

To Study the Effect of Oligohydramnios on Maternal and Fetal Outcomes in 37 Weeks or More Gestation Period

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Abstract: Oligohydramnios is a threatening condition to maternal and fetal health. It is a clinical condition characterized by amniotic fluid index (AFI) of ≤ 5 cm by sonographic assessment. **Aim and objectives:** The aim of this study was to compare the maternal and fetal outcome in parturient women with oligohydramnios versus others with normal amniotic fluid, and to suggest plan of action in management of oligohydramnios women. **Study design:** Prospective comparative observational. **Methodology:** Antenatal women with gestational age 37 weeks and above and fulfilling inclusion criteria attending our Out Patient Department or Labour rooms were included in the present study. Detailed antenatal history including presence of high risk factors were elicited from the patients, then they were clinically examined and subjected to ultrasonography. purposive sample of 168 parturient women (84 study group and 84 control group) were taken. The tools used for data collection were; a structured interview sheet, maternal assessment sheet, Partogram, and neonatal assessment record. **Results:** The results of the present study revealed that the rate of Caesarian section was significantly higher in oligohydramnios group compared to the control group (44.0% vs. 30.0% respectively). There was significant increasing in FHR decelerations, low Apgar score at 5 min, low birth weight, admission to NICU. **Conclusion:** It can be concluded that an amniotic fluid index of ≤ 5 cm detected after 37 completed weeks of gestation is an indicator of poor perinatal outcome. It is recommended that determination of AFI through regular antenatal care visits can be used as an adjunct to other fetal surveillance methods to identify those infants at risk of poor perinatal outcome.

Abbreviations

Short form	Long form
AFI	Amniotic fluid index
FHR	Foetal heart rate
NICU	Neonatal intensive care unit
LSCS	Lower segment caesarean section
FTND	Full term normal delivery
PROM	Pre mature rupture of membrane
IUGR	Intra uterine growth retardation
NST	Non stress test
PIH	Pregnancy induced hypertension
SGA	Small for gestational age
AFV	Amniotic fluid volume
C/S	Caesarean section

1. Introduction

Amniotic fluid is a clear, a little yellowish liquid that surrounds the fetus during pregnancy. It is contained in the amniotic sac. While in the uterus, the fetus floats in the amniotic fluid. The amount of amniotic fluid is maximum at 34 weeks of gestation into the pregnancy, when it averages 800 mL. About 600 mL of amniotic fluid surrounds the fetus at 40 weeks of gestation. The amniotic fluid constantly moves as the fetus swallows "inhales" the fluid and then discharges it [1].

Amniotic fluid protect the fetus from infection, cushions umbilical cord, provide space, nutrients and hormones to help the fetus grow [2].

The amniotic fluid aids the developing fetus to move in the uterus, which allow for appropriate bone growth, the lungs to develop well, maintain a relatively stable temperature around the fetus, defends from and outside injury and heat loss by cushioning sudden blows or movements [1]. Amniotic fluid is an essential factor in the prophecy of fetal survival. Amniotic fluid acts as a defensive cushion for the fetus against the force exerted on the abdomen and prevent contact to the fetal membranes. In addition, the floating characteristics of amniotic fluid help the movement and symmetrical growth of the fetus [3]. During second half of pregnancy, amniotic fluid is made up of the fetus's urine and lung secretions. This fluid initially came from the mother then flowed through the placenta, to the fetus and excreat through the fetus's bladder [2].

Amiotic Fluid is primarily produced by fetal urine in the latter half of the pregnancy; therefor the absence or reduction of the fetal urine production or blockage in the urinary tract can result in oligohydramnios.(61) However, rupture of the membranes is the most common cause of oligohydramnios.

Oligohydramnios is where there is too little fluid surrounding the fetus in the uterus. This may take place

because the fetus is not thriving appropriately [5]. Decline in the amniotic fluid influences 1-5% of term pregnancies [3].

The majority physicians revealed that isolated oligohydramnios, or little amniotic fluid in an otherwise healthy pregnancy at term, was a risk factor for bad outcomes [2]. Oligohydramnios happen in 3rd trimester of pregnancy usually predict an increasing risk to the pregnancy [7]. Assessment of amniotic fluid pockets with ultrasound is a competent and reasonably reliable method of evaluating amniotic fluid volume and categorizing relative risk of perinatal morbidity. In pregnancies beyond 34 weeks, making use of amniotic fluid index to diagnose oligohydramnios can be expected to reliably identify fetuses at risk for compromised perinatal result [5].

Oligohydramnios, may place the fetus at major risk. In such cases, delivery is the optimal intervention [8]. Oligohydramnios influences the pregnancy result and the wellbeing of the fetus. Oligohydramnios, in the absence of pre-mature rupture of membranes and fetal anomalies, is considered as a symptom of chronic reduction in placental function, which results in reduction of fetal urinary output [3]. It may be related to uteroplacental insufficiency, viral diseases, cause the fetus to be not capable to turn into the head down position for the birth, or compression of the fetus's umbilical cord unidentified fetal growth restriction (FGR), premature rupture of the fetal membranes and/ or postmaturity syndrome and malpresentations [9].

Diminishing amniotic fluid volume has been associated with increased risk of severe birth asphyxia, intrauterine growth retardation, meconium aspiration syndrome, low APGAR scores and congenital anomalies [37]. Some cases of amniotic fluid decline are accompanied by urinary tract obstruction or renal agenesis, fetus growth disorders, chronic leaks from gaps in the fetal membrane and in 15-25% of cases fetal anomalies.

Fetal urinary tract anomalies, such as renal agenesis, polycystic kidneys, or any urinary obstructive lesion (eg, posterior urethral valves). Maternal problems, including placental vascular insufficiency, premature rupture of membranes or chronic leakage of amniotic fluid. The major maternal complication from this is chorioamnionitis. The incidence of this varies in the literature and has been reported anywhere from 21-74%. (62) The earlier this occurs in pregnancy causes increased risk to the fetus. Thus, increasing the risk of neurologic complications, pulmonary hypoplasia and in severe cases, respiratory failure. Maternal use of prostaglandin synthase inhibitors or angiotensin-converting enzyme (ACE) inhibitors. Postmaturity syndrome in infants when a pregnancy extend beyond 42-weeks.

Previous research has found that the consequences of reduced fluid index increased likelihood hazard of caesarean delivery because of fetal distress, diminish Apgar score to lower than seven in the fifth minute, hazard of stillbirth and non-reassuring heart rate, preterm labour, admission to the neonatal intensive care unit and meconium aspiration syndrome. fetal hypoxia may also happen as a consequence of umbilical cord prolapse caused by rupture of the water

sac, or because of cord compression caused by decrease amniotic fluid resulting in dropped fetal heart rate [3]. Oligohydramnios at term in the lack of maternal and fetal complications produce a problem in management. It is one of the major caution for antenatal surveillance and induction of labour [9].

Early detection of oligohydramnios and its management may aid in decreased perinatal morbidity and mortality on one side and reduce caesarean deliveries on the other side [37]. Best management of isolated oligohydramnios (IO) remains questionable. With a favorable cervix, 34% and 82% would consider suggesting labor without recognized lungs maturity prior to 37 and 39 weeks, respectively. When asked whether initiation of labor in cases of IO reduces perinatal morbidity, 45% were hesitant and 21.4% thought it would not. Only 33% believe bringing on could decrease bad outcomes. Practitioners were more likely to believe that induction is competent in declining morbidity [11].

