

Original Article

Effectiveness of Sildenafil Citrate in the Management of Oligohydramnios and Intrauterine Growth Restriction

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Abstract

Background: Intrauterine growth restriction (IUGR) and oligohydramnios are the major causative factors linked to increased perinatal morbidity and mortality. IUGR refers to a condition where the fetus fails to achieve its genetically predetermined normal growth, often restricted by impaired placental perfusion. A phosphodiesterase-5 (PDE-5) inhibitor, acts as a vasodilator that enhances utero-placental blood circulation, thereby supporting improved fetal growth.

Objective: To determine the therapeutic effectiveness of Sildenafil Citrate in the treatment of IUGR pregnancies associated with impaired sufficiency of placenta.

Methods: A prospective interventional study was carried out at Obstetrics and Gynaecology department, Sir Ganga Ram Hospital Lahore from December 2022 to December 2023. Women aged 18 to 35 years diagnosed with IUGR, having an estimated fetal weight below the 10th percentile for gestational age and evidence of impaired uteroplacental circulation, were included and divided into two groups: the study group received standard antenatal care plus Sildenafil Citrate 25 mg orally three times daily, while the control group received standard antenatal care alone. All the patients underwent ultrasound for fetal biometry AFI and umbilical artery Doppler for S/D ratio followed by after one week to monitor blood pressure and fetal well-being, and after two weeks for reassessment of fetal biometry. Data was entered and analyzed via SPSS version 26.

Results: Mean age of the patients was 27.1±4.3 years, gestational age was 30.9±1.8 weeks and parity was 1.7±1.3. Baseline demographic and obstetric parameters were similar in both study groups ($p > 0.05$). When compared two-week post-intervention, Sildenafil citrate group demonstrated higher means of abdominal circumference (25.9±1.4 vs. 25.1±1.2, $p 0.018$); fetal weight (1717.4±306.4 vs. 1582.9±266.2, $p 0.054$); and lower means of systolic/diastolic ratio (3.6±0.4 vs. 3.8±0.3, $p 0.034$); amniotic fluid index (6.7±1.4 vs. 6.9±1.0, $p 0.554$) than the counterpart.

Conclusion: Sildenafil Citrate observed to be a potentially effective therapeutic option for managing IUGR and Oligohydramnios.

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Introduction

Intrauterine growth restriction (IUGR), affecting approximately 10% to 15% of pregnancies throughout the world, is a significant concern in developing nations and a major contributor to perinatal mortality

and complications,¹ including respiratory issues, neuro-developmental disabilities, and long-term health challenges for the child, such as an increased risk of obesity and hypertension, primarily due to impaired placental development and blood flow.^{1,2} At present, no proven clinical treatments exist that can enhance perinatal survival, promote intrauterine growth, or improve the long-term outcomes of infants affected by FGR. Management primarily involves close monitoring to identify the most appropriate time for delivery.³ It refers to an abnormal slowing of fetal growth along the expected intrauterine growth curve; however, its definition remains controversial, with no universally accepted criteria established in the literature.⁴ It is the 2nd most common causative factor of perinatal death and is associated with an elevated risk of complications including low apgar score, hypoxemia and the cord blood acidemia, which can adversely affect neonatal outcomes.^{5,6} On the other hand oligohydramnios also linked to an raised risk of the adverse pregnancy outcomes, such as IUGR, defects in developmental, and complications during labour and birth. In a normal pregnancy, trophoblastic cells infiltrate and transform the maternal spiral arteries, converting them into wide, low-resistance vessels that allow increased blood flow to the placenta.⁷ Impaired transformation of spiral arteries is a central mechanism underlying fetal growth restriction. The continued presence of vasoactive smooth muscle cells restricts placental circulation, leading to decreased placental perfusion and subsequent hypoxia-reperfusion stress.⁸

