), <i>vyānā</i> (touch sense, circulation of fluids all over etc), and <i>udāna</i> (thinking, belching, vomiting etc). <i>prāṇa</i> circulates through an intricate and invisible system of pathways called <i>nadis</i>. The main three <i>nadis</i> are <i>ida</i>, <i>piṅgalā</i>, and <i>śuśumanā</i> in the spine. They branch out to about 72,000 <i>nadis</i>, the pathways for <i>prāṇa</i> to flow throughout the body. The <i>ida</i> and <i>piṅgalā</i> channels correlate with left and right nostrils, making it possible to manipulate <i>prāṇa</i> through controlled breathing.
<i>manomaya kośa</i> (मनोमाया कोश)	‘manah’ means mind. This <i>kośa</i> is the seat of perception and emotions. Using the five senses, information is acquired to create a perception of the world outside and then used to prepare appropriate emotional responses to those perceptions.
<i>vijñānamaya kośa</i> (विज्ञानमाया कोश)	‘vijñāna’ means knowledge. This is the seat of wisdom that facilitates the thinking process of the mind. Utilizing this faculty, we are able to discriminate right from wrong and make appropriate judgments (<i>viveka</i>) for a healthy lifestyle. More significantly, this is the place of intuition that is used when analytical process fails to guide us.
<i>ānandamaya kośa</i> (आनन्दमाया कोश)	‘ānanda’ means bliss. This forms the unchanging template of (existence, consciousness, and bliss) of our being on which the other <i>kośas</i> carry on their activities. This is also the basic stuff of this entire creation. <i>ānandamaya kośa</i> is experienced as a blissful ecstatic state of pure awareness when all mental activity ceases. The main approach of yoga therapy as a mind-body medicine is to maintain the practitioner in this state that is regarded as a state of perfect health.
1. The bodies are listed from the grossest, physical, to the subtlest, bliss. 2. Taittiriya upaniṣada 3.2.	

which ensures the proper flow of *prāṇa* in the *prāṇamaya kośa* and leads to healthy functioning of the organs in the *annamaya kośa*.⁸²

Integrated Approach of Yoga Therapy (IAYT) includes several practices for *annamaya kośa* that correct the imbalances in the disturbed *kośas* and help the person to settle in the state of *vijñānamaya* and *ānandamaya kośas* which are free from diseases. These practices include a healthy diet, cleansing techniques, and various physical postures.

2.3.3 YOGIC DIET AND THE THREE GUṆAS

In *taittiriya upaniṣada* 3.2, it is said that “And he knew that food is Brahman. From food all beings are born, by food they live, and into food they return.” For a pregnant woman in particular, a healthy lifestyle (*dinacaryā*) in which diet is a major component is highly recommended. Therefore, yogic diet deserves a more detailed explanation, in general and as related to pregnancy. Generally speaking, the yogic science classifies food in three categories: 1) *sāttvika*: foods that are easy to digest, provide the essential nourishment to the body, and bring clarity of perception to mind (this effect on the mind is possible only when the food is freshly cooked and served with love within six hours after cooking), 2) *rājasika*: food that stimulates the mind and results in exiting emotionally charged behavior; , and 3) *tāmasika*: food that makes the mind become lethargic and dull leading to uncontrolled behavior and even violence.⁸³ Raw foods (such as many fruits and vegetables), grains, legumes, and dairy products are examples of *sāttvika* foods; whereas garlic, onion, and chili are all rajasic in nature; and some types of meats, stale food, processed or frozen foods, and fermented foods are all tamasic in nature.⁸⁴ Intake of tea, coffee, and tobacco have a *rājasik* effect on the body; whereas alcoholic beverages and recreational drugs have *tāmasik* effect.⁸⁴ In figure 2.7, we see that a yogic diet feeds the physical body, satisfying it through its high nutrient content, contributes to the energy body through its *prāṇik* nature, and also avoids excitement of the mind.⁸² It should now be easy to appreciate the age old adage that says: “a healthy mind resides in a healthy body.” The *sāttvika*, *rājasika*, and *tāmasika* qualities are often referred to as the three *guṇas* in the yogic text books and apply to everything in the material world-- not just the food.⁸³

2.3.4 AYURVEDIC DIET

The yogic and Ayurvedic diet recommendations are not always the same as the main purpose of yoga is transcending the body consciousness while the primary objective of Ayurveda is balancing the body's functions for promoting and preserving health.⁸⁴ Even so, there is a clear link between the two. The Vedic literature, as a whole, emphasizes on the effects of diet on the internal milieu of subtle energy systems and the three *guṇas*.⁸⁴ Ayurveda, the science of medicine, goes on to give detailed descriptions of how these *guṇas* are responsible for the functions at grosser levels of *prāṇamaya* and *annamaya kośa*s by positing the concept of *tri-dosas*, the *vāta*, *pitta*, *kapha*.⁸⁴ Again a balanced functioning of these three *dosas* is health and imbalance is ill health. The longer the imbalance goes on, the more chronic will be the disease.⁸⁴ Rice, milk, and clarified butter (ghee) medicated with various herbs play a major role in the diet of a pregnant woman according to the yogic and Ayurvedic teachings as outlined in Table 2.3.⁸⁵ Several medicinal herbs are also included as a part of this diet. Those belonging to the group of *madhura-auṣadhi*, such as *roscaea procera* (*kakoli*), grapes (*draksha*), and liquorice (*yashti madhu* or *glycyrrhiza glabra*) are recommended during the second month.⁸⁵ No medicinal herbs are recommended during the third, fourth, and fifth months of pregnancy.⁸⁶ During the sixth month, ghee prepared with 'small caltrops' (*gokshura*) is given and in the seventh month ghee made with the *prthak parṇyā* group of herbs are used.⁸⁶ The pregnant woman is advised to consume rice cooked with milk and added ghee for the additional protein needed for proper development of the fetus.⁸⁵ Such a diet will provide proper nourishment for the *annamaya kośa*, enriches the *prāṇamaya kośa*, and provides calmness of the mind in the *manomaya kośa*.⁸²

2.3.5 CLEANSING TECHNIQUES

Kriyas are cleansing practices that form a part of *annamaya kośa* practices. *Kriyas* play an important role in the wellness of the expecting mother. Ayurvedic physicians recommend:

- 1) Daily bathing after the 36th week of gestation with water boiled with medicinal leaves, such as those of castor bean (*Eranda- Ricinus Communis*) and five-leaved chaste tree (*nīrguṇḍī - vitex negundo*), which reduce the *vāta doṣa*.⁸⁷
- 2) Daily full body massage with medicated oils to remove the toxins from the skin, which is considered a good excretory organ.⁸⁷

- 3) Application of enema (*sthāpana basti*) from 28th to 32nd weeks followed by unctuous enema (*anuvāsana basti*) of medicated oil with milk and decoction of drugs of sweet group, like *madhukā*.⁸⁸ During the eighth month, the expectant mother is recommended to take a medicated enema (*sthāpana basti*) of the decoction of jujube fruit (*bādarā*) mixed

Table 2.3: Yogic-Ayurvedic Diet During Pregnancy

Gestational Age		Diet Recommendations
First Trimester	0-4 weeks	Non-medicated milk repeatedly, generally sweet, cold and liquid diet.
	5-8 weeks	Milk medicated with herbs belonging to the group of <i>madhura-aushadhi</i> , such as <i>kakoli</i> (<i>Roscaea procera</i>), <i>draksha</i> (grapes), and <i>yashti madhu</i> (<i>Glycyrrhiza glabra</i>).
	9-12 weeks	Milk with honey and ghee
Second Trimester	13-16 weeks	Butter mixed with milk (Ch.Sh.8/32), cooked <i>śasti</i> rice (rice grown for 60 days) with curd.
	17-20 weeks	Ghee and milk
	21-24 weeks	Milk prepared with <i>madhura guṇa dravyās</i> with ghee. Ghee or rice gruel medicated with <i>gokshura</i> (Small caltrops)
Third Trimester	25-28 weeks	Ghee medicated with drugs of <i>prṛthak parnyādi</i> (<i>Uraria picta</i> etc) group.
	29-32 weeks	Medicated oil enemas: 1) Asthapana Basti using a decoction of <i>badara</i> (jujube fruit), <i>balā</i> (Country mallow), <i>atibalā</i> (Indian mallow), <i>śatapušpā</i> (fennel), <i>palālā</i> (pestled sesame seeds), milk, curd, mastu (whey/supernatant liquid of butter milk), oil, salt, <i>madanaphala</i> (emetic nut), honey and ghee, and 2) followed by <i>ānuvāsana basti</i> with ghee medicated with <i>madhura guṇa dravyas</i> mentioned above.
	33 weeks to delivery	Thick rice gruel, mixed with ghee (<i>Yavāgu</i>).

with country mallow (*balā*), Indian mallow (*atibalā*), fennel (*śatapušpā*), pestled sesame seeds (*palālā*), milk, curd, whey/buttermilk (*mastu*), oil, salt, emetic nut (*madanaphala*), honey and ghee.⁸⁶ This should be followed by medicated oil enema (*anuvāsana basti*) with oil prepared with milk and *madhura guṇa dravyās* described above.⁸⁶

4) Vaginal tampons soaked with oil can be used from 36th week onwards to lubricate the cervix, the vaginal canal and the perineum.⁸⁷

Other *kriyas* that are safe and useful for the healthy progression of pregnancy and prevention of complications include:

- 1) *Vamana dhauti* is recommended for prevention and treatment of pregnancy induced nausea and vomiting.⁸⁹
- 2) Mild *kapālabhāti* (done at a rate of 27 breaths /minute) helps in normalizing breathing patterns and promoting calmness of the mind during the first trimester of low-risk pregnancies.
- 3) *Jalaneti* is useful to cleanse the nasal passage and may be safely practiced throughout during high and low risk pregnancies.

2.3.6 ĀSANA AND BREATHING EXERCISES

Āsanās are yogic postures that involve stretching of specific parts of the trunk and limbs, and maintained with ease and effortlessness (*sthira sukham āsanam*). Yoga *āsana* are better defined as relaxation and expansion with internal awareness (प्रयत्नशैथिल्याननन्तसमापत्तिभ्याम् *prayatna śaithilyam tasama pattibhyam*) while maintaining in the final posture. According to the sage Patanjali, this is the trick to develop mastery over the modifications of the mind (योगश्चित्तवृत्ति निरोधः *yogaścittavrtti nirodhaḥ*).⁹⁰

From the physiological point of view, yogic postures help in providing deep rest to the organs. The following exercises and *āsanas* were used during pregnancy without any reported difficulties or safety issues^{55, 56, 91}: *pādasañcālanam* (cycling in supine pose), *gulphaghurṇam* (ankle rotation), *jānuphalakarśnam* (kneecap contraction), *ardhatitaliāsana* (half butterfly exercise), *purnatitaliāsana* (full butterfly exercise), *jyoti trāṭaka* (eye exercises), and *matsyakrīḍāsana* (*lateral shavāsana*). Other *āsanas* have been shown to be safe in low-risk pregnancies⁵⁴: *tāḍāsana* (mountain pose), *ardhakaṭi-cakrāsana* (lateral arc pose), *trikoṇāsana*

(triangle pose), *vajrāsana* (the ankle posture), *vakrāsana* (spine twist pose), *siddhāsana* (sage pose), *baddhakoṇāsana* (bound ankle pose), *upaviṣṭa koṇāsana* (sit with legs apart), *malāsana* (garland pose), *vīparita karaṇī* (half shoulder stand), and *ardha- pavanamuktāsana* (folded leg lumbar stretch).

Breathing practices aim at reducing the breathing rate, which in turn calm the mind (श्वास प्रश्वासयोर्गति विच्छेदः प्राणायामः *śvāsa praśvāsayorgati vicchedaḥ prāṇayāmā*).⁹⁰ The following breathing exercises were used in both high and low-risk pregnancies:^{54, 91} *hasta āyāma śvasanam* (Hands In and Out Breathing), *hastavistāra śvasanam* (hands stretch breathing), *gulphavistāra śvasanam* (ankles stretch breathing with wall support), *kaṭiparivartana śvasanam* (side twist breathing), *uttānapādāsana śvasanam* (leg raise breathing), *setubandhāsana śvasanam* (hip raise breathing), *supta udarakarana śvasanam* (supine abdominal stretch breathing), *vyaghrāsana śvasanam* (tiger stretch breathing).

The *āsanas* and the breathing exercises are intended to strengthen the musculoskeletal system, stretch ligaments, massage organs, and bring oxygen-rich circulation to the various parts of the body in the *annamaya kośa*. In the *prāṇamaya kośa*, they move the *prāṇa*, remove blockages in the *nādis*, and open the chakras. Finally, and most importantly, they gradually make the mind one pointed in the *manomaya kośa*.⁸²

2.3.7 MEDITATION, PRĀNAYAMA, AND RELAXATION

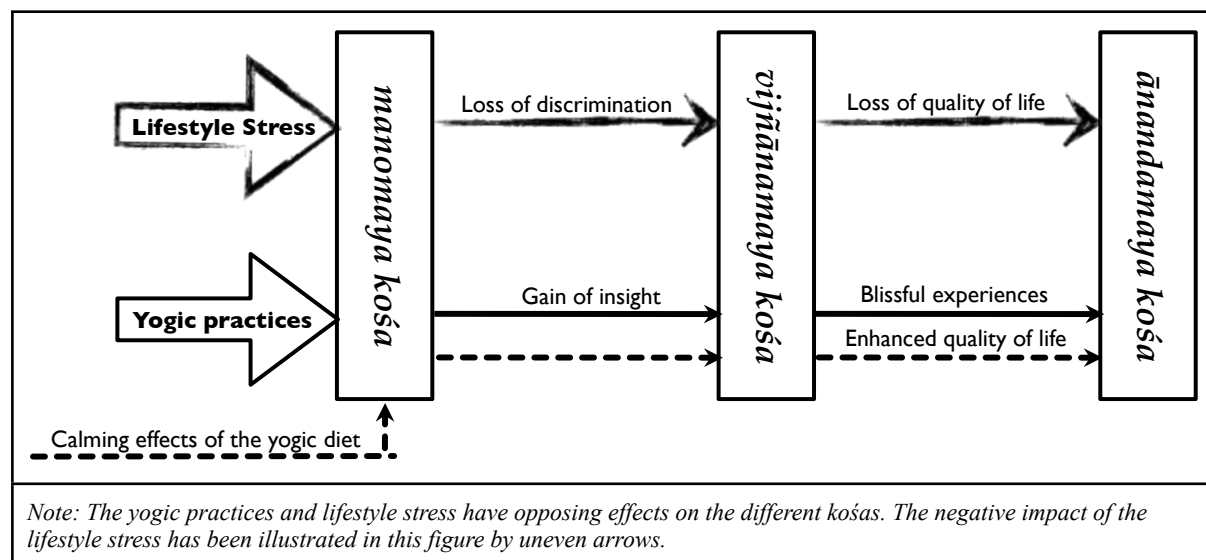
As mentioned before, from the Vedic point of view, stress begins in the mind as suppressed emotions. The scriptures provide the logical steps of arriving at an understanding of the nature of any emotion (suppressed or expressed) and define it as ‘uncontrolled fast rewinding of thoughts in the mind (कामक्रोधोद्वेगम् वेगम् *kāmakrodhodbhavam vegam*)’⁹². All recommended practices are meant to reduce stress by slowing down the mind (मनः प्रशमनोपायः *manaḥ praśamanōpāyaḥ*) These include meditation of various types, *prāṇayama* practices, and some relaxation techniques. Many of the recommended practices have been used successfully as interventions in past studies.^{54, 93} The following *prāṇayama* that have been used in several published studies are recommended for pregnancy: sectional breathing,

nāḍīśuddhi, *śitalī*, *bhrāmari*, *nāḍīśodhana*.⁹³ Om meditation, visualization, guided-imagery, and *trāṭaka* are all meditation and relaxation techniques that can be practiced by all pregnant women. Perhaps the most useful relaxation practice is guided *śavāsana* in the lateral pose (*matsyākṛīḍāsana*) during pregnancy.

2.3.8 QUALITY OF LIFE DURING PREGNANCY

The quality of life of a pregnant woman can have a direct impact on the health of both mother and the fetus, as well as influence the outcome of the pregnancy.⁵⁴ The yogic recommendation for improving the quality of life of the pregnant women is through the three most subtle *kośas*. The *manomaya kośa* influences the other two, more subtle *kośas*, *vijñānamaya* and *ānandamaya*. A disturbed mind in the *manomaya kośa* leads to lack of judgement (*viveka*) in the *vijñānamaya kośa* and ultimately loss of happiness, or quality of life. In contrast, a centered mind promotes increased intuition and wisdom and frequent contacts with the *ānandamaya kośa*, which according to the Vedic understanding, translates into higher quality of life (see figure 2.8).

Figure 2.8: Effects of Lifestyle Stress Versus Yoga on Quality of Life



Figures 2.7 and 2.8 show the impact of lifestyle stress as an aggressor and yogic practices as a pacifier on the mind from the Vedic point of view. But what is the impact of this stress on the body physiologically?

Stress is the built-in response of a living organism, evolved to handle demanding situations; often referred to as ‘fight or flight’ -- that is, either to prepare to fight or run away to safety.⁴⁸ In mammals, either choice triggers the sympathetic nervous system (SNS) into action, which will cause the pupils to dilate for better vision, move blood away from the intestine toward the big skeletal muscles that need fuel for action, and increases the heart rate as well as breathing rate to provide the necessary oxygen to the muscle cells. However, once the threat is over, the parasympathetic nervous system (PNS) kicks in to bring the body back to its normal homeostatic state.⁴⁸

The human body has evolved very well to handle the stress caused by such occasional demanding situations. The problem is that the stress caused by the modern lifestyle or an illness is usually continuous and does not allow the PNS come into action and do its part.⁴⁸ As a result, the body forgets its normal homeostatic state and adapts a hyper sympathetic state, even in the absence of any danger. Such a hypersympathetic state usually compromises the health and the quality of life of the individual.⁴⁸ When administered properly, yoga practices generally involve a set of stimulations followed by deep relaxations to reverse this condition and reactivate the parasympathetic functions in the body.² Swami Sivananda, a physician and one of India’s greatest yogis, once said: “*Hatha yoga* is a course of psycho-physiological discipline for the attainment of complete mastery over the body, the nervous system and *prāṇa*.” But this mastery comes with other self development practices for a pregnant woman.

Responsibility (*prabhutvama*), tolerance (*titikṣā*), contentment (*santoṣa*), and self confidence (*ātma viśvāsa*) are some of the essential qualities necessary for moving towards a healthy motherhood. Yoga is also defined as ‘freedom’ or ‘personal autonomy’; that is to be able to shift from established patterns of psychological responses to a desired response at will. To do, not to do, or to do differently is the freedom we all possess (कर्तुमकर्तुमन्यथा वा कर्तुम् शक्यम् *kartuma kartumanyatha va kartum sakyama*).⁹⁴ This freedom evolves by dwelling in the inner silent state marked by blissful awareness during yoga practices.⁹⁴ There are numerous such practices that could be incorporated in the design of trials based on the teachings of the four paths of yoga, which are *jñāna yoga* (yoga of knowledge), *bhakti yoga* (yoga of devotion), *karma yoga* (yoga of service), and *rāja yoga* (yoga of controlling the mind): i)

dhāraṇā (concentration), ii) *bhāvanā* (contemplation on a deity), iii) *padhanā* (study of the scriptures), iv) *satsaṅga* (being in the company of wise people), v) *japaḥ* (chanting of the holy names), vi) *sevā* (selfless service), vii) *viveka* (developing discrimination between right and wrong), viii) *virāgia* (developing dispassion toward the objects of the senses), and ix) *bhakti* (transforming hard emotions into soft, divine emotions, as it is said in the *narada bhakti sutra*: the purest form of love is devotion परम प्रेम रूप भक्ति: *param parama prema rupa bhakti*).⁴⁸ Practices of *bhakti yoga* are deeply embedded in the Indian traditions starting from regular daily worship of the personal God (*iṣṭadevatā*) to special celebrations (*samskārā*) with intense practices (*vratās*) for different phases of pregnancy. The abode of the mother should be well fumigated, worshiped, having sound of the Vedic hymns (or other spiritual songs from other faiths) being recited by *brāhmanās* (holy priests). The pregnant woman after getting up in the morning and performing her regular chores should be busy in worship of god and should do selfless service (*sevā*).⁹⁵ Table 2.4, outlines the different practices recommended for women in high-risk or low-risk pregnancies.

Table 2.4: Recommended Vedic Practices During Pregnancy

PRACTICES	LOW-RISK PREGNANCIES (LRP)	HIGH-RISK PREGNANCIES (HRP)
Diet	Sattvic diet plus folic acid, calcium, vitamin D supplements.	Same as LRP, but with reduced consumption of salt, sugar, and simple carbohydrates.
Kriyas	<i>vamanadhauti</i> and <i>kapālabhāti</i> (during the 1st trimester only) and <i>Jala neti</i>	<i>Jala neti</i>
Āsanās, and stretching practices	<i>tādāsana</i> , <i>ardhakāṭi-cakrāsana</i> , <i>trikoṇāsana</i> , <i>vajrāsana</i> , <i>vakrāsana</i> , <i>siddhāsana</i> , <i>baddha koṇāsana</i> , <i>ūpaviṣṭa koṇāsana</i> , <i>vīparita karaṇī</i> , <i>ardha-pāvanamuktāsana</i>	<i>pādāsañcālanama</i> , <i>gulphaghurṇama</i> , <i>jānuphalakarṇama</i> , <i>ardhatitaliāsana</i> , <i>purṇa titaliāsana</i> , <i>matsyakriḍāsana</i>
Breathing exercises	<i>hasta āyāma śvasanam</i> , <i>hastavistāra śvāsanam</i> , <i>gulphavistāra śvasanam</i> , <i>setubandhāsana śvasanam</i>), <i>kaṭiparivartana śvasanam</i> , <i>uttānapādāsana śvasanam</i> , <i>supta udarakarāsana śvasanam</i> , <i>vyaghrāsana śvasanam</i>	
Prāṇayama	Sectional breathing, <i>nāḍīśuddhi</i> , <i>śitalī</i> , <i>bhrāmari</i> , <i>nāḍīśodhana</i>	
Kriyās	<i>Jala neti</i> throughout pregnancy.	
Meditation	Visualization, guided imagery, <i>trāṭaka</i> , Om meditation	
Samskāras during pregnancy	Garbhādhāna, <i>Purīśavana</i> , <i>Sīmanatonnayana</i> , and <i>Jātakarma</i>	
Spiritual	<i>jñāna yoga</i> , <i>bhakti yoga</i> , <i>karma yoga</i> , <i>rāja yoga</i> : <i>dhāraṇā</i> , <i>padhanā bhāvanā</i> , <i>bhakti</i> , <i>viveka</i> , <i>sevā</i> , <i>satsaṅga</i> , <i>vairāgya</i>	
Self Care	Daily bath, massage, enema, vaginal tampons, and/or lubrication	

CHAPTER 3

SCIENTIFIC LITERATURE SEARCH

CHAPTER CONTENTS:

- Etiology of Pregnancy Complications
- Pathophysiology of Pregnancy Complications
- Doppler Velocimeter
- Effects of Stress on Pregnancy
- Effects of Exercise on Pregnancy
- Effects of Other Mind-Body Therapies on Pregnancy
- Effects of Yoga on Pregnancy

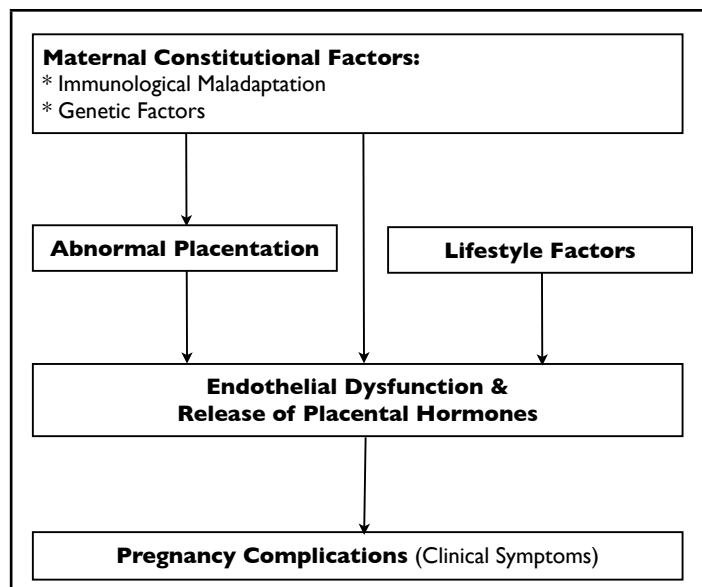
Chapter 3: Scientific Literature Search

In chapter 1, we have seen that high-risk pregnancies are on the increase and the incidence of common complications of pregnancy have dramatically increased in common years. There are many factors that seem to contribute to these complications. Lifestyle and psychosocial stress have been shown to play an important role in their etiology. Stress management techniques can complement the present conventional management measures to further reduce the health risks to the mother and her child. There is now mounting evidence that yoga can reduce stress substantially. In this chapter, we review the scientific data in the literature that provides a rationale for conducting this study of yoga in high-risk pregnancy.

3.1 Etiology of Pregnancy Complications

The etiology of most pregnancy complications is still not clear. There are several hypotheses on how these complications originate and evolve. Maternal constitutional factors, such as immunological maladaptation and genetic predisposition are believed to lead to abnormal placentation, which in turn results in endothelial dysfunction and ultimately manifestation of pregnancy complications.⁹⁶ Figure 3.1 provides an schematic view of this hypothetical process. In addition, it has been shown that a number of other factors play a strong role in the etiology of pregnancy complications

Figure 3.1: Etiology of Pregnancy Complications



investigated in this study. These include: increased insulin resistance^{22, 97, 98} and associated elevations in the levels of insulin²², elevated levels of free fatty acids and triglycerides,^{99,100} increased oxidative stress,^{101,102} presence of microvillus particles¹⁰³⁻¹⁰⁵ and other cytokines¹⁰⁶ in maternal blood, and finally imbalances in maternal hormones, such as progesterone,¹⁰⁷ estrogen,¹⁰⁸ and Lactogen^{108,109}.

