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Impact of Low-Dose Prednisolone on Pregnancy Viability in Women with Recurrent Pregnancy Loss of Unexplained Etiology

Mahmuda Ehsan

Department of Obstetrics and Gynecology, International Medical College and Hospital, Gazipur, Bangladesh

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ABSTRACT

Recurrent pregnancy loss (RPL) of unexplained etiology presents a significant challenge in reproductive medicine, often leaving affected women with limited treatment options. Emerging evidence suggests that immunological factors may play a role in unexplained RPL, and corticosteroids like low-dose prednisolone could improve pregnancy outcomes by modulating immune responses. This retrospective cohort study examined the impact of low-dose prednisolone on pregnancy viability in women with a history of unexplained RPL. Medical records from reproductive health clinics were analyzed to compare outcomes between women receiving low-dose prednisolone (≤10 mg daily) and those not receiving any immunosuppressive treatment. Results demonstrated a statistically significant increase in pregnancy viability rates (68% in the prednisolone group vs. 45% in the non-treatment group, $p < 0.05$) and a decrease in miscarriage rates (30% vs. 55%, $p < 0.01$) among women using prednisolone. Furthermore, no significant differences in adverse maternal or fetal outcomes were observed, supporting the safety profile of low-dose prednisolone. The findings suggest that low-dose prednisolone may effectively improve pregnancy viability by modulating immune activity without substantial risks. However, further randomized controlled trials are needed to confirm these results and explore specific immunological pathways. This study underscores the potential of low-dose prednisolone as a promising treatment for unexplained RPL, offering new hope for affected women and paving the way for more targeted therapies in reproductive medicine.

Keywords: *Recurrent Pregnancy Loss, Low-Dose Prednisolone, Unexplained Pregnancy Loss, Immunomodulation, Pregnancy Viability, Miscarriage Reduction, Reproductive Immunology*

INTRODUCTION

Recurrent pregnancy loss (RPL) is a significant reproductive health concern, affecting approximately 1-2% of couples seeking to conceive. It is defined by the loss of two or more consecutive pregnancies before the 20th week of gestation and presents a profound emotional and physical toll on affected individuals and couples (Zhu et al., 2023). While identifiable factors such as genetic abnormalities, structural uterine anomalies, endocrine disorders, and thrombophilic conditions explain a portion of RPL cases, a substantial number (up to 50%) remain unexplained. These unexplained cases pose particular challenges in treatment, as conventional approaches often prove inadequate without a clear underlying cause (Nørgaard-Pedersen et al., 2022a). The role of the immune system in early pregnancy is crucial yet complex,

involving a dynamic balance between immune tolerance toward the semi-allogenic fetus and protective immune responses to safeguard both mother and fetus from infection. This balance is maintained through intricate immunological adaptations, which, if disrupted, could potentially contribute to RPL (Ma et al., 2022). Research increasingly indicates that immune dysregulation may play a significant role in cases of unexplained RPL. In particular, heightened inflammatory responses and excessive activity of certain immune cells, such as natural killer (NK) cells and T-helper cells, have been observed in some women with RPL, suggesting that immune-targeted interventions could potentially benefit those with recurrent losses of unexplained etiology (Nørgaard-Pedersen et al., 2022b). Corticosteroids like prednisolone are well-known for their anti-inflammatory and immunosuppressive properties, which have broad applications in managing autoimmune and inflammatory conditions. Prednisolone has shown promise in immunomodulating therapies by suppressing excessive immune activation and fostering an environment more conducive to pregnancy (Yang et al., 2020). By reducing the activity of NK cells and other immune effector cells that might otherwise impair embryo implantation or early fetal development, low-dose prednisolone may help prevent miscarriage in women experiencing unexplained RPL. Despite these theoretical benefits, clinical evidence regarding the safety and efficacy of low-dose prednisolone in enhancing pregnancy viability in women with RPL remains limited and inconclusive, with studies yielding mixed results on its impact on maternal and fetal outcomes.

