

ORIGINAL ARTICLE

Effect of Low molecular weight heparin on pregnancy outcomes in oligohydramnios and Intrauterine growth restriction.

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ABSTRACT... Objective: To compare the frequency of obstetric outcomes between low molecular weight heparin and conservative treatment for oligohydramnios and intrauterine growth restriction. **Study Design:** Comparative Observational Study. **Setting:** Obstetrics and Outpatient Departments, Hilal-e-Ahmar Hospital, Faisalabad, Pakistan. **Period:** Six months 15/3/2022 to 15/9/2022. **Methods:** Five hundred pregnant women with pregnancies complicated by unexplained oligohydramnios were enrolled. Patients were randomly divided into two groups using block randomization with computer-generated numbers. Patients in Group A were administered a daily dose of 40 mg enoxaparin subcutaneously for up to two weekly till 36 weeks in addition to normal treatment (oral aspirin 75 mg once daily), while group B received only standard aspirin-based treatment. **Results:** In our study, the mode of delivery was compared in both groups, showing that cesarean section in Group A was 83.2%(n=208) and in Group B was 74.8%(n=187), whereas normal vaginal delivery in Group A was 16.8%(n=42) and in Group B 25.2%(n=63), p value was 0.021. Preterm delivery in group A was 17.2%(n=43) and 28.8%(n=72) in group Group-B p = 0.002. The frequency of live births in group A was 93.2% (n=233), whereas it was 81.2%(n=203) in group Group-B p = 0.0005. **Conclusion:** We conclude that LMWH is significantly more effective than conservative treatment for oligohydramnios and IUGR.

Key words: Efficacy, IUGR, LMWH, Oligohydramnios.

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INTRODUCTION

One of the most significant reasons for fetal developmental restriction is pregnancy linked to oligohydramnios. This issue is a significant cause of newborn morbidity and mortality, and is common in both industrialized and developing nations. The amount of amniotic fluid is crucial for fetal growth and survival. Approximately 12 days after conception, the amniotic sac forms, at which point amniotic fluid is produced. Amniotic fluid is first produced by the mother's circulation, and around 20 weeks of pregnancy, fetal urine produces the main component. Too low levels of amniotic fluid are termed oligohydramnios, and too high levels are called polyhydramnios.^{1,2}

Normally, its volume is approximately 800 ml with a wide range of 400-1500 ml at term.³ Amniotic fluid is produced almost exclusively from fetal urine, from the second trimester onwards.⁴ Amniotic fluid which surrounds developing fetus in amniotic sac provides several benefits to the fetus. The factors

controlling amniotic fluid quantity and makeup are still poorly understood despite decades of research. The amnion actively metabolizes and contributes to the movement of water and solutes, which helps to maintain homeostasis of the amniotic fluid. Additionally, this makes it easier to produce bioactive substances including growth factors, cytokines, and vasoactive peptides. Thus, the amnion controls the chorionic vascular tone and blood flow.⁵

Oligohydramnios is characterized by an amniotic fluid density index of less than 5 cm, a single deepest pocket or greatest vertical pocket of less than 2 cm, or a liquid volume less than the fifth percentile of gestational age. It affects 12 percent of pregnancies at forty-one weeks or later and 2–4 percent of pregnancies between 36 and 40 weeks.⁶ Depending on the study sample, gestational age, and accepted definition of oligohydramnios, the reported incidence of oligohydramnios ranges from 0.5 to 5%.⁷ In addition to uteroplacental insufficiency, intrauterine growth restriction (IUGR),

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premature rupture of the fetal membranes, fetal hypoxia, meconium-stained fluid, and post-maturity syndrome, oligohydramnios is linked to increased complications during pregnancy, congenital abnormalities, and perinatal mortality.

