Chapter - 3

Methodology

The purpose of the study was to examine and evaluate the safety and efficacy of medical inducing agent misoprostol during labour and related control and experience of mothers during this procedure. To date many RCT, Cohort and prospective analytical studies have shown the outcomes of the inducing agents. But the results are contradicting and confusing. Again the experience and the maternal control during this procedure is not much studied. Induction has become easy and convenient method to dilate cervix and achieve active stage of labour but associated with more incidence of caesarean section. Hence it is important to examine the effect of labour induction on maternal and foetal health.

The study observed and documented the labour progress, maternal response, cervical status, CTG pattern, nature of contraction and satisfaction outcomes in terms of expectation and control. Characteristics of women with different response pattern were also evaluated and explored.

The study tries to explore the followings:

a. Why this induction procedure is opted and what was the reason behind this?

b. In which way the mother and baby affected or benefitted out of this?

c. Whether maternal co-variables have any influence in modifying the effect?

Through this study the researcher tried to examine the effect of labour induction on maternal and fetal outcomes. The researcher was interested to associate the variables based on hypothetical view and causation. Methodology is an important part of research work, as it gives
framework for conducting a study. Through a methodological plan we can gather valid & reliable data for investigation.

### 3.1. Research Approach

It tells the research in relation to collection of data and the way to access the sample and how to collect data from them. The present study aims to evaluate or analyze the effect of induction on mother and baby through structured observation check list. The approach used here is observation & evaluation. Observational research is a type of correlational (i.e., non experimental) research in which a researcher observes the ongoing behavior or effect of certain treatment, procedure or intervention.

### 3.2. Research Design

Research design is the framework of the study. It tells what is to be done, how will it be done and how will the data be analyzed. Keeping in view the objectives of the study, the researcher has adopted a mix method design that is an observational & evaluative descriptive design. This form of research design, which involves the judgment about how well a specific programmed, practice, procedure is working. It determines the effectiveness or value of a procedure, agent or a treatment. It may be summative or formative. Here both the methods of evaluation are adopted to know the maternal, foetal and neonatal health after controlling the extraneous variables.
Fig. 3.1: Schematic Diagram of Research Design
### 3.3. Setting

The setting is a medical college hospital selected for the study on basis of availability of subjects and feasibility of the researcher to conduct the study. This hospital with obstetric unit is situated in the city of Bhubaneswar, serving almost 1 lakh population. This Hospital provides all types of facilities for urban & rural population. This is basically training and research institution for medical, nursing and other paramedical courses. This super speciality hospital serves as tertiary referral centre. All the referral and emergency cases from nearby districts are managed effectively by the experts. The hospital bed size is 750. The ownership is private. The MRD (Medical Record Department) section shows following statistics for the year 2013-15.

**Table 3.1: Labour room statistics from the year 2013-15**

<table>
<thead>
<tr>
<th>IMS&amp; SUM Hospital</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Delivery</td>
<td>5554</td>
</tr>
<tr>
<td>Normal Vaginal Delivery</td>
<td>2395</td>
</tr>
<tr>
<td>Caesarean Section Delivery</td>
<td>3159</td>
</tr>
<tr>
<td>Delivery by Induction</td>
<td>848</td>
</tr>
<tr>
<td>Caesarean section after induction</td>
<td>432</td>
</tr>
<tr>
<td>Normal vaginal delivery after induction</td>
<td>416</td>
</tr>
</tbody>
</table>

The number of delivery per month ranges from 150 to 200. About 12% of total hospital delivery undergoes induction as found by a retrospective survey. Normal vaginal delivery
accounts for 47.33% of total delivery and caesarean section of 40.66% of that. Approximately 50% of induction ends with caesarean. The experienced midwives working in the labour room have great influence on maternal care and their satisfaction by their consistent support and approach to labour management. The mothers who undergo induction are observed and monitored through CTG and obstetrical examination. The untoward complications are managed in operation theatre. Round the clock obstetrician and pediatrician are available to attend the mothers and other emergency calls. Neonatal intensive care units are attached to the obstetrics unit and it is so equipped that all critical new-born cases are managed effectively by the neonatologists. Overall this hospital was considered for conducting the present study due to:

