Study Protocol

Assessment of Correlation between Amniotic Fluid Index (AFI) and Feto-maternal Outcomes of In-term Pregnancies

ABSTRACT

Background: Amniotic fluid plays a crucial role in providing basic life support to the fetus. This clear, slightly yellowish liquid that surrounds the fetus is helpful in the development of fetal systems by providing thermally controlled and a non-restricted sterile environment for fetal growth. During labour, amniotic fluid helps in providing an adequate cushion for umbilical cord. It is this mechanical function of the cushion which aids in preventing compression of cord in-between fetus and uterine wall during uterine contractions and fetal movements. Therefore, helps to prevent fetal distress . It protects fetus from any kind of injury and helps in preventing infection by its bacteriostatic properties. This study aims to estimate the effect of decreased amniotic fluid index (AFI) on maternal and fetal outcomes in term pregnancy.

Material and Method : This will be a Prospective cross sectional observational study conducted in OBGY dept. of AVBRH, Wardha. Pregnant women will be enrolled and divided into 3 groups as per Amniotic Fluid Index. Group A with low amniotic fluid index(AFI< 5 cm) Group B with borderline amniotic fluid index (AFI>5cm and <8cm)and Group C with normal amniotic fluid index (AFI 8cm-24cm). Data will be collected, analysed and compared between the groups in terms of the ultrasonographic findings and feto-maternal outcomes of in term pregnancy.

Expected Results : Significant correlation is expected between AFI and feto-maternal outcomes.

Conclusion: Unexpected adverse outcomes can be minimized by estimation of AFI and timely antepartum treatment in mothers with decreased AFI.

Keywords: Pregnancy, Amniotic fluid index, term pregnancy, Feto-maternal outcomes.

INTRODUCTION:

The amniotic fluid (AF) plays a crucial role in providing basic life support to the fetus. It helps in the formation and development of lungs, limbs, muscles and gastrointestinal system. Immediately after the amniotic sac is formed, nearly at around 12 days after the day of conception amniotic fluid is produced. It initially comprises of effusion that is provided by

the mother's circulation. Then primary constituent becomes fetal urine at about 20th week of gestation. (1)

During labour, amniotic fluid helps in providing an adequate cushion for umbilical cord. It is this mechanical function of the cushion which aids in preventing compression of cord in-between fetus and uterine wall during uterine contractions and fetal movements. Therefore, helps to prevent fetal distress . It protects fetus from any kind of injury and helps in preventing infection by its bacteriostatic properties. It is noted that it also protects the fetus from nutritional and vascular derangement.(2)
Amniotic fluid volume regulation and composition is found to remain largely unknown. Many different studies coexist for both formation and removal of amniotic fluid. It is observed that amniotic fluid is formed initially by transfer across fetal skin followed by fetal urine and production of fluid by lungs. While removal is observed to be through swallowing followed by trans membranous and intramembranous absorption of amniotic fluid. Most of the times, these pathways work in coordination so as to maintain amniotic fluid within the typical range.Specially in the second trimester, where noticeable deviations from this normal range occur, perinatal morbidity and mortality incidence is observed (3).
Amniotic fluid (AF) being a tremendously dynamic and complex component is found to change as pregnancy progresses (4). There are several techniques for the measurement of amniotic fluid volume (AFV). It can be estimated at the time of amniocentesis by dye dilution techniques (5)(6)or it can also be directly measured at the time of caesarean section delivery (7). For the assessment of amniotic fluid volume, gold standard test is found to be the dye-dilution test (5)(7). Since this is an invasive modality ,it is found to be associated with greater complications specially in the presence of decreased amniotic fluid volumes .Therefore, in routine clinical practice , ultrasonography is more feasible to estimate AFV .

Following are the ultrasonographic methods used to determine AFV:

1) Maximal vertical pocket (MVP): It is described as the deepest or the largest vertical fluid pocket ranging between 2 cm and 8 cm with the normal amount of amniotic fluid (8).

2) Amniotic fluid index (AFI): It is proposed to be more reproducible and objective method. It measures the amniotic fluid in four divided quadrants .The usual range of AFI varying between 12.9 ± 4.6 cm (5-18 cm).We define it as Borderline if AFI is found to be >5cm and < 8 cm . AFI less than 5 cm is considered to be oligohydramnios (2,9).

3) Two diameter pocket: On ultrasound, when the deepest/largest pocket in both horizontal plane and vertical plane measures less than 2 cm is described as oligohydramnios. (10) Any change which is found to be below or above the normal values for amniotic fluid volume is observed to be in association with adverse perinatal morbidity and mortality. According to the method used for estimating amniotic fluid volume, the exact definition of oligohydramnios keeps varying.