Hofmeyr et al. [7] reported that pregnant women who drunk more water or had intravenous fluid dripped directly into their bloodstream (Both forms of maternal hydration) increased the volume of the fluid surrounding the fetus. In addition maternal hydration with isotonic solution or water improved the AF index in women with normohydramnios. In addition, hydration can enhance blood flow through the placenta and improve urination by the fetus. As a result, amniotic fluid levels may improve for a short time [12]. Maternal bed rest and hydration promote the production of amniotic fluid by increasing the production of amniotic fluid by increasing the maternal intravascular space [13].

The maternal position influences uterine and umbilical blood flow. The enlarging uterus compresses the inferior vena cava and the lower aorta and decreases cardiac output, resulting in a decrease in uterine and placental perfusion, particularly when the mother is in the supine position. at 36–38 weeks of gestation the maternal left lateral position, when compared with any other position, has the least disturbing effect on fetal hemodynamics. An increase in uterine and placental blood flow is likely the explanation for the increase in the amniotic fluid index and fetals urine production rate observed in study [20].

2. Aims & Objectives

Aim: Determination of effect of oligohydramnios on maternal and fetal outcomes.

Objectives:

To study effect of oligohydramnios on maternal outcomes namely:

- 1) Incidence of spontaneous labour & Induction of labour.
- 2) Incidence of vaginal delivery, instrumental delivery & Lscs

To study effect of oligohydramnios on fetal outcomes namely:

- 1) Birth weight <2.5 kg and ≥ 2.5 kg
- 2) foetal distress
- 3) NICU admission

3. Review of Literature

Oligohydramnios is a severe and common complication of pregnancy that is associated with a poor perinatal outcome.(41) Etiologies include congenital anomalies, premature rupture of membranes (PROM), intrauterine growth restriction (IUGR), postdatism, abruptio placentae, drugs, abnormality of twinning, significant maternal illness and idiopathic oligohydramnios. Sequelae from prolonged oligohydramnios including pulmonary hypoplasia and fetal compression syndrome can be devastating. Perinatal morbidity and mortality are both significantly increased in pregnancies complicated by oligohydramnios.(42)

Ultrasound detection of oligohydramnios should prompt the clinician to thoroughly evaluate the gravida for hypertension and other significant illness. In addition, a thorough fetal anatomic survey focusing on the genitourinary tract and attempt at visualization of free amniotic bands should be performed with ultrasound. Once diagnosed, oligohydramnios, with or without associated conditions should lead to intensive fetal biophysical surveillance including frequent ultrasound evaluation; delivery in the term patient must be considered. Ultrasound detection of oligohydramnios should prompt the clinician to thoroughly evaluate the gravida for hypertension and other significant illness. In addition, a thorough fetal anatomic survey focusing on the genitourinary tract and attempt at visualization of free amniotic bands should be performed with ultrasound. Karyotype should be considered. The role of amnioinfusion to assist in diagnosis should be considered. Once diagnosed, oligohydramnios, with or without associated conditions should lead to intensive fetal biophysical surveillance including frequent ultrasound evaluation; delivery in the term patient must be considered. The role of amnioinfusion as an adjunct to continuous fetal monitoring in labor to improve neonatal outcome appears beneficial in selected series.(63)

Magann EF1 et conducted a study to evaluate Peripartum outcomes of high-risk pregnancies complicated by oligo- and polyhydramnios. In high-risk pregnancies undergoing antenatal testing, the last amniotic fluid index (AFI) prior to delivery in pregnancies with polyhydramnios (>97.5th percentile) and oligohydramnios (<2.5th percentile) was correlated with pregnancy outcomes. There were 2597 pregnancies with a normal AFI (2.5th-97.5th percentile), 73 with hydramnios (AFI > 97.5th percentile) and 72 with oligohydramnios (<2.5th percentile). Polyhydramnios and oligohydramnios adversely influenced different pregnancy outcomes. Pregnancies with oligohydramnios versus normal AFI had a greater risk of labor induction (18% vs 9%, OR = 3.18, 95%CI 1.62-6.25, P = 0.001), intrauterine growth restriction (25% vs 9%, OR = 3.4, 95%CI 1.94-5.97, P < 0.001) and preterm delivery (29% vs 17%, OR = 1.97, 95%CI 1.17-3.31, P = 0.010). The fetuses of pregnancies complicated by oligohydramnios had a greater risk of labor induction, intrauterine growth restriction and preterm delivery. (29)

Manzanares S1 did retrospective study to analyse the obstetric and perinatal outcome of 412 singleton term pregnancies with cephalic presentation and no maternal risk

factors or fetal abnormalities. Two groups were compared: 206 deliveries after induced labor for isolated oligohydramnios, and 206 deliveries matched for gestational age following spontaneous labor with normal amniotic fluid index. they concluded that Active induction of labor in term low risk gestations with isolated oligohydramnios translated into higher labor induction, operative vaginal delivery and cesarean section rates. This led to increased maternal risk and an increase in costs with no differences in neonatal outcome. (30)

Locatelli A1 et evaluated the effect of oligohydramnios on perinatal outcome in uncomplicated pregnancies between 40.0 and 41.6 weeks. From January 1997 to December 2000, all uncomplicated pregnancies reaching 40.0 weeks' gestation with a singleton non-malformed fetus and reliable dating underwent monitoring with serial determination of amniotic fluid index (AFI) and biophysical profile. Labour was induced for AFI \leq 5 cm, biophysical profile score of 6 or less, rise in maternal blood pressure >140/90 mm Hg, or gestational age of 42.0 weeks. Perinatal outcome was compared between cases with AFI \leq 5 cm and those with AFI > 5 cm. Three thousand and forty-nine women met the inclusion criteria, 341 of which (11%) had an AFI \leq 5 cm. Gestational age at delivery, rates of nulliparity and induction of labor were significantly different between cases with oligohydramnios and those with normal AFI (all $p < 0.001$). Rates of cesarean delivery for non-reassuring fetal testing (8.2% vs. 3.9%, $p < 0.001$) and of neonates with birth weight <10th percentile (13.2% vs. 5.5%, $p < 0.001$) were significantly higher in the AFI \leq 5 cm group compared with the AFI > 5 cm. No significant differences were identified between the two groups in rates of meconium-stained amniotic fluid, 5-min Apgar score <7, or umbilical artery pH <7. In conclusion, in uncomplicated pregnancies at 40.0 to 41.6 weeks, oligohydramnios is independently associated with a higher risk of low birth weight centile.(31)

In study done by Conway-DL; et al women undergoing labor induction for isolated oligohydramnios between 37-41 weeks of gestation were matched by gestational age and parity to women with normal AFI, who presented in spontaneous labor. Pregnancies complicated by hypertension, diabetes, fetal anomalies, or suspected IUGR were excluded. The primary outcome variable was route of delivery. Secondary outcomes examined included presence of meconium, acidosis, low Apgar score and NICU admission. A total of 183 women underwent induction for isolated oligohydramnios. When compared to the control group, neonatal outcome measures did not differ in the group induced for oligohydramnios. However the women who were induced had significantly more C/S deliveries (15.8% vs. 6.6%, $P < 0.01$, odds ratio 2.7). The increased need for operative delivery was not attributable to more fetal distress in the oligohydramnios group. They concluded that isolated oligohydramnios in the otherwise normal term pregnancy may not be a marker for fetal compromise; an induction of labor may not be warranted in most cases.(28)

