Comparative study of intracervical dinoprostone gel and vaginal misoprostol for induction of labour- one year randomised control trial at tertiary care centre, Belagavi"

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This is to certify that the dissertation entitled **"Comparative study of intracervical dinoprostone gel and vaginal misoprostol for induction of labour- one year randomised control trial at tertiary care centre, Belagavi"** is a bonafide research work done by **Reg. no** B J 0 1 1 6 0 0 6 .

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ABSTRACT

Comparative study of intracervical dinoprostone gel and vaginal misoprostol for induction of labour- one year randomised control trial at tertiary care centre, Belagavi

Introduction:

Induction of labour is the artificial initiation of labour before its spontaneous onset for the purpose of delivery of the fetoplacental unit using mechanical or pharmacologic methods. There has been a rise in the incidence of labor over the past decades and as per the WHO Global survey, 9.6% deliveries required induction and in developed countries the incidence is up to 25%. This study is an attempt to compare the number of successful induction in dinoprostone and misoprostol group and also to compare the maternal and fetal outcome in both the groups.

Material and Methods:

Antenatal cases getting admitted to labour room of KLES Dr. Prabhakar Kore Hospital & MRC, Belgavi at term for induction of labor were enrolled for the study. Patients were divided randomly into 2 groups of intracervical dinoprostone (group 1) and vaginal misoprostol (group 2) and then number of successful and failed inductions, indication for the induction, time of initiation to active labour time, induction to delivery, need for augmentation, important outcomes of labour was recorded along with fetal and maternal outcome.

Results:

A total of 240 cases were included in the study. Majority of the females belonged to the age group of 20-30 yrs in both the groups with mostly multigravida

and Mean gestational age around 39± 1.26 wks and 39.12 ± 1.35 wks in group 1 and 2. There were a total of 170 successful inductions and there were 24 failed induction in our study. The major indication for induction in both the groups was PIH followed by decreased fetal movements in both the groups respectively. The mean time to active labour in Dinoprostone group was 8.93 ± 4.42hrs while in other group was 9.71 ± 4.58. The mean time to delivery in the dinoprostone group was 11.72 ± 5.1 hrs while in other group was 12.43 ± 4.58hrs. Need of augmentation, modes of delivery, indications of cesarean section, maternal outcomes and fetal outcomes when compared in both the groups, difference were statistically insignificant.

Conclusion:

Comparison of dinoprostone and misoprostol with respect to successful induction, maternal and fetal outcome was similar and found to be statistically insignificant. There is a need for further larger studies to establish and document the findings of our study.

ABBREVIATIONS

LSCS	-	lower segment caesarean section
IOL	-	induction of labor
PIH	-	Pregnancy induced hypertension
VBAC	-	vaginal birth after caesarean Section
IUD	-	intrauterine death
LBW	-	Low birth weight
MAS	-	Meconium Aspiration Syndrome
FHS	-	fetal heart sounds
GDM	-	gestational diabetes mellitus
PROM	-	premature rupture of membrane
BS	-	Bishop Score
APH	-	antepartum haemorrhage
IUGR	-	intrauterine growth restriction
No.	–	number

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INTRODUCTION

Induction of Labor (IOL) is the process of artificially stimulating the uterus for the onset of labor, which is performed by medical or natural methods. There has been a rise in the incidence of labor over the past decades and as per the WHO Global survey, 9.6% deliveries required induction and in developed countries the incidence is up to 25%[1,2].

The intervention is intended to artificially start uterine contractions leading to progressive effacement and dilat ion of cervix and delivery of the foetus. It attempts to induce two interlinked components of labour, cervical ripening and uterine contractility. Over the past several decades, the incidence of labour induction has continued to rise to the point that in developed countries the proportion of infants delivered following induction of labour can be as high as one in four of all deliveries[2].

IOL has a major health impact on the woman and on her baby. Therefore the policies of induction, chiefly indications and methods, remain key priorities for research in obstetrics, with a view to improve the quality of care and outcomes. Generally IOL has merit as a therapeutic option when the benefits of expeditious delivery outweigh the risk of continuing the pregnancy. Therefore, labour induction is indicated where the benefits to either the mother or the foetus outweighs the benefits of continuing pregnancy[3].

The various reasons for induction of labor include gestational hypertension, postdatism, preeclampsia, eclampsia, premature rupture of membranes, foetal demise, chrioamnionitis, abruptio placenta, gestational diabetes mellitus, maternal medical conditions (eg diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension, antiphospholipid syndrome) and foetal compromise (eg severe foetal growth restriction, isoimmunization, oligohydramnios). IOL using various methods

may be associated with an increased risk of: failure to achieve labour, higher incidence of caesarean section, operative vaginal delivery, tachysystole with or without foetal heart rate changes, chorioamnionitis, cord prolapse with artificial rupture of membranes, inadvertent delivery of preterm infant in the case of inaccurate dating and uterine rupture. Before labour induction, there are several clinical elements that need to be considered. Factors that have been shown to influence success rates of induction include the Bishop score, parity, body mass index, maternal age and estimated foetal weight. The first step in induction of labour includes assessing cervix for its favourability as described by Modified Bishop Score[4].

It involves assessment of dilatation, length, consistency, position of cervix and station of the presenting part (relative to ischial spine). On a scale of 0-12, a favourable pre induction Bishop score of >6 is predictive of successful vaginal delivery[5].

Assessment of cervical status is fundamental for the clinician to estimate the likelihood of successful vaginal delivery[6]. Labour induction that is performed when the cervix is unripe is associated with higher incidence of prolonged labour[7], instrumental delivery[8] and caesarean birth[9].

Methods for IOL in the presence of an unripe cervix can be classified into non pharmacological and pharmacological methods.

Methods of cervical ripening and induction of labour:

- Mechanical methods –hygroscopic dilators and catheters
- Pharmacological methods – Prostaglandins, oxytocin. Recently explored methods: mifepristone, oestrogens, relaxin, nitric oxide
- Surgical methods – sweeping of membranes, amniotomy
- Natural and complementary methods[10,11].

Prostaglandins have been used for induction of labour since 1960s. PGs act on the cervix to enable ripening by number of different mechanisms. They alter the extracellular ground substance of the cervix, and PGE2 increases the activity of collagenase in the cervix. They cause an increase in elastase, glycosaminoglycans, dermatan sulfate, and hyaluronic acid levels in the cervix[12]. Finally, prostaglandins allow for an increase in intracellular calcium levels, causing contraction of myometrium[13].

The PGs are a group of physiologically active lipid compounds having diverse hormone-like effects. They are synthesized in the cell from the essential fatty acids (EFAs). An intermediate arachidonic acid is created from diacylglycerol via phospholipase-A2, then the cyclooxygenase pathway produces thromboxane, prostacyclin and prostaglandin D, E and F. Alternatively, the lipoxygenase enzyme pathway is active in leukocytes and in macrophages and synthesizes leukotrienes. The structural differences between PGs account for their different biological activities. A given PG may have different and even opposite effects in different tissues. They act as autocrine or paracrine factors with their target cells present in the immediate vicinity of the site of their secretion. PGs differ from endocrine hormones in that they are not produced at a specific site but in many places throughout the human body[14].

Two different preparations of prostaglandins used for cervical ripening and IOL are – Dinoprostone and Misoprostol. Dinoprostone is a PGE2 analogue with a good safety profile and high efficacy but it is costly and requires refrigeration for storage (2-8 degree celcius). Misoprostol is a synthetic PGE1 analogue, which was commercialized in 1987 for antiulcer, antisecretory and cytoprotective effects.

Misoprostol is also effective as cervical priming agent[15]. Various routes of administration are orally, intravaginally[16] and intracervically for IOL[17].

Misoprostol is inexpensive, easy to administer, stable at room temperature. Studies have shown that misoprostol may increase the rates of tachysystole and hyperstimulation, with higher rates of meconium staining and aspiration. Few studies have also shown a higher rate of cesarean delivery[18].

Both forms of PGE2 (dinoprostone) are available commercially. In randomized trials, the two forms are similar in efficacy[19, 20]. The first form is formulated as a gel and is placed endocervically but not above the internal os. The application contains 0.5 mg dinoprostone in a 2.5 ml syringe, can be repeated in 6 hours, and should not exceed three doses in 24hours.

Advantages of PGE_2 include patient acceptance, a lower operative rate than oxytocin, and less need for oxytocin augmentation when used with an unfavourable cervix (Bishop < 7). Cost savings may be realized by a reduction in operative deliveries and/or lengths of stay. PGE_2 is a bronchodilator and is not contraindicated in women who suffer from asthma. Adverse effects with the use of prostaglandin E_2 include uterine tachysystole and maternal effects (i.e. fever, chills, vomiting, diarrhea)[21].

Both intravaginal as well as intracervical PGE2 have been shown to be more successful in achieving vaginal delivery within 24 hours when compared to oxytocin, alone or in combination with amniotomy, the benefit being even more marked when used in women with unfavourablecervix and in those with intact membranes[22].

Induction should be considered when it is felt that the benefits of vaginal delivery outweigh the foetal risks of induction. These issues should be discussed with the woman prior to initiation of induction[23,24].

OBJECTIVES

Primary Objective:

- To compare the number of successful inductions in dinoprostone group and misoprostol group

Secondary Objective:

- To compare the maternal and fetal outcomes in dinoprostone group and misoprostol group

REVIEW OF LITERATURE

IOL is defined as the stimulation of regular uterine contractions before the spontaneous onset of labor, using mechanical or pharmacologic methods in order to generate progressive cervical dilation and subsequent delivery. It is performed frequently in approximately 25% of term pregnancies in developed countries. The frequency in which induction is performed varies with wide variation according to person-to-person and hospital-to-hospital with wide range of variation depending upon patient's requirement and local preference. Done for the correct reasons and in the correct way, induction of labor is useful and benefits the woman and her fetus. If done incorrectly or inappropriately, unnecessary risks may be encountered. The goal of induction of labor is to eliminate the potential risks to the fetus with prolonged intrauterine existence while minimizing the risk of operative delivery and support as natural a birth experience as possible[1].

The rate of labour induction continues to rise significantly for all gestational ages. The reason for this increase is unclear, although it may partly reflect a growing use of labour induction for post-dated pregnancies and an increasing trend toward elective IOL for other indications. It is considered when the risk–benefit analysis indicates that delivering the baby is a safer option for the baby, the mother, or both, rather than continuing the pregnancy. IOL should be simple, safe and effective. Various methods of induction include medical, surgical or combined method. Surgical methods include sweeping of membranes and ARM. Medical methods include use of oxytocin and prostaglandin. The obstetricians also follow a combined approach that means the use of medical and surgical methods together[25].

One of the most common indications for induction is post term pregnancy with a gestational age of at least 41 completed weeks[26]. Induction for this indication has been shown to reduce the likelihood of perinatal death[27]. Other indications for induction include PROM[28], potential foetal compromise (significant foetal growth restriction[29], non-reassuring foetal surveillance), maternal medical conditions (type I diabetes, renal disease, significant pulmonary disease, hypertension-gestational or chronic), ant phospholipid syndrome, suspected or proven chorioamnionitis, abruption, and foetal death[30].

Induction is sometimes performed for "social" or "geographic" reasons[31], without a medical or obstetric indication[32]. There have been few well-designed studies evaluating induction for this indication[33,34]. Two early-randomized clinical trials suggest no increased risks to the mother[35] or foetus[36], but the sample size did not provide adequate power to make these conclusions. A retrospective study concluded that elective induction should be discouraged in the nulliparous woman, since the rate of Caesarean delivery is increased with elective induction[37]. A case control studydid not find elective induction itself to be predictive of Caesarean delivery[38]. A meta-analysis of early trials concluded that there is no benefit to elective induction and there is no place for it in term pregnancy[39].

Potential risks of induction include increased rate of operative vaginal delivery, Caesarean birth, excessive uterine activity, abnormal foetal heart rate patterns, uterine rupture[40], maternal water intoxication[41], delivery of preterm infant due to incorrect estimation of dates, and possibly cord prolapse with ARM.

The contraindications include previous myomectomy, previous uterine rupture, transverse lie, placenta previa, vasa previa, invasive cervical cancer, active genital herpes, and previous classical or inverted T uterine incision[5].

The need to time delivery has been recognized and practised for centuries. Although the indications have clearly changed during the past 200 years from a need to expel a dead foetus to the pre-emptive action to reduce the threat to foetal or maternal health. Effective and safe methods of achieving delivery always have been the primary objectives. The history of labour induction dates back to Hippocrates' original descriptions of nipple stimulation and mechanical dilation of the cervical canal. During the second century AD, Soranus practiced a combination of procedures to induce labour, including ARM. Other labour induction methods were introduced during this period; Moshion was the first to describe manual dilation of the cervix, and Casis invented several instruments capable of cervical dilation. Midway through the 16th century, Paré devised a technique that combined manual cervical dialation and internal podalic version in patients with uterine haemorrhage. Bourgeois, a disciple of Paré, continued this practice and also induced and augmented labour with strong enemas and mixtures of several folk medicines. From the 2nd through the 17th centuries, mechanical methods to induce labour came into more common use. In 1756, at a meeting held in London, physicians discussed the efficacy and ethics of early delivery by rupturing the membranes to induce labor[42].

In 1906, Dale observed that extracts from the infundibular lobe of the pituitary gland caused myometrial contractions. Three years later, Bell introduced use of pituitary extract as a hormonal method of labor induction in 1913. The use of this method gained acceptance among obstetricians. However, due to the use of large

doses and the impurity of the extract, numerous adverse effects were reported. Gradually, as the number of reported cases of uterine rupture increased, pituitary extract became discredited in many centers[43].

In 1968, Karim and colleagues were the first to report the use of prostaglandins for labour induction. Since then, the use of prostaglandins, in different varieties and forms of administration, has become a common method of labour induction. More recently, the synthetic prostaglandin analogue misoprostol has also gained acceptance as an effective and safe method of labour induction[44].

As per the WHO recommendations, IOL should be performed only when there is a clear medical indication for it and the expected benefits outweigh its potential harms. Emphasis should be placed on the cervical status, the specific method of IOL and associated conditions such as parity and rupture of membranes. Wherever possible, induction should be carried out in places where facilities for assessment of maternal and foetal well being are available as the procedure carries the risk of uterine hyperstimulation, rupture and foetal distress[45].

The success of induction depends on the state of the cervix before commencement with the most favourable outcomes occuring in cervix which are soft and effaced. In 1964, Bishop developed a scoring system to assess the cervix for its favourability[46] .The scoring system is based on the properties of the cervix that may be assessed clinically at the time of pelvic examination such as dilatation, effacement, consistency, and position as well as the station of the foetal presenting part. Calder modified the original Bishop score in 1974 which is known as the Modified Bishop score.

He replaced the 'effacement of cervix' denoted as percentage in the original score with 'length of cervix' in centimeters. An unfavourable cervix generally has been defined as a Bishop Score of less than 6 in most randomized trials. If the total score is more than 8, the probability of vaginal delivery after labour induction is similar to that after spontaneous labour. There is an inverse relationship between the Bishop Score and the failure of labour induction, with low scores being associated with a high rate of failed induction and cesarean section or vaginal delivery after prolonged labour which in turn requires prolonged foetal monitoring as extended exposure to uterine contractions resulting in reduction in intervillous blood flow which can result in foetal hypoxia and acidosis. Thus, it is useful to employ cervical ripening agents to prepare the unripe cervix for labour induction.

Many comparative studies have been done on different methods of induction. The most commonly used methods of induction are medical methods which include PGs and oxytocin.

The naturally occurring PGE2 is known as dinoprostone. It was discovered by Bunting, Gryglewski, Moncada and Vane in 1976. It has important effects in labour (softening the cervix and causing uterine contraction)[47]. Dinoprostone acts as direct vasodilator, relaxing smooth muscles, and it inhibits the release of noradrenaline from sympathetic nerve terminals. It does not inhibit platelet aggregation, whereasPGI2 does. It works by binding and activating the prostaglandin E2 receptor. It also stimulates osteoblasts to release factors that stimulate bone resorption by osteoclasts and can induce fever also. PGE2 also suppresses T cell receptor signaling and may play a role in resolution of inflammation[47]. Like other PGs, dinoprostone can be used as an abortifacient. Precautions should be taken in patients with uterine scar tissues;

asthma; low blood pressure; heart disease; adrenal problems; anemia; diabetes; glaucoma; icterus (jaundice); multiparity (twins, triplets, etc.); heart, lung or liver disease[47].

A meta-analysis of initial studies suggested that delivery within 12 hours occurred more often with intracervical than with intravaginal gel but noted no other differences[48]. The choice of route, therefore, could be based on the preferences of the woman and caregivers (related to the ease of administration and comfort). More recent studies have noted a higher success rate of induction[49] increased ease of administration[50], greater change in Bishop score, and shorter induction to delivery times with vaginal gel[51]. Therefore, there may be some potential advantages to the use of vaginal PG over intracervical PG.

There are no randomized trials evaluating the duration of foetal heart rate and uterine activity monitoring required after PG gel dosing. The manufacturers do not comment on monitoring specifically[52]. The pattern of uterine activity with PG gel suggests that contractions usually start one hour after PG gel application and peak in the first four hours[53]. Most studies suggest monitoring 30 minutes to two hours after administration of gel and to continue monitoring if regular uterine contractions are noted[54,55].