- Easy accessibility
- Getting Permission from hospital authority
- Convenient to conduct the study
- Familiarity with the set up
- Availability of required sample
- Support of the staff working in the labour room
- Ethical permission from the authority

### 3.4. Population

The study considered all the women admitted in labour room and expected to undergo induction, as the population for this study.
3.4.1. Target population

Population of interest for this study were pregnant women admitted in labour room in their 37 to 42 weeks of pregnancy and induction was planned for them by inducing agent misoprostol. It was estimated that in Bhubaneswar city, 14 numbers of hospitals with maternity units are functioning with good evidence of induction by misoprostol. As misoprostol found to be effective in cases of poor cervical scoring \(^{182}\) and with oxytocin augmentation for non-progress of labour, the cases induced with these agents were targeted. The population estimated to be 1250 approx. by a survey.

3.4.2. Accessible population

Accessible population is the portion of population which fulfill the designated criteria and easily accessible to the researcher. In the present study, the accessible populations were the women admitted in labour room of SUM Hospital those shall undergo induction of labour.

3.5. Sample

The women those were admitted in labour room of SUM Hospital for the purpose of delivery without any labour pain and for whom the induction was planned by misoprostol were the sample of this study.

3.5.1. Sampling criteria

Inclusion criterias

The women were included in the study those were:

- Within 35 years of age at the expected date of delivery.
Admitted in labour room for expecting labour.

Pregnant with singleton live fetus with cephalic presentation.

Undergone induction with misoprostol or misoprostol with oxytocin for acceleration.

With gestational age of >37 weeks to <42 weeks.

Indicated for induction with complications like post dated pregnancy, oligohydramnios, PIH, PROM and Gestational Diabetes mellitus.

Willing to be included in the study.

Exclusion criterias:

Women are excluded from the study those had:

1) Induction for pre term labour, IUD, congenital anomalies, twins, APH and fetal distress.

2) Induced by other methods of induction: oxytocin, Foleys, ethacradyl, carboprost, dinoprostone.

3.5.2. Sampling Technique

The samples were obtained from the labour room on basis of exclusion criteria that is whole population sampling technique. This is a type of purposive sampling technique that involves examining the entire population that have a particular set of characteristics (e.g., specific attributes/traits, experience, knowledge, skills, exposure to an event, etc.).

3.5.3. Sample Size Calculation

For calculation of sample size, no specific formula was used. As all the women undergoing induction by misoprostol were selected as sample, hence the women those were
intervened by induction during my data collection period were taken as sample except those who were not fulfilled the criterias of being a sample. Still then the cohens’ table was used to calculate the approximate sample size.

**Sample Size Calculation**

For effective calculation of sample size with various types of analysis as will be involved, the statistician was consulted for a power analysis. This analysis will help to assess the number of subjects required with significance criterion that is alpha 0.05 and power of 0.80 for small size effect (30%). According to Jacob Cohen (1988) power is the probability of significant results. The desirable power level for a study is at least 0.80.\(^2\) Power is affected by level of significance, sample size and effect size.\(^3\) Three factors required for sample size calculation: p value, power and effect. For a larger sample size, alpha level should be low,

To control type – I error and risk of type – II error, a 0.05 level of significance was used in this study. Another factor that is considered in power analysis is effect size. Effect size may be low, moderate or high.\(^3\) Large effect size require small sample size to prove and vice versa.\(^2\) The population based survey prior to the present study shows the effect size for induction of labour is of smaller to moderate degree that shows 30% successful effect will be seen after this procedure. So a effect of 0.3 (30%) is appropriate for this study. A power analysis was done and power of the study was decided to be 80% that means 20% false negative result will be accepted.

**For this study :**

Level of significance (p) is = 0.05

Required power = 80%

Expected effect size = 30%
Using Cohens' table, the required sample size at 'p' value of 0.05 with power of 80% and effect size of 0.5 is 586. Through a flow chart which was based on exclusion criteria, researcher planned to obtain desired sample size approximately to 586 as presented below.