Chauhan SP et performed meta-analysis of 18 studies comprising more than 10,500 pregnancies in which the intrapartum AFI was less than 5 cm. Compared with controls whose index was greater than 5 cm, women with oligohydramnios had a significantly increased 2.2-fold risk

for cesarean delivery because of foetal distress and a 5.2-fold increased risk for a 5-minute apgar score of less than 7. Cord compression during labour is common with oligohydramnios.(27)

Krishna jagatia et found incidence of oligohydramnios was more in primipara (52%) in their study. And operative morbidity was also more in primipara. Most common cause of Oligohydramnios is idiopathic (52%). Second commonest cause is PIH (25%). Operative morbidity is highest in PIH (60%). Operative morbidity was significantly higher in NST (non-stress test) non-reactive ($3.12 \pm 75=78.12\%$) group than NST reactive (26.47%) group. Most common reason to perform caesarean was fetal distress which was either due to cord compression or IUGR. 7% patients were found with fetoplacental insufficiency on Doppler study. Oligohydramnios was related to higher rate of growth retardation and NICU (neonatal intensive care unit) admission.(37)

Sowmya et found rate of caesarean section was 68% in the group with oligohydramnios and 28% in the group with normal liquor volume. The difference was significant. The incidence of intrauterine growth restriction was significantly high in the study group (48%) as compared to the control group (22%). The prevalence of thick meconium (8% vs 6%) and non reassuring non stress test (12% vs 8%) was not significantly different in between the two groups. The fetal outcome as assessed by the apgar score and the neonatal intensive care unit admission rate (14% vs 4%) were not different in between the two groups. There were no babies needing ventilatory support and no perinatal deaths in either of the two group.(38)

A.Cristina et Four articles provided 679 cases with isolated oligohydramnios (IO) and 3264 with normal amniotic fluid (AF). Obstetric interventions occurred more frequently in the IO than normal AF group. Meta-analysis did not show differences with regard to meconium, Apgar, pH, SGA, NICU and perinatal death.(39)

Shipp TD1 et conducted study of total 250 singleton pregnancies met the criteria of having severe oligohydramnios in 1996. they evaluated the significance of severe oligohydramnios, or anhydramnios, in the second and third trimesters. All prenatal ultrasound results on pregnancies found to have severe oligohydramnios over a 7.5-year period at 13-42 weeks' gestation were retrospectively collected. Follow-up results were obtained from review of medical records, autopsies and pathology reports. Fetal abnormalities were present in 50.7% of those diagnosed with severe oligohydramnios in the second trimester and in 22.1% of those in the third trimester. There were 10.2% and 85.3% survivors when severe oligohydramnios was diagnosed in the second and third trimesters, respectively. The rate of aneuploidy was at least 4.4% for the entire singleton population (36)

Guin Gita et studied 200 pregnant subjects between 20 and 42 weeks of gestation in 2011, who were clinically suspected to have an abnormal amniotic fluid volume (oligohydramnios or polyhydramnios) were subjected to ultrasonographic (USG) assessment of amniotic fluid index. The subjects were closely monitored through pregnancy,

labour and puerperium. Observation(s) Ultrasonically, abnormal liquor volume was confirmed in 90–93% clinically suspected patients. Post term pregnancy (38.5%), PROM (30%) and prolonged pregnancy (23.5%) were associated with oligohydramnios. The incidence of labour induction, fetal labour intolerance, CS for fetal distress and 1 min Apgar of 7 was high in oligohydramnios subjects. The overall incidence of congenital anomalies (14%) and perinatal mortality (20%) in subjects with abnormal liquor volume was significantly higher ($P<0.001$) than in women with normal liquor volume (0.3, 2.3% respectively). They found that a good clinical examination can pick up most subjects of abnormal liquor volume. Abnormal liquor volumes are associated with increased maternal morbidity and adverse perinatal outcome (35)

Gayatri Mathuriya et did a case control prospective comparative study performed on 200 randomly selected low risk pregnant patients at term (37-40 weeks of gestation) admitted in Obstetrics and Gynaecology Department. 100 patients with AFI <5 cm (cases) and 100 patients with AFI 8-20 cm (control). Increased number of LSCS in cases that is 35 while only 10 in control and almost equal incidences of MSL and FD in both the groups, while in cases 17 women were planned for elective LSCS for various indications in expectation of better fetal outcome. There was significant low APGAR score in babies of cases, but clinically they refute this. In present study almost double the no. of babies in cases were IUGR. Significant association between low AFI and congenital anomalies in babies. Most of the anomalies were of urinary tract system.(40)

Sultana S1 et studied 100 pregnant women at term gestation in 2008. Each high-risk woman at term with an AFI of $< \text{ or } = 5$ cm admitted for delivery through emergency or outpatient department was labeled as predictor of poor outcome. The next high-risk pregnant woman at term with the same pregnancy complication but an AFI of > 5 cm was labeled as predictor of good outcome at birth. The Apgar score was calculated at 5 minutes of birth. The newborns, with Apgar score $< \text{ or } = 6$ at 5 minutes of birth were labeled as diseased and > 6 were labeled as healthy. AFI was compared with Apgar score, using Chi-square and a p-value was calculated to determine the statistical significance. Only 8 neonates of 50 women with low AFI had low Apgar score. Similarly, 6 neonates of 50 women with normal AFI had poor Apgar score. they concluded that Low AFI is a poor predictor of adverse outcome for high-risk term patients. AFI is not a good screening test for high-risk pregnant women at term for birth of an infant with low Apgar score 4.(34)

Casey BM1 et found that Women delivered between July 1, 1991, and September 30, 1996, who underwent ultrasonography at ≥ 34 weeks' gestation were analyzed. Oligohydramnios was defined as an amniotic fluid index ≤ 5 cm. Perinatal outcomes in pregnancies with oligohydramnios were compared with those with an amniotic fluid index of > 5 cm. In their analysis of 6423 pregnancies, 147 (2.3%) were complicated by oligohydramnios. This complication was associated with increased labor induction (42% vs 18%; $P < .001$), stillbirth (1.4% vs 0.3%; $P < .03$), nonreassuring fetal heart rate (48%

vs 39%; $P < .03$), admission to the neonatal intensive care nursery (7% vs 2%; $P < .001$), meconium aspiration syndrome (1% vs 0.1%; $P < .001$), and neonatal death (5% vs 0.3%; $P < .001$). They concluded that Antepartum oligohydramnios is associated with increased perinatal morbidity and mortality.(33)

Megha Bhagat et al evaluated the predictive value of amniotic fluid index (AFI) (<5) for adverse perinatal outcome in terms of cesarean section for fetal distress, birth weight, meconium staining, Apgar scores, and cord pH at birth. They did a prospective study of 200 antenatal women booked at Ram Manohar Lohia (RML) Hospital during the years 2009–2011 with gestational age between 34 and 41 weeks. The women's history, clinical examination recorded, and AFI were measured and the perinatal outcome was compared between two groups, i.e., $AFI < 5$ and >5 . The cesarean section rate for fetal distress and low birth weight babies, <2.5 kg, was higher in patients with oligohydramnios ($p = 0.048, 0.001$, respectively). There was no significant difference in meconium staining, Apgar score at 5 min <7 , and cord pH at birth between the two groups ($p = 0.881, 0.884, 0.764$, respectively). So they concluded that Oligohydramnios has a significant correlation with cesarean section for fetal distress and low birth weight babies.(32)