A meta-analysis from the Cochrane Database concluded that although vaginal misoprostol appears to be more effective in inducing labour than conventional methods, it may result in an increase in uterine hyperstimulation[56]. A meta-analysis by Sanchez-Ramos et al has concluded that although there was a higher rate in tachysystole (20.1% misoprostol, 8.2% control) and hyperstimulation (5.8% misoprostol, 3.4% control) with misoprostol (OR = 2.98, 95% CI 2.43-3.66 and OR =

1.73, 95% CI 1.25-2.40 respectively), there were no significant differences in NICU admissions (13.8% misoprostol, 13.6% control) or Apgar score less than seven at five minutes (1.4% misoprostol, 1.4% control). It was also noted that there was a shorter induction to delivery interval with misoprostol and a lower Cesarean delivery rate (17.3% versus 22.9%, OR = 0.88, 95% CI 0.77-0.99)[57].

Other potential benefits of misoprostol lie in the fact that it is much cheaper than currently available inducing agents and is easily stored and stable at room temperature. Its ease of administration may also be of benefit if oral misoprostol is shown to be safe and effective. Oral misoprostol has also been studied with conflicting results[56]. Vaginalmisoprostol is used for cervical ripening in lower doses of 25 μg every four to six hours, as higher doses may be associated with more excessive uterine activity[58].

Various researches have been done on comparing the efficacy of Misoprostol and PGE2 on IOL and it has been found that Vaginal misoprostol is equally efficacious in labour induction as compared to PGE2 gel and demonstrates a similar foetal and maternal safety profile to PGE2 gel. In a study by Nanda et al, misoprostol was found to be superior to dinoprostone for induction of labour especially in developing and tropical countries because of it being cheaper, stable at room temperature, having shorter Induction Delivery Interval and requires less oxytocin[59].

Wing et al in the study done in 1995, stated that misoprostol is associated with a higher prevalence of tachysystole and meconium passage than is dinoprostone and there is a requirement of futher studies to validate the optimal dosing regimen for misoprostol. Ion this study, 50 microgram tablets of misoprostol were used and 0.5mg

gel of dinoprostone was used and the study included 135 patients, amongst which 68 received misoprostol and 67 received dinoprostone[60].

Kulshreshtha S et al did a study to compare the safety and efficacy of intra-vaginal misoprostol (PGE1 analogue) with intra-cervical dinoprostone (PGE2) in progress and induction of labour, the maternal side effects and the foetal outcome. In this study 40 pregnant women aged between 16-35 years with indication of induction of labour participated. Twenty patients (control) were administered 0.5 mg dinoprostone intra-cervically 12 hourly while 20 patients (study group) were given misoprostol 100 microgram, 4 hourly, intravaginally. The mean induction of labour initiation interval was 2.08+/-1.46 hours in study group and 2.21+/-1.20 hours in dinoprostone group. The Induction delivery interval was 6.92+/- 4.01 hours in misoprostol group and 12.54+/-7.73 in dinoprostone group, whereas vaginal route of delivery was 95% in misoprostol group and 85% in dinoprostone group. Average dosages required were 1.55+/-1.02 in misoprostol group and 1.30+/-0.46 in dinoprostone group. All these result were statistically significant. Very few maternal side effects were reported in study group. There was no significant difference in foetal out come in either group. Therefore, it was concluded that misoprostol is easy to administer and is cheap, effective, safe and convenient drug for induction of labor[61].

Another study done by Neiger R et al compared the efficacy of intravaginal misoprostol (Cytotec) to intra cervical dinoprostone (Prepidil) for pre-induction cervical ripening. In this study sixty-one patients were admitted for induction of labor, whose cervices were unfavorable (Bishop score: 4), were randomly assigned to either intravaginal placement of a 50 micrograms misoprostol tablet or intracervical administration of dinoprostone gel. Within 12 hrs, 18 patients in dinoprostoen group

and 5 in misoprostol group had cervical ripening (P = 0.007). In misoprostol group, less doses were required and time for induction to delivery was shorter.Mode of delivery and neonatal outcome were similar in both groups. Vaginal misoprostol was found to be more effective than cervical dinoprostone. The mainstay of current study is to compare the efficacy of dinoprostone with misoprostol in induction of labour[62].

In a study done by A. Lui in 2014, they concluded that the use of misoprostol was significantly effective in increasing the rate of vaginal delivery within 24 h and less oxytocin augmentation when compared with dinoprostone. However, the incidents of uterine hyperstimulation and tachysystole were significantly higher under the misoprostol protocol than dinoprostone protocol. Furthermore, we found similar efficiency in the rate of cesarean delivery, NICU admission and Apgar score at 1 and 5 min among the study groups [63].

Another study done in Nepal in 2012, Two hundred women--100 in each group were evaluated. Comparatively more women (62% vs. 58%) in the Misoprostol group achieved cervical ripening (BS≥6) after one dose. 78% vaginal deliveries in misoprostol group while 71% in dinoprostone group Incidence of maternal complications and fetal outcome was similar in both groups with slightly higher meconium staining in dinoprostone group[64].

A randomized control trial done in 2011, Induction to vaginal delivery interval was significantly lower ($p < 0.05$) for 50 microg (13.8 +/- 6.62 hours) as compared to 25 microg misoprostol (16.4 +/- 7.34 hours) or dinoprostone group (16.3 +/- 7.49 hours). No significant difference was observed for women delivering vaginally within 24 hours, patients delivering after one dose, cesarean deliveries, fetal outcome, and complications for the 50 vs. 25 microg misoprostol vs. dinoprostone group R. Shakya

did a study in 2010, they concluded that No uterine hyperstimulation was observed in both groups. 3 patients in misoprostol group and 2 in dinoprostone group had abnormal heart rates. There was no statistically significant difference in meconium passage in two groups. Both drugs were found to be equally effective in improving Bishops score with no significant difference in mean induction to delivery time. Cesarean section in 32.3% cases of dinoprostone group and 28.6% cases of misoprostol groups. There was significant reduction in the need for oxytocin augmentation in misoprostol (37.1%) group than in dinoprostone (67.7%) group so vaginal misoprostol is an effective, safer and cheaper alternative to dinoprostone as a cervical ripening agent in underdeveloped countries[65].

S. Ozkan did a study on comparative efficacy in 2009 and they concluded that Time interval from induction to vaginal delivery was found to be significantly shorter in misoprostol group when compared to dinoprostone subjects. More subjects required oxytocin augmentation in dinoprostone group and cardiotocography tracings revealed early decelerations occurring more frequently with misoprostol induction (10.7 vs. 0%, P = 0.03). Tachysystole and uterine hyperstimulation, mode of delivery, rate of cesarean sections due to fetal distress and adverse neonatal outcome were not demonstrated to be significantly different between groups[66].

A study by P Tsikouras in 2016 comparing the effectiveness and safety of 50 µg misoprostol versus 3 mg dinoprostone for Induction of Labor in Post-- Term Nulliparous and Parous Women, they concluded that Misoprostol is a more effective agent than dinoprostone gel in post-- term pregnancy for labor induction with few maternal adverse effects. 107 patients received misoprostol (Group A) and 99 patients received dinoprostone (Group B). Compared with group A, more women in Group B

needed a second vaginal dose of prostaglandin or oxytocin infusion in order to proceed to labor (21.5 vs. 43.4 %;; p = 0.01). Misoprostol alone as a single or double vaginal dose was more effective than dinoprostone alone in inducing labor without oxytocin administration (85.0 vs. 50.4 %;; p = 0.04). Overall, the rate of successful induction of labor did not differ between groups (91.6 vs. 85.8 %;; p = 0.75). Vaginal delivery, operative vaginal delivery and Caesarean section rates were not significantly different. Time interval from induction to delivery however, was shorter for Group A (median 11 hours vs. 14.1 hours;; p < 0.001). Though emergency Caesarean section due to fetal distress was more frequent in Group A (16.8 vs. 4.0 %;; p = 0.007), low Apgar scores < 7 and NICU admissions did not differ significantly. Misoprostol use was shown to be safe, with no serious maternal complications and no adverse neonatal outcomes. Multiple clinical trials support the effectiveness and safety of this cost--effective drug for labor induction[67].

METHODOLOGY

The present study was conducted in Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College, Belgavi during a period of between 1st January 2017 to 31st December 2017.

Study Design:

Type of the study: Prospective single blinded randomised controlled phase four [post marketing surveillance] trial

Study period:

The present study was conducted during the period of 1st January 2017 to 31st December 2017.

Sample Size:

The present study included 240 cases

Sampling Procedures:

All the women who were antenatal cases getting admitted to labor room of KLES Dr. Prabhakar Kore Hospital & MRC, Belgavi at term for induction of labor during the study period were included.

- Approximate sample size was240 patients

	Mean I-T	S. D
Vaginal route	15(χ_1)	9 (S_1)
Oral Route	11(χ_2)	5 (S_2)

$\alpha = 0.05$ $\beta = 0.1$ p = 95%

$$n = \frac{2(z_\alpha + z_\beta)^2 \ (S_1^2 + S_2^2)}{(\bar{\chi}_1 - \bar{\chi}_2)^2}$$

$Z\alpha = 1.96$ $\alpha = 0.05$

$Z\beta = 1.28$ $\beta = 0.1$

= 91 per group

Sample size was taken as 120 per group.

Selection criteria:

Inclusion Criteria:

- Term pregnancy [defined as period of gestation ranging from 37-42 weeks],
- Single live fetus
- Vertex presentation,
- Intact membranes
- Modified Bishop score less than 6

Exclusion Criteria:

- Cardiac Disease
- Hypertensive disorders of pregnancy
- Previous LSCS
- Severe Pre-eclampsia
- PROM

Method of data collection:

Ethical Clearance:

The ethical clearance was obtained from Review Board of Jawaharlal Nehru Medical College, Belgavi (Letter No. 22, dated 17 / 07/2017).

Informed Consent:

All the antenatal cases getting admitted in the labor room were screened for eligibility. Written informed consent was obtained in the presence of witness from the woman who fulfilled the inclusion criteria. It was also explained that lack of participation would not affect the usual and anticipated standard of care. The women were enrolled in the study only after taking their signature or left hand thumb impression on informed consent form.

Data Collection form:

All patients were informed regarding the need for induction of labor and the trial procedure. Those patients not opting to be a part of the trial were excluded.

A detailed history of the present pregnancy, menstrual history with special regard to the length and regularity of the cycles, obstetric history, past medical, surgical, personal and socio-economic history were recorded for each participant. The period of gestation was calculated from the first day of the last menstrual period by Naegles formula if the patient was certain of her menstrual cycle regularity. A dating scan or subsequent ultrasonography scans were opted for as a means to calculate period of gestation if there was any uncertainty regarding the certainty of the last menstrual period. Those patients not opting to be a part of the trial were excluded.

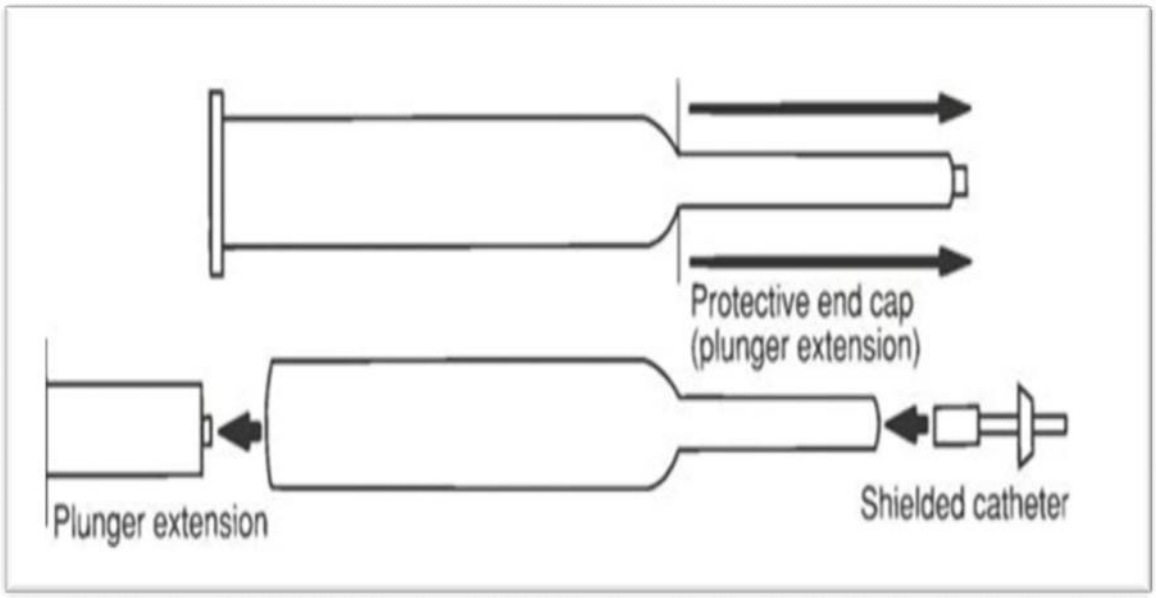
All patients underwent a clinical examination to confirm the presentation and lie and per vaginal examination including a per speculum examination to confirm status of membranes and to document pre induction bishops score. A general systemic examination to rule out associated medical comorbidities was conducted in all patients. After confirming the indication of induction, patients were randomly allocated into two groups. A total of 240 opaque numbered envelopes with serial number 1 to 240, were mixed and placed in a box, and were randomly picked for patients who were fulfilling the inclusion criteria. Each envelope was numbered serially. The treating obstetrician then segregated the patients into two groups based on odd even numbering of the envelopes. All patients with odd numbered envelope were allocated to the dinoprostone gel group and the patients with even numbered envelope were allocated to misoprostol tablet group.

On confirming the fetal and maternal well being, the patients in the dinoprostone group were induced using dinoprostone gel –every 6^{th} hourly upto maximum of 3 doses. Intracervical administration through per vaginal route using

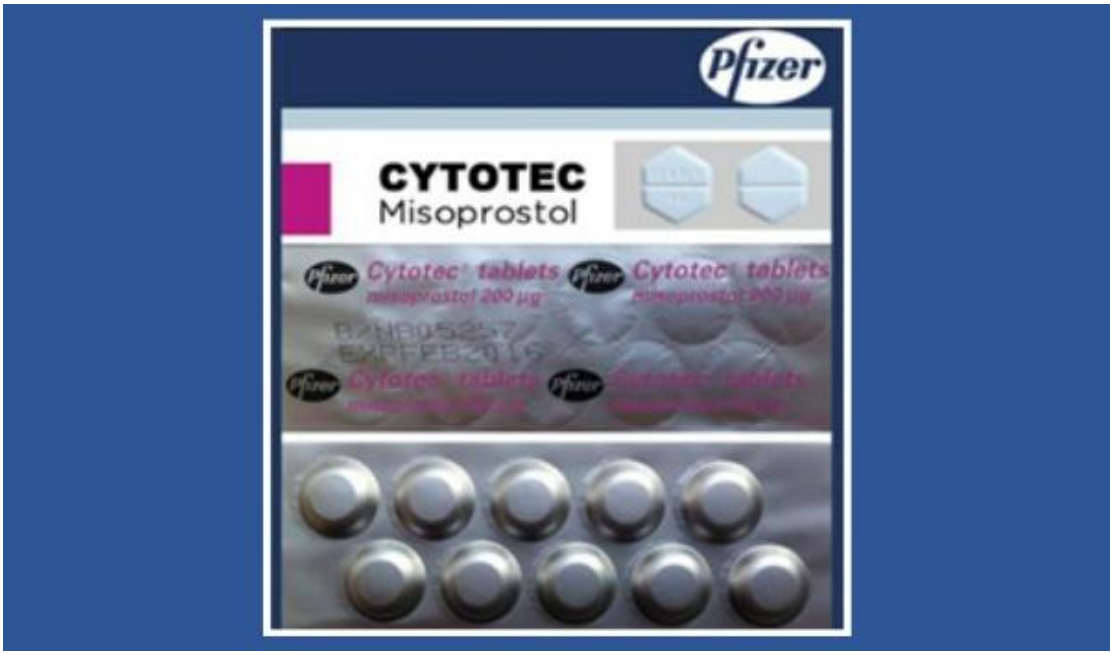
strict antiseptic precautions was carried out. A preinduction CTG was obtained prior to every induction and fetal heart rate was monitored in between induction intervals using intermittent auscultation every 15 min. Patients in the misoprostol group received 25 mcg of tablet misoprostolupto maximum of 6 doses every 4th hourly. Tablet misoprostol was inserted intravaginally in the posterior vaginal fornix under aspetic precautions. Fetal monitoring was conducted as in the dinoprostone arm.

In Group I, under aseptic conditions, a prefilled syringe containing 0.5 mg of dinoprostone (PGE2) gel was instilled endocervically. Continuous CTG and uterine activity monitoring was done for one hour after the instillation. Four hours after the initial PGE2 instillation, a per vaginal examination was done to reassess the Bishop's score. If Bishop's Score remained less than 6, then next dose was administered and then a total of maximum 3 doses were given.