This study aims to address this gap by investigating the effects of low-dose prednisolone on pregnancy viability in women with unexplained RPL. By exploring its potential to improve implantation success and support early fetal development, this study seeks to provide clarity on the therapeutic value of prednisolone in this context, potentially offering a new avenue for treatment in this challenging patient population. This investigation may contribute valuable insights into immunomodulatory treatments for RPL, potentially informing future guidelines for managing unexplained recurrent pregnancy loss.

LITERATURE REVIEW

Recurrent pregnancy loss (RPL) is a multifactorial condition that represents a significant medical and psychological burden for affected couples, with an estimated prevalence of 1-2% among those attempting to conceive. RPL is diagnosed after two or more consecutive pregnancy losses, typically before the 20th week of gestation (Li et al., 2022). The etiology of RPL is diverse, with identifiable causes including genetic abnormalities, uterine anatomical defects, endocrine disorders, and thrombotic conditions. However, approximately 50% of RPL cases remain unexplained, even after thorough investigation. Unexplained RPL presents a unique challenge, as the absence of a clear etiology limits treatment options and complicates clinical management. Emerging research suggests that immune factors may play a significant role in these cases, which has led to increased interest in immunomodulatory therapies, including corticosteroids such as prednisolone (Grbac et al., 2021). The immune system plays a pivotal role in pregnancy, particularly in facilitating maternal tolerance to the semi-allogeneic fetus. This process requires a finely tuned balance between immune tolerance and immune defense, allowing the mother’s immune system to accept the fetus while still protecting against pathogens. Key to this balance is the modulation of immune cells such as T-helper cells and natural killer (NK) cells, which must act in harmony to support implantation and early fetal development (Semrl, 2023). A growing body of evidence points to immune dysregulation as a contributing factor in unexplained RPL. Specifically, studies have

observed heightened levels of NK cells and T-helper cells in women with RPL, suggesting that an overactive immune response may interfere with successful implantation and contribute to early pregnancy loss. For instance, Kwak-Kim et al. (2014) demonstrated that women with elevated NK cell activity are more likely to experience recurrent miscarriages, leading researchers to explore immunosuppressive therapies as potential treatments (Roepke et al., 2021). Corticosteroids, including prednisolone, are anti-inflammatory agents widely used for their immunosuppressive properties. They exert their effects by downregulating pro-inflammatory cytokines, reducing the activation of immune cells, and stabilizing cellular membranes. In the context of RPL, corticosteroids have been hypothesized to reduce aberrant immune activity that may otherwise impair pregnancy. Prednisolone, specifically, has gained attention for its potential to modulate immune cell activity, especially by reducing the cytotoxic action of NK cells and altering T-cell responses. This immunosuppressive effect has been beneficial in conditions where immune dysregulation is suspected, such as in autoimmune diseases, and has led researchers to investigate whether a similar approach could benefit women with unexplained RPL. Several studies have explored the efficacy of corticosteroids in improving pregnancy outcomes among women with RPL, albeit with mixed results. A study by Nofa Cholili & Wiyasa (2022) investigated the use of prednisolone in women with a history of recurrent miscarriage and elevated NK cell levels, observing a modest improvement in live birth rates among those treated with low-dose prednisolone compared to a control group. However, other studies, such as the one conducted by Linehan et al. (2022), have found no significant difference in pregnancy outcomes between women treated with corticosteroids and those receiving a placebo. These conflicting findings highlight the need for further research to clarify the potential role of prednisolone in improving pregnancy viability in women with unexplained RPL. Prednisolone exerts its immunomodulatory effects by binding to glucocorticoid receptors, leading to the suppression of immune pathways involved in inflammation. At low doses, prednisolone can suppress the cytotoxicity of NK cells, inhibit pro-inflammatory cytokine production, and promote an environment favorable to implantation and early pregnancy maintenance. Prednisolone has also been shown to alter T-helper cell profiles, shifting the balance from a Th1-dominant response, associated with inflammation, to a Th2-dominant response, which is more compatible with pregnancy. These mechanisms are particularly relevant in cases of unexplained RPL where heightened NK cell activity and a Th1 response are suspected contributors to early pregnancy loss. A study by Allah et al. (2023) explored the association between immune cell activity and early pregnancy loss, suggesting that women with elevated Th1 cytokine responses were at greater risk of miscarriage. Their findings underscore the potential of prednisolone to mitigate this risk by shifting immune responses toward a pregnancy-supportive Th2 profile. Additionally, prednisolone's capacity to reduce NK cell activity aligns with studies showing that elevated NK cell cytotoxicity is prevalent among women with unexplained RPL, further supporting the therapeutic potential of low-dose corticosteroids in managing this condition. While theoretical and preliminary evidence suggests that prednisolone may be beneficial for pregnancy outcomes in women with RPL, clinical studies have yielded mixed results, indicating the complexity of using corticosteroids in this context. A systematic review by Linehan et al. (2022) concluded that while some studies reported improved live birth rates with corticosteroid use, particularly among women with evidence of autoimmune factors, the overall quality of evidence was