Golan –A; et al diagnosed 145 cases of oligohydramnios in the 2nd & 3rd trimester by ultrasonography out of 25,000 obstetric patients (0.58%). In that group, pregnancy complications were common such as induced hypertension (22.1%) and bleeding in the 2nd trimester (4.1%). They found a high incidence of meconium-stained amniotic fluid (29.1%), fetal distress (7.9%) and premature placental separation (4.2%) IUGR occurred in (24.5%) of cases. Asphyxia during labor occurred in (11.5%) and different other perinatal problems in (23.5%). C/S was performed in (35.2%) of these pregnancies. 17% of the cases presented as breech. IUFD occurred in (5.5%) of these pregnancies. The gross perinatal mortality was (16%) and the corrected perinatal mortality was (10.7%). The overall rate of fetal malformations was (11%) & that of lethal malformations (4.8%). The skeletal (7.6%) and urinary system (4.1%) were predominant systems affected. Oligohydramnios was associated with a high rate of pregnancy complications and increased fetal morbidity and mortality, thus termination should be considered when pulmonary maturity was present or in case of fetal distress.(14)

Sarno-AP; et al studied 200 term gravidas presenting in the latent phase of labor with vertex- presenting fetuses. An intrapartum AFI <5 cm was associated with significant increase in the risk of C/S for fetal distress and of an Apgar score of <7 at one minute as well as abnormal fetal heart rate patterns in late labor, the majority (71.4%) of the patient with an intrapartum AFI <5 cm had ruptured membranes on entry; however, there was no significant difference in outcome when they were compared to patients with intact membranes and oligohydramnios. Variable decelerations on entry were associated with oligohydramnios in (43.8%) of the patients. An AFI <5 cm in the early intrapartum period is a risk factor for perinatal morbidity and abnormal fetal heart rate patterns in subsequent labor, and ruptured membranes in early labor are risk factor for oligohydramnios.(44)

Sequelae from prolonged oligohydramnios including pulmonary hypoplasia and fetal compression syndrome can be devastating. Perinatal morbidity and mortality are both significantly increased in pregnancies complicated by oligohydramnios. (64)

Hsieh TT, et al; set to investigate the perinatal outcome of patients with oligohydramnios (AFI <5 cm) but without PROM and congenital fetal malformations, data from (245) singleton pregnancies were analyzed and compared to those with normal AFVs ($5 < AFI < 24$ cm $n=27, 261$). Significantly high in incidences of primiparity, PIH, premature separation of the placenta, past history of IUFD, past history of preterm delivery, postterm pregnancy and advanced maternal age were noticed to be associated with occurrence of oligohydramnios. Pregnancies complicated by markedly diminished AFV assessed antenatally by ultrasound were significantly more frequently associated with adverse perinatal outcomes such as preterm delivery, low or very low birth weight, low Apgar scores, IUFD, small-for-gestational age newborn, meconium stained amniotic fluid, C/S delivery, neonatal intensive care and neonatal death.(45)

4. Materials & Methods

Study Area: Department of Obstetrics & Gynaecology, Deenanath Mangeshkar Hospital (DMH) & Research Centre, Pune, Maharashtra.

Study Population: All Pregnant women with gestational age 37 weeks or more coming for delivery to Deenanath Mangeshkar Hospital, Pune.

Study type: Prospective comparative observational study.

Sample size with Justification: A sample of size 84 cases (minimum in each study group, i.e. total 168 cases with Group 1 (Oligohydramnios) to Group 2 (Controls) ratio being 1:1) satisfying the inclusion criteria would produce 80.0% statistical power (type II error = 0.20) and 5% type I error probability ($\alpha = 0.05$) to be able to detect the desired clinical significant difference (20% and higher incidence) in outcome measures (such as incidence of IUGR, NICU, Fetal distress etc) between two study groups with a two-tailed alternative hypothesis.

Time Frame to address the study: March 2016 to March 2017.

Inclusion Criteria:

- 1) Patient with AFI (amniotic fluid index) <5 cm taken as study group and AFI (amniotic fluid index) 5-18 cm taken as control.
- 2) Gestational age of 37 or above
- 3) Singleton pregnancies with cephalic presentation

Exclusion criteria:

- 1) Patient with premature rupture of membranes
- 2) Polyhydramnios (AFI >25 cm)

Measurement of outcomes of interest:**Maternal outcome/obstetric outcome**

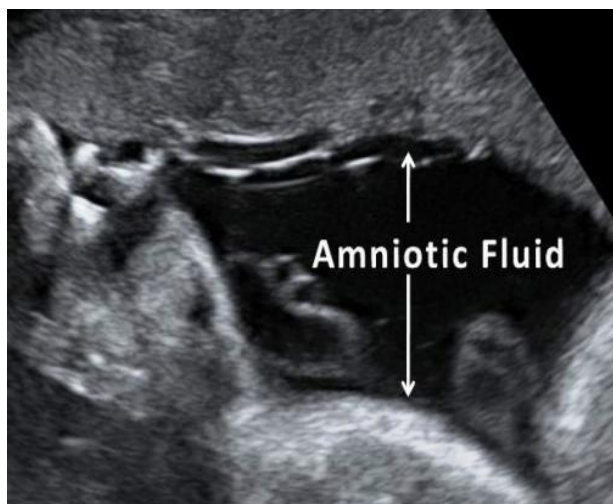
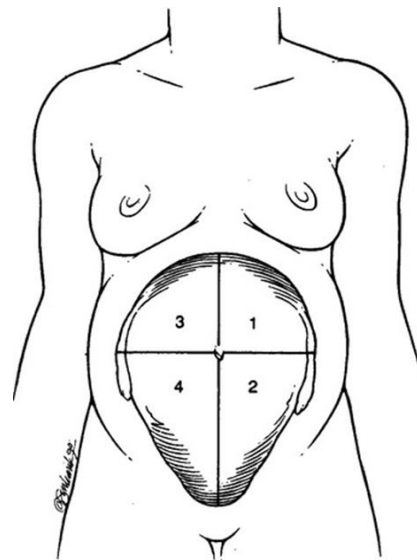
- 1) Incidence of Spontaneous labour
- 2) Incidence of Induction of labour
- 3) Incidence of Normal delivery/ Assisted Delivery /L.S.C.S.

Foetal outcome

- 1) Apgar score
- 2) Birth weight
- 3) NICU admission
- 4) Neonatal death

5. Methodology

Antenatal women with gestational age 37 weeks and above and fulfilling inclusion criteria attending our Out Patient Department or Labour rooms were included in the present study. Detailed antenatal history including presence of high risk factors was elicited from the patient, then they were clinically examined and subjected to ultrasonography. (In 1987 Phelan et al. described AFI as a method of semi-quantitatively estimating amniotic fluid volume [5]. Phelan et al. defined oligohydramnios as an AFI < 5cm were allotted into the study group and another 50 women with AFI 8-18 cm were included into the control group. Labour was either spontaneous or induced in both study and control group.) Labour will be monitored as per standard labour room protocols to detect any signs of fetal distress. Mode of delivery and intrapartum complications will be noted. At birth neonate will be assessed using 5-minute APGAR score, birth weight and need of NICU admission.

**Figure 1****Figure 2****Figure 3****Statistical Methods**

Descriptive statistical analysis will be carried out to explore the distributions of several variables of the cases studied. Results on categorical data will be shown as n (% of cases) and the results on quantitative variables will be shown as Mean \pm Standard deviation across two study groups. The statistical significance of difference of various qualitative responses will be tested using Chi-square test for independence of attributes or Fisher's exact probability test. For comparing quantitative variables across two study groups, independent sample 't' test will be used after confirming the underlying normality assumption. P-values less than 0.05 would be considered to be statistically significant. The entire statistical analysis will be performed using Statistical Package for Social Sciences (SPSS version 11.5, Chicago, IL) for MS Windows.

