RESEARCH PAPER

Role of Enoxaparin in Unexplained Repeated Pregnancy Loss

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ABSTRACT

Background: Unexplained recurrent pregnancy loss (URPL) is a distressing reproductive disorder affecting many women worldwide. Despite extensive investigations, the underlying cause remains unidentified in nearly half of recurrent miscarriage cases. Low-molecular-weight heparin (LMWH), particularly enoxaparin, has been suggested to improve pregnancy outcomes because of its anticoagulant, anti-inflammatory, and immunomodulatory effects; however, evidence regarding its effectiveness remains inconclusive. ***Objective:*** To evaluate the role of enoxaparin in improving pregnancy outcomes among women with unexplained recurrent pregnancy loss. ***Materials and Methods:*** This hospital-based randomized controlled trial was conducted in the Department of Gynae & Obs, Dhaka Central International Medical College Hospital, from July 2024 to December 2025. A total of 60 pregnant women aged 18–40 years with unexplained recurrent pregnancy loss were enrolled and randomly allocated into two groups: Enoxaparin group (n=30) and Control group (n=30). The Enoxaparin group received enoxaparin 40 mg subcutaneously once daily from early pregnancy until 35 weeks of gestation, while the Control group received placebo/standard supportive care. Pregnancy outcomes, maternal complications, and neonatal outcomes were analyzed using SPSS version 26. ***Results:*** Among 60 women with URPL, the Enoxaparin group showed a higher live birth rate than controls (80.0% vs. 66.7%, p=0.24) and lower rates of miscarriage (20.0% vs. 33.3%, p=0.24), preterm delivery (16.7% vs. 23.3%, p=0.52), and low birth weight (16.7% vs. 26.7%, p=0.35), though differences were not statistically significant. Adverse events and neonatal outcomes were comparable between groups. ***Conclusion:*** Enoxaparin did not significantly improve live birth rates or reduce adverse pregnancy outcomes in women with unexplained recurrent pregnancy loss. Larger multicenter studies are recommended to establish its therapeutic value.

Keywords: Unexplained recurrent pregnancy loss; Enoxaparin; Low-molecular-weight heparin; Recurrent miscarriage; Pregnancy outcome.

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INTRODUCTION

Infertility is a major reproductive health problem affecting millions of couples worldwide. It is generally defined as the inability to achieve pregnancy after 12 months of regular unprotected intercourse. In women aged 35 years or older, infertility may be diagnosed after 6 months because fertility declines with advancing maternal age.[1] Recurrent pregnancy loss (RPL), another important reproductive disorder, is characterized by repeated spontaneous miscarriages and affects approximately 1–2% of women of reproductive age.[2] The American Society for Reproductive Medicine (ASRM) currently defines RPL as two or more failed clinical pregnancies documented by ultrasonography or histopathological examination.[3]

The etiology of recurrent pregnancy loss is multifactorial and includes genetic abnormalities, congenital uterine anomalies, endocrine dysfunction, infections, autoimmune diseases, and thrombophilic disorders.[4–6] Despite extensive investigations, nearly 50–60% of RPL cases remain unexplained and are categorized as unexplained recurrent pregnancy loss (URPL).[2,7] Genetic factors such as embryonic chromosomal aneuploidy and methylenetetrahydrofolate reductase (MTHFR) polymorphisms have been associated with pregnancy loss.[8–10] Immunological imbalance, particularly altered Treg/Th17 cell activity and increased inflammatory cytokines, has also been implicated in the pathogenesis of URPL.[11] In addition, thrombophilia, especially

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antiphospholipid syndrome (APS), has been reported in a considerable proportion of women with recurrent miscarriages.[7],[12]

Low-molecular-weight heparin (LMWH), particularly enoxaparin, has been widely investigated for the prevention of pregnancy loss because of its anticoagulant, anti-inflammatory, and immunomodulatory properties. Enoxaparin has proven benefit in women with APS-associated pregnancy complications, leading researchers to explore its potential role in unexplained RPL.[13],[14] Experimental studies suggest that some women with clinical features suggestive of APS may harbor pathogenic antibodies undetectable by conventional assays, providing a possible explanation for the beneficial effect of heparin even in antibody-negative patients.[15]