3.1.1 IMMUNOLOGICAL MALADAPTATION

Pregnancy has been defined as a state of “altered immune competence”.¹¹⁰ While inflammatory response and hemostasis are innate immunological responses of human body to foreign insults, maternal immunity undergoes subtle alteration in order to tolerate the embryo and maintain proper defense against potential pathogens.¹¹¹ Immune maladaptation and hemostatic imbalance have been suggested to be responsible for adverse pregnancy outcomes, including preeclampsia, preterm delivery, and IUGR.¹¹²⁻¹¹⁴ Improper placentation and shallow cytotrophoblast invasion have been implicated for this immunological maladaptation that leads to these complications, particularly preeclampsia.¹¹⁵ Preeclampsia is most prevalent among women in their first pregnancy and those of extreme ages.¹⁸ But interestingly, pregnancy in multigravidae by a new partner have a risk of preeclampsia close to the women in their first pregnancies.¹¹⁶ This seems to support the hypothesis of ‘immunological maladaptation’, wherein the maternal immune system fails to properly handle the new paternal antigen.^{22, 117, 118} The hypothesis is also supported by observations that the risk of preeclampsia is reduced when the partners have had a longer period of sexual intercourse prior to conception¹¹⁹ and that the risk is increased when partners use contraceptives that limits the female from exposure to semen.¹²⁰ It has been shown that the lymphocytes of women with PE do not exhibit the same cellular hypo-responsiveness to fetal cells than those of normal pregnant women.¹²¹ This idea is further backed by realizing that the activity of proinflammatory cytokines, such as TNF- α , IL-6, IL-2 and IL-12, are increased in women with PE.¹²² The increased activity of these cytokines can in turn result in endothelial dysfunction.⁹⁶

3.1.2 GENETIC FACTORS

Preeclampsia is two to five times more prevalent among mothers, daughters, sisters, and granddaughters than in mothers-in-law, daughters-in-law, or control populations;¹²³ suggesting the involvement of both maternal and fetal genes in the syndrome.^{22,124,125} Since both genotypes must be considered, deciphering the genetic involvement in PE becomes challenging.¹⁰ Maternal and fetal genes may have independent or interactive effects on the risk of pre-eclampsia.¹⁰ Other pregnancy complications, such as IUGR and GDM, follow the same challenges. But in general, the role of the placenta in the primary pathogenesis of the

complications of pregnancy, particularly in preeclampsia, strongly suggests a fetal contribution to the susceptibility to these disorders.^{126,127} Previous studies have reported a higher rate of pre-eclampsia in pregnancies fathered by men who were themselves born of pre-eclamptic pregnancies, suggesting the paternal role in the disorder.¹²⁸ According to the genetic conflict hypothesis, fetal (paternal) genes will be selected to increase the transfer of nutrients to the fetus, whereas maternal genes will be selected to limit transfer in excess of a specific maternal optimum.¹⁰ Fetal genes are predicted to raise maternal blood pressure in order to enhance the uteroplacental blood flow, whereas maternal genes act the opposite way.¹⁰ Based on this logic, we could interpret the endothelial dysfunction in mothers with pre-eclampsia, as a fetal attempt to compensate for an inadequate uteroplacental nutrient supply.¹⁰

3.1.3 ABNORMAL PLACENTATION

All eutherian species have placenta to deliver nutrition to the fetus. To accomplish this task, the placenta is developed in two stages: 1) invasion of the trophoblast cells into the uterus to promote maternal blood flow to the implantation site, and 2) increasing the surface area of this site by complex folding and branching of the chorionic trophoblast surface for more nutrition to pass through the placenta corridor.¹²⁹ Interference with either one of these developmental events can endanger the life of the fetus and lead to serious pregnancy complications.¹²⁹ In fact, it is widely accepted that abnormal placentation is involved in the genesis of preeclampsia,^{130,131} IUGR²⁴ and IUFD.¹²⁹ The very fact that placental delivery reverses the symptoms of preeclampsia,¹³² suggests that the placenta, the placental hormones¹³³, and the placental perfusion have a pivotal role in the condition.^{23, 131} Successful placentation is crucial in fetal development and can directly impact perinatal outcome.¹³⁴ Furthermore, laboratory examinations of placenta after delivery have been shown to relate placental pathology to adverse perinatal outcomes.¹³⁵ The adverse perinatal outcomes that has been linked to placental abnormalities include stillbirth,¹³⁶ infant death syndrome,¹³⁷ PIH,^{8,138} GDM,¹³⁸ and asymmetric IUGR,¹³⁹ where the vital organs of a fetus, such as the brain and heart, are protected at the expense of the liver, muscle and fat.

3.1.4 PLACENTAL FACTORS

It has been shown that the sera of PE patients are toxic to endothelial cells.^{140, 141} This toxicity, along with the clinical symptoms of PE, seems to remit after delivery.¹⁴⁰ Furthermore, the toxicity seems to modulate endothelial cell function rather than damage the cells.⁹⁶ Some studies have suggested that oxidative stress plays a key role in this toxicity.⁹⁶ Activated decidual large granulocytes produce cytokines, proteases and oxygen free radicals.⁹⁶ When oxygen free radicals are not eliminated by antioxidants, lipid peroxide formation is induced,¹⁴² which can cause endothelial damage.¹⁴³ This is supported by the results of other studies that have reported increased levels of lipid peroxidation products in the blood, decidua basalis,¹⁴⁴ and also in the placentae of PE subjects,¹⁴² as well as the studies that have shown administration of high dose of antioxidants can in fact reduce the risk of PE.¹⁰¹ The alterations in the lipid concentration in PE could be caused by cytokines, like TNF- α , IL-1 and IL-6.¹⁴⁵

3.1.5 ENDOTHELIAL DYSFUNCTION

The endothelium plays a major role in the vascular changes in pregnancy.⁹⁶ In normal pregnancy, the increased presence of vasodilators and/or the decreased production of vasoconstrictors cause vasodilation.¹⁴⁶ In PE there is overwhelming evidence for functional^{101, 102} and structural¹⁰⁴ disorder in the endothelium, which are detected in a variety of ways. A marker for endothelial dysfunction that has recently been widely studied is Endothelin-1 (ET-1), a potent vasoconstrictor produced by many tissues including lung, kidney, brain, endocrine glands, and placenta.¹⁴⁷ ET-1 is also expressed by several cell types, the most prominent source is vascular endothelium. Elevated blood ET-1 levels are associated with a variety of diseases, particularly endothelial dysfunction, which, as we have seen, has been implicated for a number of pregnancy complications.¹⁴⁷⁻¹⁵⁰ In one study, uterine vein ET-1 levels were three times higher in PE.¹⁴⁸ Another prominent marker is vascular endothelial growth factor (VEGF), which is not only involved in vascular growth, but also has a vasoactive effect and causes increased vascular permeability.¹⁵¹ Circulating levels of VEGF were found to be elevated¹⁵¹⁻¹⁵⁴ and correlated to blood pressure in patients with PE.¹⁵⁵ Increased VEGF concentrations could contribute to the extravasation of plasma proteins and subsequent development of proteinuria, both characteristic features of PE.¹⁵⁶

3.1.6 LIFESTYLE FACTORS

It has been long understood that lifestyle habits play an important role in clinical manifestation of pregnancy complications.^{157, 158} Women who adopt a sedentary lifestyle, have a poor diet, and are exposed to excess psychological stress are more susceptible to complications during their pregnancies.^{157, 158}

3.2 Pathophysiology of Pregnancy Complications

While there are multiple factors involved in the pathophysiology of pregnancy complications considered in this study, it is likely that abnormal placentation plays an important common role. More specifically, it is believed that endothelial dysfunction is the common denominator of the clinical symptoms of many complications of pregnancy, in particular those that are related to hypertension.¹⁵⁹ Placental ischemia is thought to lead to widespread activation/dysfunction of the maternal vascular endothelium that results in enhanced formation of endothelin, increased vascular sensitivity to angiotensin II, and decreased formation of vasodilators.¹⁶⁰ Oxidative stress, impaired function of vasodilators, cellular and humoral immunological factors play an important role in the pathophysiology of the placenta.

It is important to understand the relationship between placental dysfunction and oxygen intake. As the normal pregnancy progresses, extravillous trophoblasts surround and invade the arterial walls, fibrinoid matrix accumulates, and musculoelastic tissue is lost.¹⁶¹ This in turn creates a high-flow, low-resistance zone within the placenta where maximal exchange of nutrients, respiratory gases, and waste products between the maternal and fetal circulations can occur.¹²⁹ Any disruption to transfer at any point in the oxygen pathway could translate into absent or reversed end-diastolic flow (A-EDF or R-EDF) velocity in the umbilical arteries,¹²⁹ which can be detected on a Doppler velocimetry. Studies have shown that such disruptions cause the small fetuses of IUGR pregnancies to become hypoxic and acidotic.¹⁶² As fetuses become hypoxic, they begin to develop a mixed respiratory and metabolic acidosis.¹²⁹ In a study of small fetuses with A-EDF on Doppler velocimetry of the umbilical artery, 88% of the fetuses were either hypoxic, acidotic, or both.¹⁶³

An interesting phenomenon during pregnancy is the presence of hemodilution. In pregnancy, plasma volume increases progressively beginning in the first trimester, peaking in the third

trimester, and maintaining that peak level until delivery.^{164, 165} It is believed that this increase in plasma volume is due to the fetal requirements for higher circulation during its development.¹⁶⁶ However, while plasma increases by as much as 50%, the red blood cells increase only about 30% during this plasma expansion period, resulting in a physiologic dilution of red blood cells called “hemodilution” that can look a lot like anemia.¹⁶⁷ In a normal pregnancy, after the 28th week of gestation, the hemoglobin values begin to rise again as the plasma stops expanding and red blood cells continue to increase.¹⁶⁷ In complicated pregnancies either the expansion of plasma volume is inadequate resulting in “small for gestational age” babies, or the platelet count values don’t increase sufficiently, leading to a condition called thrombocytopenia¹⁶⁸ as well as other cardiovascular deterioration¹⁶⁹.

Aside from platelet count, uric acid also plays an important role in the pathophysiology of pregnancy, particularly in preeclampsia and eclampsia. In pregnancy, maternal serum uric acid level decreases until the 8th week of gestation and remains at this level until the 24th week when it starts increasing until term.¹⁷⁰ At term, it is higher than the pre-pregnancy level and an elevated concentration is maintained for at least 12 weeks postpartum.¹⁷⁰ In a normal pregnancy, the renal clearance of uric acid is high, especially in the middle period when the serum level is low in spite of the increased production of uric acid by the fetus.^{171, 172} However, in preeclamptic pregnancy, this renal clearance of uric acid is not maintained, resulting in higher uric acid concentrations (more than 2.0mg% above normal for gestational age¹⁶⁹) than in normal pregnancy.^{169, 171} It has been shown that women with abnormal Doppler have a significantly higher levels of serum uric acid level, a condition called hyperuricemia,¹⁷³ and Hyperuricemia is a well-recognized risk factor for cardiovascular diseases,¹⁷³ and in preeclampsia, the degree of hyperuricaemia has been shown to reflect the severity of the disorder.¹⁷⁴ It is important to point out that often the fall in the platelet count and rise in the serum uric acid levels coincide.¹⁷⁴

3.2.1 PREGNANCY INDUCED HYPERTENSION

Although PIH has been identified as the leading cause of maternal death and a major contributor of maternal and perinatal morbidity, the mechanisms responsible for its pathogenesis have not yet been clearly understood.¹⁶⁰ Some studies suggest that the reduced uteroplacental perfusion as a result of abnormal cytotrophoblast invasion of spiral arterioles

to be the initiating cause.¹⁶⁰ This insufficient perfusion causes the placenta to secrete various kinds of proinflammatory molecules that damage the maternal endothelial cells, and in consequence, vascular resistance is increased that further burdens maternal organs with hypertension.¹⁷⁵ It is thought that systemic inflammatory response and dysfunction of the maternal endothelial cells represent the pathological scheme of PIH.^{160, 176, 177}

3.2.2 PREECLAMPSIA AND ECLAMPSIA

Similar to PIH, it is believed that the symptomatic phase of preeclampsia and eclampsia originates with the placenta, as delivery of the fetus alone is not palliative, and only removal of the entire placenta will cause the condition to remit.^{159, 178, 179} Recent research has begun to elucidate the link between placental ischemia and hypertension in the preeclamptic patients.¹⁸⁰ The placental ischemia, in turn, results in hypoxia and leads to the release of soluble factors, in particular angiogenic factors, such as vascular endothelial growth factor (VEGF) and its variant soluble fms-like tyrosine kinase-1 (sFlt-1), into the maternal bloodstream, which act as pathological agents.¹⁷⁹ During pregnancy, VEGF and sFlt-1 are both produced in abundance from the placenta, and one of the recent findings in preeclampsia research has been that sFlt-1 is elevated significantly in response to placental ischemia.¹⁸¹ In fact, several studies have suggested that inhibition of sFlt-1 can actually attenuate many the symptoms of preeclampsia in animals.^{179, 182, 183} In humans, a small pilot study demonstrated that removal of sFlt-1 could improve BP and proteinuria in patients suffering from early-onset preeclampsia.¹⁸⁴ All this data point to the hypothesis that the release of soluble factors into the maternal blood stream from the ischemic placenta is a key event in the pathogenesis of preeclampsia.¹⁷⁹ In addition to the soluble factors, the maternal immune responses are also induced by placental ischemia, which results in elevated circulating levels of inflammatory cytokines (such as TNF- α and IL-6) and contribute significantly to the maternal symptoms.^{179, 185} Finally, as we saw earlier, several studies have suggested that endothelin-1 plays a key role in the pathophysiology of preeclampsia.¹⁷⁹ It is further suggested that high levels of endothelin-1 in preeclamptic women¹⁸⁶ act as a common pathway by which the antiangiogenic factors and autoimmune response lead to maternal hypertension.^{180, 187, 188} Accordingly, sFlt-1, placental growth factor, endoglin, and VEGF, all of which increase 4–8 weeks before onset of the disease, may be useful predictors of pre-eclampsia.¹⁸⁹

The effect of systemic endothelial dysfunction leads to impairment in many organs. This impairment in the hepatic endothelium contributes to onset of the HELLP (Hemolysis, Elevated Liver enzymes and Low Platelet count) syndrome, in the cerebral endothelium induces refractory neurological disorders, and in the renal endothelium decreases glomerular filtration causing proteinuria- all of which could eventually lead to eclampsia.¹⁸⁹ Finally, endothelial dysfunction promotes microangiopathic hemolytic anemia, and vascular hyperpermeability associated with low serum albumin which in turn causes edema, particularly in the lower limbs or lungs observed in severe preeclampsia and eclampsia.¹⁸⁹

3.2.3 GESTATIONAL DIABETES

During normal pregnancy, there is a slight but progressive decrease in insulin sensitivity.¹⁹⁰ To maintain a proper glucose metabolism in pregnancy, the maternal production of insulin must increase to counteract the fall in insulin sensitivity.¹⁹⁰ In women with GDM, this increase in production of insulin does not occur.¹⁹⁰ Hormones present in the pregnancy, especially human placental lactogen, are thought to be responsible for this shortfall.¹⁹¹ At least one study, has suggested that the reason only a subgroup of women suffer from this hormonal impact may be related to the antigenic load imposed by the fetus itself.¹⁹¹ The rationale for this hypothesis is that some transplant recipients develop diabetes shortly after the operation with very similar characteristics as GDM.¹⁹¹ Again, the inability to handle the fetal antigenic load has been suggested to be due to improper development of placenta,¹³ which some authors have suggested to be due to excessive oxidative stress.¹⁹²

3.2.4 INTRAUTERINE GROWTH RESTRICTION AND SMALL FOR GESTATIONAL AGE

Similar to preeclampsia, levels of endothelin-1 have been shown to be elevated in pregnancies complicated by IUGR, suggesting a common etiology.¹⁹³ This common etiological factor appears to be the reduced trophoblast invasion that leads to deficient conversion of the myometrial segments of uterine spiral arteries. Defective trophoblast invasion will result in reduction of uteroplacental blood flow and in turn less nutrients to the fetus.¹⁹⁴ This has long been implicated in the causation of IUGR, SGA, and preeclampsia.¹⁹⁴⁻¹⁹⁶

3.3 Doppler Velocimetry

Doppler assessment is a non-invasive procedure and hence acceptable to patients. It is a reliable method of examining utero-placental perfusion and identifying many conditions that would be harmful to the mother and the baby.¹⁹⁷ World Health Organization has stated that "Diagnostic ultrasound is recognized as a safe, effective, and highly flexible imaging modality capable of providing clinically relevant information about most parts of the body in a rapid and cost-effective fashion"¹⁹⁸ Obstetric ultrasound is primarily used to find out the date the pregnancy, confirm fetal viability, determine location of the fetus and the placenta, check for the number of fetuses, check for any physical abnormalities, assess fetal growth (evidence of IUGR), check for fetal movement and heartbeat, and determine the sex of the baby.

3.3.1 DOPPLER MEASUREMENTS

In a typical pelvic ultrasound study, the following parameters are measured:

a) Fetal measurements

- i) Bi-parietal diameter or the diameter of skull in mm (BPD),
- ii) Head circumference in mm (HC),
- iii) Abdominal circumference in mm (AC),
- iv) Femur length in mm (FL),
- v) Fetal heart rate in bpm (FHR), and
- vi) Estimated fetal weight in grams (EFW).

b) Placental data

- i) Position of placenta in relations to the cervix and
- ii) Grading of placental maturity

c) Gestational age - Early ultrasound examination, ideally at eight to 13 weeks of gestation, is also an accurate method for estimating gestational age.¹³⁹

In a full Doppler study, the following parameters are measured for left uterine artery, right uterine artery, umbilical artery, and fetal middle cerebral artery:

- a) Systolic over diastolic ratio (S/D ratio) - When this number is above 2.6, it is considered elevated. Elevated S/D ratio when accompanied by a diastolic notch can be considered as a marker for PE and IUGR.¹⁹⁹ A diastolic notch is seen as a trough like notch between the systolic and diastolic phases in a flow velocity waveform of an ultrasound and has been shown to be closely associated with uteroplacental insufficiency.¹⁹⁹
- b) Peak systolic velocity (V_{max}), which is used to detect fetal anemia;²⁰⁰
- c) Minimum forward diastolic velocity (V_{min}), which is the minimum forward diastolic velocity in unidirectional flow or the maximum negative velocity in diastolic flow reversal.
- d) Pulsatility Index (PI) in an arterial blood-flow velocity waveform index designed to quantify the pulsatility or oscillations of the waveform. The index is particularly valuable when there is diastolic flow reversal, i.e. bidirectional flow. PI is calculated from values of V_{max} and V_{min} in the following formula and the lower values of it shows improvement:

$$PI = (V_{max} - V_{min}) / (V_{max} \text{ mean})$$

where V_{max} mean is the maximum velocity
averaged over (at least) one cardiac cycle

- e) Resistance Index (RI) in an arterial blood flow velocity waveform, intended for use in arteries where there is no reverse flow. It should be noted that although increased vascular resistance may increase the RI, the index is also affected by several other factors, such as upstream stenosis, vessel-wall compliance, elevated blood pressure and heart rate. At increasing heart rates, the systolic upstroke occurs earlier on the declining diastolic velocity curve, resulting in an increase in the end-diastolic velocity. The lower the values of RI, the less resistance there is in the arterial blood flow. RI is calculated from the following formula:

$$RI = (V_{PS} - V_{ES}) / V_{PS}$$

where V_{PS} is the peak systolic velocity,
and V_{ES} is the end-diastolic velocity

3.3.2 DOPPLER DURING PREGNANCY

Recent findings indicate that indices of uterine artery resistance correlate not only with birth weight²⁰¹, but also with the extent of trophoblast invasion.^{197,202,203} This is important because, as we have seen earlier, the placental dysfunction is strongly implicated as a contributor to many complications of pregnancy. As a rule, demonstration of an absent or reversed flow in end diastole in the umbilical arteries carries with it a very specific indication of serious fetal compromise.²⁰⁴ In a cross-sectional study of 265 consecutive pregnant women attending routine ultrasound examination at 11-14 weeks' gestation, both uterine arteries were identified using color Doppler ultrasound and the uterine artery resistance index (RI) was measured.¹⁹⁷ The objective was to determine reference values for first-trimester RI in healthy pregnant women with uncomplicated pregnancies and to investigate the relationship between uterine artery Doppler indices and birth weight. The 5th, 50th and 95th centiles for uterine artery RI between 11 and 14 weeks' gestation were 0.53, 0.71 and 0.85, respectively. The study reported a significant negative correlation between birth weight and first-trimester uterine artery Doppler parameters. In one study, it was shown that pregnant women with abnormal Doppler had significantly higher serum uric acid level and significantly lower platelet count than the group with normal Doppler.¹⁶⁸ The same study also found that the incidence of IUGR, low Apgar score, perinatal deaths and operative delivery for fetal distress was significantly higher in the group with abnormal Doppler.

3.3.3 DOPPLER AS A PREDICTOR

Accurate prediction of pregnancy complications, in particular pre-eclampsia (PE) and intrauterine growth restriction (IUGR), is crucial to improve maternal and perinatal outcomes.^{205, 206} Doppler Velocimetry has been the most widely used marker for predicting pregnancy complications. There is substantial evidence in the literature that there is a correlation between uterine artery resistance and manifestation of complications, such as PIH,²⁰⁷ preeclampsia,^{202, 208-213} SGA,^{201, 213, 214} IUGR,^{202, 207, 214, 215} and preterm deliveries^{207, 216, 217}. However, expert opinions vary on the gestational age to perform the Doppler assessment to obtain the best predictive results. Some suggest a first-trimester uterine artery examination,^{208-210, 212, 214, 216} while others prefer a mid-gestation or third trimester assessment.^{201, 207, 213, 218}

3.4 Effects of Stress on Pregnancy

Emotional and psychological stress has been shown to aggravate chronic pain, promote coronary heart disease, and weaken the immune system²¹⁹. Stress is a powerful sympathetic nervous system stimulant, leading to increased heart rate and blood pressure.²²⁰ In the earlier chapters, we saw how lifestyle stress can impact the health and quality of life of the mother. In this chapter we see how this stress can impact the fetus and the outcome of the pregnancy. Psychosocial stress in pregnancy has been defined as “the imbalance that a pregnant woman feels when she cannot cope with demands...which is expressed both behaviorally and physiologically”.²²¹ Psychosocial stress during pregnancy (‘maternal stress’) has been shown to adversely affect the pregnancy outcomes.²²² In fact, several studies have reported that events in the maternal environment will filter through the placental barrier and can affect its development.^{223, 223, 224} Furthermore, there is now a mounting evidence that maternal stress can, not only increase the risk of morbidity and premature mortality,^{225, 226} but it can also predispose the affected individuals to diseases over the course of their lives.²²⁷ It is then not surprising that the National Institutes of Health (NIH) and the World Health Organization (WHO) have both advised that the role of maternal stress during pregnancy should be given high research priority.^{228, 229} The research that has followed these recommendations have linked maternal stress to an increased risk of specific diseases such as malformations,²²² asthma,²³⁰ mental and behavioral disorders,²³¹ and attention deficit hyperactivity disorder in the childhood. These results were confirmed by a large population-based cohort study that found maternal life stress during pregnancy was associated with an increased risk of a wide range of diseases during childhood.²³² Maternal stress has also been shown to increase the rate of spontaneous abortions and preterm birth.²³³

A strongly supported hypothesis relies on the activity of the hypothalamic-pituitary-adrenal (HPA) axis to explain biologically the effects of maternal stress on the fetus.²³⁴ Activation of the HPA axis, in response to physical or psychological stress, results in the release of circulating cortisol.²³⁴ In stressful situations, elevated maternal cortisol could exceed the placental capacity to degrade it, cross the placental barrier and influence the developing brain and/or ‘program’ the fetal HPA axis.²³⁵ At the same time, maternal stress could cause a constriction of the uterine artery, leading to decreased blood flow to the fetus.²³⁴ The resulting fetal hypoxia may hinder fetal development and predispose the child to health problems later in life.²³⁶

In connection with psychological stress, oxidative stress in utero–placental tissues also plays a key role in the development of pregnancy complications.²³⁶ Modern lifestyle exposes us to many ‘free radicals’ through pollution, pesticides, and preservatives. Free radicals are organic molecules having some unpaired electrons, which makes them highly reactive and prone to bond with oxygen atoms. The most important free radicals seem to be reactive oxygen species (ROS) and reactive nitrogen species (RNS).²³⁷ Formation of ROS and RNS in the human body can cause oxidative damage to the organ tissues and cells.²³⁷ In normal pregnancies, the production of free radicals and lipoperoxidation increase towards the end of the pregnancy, as compared to non-pregnant women.²³⁸ At the same time, the antioxidant capacity gradually increases during pregnancy, leading to an oxidative balance that is maintained throughout pregnancy.²³⁹ On the other hand, a lack of balance between free radicals and antioxidants leads to oxidative stress.¹¹ Diet rich in antioxidants, such as vitamin C, vitamin E, carotenoids, and flavonoids, have been suggested to scavenge ROS and RNS.²⁴⁰

3.5 Effects of Exercise on Pregnancy

Exercise has been shown to reduce pregnancy related physical problems, such as fatigue, varicosities, and swelling of extremities,^{241,242} as well as psychological disorders such as insomnia, stress, anxiety and depression.²⁴³ Fetuses of exercising women may tolerate labor better than those of non-exercisers.^{244, 245} Furthermore, clinical evidence of stress, as exhibited by meconium, fetal heart rate pattern and Apgar scores is less frequent in women who exercise at 50% of preconception level throughout pregnancy, compared with well-conditioned athletes who discontinued exercise before the end of their first trimester.²⁴⁵ In contrast, a sedentary lifestyle during pregnancy may contribute to loss of muscular and cardiovascular fitness, excessive maternal weight gain, raised risk of gestational diabetes mellitus²⁴⁶, and pre-eclampsia^{23, 247, 248}.

In a study conducted in Japan, 573 primiparous women underwent simple water exercises.²⁴⁹ Blood pressure and the incidences of hypertension, proteinuria and leg edema were compared with 264 primiparous women in the control group who did not practice these exercises. Significant reduction in systolic and diastolic blood pressure was reported in the water-exercise group after 20 weeks of water exercises. Furthermore, the incidence of proteinuria

was reduced by 53%, edema by 60%, and preeclampsia by 57% in the water-exercise group as compared to the control group.

It has been suggested that regular physical activities may protect against preeclampsia by intervening at three key stages²⁴⁸ in the disease process:

- a) Enhanced placental growth and vascularity (protection against abnormal placental development),
- b) Reduction of oxidative stress, and
- c) Reversal of endothelial dysfunction.

3.6 Effects of Other Mind-Body Therapies on Pregnancy

Mind-body therapies follow the beliefs of many ancient medicine systems that the self is comprised of the mind and body. Therefore, if by “healing” we imply "to make whole," the body cannot truly be healed without healing the mind. The conventional medicine is mainly focused on removing the symptoms of the disease, while traditional mind-body therapies seek to remove the root cause of them. Yet, both systems have their duly earned place in treating ailments. Mind-body therapies usually require a long time to address the root cause of ailments; therefore in emergencies, it is the allopathic medicine that saves lives. In contrast, using pharmacological solutions for a long period of time to manage ailments may not be the best alternative. In general, mind-body therapies incorporate a wide array of modalities, which all center on the connection in healing between the mind and the body. There are many different mind-body therapies. Some of the techniques that have previously been studied during pregnancy and/or are relevant to this study are very briefly discussed below.