6. Observations and Results**Observations and results**

- Recruitment started from March 2016, last patient in the study was enrolled in March 2017
- Total 168 patients (84 study group, 84 control group) satisfying inclusion and exclusion criteria were enrolled in our study.
- All 168 pregnancies resulted in live births.

Table 1: Age wise distribution of women participated in the study

Group	Number of patients	Maternal age (years)		p-value
		Mean	SD	
Group A(study)	84	27.10	3.16	0.435
Group B(control)	84	27.46	2.94	

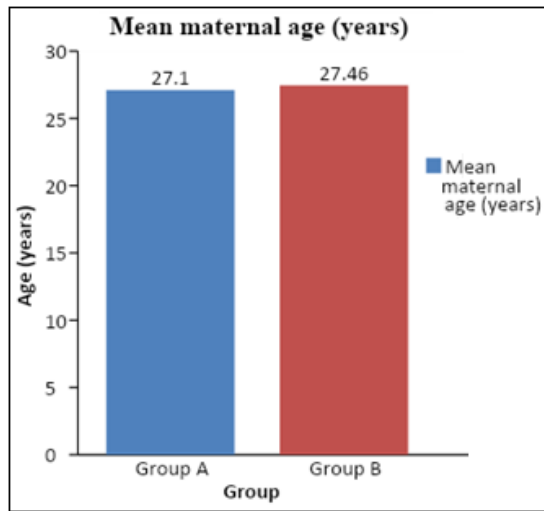


Figure 4

- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between mean maternal age (years) in group A and group B.

Table 2: Gravida wise distribution of women participated in the study:

Gravida	Group		Total	p-value
	Group A(study)	Group B(control)		
Primigravida	54	53	107	0.999
Multigravida	30	31	61	
Total	84	84	168	

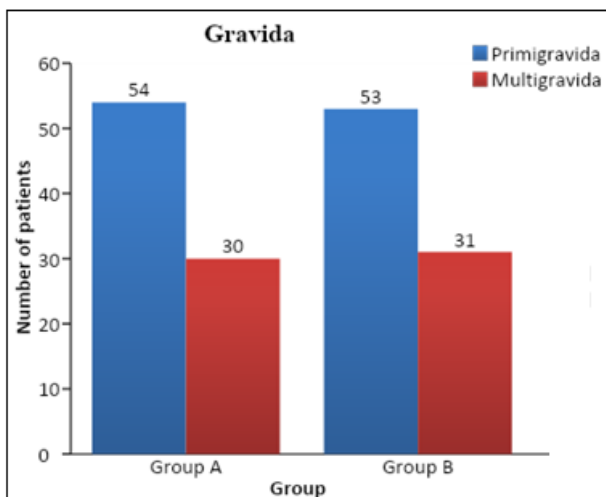


Figure 5

- p-value>0.05(not significant) chi-square test used.
- Out of 168 women enrolled in the study,107 were primigravida and 61 were multigravida.Group A included 54 primigravida and 30 multigravida and Group B included 53 primigravida and 31 multigravida. The difference in the selection of women in the both the group was statistically insignificant with p value of 0.999.

Table 3: Mode of delivery wise distribution of women participated in the study:

	Vaginal delivery	Caesarean section (l.s.c.s.)	Total	P value
Group A(study group) n=84	44	40	84	0.044
Group B (control group) n=84	58	26	84	

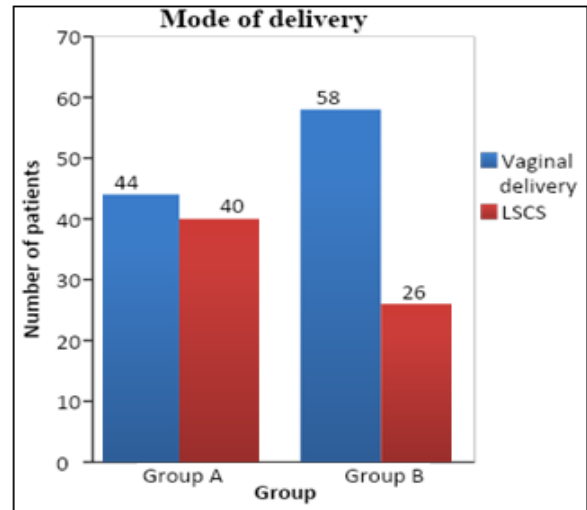


Figure 6

- p-value <0.05(significant) chi square test used.
- Out of 84 women of study group, 44(52.38%) delivered vaginally and 40(47.61%) women delivered by caesarean section. while Out of 84 women of control group, 58(69.04%) delivered vaginally and 26(30.95%) women delivered by caesarean section. The difference in mode of delivery in the both the group was statistically significant with p value of 0.044.

Table 4: Initiation of labour(spont/Iol/elective lscs) wise distribution of women participated in the study:

Initiation of labour	Group		Total	p-value
	Group A(study)	Group B(control)		
Spontaneous	31	71	102	< 0.001
IOL	44	13	57	
Elective LSCS	9	0	9	
Total	84	84	168	

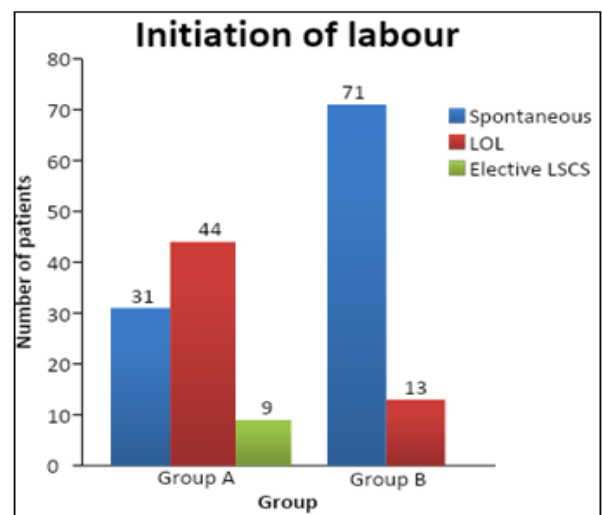


Figure 7

p-value <0.05(significant) chi square test used.

- Out of 84 women of study group,31 women underwent spontaneous labour,44 women induced for oligohydramnious and 9 women underwent elective cesaerean section for severe oligohydramnious while Out of 84 women of control group, 71 women underwent spontaneous labour,13 women induced and no women underwent elective cesaerean.The difference in intiation of labour of both the group was statistically significant with p value of <0.001.

Table 5: NICU admission in the two groups

NICU admission	Group		Total	p-value
	Group A(study)	Group B(control)		
Yes	16	6	22	0.039
No	68	78	146	
Total	84	84	168	

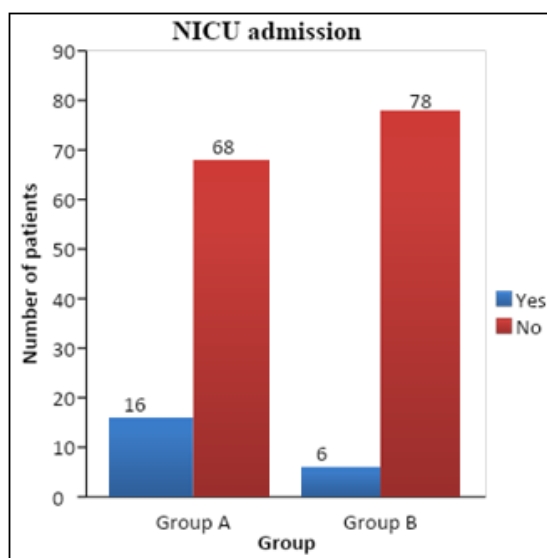


Figure 8

p-value <0.05(significant) chi square test used.