Dinoprostonegel and its parts



In Group II: Each woman was administered 25 µg misoprostol tablet in the posterior fornix of the vagina under aseptic conditions. Depending on the Bishop score, each dose was given. Subjects received uptomaximum of 6 doses. Dose was repeated every 4th hourly until an adequate uterine contraction pattern.



Maternal parameters including vital signs and progress of labour were charted using WHO partograph. Any signs of fetal or maternal distress were acted upon by prompt resuscitation and subsequent prompt termination of pregnancy by caesarean section if the former was not successful. The indications for caesarean section were recorded. Induction was discontinued once the labor was initiated and or cervical findings were in the range of a favorable bishop score.

Successful induction of labor was defined as onset of active uterine contractions associated with cervical dilatation of at least 4cm and or modified bishop score of 6 or more. Failed induction was defined when a patient has received a maximum of 6 doses of misoprostol or a maximum of 3 doses of dinoprostone and still the cervical dilation is less than 4 cms.

Patients demographics and the indication for the induction, number of successful inductions, time of initiation to active labor time, induction to delivery, need for augmentation was recorded for each subject as per the case report form. Mode of delivery and fetomaternal outcomes were documented. Neonatal outcome was assessed on the basis of APGAR score at birth and at 5 mins, need for NICUadmission and presence or absence of meconium staining of the amniotic fluid.

STASTICAL ANALYSIS

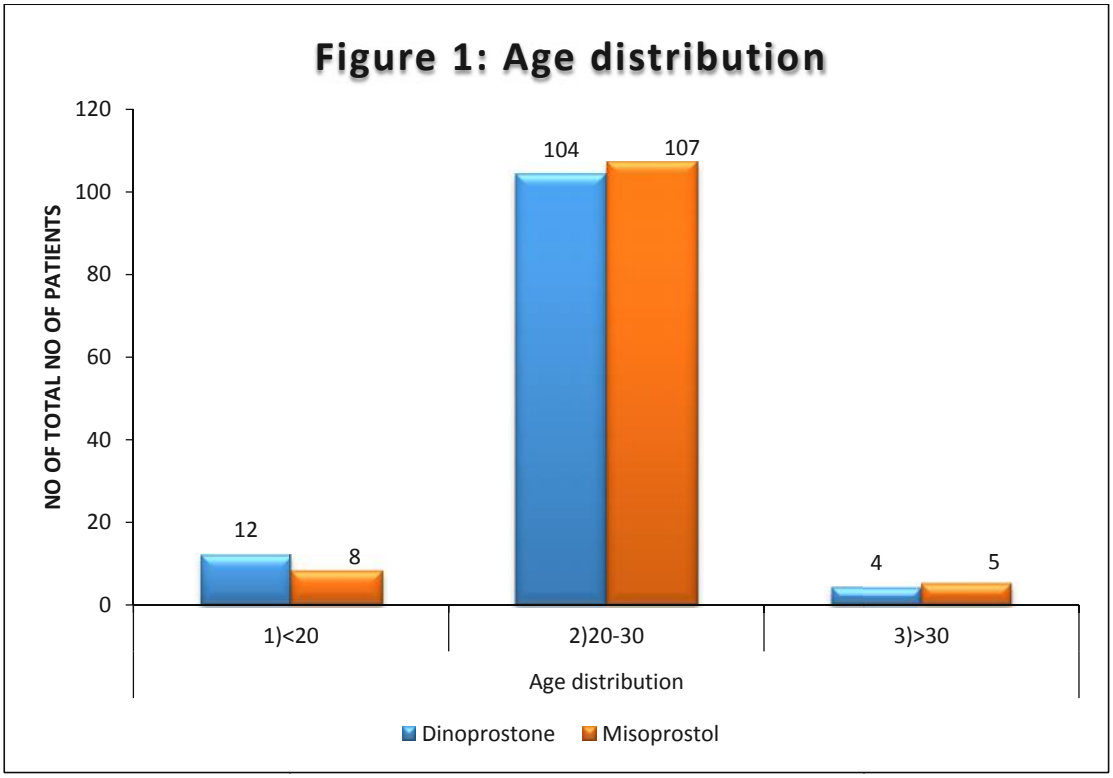
All data was entered in the individual case report forms and eventually compiled in Microsoft excel sheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used. Quantitative variables were compared using Independent T test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups. Qualitative variables were correlated using Chi-Square test/Fisher's exact test. A p value of <0.05 was considered statistically significant.

RESULTS

This is a prospective study conducted between 1st January 2017 to 31st December 2017 in the Department of Obstetrics and Gynecology, Jawaharlal Nehru Medical College, Belgaum. This study was a one year randomized controlled trial at a tertiary center, Belgavi for comparative analysis between intracervical dinoprostone gel and vaginal misoprostol for induction of labour.

Table 1: Demographic Profile (n=240)

Age Distribution	**Dinoprostone (n=120)**	**Misoprostol (n=120)**	**Total**	**Age Distribution**
<20 years	12	8	20	<20 years
20-30 years	104	107	211	20-30 years
> 30 years	4	5	9	> 30 years
Total	120	120	240	Total
Mean	23.35 ± 3.26	23.58 ± 3.26		Mean
Gravida				**Gravida**
Primigravida	36	26	62	Primigravida
Multigravida	84	94	178	Multigravida
p-value	0.184	0.184		p-value
Mean gestational age (inwks)	39 ± 1.26	39.12 ± 1.35		Mean gestational age (in wks)
p-value	0.266			p-value



Majority of the females belonged to the age group of 21-25yrs in both the groups with average age being similar in two groups with no significant difference in age distribution between the two groups.

Majority of the patients in both the groups were primigravida with mean gestational age around 39 ± 1.26wks and 39.12 ± 1.35wks in-group 1 and 2 respectively.

There were a total of 170 successful inductions and there were 24 failed induction in our study. The results in both the groups were comparable and no statistical significance.

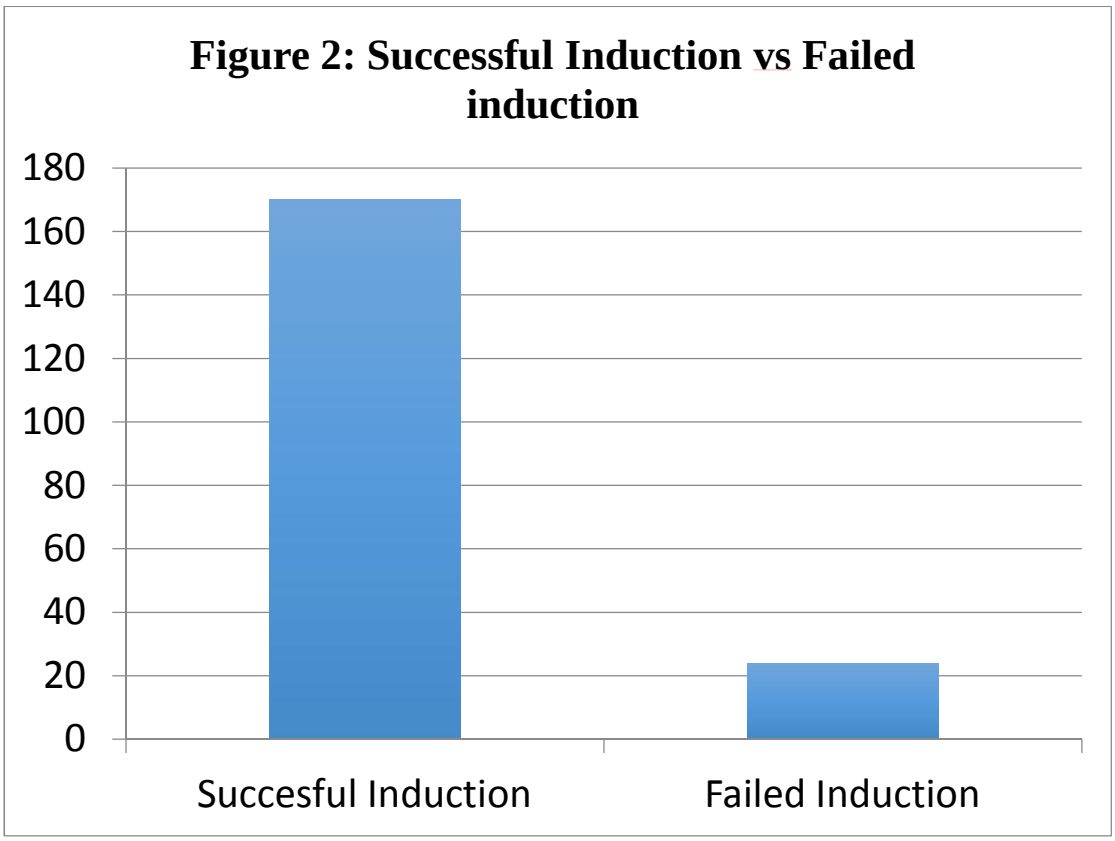


Table 2: Indications for Induction

Indications for Induction	Dinoprostone (n=120)	Misoprostol (n=120)	Total	p-value
Decreased fetal movement	24	26	50	0.873
GDM	21	12	33	0.133
IUGR	12	17	29	0.428
Oligohydraminos with IUGR	11	5	16	0.195
PIH	40	47	87	0.42
Postdatism	7	8	5	0.746
Rh-ve pregnancy	5	5	15	0.746
Total	120	120	240	

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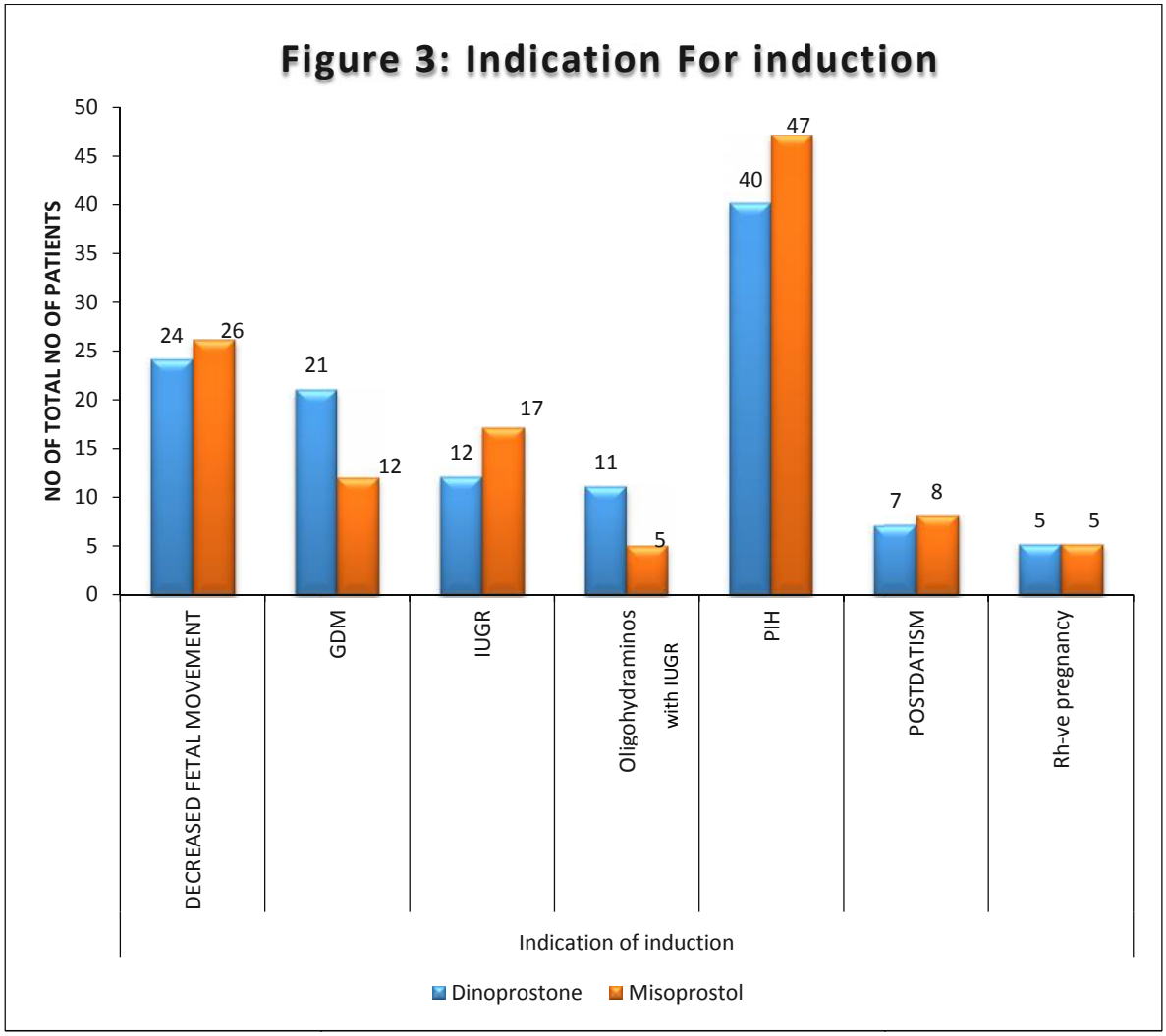
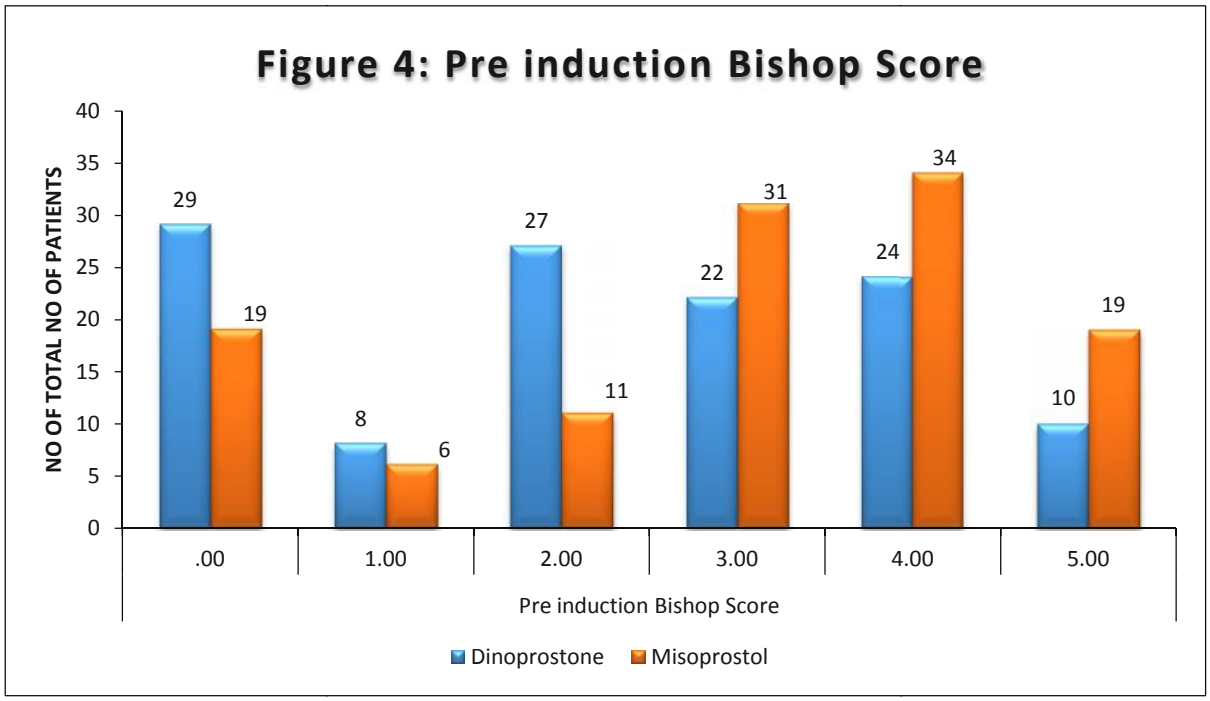


The major indication for induction in both the groups was PIH followed by decreased fetal movements in both the groups respectively. Difference being insignificant in between the two groups in most of the indications.