Sample selection flow chat as per exclusion criteria

All the women undergone induction between Jan-2013 to Dec 2015

- Exclude women < 18yrs and >35yrs
- Exclusion of inductions at < 37wks & > 42wks
- Exclusion of women who indicated induction for IUD, Congenital anomalies, twins etc.
- Exclusion of women with induction by oxytocin only
- Women induction by other methods (Foley's Ethacardyl)

Final selection of sample with all inclusive criteria

Fig. 3.2 : Flow diagram of sample selection
3.6. Description of material & instrument

The study comprised of observation of labour events and their evaluation at par with standard measurement and existence of complications. The purpose of the study was very well previewed and extensive literatures were reviewed.

The variables were thought to be categorized as:

Section:A

Baseline characteristics of mother

Section:-B

Indications of Induction

Section:C

Maternal outcome measures

Section :D

Foetal outcome measures

Sec-E,

The maternal experience of control by labour agentry scale

3.6.1. Section A: Baseline characteristics of mother

The major covariates considered in this study are those which have indirect influence on outcome variables.
a) Maternal age:

The risk of obstetric complications like caesarean section, poor labour progress which are related to maternal age like nulliparous >35 yrs & multipara >40 yrs. The age has been categorized as <20yrs, 20-25, 26-30, 31-35 years.

b) Gravida

Gravida or parity has direct influence on labour and foetal outcome. The parity influences the birth weight. The gravida has been categorized as primi gravida and multi gravida.

c) Gestational Week

Labour induction beyond 41 weeks is associated with better perinatal outcomes compared to expectant management. The gestational age has been categorized as 37wks to <39wks, 39 to <40wks, and 40 to 42wks.

d) Doses of drug used and oxytocin augmentation

This may be considered as active independent predictive factor which may decide the fate of labour along with indications. The chief agent used to induce labour is the misoprostol with different doses and labour augmented by oxytocin in case of slow progress. The protocol for use of oxytocin as recommended is, only for augmentation of labor in an institution where emergency cesarean section can be done. The doses are considered as: one, two, three and more.

e) BMI

The body mass index based on body weight in comparison to height shows the level of body nourishment. The high or low BMI that influence foetal growth and maternal strength and
physiological status for the progress of labour. The BMI was categorized as: underweight, normal, over weight, obese.  

f) Cervical dilatation

The cervical status is a major parameter for successful outcome. This predicts the degrees of progress which is again influenced by the inducing agents. A statistically significant relationship is evident between the Bishop’s score and success of labour induction. The cervical dilatation was divided as: 0-3cm, 4-8cm and 8cm and more.

3.6.2. Section B: Indications of induction

The second section focused on indices of induction which are selectively named based on their relative effect on labour outcome. The most occurring indications that were considered in this study are post-dated pregnancy, oligohydramnios, PROM, PIH and GDM.

a) Post-dated pregnancy

Postdates has been recorded as the highest indication for induction of labour. The delivery in case of post-term pregnancy is associated with adverse maternal and fetal outcomes with higher rate of maternal and neonatal morbidity.

b) Oligohydramnios

Reduced amniotic fluid endangers the foetus with cord compression. This is mostly associated with foetal hypoxia and meconium stained liquor. E Mozurkewich found oligohydramnios as indication of labour with moderate evidence from various studies.
c) **PROM**

Most of the term PROM cases end with spontaneous labour except few which require induction for cervical ripening and initiation of uterine contraction.²¹⁸ Many times it requires induction to prevent foetal distress and prolonged labour. It was observed that the induction by prostaglandin in cases of term PROM reduces the duration of labour delivery with reduction in maternal–neonatal sepsis.²¹⁹

d) **PIH**

Gestational hypertension predisposes women to increased risk of hypertensive disorders and may be attributed to fetal growth restriction resulting from significant maternal vascular diseases. Severe maternal and neonatal complications can be prevented in case of pre eclampsia by induction of labour.²¹⁵

e) **Gestational Diabetes Mellitus**

The incidence of diabetes during pregnancy is rising slowly due to one or other causes and it has adverse effects on pregnancy, labour and newborn.²¹⁶ The continuation of pregnancy may have more impact on foetus. NICE recommended that elective birth through induction of labor should be offered after 38 completed weeks to the pregnant women with diabetes.²¹⁷