Several clinical trials and meta-analyses have evaluated the efficacy of enoxaparin in improving pregnancy outcomes among women with URPL, but the findings remain controversial. Some studies demonstrated improved live birth rates and reduced miscarriage rates with LMWH therapy,[16–18] whereas others failed to show significant benefit compared with placebo or low-dose aspirin alone.[19–21] A recent systematic review and meta-analysis also concluded that evidence regarding the effectiveness of LMWH in unexplained recurrent miscarriage remains inconclusive and further well-designed randomized controlled trials are required.[22] Moreover, women's preferences, treatment burden, daily injections, cost, and safety concerns should also be considered when prescribing LMWH during pregnancy.[23]

Given the inconsistent evidence and ongoing debate regarding the therapeutic role of enoxaparin in unexplained recurrent pregnancy loss, further evaluation is essential to determine its effectiveness in improving live birth outcomes and reducing miscarriage rates. Therefore, this study aims to assess the role of enoxaparin in women with unexplained recurrent pregnancy loss.

MATERIALS AND METHODS

This hospital-based randomized controlled trial was conducted in the Department of Gynae & Obs, Dhaka Central International Medical College Hospital, over a period of one and half year from July 2024 to December 2025. The study was carried out to evaluate the role of enoxaparin in women with unexplained recurrent pregnancy loss. Prior to commencement of the study, all obstetricians working within the hospital catchment area were informed about the trial and requested to refer potentially eligible participants. Pregnant women aged 18–40 years with a history of recurrent pregnancy loss, where other possible causes had been excluded and the condition was diagnosed as unexplained recurrent pregnancy loss, were considered eligible for enrollment. The current pregnancy had to be clinically confirmed. Recurrent miscarriage was defined as consecutive pregnancy losses before 15 weeks of gestation with the same partner and without any live birth after the consecutive miscarriages. Biochemical pregnancies, defined as transient elevation of serum human chorionic gonadotropin near menstruation without clinical evidence of pregnancy, were excluded.

Unexplained recurrent pregnancy loss was diagnosed after exclusion of known etiological factors including abnormal parental karyotypes, uterine anatomical abnormalities, antiphospholipid syndrome and deficiencies of Protein C, Protein S, and antithrombin III.

Women with indications for anticoagulant or aspirin therapy for other medical conditions, contraindications to enoxaparin therapy (such as anemia with hemoglobin <10 g/dL, platelet count <150×10⁹/L, creatinine clearance <30 mL/min), or inability/unwillingness to provide informed consent were excluded from the study.

Eligible women were enrolled very early in pregnancy, preferably before 5 weeks of gestation following a positive pregnancy test. After obtaining written informed consent, participants were randomized into two groups using a computer-generated randomization system with a 1:1 allocation ratio. One group received enoxaparin 40 mg subcutaneously once daily, while the control group received placebo/standard supportive care. Treatment was initiated at enrollment or within 24 hours thereafter and continued up to 35 weeks of gestation.

Participants were educated regarding self-administration of subcutaneous injections. Follow-up visits were scheduled monthly until delivery and once again approximately two months postpartum. During each visit, pregnancy progress, platelet count monitoring, treatment compliance, and adverse effects were assessed using a structured data collection form. Compliance was evaluated using a treatment adherence notebook maintained by each participant.

All participants received routine antenatal care including fetal ultrasonography and folic acid supplementation throughout pregnancy. Obstetric and neonatal data were collected from hospital records and follow-up visits.
The primary outcome measure was the rate of live and viable births. Secondary outcome measures included miscarriage rate, intrauterine fetal death, preeclampsia, placental abruption, preterm delivery, small-for-gestational-age neonates, maternal thrombocytopenia, bleeding complications, and skin reactions.

Collected data were analyzed using Statistical Package for Social Sciences (SPSS) software version 26. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequency and percentage. Comparisons between groups were performed using Student's t-test for continuous variables and Chi-square test or Fisher's exact test for

categorical variables where appropriate. A p-value of <0.05 was considered statistically significant.