- Out of 84 babies of study group,16 babies required NICU admission while Out of 84 babies of control group, 6 babies required NICU admission .The difference in number of NICU admission of both the group was statistically significant with p value of 0.039.

Table 6: Birth weight of babies born in both the groups:

Birth weight	Group		Total	p-value
	Group A(study)	Group B(control)		
< 2.5 kg	20	7	27	0.011
≥ 2.5 kg	64	77	141	
Total	84	84	168	

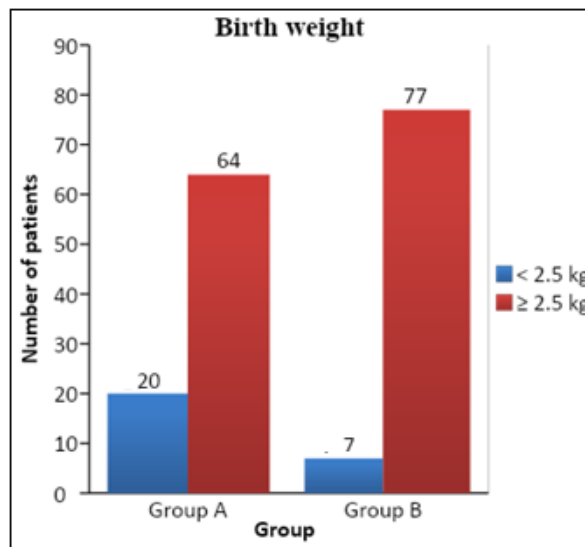


Figure 9

p-value <0.05(significant) chi square test used.

- Out of 84 babies of study group,20 babies have <2.5 kg birth weight while Out of 84 babies of control group, 7 babies have <2.5 kg birth weight. The difference in number of babies having low birth weight was statistically significant with p value of 0.011.

Table 7: APGAR score at 1 min and 5 min in babies born in both the group:

APGAR score	Group		Total	p-value
	Group A(study)	Group B(control)		
< 7	13	5	18	0.080
≥ 7	71	79	150	
Total	84	84	168	

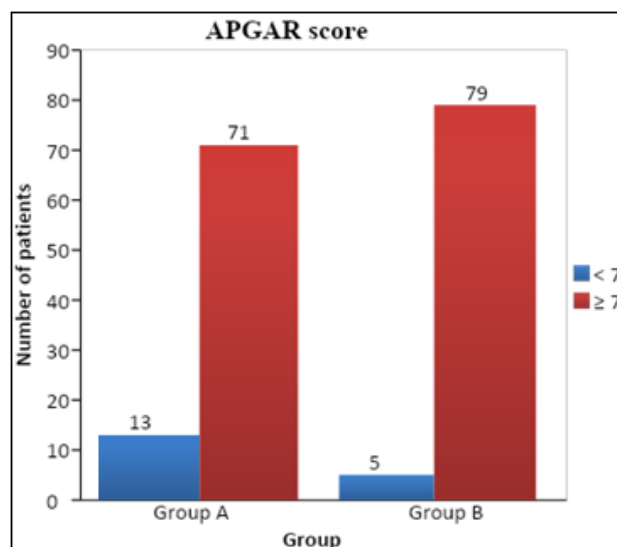


Figure 10

p-value >0.05(insignificant) chi square test used.

- Out of 84 babies of study group,13 babies have APGAR score <7 at 1 min and 5 min after birth while Out of 84 babies of control group, 5 babies have APGAR score <7 at 1 min and 5 min after birth. The difference in APGAR score at 1 min and 5 min in both the group was statistically not significant with p value of 0.080.

7. Discussion

The primary objective of the antenatal screening is to detect any conditions which can lead to a high risk pregnancy. Ultrasound examination during that period is a sensitive and reliable method of assessing the amniotic fluid and to detect oligohydramnios or polyhydramnios. Assessment of AFV during the antenatal period is considered a helpful tool in determining who is at risk for potentially adverse perinatal outcome. (48) Thus This study was carried out to assess the impact of oligohydramnios on maternal and fetal outcome.

In our case-control study Out of 168 patients 84 (study group) and 84 (control group) recruited, maximum patients (85%) were in 20-30 years age group. In Casey et al, [47] the mean maternal age was 23.9 years which is comparable to the present study.

In the present study, the highest percentage of women in the study group and control groups (64% & 63 % respectively) were primigravida, This is agreement with that of Ghike et al., (49) who observed that the majority of the women in both the groups were either nulliparous or Para one. Conversely, Jagatia et al., (50) reported that the incidence of oligohydramnios was more in primipara (52.0%) which is compatible with the study of Jandial et al., (51) and Petrozella et al., (52) who showed that the incidence of oligohydramnios was 60.0% in primigravida.

The present result also revealed that, the women in the study group were more likely to have a shorter mean weeks of gestation compared to the control group (mean 38.91 vs. 39.23 respectively). In agreement with this Gumus et al., (53) reported that gestational age at delivery was 37.7 weeks for study group and 38.3 weeks for control group ($p=0.004$). In addition, Ghike et al., (49) reported that the mean age of gestation in women with severe oligohydramnios was 40.30 ± 1.6 weeks and in women with borderline oligohydramnios was 40.08 ± 1.61 weeks. A possible explanation of the above findings might be related to the fact that oligohydramnios is mostly associated with fetal distress which requires an early interference through induction of labor. (54) Concerning the current study finding of the significantly higher proportion of abnormal fetal heart rate (fetal deceleration) in the oligohydramnios group, (33); (56); (57) and (49) asserted that the most strongly associated characteristics with oligohydramnios was the higher percentage of women with abnormal fetal heart rate. Also in agreement with the present study finding Voxman et al., (58) and Jandial et al., (51) observed that, women with oligohydramnios were significantly ($p<0.005$) more likely to have abnormal fetal heart rate tracings. In addition, Desai et al., (59) found an increase in late decelerations in women with low AFI which was statistically of just borderline significance. This is in agreement with the current study finding which revealed that 36% of women who complained from oligohydramnios underwent emergency cesarean section for foetal distress. The FHR pattern changes and decelerations can be explained by the poor placental functions associated with oligohydramnios. This results in deficient fetal oxygenation and fetal asphyxia which results in abnormal FHR changes.

The incidence of oligohydramnios was 54% in primigravida in our study. Garmel et al. supported that 67 % of women with Oligohydramnios were primigravida (46) and Charu et al supported that 66 % of women were primigravida (47) In Donald D et al, [51] the incidence of oligohydramnios was 60% in primigravida which is comparable to our study.

According to the present study findings, the rate of spontaneous delivery was higher in the control group (84%), compared to the study group (37%). Conversely, the rate of caesarean section(C.S.) was higher in oligohydramnios group (47.67%). This is in coherence with Hanafy (60) who reported that there is statistically significant increase in the rate of C.S in oligohydramnios group compared with those in the control group (40.0% vs. 20.0% respectively). He also, reported a higher rate of vaginal delivery among the control group than that in the study group (80.0% vs. 60.0%). In addition, Kahkhaie et al., (6) observed that C.S. was done in 20.2 % in oligohydramnios group and 8.6% in control group. Also, Ahmad and Munim (62) noticed a more than two fold higher C.S. rate in the isolated oligohydramnios group (42.0%) compared to 18% in the control group. Moreover, Voxman et al., (58) study in low AFI as a predictor of adverse perinatal outcome found an increased rate of C.S. in oligohydramnios group (14.7%) because of fetal distress. Such discrepancies could be explained by the fact that deficient quality resources of antepartum and intrapartum fetal monitoring in the present study setting might influence the rate of detection of all the parameters of fetal heart rate tracing. Thus C.S. was mostly the best option to overcome the adverse effect on the perinatal outcome.