3.6.1 MEDITATION AND RELAXATION

Although meditation and relaxation have long held a place in religious and spiritual contexts, it wasn't until the late 1960's that they were studied in traditional western medicine.²⁵⁰ Meditation and relaxation are best used together for therapeutic purposes.²¹⁹ The effects of meditation were first detailed in a research conducted by Dr. Herbert Benson at Harvard University Medical School who described a state of relaxation induced by meditation, which manifested itself in the form of decreased sympathetic nervous system activity and increased parasympathetic nervous system activity.²¹⁹ While many meditation techniques are based on

concentration on a single object or action, mindfulness meditation technique encourages the practitioner to be in the present and stay fully aware of his/her surroundings. In pregnancy, mindfulness meditation has been used to improve the pregnant woman's mood,²⁵¹ reduce her stress,²⁵¹⁻²⁵³

3.6.2 ACUPUNCTURE

Acupuncture literally means to puncture with a needle. It originated in China many centuries ago and soon spread to Japan, the Korean peninsula and elsewhere in Asia, where it is widely used in health care systems, officially recognized by governments, and well received by the general public.²⁵⁴ In the Western countries, its popularity is tempered by skepticism of its true therapeutic effect; some have claimed that it works merely through the placebo effect, the power of suggestion, or the enthusiasm with which patients wish for a cure.²⁵⁴ According to Traditional Chinese medicine, stimulating these points can correct imbalances in the flow of qi (corresponding to *prāṇa* in yoga) through channels known as meridians (corresponding to nadhis in yoga),²⁵⁵ although scientific research has not found any histological or physiological correlates for qi, meridians and acupuncture points.²⁵⁶ The advantages of acupuncture are that it is simple, convenient, has few contraindications, and is safe if it is performed properly by a well-trained practitioner.²⁵⁷ Unlike many drugs, it is non-toxic, and adverse reactions are minimal.²⁵⁵ This is probably one of the chief reasons why acupuncture is so popular in the treatment of chronic pain in many countries.²⁵⁴ Acupuncture has also been shown to be effective in reducing pain,²⁵⁸⁻²⁶⁰ nausea,²⁶¹ and insomnia²⁶² during pregnancy.

3.6.3 QIGONG

Qigong (pronounced “chee-gong”) means “cultivating vital energy”.²⁶³ It is an over 5000 year-old Chinese health method that combines slow movements with mental awareness and breathing to increase and balance a person's vital energy (qi).²⁶⁴ In some texts, it has been referred to as Chinese yoga, due to its similarity to the yoga practices to balance the *prāṇa*.²⁶⁵ In pregnancy, Qigong relaxation techniques were shown to reduce the frequency of incidence of PIH.²⁶⁶

3.6.4 GUIDED IMAGERY

Interactive Guided Imagery (IGI) and visualization are therapeutic techniques that lead the participant through a series of images that promote relaxation by calming the body's natural anxiety-provoking chemicals.²⁵⁰ These images are not restricted to visual pictures, but may involve any of the body's other senses, including touch, smell, motion, and hearing.²⁵⁰ Imagery is a unique field within mind-body therapies because it can be a stand-alone therapy, as well as an important component of other mind-body therapies,²⁵⁰ as it has been used in this research study. For example the repeating of a mantra in meditation is a type of imagery and the use of imagery is evident in biofeedback and hypnosis.^{219, 267} Studies have shown that imagery has profound and dramatic effects on heart rate, respiration, blood pressure, blood lipids, pain perception, and immune function.²⁵⁰ As of yet, there are no previous studies that has effectively investigated the effects of IGI in pregnancy and therefore, this study the first of its kind in this regard.

3.7 Effects of Yoga During Pregnancy

Yoga is an economical, low-impact, stress-reducing, and non-invasive intervention used in prevention and management of many ailments.²⁶⁸⁻²⁷¹ Having few side effects and offering much in the way of lifestyle benefits,^{269, 270, 272, 273} yoga is safe, it is simple to learn, and can be practiced even by elderly, ill, or disabled individuals.²⁷⁴ It is important to understand the proposed mechanism that yoga improves the condition of different ailments.

As we saw in chapter 2, lifestyle stress can play a major role in the manifestation of ailments. Yoga is able to rehabilitate the body to its original and natural way of handling stress by introducing continuous stimulations through *yoga āsanās*, breathing, guided imagery, and visualization techniques, followed by mindful rest. Many studies done by our institution have demonstrated that meditation, breathing, and relaxation techniques have a direct and positive impact on the activities of the autonomic nervous system.^{55, 275-277} In this section, we review the meaning and benefits of yoga, different elements of yoga, the various paths of yoga, and finally the role and effect of yoga in pregnancy.

3.7.1 MEANING OF YOGA

Yoga is derived from the sanskrit root verb ‘yuj’ meaning ‘to unite’. Although many people think this term refers to union between body and mind or body, mind and spirit, the traditional acceptance is union between the *Jivatman* (living soul) and *Paramatman* (higher soul) that is between one's individual consciousness and the Universal Consciousness.²⁷⁸ Therefore Yoga refers to a certain state of consciousness as well as to methods that help one reach that goal or state of union with the divine.⁴⁸

3.7.2 THE 5 POINTS OF YOGA

To clarify the science of Yoga and make it accessible to the majority of seekers, Swami Vishnudevananda extracted its essence and presented it in these universal principles for physical and mental health as well as spiritual growth.²⁷⁹

3.7.2.1 PROPER EXERCISE (*āsanas*)

Our physical body is meant to move and exercise. If our lifestyle does not provide natural motion of muscles and joints, then disease and great discomfort will ensue with time. *Yoga āsanas* are physical postures often imitating the natural positions of the animals meant to make the mind tranquil. Through these postures, the physical revitalization and deep relaxation and mental calmness are achieved.

3.7.2.2 PROPER BREATHING (PRĀṆĀYAMA)

Yoga teaches us how to use the lungs to their maximum capacity and how to control the breath. Proper breathing should be deep, slow and rhythmical. This increases vitality and mental clarity.²⁸⁰

3.7.2.3 PROPER RELAXATION (SAVĀSANA)

Long before the invention of cars, planes, telephones, computers, freeways and other modern triggers of stress, the Rishis (sages or seers) and Yogis devised very powerful techniques of deep relaxation. In fact, many modern stress-management and relaxation methods borrow heavily from this tradition. By relaxing deeply all the muscles the Yogi can thoroughly rejuvenate the nervous system and attain a deep sense of inner peace.

3.7.2.4 PROPER DIET (VEGETARIAN)

Besides being responsible for the building our physical body, the food we eat profoundly affect our mind. For maximum body-mind efficiency and complete spiritual awareness, Yoga advocates a lacto-vegetarian diet. This is an integral part of the yogic lifestyle.

3.7.2.5 MEDITATION

Meditation is a yogic process of providing deep rest to the system by allowing the mind to calm down to its basal states. Features of meditation are:

- Mind dwell on a single thought of choice.
- Deep relaxation of all part of the body.
 - Reduced metabolic rate.
 - Freshness, lightness and a feeling of expansion at mental level
 - Calmness, peace and serene bliss
 - Continuous awareness

The benefits are many. Improved concentration, memory, emotional equipoise and higher creativity are observed.

3.7.3 THE PATHS OF YOGA

There are four main paths of Yoga - Karma Yoga, Bhakti Yoga, Jnana Yoga and *Raja Yoga*. Each is suited to a different temperament or approach to life. All the paths lead ultimately to the same destination - to union with Brahman or God - and the lessons of each of them need to be integrated if true wisdom is to be attained.²⁷⁹⁴⁸

3.7.3.1 KARMA YOGA

Karma yoga is the path of action with an attitude of detachment to the fruits of one's action. It is the path chosen primarily by those of an outgoing nature. It purifies the heart by teaching how to act selflessly, without concerns for rewards. By detaching from the fruits of one's actions and making those results an offering to God, ego becomes sublimed. To achieve this, it is helpful to keep the mind focused by repeating a mantra while engaged in any activity.

3.7.3.2 BHAKTI YOGA

This path appeals particularly to those of an emotional nature. The Bhakti Yogi is motivated chiefly by the power of love and sees God as the embodiment of love. Through prayer, worship and ritual he surrenders himself to God, channeling and transmuting his emotions into unconditional love or devotion. Chanting or singing the praises of God forms a substantial part of Bhakti Yoga.

3.7.3.3 JNANA YOGA

Taking the philosophy of Vedanta, the Jnana Yogi uses his mind to inquire into its own nature. We perceive the space inside and outside a glass as different, just as we see ourselves as separate from the universal consciousness (God). Jnana Yoga leads the devotee to experience his unity with God directly by breaking the glass and dissolving the veils of ignorance. Happiness analysis is one such technique elaborated in the Upanishads, in which the aspirant contemplates in the nature of true happiness and eventually concludes that such eternal happiness is only a state of inner silence. Jnana yoga is a difficult path, because a prerequisite to it is selfless actions and pure devotion to God developed through a strong will and discipline.

3.7.3.4 RAJA YOGA

The yoga of mind culture or psychic control gives a practical and ease approach to reach higher states of consciousness. It is based on the Astanga Yoga of Patanjali's yoga system. Raja Yoga is also called Ahtanga Yoga referring to the eight limbs leading to absolute mental

control. The chief practice of Raja Yoga is meditation. It also includes all other methods that help one to control body, energy, senses and mind. The eight limbs are:

- *Yamas* (the disciplines)
- *Niyamas* (the injunctions)
- *Āsanas* (the posture of the body)
- *Prāṇāyama* (the control of *prāṇa*, the life force)
- *Pratyahara* (restraint of senses from their objects of enjoyment)
- *Dharana* (concentration)
- *Dhyana* (meditation- effortless flow of a single thought)
- *Samadhi* (absorption into super consciousness)

3.7.4 MAIN PRINCIPLES OF YOGA

- Love and help all living beings
- Respect for life
- Peace in the world
- Have pure thoughts and positive lifestyle
- To do regular physical, mental and spiritual practices
- Protection of the nature and the environment
- Have pure thoughts and positive lifestyle
- To do regular physical, mental and spiritual practices
- Tolerance for all - nationalities, cultures and religions

3.7.5 SAFETY OF YOGA DURING PREGNANCY

Stretching exercises, similar to the interventions used in this study, have been widely recommended in maternity care booklets and nursing textbooks and have been found safe in high-risk pregnancy populations.²⁸¹ Although at present there are no recommendations from regulatory organizations regarding the role or safety of yoga during pregnancy, there is at

least one randomized trial that has concluded that: “Yoga by its holistic approach to health appears to be safe in pregnancy and leads to improved outcomes.”⁵⁵ In any case, one of the primary objectives of this study is to find the feasibility and safety of yoga interventions in high-risk population.

3.7.6 EFFECTS OF YOGA IN LOW-RISK PREGNANCIES

In a randomized controlled trial, *Satyapriya et al* studied the effects of yoga interventions on the outcome of pregnancies. While this paper is still under peer review, the results are relevant and notable here. The study randomized 96 low-risk pregnant women into two groups of yoga (n=51) and control (n=45). Primigravidae were excluded from the study. The yoga group received an hour yoga session every alternate day for two months, then an hour twice a week for one month; and finally an hour once a week for a month. The control group received antenatal exercises for the same time. Subjects were recruited in 18 to 20 weeks gestation. The results showed significant improvement in the duration of labor in all three stages ($p < 0.001$ in all three cases). Significantly fewer women in the yoga group in contrast to the control required epidural analgesia ($p < 0.002$), emergency c-section ($p < 0.005$), or preterm delivery ($p = 0.0323$). Furthermore, the yoga interventions in this study were able to significantly reduce the clinical manifestation of PIH and IUGR, as well as improve infant birth weight ($p < 0.001$) and APGAR scores ($p < 0.001$).

In a study conducted in Taiwan, *Sun et al.* investigated the effects of prenatal yoga on the discomforts of pregnancy.¹⁵ This nonrandomized study assigned 88 healthy pregnant women between 26 to 28 weeks gestation to two groups, yoga (n=45) and control (n=43). The yoga group received 30-minutes yoga classes, three times a week, for 12 to 14 weeks. The results showed significant reduction of discomforts in the yoga group ($p = 0.01$).

Beddoe et al. recently showed that mindfulness-based yoga has a positive and significant impact on the sleep quality of the pregnant women.²⁸² This study recruited fifteen healthy, nulliparous women pregnant with single fetus who were in their second or third trimesters. The subjects attended a weekly mindfulness meditation and prenatal Hatha yoga classes for 7 weeks. Sleep variables were measured by 72-hourr of continuous wrist actigraphy and the General Sleep Disturbance Scale (GSDS) at baseline (pre-study) and at the end of the 7-

weeks intervention (post-study). The baseline data from subjects recruited in their third trimester were used as control. Subjects who began the intervention in the second trimester had significantly longer sleep time, fewer awakenings, and less perceived sleep disturbance at post-study than at baseline. Those who began during the third trimester had poorer sleep over time in spite of the intervention. Using the same interventions *Beddoe et al* also studied their effects on the maternal psychological and physical distress.²⁵² The study consisted of only one group (no control) and evaluated self-report measures of psychological distress (Perceived Stress Scale, PSS, and Pregnancy Psychological Profile, PPP), physical distress (pain was measured using a modified version of the Brief Pain Inventory, BPI); salivary cortisol levels were assessed before the first day of the group intervention (pre-assessment) and immediately after completion of the seven weekly intervention sessions (post-assessment). Subjects were all primi, at least 18-years old, and between 12 and 32 weeks gestation. The seven weeks intervention combined elements of Iyengar yoga and mindfulness-based stress reduction techniques. The investigators reported significant reduction in perceived stress ($p=0.05$), no significant improvement in the PPP instrument ($p=0.10$), significant reduction in the trait anxiety ($p=0.03$), and significant lower BPI scores ($p=0.02$). The average morning salivary cortisol level increased from baseline (3.2 ± 3.7 nmol/L) to post-intervention (16.1 ± 5.4 nmol/L; $t=3.06$; $p<0.01$). The results also showed that women who began the yoga intervention in the second trimester reported less pain than women who began in the third trimester, which is consistent with the previous findings that the earlier yoga is practiced in pregnancy the better results that can be expected.

A similar study to that of *Sun et al.* was conducted in Thailand, where *Chuntharapat et al* studied the effects of yoga in reducing labor pain and improving maternal comfort and birth outcomes.²⁸³ In this study, 74 primiparous Thai pregnant women above 18 years of age were randomly assigned to two equal-sized groups of 'prenatal yoga' group and 'usual care' group. The yoga group received 1-hour yoga classes at the 28th, 30th, 32nd, 34th, 36th, and 37th week of gestation (a total of six classes) and were encouraged to practice at least three times per week at home. The control group received usual care only. Pain and comfort were assessed during the labor using multiple instruments: the visual analogue sensation of pain scale (VASPS), the maternal comfort questionnaire (MCQ), the visual analogue scale to total comfort (VASTC), and the pain behavior observation scale (PBOS). The study concluded that

the experimental group had significantly less pain (VASTC: 29.64 ± 9.31 in yoga group vs. 23.67 ± 9.22 in control, $p < 0.05$; VASPS: 83.48 ± 8.89 versus 88.03 ± 8.05 , $p < 0.05$) and had more comfort (MCQ: 156.7 ± 13.43 vs. 150.36 ± 11.70 , $p < 0.05$; PBOS: 9.82 ± 1.76 versus 8.52 ± 1.97). The first stage of labor and total labor duration were also significantly less in the experimental group but the APGAR scores were not significantly improved.

In a randomized controlled trial, *Satyapriya et al.* examined the efficacy of yoga in reducing stress of healthy Indian pregnant women.⁹³ 90 pregnant women were randomized into two equal sized group ($n=45$ for each group) of yoga and control. The yoga group received 1-hour yoga sessions, from 18-20 weeks of pregnancy to term, while the control group received prenatal exercises prescribed by the physician. Perceived stress decreased by 31.57% in the yoga group and increased by 6.60% in the control group ($P=0.001$). In addition, the parasympathetic activity increased in the yoga group significantly ($p < 0.001$). This study also found that yoga is effective in improving the quality of life of pregnant women and in enhancing certain aspects of their interpersonal relationships.⁵⁴

Narendran et al. conducted a study of 335 healthy pregnant women in India that investigated the effects of yoga on pregnancy outcomes.⁵⁵ Subjects recruited between 18 and 20 weeks of pregnancy were assigned to two groups, yoga ($n=169$) and control ($n=166$). They were matched for age, parity, body weight, and Doppler velocimetry scores of umbilical and uterine arteries. The yoga group practiced a combination of physical postures, breathing, and meditation for one hour daily, from the date of entry into the study until delivery. The control group walked 30-minutes twice a day during the same period. The study reported that infants in the yoga group had significantly higher weight ($p < 0.01$; 2.78 ± 0.52 kg compared with controls 2.55 ± 0.52 kg) and mothers in the yoga group experienced significantly less complications like intrauterine growth restrictions ($p < 0.003$), pregnancy induced hypertension ($p < 0.025$), and preterm labor ($p < 0.0006$). The reduction in frequency of pregnancy complications was also significant even among the subject with abnormal Doppler study.⁵⁶

3.7.7 EFFECTS OF YOGA IN HIGH-RISK PREGNANCIES

The present study is the first randomized controlled trial that has used yoga intervention in high-risk pregnancies. However, there have been previous studies that have shown the relationship with pregnancy complications and autonomic systems. One study has shown that preeclampsia is associated with abnormal autonomic behavior and is manifested as increased sympathetic outflow.²⁸⁴ The results of this study indicated that in the preeclamptic subjects the sympathetic-nerve activity is more than three times as high as that in the normotensive pregnant women and more than twice as high as in the group of non-pregnant women with hypertension. The study concluded that the autonomic nervous system adaptations that promote reduced peripheral vascular resistance in normal pregnancy are absent in preeclampsia.

CHAPTER 4

MATERIALS & METHODS

CHAPTER CONTENTS:

- Aims and Objectives
- Design and Settings
- Methods
- Interventions
- Measurements
- Statistical Considerations

Chapter 4: Materials & Methods

We have reviewed the Vedic guidelines for a healthy pregnancy. The scientific literature has been reviewed and we have build a compelling case for the importance of this study of yoga in high-risk pregnancy. A great deal of efforts was spent in design this study in order to collect valuable data that could contribute to the understanding of how yoga impacts the health of the mother and her fetus during pregnancy. Some of the more important issues to decide were:

- As we saw in chapter 1 (table 1.1), there are many different pregnancy complications. Careful attention was paid to selecting the disorders that are prevalent in India and those that could respond to yogic treatments based on the results of previous studies of diseases with similar pathology that had used yoga interventions successfully.
- The selection criteria also had to be chosen with similar attention to the Indian population of this study.
- We visited several hospitals before we chose St. John's Medical College & Hospital and Gunasheela Maternity Hospital in Bengaluru. These two sites were chosen in part due to the diversity of their socio-economic patients.
- The selection of interventions was extremely critical to this trial. Since we did not have any published literature on the effects of yoga in high-risk pregnancy, we selected yoga practices that were safe for this population and had proven value for stress management.
- The choice of parameters to be studied was also vital to the significance of the results. Aside from fetal and outcome measurements, we opted for Doppler study that was also used successfully in previous trial of yoga in low-risk pregnancies. The relationship between visualization and the results of the Doppler study was key to better understanding of the mechanism of action of yoga in high-risk pregnancies.

Finally, selecting and training the research staff was instrumental in conducting an unbiased exact research study. Administration of the interventions had to be uniform among the instructors, the measurements, such as blood pressure and heart rate variability, had to be taken consistently to reduce the impact of confounders, and perhaps most importantly, randomization had to be executed precisely.

4.1 Aims and Objectives

4.1.1 AIMS

To assess the effects of yoga in high-risk pregnancy through a set of biological, psychological, and scientific parameters.

4.1.2 PRIMARY OBJECTIVES

- (i) *To evaluate the hypothesis that practice of yoga intervention in high-risk pregnant women is feasible, safe, and acceptable.* ASSESSMENT STRATEGY: Recorded adverse events and obtained feedbacks from patients.
- (ii) *To evaluate the hypothesis that a regularly practiced yoga intervention will significantly reduce the incidence of the complications in women with high risk of developing pregnancy complications.* ASSESSMENT STRATEGY: Incidents of pregnancy complications were recorded from the patients' hospital antenatal chart.
- (iii) *To evaluate the hypothesis that a regularly practiced yoga intervention will significantly improve pregnancy outcomes in women with high risk of developing pregnancy complications.* ASSESSMENT STRATEGY: Fetal measurements, Apgar scores, gestational age of delivery, and mode of delivery were recorded after delivery.

4.1.3 SECONDARY OBJECTIVES

- (i) *To evaluate the hypothesis that yoga interventions can improve the uterine and umbilical artery blood flow in women with high-risk of developing pregnancy complications and will also improve the blood flow in the fetal middle cerebral artery.*

ASSESSMENT STRATEGY: Uterine artery resistances were assessed by ultrasound at 12 weeks gestation and by Doppler study at 20th and 28th week of gestation.

4.1.4 RESEARCH QUESTION

Will 16 weeks of meditative yoga be safe and feasible to practice for high-risk pregnant in hospital settings and will it prevent complications of pregnancy and/or improve their pregnancy outcomes?

4.2 Design and Settings

This was a single-blind prospective stratified randomized controlled clinical trial on 60 pregnant women at high risk of developing pregnancy complications. The study was conducted at the obstetric unit of St. John's Medical College & Hospital (SJMCH) and Gunasheela Maternity Hospital (GMH) in Bengaluru, India. The data collection began in February 2010 and continued till April 2011. Data analysis and preparation of the manuscripts started in May 2011.

4.3 Methods

4.3.1 SAMPLE SIZE

To this date, there has been no other study that has directly assessed the effect of yoga in high-risk pregnancies. According to our literature search, the nearest RCT with non-pharmacological interventions that aimed at prevention of pregnancy complications was that of *Kanako et al.*²⁴⁹ which used simple water exercises to prevent preeclampsia. Using the event ratios ($106/573 = 0.185$ in the experimental group and $83/164 = 0.506$ in the control group) reported in that study (see table 4.4), with α set at 0.05, probability of type I error at 0.01, and powered at 0.8, a minimum sample size of 27 per group was obtained. The final analysis was made on 30 subjects in the yoga group and 38 in the control group.

Table 4.1 Data Reported by Kanako et al.

	Swimming (primipara)	Control (primipara)
Preeclampsia	106	83
Normal	467	181
TOTALS	573	164

4.3.2 INCLUSION CRITERIA

Pregnant women between 8 to 12 weeks of pregnancy and with the following risk factors for high-risk pregnancy were selected for the study:

- (i) History of poor obstetric outcomes - i.e. history of pregnancy complications,
- (ii) Twin pregnancies,
- (iii) Extremes of age - below 20 or above 35 years of age,
- (iv) Obesity - with BMI greater than 30, and
- (v) Family history - with history of pregnancy complications among blood relatives: sister, mother, and/or grandmother.

While we had also included women with essential hypertension and diabetes mellitus, by the end of the study, we had not recruited any subjects with these conditions.

4.3.3 EXCLUSION CRITERIA

Pregnant women with the following disorders were excluded from the study:

- (i) Severe renal, hepatic, or heart disease,
- (ii) Structural abnormalities in the reproductive system,
- (iii) Hereditary anemia (such as sickle cell disease hemoglobinopathies,
- (iv) Seizure disorders,
- (v) Taking chemotherapy drugs,
- (vi) Sexually transmitted diseases including syphilis and HIV infection,
- (vii) Who have previously given birth to babies with birth defects,
- (viii) Any medical conditions that prevent them from safely and effectively practicing the interventions (e.g. spinal deformities), and
- (ix) Regular practice of yoga over the past 3 months.

While we did not exclude women with diabetes or essential hypertension, none of the participants enrolled in the study were ever diagnosed with these conditions before this pregnancy. Table 4.1 defines the pregnancy complications studied in our project.

Table 4.2: Definitions of the Complications of Pregnancy

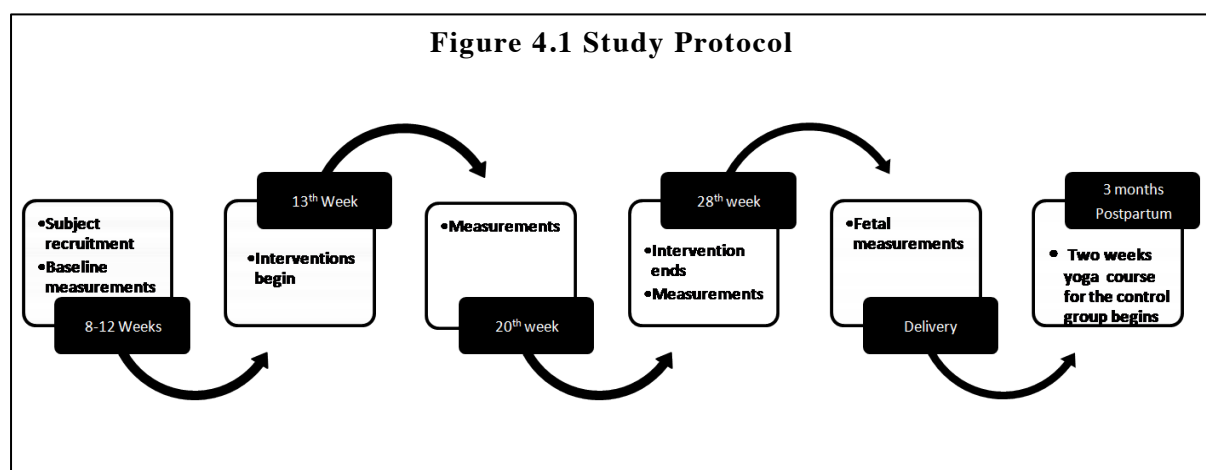
Complication	Definition
Pregnancy induced hypertension (PIH)	Development of new arterial hypertension (BP systolic ≥ 140 mm Hg ; diastolic ≥ 90 mm Hg) after 20 weeks gestation without proteinuria.
Preeclampsia (PE)	PIH with new onset of proteinuria (24-hour urine protein ≥ 300 mg).
Eclampsia (E)	Severe preeclampsia associated with grandmal seizures.
Gestational diabetes mellitus (GDM)	New onset of glucose intolerance during pregnancy (serum glucose ≥ 100 mg /100 ml).
Premature rupture of membranes (PROM)	Spontaneous rupture of the amniotic sac before the onset of labor.
Low birthweight (LBW)	≤ 2500 grams irrespective of the duration of the gestational period.
Small for gestational age (SGA)	≤ 10 th percentile for their gestational age.
Large for gestational age (LGA)	≥ 90 th percentile for their gestational age.
Normal for gestational age (NGA)	Between 10 th and 90 th percentile for their gestational age.
Intrauterine growth restriction (IUGR)	Fetus unable to reach its required growth potential for its gestational age due to some pathological inhibition. Calculated using estimated fetal weight and gestational age from the ultrasound and Doppler data.
APGAR score	A total score (0 to 10) obtained by summing individual scores (0-2) given to each of the five items of the newborn's skin color, heart rate, flexibility, muscle tone, and breathing pattern.
Preterm deliveries	Deliveries prior to the 37 weeks of gestation.

4.3.4 ETHICAL CLEARANCE AND INFORMED CONSENT

Clearance from the ethical committee of SJMCH was obtained before commencement of the study. All subjects were required to sign this informed-consent form approved by the ethical committee of SJMCH before recruitment.

4.3.5 SUBJECTS RECRUITMENT

Subjects were recruited from the Obstetrics & Gynecology departments at St. John's Medical College & Hospital (SJMCH) and Gunasheela Maternity Hospital (GMH) in Bengaluru, India. Both hospitals' registries were used to identify potential subjects. Our recruitment provided all applicants with an equal opportunity to participate regardless of religion, color, creed, or cast. The research staff were primarily responsible for recruiting subjects. Subjects below the 13th week gestation were approached by a research staff on duty about participating in this study during their routine visit at the Obstetrics and Gynecology (OBG) department of each Hospital. The subjects were told the purpose, risks, and possible benefits of participating in this research study. Once eligibility was determined and the subjects had agreed to participate by signing the informed consent, they were randomized to one of the two groups and the pretreatment baseline assessments were carried out. All baseline data were collected before starting her yoga or prenatal treatment. Figure 4.1 provides a graphical presentation of the trial's timeline.



