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# STUDY OF EFFECT OF SILDENAFIL CITRATE IN PREGNANT WOMEN WITH OLIGOHYDRAMNIOS

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## ABSTRACT

**Background**: About 1 to 2 percent of pregnancies are complicated by oligohydramnios, It puts the fetus at danger by causing iatrogenic premature birth and perinatal morbidity and mortality. The health of the mother and fetus is seriously endangered by oligohydramnios, This study was conducted on the safety andeffectiveness of sildenafil citrate in treating oligohydramnios or borderline oligohydramnios among pregnant woman.

**Materials and Methods**: 60 pregnant women with oligohydrominos or borderline oligohydramnios participated in a hospital-based prospective case control study at Viswabharathi Medical College and General Hospital. The pregnant women were divided into two groups, each consisting of thirty patients. Group A was allocated to the case group, whereas Group B was associated to the placebo group. The primary amniotic fluid index of the patients was measured when hospitalized. In Group A, 3 liters of isotonic solution (Ringer lactate) were delivered intravenously every 24 hours, along with 50 mg of oral sildenafil citrate every 8 hours and hydration therapy. The control group received a placebo. The amniotic fluid index was re-measured one and two weeks after the intervention among the pregnant woman in both the groups. Drug adverse effects and the maternal pregnancy termination were noted

**Results**: In both the groups, the amniotic fluid index rose gradually. The Amniotic fluid index was compared between the two groups during the first and second week. No significant increase in the amniotic fluid index is observed in either group over the course of one week. In the second week, the intervention group had a statistically significant increase in amniotic fluid index (7.36 ± 2.86) compared to the control group (6.12 ± 1.36).

**Conclusion**: our findings indicate that sildenafil citrate consistently increased AFI without causing deleterious embryonic consequences and it is recommended that the incorporation of sildenafil citrate into the treatment of oligohydramnios may be a beneficial approach.

**KEYWORDS**: Oligohydramnios; Sildenafil citrate, amniotic fluid index (AFI).

## INTRODUCTION

Amniotic fluid, which envelops the developing baby, performs a number of roles, including protecting it from harm to the mother's abdomen by acting as a buffer between it and the umbilical cord. Additionally, amniotic fluid reduces the risk of uterine wall compression and protects the umbilical cord [1]. The antibacterial qualities of amniotic fluid help shield the baby from harmful germs. In addition, the fetus stores nourishment and fluids, including vitamins, proteins, electrolytes, and immunoglobulins. For the fetal organs—the musculoskeletal, digestive, and pulmonary systems—as well as for appropriate development and maturation, this fluid provides the environment and vital growth factors. Amniotic fluid may be used by doctors to monitor the progress of a pregnancy and predict the outcomes of the fetus [2].

The amount of fluid entering and leaving a woman's amniotic sac determines its size. Late pregnancy, swallowing, fetal urine, and lung fluid evacuation all play an important role in fluid transport, with limited aid from other sources [3, 4]. Amniotic fluid volume varies as a result of prenatal disorders affecting any of these processes. For example, growth-restricted fetuses may reroute blood flow away from their kidneys, resulting in reduced fetal urine output and oligohydramnios [5].

In pregnancy, oligohydramnios is characterized by an unusually low level of amniotic fluid. It causes complications in around one to two percent of pregnancies [6]. Sonographically, it is described as amniotic fluid volume <5% anticipated for gestational age, Amniotic Fluid Index (AFI) <5 cm, or Single Deepest Pocket of Liquor (SDP) <2 cm [7,8].

Sildenafil citrate, a phosphodiesterase type 5 inhibitor, increases uterine-placental perfusion [9]. Sildenafil citrate has been shown to increase uterine blood flow and enhance estrogen-induced vasodilation [10]. This study was conducted on the safety andeffectiveness of sildenafil citrate in treating oligohydramnios or borderline oligohydramniosamong pregnant woman.

## MATERIALS AND METHODS

The present hospital based prospective case control study was carried out on 60 pregnant women with oligohydrominosor border line oligohydrominosat Viswabharathi Medical College and general Hospital for a period of one year from January 2024 to January 2025.