Nitric oxide enhances placental perfusion by inducing vasodilation in maternal vessels. Its second messenger, cyclic guanosine monophosphate (cGMP), is broken down by the phosphodiesterase enzyme family. As a selective inhibitor of (PDE-5), Sildenafil citrate specifically targets the major PDE enzyme expressed in reproductive tract.⁹⁻¹¹ Sildenafil citrate has demonstrated potential in several studies addressing fetal growth restriction and pre-eclampsia, as well as in animal models and research involving human tissues.¹²⁻¹⁴ The growing worldwide interest in sildenafil as a potential therapy for restriction in growth of fetus has led to multiple coordinated national trials conducted through the Global Obstetric Network. The such initiative involves randomized data collection and a commitment to conducting a prospective meta-analysis using individual data of the patients. This trial hypothesizes that sildenafil can prolong the gestation of severely growth-restricted fetuses by at least one week. The proposed mechanism involves the enhancing uteroplacental perfusion, resulting in the promote better fetal growth

and intrauterine well-being.^{15,16} Cause of the IUGR is often unknown, while in many cases, it is possible to identify various factors that contribute to the condition. These factors can be fetal-related, such as infections, malformations, and chromosomal abnormalities. Several placental factors, including chorioangioma, circumvallate formation, infarction, confined placental mosaicism, and vascular obliteration within the placental bed, can also influence its development. Maternal factors such as chronic hypertension, pre-gestational diabetes, cardiovascular diseases, substance abuse, and autoimmune disorders are commonly linked to IUGR. Additionally, external factors can influence fetal growth by affecting the genetically determined growth potential of the fetus.¹⁷

Recent studies have shown that sildenafil citrate significantly improves vasodilation in myometrial small arteries and is linked to fetal weight gain.¹⁶⁻¹⁸ This suggests that sildenafil may offer a promising therapeutic option for the management of IUGR.¹⁸

At present, there is no effective treatment for IUGR pregnancies. However, drugs that enhance the effects of nitric oxide may prove to be beneficial agents in managing growth restriction.⁹⁻¹¹ There are limited number of studies available which can show the benefit of using sildenafil citrate in the treatment of Intrauterine growth restriction associated with placental insufficiency, so more trials are required to reveal encouraging results.

Methods

This Prospective interventional study was conducted at Obstetrics and Gynaecology Sir Ganga Ram Hospital Lahore from December 2022 to December 2023 after approval from Ethics Review Committee (ERC) of Fatima Jinnah Medical University (No. 33-Res-Publication-Gynae-ERC). A total of 70 patients, 19 to 35 years of age with singleton pregnancy at gestational age of 28 to 34 weeks, PIH/uncomplicated preeclampsia, umbilical artery doppler showing raised or normal S/D ratio, amniotic fluid index (AFI) <8cm and intrauterine growth restriction confirmed by ultrasonography were included in the study. Women with multiple pregnancy, fetal anomalies, chronic medical disorders, allergic to sildenafil drug, absent or reverse diastolic flow and those requiring emergency delivery were excluded. Out of 70 patients, 35 were included in Group 1 and 35 were included in Group 2. They were assigned into two study groups. After taking informed consent, their demographic profile i.e. name, age, gestational age (confirmed by dating or the earliest scan available), parity and expected date of delivery were noted. Then

each patient underwent an ultrasound for fetal biometry, AFI and umbilical artery doppler for S/D ratio. Group 1 patients were given tab sildenafil citrate orally 25mg every 8 hours and were observed for drug's side effects (mild allergic reaction, headache, gastritis, flushing and temporary problem in colour differentiation) and fetomaternal monitoring for 48 hours. Then patients were discharged and followed after 1 week to check their blood pressure and reassurance of the fetal movements. Then they were again called after 2 weeks with obstetrical ultrasound for fetal biometry, AFI and umbilical artery doppler (S/D ratio) from the same sonologist. Dexamethasone was administered in two divided doses of 12mg each, 12 hours apart. Group 2 patients were not given tablet sildenafil citrate. Routine feto-maternal monitoring and standard treatment was given for 48hours. They were followed after 1 week to check their blood pressure and reassurance of the fetal movements. They were called again after 2 weeks with obstetrical ultrasound for fetal biometry, AFI and umbilical artery doppler for S/D ratio from the same sonologist. All the collected data was entered into SPSS version 25. Data was stratified for intervention and no intervention groups. The numerical variables were expressed using mean ± standard deviation, while categorical variables using number (percentage). The comparison of means between groups was performed by using t test and of percentages by using chi square test and presented using stacked columns and bar charts. Ap-value < 0.05 was considered statistically significant.