4.3.6 RANDOMIZATION

The research coordinator was responsible for producing the randomized sequentially numbered selection envelopes, as outlined below. An online random number generator by GraphPad Software (<http://graphpad.com/quickcalcs/randomize1.cfm>) was used to randomize subjects into two groups. The group name (yoga or control) was then written on papers and placed in sealed opaque envelopes which were kept in a locked cabinet. The research staff was responsible for enrollment and assignment of the participants to the interventions in the following manner. The recruited subject was assigned an ID according to her diagnostic category and was asked to pick up one of the envelopes from that specific set. The research staff opened the envelope and informed the subject of the group she has been randomized into, and recorded her ID in the study log. When the next subject was recruited, the remaining envelopes from the specific category was presented and the allocation continued.. Permitting the subjects to pick an envelope randomly from her set of envelopes offered a second level of randomization and reduced the chances of dissatisfaction.

4.3.7 BLINDING AND MASKING

As this was an interventional study, it was not possible to keep the research staff or the participants blinded to the group or the nature of the intervention. However, this was a single-blind study in which the lab technicians and those doing the assessments were fully blinded. Only the patients, the medical staff, and the research staff knew the treatment group assignment.

4.3.8 SUBJECTS BURDEN

To minimize the subject burden, we scheduled measurements and assessments on the same days and in the same place, as the subjects' scheduled interventions. We gave the subjects flexibility to choose the timing of their interventions according to their schedule by offering morning, afternoon, and evening slots three days a week.

4.4 Interventions

The yoga group received standard care plus one-hour yoga session three times a week from the beginning of the 13th week to the end of the 28th week of gestation (a total of 28 sessions),

while the control group received standard care plus advice for walking for half an hour mornings and evenings (the routine antenatal exercise offered by the hospital) during the period of the study. The rationale for selecting these gestational periods for the interventions was that:

- a) Most women detect pregnancy by the 12th week of gestation,
- b) The type of pregnancy complications investigated in this study depends on proper placentation and if placental blood flow is not proper by this time, the clinical manifestations of the complications would be observed by the 28th week,
- c) Women that are at high risk are likely to deliver preterm, and finally
- d) Organ developments are usually fully completed by the 28th week of gestation.

The yoga classes were conducted by well-trained certified yoga therapists, who used an instruction manual to conduct the classes in a room reserved for yoga classes within the premises of SJMCH/GMH. Standard care offered to both groups included:

- a) Educational pamphlets about diet and nutrition during pregnancy;
- b) Check-ups by the obstetrician, and
- c) Bi-weekly telephone follow-ups by the research staff. The purpose of these bi-weekly telephone follow-ups were to check if the subjects were adhering to their practices and routine hospital check-ups.

Three categories of yoga interventions were offered to the study group: 1) breathing exercises, 2) yogic postures, and 3) meditative practices. The latter included visualization, guided imagery, and sound resonance techniques. The subjects were asked to visualize the fetus in the uterus, the umbilical cord, and the placenta. Then the subjects were guided to imagine the blood flowing from their bodies, into the placenta, through the umbilical cord, and bringing nourishment to their fetuses. Table 4.2 outlines the exercises practiced by the yoga group.

Table 4.3 List of Yoga Interventions

Practices	Duration
Hasta āyama śvasanam (Hands In and Out Breathing)	1 Min.
Hastavistāra śvasanam (Hands Stretch Breathing)	2 Mins.
Gulphavistāra śvasanam (Ankles Stretch Breathing with wall support)	1 Min.
Kaṭiparivartana śvasanam (Side Twist Breathing)	1 Min.
Visualization and Guided Imagery in Sitting Posture	5 Minutes
Uttānapādāsana śvasanam (Leg Raise Breathing)	1 Min.
Setubandhāsana śvasanam (Hip Raise Breathing)	1 Min.
Pādasañcālanam (Cycling in supine pose)	1 Min.
Supta udarākarṣaṇasana śvasanam (Supine Abdominal Stretch Breathing)	1 Min.
Vyāghrāsana śvasanam (Tiger Stretch Breathing)	1 Min.
Visualization and Guided Imagery in Sitting Posture	5 Minutes
Gulphagūraṇam (Ankle Rotation)	2 Mins.
Jānuphalakākarṣaṇam (Kneecap Contraction)	1 Min.
Ardhātitaliāsana (Half Butterfly Exercise)	3 Mins.
Poornātitaliāsana (Full Butterfly Exercise)	1 Min.
Visualization and Guided Imagery in Sitting Posture	5 Minutes
Jyotitrāṭaka (Eye Exercises)	2 Mins.
Nāḍīśuddhi prāṇayam (Alternate Nostrils Breathing)	2 Mins.
Guided Imagery in matsyākṛīḍāsana (Lateral Shavasana)	10 Minutes

While the effectiveness of pharmaceutical interventions solely depends on the dosage administered, the effectiveness of mind-body therapies could also depend on the therapist's style. That could make the mind-body research biased. In order to overcome this bias, detailed instructions of the practices were written and the instructors were asked to conduct the classes from those instructions. The appendix 5 provides those instructions.

4.5 Measurements

For this study, we have chosen a few markers that have been shown to be influenced by yoga. These measurements were taken from all subjects in the yoga and the control groups. Table 4.3 summarizes the list of these variables and the date of their measurements. The justifications for selecting each measure are given in the notes following the table.

Table 4.3 Schedule of Measurements

PARAMETER	12 th Week Gestation	20 th Week Gestation	28 th Week Gestation	Delivery
Maternal Blood Pressure	X	X	X	
Fetal Measurements	X	X	X	X
Uterine Arteries Resistance	X	X	X	
Umbilical Artery Resistance		X	X	
Fetal Middle Cerebral Resistance		X	X	
Pregnancy Complications				X
APGAR Scores				X
Gestational age at delivery				X
Mode of delivery				X

4.5.1 DEMOGRAPHY

Demographic information, such as name, age, gender, marital history, parity, socio-economic data, body mass index, medical history, and family medical background were collected at the time of recruitment of each subject.

4.5.2 ANTENATAL CLINICAL ASSESSMENTS

In 1952, Dr. Virginia Apgar devised a simple and repeatable method to quickly assess the health of newborn babies right after delivery. The babies are evaluated on five criteria: skin color, heart rate, flexibility, muscle tone, and breathing pattern. Appendix 6 offers the table that is used to determine the Apgar score for each newborn, which ranges from zero to ten. The APGAR score after one minute of delivery (APGAR-1) and five minutes of delivery

(APGAR-5) were recorded. For our analysis, we considered an APGAR-1 score of 7 or below to be low and APGAR-5 score of 8 or below to be low.

Due to the diversity in demographics of the Indian population and the non-availability of normative birth weight graphs for Indian babies in Bengaluru, substantial amount of time was spent searching for suitable normograms to determine SGA or LGA. It was finally decided to use the data from a US study²⁸⁶ for the singleton babies since it included African-American and Latino babies, who have birth weights lower than those of white Caucasians and the one from an English study²⁸⁷ for twin pregnancies.

4.5.3 ULTRASOUND AND DOPPLER ASSESSMENTS

Antenatal scan was done using a GC VOLUSON 730 PRO ultrasound unit. A broadband conveyor of 3 to 5 MHz was used to perform the scan after entering patient's demographic. For the 1st trimester scan, the following parameters were taken: CRL, BPD, HC, AC, FL, FHR, and EFW. Fetal cardiac activity was documented along with placental implantation, liquor volume, fetal weight, and the estimated gestational age, which was calculated from the fetal biometry.

For ultrasound scan in the first trimester, both uterine arteries were sampled and $V_{\max}$, $V_{\min}$, PI, RI and S/D ratio were taken. The spectral pattern was also noted. For second and third trimester scans, fetal biometry was performed and Bi-Paredial Diameter (BPD), head circumference (HC), abdominal circumference (AC), and femur length (FL) were measured. The liquor volume, placental localization and maturity were noted. Fetal weight and average gestational age were recorded. Finally, the fetus was scanned for any congenital anomalies. For doppler studies both uterine arteries, umbilical artery, and fetal MCA were sampled. Then, PI, RI, and S/D ratios were taken and the spectral patterns were documented.

4.5.4 PREGNANCY OUTCOMES

Fetal measurements, clinical manifestations of pregnancy complications, gestational age of delivery, and mode of delivery were recorded at the time of delivery.

4.6 Statistical Considerations

4.6.1 STATISTICAL ANALYSIS

Measurements were taken once at pre-treatment (12th week of gestation), at mid-treatment (20th week of gestation), and again at end-treatment (28th week of gestation), and finally at delivery. Statistical software PASW Statistics (formerly known as SPSS) version 18.0.3 for Mac was used for the analysis. Shapiro-Wilk test was utilized to test the normality of the data. Baseline comparison of the two groups was performed using Independent Samples T-test. For parameters with three measurements in time, RM ANOVA was performed and then ANCOVA test was followed keeping the baseline data as covariate. When there were only two measurements in time, Independent Sample T-test was used for variables that followed a gaussian distribution at baseline and Mann-Whitney non-parametric test for those that didn't. Chi-Square test was used to test significance between groups when frequencies were used.

4.6.2 DATA ENTRY AND MANAGEMENT

The research staff were responsible for data collection and data entry. Forms for each visit were prepared and maintained in the OBG department. Subjects filled out the forms without influence by the staff, but the staff were available to answer questions and provide unbiased guidance. Doppler test, ultra-scan, blood tests, and urine analysis were performed by the hospital. Lab reports were kept in each subject's file until it was entered into the computer by the research coordinator. All forms were thoroughly screened for completeness of response. Every effort was made to find missing data. Once data collection was completed the research coordinator double checked every single data with the help of one of the staff.

4.6.3 ATTRITION AND MISSING DATA

As discussed in the trial profile section, subjects chose to withdraw from the study for a number of reasons. If withdrawal occurred before a subsequent measurement, the subject was dropped out. However, every effort was made to avoid missing data and utilize data in the analysis without compromising the integrity of the protocol. When subjects had moved away from Bengaluru metropolitan area, research staff communicated with them regularly to obtain as much data as possible from the other hospitals they attended to. Due to complex nature of pregnancy, statistical attempts to estimate the missing data was not possible.

CHAPTER 5

RESULTS

CHAPTER CONTENTS:

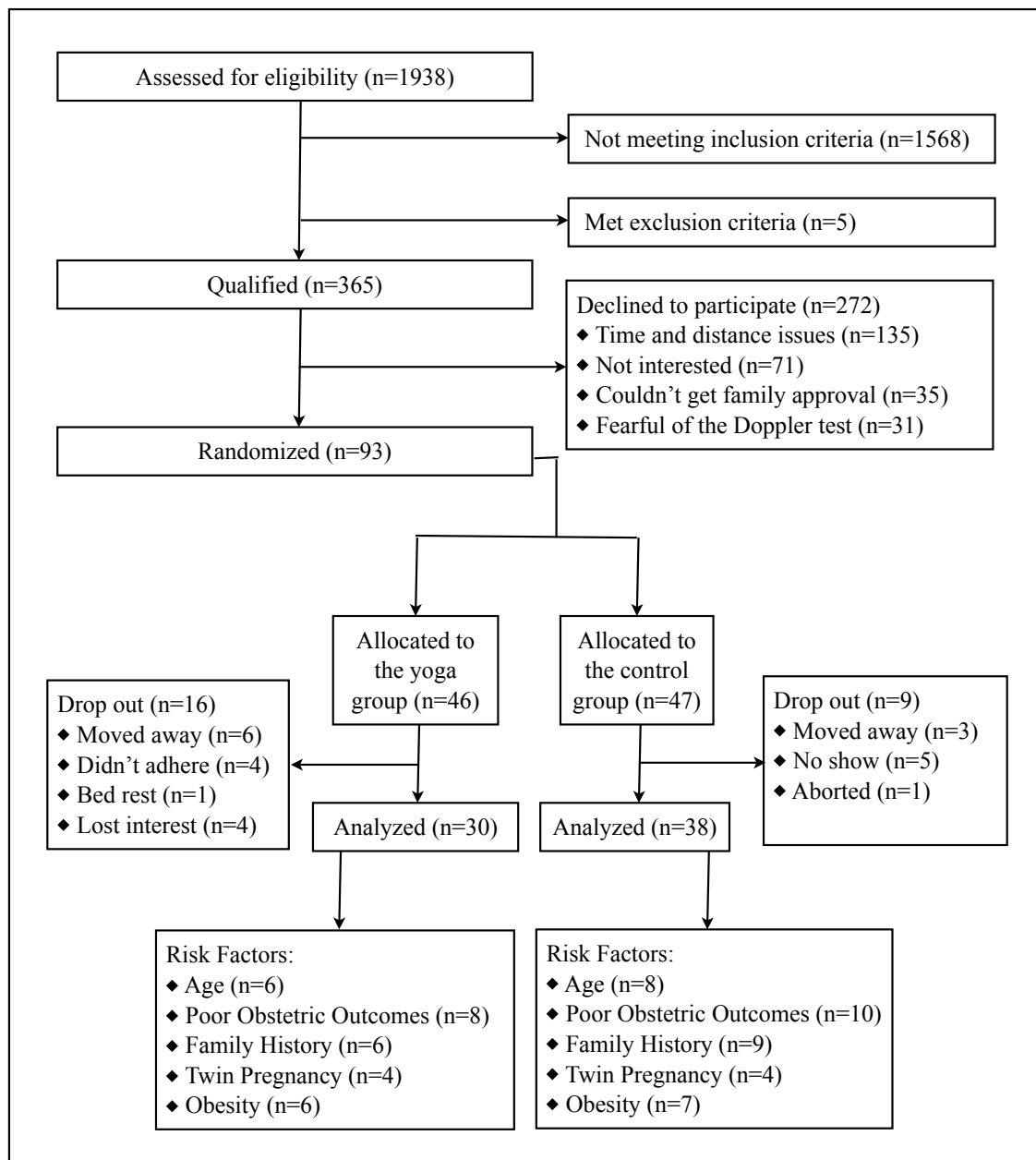
- Trial Profile
- Demographic Data and Baseline Comparisons
- Primary Outcome Measures
- Secondary Outcome Measures

Chapter 5: Results

5.1 Trial Profile

As illustrated in the trial profile in Figure 5.1, a total of 1938 women were interviewed during the course of this study. Out of these patients, 370 met the inclusion criteria. Five subjects were excluded for having conditions listed in the exclusion criteria (see Selection Criteria).

Figure 5.1 Trial Profile



From the remaining 365 qualified subjects, 71 were not interested, 135 either had schedule conflicts or were living too far away to come for the regular classes, 35 subjects could not

obtain permission from the immediate family and surprisingly, 31 subjects were fearful that the Doppler scanning could harm their babies and the physicians couldn't convince them otherwise. The remaining 93 subjects were randomized into two groups, yoga and control. During the course of the project, 16 subjects from the yoga group and 9 from the control group dropped out:

- (i) In the yoga group, six subjects moved away, four subjects did not adhere to the intervention schedule and had to be dropped, one subject was wrongly recruited, one subject was advised strict bed rest by her obstetrician, and four subjects lost interest in the study.
- (ii) In the control group, one subject aborted, three moved away, and five did not show up for follow up measurements.

5.2 Demographic Data & Baseline Comparisons

5.2.1 AGE

The average age of the subjects in both groups was not only about the same but the standard deviation was also very comparable with non-significant differences between the groups. (see *Table 5.1*) This is important to note because age plays a big role in the development of pregnancy complications; particularly in high-risk pregnancies.

Figure 5.2 Age Distribution Between Groups

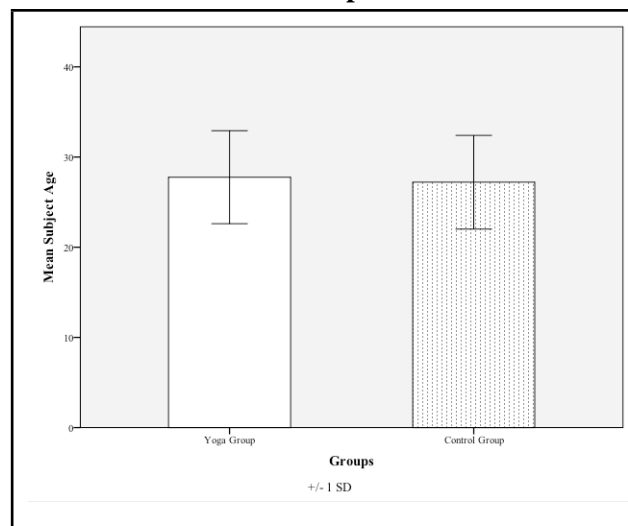


Table 5.1 Age Profile

Parameter		Yoga Group (n=30)	Control Group (n=38)	P-values ¹
Age	Mean±SD	27.77 ± 5.15	27.21 ± 5.20	0.662
	95% CI	25.84 - 29.69	25.50 - 28.92	
1. Independent-Samples T-test				

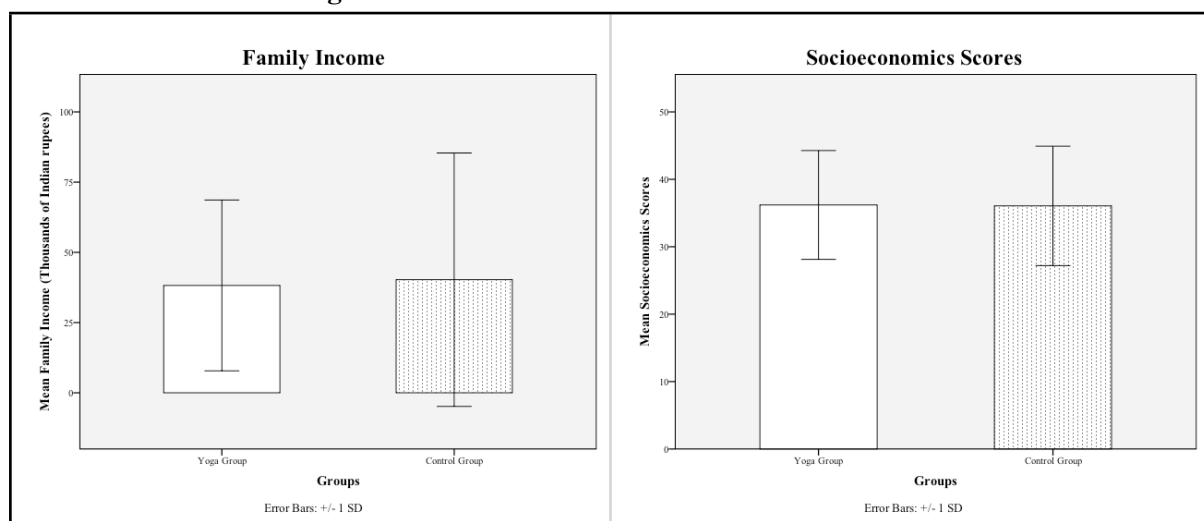
5.2.2 FAMILY INCOME

The financial status of the subjects were measured in two ways: (1) subjectively - by recording the monthly family income reported by the subjects, and (2) objectively - by a self-administered socioeconomic form, used by other Indian studies, which listed the number of household features and possessions owned and scored each item accordingly. Table 5.2 lists the subjects income profile at baseline. The average monthly income is in thousands of Indian rupees while the socioeconomic values are scores. As shown in figure 5.3, the income distributions for both groups had large standard deviations. There was a highly significant Pearson correlation between the Family income and the self-reported socio-economics scores ($p < 0.001$) and both indicated that the mean of the values between the two groups were closely matched.

Table 5.2 Income Profile

		Yoga Group (n=30)	Control Group (n=38)	P-values ²
Family Income ¹	Mean±SD	37.02 ± 29.36	40.27 ± 45.12	0.662
	95% CI	25.86 - 48.19	25.01 - 45.12	
Socio- Economic ¹	Mean±SD	37.37 ± 11.28	36.05 ± 8.86	0.739
	95% CI	33.16 - 41.58	33.10 - 39.01	
1. Family income is in thousands of Indian rupees. Socio-Economic values are scores. 2. Independent-Samples T-test				

Figure 5.3 Income & Socioeconomics Profile



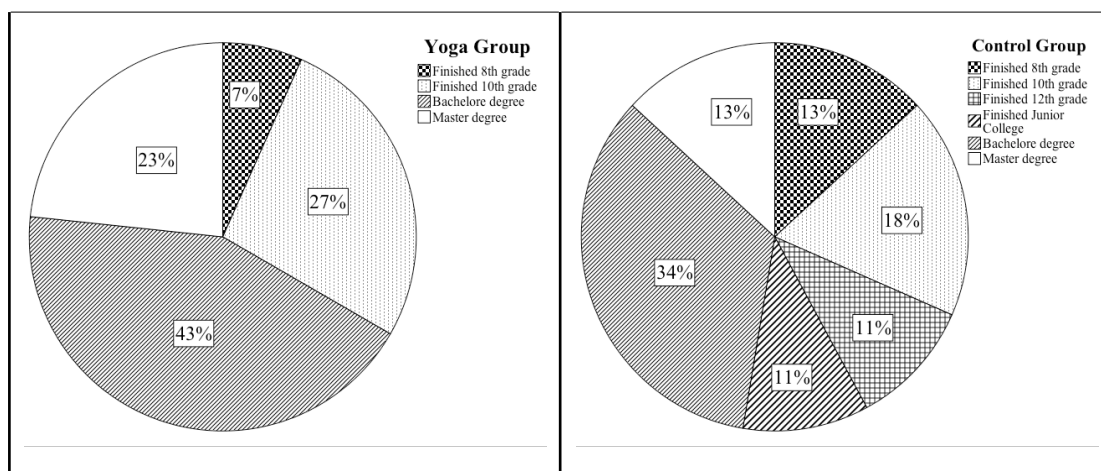
5.2.3 EDUCATION

As depicted in Table 5.3, the majority of subjects in both groups were college graduates and living independently, which is also not surprising from the Bangalorian IT population.

Table 5.3 Education Profile

Educational Level Completed	Frequencies		Chi-squared p-values
	Yoga Group	Control Group	
Subjects' Educational Profile ¹			
Completed 8th grade	2	5	0.114
Completed 10th grade	8	7	
High School degree	0	4	
Junior College degree	0	4	
Bachelor degree	13	13	
Master degree	7	5	
Husbands' Educational Profile			
Illiterate	1	2	0.663
Completed 5th grade	1	3	
Completed 8th grade	1	2	
Completed 10th grade	3	5	
High School degree	4	4	
Junior College degree	1	5	
Bachelor degree	13	9	
Master degree	6	8	

Figure 5.4 Subjects Education Profile



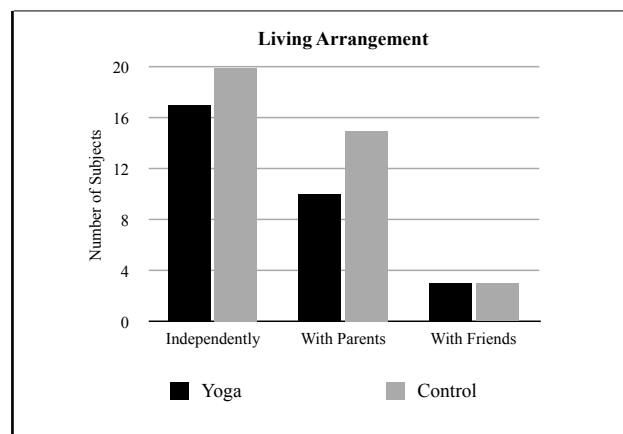
5.2.4 LIVING ARRANGEMENT

The majority of the subjects were living independently although joint family living is still widely practiced in India. Figure 5.5 illustrates graphically the three classifications of the living arrangement of the subjects.

Table 5.4 Living Arrangement Profile

	Groups		Chi-Square P-Value
	Yoga Group	Control Group	
Living Independently	17	20	0.858
Living with Parents	10	15	
Living with Friends	3	3	

Figure 5.5 Subjects Living Arrangements

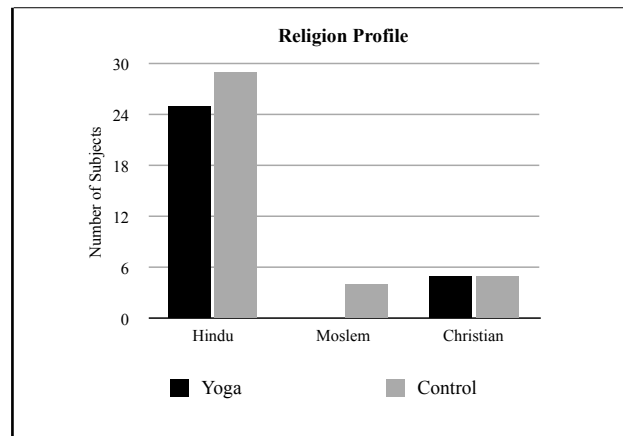


5.2.5 RELIGION

As the majority of the population of India are Hindu, the majority of the subjects in our study were also Hindu. We found some resistance toward the yoga practices in other faith, particularly in the Moslem population.

Table 5.5 Religion Profile

Religion	Groups		Chi-Square P-Value
	Yoga Group	Control Group	
Hindu	25	29	0.182
Moslem	0	4	
Christian	5	5	

Figure 5.6 Subjects Religion Profile

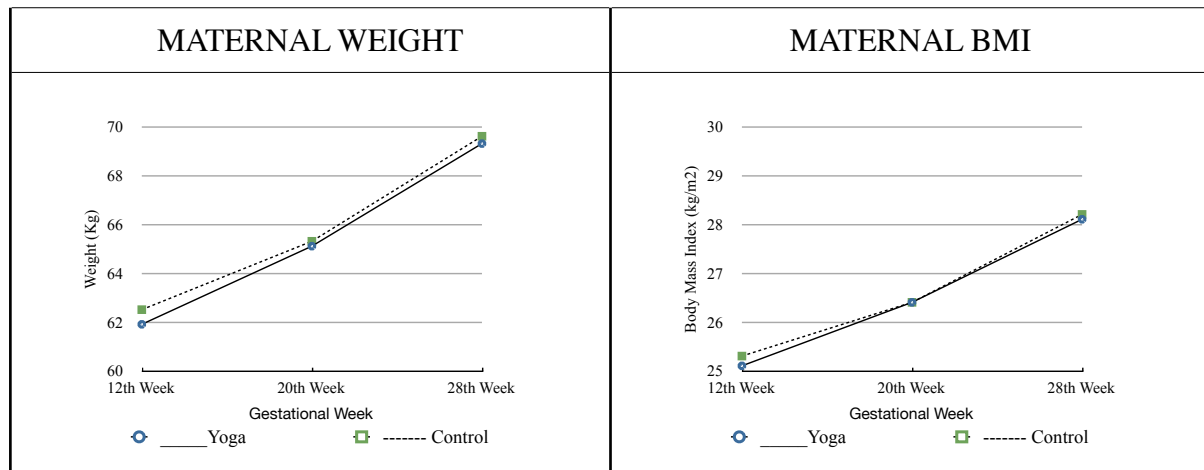
5.2.6 MATERNAL WEIGHT AND BMI

Since our interventions were meditative in nature and were not rigorous to reduce weight, maternal weight and BMI did not change significantly throughout the study ($p=0.918$ and 0.913 , respectively, RM-ANOVA).