Table 3: Mean Pre-induction Bishop Score in both groups

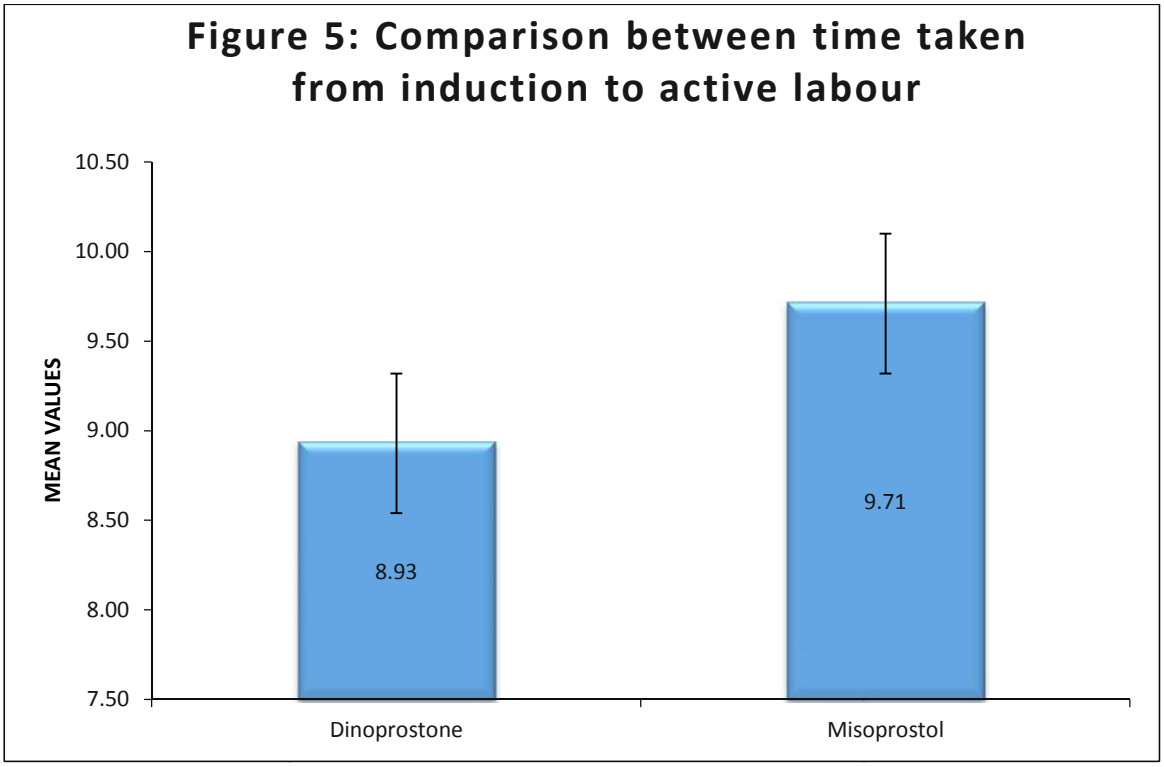
Pre Induction Bishop Score	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	Total	p-value
.00	29	19	48	0.146
1.00	8	6	14	0.783
2.00	27	11	38	0.008
3.00	22	31	53	0.213
4.00	24	34	58	0.175
5.00	10	19	29	0.113
Total	120	120	240	
Mean ± Stdev	2.28 ± 1.65	2.93 ± 1.63		0.102



Mean pre-induction Bishop's score was almost equal in both the groups with the difference being insignificant (P value ≥ 0.05).

Table 4: Comparison between time taken from induction to active labour

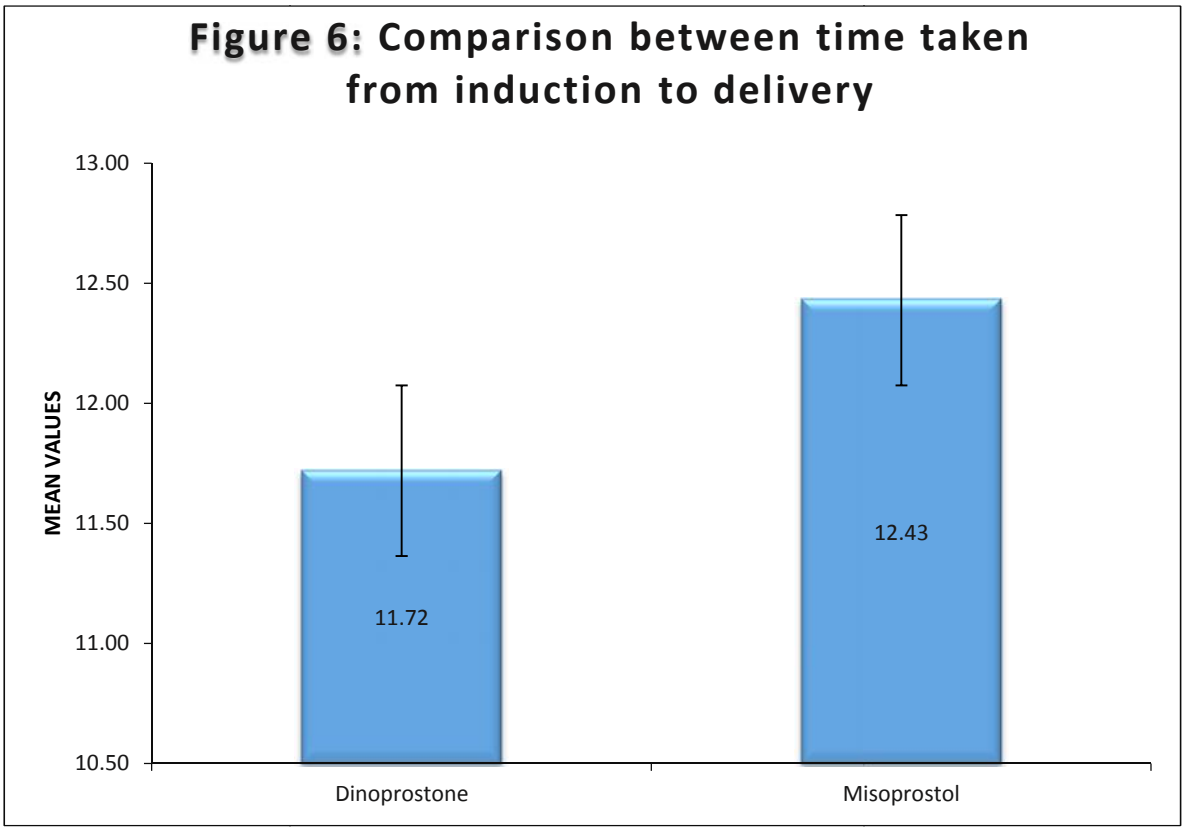
Time taken from induction to active labour	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	p-value
Mean ± Stdev	8.93 ± 4.42	9.71 ± 4.58	0.119
Median	8	9	



Time taken for induction to active labour was shorter in the dinoprostone group, but not statistically significant.

Table 5: Comparison between time taken from induction to delivery

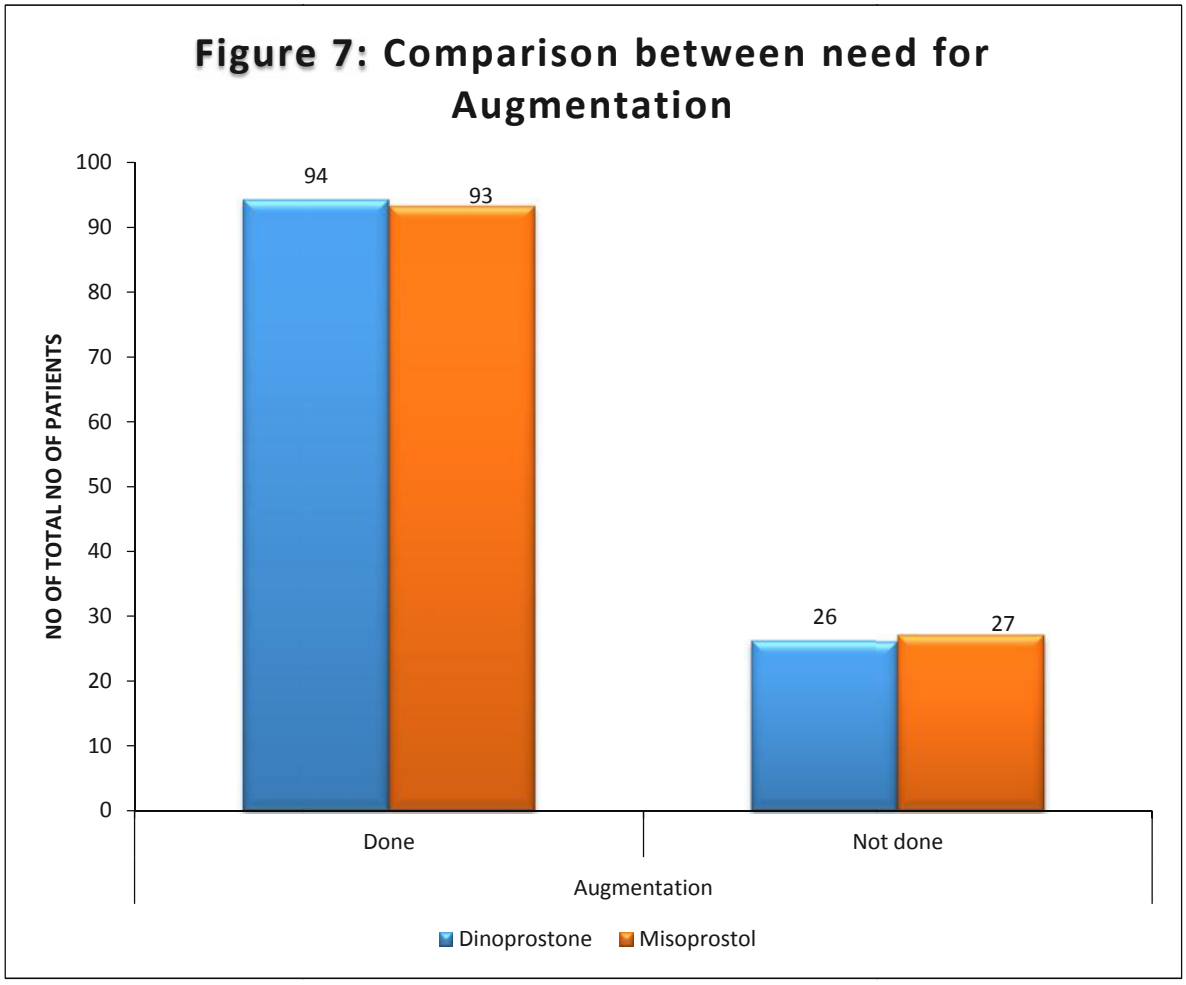
Time taken from induction to delivery	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	p-value
Mean ± Stdev	11.72 ± 5.1	12.43 ± 4.58	0.164
Median	10.5	12	



Time taken for induction to delivery was shorter in the dinoprostone group, but not statistically significant.

Table 6: Comparison between need for Augmentation

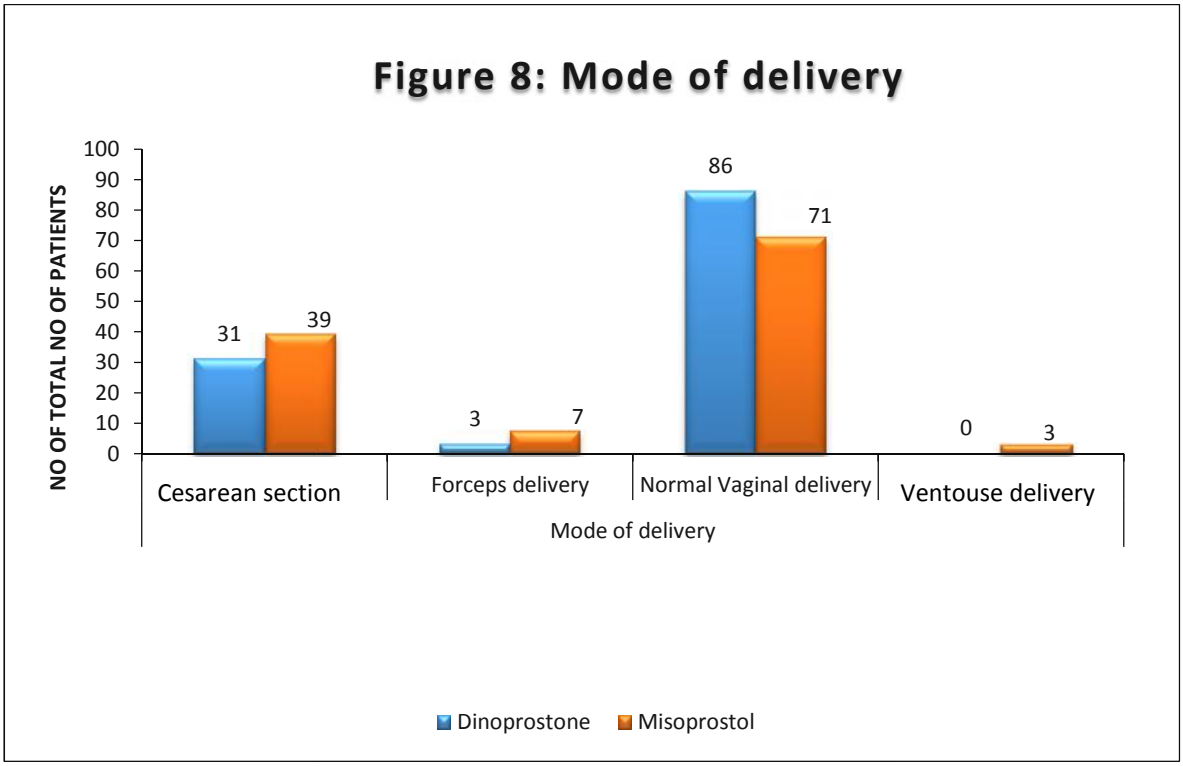
Augmentation	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	Total	p-value
Done	94	93	187	1.000
Not done	26	27	53	1.000
Total	120	120	240	



Need for Augmentation was compared in both the groups but the difference was insignificant

Table 7: Mode of Delivery

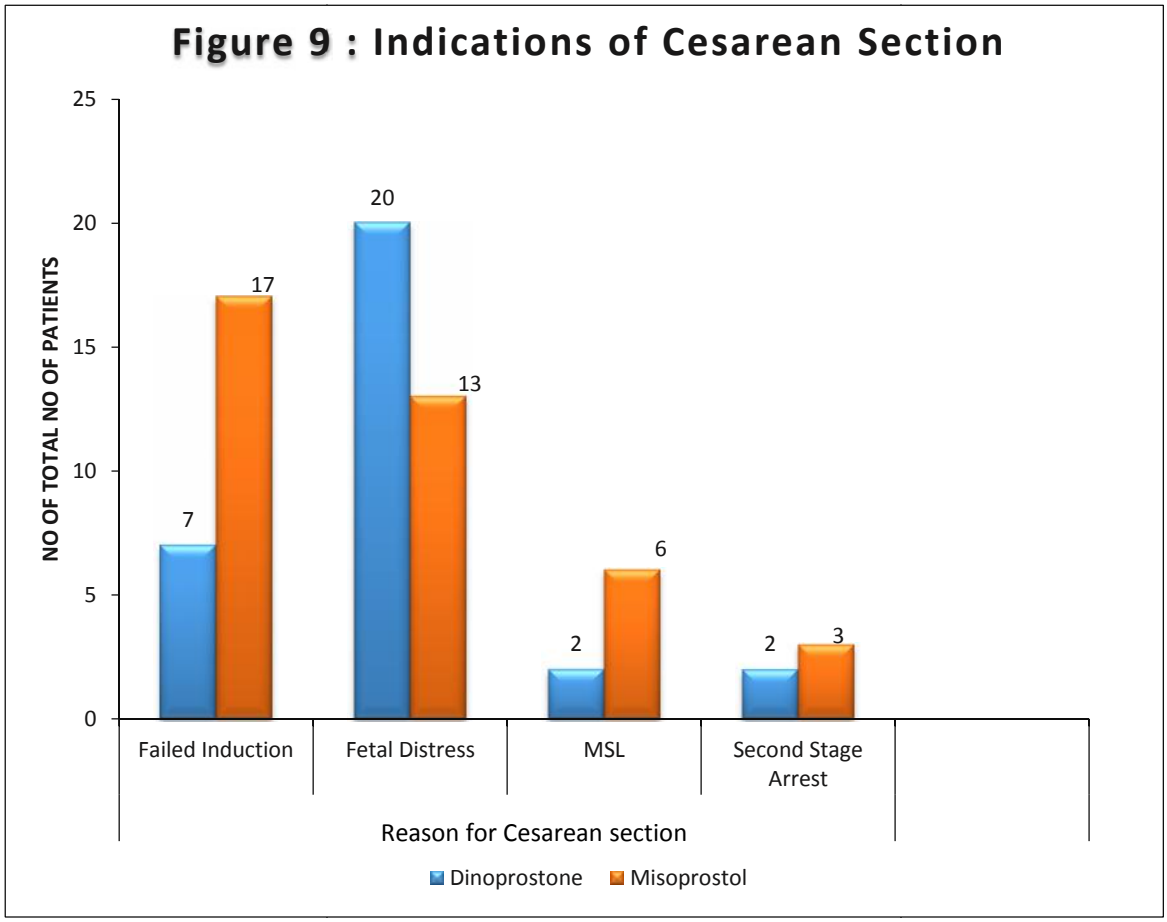
Augmentation	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	Total	p-value
Cesarean Section	31	39	70	0.32
Forceps delivery	3	7	10	0.171
Vaginal delivery	86	71	157	0.057
Ventouse delivery	0	3	3	0.246
Total	120	120	240	



Comparison in terms of mode of delivery showed no significant difference (P value ≥ 0.05) in between the two groups. Incidence of LSCS was higher in group 2 than in group 1, but without any statistical significance.