### 3.6.3. Section C: Maternal outcome measures

This section focuses on adverse maternal responses to the inducing agent like hyper stimulation, tachysystole, vomiting, and length of labour.

a) **Nausea and vomiting**

Sometimes appears after induction by stretching of cervical lining.
b) **Hyper stimulation**

It is an exaggerated uterine response accompanied by FHR changes.

c) **Tachysystole**

It was defined as more than five uterine contraction in 10 minute period without FHR changes.

d) **Induction to delivery hour**

It was categorized as >12 hours, 12-24 hours and more than 24 hours.

e) **Failed to progress/ Non progress of labour**

When the labour has progressed to some extent and then there is neither further dilatation nor any descent of part, it is called non progress of labour.

f) **Failed induction**

When the progress of labour remains stand still without any dilatation or contraction the induction is called as failed.

g) **Mode of delivery**

The induction ends with normal vaginal delivery or cesarean section is termed as primary outcome in this study.

3.6.4. **Section D : Neonatal outcomes**

Neonatal outcomes were Apgar score < 7 at 5 mins, meconium stained liquor, and NICU admissions.
a) **Apgar at 5 minute < 7**

This score refers to number assigned to the newborn baby after assessment for activity, grimace, appearance and respiration.

b) **Meconeum stained liquor**

Presence of meconeum in liquor due to strong and repeated contractions may appear after misoprostol administration. Any form of meconeum (may be mild or severe) present in liquor was considered as meconeum stained liquor.

c) **NICU admission**

Any admission to NICU soon after delivery by induction due to any foetal/neonatal causes like distress or meconeum aspiration.

**3.6.5. Section E: Measurement of Maternal Experience by Modified Labour Agentry Scale**

The maternal experience of control over labour situation has been taken as secondary outcome of induction of labour in this study. The interest is in mother’s satisfaction with all aspects of her labour, not only the adverse physiological response but also her overall birth experiences and control over environment, not only the adverse physiological responses. Hodnett and Simmons (1987), used Oliver’s labour satisfaction scale as the basic tool. The 29 items on labour experience described the maternal control (internal & external) over birth experience. The shorten form of LAS presents 10 items which is equally reliable and valid as 29 items. The scale measures the labour expectancies of mother and experiences of personal control during childbirth. This is a self report scale with strong psychometric properties and internal reliability co-efficient of 0.97. ¹⁸⁶
Scoring of modified LAS

The 10-items LAS score was slightly modified for the convenience of investigator and participants. The language was simple to understand and the basic theme was kept unchanged. The original 10 items LAS score which had 6 positive and four negative description of perceived degree of control during child birth was modified and all the items were kept in negative form, so that understanding of both researcher and participant would be better and easy for scoring and interpretation. The original 7 point likert scale was changed to 4 point rating scale like always, often, rarely and never. The answer 'always' carried ‘4’ mark whereas never of ‘1’ mark. The Score ranged from 10 to 40. Higher score demonstrates higher control that demonstrates maternal satisfaction and high experiences of control. In childbirth the control has been demonstrated to have significant short term and long term effects on women’s appraisal and emotional response to their child birth experience.220, 221, 222, 223

3.7 Validity

The issue of validity depends on type of tool prepared. In a standardized tool the validity seems to be very predictive and control all the bias. But for a self-designed observation check list, internal and external validity are not assured. However the previous similar studies shows self-designed check list for an induction of labour demonstrates good reliability & validity. 224

3.7.1 Construct validity

The designing of this instrument for medical and nursing information was done after an intense review of literature where similar instrument are made and subsequently utilized in other studies to gather required information without any confusion (that the effect is due to the cause),
shows a good construct validity. When a instrument based on a good construct, it easily gathers, document and record the data directly from record or subject even in the absence of investigator.

3.7.2. Face validity

It is the appearance of instrument that shows that it is for the measurement of that test criteria, but whether it will measure the phenomenon or not, there is no guarantee. Test with high validity some time show low face validity. Observation check list for maternal and foetal outcomes and LAS inventory for maternal experience of control was prepared after an intense literature review. The prepared tool when administered in the pilot study, the research assistant and in charge resident found this tool in appearance, is pertinent to the research topic, which ensured the face validity.