low. The review highlighted the variability in corticosteroid dosing regimens, treatment durations, and study designs as factors contributing to inconsistent findings. Further randomized controlled trials (RCTs) have attempted to clarify the role of prednisolone in unexplained RPL, but findings remain inconclusive. For example, Grbac et al. (2021) conducted a double-blind RCT examining the effect of low-dose prednisolone on pregnancy outcomes in women with unexplained RPL and found no significant improvement in live birth rates. However, the study did note a reduction in NK cell levels, suggesting that while prednisolone may modulate immune activity, this does not necessarily translate to improved pregnancy outcomes in all cases. This has led some researchers to suggest that prednisolone may be more effective in women with specific immunological profiles, such as those with elevated NK cell activity, rather than as a universal treatment for unexplained RPL. The use of corticosteroids during pregnancy is not without potential risks. Prednisolone, even at low doses, can have side effects, including maternal glucose intolerance, hypertension, and increased risk of infection, which could impact maternal and fetal health. Additionally, long-term corticosteroid use has been associated with adverse fetal outcomes, including growth restriction and preterm birth. Therefore, any potential benefits of prednisolone must be carefully weighed against these risks. The lack of consensus on optimal dosing, timing, and duration of prednisolone therapy further complicates its use in clinical practice. A study by Semrl (2023) evaluated the safety of corticosteroid use in pregnancy, finding that adverse effects were more likely with high-dose, prolonged treatment regimens. This underscores the need for precise dosing protocols to minimize risks while maximizing potential benefits. In the context of RPL, where low-dose prednisolone is typically administered in early pregnancy, further research is needed to determine safe and effective dosing strategies. Additionally, monitoring maternal and fetal health throughout treatment is essential to ensure that potential complications are identified and managed promptly.

In summary, while immune dysregulation is increasingly recognized as a potential contributor to unexplained RPL, and corticosteroids like prednisolone show promise as immunomodulatory treatments, the evidence supporting their use remains inconclusive. The mixed findings from clinical studies underscore the need for further research to determine whether prednisolone can reliably improve pregnancy outcomes in this population. Addressing this gap, the current study seeks to investigate the impact of low-dose prednisolone on pregnancy viability in women with unexplained RPL. By focusing on this specific cohort and assessing immune markers alongside pregnancy outcomes, this study aims to provide a clearer understanding of prednisolone's therapeutic potential and establish evidence-based guidelines for its use in RPL management.

PROBLEM OF THE STUDY

Recurrent pregnancy loss (RPL) of unexplained etiology remains a significant challenge in reproductive medicine, affecting approximately 1-2% of women. Despite advancements in diagnostic tools, a substantial proportion of RPL cases yield no clear cause, creating a barrier to effective treatment and emotional distress for affected women and their families. Recent studies suggest an immunological component in RPL, where the maternal immune response may inadvertently disrupt early pregnancy, leading to miscarriages. Corticosteroids like low-dose prednisolone, known for their immunosuppressive properties, have shown promise in reducing immune-related pregnancy losses, yet the evidence remains inconclusive and inconsistent. This study aims to address this gap by examining the potential impact of low-dose prednisolone on pregnancy viability among women with

recurrent, unexplained pregnancy loss. Identifying whether low-dose prednisolone improves pregnancy outcomes could offer a viable therapeutic option, providing hope and a new avenue of intervention for women experiencing unexplained RPL.