Table 5.6 Maternal Weight & Body Mass Index

Parameters			12 th Week	20 th Week	28 th Week	p-values ¹
Maternal Weight	Yoga	Mean ± SD	61.9 ± 12.6	65.1 ± 12.9	69.3 ± 13.3	0.918 ^a
		95% CI	57.2 - 66.6	60.3 - 70.0	64.4 - 74.3	
	Control	Mean ± SD	62.5 ± 14.3	65.3 ± 14.6	69.6 ± 14.6	
		95% CI	57.8 - 67.2	60.5 - 70.1	64.8 - 74.4	
Maternal BMI	Yoga	Mean ± SD	25.1 ± 4.7	26.4 ± 4.7	28.1 ± 4.7	0.913 ^b
		95% CI	23.3 - 26.9	24.7 - 28.1	26.4 - 30.0	
	Control	Mean ± SD	25.3 ± 4.9	26.4 ± 5.0	28.2 ± 4.9	
		95% CI	23.7 - 27.0	24.8 - 28.1	26.6 - 29.8	
<i>a. RM-ANOVA with df (1,66) and F=0.011. </i>						

As illustrated in Figure 5.7, the weight and BMI of the mothers in the yoga group was slightly less than those in the control group at baseline and the yoga group maintained that thin margin until the end of the study at the 28th week gestation.

Figure 5.7 Maternal Weight and Body Mass Index Profile

5.2.7 MATERNAL BLOOD PRESSURE

The RM-ANOVA test did not show a significant result for systolic ($p=0.425$) or diastolic blood pressure ($p=0.562$) as indicated in Table 5.7.

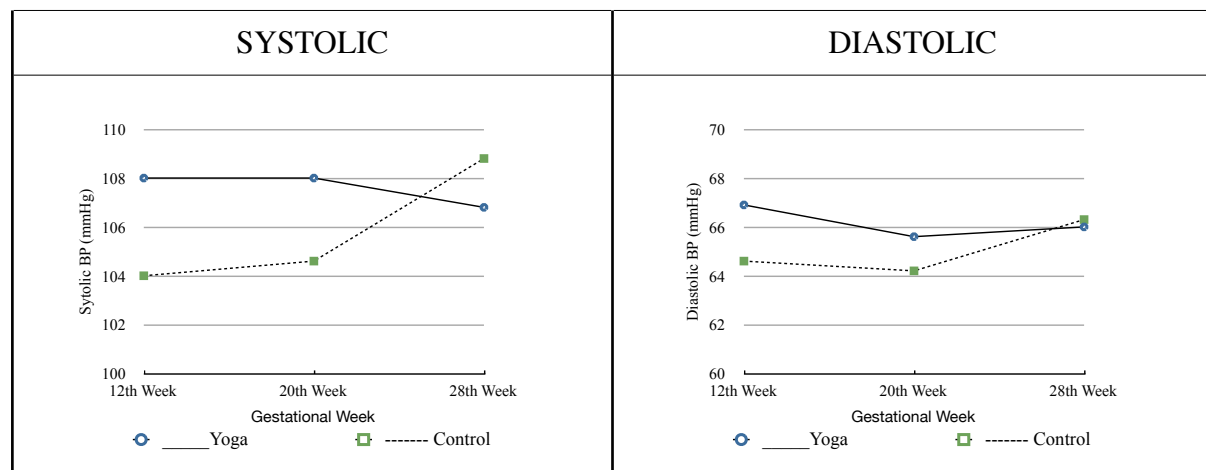
Table 5.7 Maternal Blood Pressure

Parameters			12 th Week	20 th Week	28 th Week	p-values ¹
Systolic	Yoga	Mean ± SD	108.0 ± 13.0	108.0 ± 12.3	106.8 ± 7.4	0.425 ^a
		95% CI	103 - 114	103 - 113	104 - 110	
	Control	Mean ± SD	104.0 ± 8.0	104.6 ± 11.9	108.8 ± 9.3	
		95% CI	101 - 107	100 - 109	105 - 112	
Diastolic	Yoga	Mean ± SD	66.9 ± 9.3	65.6 ± 8.5	66.0 ± 10.6	0.562 ^b
		95% CI	62.9 - 70.8	62.0 - 69.2	61.6 - 70.5	
	Control	Mean ± SD	64.6 ± 7.9	64.2 ± 7.9	66.3 ± 8.1	
		95% CI	61.6 - 67.5	61.3 - 67.2	63.3 - 69.3	
<i>a. RM-ANOVA, df (1,52) and F=0.646. b. RM-ANOVA, df (1,52) and F=0.342.</i>						
<i>Blood pressure did not change significantly between the two groups.</i>						

Nonetheless, we can see some improvements as depicted in Figure 5.8. Both systolic and diastolic in the yoga group were notably higher at the baseline. The systolic BP relatively unchanged in both groups until the 20th week of gestation. However, by the 28th week of gestation, the mean systolic BP in the control group had sharply risen while that of the yoga group had dropped. The improvement was near significance ($p=0.088$, ANCOVA with 20th week data as covariate). The diastolic BP in both groups declined slightly until the 20th week

of gestation and then rose by the 28th week with no statistical significance at any point in time.

Figure 5.8 Maternal Blood Pressure



5.3 Primary Outcome Measures

5.3.1 PREGNANCY COMPLICATIONS

The pregnancy complications relevant to this study were recorded from the patient's medical charts. Some subjects went to their hometowns as it is customary in the Indian traditions. In cases that we were not able to obtain their medical records from the hospitals that they attended to, we had no choice but having missing data for those subjects. In the tables that follow, the sample size for different complications may vary from what was reported in the trial profile (30 subjects in the yoga group and 38 in the control group) due to such missing data.

5.3.1.1 HYPERTENSION RELATED COMPLICATIONS

There were 11 (30.6%, calculated by dividing the observed number of cases by the sample size for the group- in this case 11/30) cases of PIH in the control group while only 3 (10.3%) in the study group, resulting in a highly significant difference between the groups ($p=0.018$). Two of the three cases in the yoga group were diagnosed with mild PIH and one with moderate PIH. There were no other complications with these subjects (excluding C-section). In contrast, over 33% of the subjects in the control group developed severe PIH and 6.7% developed eclampsia.

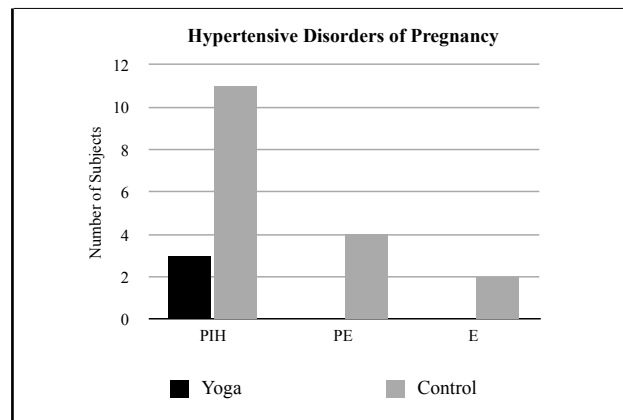
Table 5.8 Frequency of Hypertension Related Complications

Complications		Statistics		p-values ¹
		n	Observed	
Pregnancy Induced Hypertension (PIH)	Yoga	29	3 (10.4%)	0.018
	Control	30	11 (30.6%)	
Preeclampsia (PE)	Yoga	29	0 (0.0%)	0.042
	Control	30	4 (13.3%)	
Eclampsia (E)	Yoga	29	0 (0.0%)	0.157
	Control	30	2 (6.7%)	
1. Chi squared test. PIH Odd's Ratio 5.02, 95% CI (1.23-20.49).				
2. Significantly fewer cases of hypertension related complications in the yoga group.				

Table 5.9 tabulates the hypertension complications that were observed in the both groups based on the risk factors that the corresponding mothers were recruited into the study. A key observation in this table is that in our study, the obese mothers and those with poor obstetric outcomes had a higher chance of developing PIH than other women. The sample size was too small to do any meaningful data analysis between the subgroups.

Table 5.9 Hypertension Related Complications Based on Recruited Risk Factors

Risk Factors		Complications			Totals
		Pregnancy Induced Hypertension	Preeclampsia	Eclampsia	
Age	Yoga	0	0	0	0
	Control	1	0	0	1
Poor Obstetrics	Yoga	0	0	0	0
	Control	5	1	1	7
Family History	Yoga	1	0	0	1
	Control	0	1	0	1
Twin Pregnancy	Yoga	0	0	0	0
	Control	1	1	1	3
Obesity	Yoga	2	0	0	2
	Control	4	1	0	5

Figure 5.9 Hypertension Related Complications

5.3.1.2 HYPERTENSION UNRELATED COMPLICATIONS

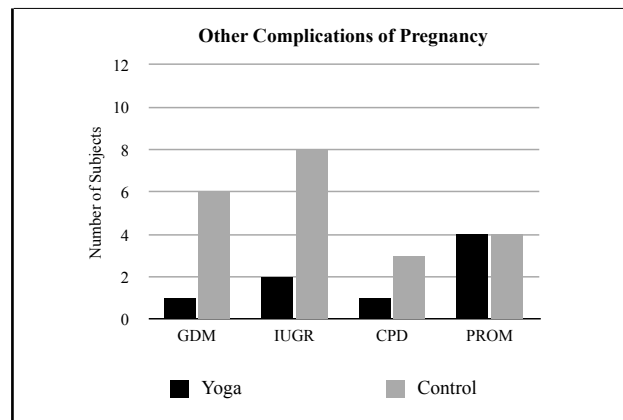
More than a quarter (25.8%) of the subjects in the control group developed IUGR, in contrast to only 6.9% in the yoga group. The result was statistically significant ($p=0.05$). Also there were significantly fewer cases of gestational diabetes in the yoga group as compared to control ($p=0.049$, χ^2).

Table 5.10 Frequency of Hypertension Unrelated Complications

Complications		Statistics		p-values ¹
		n	Observed	
Gestational Diabetes (GDM)	Yoga	29	1 (3.4%)	0.049
	Control	30	6 (20%)	
Intra-Uterine Growth Restriction (IUGR)	Yoga	29	2 (6.9%)	0.05
	Control	31	8 (25.8%)	
Cephalic Pelvic Disproportion (CPD)	Yoga	29	1 (3.4%)	0.317
	Control	30	3 (10.0%)	
Premature Rupture of Amniotic Membrane (PROM)	Yoga	29	4 (13.8%)	0.919
	Control	31	4 (12.9%)	

1. Chi squared test. GDM Odd's Ratio 7, 95% CI: (0.79-62.3). IUGR Odd's Ratio 4.7, CI: (0.9-24.4)
 2. Significantly fewer GDM and IUGR cases in the yoga group.

Figure 5.10 shows the number of non-hypertension related complications in each group graphically. Table 5.11 tabulates those complications based on the risk factor of the mothers. We can see in this table that in our study, the chances of occurrences of IUGR was much higher in the obese group.

Figure 5.10 Hypertension Unrelated Complications**Table 5.11 Hypertension Unrelated Complications Based on Recruited Risk Factors**

Risk Factors		Complications				
		Gestational Diabetes	Intrauterine Growth Restriction	Cephalic Pelvic Disproportion	Premature Rupture of Amniotic Membrane	Totals
Age	Yoga	0	0	1	1	2
	Control	1	0	0	0	1
Poor Obstetrics	Yoga	0	0	1	1	2
	Control	3	0	4	1	8
Family History	Yoga	0	0	0	1	1
	Control	1	0	1	2	4
Twin Pregnancy	Yoga	1	0	0	1	2
	Control	0	0	2	1	3
Obesity	Yoga	0	1	0	0	1
	Control	1	3	1	0	5

5.3.1.3 DELIVERY RELATED COMPLICATIONS

The number of preterm deliveries (*deliveries prior to 37 weeks gestation*) was significantly fewer in the yoga group verses the control (20.7% in the yoga group in contrast to 45.7% in the control group, $p=0.036$). There were no significance for CPD or PROM ($p=0.317$ and 0.919 , respectively). However, the results didn't show significant improvement in reducing the emergency c-sections in the yoga group. This could be partly due to the fact that c-section has become very popular in India recently and physicians tend to prescribe it at the slightest

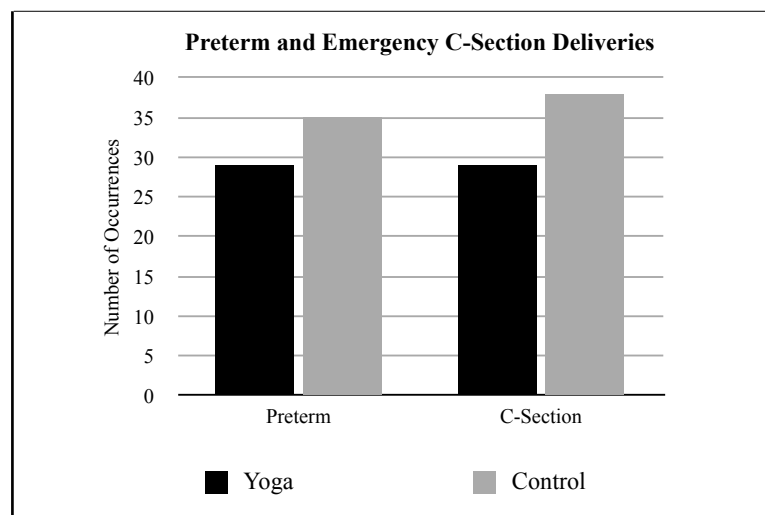
hint of fetal distress. This study did not experience any fetal death, still birth, or abortion. There were also no deformities or physical/mental abnormalities in the infants.

Table 5.12 Frequency of Delivery Related Complications

Delivery Complications		Statistics		p-values ¹
		n	Observed	
Preterm Deliveries²	Yoga	29	6 (20.7%)	0.036
	Control	35	16 (45.7%)	
Emergency C-Section	Yoga	29	15 (51.7%)	0.615
	Control	38	22 (57.9%)	

1. Chi squared test. Significantly fewer preterm deliveries occurred in the yoga group, Odd's Ratio 3.6, 95% CI: (1.25-10.23).
 2. Deliveries before 37 weeks of gestation

Figure 5.11 Delivery Related Complications



In Table 5.13 we see that emergency C-Section occurred in all risk-factor subgroups uniformly in this study. In fact, preterm deliveries were not specific to any particular risk factors either, although the numbers in the poor obstetrics group and twin pregnancy group were slightly higher. A much larger sample size is required to make any meaningful statement regarding the effects of yoga on these and the other complications studied in this trial.

Table 5.13 Delivery-Related Complications Based on Recruited Risk Factors

Risk Factors		Complications		
		Preterm Deliveries	Emergency C-Sections	Total
Age	Yoga	1	1	2
	Control	2	4	6
Poor Obstetrics	Yoga	2	6	8
	Control	6	6	12
Family History	Yoga	0	3	3
	Control	1	5	6
Twin Pregnancy	Yoga	2	1	3
	Control	4	4	8
Obesity	Yoga	1	4	5
	Control	3	3	6

5.3.2 FETAL CONDITIONS AT BIRTH

5.3.2.1 BIRTHWEIGHT RELATED OUTCOMES

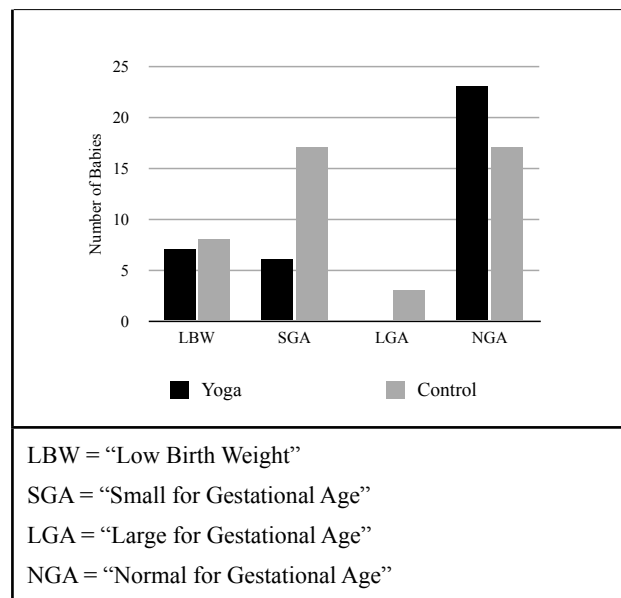
The birth weight was used to count the number of babies in each group who had low birth weight (LBW) or were small for gestational age (SGA), large for gestational age (LGA), or normal for gestational age (NGA) using birth charts for singleton²⁸⁶ and twin pregnancies²⁸⁷. There were 7 infants in the yoga group and 8 in the control with LBW. The difference was not statistically significant. The broad definition of LBW may have skewed the results. This argument is supported by the fact that the yoga group had significantly less SGA new borns than the control did (20.7% vs 45.9% respectively, $p=0.033$). Although there were no LGA in the yoga group and 3 in the control group, the results were not statistically significant. Finally, there were 23 (79.3%) babies with normal weight (within the 10th and 90th percentile) in the yoga group while only 17 (45.9%) in the control group resulting in a highly significant improvement ($p=0.006$). Table 5.14 summarizes these results.

Table 5.14 Birthweight Related Outcomes

Birthweight Conditions		Statistics		p-values ¹
		n	Observed	
Low Birth Weight (LBW)²	Yoga	29	7 (24.1%)	<i>0.764</i>
	Control	38	8 (21.1%)	
Small for Gestational Age (SGA)	Yoga	29	6 (20.7%)	<i>0.033</i>
	Control	37	17 (45.9%)	
Large for Gestational Age (LGA)	Yoga	29	0 (0%)	<i>0.117</i>
	Control	37	3 (8.1%)	
Normal for Gestational Age (NGA)	Yoga	29	23 (79.3%)	<i>0.006</i>
	Control	37	17 (45.9%)	

1. Chi squared test. Significantly less SGA babies in the yoga group (Odd's Ratio 4.33, 95% CI: 1.47-12.79) and significantly more NGA babies in the yoga group (Odd's Ratio 0.17, 95% CI: 0.06-0.51).

2. LBW infants were defined as those below 2,500 g regardless of gestational age.

Figure 5.12 Fetal Weight at Birth

5.3.2.2 APGAR SCORES

For this study, an APGAR score after 1 minute after delivery below 8 (Low-APGAR1) and APGAR score after five minutes of delivery below 9 (Low-APGAR5) were considered to be a low score. In both cases, there were significant improvements in the yoga group ($p=0.006$ and $p=0.037$, respectively).

Table 5.15 Fetal Conditions at Birth

APGAR Scores		Statistics ²		p-values ¹
		n	Observed	
Low 1 minute APGAR Score³	Yoga	23	1 (4.4%)	0.005
	Control	36	14 (38.9%)	
Low 5 minutes APGAR Score⁴	Yoga	23	1 (4.4%)	0.037
	Control	35	10 (28.6%)	

1. Chi squared test. Significantly better APGAR scores in the yoga group, Odds Ratio was 14 with 95% CI 1.7-115.8 for Low-APGAR1 and 8.8 with 95% CI of 1.0-74.4 for Low-APGAR5
2. Twins has been counted as two individual infants in these calculations. Excluding twins count for yoga and control would be 20 and 30 for Low-APGAR1 and 20 and 32 for Low-APGAR5. The p-values would be 0.006 for Low-APGAR1 and 0.04 for Low-APGAR5.
3. Scores below 8 were considered low for 1-minute APGAR score
4. Scores below 9 were considered low for 5-minutes APGAR score

In the yoga group, there was one baby with Low-APGAR1 score that was born from a mother that was recruited with bad-obstetrics history and one with Low-APGAR2 score that was born with family history of bad-obstetrics. Table 5.16 tabulates the Low-APGAR scores by risk factors. Figure 5.13 illustrates graphically the number of low APGAR scores between the two groups.

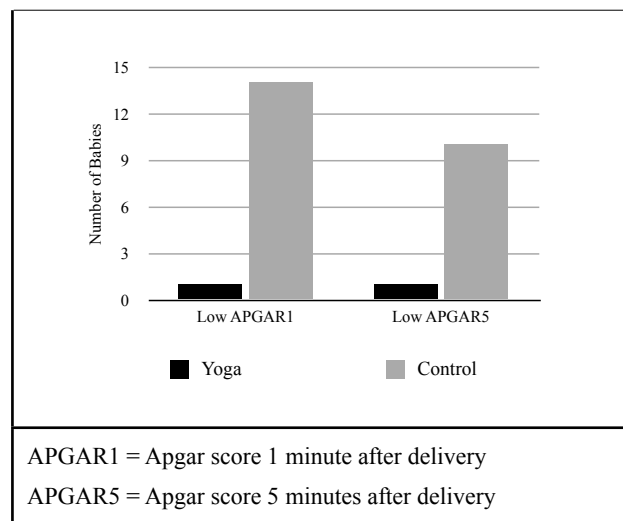
Figure 5.13 Low APGAR Scores

Table 5.16 Low APGAR Scores Based on Risk Factors

Risk Factors		Complications		
		Low-APGAR1	Low-APGAR5	Totals
Age	Yoga	0	0	0
	Control	2	2	4
Poor Obstetrics	Yoga	1	0	1
	Control	5	4	9
Family History	Yoga	0	1	1
	Control	3	1	4
Twin Pregnancy	Yoga	0	0	0
	Control	1	1	2
Obesity	Yoga	0	0	0
	Control	2	1	3

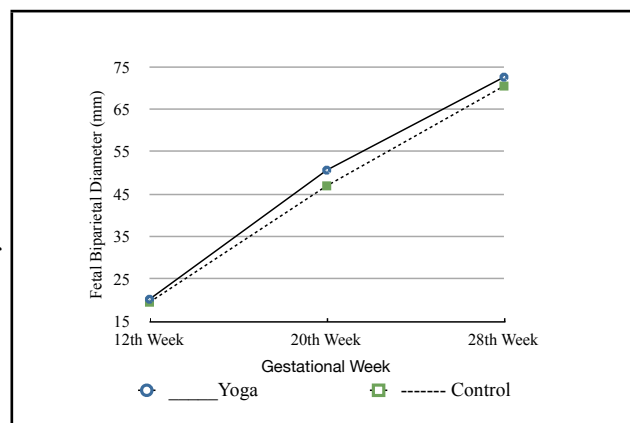
5.4 Secondary Outcome Measures

5.4.1 ULTRASOUND FETAL MEASUREMENTS

A number of measurements were taken at the 12th week, 20th week, and 28th week of gestation. These included the skull diameter, head circumference, abdominal circumference, femur length, heart rate, and estimated weight. Although we did not get statistically significant result in every measurement, we observed noticeable improvements in every category.

5.4.1.1 FETAL BIPARIETAL DIAMETER (BPD)

The sphericity of the variances between the groups was violated ($p=0.003$). The RM-ANOVA test result was highly significant ($p<0.001$). The mean BPD at baseline was slightly smaller in the yoga group compared to the control group (see table 5.17). In spite of that, by the 20th week of pregnancy, the mean skull diameter of the fetuses in the yoga group had become significantly larger. The improvement

Figure 5.14 Estimated Marginal Means for Biparietal Diameter

continued until the end of the treatment period at 28th week of pregnancy (see figure 5.14).

Table 5.17 Fetal Biparietal Diameter (Skull Diameter)

Measurements in Time		Statistics		p-values ANCOVA	p-value RM-ANOVA
		Yoga Group (n=27)	Control Group (n=32)		
12 th Week	Mean±SD	20.2 ± 4.0	19.5 ± 2.4		<0.001
	95% CI	18.7 - 21.8	17.5 - 25.4		
20 th Week	Mean±SD	50.6 ± 5.4	46.9 ± 2.4	0.008	
	95% CI	48.5 - 52.8	46.1 - 47.8		
28 th Week	Mean±SD	72.5 ± 2.9	70.4 ± 2.3	0.002	
	95% CI	71.3 - 73.6	69.5 - 71.2		
1. RM-ANOVA, <i>df</i> (1,57), <i>F</i>=14. The skull diameter of the babies in the yoga group increased significantly compared to the control. The baseline means did not vary (<i>p</i>=0.718 <i>t</i>-test) 2. ANCOVA with 12th week data as covariate, <i>df</i>(1,59) <i>F</i>=10.4 at 28th week					

5.4.1.2 FETAL HEAD CIRCUMFERENCE (HC)

The mean fetal head circumference was closely matched at baseline between groups. The Mauchly's Test of Sphericity was significant (*p*=0.014) indicating that the data was skewed. The RM-ANOVA test showed highly significant results (*p*=0.002). The mean HC of the fetuses in the yoga group significantly increased throughout the intervention periods as illustrated in figure 5.15.

Figure 5.15 Estimated Marginal Means for Head Circumference

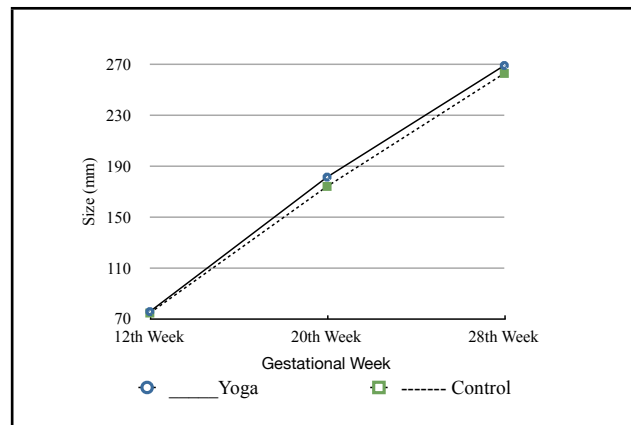


Table 5.18 Fetal Head Circumference

Measurements in Time		Statistics		p-values ANCOVA	p-value RM-ANOVA
		Yoga Group (n=27)	Control Group n=(32)		
12 th Week	Mean±SD	75.4 ± 9.4	74.3 ± 8.6		0.002
	95% CI	71.7 - 79.1	71.2 - 77.5		
20 th Week	Mean±SD	181.0 ± 7.9	173.7 ± 7.9	0.007	
	95% CI	177.9 -184.2	170.9 -176.5		
28 th Week	Mean±SD	268.6 ± 8.7	262.4 ± 8.2	0.004	
	95% CI	265.1 - 272.0	259.5 - 265.4		
1. The baseline means did not vary (p=0.934 t-test). RM-ANOVA, df(1,57) and F=10.9. Fetal head circumference improved significantly in the yoga group compared to the control.					
2. ANCOVA with 12th week measurement as covariate. df(1,59), F=8.8 at 28th week					

5.4.1.3 FETAL ABDOMINAL CIRCUMFERENCE (AC)

The baseline data between the two groups was not different ($p=0.934$, *T-test*). The variances were homogenous ($p=0.502$, *Mauchly's test*). The RM-ANOVA test results were not significant for this parameter ($p=0.099$). However, an ANCOVA test while keeping baseline data as covariate, showed significant improvements in the AC of the babies in the yoga group after 16 weeks of yoga interventions ($p=0.025$).