RESULTS

Table 1: Demographic characteristics of the participants in the treatment and control groups (n=60)

Characteristics	Enoxaparin (n=30)	Control (n=30)	Total (n=60)	P-value
Age, year (mean ± SD)	32.48 ± 4.35	31.20 ± 5.15	32.48 ± 4.35	0.347
Gravida				0.103
Three	8 (26.7%)	2 (6.7%)	10 (16.7%)	
Four	10 (33.3%)	13 (43.3%)	23 (38.3%)	
Five	12 (40.0%)	11 (36.7%)	23 (38.3%)	
Six	0 (0%)	4 (13.3%)	4 (6.7%)	
History of infertility, n (%)	8 (26.7%)	4 (13.3%)	12 (20.0%)	0.252
Consanguine marriage, n (%)	2 (6.7%)	0 (0%)	2 (3.3%)	0.241
Previous live birth, n (%)	18 (60%)	18 (60%)	36 (60%)	0.290
History of low birth weight, n (%)	5 (16.7%)	8 (26.7%)	13 (21.7%)	0.402
Number of previous miscarriages				0.228
Two	18 (60.0%)	17 (56.7%)	35 (58.3%)	
Three	10 (33.3%)	10 (33.3%)	20 (33.3%)	
Four	2 (6.7%)	3 (10.0%)	5 (8.3%)	
History of preterm delivery, n (%)	9 (30.0%)	8 (26.7%)	17 (28.3%)	0.803
History of fetal death, n (%)	14 (46.7%)	8 (26.7%)	22 (36.7%)	0.100

Table 1 presents the demographic and obstetric characteristics of the study participants in the Enoxaparin and Control groups, each comprising 30 patients. The mean age was comparable between the groups, being 32.48 ± 4.35 years in the Enoxaparin group and 31.20 ± 5.15 years in the Control group, with no statistically significant difference (p=0.347). Regarding gravida status, most participants in both groups had gravida four or five, while a smaller proportion had gravida three or six; the distribution was not statistically significant (p=0.103).

A history of infertility was reported in 26.7% of the Enoxaparin group and 13.3% of the Control group (p=0.252). Consanguineous marriage was observed only in the Enoxaparin group (6.7%), though the difference was not statistically significant (p=0.241). Previous live birth was equally reported in both groups (60%). A history of low birth weight was slightly higher in the Control group (26.7%) compared to the Enoxaparin group (16.7%), without significant difference (p=0.402).

Most participants in both groups had experienced two or three previous miscarriages, while a smaller proportion had four miscarriages (p=0.228). Similarly, the proportions of participants with a history of preterm delivery and fetal death were comparable between the groups, with no statistically significant differences observed (p>0.05). Overall, the baseline demographic and obstetric characteristics were well balanced between the two study groups.

Table 2: Pregnancy outcomes and obstetrical complications of the enoxaparin and control groups (n=60)

Outcome	Enoxaparin (n=30)	Control (n=30)	P-value
Live birth, n (%)	24 (80.0)	20 (66.67)	0.24
Preterm delivery, n (%)	05 (16.67)	07 (23.33)	0.52
Low birth weight, n (%)	05 (16.7)	8 (26.67)	0.35
Gestational diabetes, n (%)	02 (6.7)	0 (0.0)	0.15

The table shows that pregnancy outcomes were generally comparable between the Enoxaparin and Control groups. The live birth rate was higher in the Enoxaparin group (80.0% vs. 66.7%), although the difference was not statistically significant. Preterm delivery and low birth weight were less frequent in the Enoxaparin group (16.7% vs. 23.3% and 16.7% vs. 26.7%, respectively), but these differences were also not significant. Gestational diabetes occurred only in the Enoxaparin group (6.7%). Notably, a few cases of preterm delivery and low birth weight occurred in the same pregnancies, indicating overlap between these complications.