Results

Total 70 women of mean age 27.1 ± 4.3 years (range 19 to 35 years) were recruited in the study. Their gestational age ranged between 28 and 34 weeks. Other characteristics are given in Table 1.

Table 1: Characteristics of study population (n=70)

	Range			
	Mean	Std. Deviation	Min.	Max.
Age (years)	27.1	4.3	19	35
Gestational age (weeks)	30.9	1.8	28	34
Gravida	3.0	1.5	01	06
Parity	1.7	1.3	0	05
Abdominal circumference (cm)	24.3	1.4	21	27
Fetal weight (grams)	1462.8	288.8	950	2000
Systolic/diastolic ratio	3.8	0.3	3.0	4.6
Amniotic fluid index	6.1	0.8	4.0	7.0

Particularly mean age was 26.3 ± 4.3 years in the Sildenafil group and 27.8 ± 4.2 years in the control group (p = 0.162). Average GA was 30.7 ± 2.0 and 31.1 ± 1.6 weeks (p = 0.267), gravida 2.8 ± 1.7 and 3.1 ± 1.3 (p = 0.471), and parity 1.5 ± 1.4 and 1.8 ± 1.0 (p = 0.401), respectively, collectively indicating no significant difference across the groups. Table:2

Table 2: Pre-intervention distribution of means among study groups

	Sildenafil (n=35)	No intervention (n=35)	p-value
Age (years)	26.3 ± 4.3	27.8 ± 4.2	0.162
Gestational age (weeks)	30.7 ± 2.0	31.1 ± 1.6	0.267
Gravida	2.8 ± 1.7	3.1 ± 1.3	0.471
Parity	1.5 ± 1.4	1.8 ± 1.0	0.401

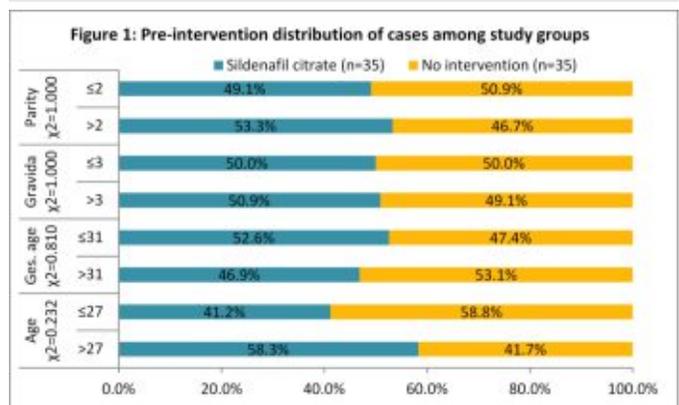


Figure 1: Pre-intervention distribution of cases among study groups.

Two-week post-intervention abdominal circumference increased in both groups. However, Sildenafil citrate group had significantly higher mean (p 0.018) and change (p 0.041) in abdominal circumference than the counterpart. Similarly, fetal weight increased in both groups. Again Sildenafil citrate group had higher mean (p 0.054) and significant change (p < 0.001) in fetal weight than the other group. Sildenafil citrate group also demonstrated significantly lower mean (p 0.034) and decrease in systolic/diastolic ratio (p < 0.001) as compared to with the control group. Table 3.