3.7.3. Content validity

Content validity is a non-statistical type of validity that involve systematic examination of the test content to determine whether it cover each domain to be measured. The content was sent to 8 experts from the field of obstetrics, pediatrics, nursing & statistics to examine the content and comment whether the items cover a representative sample. After a thorough verification the suggestion and modifications of each expert were taken into consideration and final modification was done. A refined or valid tool was developed at last. The unnecessary parts were removed like severe form of obstetrical & medical complications removed from indication section. In maternal outcomes section, the presence of episiotomy was removed. BMI was included in maternal baseline data. Instead of Bishop score, cervical dilatation was included due to feasibility in measurement of cervical dilatation rather measurement of Bishop score. In inducing agent, instead of many agents only misoprostol was considered. The rating scale was
replaced by check list as all the variables could not be divided into ‘3’ point rating scale and there was no evidence of any standard division for every item, like uterine tachysystole, apgar score and others.

3.7.4 Translation validity

When this instrument used for pre testing to collect specific medical and nursing information, accurate utility or operationalization of this scale reflected good translation validity. This tool reliably gathered, documented and recorded the data as desired.

3.7.5. Criterion validity

When the instrument reliably used to gather particular information it intended for, the criterion validity ensured. The better utilization of each items like uterine tachy systole measured the nature of contraction, foetal distress upon fetal heart rate deceleration, progress of labour upon decent of head, cervical dilatation and effacement and so on. The instrument was fully utilized during data gathering process. Each criteria or item were evaluated by certain measures in accordance with other measures like, if progress is evaluated as poor, it was supported by failed induction (cesarean section delivery) or foetal distress. A longer length of labour predicted C- section delivery. By this concurrent and predictive validity were ensured.

3.8 Pre testing of the tool

Pre testing of the tool was done to check the clarity and ambiguity of the items and feasibility of the tool in administration. All the items were clear to understand by the researcher and research assistant. The women followed the items when asked and answered appropriately. The tool was administered to 20 women in the labour room of SUM Hospital those were induced
with misoprostol. As it was an observational study the total time for data collection was differed from woman to woman. The items those were to be observed were filled and scoring was done for Labour agentry scale.

### 3.9 Reliability

#### 3.9.1 Reliability of LAS

The 29 items LAS scale is already developed with high internal reliability and found stable over time. The internal consistency of the 29 and 10 item LAS has been consistently high, ranging from alphas of 0.91 to 0.98 in postpartum sample. 226

<table>
<thead>
<tr>
<th>LAS</th>
<th>Reliability</th>
<th>‘r’ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hodnett &amp; Simmons (1987)</td>
<td>Inter-item correlation</td>
<td>0.94</td>
</tr>
<tr>
<td>Kristen Barber (2002)</td>
<td>Cronbach Alpha</td>
<td>0.82</td>
</tr>
<tr>
<td>Original version</td>
<td>Cronbach Alpha</td>
<td>0.91</td>
</tr>
<tr>
<td>Chinese Version</td>
<td>Cronbach Alpha</td>
<td>0.89</td>
</tr>
<tr>
<td>Wing Cheug (2006)</td>
<td>Cronbach Alpha</td>
<td>0.72</td>
</tr>
<tr>
<td>Davids j et al (1984)</td>
<td>Cronbach Alpha</td>
<td>0.84</td>
</tr>
</tbody>
</table>

The reliability of LAS found in many studies is mentioned in the above table. In a sample of 151 in UK, when 10 item LAS was used, Yielded a cronbach’s alpha reliability of 0.84. 227 As the LAS has been translated in many language and found valid to measure the expectation & experience of mother, the present study also used a translated format of 10 items LAS. The
present study also obtained reliability of modified LAS through correlation coefficient cronbach alpha value of 0.911.