Table 3: Secondary outcomes in Enoxaparin and Control groups (n=60)

Outcome	Enoxaparin (n=30)	Control (n=30)	P-value
Adverse events			
Congenital abnormality, n (%)	2 (6.7)	1 (3.3)	0.35

Major bleeding, n (%)	1 (3.3)	1 (3.3)	1.00
Blood transfusion, n	1	0	—
Fall in hemoglobin ≥20 g/L, n	1	1	—
Minor bleeding, n (%)	7 (23.3)	4 (13.3)	0.06
Bruising, n (%)	3 (10.0)	1 (3.3)	0.18
Nosebleed, n (%)	3 (10.0)	1 (3.3)	0.30
Bleeding gums, n (%)	1 (3.3)	1 (3.3)	1.00
Minor vaginal bleeding, n (%)	2 (6.7)	2 (6.7)	0.63
Severe skin reaction at injection site, n (%)	0 (0.0)	0 (0.0)	1.00
Thrombocytopenia, n (%)	1 (3.3)	1 (3.3)	1.00
Pregnancy outcomes before 20 weeks			
Miscarriage, n (%)	6 (20.0)	10 (33.3)	0.24
Miscarriage ≥10 weeks, n	05 (16.67)	06 (20.0)	0.74
Gestational age at miscarriage (mean ± SD), weeks	8.2 ± 1.97	8.5 ± 2.8	0.63
Medically indicated termination, n (%)	1 (3.3)	0.00	0.31
Ectopic pregnancy, n (%)	00.0	1 (3.3)	0.31
Outcomes after 20 weeks			
Intrauterine fetal death, n (%)	0 (0.0)	0 (0.0)	--
Medically indicated termination, n (%)	0 (0.0)	0 (0.0)	--
Preeclampsia, n (%)	2 (6.7)	1 (3.3)	0.28
Placental abruption, n (%)	0 (0.0)	0 (0.0)	--
Small for gestational age (<10th percentile), n (%)	0 (0.0)	1 (3.3)	0.36
Preterm delivery, n (%)	5 (16.67)	7 (23.33)	1.00
24–28 weeks, n	0.0	1 (3.3)	—
28–32 weeks, n	2 (6.67)	2 (6.67)	—
32–37 weeks, n	3 (10.0)	4 (13.33)	—
Multiple gestation, n (%)	0 (0.0)	0 (0.0)	1.00
Live birth outcomes			
Birth weight (mean ± SD), g	3003 ± 554	2800 ± 537	0.14
Gestation at delivery (mean ± SD), weeks	39.3 ± 2.2	38.9 ± 2.3	0.24

Secondary outcomes were comparable between the Enoxaparin and Control groups. Miscarriage was lower in the Enoxaparin group (20.0% vs. 33.3%, p=0.24), while preterm delivery occurred in 16.7% vs. 23.3% (p=1.00). Minor bleeding was more frequent with Enoxaparin (23.3% vs. 13.3%, p=0.06), whereas major bleeding was identical in both groups (3.3% vs. 3.3%, p=1.00). Mean birth weight (3003±554 vs. 2800±537 g, p=0.14) and gestational age at delivery (39.3±2.2 vs. 38.9±2.3 weeks, p=0.24) were similar between groups. No statistically significant differences were observed in maternal or neonatal secondary outcomes.

DISCUSSION

The present study evaluated the effectiveness of enoxaparin in women with unexplained recurrent pregnancy loss (URPL) and found that the baseline demographic and obstetric characteristics were comparable between the Enoxaparin and Control groups. The mean maternal age did not differ significantly between groups, and similar distributions were observed regarding gravida, infertility history, previous live birth, preterm delivery, fetal death, and number of previous miscarriages. These findings suggest that the study groups were well matched, thereby reducing the likelihood of confounding bias.

The baseline characteristics observed in the present study are comparable with the findings reported by Afiat et al.[5] who demonstrated no statistically significant differences between treatment and control groups regarding maternal age, gravida, duration of marriage, or number of miscarriages. Similarly, Pasquier et al.[18] reported that the baseline demographic and reproductive characteristics of women with unexplained recurrent miscarriage were comparable between enoxaparin and placebo groups. Such homogeneity among study populations strengthens the validity of treatment outcome comparisons.