Figure 5.16 Estimated Marginal Means for Abdominal Circumference

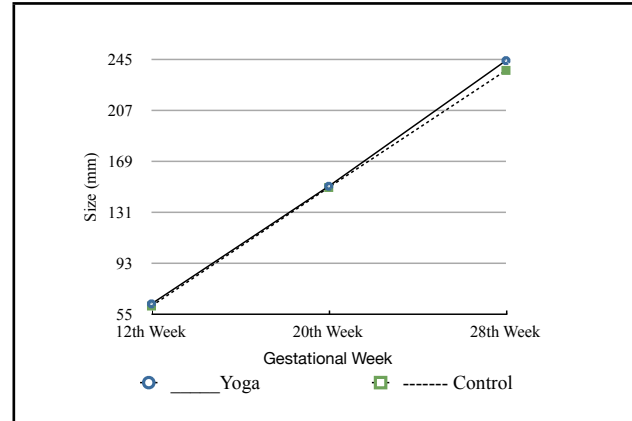


Table 5.19 Fetal Abdominal Circumference

Measurements in Time		Statistics		p-values ANCOVA ²	p-value RM-ANOVA
		Yoga Group (n=27)	Control Group (n=32)		
12 th Week	Mean±SD	62.3 ± 8.5	60.7 ± 6.2		0.099
	95% CI	59.0 - 65.7	58.4 - 62.9		
20 th Week	Mean±SD	150.0 ± 10.6	149.1 ± 8.9	0.954	
	95% CI	145.8 - 154.2	145.9 - 152.2		
28 th Week	Mean±SD	243.7 ± 13.9	236.4 ± 11.1	0.025	
	95% CI	238.2 - 249.2	232.4 - 240.4		

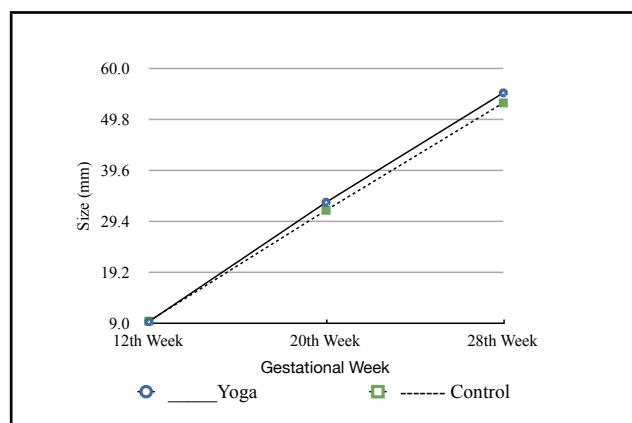
1. RM-ANOVA. Significantly better Abdominal Circumference was observed after 16 weeks of interventions.

2. ANCOVA test for the 28th week with the 12week data as covariate, *df* (1,59) and *F*=5.3

5.4.1.4 FETAL FEMUR LENGTH (FL)

The baseline data between the two groups was not different ($p=0.261$). The sphericity of the variances between the groups was met ($p=0.383$). RM-ANOVA showed highly significant results ($p=0.005$). ANCOVA test further showed that the yoga interventions improved the

Figure 5.17 Estimated Marginal Means for Femur Length



femur length of the fetuses by the 20th week of gestation ($p=0.012$) and continued that incremental improvement till the end study at 28th week of gestation ($p=0.001$).

Table 5.20 Fetal Femur Length

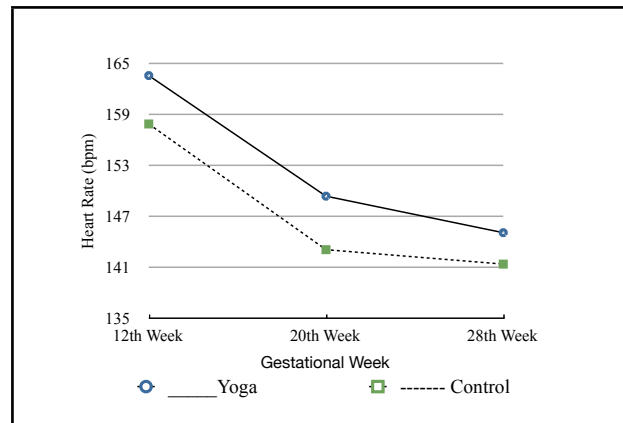
Measurements in Time		Statistics		p-value ANCOVA	p-value RM-ANOVA
		Yoga Group (n=27)	Control Group (n=32)		
12 th Week	Mean±SD	9.2 ± 1.9	9.3 ± 1.7		0.005
	95% CI	8.4 - 9.9	8.7 - 9.9		
20 th Week	Mean±SD	33.1 ± 2.1	31.5 ± 1.9	0.012	
	95% CI	32.3 - 33.9	30.9 - 32.2		
28 th Week	Mean±SD	55.0 ± 2.6	53.0 ± 2.3	0.001	
	95% CI	53.9 - 56.0	52.2 - 53.9		
1. RM-ANOVA, df (1,57) and F=8.7. Significantly better femur length in fetuses in the yoga group. 2. ANCOVA test was performed with 12th week data as covariate. For the 28th week had df (1,59) and F=11.5					

5.4.1.5 FETAL HEART RATE (FHR)

The p-value was calculated using the RM-ANOVA test, which showed highly significant result ($p=0.006$) with df (1,44) and F=8.34. However, with this parameter, the data between the two groups was statistically different at baseline ($p=0.036$) requiring ANCOVA test. The ANCOVA test was performed with the baseline data as covariate and the results were not significant at any point.

Table 5.21 Fetal Heart Rate

Measurements in Time		Statistics		p-value ANCOVA	p-value RM-ANOVA
		Yoga Group (n=27)	Control Group (n=32)		
12 th Week	Mean±SD	163.5 ± 9.4	157.8 ± 9.4		0.006
	95% CI	159.2 - 167.8	153.9 - 161.7		
20 th Week	Mean±SD	149.3 ± 7.6	143.0 ± 9.9	0.169	
	95% CI	145.9 - 152.7	138.9 - 147.1		
28 th Week	Mean±SD	145.0 ± 11.6	141.3 ± 7.2	0.345	
	95% CI	139.7 - 150.3	138.3 - 144.3		
<i>1. RM-ANOVA, df (1,44), F=8.34. No significant improvement in the fetal heart rate in the yoga group</i>					
<i>2. ANCOVA test was performed with 12th week data as covariate. For the 28th week had df (1,59) and F=11.5</i>					

Figure 5.18 Estimated Marginal Means for Fetal Heart Rate

5.4.1.6 ESTIMATED FETAL WEIGHT (EFW)

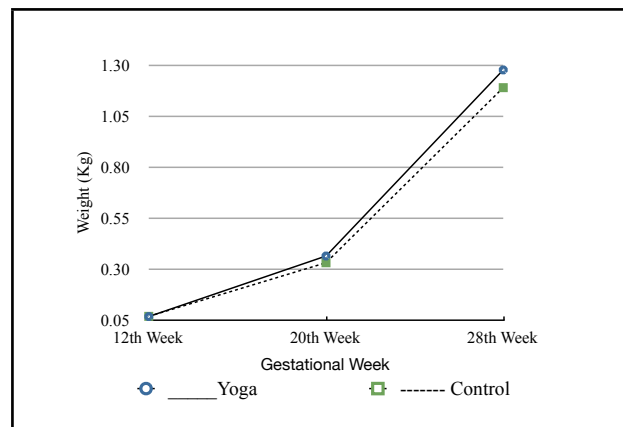
The baseline data between the two groups was not different ($p=0.615$). The Mauchly's Test of Sphericity ($p=0.001$) was highly significant for this parameter. The RM-ANOVA test results were significant ($p=0.019$).

Table 5.22 Estimated Fetal Weight (kg)

Measurements in Time		Statistics		p-value ANCOVA	p-value RM-ANOVA
		Yoga Group	Control Group		
12 th Week	Mean±SD	0.065 ± 0.02	0.066 ± 0.01		0.019
	95% CI	0.058 - 0.072	0.063 - 0.070		
20 th Week	Mean±SD	0.362 ± 0.05	0.329 ± 0.04	0.036	
	95% CI	0.338 - 0.387	0.314 - 0.343		
28 th Week	Mean±SD	1.275 ± 0.15	1.188 ± 0.13	0.010	
	95% CI	1.208 - 1.342	1.136 - 1.241		
1. RM-ANOVA, df (1,45), F=5.97. The fetal weight increased significantly in the yoga group as compared to the control.					
2. ANCOVA test was performed with 12th week data as covariate. For the 28th week: df (1,47) and F=7.2					

There was a continuous improved increase in fetal weight from the 12th week gestation ($p=0.608$) to the 20th week ($p=0.063$) to the 28th week ($p=0.01$) in the yoga group as compared to the control. The improvement is illustrated in figure 5.19 and confirmed by our infant birthweight result, which was significant.

Figure 5.19 Estimated Marginal Means for Fetal Weight



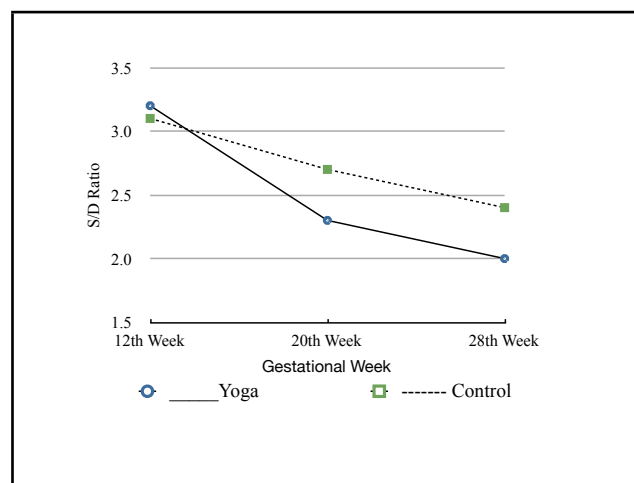
5.4.2 DOPPLER MEASUREMENTS

We were able to measure the left-uterine and right-uterine arteries parameters at baseline. The umbilical and middle cerebral arteries could only be detected at the 20th week and 28th week gestations. For each artery, the ratio of systolic over diastolic, the pulsatility index, and the resistance index were measured. The result of each parameter is tabulated, illustrated, and discussed in the sections that follow.

5.4.2.1 RIGHT UTERINE ARTERY SYSTOLIC/DIASTOLIC RATIO (RUA-SD)

The Mauchly's Test of Sphericity was not significant ($p=0.016$). The result of RM-ANOVA test was not statistically significant ($p=0.168$). Neither the Wilks' Lambda multivariate correction test was significant ($p=0.268$) nor the Greenhouse-Geisser Test of Within Subjects Effects ($p=0.210$). However, the Intercept Test of Between Subjects Effects were highly significant ($p<0.001$). At baseline, the control group had slightly better S/D ratio than the yoga group but the difference was not statistically significant ($p=0.572$, *T-test*). But as the interventions were administrated, the S/D ratio in the

Figure 5.20 Estimated Marginal Means for Right Uterine Artery Systolic/Diastolic Ratio



yoga group improved but still not statistically significant by the mid-study ($p=0.105$, ANCOVA). The improvements in the yoga group widened by the 28th week gestation with highly significant results ($p=0.001$, ANCOVA).

Table 5.23 Right Uterine Artery Systolic/Diastolic Ratio

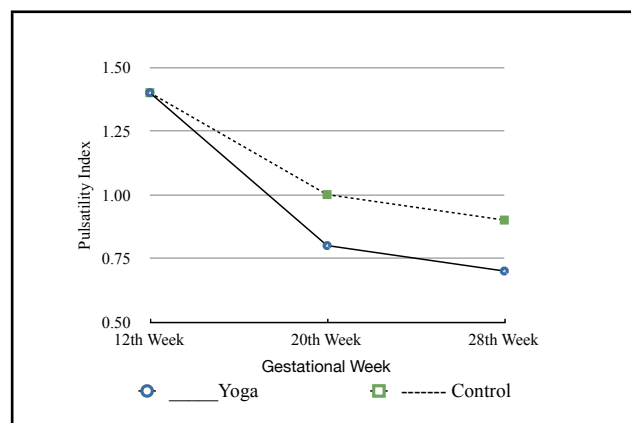
Measurements in Time		Statistics		p-values ANCOVA	p-value RM-ANOVA
		Yoga Group	Control Group		
12 th Week	Mean±SD	3.2 ± 1.4	3.1 ± 1.1		0.168
	95% CI	2.6 - 3.7	2.7 - 3.4		
20 th Week	Mean±SD	2.3 ± 0.4	2.7 ± 1.1	0.105	
	95% CI	2.1 - 2.5	2.3 - 3.1		
28 th Week	Mean±SD	2.0 ± 0.3	2.4 ± 0.7	0.001	
	95% CI	1.9 - 2.1	2.1 - 2.6		
There was a significant improvement in the right uterine artery blood flow in the yoga group, after 16 weeks of yoga interventions (p=0.001, ANCOVA with baseline data as covariate).					

Figure 5.19 illustrates this progress graphically. The control group had a relatively linear decline in the S/D ratio throughout the study, while the yoga group had a much sharper decline till the 20th week of pregnancy and continued reduction till the 28th week of gestation.

5.4.2.2 RIGHT UTERINE ARTERY PULSATILITY INDEX (RUA-PI)

The sphericity assumption was violated ($p=0.002$, Mauchly's Test). RM-ANOVA test result was near significant ($p=0.071$). The ANCOVA test also showed near significance at the 12th week of gestation ($p=0.068$) and significant results at the 28th week ($p=0.010$) suggesting that the yoga interventions had continuous improvement on the PI parameter. The baseline RUA-PI values for the two

Figure 5.21 Estimated Marginal Means for Right Uterine Artery Pulsatility Index



groups were nearly identical ($p= 0.786$, *T-test*). By the 20th week of gestation, the RUA-PI

mean dropped by almost 43% whereas the reduction in the control group was less than 29%. From the 20th week to the 28th week of gestation, the reduction in RUA-PI was paralleled between the two groups (see Figure 5.21).

Table 5.24 Right Uterine Artery Pulsatility Index

Measurements in Time		Statistics		p-values ANCOVA	p-value RM-ANOVA
		Yoga Group	Control Group		
12 th Week	Mean±SD	1.4 ± 0.5	1.4 ± 0.5	0.068	0.071
	95% CI	1.2 - 1.6	1.2 - 1.6		
20 th Week	Mean±SD	0.8 ± 0.2	1.0 ± 0.5		
	95% CI	0.8 - 0.9	0.9 - 1.2		
28 th Week	Mean±SD	0.7 ± 0.1	0.9 ± 0.4	0.010	
	95% CI	0.6 - 0.7	0.7 - 1.0		
There was a significant improvement in the right uterine artery blood flow in the yoga group, after 16 weeks of yoga interventions (p=0.01, ANCOVA with baseline data as covariate).					

5.4.2.3 RIGHT UTERINE ARTERY RESISTANCE INDEX (RUA-RI)

The variances were homogenous ($p=0.319$). The p-value was calculated using the RM-ANOVA test, which showed significant result ($p=0.012$). Similar to RUA-SD, the control group had slightly better RI values than the yoga group at baseline but not statistically significant ($p=0.743$, *T-test*). But as the interventions were administrated, the RI in the yoga group was better improved than that of the control (see Figure 5.22 and Table 5.25). Keeping the 12th week data as covariate, we performed ANCOVA test. After 8 weeks of yoga interventions, the results were near significance ($p=0.055$, ANCOVA). After 16 weeks of yoga interventions, the results were highly significant ($p<0.001$, ANCOVA) suggesting that yoga interventions were very effective in improving the blood flow to the uterus.

Figure 5.22 Estimated Marginal Means for Right Uterine Artery Resistance Index

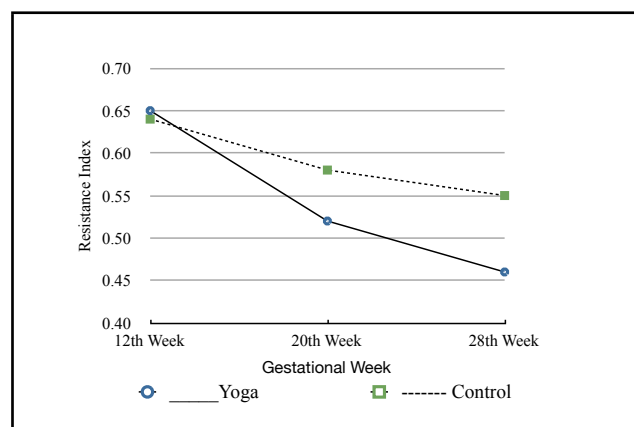


Table 5.25 Right Uterine Artery Resistance Index

Measurements in Time		Statistics		p-values ANCOVA	p-value RM-ANOVA
		Yoga Group	Control Group		
12 th Week	Mean±SD	0.65 ± 0.11	0.64 ± 0.1		0.012
	95% CI	0.61 - 0.69	0.60 - 0.68		
20 th Week	Mean±SD	0.52 ± 0.09	0.58 ± 0.11	0.055	
	95% CI	0.49 - 0.56	0.54 - 0.62		
28 th Week	Mean±SD	0.46 ± 0.09	0.55 ± 0.11	p<0.001	
	95% CI	0.44 - 0.49	0.52 - 0.58		
There was a significant improvement in the right uterine artery blood flow in the yoga group overall (p=0.012, RM-ANOVA) and after 16 weeks of yoga interventions (p=0.001, ANCOVA with baseline data as covariate).					

5.4.2.4 LEFT UTERINE ARTERY SYSTOLIC/DIASTOLIC RATIO (LUA-SD)

The baseline means were not different statistically ($p=0.772$, T -test). The data for this parameter was highly skewed ($p=0.001$). The RM ANOVA test results were not significant and nor were those of ANCOVA Test (see Table 5.26). In spite of the result not being significant, there were more improvement in the yoga group than the control as illustrated in the figure 5.23.

Figure 5.23 Estimated Marginal Means for Left Uterine Artery Systolic/Diastolic Ratio

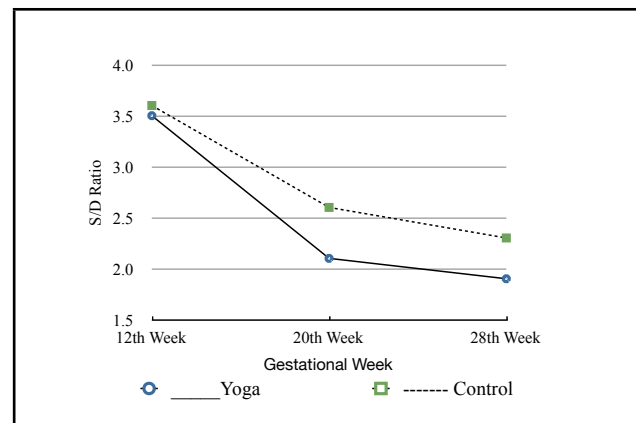


Table 5.26 Left Uterine Artery Systolic/Diastolic Ratio

Measurements in Time		Statistics		p-values ANCOVA	p-value RM-ANOVA
		Yoga Group	Control Group		
12 th Week	Mean±SD	3.5 ± 1.5	3.6 ± 1.6		0.145
	95% CI	2.9 - 4.1	3.0 - 4.2		
20 th Week	Mean±SD	2.1 ± 0.3	2.6 ± 1.1	0.118	
	95% CI	2.0 - 2.2	2.2 - 3.0		
28 th Week	Mean±SD	1.9 ± 0.3	2.3 ± 1.2	0.141	
	95% CI	1.8 - 2.1	1.9 - 2.7		

5.4.2.5 LEFT UTERINE ARTERY PULSATILITY INDEX (LUA-PI)

The data for this parameter was also skewed ($p=0.001$) but it was not different at baseline between groups ($p=0.454$, T -test). The RM-ANOVA test result was near significance ($p=0.078$). The ANCOVA test didn't show significant improvements any point in time. (see Table 5.27). The mean LUA-PI reduced in both groups at the 20th week measurement. However, from then until the end of the study, the mean values for the control group actually increased while those for the yoga group continue to decline (see Figure 5.24).

Figure 5.24 Estimated Marginal Means for Left Uterine Artery Pulsatility Index

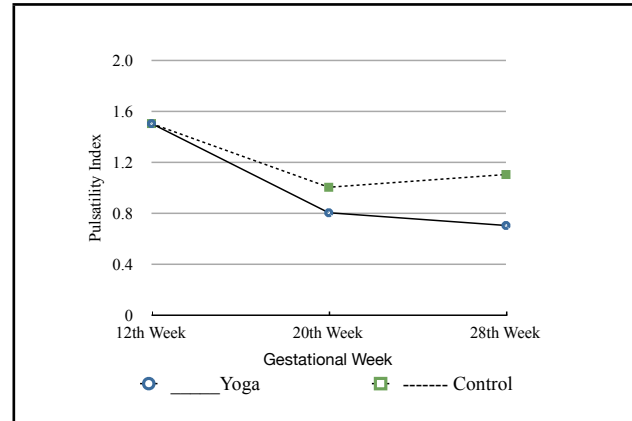


Table 5.27 Left Uterine Artery Pulsatility Index

Measurements in Time		Statistics		P-values ANCOVA	p-value RM-ANOVA
		Yoga Group	Control Group		
12 th Week	Mean±SD	1.5 ± 0.6	1.5 ± 0.8	0.109	0.078
	95% CI	1.3 - 1.7	1.3 - 1.9		
20 th Week	Mean±SD	0.8 ± 0.2	1.0 ± 0.5		
	95% CI	0.7 - 0.9	0.9 - 1.2		
28 th Week	Mean±SD	0.7 ± 0.1	1.1 ± 1.8	0.208	
	95% CI	0.6 - 0.7	0.5 - 1.8		

5.4.2.6 LEFT UTERINE ARTERY RESISTANCE INDEX (LUA-RI)

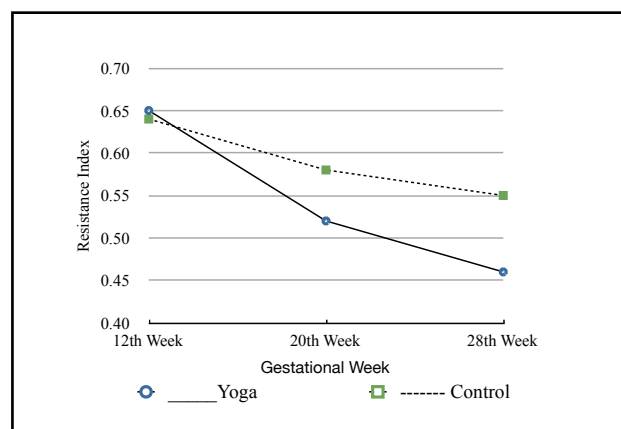
There were no differences between the groups at baseline ($p=0.551$, T -test). RM-ANOVA test showed near significant result for this parameter as well ($p=0.083$). Because the Mauchly's Test of Sphericity was significant ($p=0.015$) and epsilons were high (0.917), we used the Huynh-Feldt test of within subject correction, which showed significance ($p=0.04$). Furthermore, the Linear Test of Within-Subjects for measurements and group interactions was also significant ($p=0.004$).

Table 5.28 Left Uterine Artery Resistance Index

Measurements in Time		Statistics		p-values ANCOVA	P-value RM-ANOVA
		Yoga Group	Control Group		
12 th Week	Mean±SD	0.69 ± 0.15	0.66 ± 0.12		0.083
	95% CI	0.63 - 0.75	0.61 - 0.70		
20 th Week	Mean±SD	0.52 ± 0.06	0.57 ± 0.11	0.132	
	95% CI	0.49 - 0.54	0.53 - 0.61		
28 th Week	Mean±SD	0.47 ± 0.07	0.59 ± 0.24	0.013	
	95% CI	0.44 - 0.50	0.50 - 0.67		

As illustrated in figure 5.25, the LUA-RI in both groups reduced until the 20th week of gestation ($p=0.132$, ANCOVA). From that time, the LUA-RI for the control group started to rise while in the yoga group continued its decline resulting in significant improvements ($p=0.013$, ANCOVA).

Figure 5.25 Estimated Marginal Means for Left Uterine Artery Resistance Index

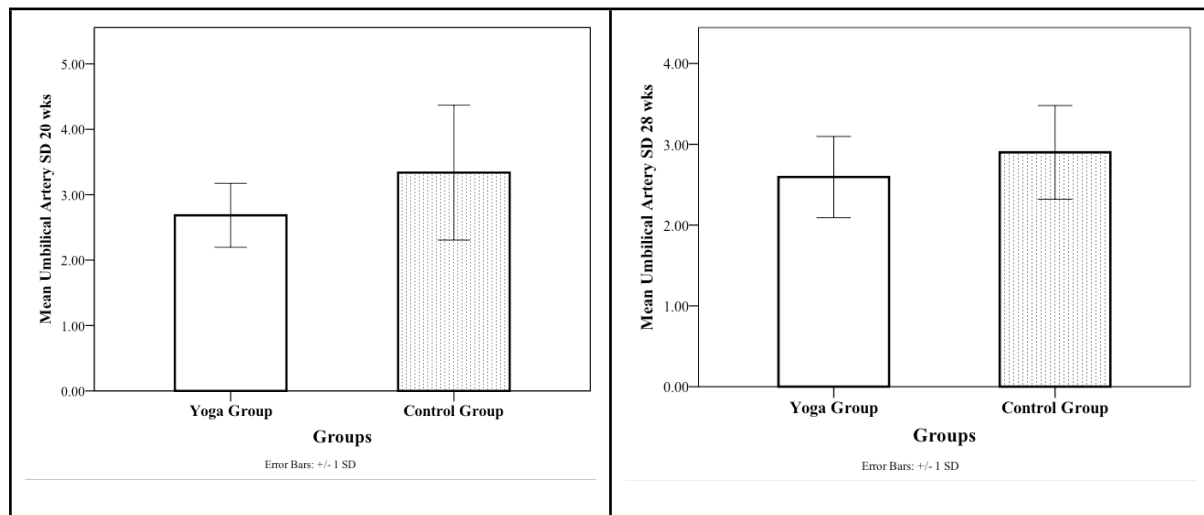


5.4.2.7 UMBILICAL ARTERY SYSTOLIC/DIASTOLIC RATIO (UA-SD)

With the data distribution being normal in both groups ($p=0.141$ and 0.374 for yoga and control group, respectively), we chose the Independent-Samples T-test for the p-values' calculations. Although it was not possible to measure the umbilical artery parameters at baseline, the yoga interventions had clearly made significant improvements in the S/D ratio of this artery by the 20th week gestation ($p=0.001$). The improvements continued in the yoga group until the end of the study at the 28th week gestation ($p=0.031$).