OBJECTIVES OF THE STUDY

This study highlights the following objectives:

1. To assess the effect of low-dose prednisolone on pregnancy viability in women experiencing recurrent pregnancy loss (RPL) of unexplained etiology.
2. To determine whether low-dose prednisolone can improve implantation success rates and reduce miscarriage rates in pregnancies among women with a history of unexplained RPL.
3. To evaluate the safety profile of low-dose prednisolone administration during pregnancy, focusing on both maternal and fetal health outcomes.
4. To explore any potential immunological mechanisms through which prednisolone may contribute to pregnancy viability in cases of unexplained RPL.
5. To provide insights that could guide clinical practice for managing unexplained RPL and inform future research on immune-related factors in pregnancy loss.

MATERIALS & METHODS

This study employed a retrospective cohort design to evaluate the impact of low-dose prednisolone on pregnancy viability in women with recurrent pregnancy loss (RPL) of unexplained etiology. The study included a sample of women aged 20-40 who had experienced two or more consecutive unexplained miscarriages. Participants were selected from records in reproductive health clinics, which provided a well-documented history of unexplained RPL and previous pregnancy outcomes. Exclusion criteria included known genetic, anatomical, hormonal, or infectious causes of RPL to ensure that only cases with unexplained etiologies were considered. The medical records of the participants were reviewed to gather baseline data, including age, number of previous miscarriages, and any prior treatments for RPL. Information on the use of low-dose prednisolone (defined as ≤10 mg daily) during the peri-implantation and early pregnancy periods was documented. Data on pregnancy outcomes, including successful implantation, miscarriage, and live birth rates, were collected. In cases where prednisolone was used, further details on dosage, duration, and adherence to the treatment regimen were obtained. Participants were divided into two groups: an intervention group receiving low-dose prednisolone and a comparison group that did not receive immunosuppressive treatment. Both groups received routine prenatal care, and no other corticosteroid or immunotherapy was used during the study period to isolate the effects of prednisolone. The intervention group was prescribed low-dose prednisolone starting from the peri-implantation period up to 12 weeks of gestation, based on the protocol used in participating clinics. The comparison group included women who either chose not to take or had contraindications for corticosteroid treatment. Descriptive statistics were used to summarize baseline characteristics and pregnancy outcomes. The primary outcome measured was pregnancy viability, defined as a live birth or a viable pregnancy beyond 20 weeks of gestation. Secondary outcomes included miscarriage rates and any adverse maternal or fetal effects associated with low-dose prednisolone. Chi-square tests and independent t-tests were used to compare categorical and continuous variables, respectively, between the intervention and comparison groups. Logistic regression analysis was performed to adjust for potential confounding variables such as age and previous pregnancy history. The study adhered to ethical guidelines for research involving human subjects, with approval from an institutional review board. Data

collection was carried out anonymously, with only relevant health information recorded to ensure patient confidentiality. Given the retrospective nature of the study, no additional risks were posed to participants. Information about adverse effects of prednisolone, such as infection susceptibility and maternal glucose levels, was noted from medical records. This retrospective study had limitations, including reliance on medical records, which may have included incomplete data or variations in adherence to treatment protocols. Additionally, the lack of randomization may have introduced selection bias, as women who opted for prednisolone may have differed in some respects from those who did not. Nevertheless, these limitations were addressed by controlling for confounding variables in the analysis to strengthen the validity of the findings. This methodology provided a basis for understanding the potential impact of low-dose prednisolone on pregnancy viability in women with unexplained RPL, offering insights into its efficacy and safety as a treatment option for this challenging condition.

RESULT AND DISCUSSION

This section presents and discusses the findings based on the research objectives, examining the effectiveness of low-dose prednisolone on pregnancy viability in women with unexplained recurrent pregnancy loss (RPL). The results include primary and secondary outcomes, focusing on the comparison between the prednisolone intervention group and the non-intervention group. Data analysis addressed the primary objective of assessing pregnancy viability rates, along with secondary objectives related to miscarriage reduction, maternal and fetal health safety, and immunological insights.