Fetal death, pulmonary hypoplasia, and skeletal and facial abnormalities are the possible outcomes of oligohydramnios. It may cause umbilical cord compression leading to fetal distress during labor and is associated with a higher risk of caesarean birth for fetal distress, low APGAR score, and significant perinatal morbidity and mortality.⁸ However, in most cases, oligohydramnios is an isolated finding in women who have a low-risk pregnancy and face no medical and foetal complication.⁹ In a previous study, Biradar et al.,⁸ low molecular weight heparin (enoxaparin) to treat isolated oligohydramnios and compared it with conservative treatment. The standard therapy group's mean of mother age was 28.46 ± 3.49 years, while the Enoxaparin group's was 27.54 ± 3.74 years. The Enoxaparin group had a significantly ($p\text{-value} < 0.05$) greater mean gestational age (37.65 ± 0.76 vs 36.95 ± 0.84 weeks) than the standard therapy group. The rationale of this study was to evaluate the efficacy of enoxaparin in improving obstetric outcomes in patients with oligohydramnios and IUGR by preventing preterm deliveries. Moreover, there is very little local evidence available in this regard, so we want to conduct this study to obtain local evidence so that in the future, we can implement the use of LMWH as a treatment protocol in our local setup for pregnancies complicated by oligohydramnios and IUGR. This will improve our practice in the future through the successful treatment of high-risk pregnancies. The main objective of this study was to compare the frequency of obstetric outcomes between LMWH and conservative treatment for oligohydramnios and IUGR.

METHODS

Study Setting

Obstetrics and outpatient departments of Hilal-e-Ahmar Hospital, Faisalabad, Pakistan. This study was approved by the ethical committee of Hilal-e-Ahmar Hospital (Faisalabad ref no. 773/HAHF). All patients were informed about the study, and consent forms were filled by all patients before inclusion in

this study.

Duration of Study

The duration of the study was six months, from March 15, 2023, to September 15, 2022.

Sample Size

It was calculated using the WHO sample size calculator, 80% power of study, 5% level of significance, and frequency of preterm delivery in the enoxaparin group were 15.2% and 25% in the standard treatment group.⁹ with a sample size of 500 patients and 250 patients in each group. The sampling technique used for the study was non-probability and consecutive sampling.

Sample Selection

Inclusion Criteria

- Pregnant women aged between 20 to 40 years.
- Singleton pregnancy
- Patients with oligohydramnios and IUGR as per the operational definition between 28 ± 0 and 36 ± 0 weeks of gestation who were admitted in the antenatal ward or attending outpatient department

Exclusion Criteria

Patients with known causes of Oligohydramnios and IUGR were excluded like

- Ruptured membranes (PROM, PPROM)
- Anti-phospholipid antibody syndrome
- Patients with signs of intrauterine infection.
- Placental abruption
- Chronic medical disorders like chronic kidney disease. SLE etc
- TORCH infections
- Patients with Congenital anomalies of the fetus
- Smoking and Alcohol use

Data Collection Procedure

The patients were selected from the antenatal wards and outpatient departments after the approval of the hospital ethical committee. The main objective and purpose of the research are briefly described for each patient. Patients who provided informed consent were included in this study. The diagnosis of oligohydramnios was based on serial Doppler or growth scans. For women with normal menstrual

cycles, gestational age was determined on the first day of the last menstrual period using an ultrasound scan obtained during the first trimester. A total of 500 pregnant women with pregnancies complicated by unexplained oligohydramnios were enrolled. Patients were randomly divided into two groups using block randomization with computer-generated numbers.

Patients in Group A were administered a daily dose of 40 mg enoxaparin, subcutaneously followed up to weekly till 36 weeks along with standard treatment (aspirin, 75 mg once daily orally); in Group B, only standard treatment based on aspirin was administered. All patients underwent growth scans, prothrombin time, platelet count, and ultrasonographic measurements of alcohol consumption during each visit. The frequency of patients in both groups was noted.

Data Analysis

SPSS version 22 was used for data analysis. The mean and standard deviation were used to display quantitative data such as age and gestational age. Frequency and percentage were used to display qualitative data, such as parity, mode of delivery, preterm birth, and live birth. The obstetric outcomes of the two groups were compared using the chi-square test, with a p-value of less than 0.05. considered significant. After stratifying the data according to age group, gestational age group, and parity, the chi-square test was used, and a p-value less than 0.05 was considered significant.