Table 8: Indications of Cesarean Section

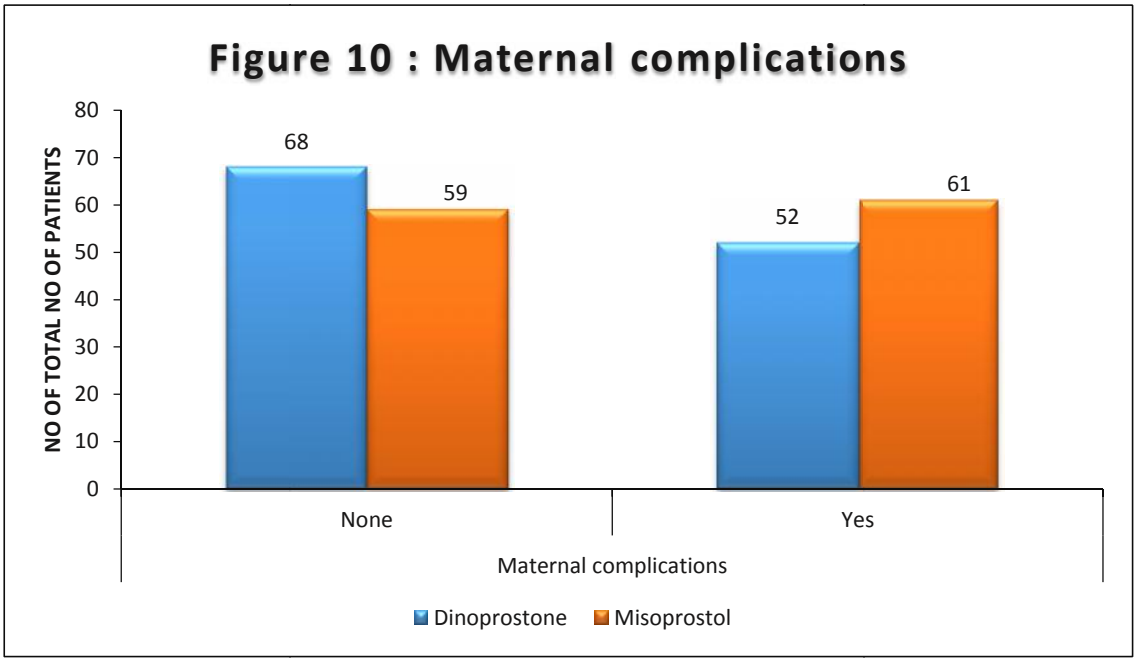
Reasons for Cesarean Section	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	Total	p-value
Failed Induction	7	17	24	0.112
Fetal Distress	20	13	27	0.445
MSL	2	6	8	0.287
Second Stage Arrest	2	3	5	1
Total	31	39	70	



The commonest indication for cesarean in dinoprostone group was fetal distress while in misoprostol group, the commonest indication was fetal distress, the difference was statistically insignificant.

Table 9: Maternal Complications

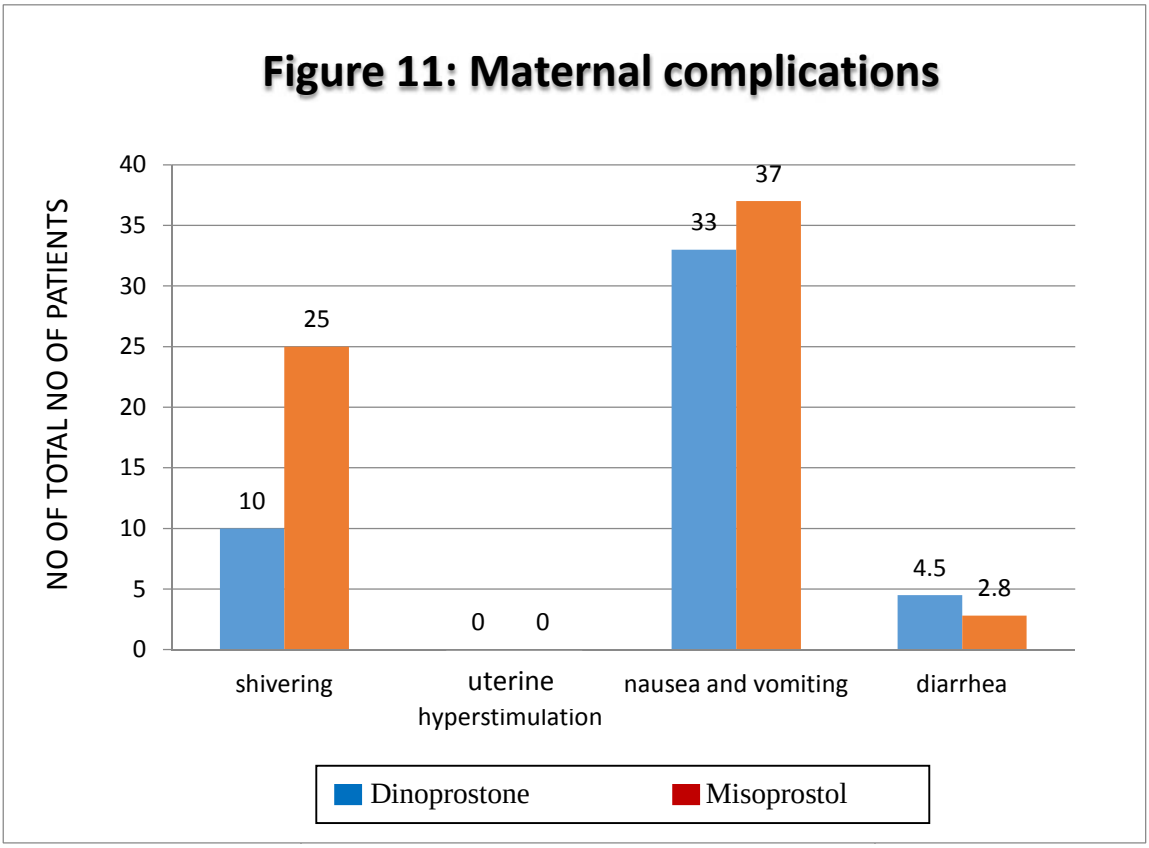
Maternal Complications	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	Total	p-value
No	68	59	127	0.301
Yes	52	61	113	0.301
Total	120	120	240	



The difference in the number of maternal complications in both groups was statsitically insignificant

Table 10: Maternal Complications

Maternal Complications	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	Total	p-value
Shivering	10	25	35	0.010
Uterus hyperstimulation	0	0		0
Nausea and vomiting	33	37	70	0.285
Diarrhea	5	3	8	0.722



There was high incidence of nausea and vomiting in both the groups, slightly higher in the misoprostol group but not statistically significant.

Table 11: Neonatal Outcome

Neonatal Outcome	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	Total	p-value
APGAR Score at '0' mins				
6.00	1	2	3	1
7.00	87	78	165	0.265
8.00	32	40	72	0.324
Mean ± Stdev	7.26 ± 0.46	7.32 ± 0.5		0.318
APGAR Score at '5' mins				
7.00	1	2	3	1
8.00	87	78	165	0.265
9.00	32	40	72	0.324
Mean ± Stdev	8.26 ± 0.46	8.32 ± 0.5		0.318
Birth Weight				
1.5-2 kgs	4	4	8	1
2.1-2.5 Kgs	36	29	65	0.383
2.6-3 kgs	58	70	128	0.154
>3 kgs	22	17	39	0.484
Mean ± Stdev	2.7 ± 0.35 Kg	2.73 ±0.36 Kg		0.479
NICU Admission				
No	92	89	181	0.764
Yes	28	31	59	0.764
Meconium Staining				
Yes	102	95	197	0.312
No	18	25	43	0.312

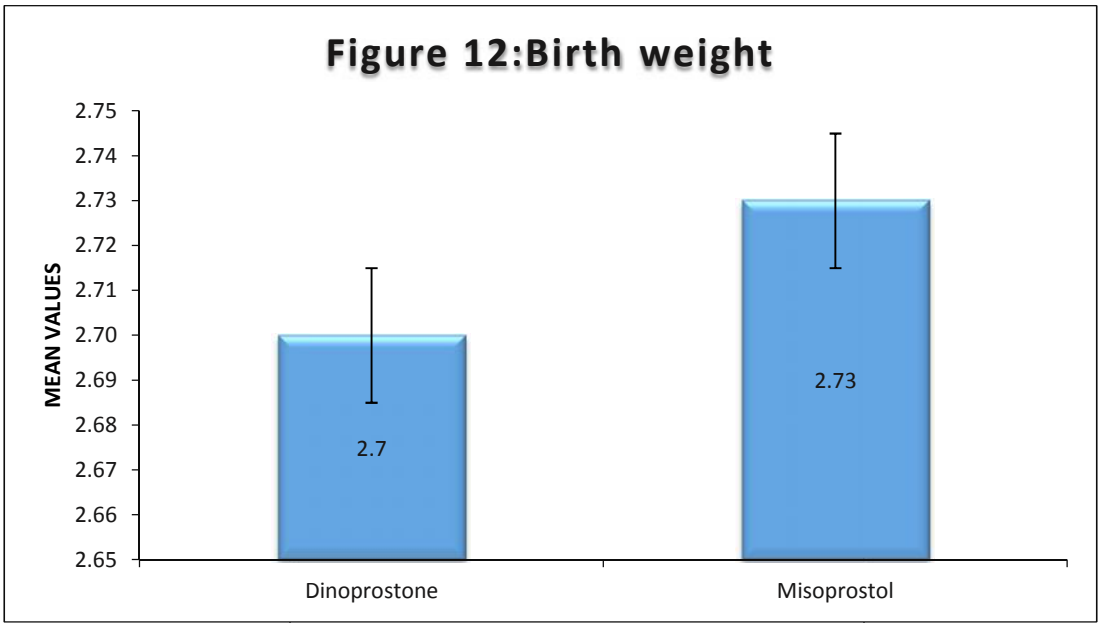


Figure 12:Birth weight
MEAN VALUES
2.75
2.74
2.73
2.72
2.71
2.70
2.69
2.68
2.67
2.66
2.65
2.7
2.73
Dinoprostone
Misoprostol

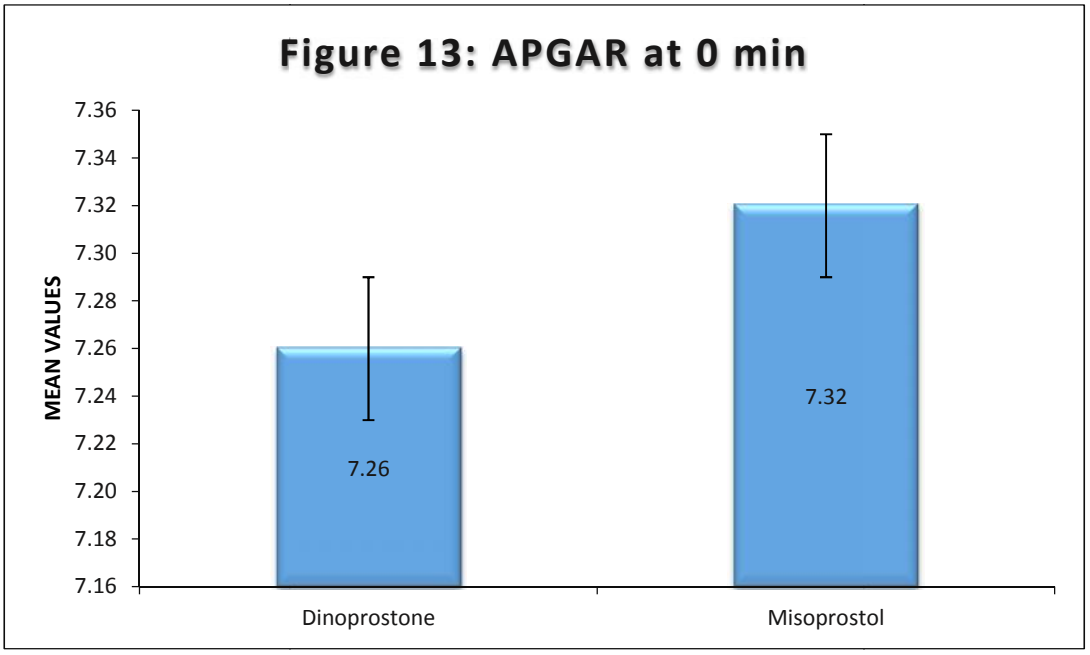
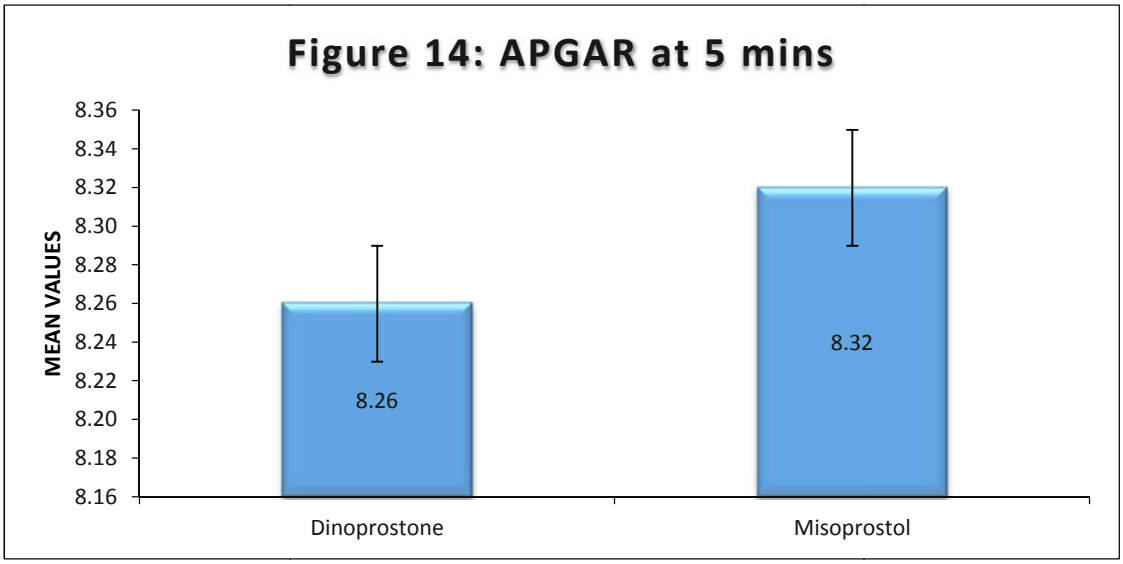
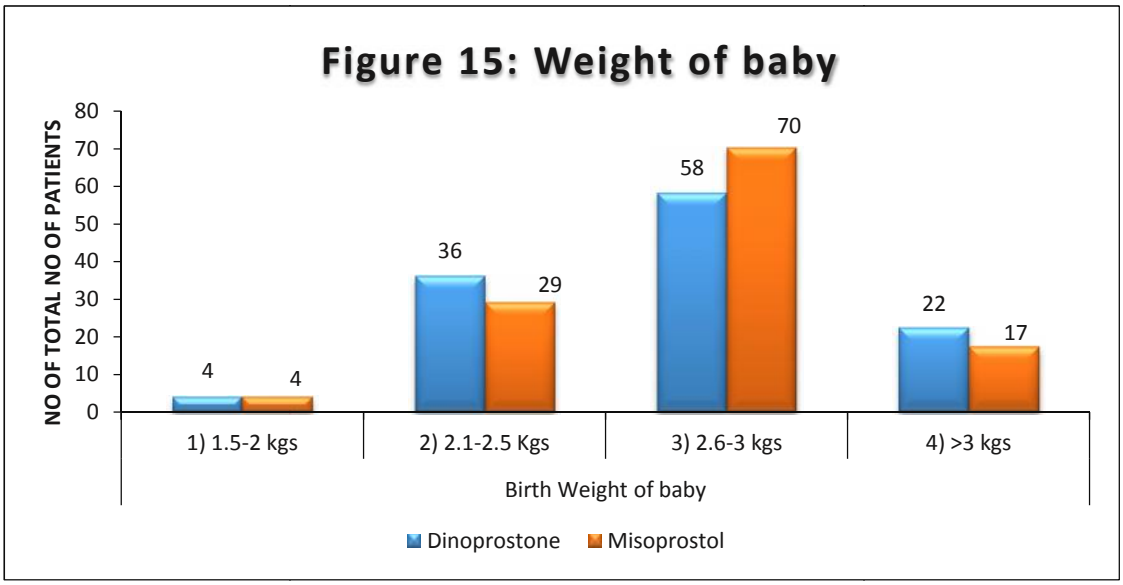


Figure 13: APGAR at 0 min
MEAN VALUES
7.36
7.34
7.32
7.30
7.28
7.26
7.24
7.22
7.20
7.18
7.16
7.26
7.32
Dinoprostone
Misoprostol