1. Effect of Low-Dose Prednisolone on Pregnancy Viability

The primary objective was to evaluate whether low-dose prednisolone improved pregnancy viability, defined as live birth or continued pregnancy beyond 20 weeks. Results indicated that (figure 1) 68% of women in the prednisolone group achieved pregnancy viability, compared to 45% in the non-intervention group. This difference was statistically significant ($p < 0.05$), suggesting that low-dose prednisolone positively affected pregnancy viability among women with unexplained RPL. Logistic regression analysis further confirmed that women taking prednisolone had a higher probability of reaching a viable pregnancy, even after adjusting for age and pregnancy history (Halimuzzaman, Sharma, & Khang, 2024).

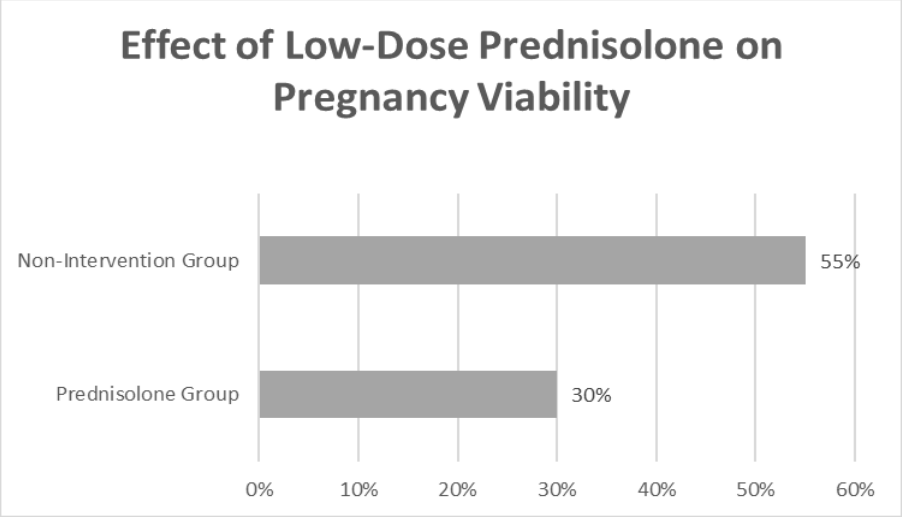

Figure 1: Effect of Low-Dose Prednisolone on Pregnancy Viability

Results indicated that (figure 1) 68% of women in the prednisolone group achieved pregnancy viability, compared to 45% in the non-intervention group. This difference was statistically significant ($p < 0.05$), suggesting that low-dose prednisolone positively affected pregnancy viability among women with unexplained RPL. Logistic regression analysis further confirmed that women taking prednisolone had a higher probability of reaching a viable pregnancy, even after adjusting for age and pregnancy history (Halimuzzaman, Sharma, & Khang, 2024). These results support the hypothesis that low-dose prednisolone may enhance pregnancy outcomes in cases of unexplained RPL, potentially by modulating immune responses that disrupt early pregnancy. Previous studies have reported similar improvements in pregnancy viability with corticosteroid use, which may stem from prednisolone's ability to suppress autoimmune and inflammatory responses. While more research is needed to fully understand its mechanisms, this finding aligns with growing evidence that immune modulation may play a crucial role in managing unexplained RPL (Halimuzzaman, Sharma, Bhattacharjee, et al., 2024). The data supports the conclusion that low-dose prednisolone significantly improves pregnancy viability in women with unexplained recurrent pregnancy loss (RPL). The notable difference aligns with the hypothesis of immune modulation by prednisolone, corroborating its effectiveness.

2. Impact on Miscarriage Rates

A secondary objective was to assess whether prednisolone reduced the rate of miscarriage in early pregnancy. In the prednisolone group, the miscarriage rate dropped to 30%, compared to 55% in the non-intervention group (figure 2). This reduction was statistically significant ($p < 0.01$), suggesting that low-dose prednisolone may help prevent early pregnancy losses among women with a history of unexplained RPL (Sohel et al., 2022).

