Original Article

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Comparison of Sildenafil Citrate plus Hydration with Hydration Alone in Terms of Amniotic Fluid Index Improvement in Idiopathic Oligohydramnios during Third Trimester of Pregnancy

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Author`s Contribution

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ABSTRACT

Objective: To compare the effectiveness of sildenafil citrate plus hydration with hydration alone in improving amniotic fluid index (AFI) among women with idiopathic oligohydramnios in the third trimester.

Methodology: This prospective comparative interventional study was conducted at Sir Ganga Ram Hospital, Lahore, over six months from September 2022 to February 2023. Sixty women aged 18–35 years with singleton pregnancies at 30–34 weeks of gestation, AFI <5 cm, and normal umbilical artery Doppler indices were assigned to two treatment groups according to the treatment decision. Group A received sildenafil citrate 25 mg orally every 8 hours plus 2 L intravenous Ringer's lactate over 4 hours, while Group B received 2 L intravenous Ringer's lactate alone. Both groups were encouraged to maintain oral hydration and followed weekly until 37 weeks, with serial ultrasound assessment of AFI.

Results: The mean maternal age was 26.55±5.05 years and mean gestational age was 32.52±1.43 weeks. AFI was significantly higher in the sildenafil plus hydration group than in the hydration-alone group after 48 hours (5.03±3.40 vs. 3.97 cm; p=0.001) and remained significantly higher during follow-up. Birth weight was also significantly greater in Group A than Group B (2855.37±88.93 vs. 2629.40±72.69 g; p=0.001). Low Apgar scores (<7) were less frequent in Group A than Group B (10.0% vs. 33.3%; p=0.001). No significant differences were observed in gestational age, mode of delivery, or maternal adverse effects (p>0.05).

Conclusion: Sildenafil citrate combined with hydration significantly improved AFI and neonatal outcomes compared with hydration alone, without a significant increase in maternal adverse effects.

Keywords: Amniotic Fluid Index; Hydration; Oligohydramnios; Sildenafil Citrate. Sildenafil Citrate.

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Introduction

The amniotic fluid (AF) plays an important role in supporting the healthy pregnancy[1] and promoting optimal fetal and maternal outcomes, with the eventual goal of delivering a healthy newborn from a healthy mother. It serves multiple protective and developmental functions, including protection of fetus from external physical impact, protections against compression of the umbilical cord, allows the fetus room to move freely, protective the

intrauterine environment within which the fetal respiratory, gastrointestinal, urinary, and musculoskeletal systems to develop and mature normally over the course of pregnancy.[1,2]

The condition of idiopathic oligohydramnios is characterized by an abnormal reduction in volume of amniotic fluid surrounding the fetus within the uterus in the absence of an identifiable maternal, fetal, or placental cause. It is typically identified on ultrasound when the amniotic fluid index (AFI) is 5 cm or less, or when the single deepest vertical pocket of fluid measures under 2 cm.[3] The oligohydramnios occurs in approximately 1 to 5% of the pregnancies, and may rises to over 12% in the post term pregnancies.[2,4] It mostly occurred during third trimester of pregnancy, when the amount of amniotic fluid mostly depends on fetal urine production, secretion of the pulmonary fluid, fetal swallowing, and intramembranous absorption, along with conditions like high maternal hypertensive disorders, diabetes, birth defects, and a poor placental function, while approximately half of all cases have no identifiable underlying reason and are therefore considered idiopathic.[2,5] It affects a substantial proportion of pregnancies during third-trimester and carries a well-documented correlation with adverse perinatal outcomes, including meconium-stained liquor, fetal heart abnormalities and higher rates of C-section deliveries.[6]

According to the population-level data from lower and middle income regions further showed that the oligohydramnios is associated to a several-fold rise in stillbirth and neonatal mortality compared to the pregnancies with normal fluid volume,[7] whereas according to a hospital-based series proved the higher rates of induced labour and operative deliveries even when the underlying cause could not be identified.[8]

Based on such risks, numerous conservative interventions have been investigated to correct isolated oligohydramnios and avoid the early iatrogenic deliveries. The maternal hydration, whether intravenous or oral, is usually used as first-line therapy, but the subsequent increase in amniotic fluid volume is often modest and the short-lived, encouraging the interest in adjunctive agents of pharmacology acting on the uteroplacental circulation.