In the current study, the live birth rate was higher in the Enoxaparin group than in the Control group (80.0% vs. 66.7%); however, the difference was not statistically significant, suggesting no significant benefit of enoxaparin on live birth outcomes in women with URPL. Preterm delivery and gestational diabetes were observed more frequently in the Enoxaparin group, while low birth weight was slightly higher in the Control group, but none of these differences achieved statistical significance. These findings are consistent with several previous randomized controlled trials and systematic reviews which reported limited or no benefit of low-molecular-weight heparin (LMWH) in women with unexplained recurrent miscarriage.[5,19, 20]

The findings of the present study also align with the ALIFE and ALIFE2 studies, which concluded that LMWH therapy did not significantly improve live birth rates in women with recurrent miscarriage, including those with inherited thrombophilia.[21] Furthermore, the Cochrane review by de Jong et al.[22] found insufficient evidence to support the routine use of aspirin and/or heparin in women with unexplained recurrent pregnancy loss. Similarly, Sun et al.[23] reported that LMWH did not provide substantial reproductive benefit in women undergoing assisted reproductive techniques.

Conversely, several studies have demonstrated potential beneficial effects of LMWH therapy. Fawzy et al. reported significantly improved live birth rates among women treated with LMWH, while Yan et al.[12] in a meta-analysis, suggested that LMWH alone or in combination with aspirin may improve pregnancy outcomes in selected women with recurrent miscarriage. Likewise, Jiang et al.[24] concluded in their systematic review and meta-analysis that LMWH could be a potentially useful treatment option for women with recurrent pregnancy loss, although they emphasized that the available evidence remains limited by heterogeneity and small sample sizes. Differences in study design, patient selection criteria, associated thrombophilic conditions, treatment duration, and dosage protocols may explain the discrepancies among various studies.

In the present study, secondary maternal and fetal outcomes, including congenital abnormalities, thrombocytopenia, and miscarriage before 20 weeks, preeclampsia, and small-for-gestational-age infants, were comparable between the groups. Minor bleeding and bruising were slightly more frequent in the Enoxaparin group, which is consistent with the known adverse effects of LMWH therapy. Greer and Nelson-Piercy.[25] also reported that bleeding episodes, bruising, hematoma formation, and injection-site reactions are among the most common side effects associated with LMWH use during pregnancy.

Interestingly, Afiat et al.[5] observed significantly higher rates of adverse pregnancy complications in the enoxaparin-treated group, including gestational diabetes, gestational hypertension, fetal growth restriction, and preterm labor. In contrast, the present study did not demonstrate any statistically significant increase in adverse maternal or fetal outcomes among women receiving enoxaparin. Variations in sample size, population characteristics, follow-up duration, and treatment protocols may account for these differing findings.

The exact pathophysiology of unexplained recurrent pregnancy loss remains unclear and is believed to involve complex immunological, inflammatory, thrombotic, endocrine, and genetic mechanisms.[4,7] Because LMWH possesses both anticoagulant and anti-inflammatory properties, it has been hypothesized that it may improve trophoblastic implantation and placental circulation. However, current evidence remains inconclusive regarding its routine clinical use in women without confirmed thrombophilia or antiphospholipid syndrome. International guidelines therefore remain cautious regarding the widespread use of LMWH in unexplained recurrent pregnancy loss.[25]

Overall, the findings of the present study suggest that enoxaparin does not significantly improve live birth rates or reduce pregnancy complications in women with unexplained recurrent pregnancy loss. Although the treatment appeared relatively safe, only minor bleeding-related complications were observed. Further large-scale multicenter randomized controlled trials with standardized protocols are necessary to establish the precise role of enoxaparin in the management of unexplained recurrent pregnancy loss.

CONCLUSION

This randomized controlled trial demonstrated that enoxaparin therapy did not significantly improve live birth rates or reduce miscarriage and obstetric complications among women with unexplained recurrent pregnancy loss. Although slightly higher mean birth weight and gestational age at delivery were observed in the Enoxaparin group, these differences were not statistically significant. Maternal adverse effects, including minor bleeding and bruising, were more frequent among women receiving enoxaparin, but serious complications were uncommon in both groups. Overall, the findings suggest that routine use of enoxaparin in women with unexplained recurrent pregnancy loss may not provide substantial clinical benefit. Further large-scale, multicenter randomized controlled trials are necessary to better define the role of enoxaparin and identify subgroups of patients who may benefit from this therapy.

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