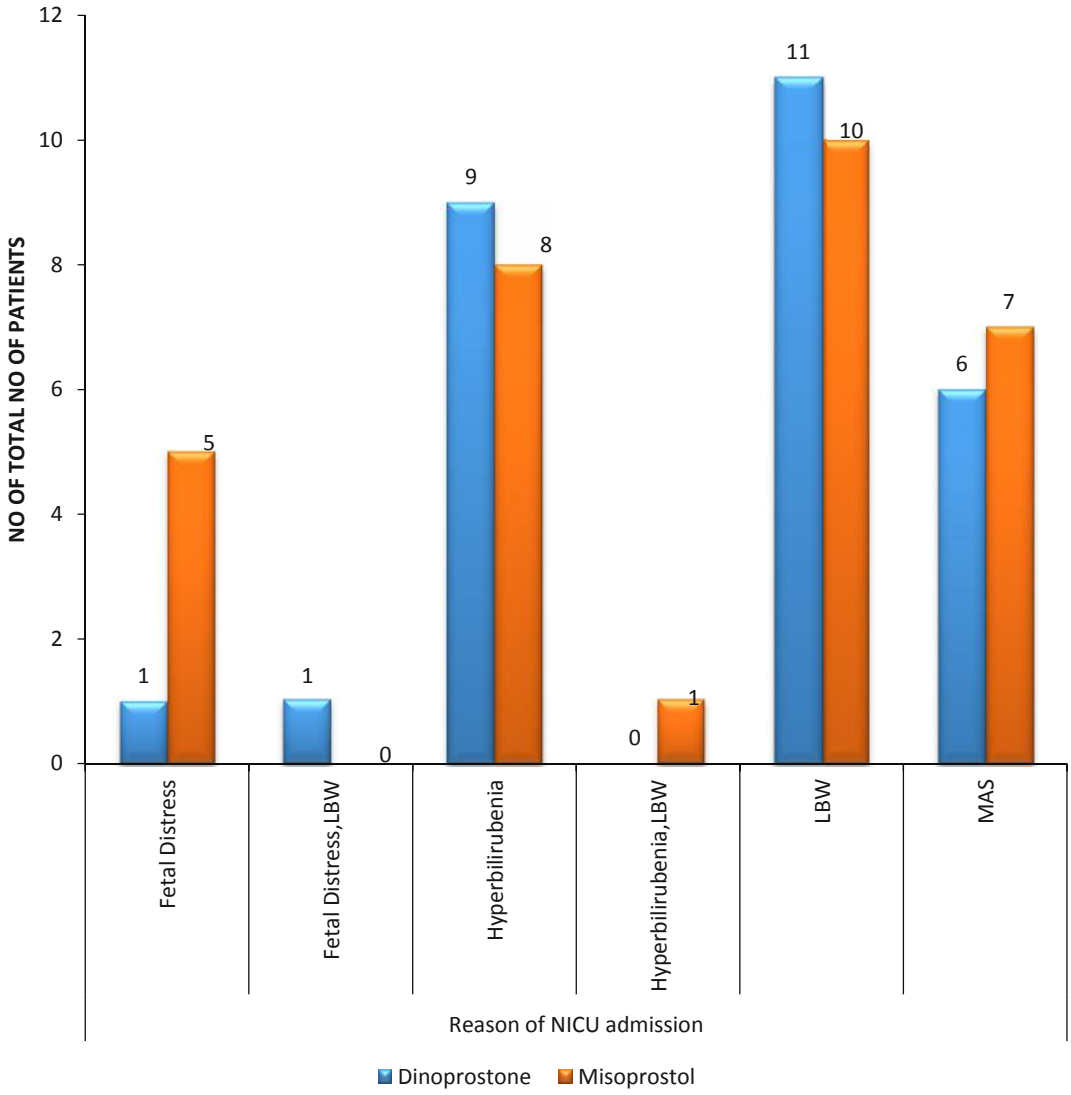


The neonatal outcome was evaluated in terms of various variables used, most of which showed no significant difference (P value ≥ 0.05). APGAR score at '0' mins and APGAR score at 5 mins, Meconium staining and number of NICU admission in both the groups showed no significant difference.

Table 12: Neonatal Outcome (Reasons for NICU Admission)

Reasons for NICU Admission	Group 1 (Dinoprostone Gel)	Group 2 (Misoprostol tab)	Total	p-value
Fetal Distress	1	5	6	0.197
Fetal Distress, LBW	1	0	1	0.474
Hyperbilirubenia	9	8	17	0.803
Hyperbilirubenia,LBW	0	1	1	1
LBW	11	10	21	0.771
MAS	6	7	13	0.835
Total	28	31	59	

Figure 16: Reason of NICU admission



Commonest reason for NICU admission in both the groups low birth weight and then followed by hyperbilirubinemia and the difference was statistically insignificant

DISCUSSION

Induction of labour is needed in conditions when there is a maternal indication or if the intrauterine conditions are detrimental and if the cervix is unfavorable, then cervical ripening is recommended for successful induction[24]. The aim of induction is successful vaginal delivery as its more like a natural phenomenon.

In current scenario, there is a rising trend for induction of labor[68]. This study aims for a comparative study between vaginal misoprostol and intra-cervical dinoprostone in relation to the successful induction, safety and feto-maternal outcomes in both the groups.

In this study, we compared the safety of Misoprostol (PGE1 analogue) with Dinoprostone (PGE2 analogue) in terms of various variables like post induction Bishop's score, need for augmentation, induction delivery interval, mode of delivery, maternal and neonatal outcome, indications of LSCS, and various intrapartum and postpartum complications.

In our study, the total number of patients induced were 240, amongst them, 170 were successfully induced, and 24 were failed induction. Amongst the successful induction, 157 were delivered by normal delivery, 86 in the dinoprostone group and 71 in the misoprostol group, while 10 patients required forceps and 3 patients required ventouse delivery and all three were in the misoprostol group (Figure 2).

In our study, while comparing the demographic profile, as discussed in Table 1; the majority of patients were seen in age group of 20-30 years in both the groups, followed by age group of less than 20 years and then the age group of more than 30 years and the mean age was 23.35 ± 3.26 years in the dinoprostone group and 23.58 ±

3.26 years in the misoprostol group. The incidence of multigravida was higher in both the groups, with 84 out of 120 cases in the dinoprostone group, while it was 94 out of 120 cases in the misoprostol group and the mean gestational age in dinoprostone group was 39 ± 1.26 weeks while in misoprostol group was 39.12 ± 1.35 weeks. Similar age group results were seen in other studies and the difference was insignificant[68,69].

Induction was done for various maternal and fetal indication (Table 2). Most common cause of induction in both the groups was pregnancy induced hypertension which was 40 cases in the dinoprostone group and 47 cases in the misoprostol group followed by decreased fetal movements in both groups, which was 24 cases in the dinoprostone group and 26 cases in the misoprostol group followed by gestational diabetes mellitus in the dinoprostone group which was 21 cases and IUGR in the misoprostol group which was 17 cases and the difference in both groups was statistically insignificant. The other indications were oligohydramnios, postdatism, Rh-ve pregnancy. Other studies have most common indication as postdatism [68,69,70].

The induction to active labor time interval was 8.93 ± 4.42hrs in dinoprostone group while it was 9.71 ± 4.58hrs in misoprostol group, difference was insignificant (Table 4). Induction delivery time interval, though insignificant, was less in the dinoprostone group and it was 11.72 ± 5.1hrs in dinoprostone group while it was 12.43 ± 4.58hrs in other group (Table 5). Similar results of statistical insignificance were seen in other studies[69,70]. Contrasting results of statistical significance were seen in few studies with statistical difference in the induction delivery time interval with lesser time in the misoprostol group[68,71,72,73]. But it is difficult to directly compare

both the groups, as in this study we have used different regimes and dosing schedules for the drugs

In our study the need for augmentation (Table 6) came out to be similar in either of the groups with difference being insignificant and similar results were seen in similar study by Herabutya Y et al[74].

In our study, there was no significant difference observed in mode of delivery (Table 7). Number of vaginal deliveries was 86 in dinoprostone group while it was 71 in misoprostol group and there was slightly higher incidence of cesarean section in the misoprostol group; the incidence of cesarean section was 31 in dinoprostone group while it was 39 in misoprostol group, though insignificant. Similar results were seen in study by Herabutya Y et al[74], Afia Ansar Shafiqet al[69] and Papanikolaou E et al[68], but our results are in contrast with study by byChitrakar NS[75].

In our study, the incidence of cesarean section (Table 8) was comparable in both the groups and the commonest reason was fetal distress in dinoprostone group which was 20 cases out of 120 while it was failed induction in the misoprostol group which was 17 cases out 120. The other indications were MSL and second stage arrest. Similar results were seen in another study[76].

Maternal complications in both the groups were similar (Table 9,10) and the difference was statistically insignificant and the highest incidence was of nausea and vomiting in both the groups followed by shivering, which was statistically significantly higher in the misoprostol group. Insignificant difference in maternal complications was seen in other studies also[77,78]. It is very important to reassess the post induction Bishop's score properly before instilling the next dose so as to assess the need and to prevent hyperstimulation consequently, which may land up into

deadly complications like rupture of uterus. The incidence of uterine hyperstimulation in our study was 0 in both the groups.

Neonatal outcome came to be similar in both the groups (Table 11). Difference in distribution of Apgar scores at '0' mins and at '5' mins, birth weight, meconium staining and number of NICU admissions was insignificant. Maximum number of patients in both the groups had a APGAR score of 7 at '0' mins and it was 8 at '5' mins. Similar results with respect to APGAR scores were seen in other studies. There was no increase in the incidence of meconium staining as well as high incidence of fetal distress in the misoprostol group; it could be attributed to the low dose regimen used in our study[79,80,81,82]. Contrasting results were seen in relation to the meconium staining in the misoprostol group[24,62].

In our study, NICU admission were similar in both groups and the commonest reason for the NICU admission was low birth weight in both the groups, which was 10 cases in misoprostol group and it was 11 cases in the dinoprostone group followed by hyperbilirubinemia in both groups, which was 9 cases in the dinoprostone group and it was 8 cases in the misoprostol group (Table 12). Comparable NICU admissions in both groups were seen in another study also[76]. The other reasons for NICU admission were fetal distress, MAS. There was increased incidence of fetal distress in the misoprostol group, which was 5 cases, and it was only 1 case in the dinoprostone group. There was no preterm baby and no baby with gross congenital anomalies. Low birth weight could be attributed to low socio-economic status and the poor nutrition of the rural population and also due to high incidence of unbooked cases, which is due to increased unawareness.

In our study, both the drugs had similar results. Misoprostol is much cheaper and do not require the additional cost of refrigeration and is stable at room temperature. Moreover, its longer shelf life makes it even more cost effective. Its ease of administration as it is to be just kept in the posterior fornix of the vagina and requires less expertise makes it even more favourable.

It is worth mentioning that cost is an important factor due to poverty, less affordability and apathy towards women in this country. Dinoprostone already being very expensive additionally requires refrigeration for storage, which incurs a heavy burden on the expense.

CONCLUSION

In present day obstetrics, induction of labor done timely and judiciously is pivotal. In our study, successful induction was seen in 170 cases (70.83%) and failed induction was in 24 cases (10%) and the results were comparable in both the groups. The induction to delivery interval (11.72 ± 5.1hrs vs12.43 ± 4.58hrs) and induction to active labor time interval (8.93 ± 4.42hrs vs9.71 ± 4.58hrs) were comparable in both the groups. No significant variation was seen in maternal and fetal outcomes in both the groups and the difference was statistically insignificant. Both are effective for induction of labor with comparable maternal complications. However misoprostol is relatively cheap, requires less stringent condition for storage and is equally effective and safe in inducing labor at term. There is a need for further larger studies to establish and document the findings of our study.

SUMMARY

- The present study was conducted in Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College, Belgavi during a period of between 1st January 2017 to 31st December 2017.
- This study included 240 patients, 120 each in dinoprostone group (Group /1) and misoprostol group (Group 2).
- Majority of the females belonged to the age group of 21-30yrs in both groups and with majority being primigravida with with mean gestational age around 39 ± 1.26 wks and 39.12 ± 1.35 wks in-group 1 and 2 respectively
- Successful induction was seen in 170 cases and failed induction was seen in 24 cases.
- Major indication for induction in both the groups was PIH followed by decreased fetal movements in both the groups
- Time taken for induction to active labor and induction to delivery was shorter in the dinoprostone group, but not statistically significant.
- Need for augmentation was comparable in both the groups.
- Mode of delivery was Normal delivery in 86 cases of dinoprostone group and 71 cases of the misoprostol group, while Cesarean Section was done in 31 cases of dinoprostone group and 39 cases of misoprostol group
- No significant difference was seen the neonatal outcome in both the groups which was compared in terms of APGAR score, body weight and NICU admission
- Commonest reason for NICU admission in both the groups low birth weight and then followed by hyperbilirubinemia

- The commonest indication for cesarean in dinoprostone group was fetal distress while in misoprostol group, the commonest indication was fetal distress
- Amongst maternal complications, there was high incidence of nausea and vomiting in both the groups

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ANNEXURE I – ETHICAL CLEARANCE CERTIFICATE

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

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Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 92 **Date: 17/10/2016**

To,

Dr.
PG student in Obstetrics and Gynaecology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"COMPARATIVE STUDY OF INTRACERVICAL DINOPROSTONE GEL AND VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR 1 YEAR RANDOMIZED CONTROL TRIAL AT TERTIARY CARE CENTRE, BELAGAVI"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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

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

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ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mrs _____ we are requesting you to enroll yourself in study title **"COMPARATIVE STUDY OF INTRACERVICAL DINOPROSTONE GEL AND VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR AT KLE DR.PRABHAKAR KORE CHARITABLE HOSPITAL "** conducted by Dr. _____, Post Graduate in M.S. Obstetrics And Gynaecology under the guidance of Dr. _____ Professor Department of Obstetrics And Gynaecology , J.N. Medical College, Belgaum under KLE university, Belgaum.

Respected Madam, we request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present and past pregnancy and you are supposed to answer to the best of your knowledge.

Objective and Purpose of study:

To compare the safety and efficacy of intracervical dinoprostone vs vaginal misoprostol for induction of labour.

Procedure Involved:

If you agree to enroll yourself in my study, you will be interviewed regarding your obstetric history and the present pregnancy

Risks and Benefits:

There will be no benefit of taking part in this research. There are observable risk factors associated with the study like uterine hypersystole, tacy systole, puerperal sepsis, fever, breast complications etc.

Voluntary Participation/Withdrawal:

Your participation in this study is voluntary. You can withdraw from this study at anytime. Your decision will not change present or future health care services offered to you at K.L.E.S hospital.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1.In emergency to protect your rights and welfare.

2.If required by law.

Authorization to Publish Results:

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

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients.

Questions:

In case you have any questions related to the study, you can contact Dr. , Principal Investigator .Post Graduate, Department of Obstetrics and Gynecology ,KLES Hospital and MRC, phone number: or my Guide Dr. , Professor Department of Obstetrics And Gynecology ,KLES Hospital and MRC,Belgaum.

If you have any queries about your rights as a study subject , you may call Dr.Ganga Pilli , Prof of Pathology as Chairperson of J.N.Medical College Institutional Ethics Committee on Human Subjects Research, Phone No.0831 2473777 ext-1527 at J.N.Medical College,Belgaum or phone number:9480275601.

CONSENT STATEMENT

I, _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read form in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print of Subject: _____

Witness Name: _____ Signature: _____

Investigators Name : _____ Signature: _____

Date: _____

Place: _____

Principle Investigator:

Dr.
Post Graduate Student,
Department of Obstetrics and Gynecology,
J. N. Medical College,
K.L.E. University,
Belgaum 590010

Guide:

DR.

PROFESSOR,

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY,

J.N.MEDICAL COLLEGE, BELGAUM-590010

ANNEXURE I – PROFORMA

SCREENING FORM

COMPARATIVE STUYD OF INTRACERVICAL DINOPROSTONE GEL AND VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR

ONE YEAR RANDOMISED CONTROL TRIAL AT TERTIARY CARE CENTRE, BELGAVI

SL NO…….

Date……..Time.

OP NO……..

IP NO……..

Patient's Name…….

Age……..