Table 5.29 Umbilical Artery Systolic/Diastolic Ratio

Measurements in Time		Statistics		P-values ¹
		Yoga Group	Control Group	
20 th Week	Mean±SD	2.7 ± 0.41	3.3 ± 1.1	0.001
	95% CI	2.5 - 2.8	2.9 - 3.7	
28 th Week	Mean±SD	2.6 ± 0.5	2.9 ± 0.6	0.031
	95% CI	2.4 - 2.8	2.7 - 3.1	
Independent-Samples T-test				

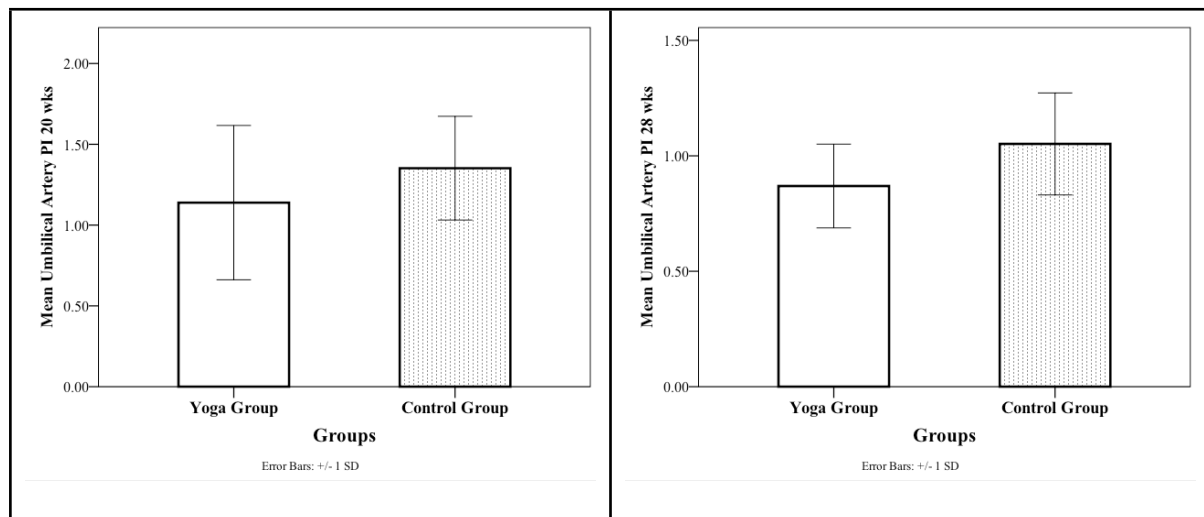
Figure 5.26 Estimated Marginal Means for Umbilical Artery Systolic/Diastolic Ratio

5.4.2.8 UMBILICAL ARTERY PULSATILITY INDEX (UA-PI)

Similar to the S/D ratio, the PI for the umbilical artery was significantly better improved in the yoga group compared to the control group by the 20th week of gestation and the improvements continued until the 28th week ($p=0.001$ for both measurements). However, unlike the S/D ratio, we used the non-parametric Mann-Whitney test because the 20th week measurement data distribution was not normal ($p=0.518$ and 0.001 for the yoga and control groups, respectively)

Table 5.30 Umbilical Artery Pulsatility Index

Measurements in Time		Statistics		P-values ¹
		Yoga Group	Control Group	
20 th Week	Mean±SD	1.01 ± 0.18	1.37 ± 0.34	0.001
	95% CI	0.94 - 1.08	1.25 - 1.49	
28 th Week	Mean±SD	0.87 ± 0.18	1.05 ± 0.23	0.001
	95% CI	0.80 - 0.94	0.97 - 1.13	
1. While the 20 th week data distribution for the yoga group was normal (p=0.518), the one for the control group was not (p=0.001); therefore p-values were calculated using Mann-Whitney Test. Highly significant improvements in the blood flow of umbilical artery was found in the yoga group both after 8 weeks and 16 weeks of yoga interventions.				

Figure 5.27 Estimated Marginal Means for Umbilical Artery Pulsatility Index

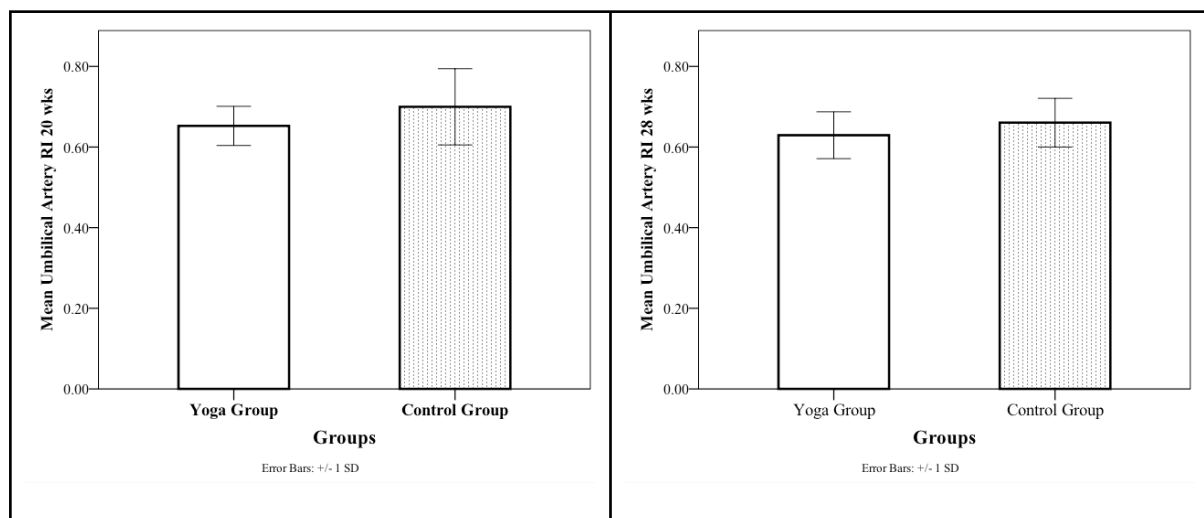
5.4.2.9 UMBILICAL ARTERY RESISTANCE INDEX (UA-RI)

Mann-Whitney test was chosen because the data distributions for the two groups were not normal at the 20th week measurement ($p=0.276$ and 0.039 for the yoga and control groups, respectively). The RI of the RUA, like the other two parameters, benefitted substantially from the yoga interventions in the first half of the study ($p=0.011$) and to the lesser extend in the second half ($p=0.091$).

Table 5.31 Umbilical Artery Resistance Index

Measurements in Time		Statistics		P-values ¹
		Yoga Group	Control Group	
20 th Week	Mean±SD	0.65 ± 0.05	0.70 ± 0.09	0.011
	95% CI	0.70 - 0.02	0.67 - 0.74	
28 th Week	Mean±SD	0.63 ± 0.08	0.66 ± 0.06	0.091
	95% CI	0.61 - 0.65	0.64 - 0.68	
1. While the 20 th week data distribution for the yoga group was normal (p=0.276), the one for the control group was not (p=0.039); therefore p-values were calculated using Mann-Whitney Test. There was a significant improvement in resistance index of the umbilical artery blood flow of the fetuses in the yoga group after 8 weeks of yoga interventions.				

Figures 5.26-5.28 show how similar has been the reaction of the three parameters of the umbilical artery to the yoga interventions.

Figure 5.28 Estimated Marginal Means for Umbilical Artery Resistance Index

5.4.2.10 FETAL MIDDLE CEREBRAL ARTERY SYSTOLIC/DIASTOLIC RATIO (MCA-SD)

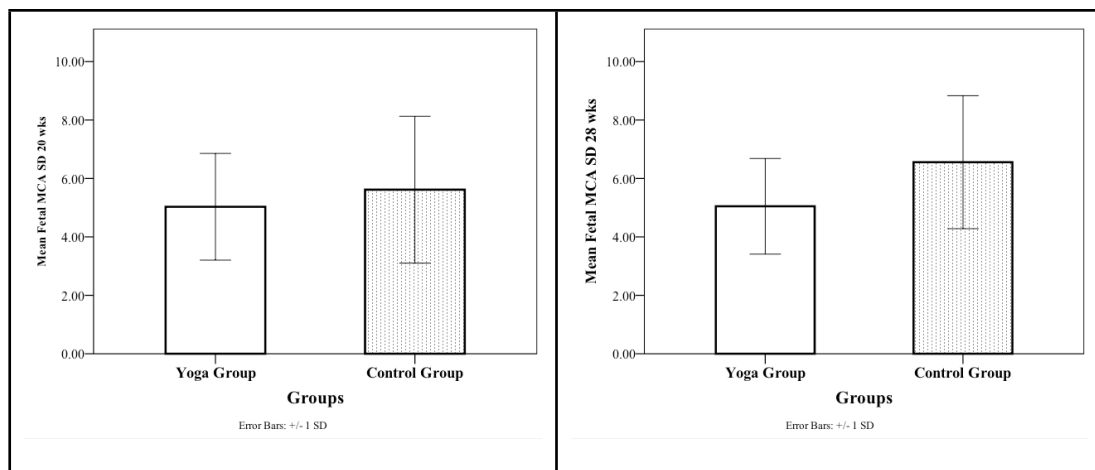
In the recent years, the MCA has emerged as the vessel of choice in Doppler assessment of fetal intracranial and other organs perfusion, because of its highest resistance indices, earlier presentation of diastolic blood flow, and improved ultrasound resolution.²⁸⁸ In a cohort study of 1037 normal pregnant women, it has been shown that SD, PI, and RI parameters of MCA follow a parabolic pattern where the values rise up to the 28th week gestation and begin to fall

thereafter till term.²⁸⁹ While our study had only a two pointed measurement for MCA (at the 20th and the 28th weeks of gestation), we also observed the same increase in our data. However the values of SD remained unchanged from the 20th week to the 28th week of gestation in the yoga group, while the values increased in the control group (see Table 5.31 and Figure 5.29).

Table 5.32 Fetal Middle Cerebral Artery Systolic/Diastolic Ratio

Measurements in Time		Statistics		P-values ¹
		Yoga Group	Control Group	
20 th Week	Mean±SD	5.02 ± 1.47	5.77 ± 2.04	0.537
	95% CI	4.24 - 5.79	4.87 - 6.67	
28 th Week	Mean±SD	5.05 ± 1.64	6.62 ± 2.26	0.010
	95% CI	4.39 - 5.71	5.83 - 7.41	
1. While the baseline data distribution for the yoga group was normal (p=0.298), the one for the control group was not (p=0.002); therefore p-values were calculated using Mann-Whitney Test				

Figure 5.29 Estimated Marginal Means for Fetal Middle Cerebral Artery Systolic/Diastolic Ratio



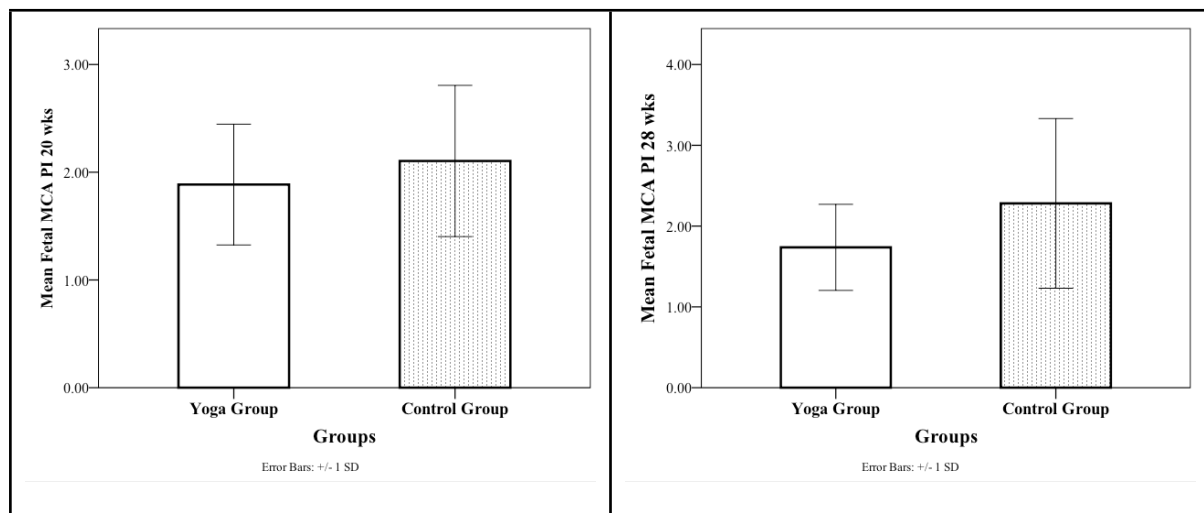
5.4.2.11 FETAL MIDDLE CEREBRAL ARTERY PULSATILITY INDEX (MCA-PI)

In the case of pulsatility index (PI), the values in the yoga group decreased from the 20th week to the 28th week gestation, while in the control group the PI values increased (see Table 5.33 and Figure 5.30).

Table 5.33 Fetal Middle Cerebral Artery Pulsatility Index

Measurements in Time		Statistics		P-values ¹
		Yoga Group	Control Group	
20 th Week	Mean±SD	1.86 ± 0.45	2.18 ± 0.67	0.151
	95% CI	1.64 - 2.07	1.92 - 2.43	
28 th Week	Mean±SD	1.74 ± 0.53	2.28 ± 1.10	0.013
	95% CI	1.53 - 1.95	1.88 - 2.67	

1. While the baseline data distribution for the yoga group was normal ($p=0.174$), the one for the control group was not ($p=0.007$); therefore p -values were calculated using Mann-Whitney Test. Significant improvements in the Fetal MCA pulsatility index was observed in the yoga group after 16 weeks of yoga interventions.

Figure 5.30 Estimated Marginal Means for Fetal Middle Cerebral Artery Pulsatility Index

5.4.2.12 FETAL MIDDLE CEREBRAL ARTERY RESISTANCE INDEX (MCA-RI)

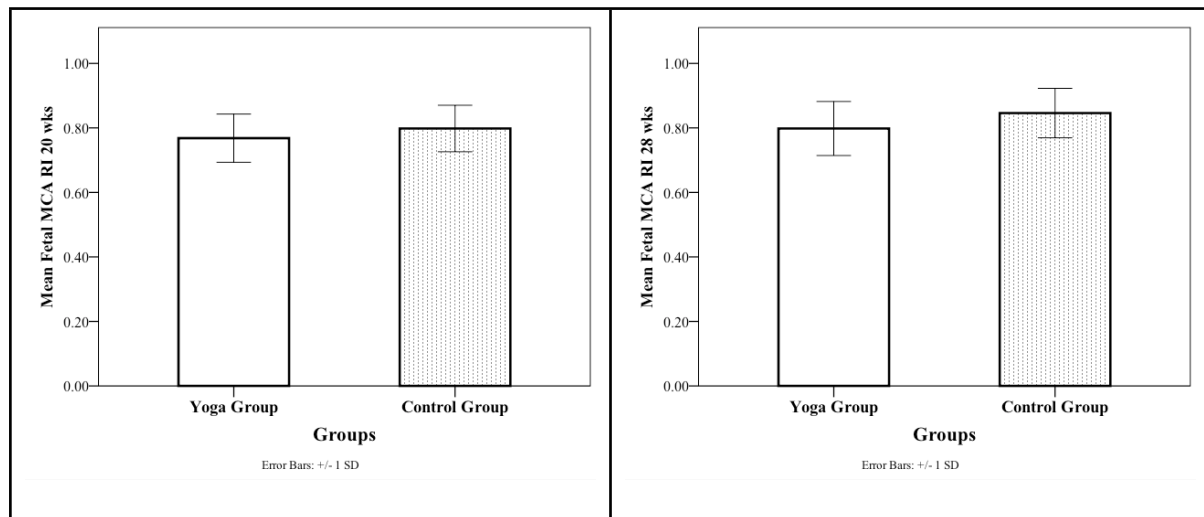
We observed an increase in the resistance index (RI) in both groups from the 20th week to the 28th week gestation although the rise in the yoga group was less sharp (see Table 5.34 and Figure 5.31).

Table 5.34 Fetal Middle Cerebral Artery Resistance Index

Measurements in Time		Statistics		P-values ¹
		Yoga Group	Control Group	
20 th Week	Mean±SD	0.77 ± 0.07	0.80 ± 0.07	0.220
	95% CI	0.74 - 0.79	0.78 - 0.83	
28 th Week	Mean±SD	0.80 ± 0.08	0.85 ± 0.08	0.048
	95% CI	0.77 - 0.83	0.82 - 0.87	

1. While the baseline data distribution for the yoga group was normal ($p=0.464$), the one for the control group was not ($p=0.030$); therefore p -values were calculated using Mann-Whitney Test

Figure 5.31 Estimated Marginal Means for Fetal Middle Cerebral Artery Resistance Index



CHAPTER 6

DISCUSSION

CHAPTER CONTENTS:

- Feasibility and Safety
- Effectiveness of the Yoga Intervention
- Mechanism

Chapter 6: Discussion

The primary aim of this study was to assess the feasibility, safety, and effectiveness of antenatal yoga in high-risk pregnancies. In this chapter, we will review the main results of the study.

6.1 Feasibility and Safety

One of the objectives of this preliminary study in high-risk pregnancies was to assess the feasibility of administering yoga interventions as a preventive medicine in women at high risk of pregnancy complications. The hospital administration proved to be very open to the practices of yoga as a mind-body medicine and was quite accommodating to the project. The research staff was able to teach yoga classes without interruptions. There were no reported complaints about the interventions taught and all subjects were able to practice them. The visualization and guided imagery exercises were particularly well received. While in the West, yoga is uniformly practiced by all faiths, we found some hesitation in the Moslem and Christian families to participate in the study, as they associated yoga with the Hindu faith. However, those that joined the study, continued with the sessions.

6.2 Effectiveness of the Yoga Intervention

Our yoga interventions were selected very carefully to ensure the safety of the subjects. They were easy, relaxing, and meditative in nature and intended to reduce maternal stress. Therefore, the parameters that were most affected by psychological stress responded better to our interventions, as will be seen in the sections that follow.

6.2.1 PREGNANCY COMPLICATIONS

Mind-body therapies have been shown to be effective in prevention of pregnancy complications. Previous studies have investigated the effects of acupuncture^{290, 291}, homeopathy²⁹², Ayurveda²⁹³, yoga^{54, 55}, and Qigong²⁶⁶ during pregnancy.²⁹⁴⁻²⁹⁶ These interventions have been shown to be effective in reducing occurrences of hypertensive disorders of pregnancy^{266, 297}, preventing preterm deliveries^{292, 298, 299}, improving fetal outcomes^{292, 300}, and enhance quality of life^{54, 82}.

In the Narendran study, yoga interventions resulted in significantly less incidents of IUGR (22.06% in the yoga group vs. 32% in the control group), PIH (17.65% in the yoga group vs. 28% in the control group), and preterm labor (13.24% in the yoga group vs. 20.75% in the control group). A study of Qi-gong practices, which are similar to yoga exercises, has shown that they can significantly reduce the clinical manifestations of PIH (55% in the yoga group vs. 90% in the control group).²⁶⁶

In line with these previous results, the present study also showed that yoga was an effective therapy in preventing PIH, GDM, preeclampsia, IUGR, and preterm deliveries in the yoga group as explained below.

6.2.1.1 HYPERTENSIVE DISORDERS OF PREGNANCY

There were 11 (36.7%) cases of PIH in the control group and 3 (10.3%) cases in the study group ($p=0.02$, chi^2). The incidents of preeclampsia was also significantly less in the yoga group (0% in the yoga group versus 13.3% in the control, $p=0.04$, chi^2). There were two cases of eclampsia in the control group and none in the yoga group; however, the results were not statistically significant ($p=0.16$, chi^2).

One study has shown that low-dose aspirin administered as early as 14-16 weeks of gestation to pregnant women at high risk of preeclampsia with abnormal uterine Doppler findings may reduce or modify the course of severe preeclampsia.³⁰¹ In this study, preeclampsia developed in 35% of women receiving aspirin and 62% of women in the control group ($p=0.003$), with severe preeclampsia developing in 8% and 23% of women ($p=0.215$), respectively. In another similar study, the relative risk of developing pre-eclampsia was 0.90 (95% CI 0.84-0.97), of delivering before 34 weeks was 0.90 (0.83-0.98), and of having a pregnancy with a serious adverse outcome was 0.90 (0.85-0.96) in the group using aspirin.²⁰⁶ A review study has claimed that antioxidants can also be effective treatment agents for preeclampsia with as large as two-thirds reduction of the frequency of preeclampsia in high-risk women.³⁰² Acetylsalicyclic acid has been investigated in prevention of hypertension related complications of pregnancy. One study has shown that the use of acetylsalicyclic acid was associated with a statistically significant reduction in the incidence of pregnancy-induced hypertension (11.6% vs 37.2%, RR = 0.31, 95% CI 0.13-0.78), pre-eclampsia (4.7% vs

23.3%, RR = 0.2, 95% CI 0.05-0.86) and the incidence of hypertension before 37 weeks of pregnancy (2.3% vs 20.9%, RR = 0.22, 95% CI 0.05-0.97).³⁰³ The result of these supplements are also similar to ours.

6.2.1.2 OTHER COMPLICATIONS

The yoga group had significantly fewer cases of IUGR ($p=0.05$, χ^2) and preterm deliveries ($p=0.04$, χ^2), which are prevalent issues in India (Park, 2000). There were also fewer occurrences of GDM in the yoga group ($p=0.05$, χ^2). There was one dropout due to abortion in the control group. There were no cases of miscarriages, fetal deaths, or congenital anomalies in either group.

6.2.2 PREGNANCY OUTCOMES

6.2.2.1 PRETERM DELIVERY AND C-SECTION

Recent research has associated maternal psychological stress with preterm delivery and shorter gestation.³⁰⁴⁻³⁰⁶ Women with high-risk pregnancies have a higher level of stress than those with normal pregnancies.³⁰⁷ Is it any wonder that mind body interventions that are aimed at giving the practitioners skills to manage lifestyle stress are becoming more and more popular in the modern societies?^{308, 309} The effectiveness of mind body techniques on maternal stress reduction and improvements of pregnancy outcomes was highlighted in a recent study.³¹⁰ More specifically, a clinical study of out-patient women with preterm labor indicated that relaxation interventions would significantly prolong gestational weeks.³¹¹ Furthermore, a more recent randomized controlled trial found significant psychological stress reduction in pregnant women with preterm labor who practiced relaxation techniques.³¹²

The interventions used in the present study was also aimed at reducing the maternal stress. Therefore, in line with the results of the previous studies mentioned above, the preterm deliveries in our study were significantly lesser in the study group compared with those in the control group ($p=0.04$, χ^2). However, although there were fewer C-Section deliveries in the yoga group compared to the control group, the results were not statistically significant (52% in the yoga group vs. 58% in the control group). Similarly, Narendran *et al* observed that the number of C-section deliveries in their study was 14 (20.59%) in the yoga group, compared to 20 (37.74%) in the control group but not statistically significant.

6.2.2.2 FETAL DEVELOPMENT

SGA is a prevalent issue in India and it has been argued that it is a key indicator of the health trajectory of a child,³¹³ and numerous adverse health outcomes in childhood have been associated with low birthweight.³¹⁴ The present study has shown that there were significantly lower SGA newborns in the yoga group than in the control group ($p=0.03$, χ^2).

It is interesting to note that although the number of SGA babies was significantly lower in yoga than in the control group, the number of LBW babies were not significantly different between the groups ($0.76 \chi^2$). This appears to be due to the fact that we adopted WHO's definition of LBW, which is babies weighing less than 3000 grams. The average weight of an Indian full-term newborn is about 2,800 grams, while in developed countries, it is about 3,000 grams.³² Therefore, the definition of LBW given by WHO, adopted by the present study, may be too broad to serve the Indian population and that could be one reason that our results for LBW was not significant. Narendran adopted a different strategy and measured the number of babies with birthweight above 2500 g, which proved to be highly significant in the yoga group, compared to the control ($p<0.001$) et al.⁵⁵

Our result for the estimated fetal weight on the ultrasound scanning was significant ($p=0.019$, RM-ANOVA), which is in line with our birthweight results and those obtained by Narendran et al in normal pregnancies which showed higher birthweight of babies in yoga group than that of the control group with conventional antenatal care ($p=0.018$).⁵⁵ These results support the hypothesis that yoga interventions could play a significant role in the development of the fetuses in low-risk as well as high-risk pregnancies and should be considered as part of the routine antenatal therapies.

It is estimated that 40% of the global 22 million LBW delivered annually occur in India.³¹⁵ This figure constitutes about 33% of all live births in the country and more than half of these are babies that are born after full gestation.³¹⁵ Another words, one third of the babies born in India are considered LBW by WHO's definition and more troubling than that is that half of these babies are born full term. These data goes to point out the urgency for a pregnancy intervention to improve infant birthweight in India and the importance of the observations of the present study.

Significantly fewer babies born from the women in the yoga group had low APGAR-1 and APGAR-5 scores ($p=0.01$ and $p=0.04$ *chi*², respectively). Better APGAR scores is now a widely accepted indicator of the wellbeing of the newborn. The APGAR score results along with the birthweight results gives a positive outlook for this set of yoga interventions. Our results are similar to previous studies that have used other mind-body therapies during pregnancy. In a study of acupuncture therapies, the investigators found that the mean APGAR-5 improved significantly in the acupuncture group.²⁹¹

A glance over the tables 5.16 to 5.21 in chapter 5, shows that the yoga interventions of this study clearly had a positive impact on the fetal development of the subjects in the yoga group. Nearly every parameter showed improvements; however, not all of them were statistically significant. Except for abdominal circumference, we obtained highly significant results in all other fetal measurements. Fetal biparietal measurements had improved in the yoga group significantly more than the fetuses in the control group ($p=0.001$, *RM-ANOVA*). Similarly, there was a highly significant difference in the size of the head circumference and the femur length of the fetuses in the yoga group compared to those in the control group ($p=0.002$ and 0.005 *RM-ANOVA*, respectively). Even in case of fetal abdominal circumference that our overall result was not significant ($p=0.099$ *RM-ANOVA*), further ANCOVA tests showed that there was significant improvements after 16 weeks of yoga interventions ($p=0.025$, *ANCOVA*). Perhaps the most important fetal measurement result of the present study was that of estimated fetal weight, which was significantly improved in the yoga group ($p=0.019$, *RM-ANOVA*).

While there are very few studies that have actively investigated the effects of mind-body therapies on the fetal measurements of Doppler or ultrasound scans, aspirin doses have been used as an intervention in at least one study.

Similar to the results in the control group of the present study, another trial investigated the effects of moderate exercise on uterine artery activities and found no significant changes.³¹⁶ This is important to note in these discussions because it emphasizes the possible role that the

meditative nature of our yoga practices to calm the mind of the mothers has played in the Doppler results of this study.

6.3 Mechanism

Scientific literature shows that yoga-based therapies seem to be promising interventions during pregnancy. Yet, none of the previous studies have been able to explain the underlying mechanisms of the physiologic and psychological effects of yoga during pregnancy. The collective results, including those of this study, suggest that the reported improvements likely occur through a number of pathways, which we can only speculate at this point.

Of the numerous processes that are involved in the physiology adaptation that ensure healthy progression of pregnancy, we propose three factors that could explain the potential observed benefits of yoga:

- (c) Improved blood flow to the fetal and uterine arteries - assessed by the results of Doppler studies. At 12th week gestation a partial Doppler study (left and right uterine arteries only) while at 20th week and 28th week gestation, full Doppler study of the four main arteries (left uterine, right uterine, umbilical, and middle cerebral arteries) were performed.
- (d) Reduction of maternal psychological stress - assessed by a self-administered psychological stress instrument, called the Perceived Stress Scale (PSS). The measurements were taken at the 12th week, the 20th week, and the 28th week gestation.
- (e) Improved physiological adaptation (better hemodilution) - assessed by the measurement of serum uric acid and whole blood platelet count taken at the 12th week, the 20th week, and the 28th week gestation.
- (f) Better flow of *prāṇa* and higher consciousness - a potential explanation of mechanism from the yogic vantage point.