Based on the ultrasonographic technique used for the assessment of amniotic fluid volume, following cut-off values for oligohydramnios have been defined :

Single vertical pocket: found to be in the range of <1.0 cm , <2 cm (11)and <3 cm (12)

AFI (Amniotic Fluid Index) measurement: Oligohydramnios found to include less than 5 cm (which represents <1st percentile) 6, <5th percentile for gestational age (which shows an AFI value between 7.1 and 9.7cm) (13)and less than 8 cm (14)

Two-diameter pocket: horizontal x vertical <15 $cm^{2.}$

The usual range of AFI is observed to be 5 to 24 cm where any value more than 24 cm will be considered as Polyhydramnios and Borderline AFI that is defined AFI >5cm and <8cm.Decreased AFI is found to be a challenging task in obstetrics for its association with adverse pregnancy and neonatal outcomes (15). Oligohydramnios is described as AFI shows fluid level of < 5th percentile for gestational age or less than or equal to 5cm or the total amniotic fluid volume of less than 500ml or lack of 2-3cm deep fluid pocket in pregnant women between 32 to 36 weeks of gestation provides us with the diagnosis of oligohydramnios. According to most of the studies , pregnant women with borderline AFI (5cm-10 cm) have demonstrated adverse effects such as deceleration of fetal heart rate (FHR), nonreactive non-stress tests, , immediate caesarean delivery, meconium aspiration syndrome, LBW, low Apgar score, small for gestational age (SGA) and admission in NICU when compared to normal subjects with usual amniotic fluid level (8.1cm-18 cm) (8-10, 14-16). Also the low amniotic index may result in a rise in the operative delivery rate(16).

RATIONALE

As controversial data exist concerning the implications of decreased amniotic fluid in pregnancy and outcomes at term pregnancy, we mainly aimed to study its association in low-risk pregnancies. This study is carried out with the objective bridging the gap in the local literature, thereby providing aid to pregnant women presenting in the third trimester with decreased AFI.In this present era of evidence based practices findings of this study will help to improve our principles of management also the local guidelines used for the management of patients with decreased amniotic fluid. Thus, helps to prevent fetal and maternal complications.

AIM AND OBJECTIVES

AIM

The purpose of this research is to compare maternal and fetal outcomes in term pregnancies with decreased amniotic fluid and normal amniotic fluid.

OBJECTIVES

The objectives of this study are-

1) To determine amniotic fluid at or >37 weeks of pregnancy by ultrasonography.

2) To observe the maternal and fetal outcomes at term with decreased amniotic fluid.

3) To observe the maternal and fetal outcomes at term with normal amniotic fluid.

4) To compare between both the groups.

MATERIAL AND METHOD

Study design: Prospective cross sectional observational study.

Setting: The study will be carried out in the department of Obstetrics and Gynaecology, at Acharya Vinoba Bhave rural Hospital (AVBRH), a tertiary care teaching hospital situated in rural area of central India. The study was undertaken after approval from the institute ethical committee.

Participants: We will prospectively enroll all the term pregnant women who have met inclusion criteria at AVBRH, Sawangi. Informed, written consent will be obtained from all participants.
Inclusion criteria: All term pregnant women (Gestational Age at or more than 37 weeks) single gestation, cephalic presentation, intact amniotic membranes at Department of Obstetrics & Gynaecology at AVBRH, Sawangi who have given written consent will be included in the study.

Exclusion criteria: Pregnant women with preterm gestation(< 37 weeks of gestation),post term pregnancy, (GDM) gestational diabetes mellitus, PIH ,multifetal gestation, premature rupture of membranes (PROM),fetal anomalies ,congenital anomalies, polyhydramnios will be excluded from the study.
Methods: Ethical clearance from institutional ethical committee will be taken. Before enrolling patients into the study, every woman will be explained the type and nature of the study. Study will be conducted in the department of Obstetrics and Gynaecology in AVBRH, Sawangi Meghe Wardha.

The study will be carried out for over a period of two years from October 2020 to October 2022. Data for study will be collected from patients attending the department of Obstetrics and Gynecology in Acharya Vinoba Bhave Rural Hospital attached to Datta Meghe Institute of Medical Sciences , Sawangi.

The patients attending OPD will be first interviewed as per a set proforma noting their personal details, address, contact number. Consent of every patient will be taken before including in the study . All the patients will be evaluated and data will be collected as following : Patient details and history followed by routine ANC profile and Ultrasonography.