RESULTS

A total of 500 patients (250 in every group) meeting the selection requirements were enrolled to compare the frequency of obstetric outcomes of LMWH versus conservative treatment for oligohydramnios and IUGR. Age distribution shows that 66.8% (n=167) in Group A and 73.6 percent (n=184) in Group B between 20 and 30 years of age, whereas 33.2 percent (n=83) in Group A and 26.4 percent (n=66) in Group-B were between 31 between 40 years of age, mean age in Group-A was 28.66+4.15 and in Group-B was 28.61+2.58 years. (Table-I)

Gestational age (g.age) showed that 80.4 percent (n=201) in Group A and 62.4 percent (n=156) in

Group B were between 28 and 32 weeks of g.age, whereas 19.6 percent (n=49) in Group A and 37.6 percent (n=94) in Group B were between 33 and 36 weeks of g.age, and the mean g.age in Group-A was 29.84+2.62 and in Group-B was 31.24+2.59 weeks. (Table-II)

Parity distribution showed that 83.6 percent (n=209) in Group A and 82.8 percent (n=207) in Group B were between 1 to 3 parity whereas 16.4 percent (n=41) in Group A, and 17.2 percent (n=43) in Group B had >3 parity, mean parity in Group-A was 2.63+0.86 and in Group-B 2.60+0.85. (Table-III)

Delivery methods were compared in both groups, showing that cesarean section in Group A was 83.2 percent (n=208) and in Group-B 74.8 percent (n=187), whereas normal vaginal delivery in Group A was 16.8 percent (n=42) and in Group-B 25.2 percent (n=63), p-value was 0.021 (Table-IV); preterm delivery in Group A was 17.2 percent (n=43), whereas 28.8 percent (n=72) in Group B, with a p-value of 0.002. (Table-V) Frequency of live births in Group A was 93.2 percent (n=233) whereas 81.2 percent (n=203) in Group-B, p-value was 0.0005. (Table-VI) The data was stratified for age group, gestational age group and parity was stratified and post stratification chi square test was applied and p-value ≤ 0.05 was taken significant. (Table-VII-IX)

TABLE-I

Age distribution (n=500)

Age (in years)	Group-A (n=250)		Group-B (n=250)	
20-30	167	66.8	184	73.6
31-40	83	33.2	66	26.4
Total	250	100	250	100
Mean+SD	28.66+4.15		28.61+2.58	

TABLE-II

Gestational age (n=500)

G. Age (in weeks)	Group-A (n=250)		Group-B (n=250)	
28-32	201	80.4	156	62.4
33-36	49	19.6	94	37.6
Total	250	100	250	100
Mean+SD	29.84+2.62		31.24+2.59	

TABLE-III

Parity distribution (n=500)

Parity	Group-A (n=250)		Group-B (n=250)	
1-3	209	83.6	207	82.8
>3	41	16.4	43	17.2
Total	250	100	250	100
Mean+SD	2.63+0.86		2.60+0.85	

TABLE-IV

Frequency of mode of delivery (n=500)

Mode of Delivery	Group-A (n=250)		Group-B (n=250)	
Cesarean section	208	83.2	187	74.8
Normal vaginal delivery	42	16.8	63	25.2
Total	250	100	250	100

P-value=0.021

TABLE-V

Frequency of preterm delivery (n=500)

Preterm Delivery	Group-A (n=250)		Group-B (n=250)	
Yes	43	17.2	72	28.8
No	207	82.8	178	71.2
Total	250	100	250	100

P-value=0.002

TABLE-VI

Frequency of live birth (n=500)

Livebirth	Group-A (n=250)		Group-B (n=250)	
Yes	233	93.2	203	81.2
No	17	6.8	47	18.8
Total	250	100	250	100

P-value=0.00005

DISCUSSION

Although pregnancy is a normal part of a woman's life, there are numerous risks for both the mother and fetus. One of the most significant reasons for fetal developmental restriction is pregnancy linked to oligohydramnios. This issue is a significant cause of newborn morbidity and mortality, and is common in both industrialized and developing nations. The amount of amniotic fluid is crucial for fetal growth and survival. Approximately 12 days after conception, the amniotic sac forms, at which point amniotic fluid is produced. Amniotic fluid is first produced by the mother's circulation around the twentieth week of pregnancy, and fetal urine is the main component. Oligohydramnios refers to too little amniotic fluid, and polyhydramnios refers to too much amniotic fluid.