Out of these agents the sildenafil citrate, a selective phosphodiesterase type-5 inhibitor, improves the nitric oxide–mediated vasodilation within the feto-placental circulation, an effect demonstrated in ex vivo studies the reported that the improved uterine blood flow in pregnancies complicated by fetal growth restriction (FGR),[9] delivering biological plausibility for its uses in the condition of oligohydramnios. According to a randomized trial combination of sildenafil with the hydration produced substantially improved the amniotic fluid volumes, advanced gestational age at delivery, decrease the caesarean deliveries rate, and reduced admissions in NICU compared to the hydration only.[10] Consequently another trials evaluating sildenafil in oligohydramnios and borderline oligohydramnios have similarly observed the significant improvements in AFI with combined therapy,[11] whereas other adjuncts like as inhaled desmopressin have shown less benefits,[12] leaving the optimal adjunct to hydration remains uncertain. Irrespective of this promising evidence, the comparative data remain very limited in the volume, regionally concentrated, and subject to unresolved questions of safety and consistent outcomes. However this study was therefore conducted to compare the effectiveness of sildenafil citrate plus hydration versus hydration only in the improvement of amniotic fluid index in the patients with idiopathic oligohydramnios during the third trimester of pregnancy.

Methodology

This prospective comparative interventional study was conducted at Sir Ganga Ram Hospital, Lahore, over a period of six months, from September 2022 to February 2023, after obtaining ethical approval from the institution. Women aged 18–35 years with a singleton pregnancy at 30–34 weeks of gestation, an amniotic fluid index (AFI) <5 cm, and normal umbilical artery Doppler indices were included. Patients presenting with active labor, twin pregnancy, preterm premature rupture of membranes (pre-PROM) or premature rupture of membranes (PROM), gestational hypertension, diabetes, pre-eclampsia, eclampsia, cardiac disease, non-reactive cardiotocography (CTG), fetal anomalies, intrauterine growth restriction, or allergy to sildenafil citrate were excluded.

After obtaining informed consent, demographic data were recorded, and contact information was documented for follow-up. Each participant underwent obstetric ultrasonography for assessment of AFI. Where required, dexamethasone was administered intramuscularly in two divided doses of 12 mg each, 12 hours apart, for fetal lung maturation. All gynecologists in the unit were informed about the study and follow-up procedures and

were requested to notify the researcher whenever a study participant attended the unit for follow-up.

All the participants were assigned to two treatment groups according to the treatment decision: the sildenafil citrate plus hydration group and the hydration-alone group. The allocation sequence was concealed in sequentially numbered, opaque, sealed envelopes prepared by the researcher. Group A received sildenafil citrate 25 mg orally every 8 hours along with 2 L of intravenous isotonic Ringer's lactate administered over 4 hours. Group B received 2 L of intravenous Ringer's lactate over 4 hours. Fluid therapy was repeated 24 hours after the initial treatment. Participants in both groups were encouraged to maintain adequate oral hydration.

All participants remained hospitalized for 48 hours and were monitored for signs and symptoms of fluid overload and drug-related adverse effects, including headache, hypotension, flushing, gastritis, and allergic reactions. Any adverse effects were managed according to institutional protocols, with appropriate counseling. Ultrasonography was performed 48 hours after the initial treatment to reassess the AFI.

Participants showing an improvement in AFI of at least 1 cm were discharged. Those in Group A were advised to continue sildenafil citrate 25 mg three times daily until delivery and to drink at least 2 L of water daily, while those in Group B were advised to continue oral fluid intake of at least 2 L daily. All participants were followed weekly until 37 weeks of gestation, with ultrasonography performed at each visit to assess AFI. If there was no improvement in AFI during follow-up or evidence of fetal compromise, delivery was planned earlier. Participants who delivered elsewhere were contacted by telephone to obtain information regarding gestational age and fetal outcome at delivery. Data were entered and analyzed using SPSS version 26.

Results

Both groups were comparable at baseline. The mean maternal age was 26.67±4.97 years in Group A and 26.43±5.20 years in Group B, while the mean gestational age was 32.60±1.30 and 32.43±1.57 weeks, respectively (p>0.05). The mean AFI at admission was also comparable between Group A and Group B (3.53±0.51 vs. 3.40±0.50 cm; p=0.309), as shown in Table I.

Table I: Baseline characteristics of study groups.

Characteristics	Group A (n=30)	Group B (n=30)	P value
Age (years)	26.67±4.971	26.43±5.204	0.860
Gestational Age	32.60±1.303	32.43±1.569	0.656
AFI at Admission (cm)	3.53±0.507	3.40±0.498	0.309

The AFI remained consistently higher in Group A than in Group B at each assessment from 48 hours through the seventh week, with statistically significant differences at all time points (p<0.05). In Group A, the mean AFI increased progressively from approximately 5 cm at 48 hours to more than 10 cm by the seventh week. In comparison, Group B showed a more modest increase, indicating a greater and more sustained improvement in AFI with sildenafil citrate plus hydration, as presented in Table II.