All term pregnant women will be closely monitored and AFI is estimated with the help of four-quadrant technique using ultrasonography and those pregnant women with AFI less

than 5th centile, i.e., AFI<5cm at term are explained as low amniotic fluid index at or >37 weeks of gestation and those pregnant women with AFI less than 8th centile, i.e., AFI <8 cm at term are defined as borderline amniotic fluid index at or >37 weeks of gestation, and those women with AFI between 8th and 24th centile, i.e., AFI 8cm – 24cm at term are explained as normal amniotic fluid index at or >37weeks of gestation .

According to the prevalence of decreased amniotic fluid, we have derived a sample size consisting of 100 term pregnant women allocated in each group. After meeting inclusion and exclusion criteria , further division will be done. It includes 100 pregnant women at term with low amniotic fluid index(AFI<5 cm) as group A , 100 pregnant women with borderline amniotic fluid index (AFI>5cm and <8cm)as group B and 100 pregnant women at term with normal amniotic fluid (AFI 8cm-24cm) as group C. Accordingly, each group will be analysed and compared based on the ultrasonographic findings for their antenatal, intranatal and postnatal maternal and fetal outcomes

Follow-up of patients identified with normal and decreased amniotic fluid will be carried out till they are presented in labor room in active phase of labour (with cervical dilation showing >4 cm and with adequate uterine contractions at the rate of 3–4 per minute lasting for at least 45 seconds) or they are admitted to labor room for other indications through OPD. Progress of labour will be monitored by plotting Partograph and accordingly intranatal and perinatal outcomes will be noted.

Documentation of neonatal outcomes will be carried out in the form of APGAR score and birth weight . Any admission to the neonatal unit (NICU)for perinatal morbidities and perinatal mortality will be noted.

The outcomes will be documented . They will be statistically analyzed using the software named SPSS 24.0 version and the outcomes will be observed.

Sample Size:

Sample size = 100 in each group

Formula with desired error or margin

$n = (Z_{\alpha/2})^2 * P *(1-P) / d^2$

where;

$Z_{\alpha/2}$ is the level of Significance a+5% i.e;

95% Confidence interval = 1.96

P = Prevalence of Borderline AFI = 6% = 0.06 (2)

d = Desired error of margin = 7 % = 0.0.7

$n = 1.96^2 \times 0.06 \times (1-0.06) / 0.07^2$

= 86.66

= 100 patients needed in each group

Statistical Analysis: Data will be entered in a predesigned proforma.

Software used in the study **:** SPSS 24.0 version

Expected Results:

The study will include 1OO pregnant women at or >37weeks gestational age in each group. The Amniotic Fluid Index (AFI) levels will be compared between the groups A , B and C. Secondary outcomes like outcome of pregnancy and neonatal wellbeing will be assessed. In this study, the desired outcome is to consider the maternal and fetal outcomes in term pregnancies with decreased amniotic fluid relative to term pregnancies with normal amniotic fluid .

Discussion:

Many studies have been performed to demonstrate the correlation of
adverse maternal and fetal outcomes with reduced amniotic fluid index(17). Amniotic fluid volume estimation has become an integral part of antenatal fetal surveillance, and in fact in some centers it is a largely weighted parameter. The amniotic fluid index has been found to be validated by ultrasonography as an effective and reproducible technique for calculating the volume of amniotic fluid .The purpose of the study was to evaluate the association of decreased amniotic fluid with adverse fetal and maternal outcomes in term pregnancies.

Findings showed that in women with reduced AFI, maternal outcomes such as
preterm delivery and labor induction were significantly higher than those in the usual popula tion. Furthermore, in women with reduced AFI a higher risk of neonatal complications such as
IUGR, LBW, Apgar score less than 7, suboptimalgrowth resulting in need for admission to NI CU is also indicated. Few of the related studies were reported(18-21). Subramanyam et. al. (22) reported a study on neonatal outcome in pregnancies with oligohydramnios. Dhok et al. reported on biomarkers for prediction of preterm delivery(23). Other related studies were reported by Taksande et. al.(24), Bhriegu et. al. (25), Kshirsagar et. al (26) and Taneja et. al. (27-34).

Conclusion:
In conclusion, because of these adverse outcomes reported in patients with decreased AFI, they should be closely examined and monitored in advance. A well-organized prospective cross sectional study is needed to determine association of AFI with adverse perinatal outcomes.

Limitation:

The study is based on observation of maternal and fetal outcomes in term pregnancies with reduced amniotic fluid compared with those with normal amniotic fluid. Limitation of this study can be cited to be due to lack of providing intervention to those with decreased AFI. Giving timely management to those with decreased amniotic fluid will result in improvement of perinatal morbidity and mortality. Eventually resulting in decrease in incidence of neonatal morbidities such as low birth weight, meconium aspiration and NICU admission.

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