Previous LSCS

Yes

No

Multiple Pregnancy

Ante Partum Haemorrhage

Abruption

Placenta previa

Informed consent

Yes

No

Eligible for study

Yes

No

DATA COLLECTION INSTRUMENT

COMPARATIVE STUYD OF INTRACERVICAL DINOPROSTONE GEL AND VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR

ONE YEAR RANDOMISED CONTROL TRIAL AT TERTIARY CARE CENTRE, BELGAVI

Obstetric History

G__P__L__A__

Menstrual history

LMP:_____

EDD:_____ USG EDD:_____

Period of Gestation:_____

Pre Delivery Diagnosis:

Post delivery diagnosis:

Induction using randomized group:

Randomization no:

Time of randomization

a. intracervical dinoprostone gel
b. vaginal misoprostol

Augmentation with oxytocin : yes/no

Results of bishop‘s score:

- PG Induction-cervical ripening time interval:_____
- PG induction-active labor time interval:_____
- PG induction delivery time interval:_____

Mode of Delivery:

Vaginal:_____

Ventouse:_____

Forceps:_____

C-Section:_____

Indication:_____

Fetal outcome:

MSB/FSB/LIVE BIRTH_____

Date of delivery:_____

Time of delivery:_____

Birth weight:_____Sex:_____

Apgar Score: 1min:_____

5 mins:_____

Meconium Stained liquor: YES/NO_____

NICU Admission:_____

Reason of NICU Admission:_____

Condition at the time of discharge_____

Date of discharge:_____

Maternal complications:

Shivering: YES/No_____

Uterine Hyperstimulation:Yes/No_____

Nausea/Vomiting_____

Diarrhea_____

Bishop's Score will be assessed after each induction

Date	Preinduction bishop's score	After 1st dose	After 2nd dose	After 3rd dose	After 4th dose	After 5th dose	After 6th dose	Time and date of delivery
Cervical Dilation (cm)								
Cervical length (cm)								
Station								
Consistency								
Position								
Bishop's Score								
No of doses of dinoprostone gel								
No of doses of vaginal misoprostol								

S.N.	Q1	Q2	Q3	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16A	Q16B	Q17	Q18	Q19	Q20	Q21	Q23
1	829295	28	1	P	40	4	1	2	1	6	15HRS	19HRS	3	3	3.1KGS	7(8)	2	2	1		1	1CP
2	829280	19	1	P	37	2	1	1	1	5=6=7	14HRS	16.5	5	3	2.7KGS	7(8)	2	2	1		2;4	3CP
3	827993	25	1	P	38	0	1	1	1	8=10	6	12	5	3	3	7(8)	2	2	1		1	2CP
4	829310	22	1	P	41	5	1	1	1	12	18HRS	19.5HRS	7	3	2.4KGS	7(8)	1	1	4		4	1CP
5	820789	23	1	P	40	2	1	1	1	5=10	15HRS	18HRS	5	3	2.6KGS	7(8)	2	2	1		1	2CP
6	821623	23	1	3	41	0	1	1	1	7	4HRS	8HRS	3	3	2.4KGS	7(8)	2	2	1		2;4	1CP
7	821826	24	1	2	39	3	1	1	1	6	4HRS	5HRS	3	3	2.6KGS	7(8)	2	2	1		1	1CP
8	823955	21	1	P	37	0	2	1	1	4=8=8	12HRS	15.5HRS	5	3	2.2KGS	8(9)	1	1	5		2;5	3CT
9	823913	26	1	2	41	0	1	1	1	7	8HRS	10HRS	1	3	2.8KGS	7(8)	2	2	1		1	1CP
10	823632	19	1	P	37	2	1	1	1	5=12	7HRS	9HRS	6	3	2.1KGS	8(9)	1	1	5		4	2CP
11	821054	26	1	P	41	1	2	2	4	3=6=6=6=6=6	F		1	3	2.6KGS	7(8)	2	2	1	1	2;4	6CT
12	819637	25	1	P	36	0	2	1	4	5=5=5=5=5=5	F		3	3	2.3KGS	8(9)	1	1	5	1	1	6CT
13	827028	23	1	P	39	2	1	1	4	5=9	16HRS		3	3	3.1KGS	7(8)	2	2	1	6	4;5	2CP
14	826688	21	1	2	40	4	1	1	1	8=10	14.5HRS	20.5HRS	6	3	3.2KGS	8(9)	2	2	1		2	2CP
15	827031	24	1	3	40	4	2	1	4	6=8=10=10	F		8	3	3.1KGS	7(8)	2	2	1	2	2	4CT
16	827857	20	1	P	40	4	2	1	4	6=6=8	12HRS		3	3	2.8KGS	8(9)	1	1	3	3	4	3CT
18	827331	24	1	2	41	0	1	1	4	6=6=10	18HRS		8	3	3.1KGS	7(8)	2	2	1	5	4;5	3CP
20	806506	22	1	3	39	1	1	2	4	2=2	F		3	3	2.9KGS	8(9)	2	2	1	4	1	2CP
21	823970	23	1	P	37	1	2	1	1	8=10	7HRS	10.5HRS	3	3	2.4KGS	6(7)	1	1	5		5	2CT
22	823878	21	1	P	41	0	2	2	1	2=7=8=8	12HRS	14HRS	6	3	2.6KGS	8(9)	1	1	4		2;4	4CT
23	832500	19	1	P	41	0	1	2	4	2	F		2	3	2.4KGS	8(9)	1	1	5	2	2;4	1CP
24	832587	25	1	P	40	2	1	1	4	5	9.5HRS	F	2	3	2.8KGS	7(8)	1	1	3	2	2	1CP
25	806509	21	1	P	40	5	1	1	1	12	6HRS	7.5HRS	2	3	2.7KGS	7(8)	1	1	4		4	1CP
26	823854	23	1	P	38	2	2	1	1	5=8	6HRS	12HRS	2	3	2.7KGS	7(8)	1	1	4		2;4;5	2CT
27	804536	22	1	P	40	2	1	2	4	2=2=2	F		2	3	2.3KGS	8(9)	1	1	5	1	2	3CP
28	804837	24	1	P	36	3	2	1	4	3=3=4=4=4=4	F		3	3	2.6KGS	7(8)	1	1	5	1	2	6CT
29	827308	28	1	P	40	5	2	1	4	5=5=5=5=5	F		2	3	2.4KGS	8(9)	2	2	1	1	4	4CT
30	823307	19	1	P	41		2	1	1		16HRS	17.5HRS		3	2.5KGS	7(8)	2	2	1		4	3CT
32	804953	19	1	P	40	0	2	2	1	6=8	6HRS	8.5HRS	2	3	3KGS	7(8)	1	1	1		2,4	2CT
33	829546	33	1	P	38	3	2	1	1	4=10	6HRS	7HRS	3	3	2.8KGS	7(8)	2	2	1		2,4	2CT
34	820789	23	1	P	40	0	2	2	4	5=5=5=5=5=5	F		5	3	2.6KGS	7(8)	2	2	1	1	2	6CT
35	826751	25	1	P	39	0	1	1	4	5=5=9	F		6	3	3KGS	7(8)	2	2	1	6	4	3CP
36	804269	29	1	P	40	0	1	1	4	3=4=8	20HRS		2	3	3.5KGS	7(8)	2	2	1	4	2	3CP
38	821706	28	1	P	41	0	2	1	1	3=4=8	12HRS	14HRS	4	3	2.8KGS	7(8)	2	2	1		4	3CT
39	821617	23	1	P	40	0	2	1	1	6=8	4HRS	5HRS	2	3	2.8KGS	7(8)	2	2	1		2,4	2CT
40	821201	29	1	P	38	3	2	2	4	9=9=10=10=10=10	F		6	3	2.5KGS	8(9)	2	2	1	2	1	6CT
41	823874	24	1	P	41	2	1	2	4	6=9	11.5HRS		4	3	3.5KGS	7(8)	2	2	1	2	4	2CP
42	832582	22	1	P	40	5	2	2	4	5	F		1	3	3.6KGS	8(9)	1	1	4	2	2	1CT
43	832585	20	1	P	40	2	2	1	1	4=5	8HRS	9.5HRS	2	3	2.7KGS	7(8)	2	2	1		4	2CT
44	832599	25	1	P	41	2	2	1	1	5=9=10	9HRS	11.5HRS	4	3	2.9KGS	8(9)	2	2	1		4	3CT
45	832596	20	1	P	41	1	2	2	4	2	F		4	3	2.6KGS	7(8)	1	1	2	2	3,4	1CT
46	832594	19	1	P	41	2	1	1	1	6=11	15.5HRS	16.5HRS	4	3	2.9KGS	8(9)	2	1	4		1	2CP
47	828343	22	1	P	37	1	1	2	4	5=5=5	F		3	3	3KGS	7(8)	2	2	1	1	4	3CP
48	823603	20	1	P	38	1	1	1	1	6	7HRS	10HRS	2	3	2.9KGS	8(9)	2	2	1		1	1CP

S.N.	Q1	Q2	Q3	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16A	Q16B	Q17	Q18	Q19	Q20	Q21	Q23
49	832733	20	1	P	39	2	1	1	1	10	5HRS	6HRS	2	3	2.6KGS	7(8)	2	2	1		4,5	1CP
50	832215	26	1	P	41	1	1	1	1	8	8HRS	10.5HRS	7	3	2.8KGS	7(8)	2	2	1		4	1CP
52	831836	26	1	P	39	0	1	1	1	2=4=4	22HRS	29.5HRS	3	3	2.6KGS	8(9)	2	2	1		4	3CP
53	832300	23	1	P	39		1	2	1		4HRS	6HRS		3	2.8KGS	6(7)	2	2	1		4,5	1CP
54	830670	31	1	P	40	1	2	1	4	3=5=6=6=6=6	F		3	3	3KGS	8(9)	2	2	1	1	2,4	6CT
55	832312	25	1	P	40	1	1	1	1	9	1HR	3.5HRS	5	3	2.4KGS	8(9)	1	1	3		1	1CP
56	829965	20	1	P	40	4	1	2	4	6=6=6	F		3	3	3.1KGS	7(8)	2	2	1	1	2,4	3CP
57	830328	22	1	P	40	4	1	1	1	6=9	7HRS	8.5HRS	5	3	3KGS	7(8)	2	2	1		1	2CP
58	829592	20	1	p	40	3	1	1	1	6=9	7.5HRS	10HRS	3	3	3KGS	7(8)	2	1	4		4	2CP
59	830386	20	1	P	40	3	2	1	1	7	3HRS	4HRS	2	3	2.6KGS	8(9)	2	2	1		1	1CT
61	830150	25	1	P	39	4	2	1	1	7=10	4HRS	7.5HRS	5	3	2.5KGS	8(9)	2	2	1		2;4	2CT
62	830394	22	1	P	40	4	2	2	4	4	F		2	3	2.7KGS	7(8)	1	1	3	2	2;4	1CT
63	829859	23	1	P	39	4	2	2	4	4=6=6=6=6=6	F		5	3	2.7KGS	7(8)	1	2	1	5	2;4	6CT
64	830181	20	1	P	39	4	2	2	1	5=8	8HRS	12HRS	5	3	2.1KGS	7(8)	2	1	5		4	2CT
65	831615	23	1	P	37	3	2	1	1	4=9	8HRS	11HRS	2	3	2.3KGS	7(8)	2	1	5		2;4	2CT
67	830767	23	1	P	34	0	2	1	4	5=5=5=5=5=5	F		3	3	1.6KGS	7(8)	2	1	5	2	4	6CT
68	831303	29	1	P	38	1	1	2	4	1=3=3	F		3	3	2.4KGS	7(8)	2	1	5	2	1	3CP
69	831595	22	1	P	40	2	2	2	2	4=5=7=8=8=10	18HRS	22.5HRS	3	3	3KGS	7(8)	1	1	3		4	6CT
70	830670	31	1	P	40	2	2	1	4	3=5=6=6=6=6	F		3	3	3KGS	7(8)	2	2	1	1	4	6CT
71	832695	21	1	2	40	3	1	1	1	10	3	4	1	3	2.4KGS	8(9)	2	2	1		4	1CP
72	833923	25	1	P	39	4	2	2	4	5=8=11=11=11=12	12		2	3	2.7KGS	7(8)	2	2	1	2	2	6CT
73	832401	24	1	2	41	2	1	1	1	6=10=11	4	9	4	3	2.9KGS	8(9)	2	2	1		2,4	3CP
74	832439	24	1	P	37	0	2	1	1	4=6=10	12	15	1	3	2.9KGS	7(8)	2	2	1		2,4	3CT
75	828343	22	1	P	37	0	1	2	4	5=5=5			3	3	3 KGS	8(9)	2	2	1	1	4	3CP
76	833112	23	1	2	39	4	2	2	1	4=7=8=8=11	13	18	2	3	2.9KGS	7(8)	2	2	1		4	5CT
78	852795	21	1	P	40	1	2	1	1	7=12	7	13	3	3	2.8KGS	7(8)	2	2	1		2,4	2CT
81	833564	21	1	2	38	4	1	1	4	4=12	6		3	3	3KGS	7(8)	1	2	1	4	4	2CP
82	834257	24	1	2	37	0	2	1	1	7=10=11	8	11	3	3	2.8KGS	7(8)	1	2	1		1	3CT
83	853042	27	1	3	39	0	1	1	1	3=7=12	18	23	2	3	3.4KGS	8(9)	2	2	1		4	3CP
84	853604	23	1	P	39	3	2	1	1	8=11	12	13	7	3	2.8KGS	6(7)	2	2	1		1	2CT
85	853395	22	1	P	39	3	1	1	1	11	6	8	1	3	2.6KGS	8(9)	2	2	1		4	1CP
86	852095	24	1	P	39	4	2	1	2	10	2	5	3	3	3.5KGS	8(9)	2	1	2		2	1CT
87	852096	23	1	2	40	3	1	2	4	7=7=7			2	3	3.2KGS	7(8)	2	2	1	2	4	3CP
88	853394	21	1	2	39	4	2	1	1	7=11	12	17	2	3	2.7KGS	7(8)	2	2	1		4	2CT
89	852795	21	1	P	40	0	1	1	1	8	6	12	2	3	2.8KGS	7(8)	2	2	1		1	1CP
90	853613	25	1	2	38	4	2	1	1	7=9=11	12	15	3	3	3.2KGS	8(9)	2	2	1		1	3CT
91	852376	22	1	P	38	2	1	2	4	4=4			7	3	2.2KGS	7(8)	1	1	2,5	2	4	2CP
92	852549	29	1	P	40	0	2	1	1	5=8=8=10	13	18	3	3	2.4KGS	8(9)	2	2	1		4	4CT
93	852464	22	1	P	40	4	1	2	4	7			3	3	2.6KGS	7(8)	2	2	1	2	2	1CP
94	851649	19	1	P	39	3	2	1	1	5=9=11	12	17	1	3	3KGS	7(8)	2	1	4		1	3CT
95	852729	27	1	3	40	1	1	1	1	4=8	9	13	1	3	3.1KGS	7(8)	2	2	1		1	2CP
96	851807	25	1	P	38	0	2	1	3	0=7	5	6	2	3	3KGS	7(8)	2	1	4		1	2CT
97	851639	20	1	P	38	4	1	1	1	8	9	10	5	3	2.4KGS	7(8)	2	2	1		1	1CP
98	851942	23	1	P	40	0	2	2	4	7=9=9			3	3	2.9KGS	7(8)	2	2	1	3	4	3CT

S.N.	Q1	Q2	Q3	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16A	Q16B	Q17	Q18	Q19	Q20	Q21	Q23
99	804290	23	1	P	39	2	1	1	1	4=8	9	15	2	3	3.2KGS	7(8)	2	2	1		4	2CP
100	851959	19	1	P	41	5	2	2	4	7			5	3	2.1KGS	7(8)	2	1	3	3	4	1CT
101	852105	21	1	P	38	4	1	1	4	11	4		2	3	2.4KGS	7(8)	1	1	3	2	4	1CP
102	846739	28	1	P	40	4	2	1	2	8=10=13	9	10	3	3	3.4KGS	7(8)	2	2	1		1	3CT
103	851951	24	1	3	38	3	1	1	1	10	4	6	3	3	2.8KGS	7(8)	2	2	1		1	1CP
104	843861	33	1	3	40	3	2	1	1	10=12	7	10	1	3	3KGS	7(8)	2	2	1		1	2CT
105	852149	22	1	P	40	0	1	2	1	7=8	10	14	7	3	2.4KGS	7(8)	2	2	1		1	2CP
106	852176	24	1	P	40	5	2	2	4	7=8			3	3	2.9KGS	7(8)	1	2	1	2	4	2CT
107	856787	22	1	P	40	4	1	1	1	12	6	8	1	3	2.4KGS	7(8)	2	2	1		1	1CP
108	852874	21	1	P	40	3	2	1	3	7=11	8	11	3	3	2.5KGS	7(8)	1	1	2		1	2CT
109	852548	26	1	P	40	0	1	1	4	12	12		3	3	2.8KGS	7(8)	2	1	4	3	4	1CP
110	852957	21	1	P	40	3	2	1	1	8=10	9	12	5	3	2.4KGS	8(9)	2	2	1		4	2CT
111	833930	28	1	3	41	3	1	2	4	3			4	3	3.1KGS	7(8)	1	1	3	2	2	1CP
112	853109	23	1	2	40	3	2	1	1	7=12	8	10	3	3	3.2KGS	8(9)	2	2	1		2	2CT
113	851173	27	1	2	40	4	1	1	1	9	5	10	3	3	3.1KGS	7(8)	2	2	1		1	1CP
114	853719	21	1	p	40	5	2	1	1	10=11	8	13	3	3	3.4KGS	8(9)	2	2	1		2,4	2CT
115	848727	33	1	P	40	3	1	1	4	6=7=9	12		6	3	3.6KGS	7(8)	2	2	1	5	1	3CP
117	849478	20	1	P	39	0	1	2	4	2			1	3	2.8KGS	7(8)	2	2	1	4	2	1CP
118	856609	24	1	P	41	3	2	1	1	8=8	12	13	4	3	2.8KGS	7(8)	2	2	1		4	2CT
119	849692	26	1	P	37	4	1	1	1	12	6	14	1	3	3.1KGS	7(8)	2	2	1		1	1CP
120	856260	23	1	P	38	0	2	2	4	3=3=3=3=3=3			3	3	2.6KGS	7(8)	2	2	1	1	4	6CT
121	849131	25	1	P	39	3	1	1	1	11	7	10	3	3	2.4KGS	7(8)	2	2	1		1	1CP
122	807245	22	1	P	39	0	2	1	1	0=3=3=3=10=10	26	28	6	3	2.8KGS	7(8)	2	2	1		4	6CT
123	848801	19	1	P	36	2	1	2	4	3=3=3			3	3	1.8KGS	7(8)	2	1	5	1	1	3CP
125	854410	20	1	P	39	4	1	1	1	4=7	12	15	1	3	2.6KGS	7(8)	2	2	1		1	2CP
127	854942	20	1	P	37	5	1	1	1	12	5	7	3	3	2.4KGS	7(8)	2	2	1		1	1CP
128	856218	22	1	P	40	5	2	1	2	8=11	8	12	3	3	2.9KGS	8(9)	2	2	1		1	2CT
129	854034	24	1	p	38	0	1	2	4	4=5			1	3	2.5KGS	7(8)	1	1	3	2	4	2Cp
130	849308	20	1	P	38	0	2	1	1	5=6=10	12	17	1	3	2.4KGS	8(9)	2	1	4		2,4	3CT
131	854383	21	1	P	38	5	1	1	1	12	6	8	3	3	2.8KGS	7(8)	2	2	1		1	1Cp
132	854360	19	1	P	38	3	2	2	4	8			3	3	2.5KGS	8(9)	1	2	1	3	2,4	1CT
133	854688	27	1	P	37	3	1	1	1	3=5=8	8	10	2	3	2.4KGS	7(8)	2	2	1		1	3CP
134	874741	20	1	p	37	4	2	1	4	5=5=8	3		2	3	2.4KGS	7(8)	2	2	1	1	1	3CT
136	854290	21	1	P	40	0	2	1	4	0			6	3	2.3KGS	8(9)	2	1	5	1	4	6CT
137	846351	21	1	P	40	3	1	1	1	9	8	14	3	3	2.5KGS	6(7)	2	2	1		4	1CP
138	854711	28	1	2	40	4	2	2	4	4=5	17		3	3	2.8KGS	8(9)	1	2	1	3	2	2CT
139	846950	30	1	3	37	4	1	1	1	9	6	8	7	3	2.6	8(9)	2	1	4		1	1CP
140	847954	23	1	2	39	4	2	1	1	5=10	8	11	2	3	2.7KGS	7(8)	2	2	1		4	2CT
141	854683	30	1	P	40 -	3	1	1	4	3=3			2	3	2.7KGS	7(8)	1	1	3	3	4	2CP
142	856219	19	1	P	40	3	2	1	1	10	6	7	5	3	2.5KGS	7(8)	2	2	1		1	1CT
143	846832	27	1	2	40	2	1	2	4	3			1	3	2.7KGS	8(9)	2	2	1	2	4	1CP
144	847796	23	1	P	38	4	2	2	4	4=4=4=4=4=4			3	3	2.8KGS	7(8)	2	2	1	1	1	6CT
145	846658	19	1	P	39	1	1	1	1	8=9	8	12	3	3	2.9KGS	8(9)	2	2	1		1	2CP
146	854993	20	1	P	36	0	2	2	4	0			7	3	1.7KGS	7(8)	2	1	5	1	1	6CT