Number of cases with increased abdominal circumference and fetal weight was higher in the Sildenafil citrate group, (p>0.05). However, cases with decreased or static systolic/diastolic (S/D) ratio (p= 0.001) and static amniotic fluid index (AFI) (p = 0.003) were significantly more frequent in the Sildenafil citrate group compared to the control group. Figure: 2

Table 3: Effect of Sildenafil citrate on IUGR and oligohydramnios

	Sildenafil citrate (n=35)	No intervention (n=35)	p-value	
Pre-intervention	Abdominal circumference (cm)	24.6 ± 1.5	24.1 ± 1.3	0.145
	Fetal weight (grams)	1472.3 ± 308.9	1453.3 ± 271.4	0.786
	Systolic/diastolic ratio	3.8 ± 0.4	3.7 ± 0.3	0.161
	Amniotic fluid index	6.1 ± 0.7	6.1 ± 0.8	1.000
Post-intervention	Abdominal circumference (cm)	25.9 ± 1.4	25.1 ± 1.2	0.018
	Fetal weight (grams)	1717.4 ± 306.4	1582.9 ± 266.2	0.054
	Systolic/diastolic ratio	3.6 ± 0.4	3.8 ± 0.3	0.034
	Amniotic fluid index	6.7 ± 1.4	6.9 ± 1.0	0.554
Mean change	Abdominal circumference (cm)	1.3 ± 0.6	1.0 ± 0.5	0.041
	Fetal weight (grams)	245.1 ± 88.1	129.6 ± 48.0	<0.001
	Systolic/diastolic ratio	-0.2 ± 0.2	0.1 ± 0.2	<0.001
	Amniotic fluid index	0.6 ± 1.0	0.8 ± 0.5	0.379

Discussion

Sufficient blood flow to the placenta is crucial for the effective delivery of nutrients and the growth of the fetus. Fetal growth restriction occurs when pathological and environmental factors disrupt placental function, thereby limiting the availability of nutrients to the fetus. The standard approach for managing IUGR is expectant management until pregnancy termination. This includes modifying the mother's lifestyle and conducting regular fetal surveillance to monitor the well-being of the fetus. Since restricted placental circulation is a major concern, vasodilator like sildenafil citrate has emerged as a drug that improves the placental circulation. It is useful in pregnancy affected by fetal growth restriction by improving fetal weight and oligohydramnios. In this study, the sildenafil citrate group demonstrated a significantly greater mean (p = 0.018) and change (p = 0.041) in abdominal circumference compared to the control group, suggesting improved fetal growth. These findings are consistent with previous studies. For instance, Von Dadelszen et al¹¹ reported a significant increase in abdominal circumference in the sildenafil group, supporting the vasodilatory effect of sildenafil on uteroplacental circulation. Similarly, a randomized controlled trial by Shehata et al¹⁹ observed a marked improvement in abdominal circumference growth velocity after two weeks of sildenafil administration (p = 0.001), reinforcing shared pathophysiological mechanism sildenafil enhances nitric oxide-mediated vasodilation, leading to improved uteroplacental perfusion and nutrient delivery.

Similarly, fetal weight increased in both groups; however, the sildenafil citrate group showed a higher mean fetal weight (p = 0.054) and a statistically significant change (p<0.001) compared to the control group. These findings were in agreement with a systematic review and meta-analysis by Rakhanova et al which reported a significant increase in fetal weight following sildenafil exposure.¹⁸ Likewise, a randomized controlled trial by Maged et al reported that there was a significant improvement noted in mean birth weight at delivery, with more favorable outcomes the sildenafil-treated group in contrast to the control group.²⁰ Furthermore, the sildenafil group exhibited a significantly lower mean (S/D) ratio (p = 0.034) and a significant reduction in S/D ratio change (p < 0.001) when compared to the no-intervention group. These results are supported by the trial conducted by Shehata et al¹⁹ which demonstrated a significant decrease in the umbilical artery pulsatility index (p = 0.001) in women administered sildenafil citrate. Almost similar findings across studies may be due to the well-established pharmacological action of