**Inclusion criteria**: Pregnant women aged from21 to 45years old, pregnant women at gestational age from 24 week of gestation to 36 week of gestation, A.F.I. <8 cm;

**Exclusion criteria:** pregnant women with multiple pregnancies, pregnant women with congenital fetal malformations, pregnant women with premature rupture of membranes, pregnant women using any vasodilator drugs in treatment of preconceptional medical diseases, maternal vascular diseases that affect fetal Doppler as autoimmune diseases, pregnant women who were smokers or alcohol abusers, and pregnant women who developed an urgent delivery during follow up. Unbooked cases and in mothers with cardiovascular morbidity

60 Pregnant women admitted to Viswabharathi Medical College & General Hospital, Kurnool, were separated into two groups. Group A was allocated to the case group, whereas Group B was associated to the placebo group. Random distribution included the use of sealed and concealed envelopes. In addition, a statistician who was uninformed of the study's groups completed the statistical analysis. When the patients were hospitalized, they had their primary amniotic fluid index assessed. In the intervention group, 3 liters of isotonic solution (Ringer lactate) were delivered intravenously every 24 hours, along with 50 mg of oral sildenafil citrate (Pharma Chemistry-Iran) every 8 hours and hydration therapy. The control group received a placebo. The amniotic fluid index was re-measured one and two weeks following the intervention in both the groups. If an ultrasound showed an increase of atleast 8 cm in the amniotic liquid index, the mother was discharged. Drug adverse effects and the maternal pregnancy termination were noted

Statistical analysis: SPSS version 22 was used to do statistical analysis of the data. p value $\leq 0.05$ was considered significant. Quantitative data were described using the mean and standard deviation, whereas qualitative data were described using frequency and percentages. The unpaired*t*-test was performed to analyse quantitative variables between thetwo groups and the chi-square test was utilized for theanalysis of qualitative data.

## RESULTS

Maternal age, BMI, and amniotic fluid indexbefore the intervention are not significantly differentbetween the two groups as shown in Table 1

**TABLE 1: COMPARISON OF BASELINE CHARACTERISTICS**

| Characteristics | Sildenafil (n=30) | Placebo (n=30) | p value |
|---|---|---|---|
| Age (years) | 28.61± 6.74 | 28.74 ± 6.65 | 0.376 |
| BMI ($kg/m^2$ | 25.3 ± 2.2 | 25.4 ± 2.1 | 0.473 |
| Basic amniotic fluid index (cm) | 5.51 ± 1.21 | 5.52±1.18 | 0.352 |

As considered in Table 2, the amniotic fluid levels wereincreased over time in two groups. During the first and second weeks, the amnioticfluid change was compared between the two groups. Over one week, neither group's amniotic fluid indexincreases significantly. This changewas significant at the end of two weeks.

**TABLE 2: COMPARISON OF AMNIOTIC FLUID INDEX IN THE TWO GROUPS BEFORE AND AFTER TREATMENT**

| AFI | SILDENAFIL (N=30) | PLACEBO (N=30) | P value |
|---|---|---|---|
| Basic | 5.51 ± 1.21 | 5.52±1.18 | 0.352 |
| After $1^{ST}$week | 5.98 ± 0.86 | 5.76 ± 0.97 | 0.173 |
| After $2^{ND}$week | 7.36± 2.86 | 6.12 ± 1.36 | 0.002* |

Women were monitored for adverse side-effects such as headache, palpitation, flushing and visual disturbance. Decision for termination of pregnancy was made after standard clinical assessment. There was no significant difference between the twogroups regarding pharmacological side effects as shown in Table 3.

**TABLE 3: COMPARISON OF SIDE EFFECTS IN THE TWO GROUPS**

| SIDE EFFECTS | Sildenafil (n=30) | Placebo (n=30) | p value |
|---|---|---|---|
| headache | 1 (3%) | 4 (13%) | 0.342 |
| palpitation | 1 (3%) | 5 (17%) | 0.265 |
| flushing and visual disturbance | 2 (7%) | 4 (13%) | 0.254 |
| Termination of pregnancy | 1 (3%) | 3 (10%) | 0.532 |

**DISCUSSION**

The findings showed that sildenafil citrate and hydration, compared to hydration alone, can improve AFIwithout causing negative side effects and is an effectivetreatment strategy. The present study found no significant difference between groups regarding age. This was consistent with the findings of Mohammed et al.11]. In our study there was no significant difference between groups regarding BMI. This was consistent with the findings of Mohammed et al. [11].

This study's findings are consistent with those of Choudhary et al., who found a considerable rise in the amniotic fluid index after the use of sildenafil citrate during pregnancy, with no particular negative effects recorded for the mother or fetus [12]. Furthermore, Maher et al. demonstrated that the combination of sildenafil citrate and intravenous hydration is related with increased amniotic fluid volume and a longer pregnancy than hydration alone [13]. According to Nath et al. [14], individuals with oligohydramnios may benefit greatly from sildenafil citrate.

A randomized controlled experiment study especially emphasized the ability of sildenafil citrate to boost amniotic fluid production in pregnant women with oligohydramnios and borderline oligohydramnios, finding no significant detrimental effects for either the mother or the baby [15]. In the Dunn et al. study, women who received sildenafil citrate had no notable side effects, confirming the safety of this medication [16].

## CONCLUSION

Based on the results, sildenafil citrate consistentlyincreased AFI without causing negative embryonicconsequences. Our studysuggests that integrating sildenafil citrate into the management of oligohydramnios could be a valuable strategy.

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