S.N.	Q1	Q2	Q3	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16A	Q16B	Q17	Q18	Q19	Q20	Q21	Q23
147	844961	34	1	2	37	0	1	1	4	2=2			1	3	2.6KGS	7(8)	1	2	1	2	1	2CP
149	839677	25	1	P	39	3	1	1	1	10=12	12	15	3	3	2.6KGS	7(8)	2	2	1		1	1CT
151	856191	24	1	P	39	5	1	2	4	5=5			3	3	3.07KGS	7(8)	1	1	2	2	1	2CP
152	850701	23	1	P	40	4	2	1	1	6=10	8	11	3	3	2.5KGS	7(8)	2	2	1		1	2CT
155	849469	23	1	2	40	2	1	1	1	11	6	10	5	3	2.8KGS	7(8)	2	2	1		4	1CP
156	849677	23	1	2	40	2	2	1	1	4=6=10	12	16	3	3	2.8	8(9)	2	2	1		1	3CT
157	845615	22	1	2	40	3	1	1	1	9	6	11	3	3	2.5KGS	7(8)	2	2	1		1	1CP
158	849519	30	1	2	37	3	2	1	1	5=10=11	12	24	3	3	2.9KGS	8(9)	2	2	1		1	3CT
159	845184	25	1	P	37	0	1	1	1	7	6	10	3	3	2.6	7(8)	2	2	1		1	1Cp

S.N.	Q1	Q2	Q3	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16A	Q16B	Q17	Q18	Q19	Q20	Q21	Q23
160	845719	24	1	P	40	2	2	1	1	10	6	8	1	3	2.4	8(9)	2	1	4		1	1CP
162	833311	23	1	P	38	4	2	1	4	6=9=9	7		2	3	2.4	8(9)	1	1	2	5	4	3CT
163	849369	26	1	P	39	3	1	1	2	10	6	10	3	3	2.8	7(8)	2	2	1		4	1CP
164	849369	26	1	P	39	3	2	1	1	11	5	8	1	3	2.8	8(9)	2	1	4		2	1CT
165	843225	22	1	P	39	2	1	1	1	10=12	12	14	7	3	1.9	7(8)	2	1	5		4	2CP
166	834748	24	1	2	40	3	2	1	1	5=8=10	2	6	1	3	3	7(8)	2	2	1		1	3CT
167	832547	28	1	2	40	3	1	1	1	10	6	8	4	3	2.8	7(8)	2	2	1		1	1CP
168	860272	22	1	P	40	3	2	2	1	4=6=11	12	13	3	3	1.9	8(9)	2	1	45		24	3CT
169	832900	21	1	P	38	4	1	1	1	8=11=12	4	6	1	3	2.4	6(7)	2	2	1		4	3CP
170	861600	22	1	P	38	4	2	1	1	7=7=9=10	15	17	5	3	2.4	8(9)	2	2	1		4	4CT
172	861963	25	1	2	38	4	2	1	1	5=6=8	10	12	2	3	3	7(8)	2	2	1		1	3CT
173	861719	20	1	P	39	0	1	1	4	5			7	3	2.3	7(8)	2	1	5	1	1	6CT
175	857130	19	1	P	37	0	1	1	1	4=10	13	14	3	3	3	8(9)	2	2	1		1	2CP
177	855957	20	1	2	37	0	1	1	1	5=11	14	15	7	3	2.1	8(9)	2	1	5		4	2CP
178	842869	22	1	P	40	5	2	1	1	5=9	8	11	3	3	3.4	7(8)	2	2	1		1	2CT
179	834338	26	1	4	38	2	1	1	1	6=7=10	16	18	2	3	2.6	7(8)	2	2	1		1	3CP
180	843070	28	1	P	40	4	2	1	1	4=4=4=4=6=8	27	30	3	3	2.8	7(8)	2	2	1		24	6CT
182	846036	27	1	P	40	3	2	1	1	3=4=10	11	12	3	3	2.8	8 (9)	2	2	1		4	3CT
184	879063	20	1	P	36	3	2	1	1	3=4=5=7=7=11	8	14	5	3	1.9	6(7)	2	1	5		4	6CT
185	856234	21	1	P	39	5	1	1	1	11	4	5	3	3	2.4	7(8)	2	2	1		1	1CP
186	879050	28	1	P	39	3	2	2	4	3=3=3=3=3=3				3	2.8	7(8)	2	2	1	1	4	6CT
187	879014	34	1	2	38	5	1	1	1	5	6	7	5	3	2.2	7(8)	2	2	1		1	1CP
188	877068	25	1	P	40	4	2	1	1	7=10=12	12	12.5	2	3	3	7(8)	2	2	1		1	3CT
189	856296	19	1	P	40	5	1	1	1	10	10	12	1	3	2.3	7(8)	2	2	1		1	1CP
190	875039	20	1	P	40	5	2	1	4	5=6=6=6=6=9	24		6	3	3.4	7(8)	2	2	1	2	1	6CT
192	874003	29	1	P	39	3	2	2	4	3=3=3=3=3=3			7	3	2.9	7(8)	2	1	4	1	4	6CT
193	855907	22	1	P	39	4	1	1	1	6	6	8.5	3	3	2.7	7(8)	2	2	1		1	1CP
194	874723	26	1	P	40	5	2	1	1	5=11	9	10	3	3	2.8	7(8)	2	2	1		1	2CT
195	849158	28	1	P	39	0	1	1	1	10	8	10	2	3	2.3	7(8)	1	1	5		5	1CP
196	874548	26	1	P	39	3	2	1	1	5=12	10	12.5	2	3	2.8	7(8)	2	2	1		1	2CT
197	833771	23	1	P	39	0	1	1	1	5=5=10	24	32	3	3	3.2	7(8)	2	2	1		1	3CP
198	878199	21	1	P	40	5	2	1	1	12	4	7	2	3	3.2	7(8)	2	2	1		1	1CT
200	879378	23	1	2	39	4	2	1	1	5=10	8	12	1	3	3.3	7(8)	1	2	1		1	2CT
201	847629	23	1	P	37	0	1	1	1	3=6	12	14	1	3	2.5	8(9)	2	2	1		1	2CP
202	879050	23	1	P	39	2	2	1	1	6=10	6	9	3	3	2.7	8 (9)	2	2	1		1	2CT
203	879556	25	1	P	38	2	1	1	1	11	4	9	2	3	2.9KGS	7(8)	2	2	1		2	1CP
204	879565	22	1	P	39	4	2	1	1	5=9=10=12	6	11	3	3	2.7KGS	6(7)	2	2	1		1	4CT
205	879581	21	1	P	39	3	1	1	1	4=7=10	10	12	2	3	2.5KGS	7(8)	2	2	1		1	3CP
207	843839	23	1	P	40	3	1	1	1	10	11	23	7	3	2.5	7(8)	2	2	1		1	1CP
208	874652	23	1	P	40	4	2	1	1	7=9=12	8	10	2	3	2.8	7(8)	2	2	1		4	3CT
209	846429	22	1	P	38	0	1	2	4	0			2	3	2.1	7(8)	2	1	5	1	4	3CP
210	879251	25	1	P	40	2	2	1	4	5=5=9=9=11	17		2	3	2.6	7(8)	1	2	1	3	1	5CT
211	848078	20	1	P	40	0	1	1	1	5=12	10	15	5	3	2.4	7(8)	2	2	1		1	2CP
212	876590	25	1	P	41	4	2	1	4	10=10=12	10	12	8	3	2.9	7(8)	1	2	1	2	1	3CT

S.N.	Q1	Q2	Q3	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16A	Q16B	Q17	Q18	Q19	Q20	Q21	Q23
213	831618	21	1	2	40	2	1	1	1	12	3	4	3	3	2.7	7(8)	1	2	1		24	1CP
214	876046	24	1	P	40	5	2	1	4	5=9=12	12	15	3	3	2.8	7(8)	1	1	3	3	1	3CT
215	833771	23	1	P	39	0	1	1	1	5=12	8	12	3	3	2.4	8(9)	2	2	1		1	2CP
216	874620	23	1	P	40	2	2	1	4	7=7=12			7	3	3.1	7(8)	1	2	1	2	1	3CT
217	879378	27	1	2	39	0	1	1	1	4=12	10	12	1	3	2.8	8(9)	2	2	1		1	2CP
218	875894	21	1	P	41	4	2	1	2	5=10	10	12	8	3	2.8	7(8)	2	2	1		24	2CT
219	890189	23	1	P	37	4	1	1	2	12	6	8	3	3	2.7	8(9)	2	2	1		1	1CP
220	882330	22	1	P	38	5	2	1	1	6=8=8=9=12	9	10	3	3	2.4	7(8)	2	2	1		1	5CT
221	890608	19	1	P	40	2	1	1	1	2=11	10	12	1	3	3.4	8(9)	2	2	1		1	2CP
222	889909	26	1	P	40	3	2	2	4	3			1	3	2.5	7(8)	2	1	1	2	1	1CT
223	890515	20	1	P	38	4	1	1	1	12	6	7.5	2	3	2.5	8(9)	2	2	1		4	1CP
224	882323	21	1	P	40	4	2	1	1	4=5=8=12	16	18	5	3	2.6	7(8)	2	2	1		1	4CT
226	876715	24	1	3	38	3	2	1	1	4=12	8	13	3	3	3	7(8)	2	2	1		1	2CT
227	890794	26	1	2	39	2	1	1	1	12	6	7	2	3	2.8	8(9)	2	2	1		1	1CP
228	880274	19	1	P	39	4	2	1	2	5=10	6	8	1	3	2.8	6(7)	1	1	3		1	2CT
229	890236	23	1	P	40	2	1	2	1	2=10	12	15	5	3	2.6	8(9)	2	2	1		1	2CP
230	886212	25	1	2	38	0	2	1	1	4=8=12	12	15	5	3	2.6	8(9)	2	2	1		1	3CT
231	884577	22	1	P	39	2	1	1	1	6=8=10	6	14	3	3	2.9	7(8)	2	2	1		1	3CP
232	884719	21	1	P	40	2	2	1	1	2=6=12	12	16.5	5	3	2.4	7(8)	2	2	1		1	3CT
233	890482	25	1	P	39	4	1	1	1	4=12	12	14	7	3	2.7	7(8)	2	2	1		1	2CP
234	880436	19	1	P	39	5	2	1	1	5=8=12	8	13	2	3	2.5	8(9)	1	1	3		1	3CT
235	890281	31	1	2	38	0	1	1	1	4=11	12	14	1	3	3	7(8)	2	2	1		1	2CP
236	877068	25	1	P	40	4	2	1	3	4=7=10	12	15	2	3	3	8(9)	2	2	1		1	3CT
237	890273	23	1	P	38	3	1	1	1	11	6	7	6	3	2.7	7(8)	2	2	1		1	1CP
238	879591	25	1			3	2	1	1	8=12	8	12	3	3	2.9KGS	7(8)	2	2	1		1	2CT
239	890486	21	1	P	38	4	1	1	1	12	6	7	1	3	2.4	7(8)	2	2	1		1	1CP
240	881750	22	1	2	40	5	2	1	1	6=9	8	9	2	3	3.2	8(9)	2	2	1		1	2CT
241	880602	24	1	2	40	4	1	1	1	8	4	7	2	3	3.1	8(9)	2	2	1		1	1CP
242	881740	28	1	2	36	4	2	1	1	6=6=12	12	14	7	3	2.1	7(8)	2	2	1		1	3CT
243	884892	25	1	P	37	4	1	1	1	9=11	9	12	3	3	2.4	7(8)	2	2	1		1	2CP
244	887667	25	1	2	38	5	2	1	1	12	4	8	3	3	2.9	8(9)	2	2	1		1	1CT
247	889658	22	1	P	40	4	1	1	1	10	9	12	1	3	2.3	7(8)	2	1	4		1	1CP
250	885083	21	1	P	39	4	2	1	1	12	4	7	3	3	2.7	8(9)	2	2	1		24	1CT
251	883977	23	1	3	38	2	1	2	4	2			7	3	2.6	8(9)	2	2	1	2	1	1CP
254	882336	34	1	2	38	5	2	1	1	5=8=12	12	15	3	3	2.6	8(9)	2	2	1		1	3CT
255	879583	24	1	2	39	4	1	2	2	7=10	12	15	2	3	2.1	7(8)	2	1	4		1	2CP
256	884217	20	1	2	36	5	2	1	1	6=10	12	16	3	3	2.6	7(8)	2	2	1		1	2CT
257	883980	26	1	P	40	5	1	1	1	5=12	9	10	3	3	2.6	7(8)	2	2	1		1	2CP
258	886600	20	1	3	37	4	2	2	1	4=4=12	10	12	3	3	3.3	7(8)	2	2	1		1	3CT
260	889918	21	1	P	39	3	2	1	4	3=3			5	3	2.1	7(8)	2	2	1	2	1	2CT
261	883976	19	1	P	41	3	1	1	1	12	6	8	8	3	3.2	8(9)	2	1	4		4	1CP
262	883388	29	1	P	39	5	2	1	4	7=7=7=7=7=7			1	3	3.2	8(9)	2	2	1	1	1	6CT
263	889622	23	1	P	39	3	1	2	4	3=3=3			1	3	3	7(8)	1	2	1	1	1	3CP
264	884489	26	1	2	40	3	2	1	1	4=12	8	9	2	3	2.8	8(9)	2	2	1		1	2CT

S.N.	Q1	Q2	Q3	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16A	Q16B	Q17	Q18	Q19	Q20	Q21	Q23
265	816312	19	1	P	40	2	1	1	1	4=8=11	13	18	1	3	2.9	8 (9)	2	2	1		1	3CP
266	884500	25	1	2	38	2	2	2	1	2=12	5	8	5	3	2.1	7(8)	2	2	1		1	2CT
267	882273	21	1	2	40	2	1	1	1	6=12	8	11	3	3	2.6	8(9)	2	2	1		1	2CP
268	882323	21	1	P	40	4	2	1	4	4=4=4=4=4=4			5	3	2.6	8(9)	2	2	1	1	1	6CT
269	882960	22	1	2	36	0	1	1	1	2=10	8	13	3	3	2	7(8)	2	1	5		4	2CP
270	882159	23	1	2	40	4	2	1	2	4=6=12	12	14	3	3	3.3	7(8)	2	2	1		1	3CT
271	881897	24	1	2	37	5	1	1	1	12	6	10	5	3	2	6(7)	2	1	5		4	1Cp
272	885456	28	1	4	40	3	2	1	1	12	3	8	5	3	2.3	8(9)	2	2	1		1	1CT
273	885703	18	1	P	39	3	1	1	1	5=9=12	13	17	5	3	2.8	7(8)	2	2	1		1	3CP
275	879769	25	1	P	37	0	1	2	4	3=6=6			1	3	2.8	8(9)	2	2	1	1	1	2CP
279	883978	25	1	P	39	0	1	2	1	4=12	12	15	3	3	3.2	7(8)	2	2	1		1	2CP