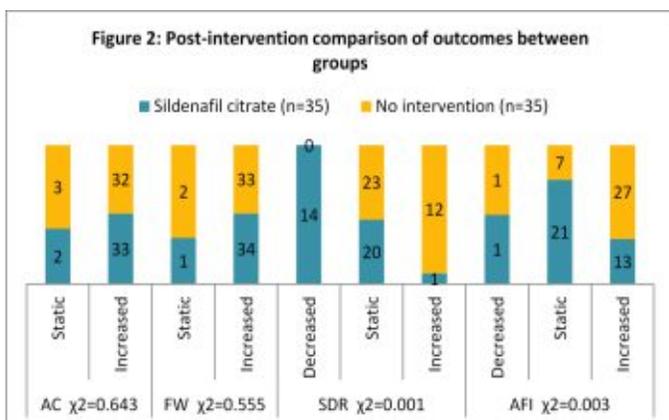


Figure 2: Post-intervention comparison of outcomes between groups

sildenafil citrate. According to another study conducted by A. Trapani Jr. et al. demonstrated that sildenafil citrate use in pregnancies complicated by IUGR was related to the significant decreases in both uterine artery and umbilical artery Doppler pulsatility indices, indicating improved uteroplacental blood flow.²⁰ Consistent findings were reported in a trial by Mohammad Maged et al. where significant hemodynamic improvements were observed after four weeks of sildenafil therapy.²¹ Though the increase in amniotic fluid index (AFI) in our study's sildenafil group was statistically insignificant ($p = 0.379$), the number of cases with a static AFI ($p = 0.003$) was significantly lower compared to the control group. These findings suggest a possible stabilizing effect of sildenafil on amniotic fluid levels. Consistent results were observed in the study by Shahla Nasrolahi et al who reported a notable increase in AFI among participants receiving sildenafil citrate.²² Based on these findings and supporting literature, sildenafil citrate may serve as a promising therapeutic strategy in managing IUGR. Nath J. et al. further corroborated this, concluding that sildenafil enhances utero-placental circulation by dilating myometrial arteries, thereby promoting fetal growth and presenting a potential treatment for early-onset severe IUGR and oligohydramnios.²³ This study supports the potential role of sildenafil citrate in improving uteroplacental blood flow and fetal outcomes in high-risk pregnancies, particularly those with IUGR and oligohydramnios. The findings of the study are limited small sample size, single-center design, and lack of long-term outcome assessment restrict the generalizability of findings. Hence future large-scale, multi-center randomized trials are recommended to confirm efficacy, optimize dosing, and ensure maternal-fetal safety, to offer as a promising therapeutic option for managing placental insufficiency.

Conclusion

This study revealed a potential role of sildenafil citrate in improving pregnancy outcomes in women with IUGR and oligohydramnios by enhancing uteroplacental blood flow, which may support fetal growth, increase amniotic fluid levels, delay preterm delivery, and improve neonatal outcomes. However, due to certain limitations, further large-scale, well-designed randomized controlled trials are recommended to confirm the therapeutic efficacy of sildenafil citrate, establish optimal dosing strategies, and to evaluate its long-term maternal and fetal safety. Support by the future clinical evidence, sildenafil citrate could represent a significant advancement in the management of high-risk pregnancies,

offering the potential to improve perinatal outcomes and enhance fetal well-being.

Ethical Approval:

The Ethics Review Committee (ERC, Fatima Jinnah Medical University/ Sir Ganga Ram Hospital, Lahore approved this study vide No. 33-Res-Publications-Gynae/ ERC.

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Authors' Contribution:

FS: Conception & design, acquisition of collection

QS: Conception & design, acquisition of collection, drafting of article, critical revision for important intellectual content

SN: Acquisition of collection, drafting of article

HMF: Analysis & interpretation of data

MJ: Critical revision for important intellectual content, final approval

SR: Final approval of the version to be published

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