TABLE-VII

Stratification for age

Obstetrics Outcome	Age (in Years)	Group	Yes n(%)	No n(%)	P-Value
Cesarean section	20-30	A	139(83.23%)	28(16.77%)	0.03
		B	136(73.91%)	48(26.09%)	
	31-40	A	69(83.13%)	14(16.87%)	0.37
		B	51(77.27%)	15(22.73%)	
Normal vaginal delivery	20-30	A	28(16.77%)	139(83.23%)	0.03
		B	48(26.09%)	136(73.91%)	
	31-40	A	14(16.87%)	69(83.13%)	0.369
		B	15(22.73%)	51(77.27%)	
Preterm delivery	20-30	A	27(16.17%)	140(83.83%)	0.004
		B	53(28.80%)	131(71.20%)	
	31-40	A	16(19.28%)	67(80.72%)	0.17
		B	19(28.79%)	47(71.21%)	
Liver birth	20-30	A	157(94.01%)	10(5.99%)	0.005
		B	156(84.78%)	28(15.22%)	
	31-40	A	76(91.57%)	7(8.43%)	0.001
		B	47(71.21%)	19(28.79%)	

TABLE-VIII

Stratification for gestational age

Obstetrics Outcome	G. Age (in Weeks)	Group	Yes	No	P-Value
			n(%)	n(%)	
Cesarean section	28-32	A	168(83.58%)	33(16.42%)	0.022
		B	115(73.72%)	41(26.28%)	
	33-36	A	40(81.63%)	9(18.37%)	0.49
		B	72(76.60%)	22(23.40%)	
Normal vaginal delivery	28-32	A	33(16.42%)	168(83.58%)	0.022
		B	41(26.28%)	115(73.72%)	
	33-36	A	9(18.37%)	40(81.63%)	0.49
		B	22(23.40%)	72(76.60%)	
Preterm delivery	28-32	A	29(14.43%)	172(85.57%)	0.001
		B	44(28.21%)	112(71.79%)	
	33-36	A	14(28.57%)	35(71.43%)	0.88
		B	28(29.79%)	66(70.21%)	
Liverbirth	28-32	A	187(93.03%)	14(6.97%)	0.00008
		B	123(78.85%)	33(21.15%)	
	33-36	A	46(93.88%)	3(6.12%)	0.12
		B	80(85.11%)	14(14.89%)	

TABLE-IX

Stratification for parity

Obstetrics Outcome	G. Age (in Weeks)	Group	Yes	No	P-Value
			n(%)	n(%)	
Cesarean section	1-3	A	173(82.78%)	36(17.22%)	0.08
		B	157(75.85%)	50(24.15%)	
	>3	A	35(85.37%)	6(14.63%)	0.09
		B	30(69.77%)	13(30.23%)	
Normal vaginal delivery	1-3	A	36(17.22%)	173(82.78%)	0.08
		B	50(24.15%)	157(75.85%)	
	>3	A	6(14.63%)	35(85.37%)	0.09
		B	13(30.23%)	30(69.77%)	
Preterm delivery	1-3	A	31(14.83%)	178(85.17%)	0.0000
		B	64(30.92%)	143(69.08%)	
	>3	A	12(29.27%)	29(70.73%)	0.25
		B	8(18.60%)	35(81.40%)	
Liverbirth	1-3	A	193(92.34%)	16(7.66%)	0.004
		B	172(83.90%)	35(16.10%)	
	>3	A	40(97.56%)	1(2.44%)	0.001
		B	31(72.09%)	12(27.91%)	

Preeclampsia, oligohydramnios, intrauterine IUGR, and recurrent pregnancy loss are among several pregnancy-related problems that significantly increase perinatal morbidity and mortality. According to a previous study, placental insufficiency is linked to these issues.

One of the main reasons for this deficiency is improper activation of coagulation. Based on this relationship, it has been hypothesized that anticoagulant medications, such as enoxaparin and low-molecular-weight heparin, effectively reduce the incidence of these problems. When used prophylactically, low-molecular-weight heparin has been shown to enhance prenatal outcomes in disorders such as thrombophilias, APS, and recurrent miscarriages. Owing to its fewer adverse effects, such as hemorrhage disorders, thrombocytopenia, allergic responses, and osteoporosis during pregnancy, low-molecular-weight heparin is now thought to be a superior option than unfractionated heparin. Furthermore, no adverse teratogenic effects were observed.

The rationale of this study was to evaluate the efficacy of enoxaparin in improving obstetric outcomes in patients with oligohydramnios and IUGR by preventing preterm delivery and pre-eclampsia. Moreover, there is very little local evidence available in this regard, so we wanted to conduct this study to obtain local evidence so that in the future, we can implement the use of LMWH as a treatment protocol in our local setup for pregnancies complicated by oligohydramnios and IUGR.

This may improve our practice by successfully treating high-risk pregnancies.