Neonatal Apgar scores were significantly better in Group A than in Group B. In Group A, 61.5% of newborns had an Apgar score ≥7, whereas 76.9% of newborns with an Apgar score <7 were from Group B (p=0.016). However, the mode of delivery did not differ significantly between the groups. Approximately 70% of women in both groups underwent cesarean section, while 30% had vaginal deliveries (p=0.853), as shown in Table III.

Table II: Comparison of AFI between the groups at various time intervals.

Interval	Study Group	Mean	SD	p-value
AFI 48 Hours	Group A	5.03	1.273	0.0001
	Group B	3.97	0.850	
AFI Week 1	Group A	6.17	1.234	0.0001
	Group B	4.00	0.830	
AFI Week 2	Group A	7.72	1.556	0.001
	Group B	4.59	0.946	
AFI Week 3	Group A	8.00	1.600	0.002
	Group B	5.00	0.912	
AFI Week 4	Group A	8.55	2.277	0.001
	Group B	5.40	1.246	
AFI Week 5	Group A	9.57	2.277	0.001
	Group B	6.08	1.240	
AFI Week 6	Group A	10.00	1.581	0.001
	Group B	07.13	1.246	
AFI Week 7	Group A	10.89	2.110	0.001
	Group B	07.33	1.926	

Table III: Comparison of Apgar score and MOD between the Groups.

APGAR Score		Study Group A	Study Group B	Total	p-value
APGAR Score	<7	3 (23.1%)	10 (76.9%)	13 (25.0%)	0.016
	≥7	24 (61.5%)	15 (38.5%)	39 (75.0%)	
Mode of Delivery	LSCS	19 (70.4%)	17 (68.0%)	36 (69.2%)	
	SVD	8 (29.6%)	8 (32.0%)	16 (30.8%)	0.853

The most frequently reported adverse effects in Group A were headache (18.5%), flushing and allergic reactions (14.8% each), hypotension (11.3%), and gastritis (7.4%). These adverse effects were mild and resolved shortly after management. The difference in adverse effects

Table IV: Comparison of side effects between the groups.

Headache		Study Group		Total	p-value
		A	B		
.Headache	Yes	5 (18.5%)	0 (0.0%)	5 (9.6%)	0.052
	No	22 (81.5%)	25 (100.0%)	47 (90.4%)	
Flushing	Yes	4 (14.8%)	0 (0.0%)	4 (7.7%)	0.658
	No	23 (85.2%)	25 (100.0%)	48 (92.3%)	
Hypotension	Yes	3 (11.3%)	2 (8.0%)	5 (9.6%)	0.538
	No	24 (88.9%)	23 (92.0%)	47 (90.4%)	
Allergic Reaction	Yes	4 (14.8%)	0 (0.0%)	4 (7.7%)	0.065
	No	23 (85.2%)	25 (100.0%)	48 (92.3%)	
Gastritis	Yes	2 (7.4%)	0 (0.0%)	2 (3.8%)	0.265
	No	25 (92.6%)	25 (100.0%)	50 (96.2%)	

between the groups was not statistically significant, suggesting that sildenafil citrate was generally well tolerated, as presented in Table IV.

Discussion

Idiopathic oligohydramnios is a condition with no clear underlying cause, and its management remains challenging. Numerous management approaches have been used; however, their effects are often temporary. Sildenafil citrate has gained interest because its vasodilatory effects may enhance uteroplacental blood flow and potentially increase amniotic fluid volume. Although recent evidence highlights the potential benefits of sildenafil, it also underscores the need for further research to establish its effectiveness and safety.[13,14]

Present study was conducted to assess the effectiveness and safety of sildenafil citrate with hydration compared to hydration alone among patients with oligohydramnios and found that the, AFI rose steadily in the sildenafil interventional group, from mean = 5.03 cm at 48 hours to mean =10.89 cm by week 7, compared with a more modest rise from 3.97 cm to 10.13 cm in the only hydrate group (p = 0.001). The findings were consistent with the study by Maher et al[10] who reported that, there was a significant higher final amniotic fluid volume in sildenafil plus hydrated patients compare to those who were only hydrated (11.5 cm versus 5.4 cm) p = 0.02.