**Reliability of the research assistant**

The data was planned to be collected in the labour room at any time when there was admission of mother for labour in case there is no pain or she is approaching the date. The research assistant was selected who was a midwife and working in the labour room mostly in night shift. The details of data collection procedure was explained to her. She went through the tool. To ensure the reliability of the data the inter-rator reliability was calculated to find out the correlation between the collected data of the research assistants and researcher. The reliability coefficient ‘r’ value of the data was 0.84. This ensured the reliability of the research assistant.

**3.10 Pilot Study**

A pilot study was carried out to discover any difficulties in administering the tool. Also it detected the deficiencies in the tool or presence of any useless items in tool. It assessed the overall inadequacies in methodology and adequacy of data collection tool. The pilot test was undertaken in labour room of SUM hospital following the approval for access of the study site from the hospital authority. The hospital research ethical committee approved the procedure of data collection from the subjects. The departmental head and doctor in charge of labour room were informed regarding the purpose of the study and later their approval to proceed for the study. After getting approval the investigator planned for the administration of tool to 20 women and data collection procedure. Mothers admitted in labour room with induction of labour were approached for their inclusion in the study. Mothers were invited through a informed consent to participate in the study. Following signing in the consent form, the researcher/research assistant started observing and measuring the parameters through record, history taking,
examination and evaluation of biophysical and biochemical profiles. Through labour agentry scale, women’s were asked to rate their level of control. The data received were recorded in check list and LAS. The items in the tool modified or deleted were:

1. Induction to delivery time: in the original tool, the duration was mentioned as >12hrs, but later it was categorized as below 12 hours, 12 to 24 hours and more than 24 hours.

2. Foetal distress was removed from neonatal outcome as it required to correlate with CTG reading.

3. Progress of labour: Instead of considering it as good/poor, the item was named as non progress of labour and it was found to be an important document recorded in all the cases.

4. Failed induction was added in outcome as many cases were failed when there was no dilatation and no pain after misoprostol administration.

5. Cord blood PH as foetal outcome in numerical value was removed, for its measurement bias or experimenter bias to accurately record it.

3.11 Ethical implications

The study proposal was approved by the hospital research ethical committee before data collection. A written permission was asked from the medical superintendent of the hospital, Professor In charge and midwifery in charge of the labour room. They were contacted prior to the study, stating the purpose and design of the study. Copy of consent form was attached. None of the obstetrician refused to allow their client to be approached for recruitment. Consent was obtained from the attending resident or junior doctor upon patient admission to the labour room. Respect for human dignity and patient’s right to privacy were addressed through several means.
3.12 Informed consent

The proposed study did not involve any forms of deception. A detailed explanation about the study was prepared in written form with its purpose, benefits, risk involved and same was explained to the subjects. They were reassured that their participation is strictly voluntary. They were also assured that their refusal to take part in the study would not affect the care they receive. They can voluntarily participate or withdraw from the study at any point. Their personal data will be kept confidential and identity will not be revealed to anybody or published anywhere.

3.13 Anonymity & Confidentiality

Participant’s names were not recorded on any of the data collection records, thereby assuring confidentiality and anonymity. Data pertaining to the participants were handled at utmost care to prevent breach in confidentiality. Only the research assistant and principal investigator had access to the collected or recorded information. Data were entered in coded form and results were presented as a group data, so identity of the participants remained anonymous. Raw data containing name of participants and their details information were stored safely and destroyed later.
3.14 Data collection procedure

Following ethical approval and written permission for conducting the study, the research assistant and principal investigator proceeded for data collection by following sequence. The subjects were recruited as per exclusion criteria as follows.

Sample selection flow chat as per exclusion criteria

- All the women undergone induction between Jan-2013 to Dec 2015 (848)
- Exclude women < 18yrs and >35yrs (848-32=816)
- Exclusion of inductions at < 37wks & > 42wks (816-53=763)
- Exclusion of women who indicated induction for IUD, Congenital anomalies, twins etc. (763-110=653)
- Exclusion of women with induction by oxytocin only (653-58=595)
- Women induction by other methods (Foley's Ethacardyl) (595-25=570)
- Final selection of sample with all inclusive criteria (570)