Concerning fetal outcomes, the present study showed significantly better Apgar score at the first and fifth minutes among babies with normal amniotic fluid index than those with oligohydramnios, although it was not significant statistically. This is similar to Chate et al., (55) who noticed that the Apgar score of the study group was less than 7 in 30% at 1st minute, and 16% at 5th minute. In disagreement with the above finding Umber et al., (43) showed that, Apgar score of <7 in the oligohydramnios group was 8.0% at 1st minute, and 6.0% at 5th minute. Furthermore, Golan et al., (14) reported a low Apgar score at fifth minutes in 4.6% of neonates. While, Ahmad and Munim (50) noticed that the Apgar scores at one and five minutes after birth did not show a significant difference between the two groups ($P=0.575$). In this respect, Sarno et al., (10) noted a significantly higher rate of fetal distress and low Apgar score in women with oligohydramnios. This is reported to be due to head and cord compression. Dissimilarities between the above mentioned results could be attributed to the available better intrapartum fetal assessment facilities in developed countries. They concluded that liberal use of amnioinfusion in women diagnosed with oligohydramnios might have resulted in improved outcomes which were not seen in previous oligohydramnios at the third trimester and perinatal outcome studies. But amnioinfusion is yet not established in the research setting.

The current study has also demonstrated that, the mean birth weight of the study group was 2.68 kg while of control group was 2.85 kg. This finding were similar with the

prospective case control study conducted by Chate et al., (55) who noticed that the mean birth weight was less in oligohydramnios group.

The current study has also demonstrated no evidence of congenital anomalies in the study group and the control group). However, the incidence reported by Guin et al., (35) and Chate et al., (55) was much higher than the present study (8.5 % & 6.0 % respectively), this is most probably due to the sample size and its characteristics.

The current study findings revealed that Statistical significant difference was noted between the two groups as regards admission to neonatal intensive care unit (NICU). As 19 % of neonates in the oligohydramnios group had been admitted to NICU compared to 7 % in the control group. This is consistent with the studies of Johnson et al., (4) and Jagatia et al., (37) who found that 20.0% of neonates had NICU admission in oligohydramnios group. It also agrees with Garmel et al., (46) and Jandial et al., (51) who noticed that the rate of NICU admission was found to be 16.0% and 18.5% respectively. Conversely, Hanafy, (60) reported that the admission to NICU was not significantly increased in the oligohydramnios group (P= 0.62).

Oligohydramnios is frequent occurrence and demands intensive fetal surveillance and proper antepartum and intrapartum care. Amniotic fluid volume is a predictor of fetal tolerance in labour and its decrease is associated with increased risk of abnormal heart rate and meconium stained fluid.

Due to intrapartum complication and high rate of perinatal morbidity and mortality, rates of caesarean section are rising, but decision between vaginal delivery and caesarean section should be well balanced so that unnecessary maternal morbidity can be prevented and on other side timely intervention can reduce perinatal morbidity and mortality.

To conclude, oligohydramnios is associated with a high rate of pregnancy complications and increased perinatal morbidity and mortality. We believe that AFI assessed antepartum or intrapartum would help to identify women who need increased antepartum surveillance for pregnancy complications, and as such women should be cared for in a unit capable of managing such complications effectively.

An amniotic fluid index of < 5 cm detected after 37 completed weeks of gestation is an indicator of poor perinatal outcome. Determination of AFI can be used as an adjunct to other fetal surveillance methods. It helps to identify those infants at risk of poor perinatal outcome.

8. Summary

- A prospective observational comparative study was conducted at our hospital to study the effect of Oligohydramnios on maternal and fetal outcomes in 37 weeks or more gestation period.
- Total 168 pregnant women (84 case and 84 control) satisfying inclusion and exclusion criteria were enrolled for the study.

- Maternal outcome/obstetric outcome as Incidence of Spontaneous labour ,Incidence of Induction of labour ,Incidence of Normal delivery/ Assisted Delivery /L.S.C.S. and foetal outcome Apgar score ,Birth weight,NICU admission were studied.
- Two group were comparable in term of maternal age and parity.
- The Incidence of caesarean section was higher(47.61%) in Group A(case) compared to (30.95%) Group B (control).thus oligohydramnios leads to increase incidence of caesarean section.
- The Incidence of spontaneous labour was higher in Group A(case) while incidence of induction of labour was higher in Group B(control).
- The incidence of low birth weight and NICU admission was higher in Group A(case) compared to Group B.
- No neonatal death recorded.

9. Conclusion

An amniotic fluid index of ≤ 5 cm detected after 37 completed weeks of gestation is an indicator of poor perinatal outcome. Oligohydramnios was found to be a high-risk factor for pregnancy in term of increased incidence of adverse pregnancy outcome like more operative interference and foetal outcome as NICU admission, low birth weight.

The incidence of adverse pregnancy outcomes as follows:

- The rate of Cesaerean section was 47.67%.
- 24% of the newborn found low birth weight(<2.5kg) .
- The incidence of neonatal resuscitation and NICU admission was 19%.
- No newborn had congenital anomalies.
- There is a significant association between the severity of oligohydramnios and fetal outcome in term of neonatal resuscitation and NICU admission.

10. Recommendations

Determination of AFI should be used as an adjunct to other fetal surveillance methods. It helps to identify those infants at risk of poor perinatal outcome and is a valuable screening test for predicting fetal distress in labor requiring cesarean section in oligohydramnios women. Continuous antepartum and intrapartum monitoring are mandatory for every women diagnosed with oligohydramnios to reduce the maternal and neonatal risks associated with oligohydramnios. Nurse's knowledge about care provided to women having oligohydramnios must be periodically upgraded through scientific conferences, meetings, seminars and workshops because nurses have a significant role and profound impact in ante and intrapartum monitoring of this risk group.

The suggested plan of action:

- 1) Development of health instruction brochure to raise the pregnant women's awareness regarding oligohydramnios and its management.
- 2) The brochure should include knowledge related to the definition of oligohydramnios and its maternal and fetal outcome.
- 3) The brochure should be distributed to the pregnant women during their scheduled antenatal visit.

- 4) Meeting with the antenatal clinic nurses to encourage them to educate pregnant women about oligohydramnios, its maternal and fetal complication, and the plan of action.
- 5) Referral of the women who had oligohydramnios to tertiary hospitals with a well-equipped Obstetrics and Neonatal Departments for further examination and management.

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Study Proforma

Name: Age:
Obstetric history
Past history
On Examination:
Weight
USG Feature

On Admission to Labour Room
-Bishops on Admission
-Method of Induction of Labour
-CTG On Admission
-Mode Of Delivery- Vaginal Delivery / Instrumental Delivery Induction Of Labour / L.S.C.S.
-Foetal Outcome namely:
1. Birth Weight
2. APGAR score
3. Nicu Admission -Yes/No
4. Neonatal Death -Yes/No

Patient Information Sheet

Study Information

You are invited to take part in this study. The details of the study are described in this document. It is important that you understand why this study is being done and what it will involve. Please take your time to read through and consider

this information carefully before you decide if you are willing to participate. After you are properly satisfied, you must sign this consent form.