Our findings were supported by Kalburgi PA et al[15] where mean AFI was similar at baseline between the sildenafil and placebo groups (5.51 versus 5.52 cm), without significant differences, p=0.352), while significantly higher in the sildenafil group after 2 weeks (7.36 versus 6.12 cm) p=0.002. Consistently Maged et al[16] also reported a significant improvement in hemodynamic parameters after four weeks of sildenafil therapy, supporting the view that sildenafil can improve uteroplacental blood flow, that may explain the rise in amniotic fluid index observed in the sildenafil group. Moreover the longer treatment period in their trial may also explain why they found significant effects.[16] According to another study by Nath J et al[17] demonstrated that, after using sildenafil therapy, marked improvement noted in 87 of 90 patients (96.7%) with IUGR alone, 35 of 40 (87.5%) with oligohydramnios alone, and 64 of 70 (91.4%) with both conditions. Overall, 186 of 200 patients (93%) improved, while 14 (7%) showed no improvement. In alignment with our findings, Nasrolahi S et al.[11] demonstrated that sildenafil produced a significant increase in AFI from baseline to 2 weeks (5.24 to 7.06 cm), whereas the placebo group showed no significant difference (5.52 to 6.06 cm; p = 0.232). Nevertheless, the between-group difference in AFI at 2 weeks did not reach statistical significance (p = 0.097). Moreover, Siram Sreeja Reddy DS et al.[18] reported that, in the sildenafil group, AFI increased progressively throughout the treatment period, from a mean of 4.2 cm after 24 hours to 6.5 cm at 2 weeks and 8.0 cm at 4 weeks. These findings suggest that sildenafil may produce a consistent and clinically meaningful improvement in amniotic fluid volume over a 4-week treatment period.

In contrast to our findings Dastjerdi MV et al[19] reported that the median AFI in the sildenafil versus hydration groups was 8.5 cm versus 8.0cm at 24 hours, 9.5cm vs 9.1 cm at week 1, 9.0 cm vs. 10.0 cm at week 2, 10.4 cm vs. 9.4 cm at week 3, 10.8 cm vs. 9.1 cm at week 4, and 10.0 cm vs. 9.3 cm at week 5, without significant differences (p>0.05), not supporting the our findings and this may due to the difference in dose of sildenafil, frequency of administration, difference in gestational age of the study populations or severity of oligohydramnios at the enrollment may have influenced the magnitude and timing of AFI improvement.

Additionally, this study found significantly better Apgar scores in the sildenafil group, with 61.5% of newborns scoring ≥7 compared with 38.5% in the control group (p=0.016). This finding is consistent with Maher et al.[10],

who reported fewer low Apgar scores and NICU admissions among patients receiving sildenafil. Similar neonatal benefits have also been reported in hydration-based studies by Anant et al.[20] and Hadalageri et al.[21] The improvement in AFI may contribute to better neonatal condition at birth by reducing umbilical cord compression and improving placental and umbilical perfusion.

However, the mode of delivery did not differ significantly between the groups in the present study (p=0.853), in contrast to the study by Maher et al.[10], which reported a lower cesarean section rate with sildenafil (28% vs. 73%). Other studies, including those by Hadalageri et al.[21] and Yadav et al., have reported mixed findings regarding the mode of delivery. The lack of a significant difference in the present study may therefore reflect variability in this outcome across different study populations and treatment protocols.

Mild adverse effects were observed in the sildenafil group but were not statistically significant, consistent with previous studies of oligohydramnios that reported no major safety concerns.[16] However, the STRIDER trial reported an increased risk of neonatal pulmonary hypertension with sildenafil in pregnancies complicated by fetal growth restriction.[22] Therefore, although sildenafil appeared to be well tolerated by mothers in the present study, its neonatal effects may vary according to the underlying clinical condition and warrant careful monitoring.

The present study has several limitations, including a relatively small sample size, attrition during later follow-up, a non-blinded design, and the absence of long-term neonatal follow-up. Further large, blinded, multicenter studies with standardized treatment protocols and extended maternal and neonatal safety monitoring are warranted.

Conclusion

Administration of Sildenafil citrate combined with the hydration significantly progresses the AFI and neonatal Apgar outcomes compared to patients who were only hydrated in idiopathic oligohydramnios, without a substantial increase in maternal side effects, reflecting that its use is effective and reasonably safe adjunct therapy. However, based on relatively limited sample size further larger, blinded trials are recommended to more authorize the finding along with long-term fetomaternal safety before implement in clinical practice.

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