Fig. 3.3 : Flow diagram of sample selection
- Informed consent obtained from the participants.
- Explained the purpose and nature of the research work.
- Confidentiality was assured to the subject.
- Observation checklist was filled by the researcher by accurate observation of labour progress, maternal outcomes and foetal outcomes and their interpretation.
- The subjective and objective data were recorded for their ‘presence’ and ‘absence’ in the particular column.
- The experimenter bias was controlled by accurate instruction for measurement of the item like uterine tachysystol, if contraction occurs > 5times per 10 min and uterine hyperstimulation for exaggerated contraction. The duration for filling each observation check list was dependent on length of labour the participant underwent.
- The second part of the instrument was the modified 10 items LAS inventory.
- The participants were explained about the LAS components, its purpose and the way to answer. Participants were assured of their voluntary participation and answer as they actually experience during labour without any influence of other variables.
- The LAS inventory was administered soon after the delivery as women found themselves stable to answer to the items.
- Confidentiality was ensured during data collection.
- It took 10-20 minutes to complete LAS.
3.15 Data management

The data were collected and recorded in the master sheet as shown in appendices. The raw data were transferred into an excel software program and downloaded in separate files for observation checklist and LAS inventory. The pooled data from the computer discs were converted into a statistical package for social science (SPSS) version 19. Data entry errors duplications or omissions were detected. The verified and corrected data were planned for analysis.

3.16 Data Analysis Plan

Data was entered into Excel Sheet and exported to SPSS 19 version. The covariates and confounding variables were planned to be analyzed by parametric test and association between predictors and outcomes by non parametric test.

The plan of analysis was classified as;

1. Maternal characteristics or analysis of covariates – Some are categorical data and some are continuous data. Both parametric and non-parametric test can be used to present the data form.

   a) Descriptive statistics for univariate analysis to produce means, range, SD

2. Comparison of primary outcome among maternal baseline variables by percentage

3. Pre-induction indices analysis: Descriptive statistics by univariate analysis: frequency, percentage, comparisons between indices and outcomes.

4. Analysis of maternal & foetal outcomes

   a) Descriptive statistics by frequency and percentage
b) Cross variable analysis will be performed by using Pearson chi square test’s for two categorical variables and students’t’ test for comparing means of two continuous variables.

5. **Binary logistic regression model.**

The degree to which the independent variables predict the dependent variables was analyzed using binary logistic regression analysis. The logistic regression will examine the association between independent predictors and dependent variable after controlling for other significant variable. All covariates and confounding variables with a p value of \( \leq 0.05 \) used the Wald statistics to be included in binary logistic regression model. Regression co-efficient and standard error of the factors retained in each model, in addition to all continuous variables. The estimates of odds ratio were 95% confidence intervals for comparing co variables with maternal and new born outcome variables.

6. **Analysis of maternal experience**

1. Descriptive statistics – mean and SD

2. Factor analysis for factor loading on dependent variables

3. Non –Parametric test by person correlation to associate various maternal characteristics with experience and control
The plan for data analysis is presented in the following table.

### Table 3.3: Plan for data analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Method of analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maternal characteristics</strong>-Age, gestational age, gravida, cervical dilatation, dose, Indications maternal and neonatal outcomes</td>
<td>Percentage, Range, mean and SD Percentage Percentage</td>
</tr>
<tr>
<td>Comparing maternal outcomes among baseline variables</td>
<td>Independent ‘t’ test, chi square test, correlation</td>
</tr>
<tr>
<td>Comparing maternal outcomes among obstetric variables</td>
<td>Independent ‘t’ test, chi square test, correlation</td>
</tr>
<tr>
<td>Comparing maternal outcomes among indication of induction</td>
<td>Independent ‘t’ test, chi square,</td>
</tr>
<tr>
<td>Comparing foetal and neonatal outcomes among baseline and obstetric variables</td>
<td>Independent ‘t’ test, chi square, correlation</td>
</tr>
<tr>
<td>Independent predictors of labour outcomes</td>
<td>Binary Logistic Regression</td>
</tr>
<tr>
<td>Maternal Experience and control during labour</td>
<td>Percentage, mean and SD, factor analysis, correlation</td>
</tr>
</tbody>
</table>