CHAPTER 7

APPRAISAL

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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 $p=0.042$, $\chi^2$, 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 $0.049$, $\chi^2$, respectively).

   c. Significantly fewer occurrences of preterm deliveries in the yoga group ($p=0.036$, $\chi^2$).
d. Significantly fewer number of small for gestational age babies \((p=0.033, \chi^2)\) and normal for gestational age babies \((p=0.006, \chi^2)\) in the yoga group.

e. Significantly fewer low APGAR scores after 1-minute of delivery \((p=0.005, \chi^2)\) and after 5-minutes of delivery \((p=0.037, \chi^2)\).

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 
   \( (p=0.012, \text{RM-ANOVA}) \).

j. Significantly better left uterine artery resistance index in the yoga group after 8-weeks 
   of yoga interventions \( (p=0.013, \text{ANCOVA}) \).

k. Significantly better umbilical artery systolic/diastolic ratio in the yoga group after 4-
   weeks of yoga interventions \( (p=0.001, \text{T-test}) \) and 8-weeks of yoga interventions 
   \( (p=0.031, \text{T-test}) \).

l. Significantly better umbilical artery pulsatility index in the yoga group after 4-weeks 
   of yoga interventions \( (p=0.001, \text{Mann-Whitney}) \) and 8-weeks of yoga interventions 
   \( (p=0.001, \text{Mann-Whitney}) \).

m. Significantly better umbilical artery resistance index in the yoga group after 4-weeks 
   of yoga interventions \( (p=0.011, \text{Mann-Whitney}) \).

n. Significantly better fetal middle cerebral artery systolic/diastolic ratio in the yoga 
   group after 8-weeks of yoga interventions \( (p=0.010, \text{Mann-Whitney}) \).

o. Significantly better fetal middle cerebral artery pulsatility index in the yoga group 
   after 8-weeks of yoga interventions \( (p=0.013, \text{Mann-Whitney}) \).

p. Significantly better fetal middle cerebral artery resistance index in the yoga group 
   after 8-weeks of yoga interventions \( (p=0.048, \text{Mann-Whitney}) \).

### 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).
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.

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.

Good sample size that was decided by statistical calculation from an earlier non-pharmacological interventional study in high-risk pregnancies.

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.

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.

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 keep in mind while design 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 of advise to 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 indicate 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.