6.3.1 UTEROPLACENTAL AND FETOPLACENTAL BLOOD FLOW

In the present study Yoga intervention proved effective in improving the blood flow to the uterine arteries, the umbilical artery, and the fetal middle cerebral artery. The blood flow to the right uterine artery in yoga group was better than the control group as observed by improved resistance index ($p=0.012$, *RM-ANOVA*). Both the systolic/diastolic and the

pulsatility index of the right uterine artery showed significant improvements at the end of the study ($p=0.001$ and 0.010 ANCOVA, respectively) and so did the resistance index of the left uterine artery ($p=0.013$ ANCOVA). The flow parameters of the umbilical artery showed remarkable improvements in the yoga group: the systolic/diastolic ratio was significantly improved after 8 weeks and 16 weeks of yoga interventions ($p=0.001$ and 0.031 T-test, respectively), the pulsatility index was highly significant after 8 weeks and 16 weeks of yoga interventions ($p=0.001$ for both using Mann-Whitney test), and the resistance index was significant after 8 weeks of yoga interventions ($p=0.011$ Mann-Whitney). All three parameters of the middle cerebral artery were significant after 16 weeks of yoga interventions (systolic/diastolic ratio: $p=0.01$, pulsatility index: $p=0.013$, and resistance index: $p=0.048$, all calculated by Mann-Whitney)

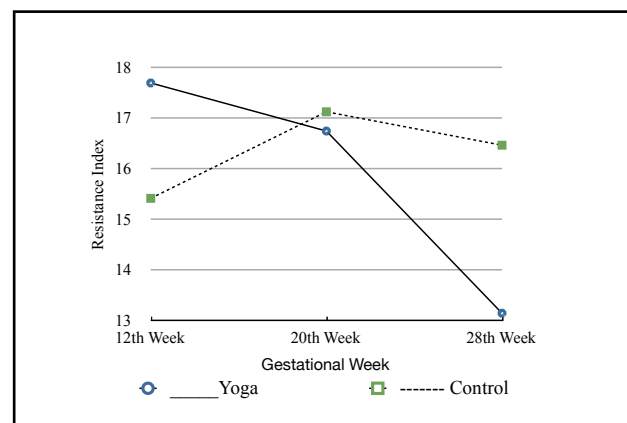
Doppler velocimetry of the umbilical and uterine arteries points to the uteroplacental and fetoplacental units.³¹⁷ It has been shown that the Doppler study of the uterine arteries can detect pathological increase in placental vascular resistance, which offers the potential to detect women at risk for diseases like preeclampsia and fetal growth restriction.³¹⁸ The flow volume in the umbilical artery increases as the pregnancy advances, while the high vascular impedance detected in the first trimester gradually decreases.³¹⁷ It is believed that the growth of placenta and with it, the increase in the number of vascular channels are the main reasons for this reduction in impedance.³¹⁹ Low vascular impedance allows a continuous forward blood flow in the uterine artery throughout the cardiac cycle and when compromised, it can be an indicator of fetal complications in high-risk pregnancies.³¹⁹ There is no substantial evidence that routine assessment of UA velocimetry in high-risk pregnancies, early in second trimester, helps the obstetrician to take preventive measures to decrease the perinatal mortality from IUGR without any increase in rate of unnecessary obstetric interventions.³¹⁹

Fetal MCA is easy to detect and has become an important part of the fetal Doppler assessments to measure cerebral blood flow that also helps in early detection of complications. A continuous forward flow in all cerebral arteries throughout the cardiac cycle is essential for healthy progression of pregnancy.³²⁰ Middle cerebral artery is now one of the highly sensitive measures to detect IUGR and its related complications.³²⁰

6.3.2 MATERNAL STRESS

Stress was measured mainly by the Perceived Stress Scale (PSS) instrument. Although PSS was not a part of the present thesis, its results are mentioned here as evidence for the mechanisms. PSS was self-administered by the subjects in the two groups in the presence of a research staff. At baseline (12th week gestation), the PSS scores of the two groups were matched and had normal distributions. As the study progressed, the maternal stress load in the yoga group was 13% and 25% less than that of the control at the 20th and the 28th weeks of gestation, respectively. The Mean and standard deviation values for PSS at 12th, 20th and 28th weeks in the yoga group were 17.68 ± 5.74 , 16.73 ± 4.94 , 13.13 ± 4.80 , and for the control group were 15.40 ± 4.27 , 17.11 ± 6.65 , 16.45 ± 6.69 in the control group respectively. The results of Repeated Measures ANOVA showed that there was a significant decrease ($F: 4.29, p = 0.016$) in the PSS scores of the women in the Yoga group as compared to those in the control group at the 28th week gestation. Figure 6.1 illustrates the progression of perceived stress between the two groups throughout the study. The control group had a lower average of perceived stress at the beginning of the treatment period. As the interventions were administered, the two groups had nearly the same mean after 8 weeks of treatments (perceived stress increased sharply in the control group while decreased in the yoga group). However, by the 28th week, the mean PSS in the yoga group had substantially dropped while it remained more or less flat in the control group.

Figure 6.1 Estimated Means for Perceived Stress Scale



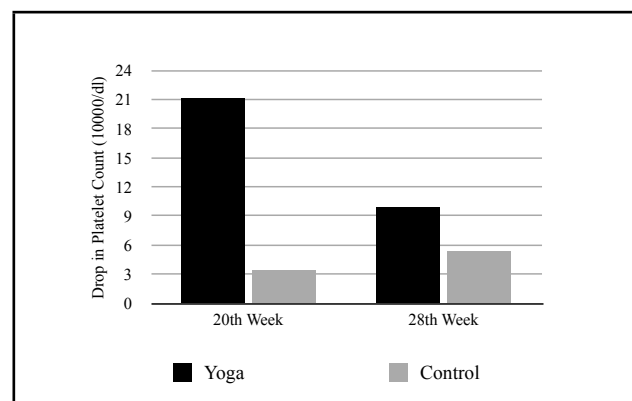
An earlier study in normal pregnancy conducted at our university has investigated the efficacy of Yoga on PSS scores and HRV.⁹³ That study showed a 31.57% reduction in the mean scores of the yoga group while the scores in the control group increased by 6.60%. The results were highly significant ($p=0.001$). HRV also showed improved adaptive autonomic responses as the pregnancy advanced ($p<0.001$).

There was a decrease in both systolic and diastolic Blood Pressure of the mother in both Yoga and control group with non-significant difference between the groups. While BP is a relevant topic to our study, the result of this parameter would have been very important if we were able to obtain a 24 hour average of the BP at each measurement in time. But we could get only one reading and that reading could have been affected by a number of environmental factors. Therefore, this result may not be an indication of the effectiveness of our interventions on the maternal blood pressure. This hypothesis is supported by the fact that hypertensive related complications of pregnancy were significantly reduced both in frequency and severity in the yoga group, as we will see later. There is now a mounting evidence in the literature that links maternal stress to reduced umbilical and uterine blood flow,^{321, 322} increased pregnancy complications,¹¹ and poor fetal development^{323, 324}

6.3.3 PHYSIOLOGICAL ADAPTATION

As we just discussed, the psychological stress results in vasoconstriction in pregnant women and causes poor blood flow to the fetal and uterine arteries, which in turn affects the hemo concentration, mainly due to reduction in plasma volume.³²⁵ In chapter 3, we also discussed the link between platelet count and the plasma volume in the context of hemodilution, where the plasma volume increases more rapidly than the platelet count does. Therefore, it has been argued that the platelet count can be used as a marker for the normal progression of gestation- that is, the lower platelet count implies higher plasma volume that has caused the hemodilution. In the present study, we observed that none of the cases developed abnormal thrombocytopenia. Within groups, there was a progressive reduction (all within normal range) in platelet count (20th week: 7.5%, $p= 0.014$; 28th week: 11%, $p= 0.006$) in the yoga group with non-significant drop in the control group (35% and 3.54%, respectively). There was no significant difference between groups at any point. The number of women who had reduction in platelet count (within normal range) at 20th week was significantly ($p<0.004$,

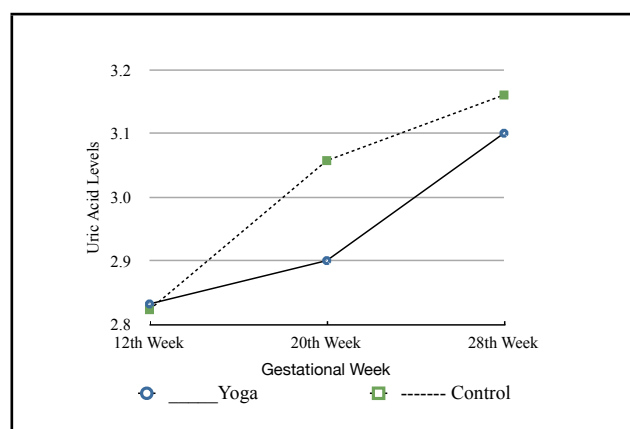
Figure 6.2 Drop in Platelet Count Between Groups



Chi² test) higher in the yoga group suggesting better plasma volume in that group. This can be better viewed in figure 6.2, which shows the degree of drop in platelet count between the two groups at the 20th week and the 28th week gestation. After 4-weeks of interventions the platelet count numbers in the yoga group dropped by 21.13 ($10^4/\text{dl}$) in contrast to the control group that saw only 3.39 ($10^4/\text{dl}$) drop. After 16 weeks of interventions, the number were 9.96 ($10^4/\text{dl}$) in the yoga versus 5.34 in the control group.

Another parameter that is often looked at as an indicator of physiological adaptation during pregnancy is the levels of uric acid. As we discussed in chapter 3 (*section 3.2- Pathophysiology of Pregnancy Complications*), in normal pregnancies, uric acid remains at a fairly constant level from the 8th week till the 24th week when it starts to rise continuously till term. However, in complicated pregnancies, the renal clearance of the uric acid is not at its optimum, leading to higher concentration of uric acid throughout pregnancy. This pattern can be clearly seen in the control group of this study (*see figure 6.3*), where the mean uric acid concentration at 12 weeks gestation is 2.8 (*mean $\pm$ standard deviation: 2.8 ± 0.6*), increased by the 20th week (*mean $\pm$ standard deviation: 3.1 ± 0.6*), and continues to rise until the end of the study at 28th week gestation (*mean $\pm$ standard deviation: 3.2 ± 0.8*). In contrast, the uric acid levels in the yoga group rose at substantially lower rate suggesting improvements in the renal uric acid clearance. However, the difference in the concentration levels between the two groups was not statistically significant. The non-significant results can have many potential explanations. One could be that our sample size was not large enough to detect statistically significant differences between the groups. Another explanation could be that our yoga practices were meditative in nature in order to be safe for the high-risk populations and more rigorous yoga exercises could have influenced the results differently. Finally, the serum concentration of uric acid is

Figure 6.3 Estimated Marginal Means for Plasma Uric Acid



determined by several factors other than renal and gastrointestinal excretion during

pregnancy, that include dietary intake of purines, metabolic production of uric acid by the mother - all of which would be considered confounding factors to the present study.

6.3.4 BETTER FLOW OF PRĀṆA

We have seen in chapter two that yoga offers a holistic approach to healing and includes several practices that influence the various *kośas* differently and correct any imbalances in them. However, the collective objective is to settle the practitioner in a state of *ānandamaya kośa*, which is free from diseases. Unlike the other parameters, assessment of this progress can be a monumental task. In the paragraphs that follow, we try to explain the mechanism that such transformation could have potentially occurred through our yoga interventions at different *kośa* levels.

6.3.4.1 ANNAMAYA KOŚA LEVEL

Āsanās that involve stretching of specific parts of the trunk when maintained with ease and effortlessness help in providing deep rest to the organs. The participants were asked to focus their minds, with intense awareness, on the particular organs affected by the stretches and then relax in the posture, as recommended by the scriptures. Furthermore, the women were asked to visualize the uterus, the fetus, and the blood flow through them. This practice would not only provide a very deep rest to these organs. We used safe *āsanas* that would not produce any compression or over stretching of the uterine area but bring the awareness to the womb and allow the woman to relax the pelvic muscles, along with the entire internal pelvic organs. All sections of the yoga session would end in deep relaxation in the left lateral posture to further enforce the calmness of the mind. In short, these techniques aimed at offering deep relaxation and rest to the uterine region through local conscious wakeful awareness and this may have contributed to the health of the reproductive organs and promoted their proper functions.

6.3.4.2 PRĀṆAMAYA KOŚA LEVEL

Two of the most unique features of the yoga interventions administered in the present study were visualization and guided imagery. As can be seen in the appendix 5, titled ‘Complete List of Yoga Instructions’, the women were asked to visualize the uterus, the fetus, and the

blood flow through a series of guided instructions. The objective behind these visualizations and guided imagery were to move the *prāṇa* through the reproductive organs. It is a yogic principal that where the attention goes, the *prāṇa* will follow and where the *prāṇa* flows, the blood will follow. This basic principal has been the cornerstone of the interventions formulated for this study and could be a plausible explanation for many of the improvements observed in the results of the study, which included:

- (a) Improved blood flow to the fetal and uterine arteries in the yoga group,
- (b) Fewer complications in the yoga group, possibly due to better blood flow in the placental corridor, and
- (c) Better fetal development in the yoga group, possibly also due to better blood flow through umbilical artery delivering necessary nutrients and oxygen to the fetuses.

6.3.4.3 MANOMAYA KOŚA LEVEL

We have repeatedly mentioned throughout this manuscript that the yoga interventions selected for the present study were meditative in nature. There were two reasons for this selection: (i) meditative practices were safer for the high-risk population of this study, and (ii) it was our hypothesis (and has been shown by many previous studies) that maternal psychological stress plays a vital role in the etiology of many of the pregnancy complications and meditative practices could potentially reduce that stress. The results of the PSS scores clearly show the effects of our practices on the maternal stress; the scores in the yoga groups drop steadily in the yoga group as the interventions are administered, while it increase or remains unchanged in the control group. This could have had a profound impact on the results that we have witnessed. Less activity in the *manomaya kośa*, as we have seen in chapter 3, translates into better *prāṇa* flow in *prāṇamaya kośa*, and in turn improved functionality of organs in the *annamaya kośa*. It also translates into better quality of life by uplifting the consciousness of the practitioner to *ānandamaya kośa* through *vijñānamaya kośa*. Figures 2.7 and 2.8 in chapter 2 show the impact of lifestyle stress as an aggressor and yogic practices as a pacifier on the mind from the Vedic point of view and reiterate these concepts. But what is the impact of this stress on the body physiologically?

Stress is the built-in response of a living organism, evolved to handle demanding situations; often referred to as ‘fight or flight’ -- that is, either to prepare to fight or run away to safety.⁴⁸ In mammals, either choice triggers the sympathetic nervous system (SNS) into action, which will cause the pupils to dilate for better vision, move blood away from the intestine toward the big skeletal muscles that need fuel for action, and increases the heart rate as well as breathing rate to provide the necessary oxygen to the muscle cells. However, once the threat is over, the parasympathetic nervous system (PNS) kicks in to bring the body back to its normal homeostatic state.⁴⁸

The human body has evolved very well to handle the stress caused by such occasional demanding situations. The problem is that the stress caused by the modern lifestyle or an illness is usually continuous and does not allow the PNS come into action and do its part.⁴⁸ As a result, the body forgets its normal homeostatic state and adapts a hyper sympathetic state, even in the absence of any danger. Such a hypersympathetic state usually compromises the health and the quality of life of the individual.⁸² When administered properly, yoga practices generally involve a set of stimulations followed by deep relaxations to reverse this condition and reactivate the parasympathetic functions in the body.⁸² Swami Sivananda, a physician and one of India’s greatest yogis, once said: “*Hatha yoga* is a course of psycho-physiological discipline for the attainment of complete mastery over the body, the nervous system and *prāṇa*.” This vision has been the backbone of the design of the present study.

6.3.5 MECHANISMS OF ACTION OF YOGA OBSERVED IN OTHER STUDIES

So far, we have hypothesized potential mechanisms of actions of yoga based on the results observed in this study. For the sake of completion, it would be beneficial to review the observations of other previous investigations. These include:

- (i) Yoga by directly activating the vagus nerve may improve parasympathetic output leading to enhanced cardiac-vagal function, mood, energy state, and related neuroendocrine, metabolic and inflammatory responses.³²⁶

- (ii) Yoga may promote a feeling of well-being by reducing the activation and reactivity of the sympathoadrenal system through increased vagal activity³²⁷ and better autonomic reactivity after yoga as pregnancy advances⁹³.
- (iii) Improved stability of hypothalamic pituitary adrenal (HPA) axis may also contribute as evidenced by decreased cortisol levels in normal adults³²⁸ and increased early morning cortisol in pregnancy^{282, 329} after yoga. Dr Tiffany Field attributes this to the “stimulation of dermal and/or sub-dermal pressure receptors that are innervated by vagal afferent fibers, which ultimately project to the limbic system including hypothalamic structures involved in cortisol secretion.”³³⁰
- (iv) By reducing psychological stress through mind management, yoga could reduce the levels of oxidative stress, which in turn could potentially reduce pregnancy complications.²²⁵
- (v) It is also possible that yogic lifestyle has a positive impact on proper placentation (particularly if practiced early in pregnancy), though research data is needed to substantiate this. Improved blood volume and hemodilution with better blood supply to the placenta may be a major contribution of the restful relaxation techniques used in yoga.³³¹

CHAPTER 7

APPRAISAL

CHAPTER CONTENTS:

- Summary
- Strengths
- Limitations
- Recommendations
- Suggestions for Future Work

Chapter 7: Appraisal

7.1 Summary

In this prospective, single blind, stratified, randomized, controlled study of 68 women with high-risk pregnancies (30 in the yoga group and 38 in the non-yoga group) who met the selection criteria (1- Extreme of age, 2- Poor obstetrics outcomes, 3- Family history, 4-Twin pregnancy, and 5- Obesity) were recruited from the antenatal outpatient clinics of SJMCH and GMH in Bengaluru, India. They were randomized into two groups, yoga and control, using a computer random number generated and by means of concealed envelope method. The yoga intervention was a specific module of meditative yoga developed specifically for the HRP by this PhD candidate. The yoga interventions were administered by certified yoga instructors, who were trained by this PhD candidate for this module of yoga. Subjects in the yoga group received the 1.5 hour long yoga classes at the hospital premises three days a week from the 13th week gestation to the end of 28th week gestation, and then were required to practice on their own till term. The yoga group received yoga plus usual care while the control group followed daily walking plus usual care. Regular practice in both group was ensured by maintaining a diary and regular follow-ups by the research staff. Outcome measures were documented at the 20th and the 28th weeks of gestation. Complications of pregnancy and pregnancy outcomes were the primary outcome measures. Ultrasound Doppler velocimetry results were secondary outcome measures. The main results of this study showed:

A. PRIMARY OUTCOME MEASURES:

- a. Significantly less number of pregnancy induced hypertension and preeclampsia cases in the yoga group ($p=0.018$ and $p=0.042$, χ^2 , respectively). No cases of eclampsia in the yoga group.
- b. Significantly fewer cases of intrauterine growth restriction and gestational diabetes in the yoga group ($p=0.05$ and 0.049 , χ^2 , respectively).
- c. Significantly fewer occurrences of preterm deliveries in the yoga group ($p=0.036$, χ^2).

- d. Significantly fewer number of small for gestational age babies ($p=0.033$, χ^2) and normal for gestational age babies ($p=0.006$, χ^2) in the yoga group.
- e. Significantly fewer low APGAR scores after 1-minute of delivery ($p=0.005$, χ^2) and after 5-minutes of delivery ($p=0.037$, χ^2).

B. SECONDARY OUTCOME MEASURES:

- a. Significantly better fetal biparietal diameter measurements in the yoga group ($p<0.001$, *RM-ANOVA*).
- b. Significantly better fetal head circumference measurements in the yoga group ($p=0.002$, *RM-ANOVA*).
- c. Significantly better fetal abdominal circumference measurements in the yoga group after 8-weeks of yoga interventions ($p=0.025$, *ANCOVA*).
- d. Significantly better fetal femur length measurements in the yoga group ($p=0.005$, *RM-ANOVA*).
- e. Significantly better fetal heart rate readings in the yoga group ($p=0.006$, *RM-ANOVA*).
- f. Significantly better estimated fetal weight measurements in the yoga group ($p=0.019$, *RM-ANOVA*).
- g. Significantly better right uterine artery systolic/diastolic ratio in the yoga group after 8-weeks of yoga interventions ($p=0.001$, *ANCOVA*).
- h. Significantly better right uterine artery pulsatility index in the yoga group after 8-weeks of yoga interventions ($p=0.010$, *ANCOVA*).

- i. Significantly better right uterine artery systolic/diastolic ratio in the yoga group ($p=0.012$, *RM-ANOVA*).
- j. Significantly better left uterine artery resistance index in the yoga group after 8-weeks of yoga interventions ($p=0.013$, *ANCOVA*).
- k. Significantly better umbilical artery systolic/diastolic ratio in the yoga group after 4-weeks of yoga interventions ($p=0.001$, *T-test*) and 8-weeks of yoga interventions ($p=0.031$, *T-test*).
- l. Significantly better umbilical artery pulsatility index in the yoga group after 4-weeks of yoga interventions ($p=0.001$, *Mann-Whitney*) and 8-weeks of yoga interventions ($p=0.001$, *Mann-Whitney*).
- m. Significantly better umbilical artery resistance index in the yoga group after 4-weeks of yoga interventions ($p=0.011$, *Mann-Whitney*).
- n. Significantly better fetal middle cerebral artery systolic/diastolic ratio in the yoga group after 8-weeks of yoga interventions ($p=0.010$, *Mann-Whitney*).
- o. Significantly better fetal middle cerebral artery pulsatility index in the yoga group after 8-weeks of yoga interventions ($p=0.013$, *Mann-Whitney*).
- p. Significantly better fetal middle cerebral artery resistance index in the yoga group after 8-weeks of yoga interventions ($p=0.048$, *Mann-Whitney*).

7.2 Strengths

The key strengths of this doctoral work are:

- (i) This study provides the first scientific evidence for the safety of an antenatal yoga module that can be offered during high-risk pregnancy (HRP).

- (ii) This is the first longitudinal yoga study that recruited only high-risk pregnancies. High-risk pregnancy is a major medical concern that can affect the health of both the mother and her baby adversely and conventional medicine offers no solution but preterm delivery, which has its own implications on the newborn's health. The simple, non-invasive practices investigated in this study can offer cost-effective and practical solution in the management of the pregnancy complications.
- (iii) Stratified randomization is the other strength of this study. Great deal of efforts were made to reduce any potential bias in the study. Randomization was conducted with extreme care. By adopting a single-blind design, we were able to limit the knowledge of group selection only to the patient and the research staff. The medical and laboratory staff who treated the patients and produced the biological data did not know the treatment groups.
- (iv) Good sample size that was decided by statistical calculation from an earlier non-pharmacological interventional study in high-risk pregnancies
- (v) Results pointing to a positive outcome with reduced occurrence of pregnancy complications and better health of the mother and fetus is the unique contribution of this work.
- (vi) Improved blood flow to the uterus and the fetus after these yoga interventions provides the objective evidence to help obstetricians to be convinced about the efficacy and safety of this antenatal yoga module.
- (vii) Reduced stress in the yoga group points to the mechanisms of yoga as a holistic mind body intervention rather than a simple physical exercise. This helps in encouraging obstetricians to promote their high-risk pregnant women to adopt this yoga module, as they are apprehensive to ask their patients to do any form of physical exercise and in fact most of these women are asked to take complete bed rest. In such cases, although they are in bed, the anxiety and fear would be the

major detrimental factors. Thus, this module provides several meditative and breathing practices that can be used safely even during the period of bed rest.

- (viii) Healthy progression of pregnancy with better physiological adaptability in high-risk pregnancy is demonstrated for the first time in this study.
- (ix) Scriptural Vedic knowledge related to pregnancy and details about the modalities of management is another major add-on to the preset day scientific knowledge.

7.3 Limitations

The main limitations for this study include:

- (i) The affluent population of the city of Bengaluru is not representative of the Indian population as a whole.
- (ii) Drop outs due to local social requirements in spite of the foresight by the researchers to obtain the signed informed consent to be under our supervision until delivery was another difficulty encountered in this study. Some subjects chose to deliver in a hospital in their home towns according to the Indian tradition, and the protocol used for determining C-section or for inducing labor at those hospitals could have been different from those at St. John's Medical College and Hospital (SJMCH) or Gunasheela Maternity Hospital (GMH).
- (iii) The subjects were recruited based on five risk factors, and it would have been interesting to see the effects of yoga on each of these categories, but the number of subjects with some of these risk factors was too small for meaningful data analysis.
- (iv) Although our research staff made regular follow-up calls to the subjects in the control group to ensure compliance to the walking regime, the documentation was ultimately self-reported.

- (v) Medication and undocumented home remedies could have been confounding factors in the study. Other confounding variables could have been the practices of Lamaz and aerobics by the participants without informing our research team, although we do not expect them in this study as these practices are not popular in India.

7.4 Recommendations

- (a) This study provides the first scientific evidence to the safety and feasibility of administering this antenatal yoga program in HRP.
- (b) The hospital administrators welcomed the project and were extremely accommodating to its requirements.
- (c) Most subjects were delighted about the prospects of participating in the study and often expressed disappointment when they did not meet the selection criteria. Previous studies had indicated that qualified subjects often refused to sign the informed consent form when they found out that they were not randomized into the yoga group. We overcame this obstacle by: (i) Adding a second level of randomization to our recruitment process by allowing the subjects to pick an envelope from the pool of available envelopes, (ii) by providing pamphlets about diet and nutrition in pregnancy to both groups, and (iii) offering a free postpartum yoga course to those in the control group.
- (d) Most of the subjects who were enrolled in the study, were enthusiastic about it and adhered to the programs.
- (e) At the 20th week and 28th week gestation when the subjects came for their measurement test, we had them fill out an evaluation form expressing any complaint or problems they felt with the study. No complaints were recorded. In this report, we also asked the subjects about their experiences with the interventions they were receiving. The consensus in the experimental group was

that they had a feeling of positive energy, relaxation, and well-being throughout the day after the yoga practices. Finally, we asked about their favorite yoga practices and by far, they liked the visualization and the guided imageries.

- (f) Subjects in both groups were encouraged to make phone calls to the therapists whenever they felt any discomfort, such as, mild back pain, low mood, stress, or anxiety (about the progress of pregnancy), to check on the specific yoga practice. All these communications were indicative that the subjects were keen to continue the practices regularly at home.
- (g) There were no adverse effects reported during or after the practice of yoga. Except for one subject who experienced a mild vasovagal attack at the end of a routine blood draw, no other adverse incident was experienced during the course of the study.

7.5 Suggestions for Future Work

The result of this study can be used to power a larger cohort follow up study, which may, not only confirm these results, but also allow meaningful statistical analysis between the subgroups. Local cultural and social practices during pregnancy and child birth need to be kept in mind while designing the future studies to reduce unexpected potential dropouts as was encountered in this study. Independent RCTs investigating the impact of yoga on each of the risk factors could offer better insight on the mechanism of action of yoga. Also, a study that starts the yoga interventions much earlier in the first trimester, or even before conception, could provide more information on the role of yoga in placentation and oxidative stress. Finally, studies may be designed to adapt the traditional life style and practices reviewed in the literary section of the chapter 2 of this thesis. As a note to advise future studies targeting the Indian population would be to review the pregnancy and childbirth related Indian traditions and rituals in the Vedic literature before embarking on the design of the study.

7.6 Conclusion

The results of this study indicates that yoga can be a promising tool for healthy progression of pregnancy and can ensure the health and quality of life of the mother and the proper development of her baby. We strongly believe that antenatal yoga should be a part of high-risk pregnancy management and be offered at all maternity hospitals or clinics.

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