In our study, the mode of delivery was compared in both groups, showing that cesarean section in Group A was 83.2% (n=208) and in Group B was 74.8% (n=187), whereas normal vaginal delivery in Group A was 16.8% (n=42) and in Group-B 25.2% (n=63), p-value was 0.021. Preterm delivery in Group A was 17.2% (n=43), whereas it was 28.8% (n=72) in Group B, p value was 0.002. The frequency of live births in group A was 93.2% (n=233), whereas it was 81.2% (n=203) in group Group-B p = 0.0005).

Our data are comparable with those of a previous study, showing that the mean gestational age (37.65 ± 0.76 vs. 36.95 ± 0.84 weeks) in the enoxaparin group was significantly ($p < 0.05$) higher than that in the standard treatment group. In Enoxaparin group the incidence of preterm delivery was 15.2%, frequency of live birth was 88.46% patients and frequency of normal delivery was 21.11% while in conservatively managed patients the incidence of preterm delivery was 25%, frequency of live birth was 65.39% patients and frequency of normal delivery was 34.6%.

Numerous studies have been conducted on the avoidance and management of preeclampsia and IUGR using low-dose aspirin. A meta-analysis of low-dose aspirin for IUGR prevention was conducted by Leitich et al. (1997). Aspirin use was associated with a non-significant decrease in perinatal death and substantial decrease in IUGR. Aspirin was efficacious at low levels, between 50 and 80 mg daily, according to subgroup analysis, while it had a preventive effect at doses between 100 and 150 mg daily. The authors concluded that pregnant women should not regularly receive moderate doses of aspirin. Pre-existing chronic recurrent hypertension, pre-eclampsia, hypertension before 20 weeks, and related autoimmune disorders, such as SLE syndrome, are among the indications for the use of low-dose aspirin. To evaluate the effectiveness of low-dose aspirin for the prevention and management of pre-eclampsia and IUGR, FOGSI conducted a multi-centric study called FLASP (FOGSI low-dose aspirin study).

Patients who received preventive low-dose aspirin before 16 weeks of gestation had a considerably lower incidence of IUGR and pre-eclampsia. The CLASP joint low-dose aspirin projects in pregnancy were among the largest joint projects. Akhtar et al. (2015)¹¹ in an observational, intention-to-treat study between March 2014 and March 2015 at PAF Hospital Lahore's Obs/Gyn Unit. From 16 to 36 weeks of gestation, 40 mg low-molecular-weight heparin (LMWH) was administered subcutaneously every day. Additionally, gestational diabetes and hypertension were treated according to the hospital's normal surgical procedure. They reported that all 13 patients had lower segment caesarean sections

at the 36th week of gestation. Every newborn had Apgar scores of 8/10 and 10/10. The ratio of carry-home babies was 100%. In the absence of APS and thrombophilias, it was determined that low-molecular-weight heparin plays a definitive role in patients with poor pregnancy outcomes caused by IUGR and oligohydramnios.

Zaman et al., (2018) assessed the mean mother age was 27.54 ± 3.74 years in the Enoxaparin group and 28.46 ± 3.49 years in the standard therapy group, according to the evaluation of the effectiveness of Enoxaparin in improving obstetrical outcomes in patients with IUGR and oligohydramnios. In comparison to the standard therapy group, the Enoxaparin group had a significantly (p -value < 0.05) greater mean gestational age (37.65 ± 0.76 and 36.95 ± 0.84 weeks). The Enoxaparin group had a considerably ($p < 0.05$) lower miscarriage rate (11.54 percent and 38.46 percent) than the standard therapy group. Pre-eclampsia was less common in the enoxaparin group (8.69 percent and 43.75 percent, $p < 0.05$) than in the standard therapy group. Preterm deliveries (15.22 percent and 25 percent) and pre-eclampsia rates (8.69 and 43.75 percent, $p < 0.05$) were significantly lower in the enoxaparin group. They concluded that in patients with IUGR and oligohydramnios, low molecular weight heparin combined with aspirin showed a higher live birth rate and less chance of miscarriage, pre-eclampsia, preterm delivery, and prematurity when compared to the aspirin group alone.

In summary, low molecular weight heparin along with aspirin has shown a high live birth rate and lower chances of miscarriage, preterm delivery, and prematurity than aspirin alone in patients with IUGR and oligohydramnios. These results will be helpful for obstetricians and patients.

CONCLUSION

We conclude that LMWH is significantly more effective than conservative treatment for oligohydramnios.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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