This study is part of a DNB thesis.

Protocol title: To study the effect of Oligohydramnios on maternal and fetal outcomes in 37 weeks or more gestation period

• What procedures are followed in this study?

This is A prospective comparative study of effect of oligohydramnios on maternal and fetal outcomes.

• Possible Risks and side effect?

No.

• Voluntary Participation:

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your management.

• Confidentiality of Study and Medical Records:

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

• Costs & Payments if Participating in the Study?

Participants in the study not incurred any cost/burden on the patient other than treatment & investigation protocol.

• Whom should I contact if I need more information or help?

If you need more information or help regarding this study, you can contact

Dr. Ashish Prajapat Mob. No. 08411842502

Dr. Pratibha Kulkarni Mob. No. 9822055894

Informed Consent Form

Subject identification number for this trial

Title of the Project: **“To study the effect of Oligohydramnios on maternal and fetal outcomes in 37 weeks or more gestation period.”**

Name of the Principal Investigator - **Dr. Ashish Prajapat**
Tel. No. **08411842502**

I have received the information sheet on the above study and have read and / or understood the written information. I have been given the chance to discuss the study and ask questions. I consent to take part in the study and I am aware that my participation is voluntary.

I understand that I may withdraw at any time without this affecting my future care.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics committee members / regulatory authorities). I give access to these individuals to have access to my records.

I understand I will receive a copy of the patient information sheet and the informed consent form.

Signature / Thumb Impression of subject Date of signature

Printed name of the subject in capitals

Signature / Thumb Impression of legally accepted representative Date of signature

<<The legally acceptable representative signature should be added if the subject is a minor or is unable to sign for themselves. The relationship between the subject and the legally acceptable representative should be stated. The impartial witness signature should be added if the subject / legally acceptable representative is unable to read or write and consent should be obtained in his presence.>>

Printed name of legally acceptable representative in capitals

Relationship of legally accepted representative to subject in capitals

Signature of the person conducting the Date of Signature informed consent discussion

Printed name of the person conducting the Informed consent discussion in capitals

Signature of impartial witness Date of signature

Printed name of the impartial witness in capitals
National Board of Examinations, New Delhi

The Institutional Ethics Committee of Deenanath Mangeshkar Hospital & Research Centre

(The Institutional Ethics Committee of Deenanath Mangeshkar Hospital & Research Centre works as per its Work Document and SOPs per provisions of Good Clinical Practices, ICMR Code 2000, Ethical Guidelines for Biomedical Research on Human Participants ICMR 2006, Guidelines for Clinical Trials on Pharmaceutical Products in India, CDSCO, DGHS, GCP, Govt. of India, Schedule 'Y' in particular; and ICH Good Clinical Practice Guidelines.)

To

Dr. Ashish Prajapat
Principle Investigator

Dr. Pratibha Kulkarni
Guide / Supervisor

Ref: Your letter(s) / mail dated: 16th February 2016

The Institutional Ethics Committee, DMHRC has reviewed your application to review the protocol /study entitled **“To study the effect of Oligohydramnios on maternal and fetal outcomes in 37 weeks or more gestation period.”**

The following documents were reviewed at the meeting:

Sr.No	Document Name
1	Thesis Protocol
2	Informed Consent Form

After considering the recommendations given by the DNB Thesis Scientific Advisory Committee (DNB-SAC), the IEC has approved the above study to be conducted in the present form.

The following members of the Institutional Ethics Committee were present at the meeting held on **18th February 2016 at 4.00 pm** at Deenanath Mangeshkar Hospital and Research Centre.

Name.	Qualification	Role
Dr. Avinash Joshi	Ph.D. (Biochemistry)	Chairperson*
Dr. Manohar Dhadphale	M.B.B.S.,DPM, MRCP (Psych)MD, FRCP(Psych)	Vice Chairperson*
Dr. Dhananjay Kelkar	M.S.(Gen Surgery)	Clinician
Dr. Jitendra Deuskar	M.S.(Gen Surgery)	Clinician
Dr. B. Y. Pawar	M.D. (Medicine) IDCC	Clinician
Dr. Ashwini Joshi	DNB (Medicine), MNAMS	Clinician
Dr Anupama Nadkarni	M.D (Paediatrics)	Clinician
Dr. Prema Shidore	M.D. (Pharmacology)	Pharmacologist (Basic Medical Scientist)*
Dr. Medha Kshirsagar	M.D. (Pharmacology)	Pharmacologist (Basic Medical Scientist)*
Dr. Sujala Watve #Dr. Vanita Patwardhan	B.Sc. (Chemistry), M.A., Ph.D. (Psychology) M.A.(Psychology), Ph.D. (Psychology), M.Ed.,Dip. In Yoga Education (Govt. recognized	Ethicist*

Adv. Sheel Rege # Adv. (Dr.) Milind Salunke	B.A., L. L. B. BHMS, DHA, MBA, L.L.B.	Legal Expert*
Mrs. Uma Vengurlekar # Mrs Hemlata Hirve	Diploma Commercial Art B.A (Sociology)	Lay Person*
Col. J.C. Pendse, VSM (Retd.)	B.A. (Hons.)	Member Secretary
Dr. Vajjayanti Pethe	Ph. D (Biochemistry)	Joint Member Secretary

Yours sincerely,

Col. J.C. Pendse, VSM (Retd) Date of Issue -15.04.2016

Member Secretary, IEC-DMH&RC, Deenanath Mangeshkar Hospital & Research Centre.

To

Dr. Ashish Prajapat
Principle Investigator

Dr. Pratibha Kulkarni
Guide / Supervisor

The DNB Thesis Scientific Advisory Committee (DNB-SAC) has reviewed and discussed your application to review the protocol / study entitled "To study the effect of Oligohydramnios on maternal and fetal outcomes in 37 weeks or more gestation period."

The following documents were reviewed:

Sr.No. Document Name

1 Thesis Protocol

2 Informed Consent Form

The DNB Thesis Scientific Advisory Committee has reviewed your study/ protocol and recommends the same for approval of Institutional Ethics Committee, DMHRC

The following members of the DNB Thesis Scientific Advisory Committee (DNB-SAC) were present at the meeting held on 11th February 2016 at 2.00 pm at Deenanath Mangeshkar Hospital and Research Centre.

Name.	Qualification	Role
Dr. Dhananjay Kelkar	MS (Gen Surgery)	Head of the Institute
Dr. Pratibha Kulkarni	MD (OBGY)	Guide
Dr. Anand Deshpande	DNB, DCH	Local Faculty - Professor – B. J. Medical College
Dr. Mrs. Asawari Kanade	M.Sc. , Ph. D (Biometry & Nutrition)	Statistician
Dr. Mahesh Mandolkar	MD, DNB (Patho)	Basic Science Faculty
Dr. Kanitkar Shreedhar	MS (Gen Surgery)	Honorary Member
Dr. Sameer Jog	M.D, DCCM	Honorary Member
Dr. Asmita Bhawe	MS (Gen Surgery)	Honorary Member
Dr. Guari Oak	MPH	Honorary Member

Please note that the Principal Investigator was invited to explain the protocol. He/She and/ or other study staff members did not participate in the decision making / voting procedures.

Please note that this is a scientific review of the project - and final approval will be granted by Institutional Ethics Committee, DMHRC.

The study can be initiated only after the approval from Institutional Ethics Committee, DMHRC

Yours sincerely,

Honorary Member, Date of Issue- 15.04.2016

DNB Thesis Scientific Advisory Committee,

Deenanath Mangeshkar Hospital & research centre.