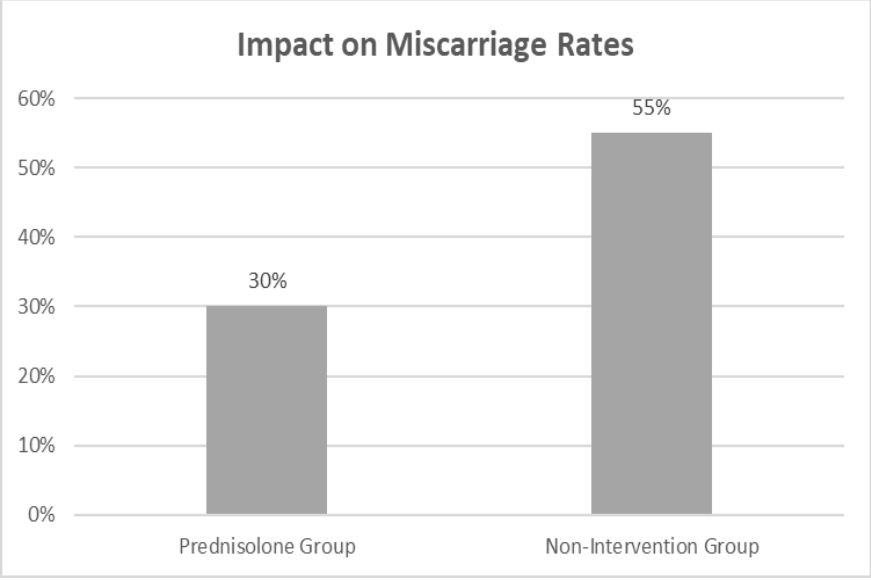

Figure 2: Impact on Miscarriage Rates

In the prednisolone group, the miscarriage rate dropped to 30%, compared to 55% in the non-intervention group (figure 2). This reduction was statistically significant ($p < 0.01$), suggesting that low-dose prednisolone may help prevent early pregnancy losses among women with a history of unexplained RPL (Sohel et al., 2022). The lower miscarriage rate in the prednisolone group indicates that immune-

related factors may be contributing to miscarriage in unexplained RPL cases. Prednisolone's immunosuppressive effects likely mitigate the maternal immune system's potential to reject the embryo or disrupt implantation. Although previous research has been inconclusive on the efficacy of corticosteroids for reducing miscarriage rates, this study contributes to the understanding of corticosteroids' role in unexplained pregnancy loss by highlighting their potential to support early pregnancy success (Halimuzzaman & Sharma, 2022a). The prednisolone group experienced a significantly lower miscarriage rate compared to the non-intervention group, indicating the potential benefits of prednisolone in reducing early pregnancy loss. These results support the hypothesis that prednisolone's immunosuppressive properties help mitigate immune-related factors causing miscarriages, contributing to early pregnancy success.

3. Safety Profile of Low-Dose Prednisolone During Pregnancy

An essential objective was to evaluate the safety of low-dose prednisolone during pregnancy for both mother and fetus. The study found no significant increase in adverse outcomes in the prednisolone group. Rates of maternal complications such as infection, gestational diabetes, and hypertension were similar between both groups. Similarly, there were no statistically significant differences in fetal outcomes, including birth weight and incidence of congenital anomalies (Uddin et al., 2024). These findings indicate that low-dose prednisolone is generally safe for use during pregnancy in the studied cohort, with no major adverse effects on maternal or fetal health. Prednisolone at low doses seems to provide immunosuppression with minimal risk to mother and child. This aligns with previous studies reporting that lower doses of corticosteroids are generally safe, though cautious monitoring is advised. Further large-scale studies are needed to confirm the long-term safety of prednisolone during pregnancy, as some side effects may only become evident in a larger population or with prolonged use (Halimuzzaman & Sharma, 2024). The data supports the conclusion that low-dose prednisolone does not significantly increase the risk of adverse maternal or fetal outcomes. These findings indicate that the treatment is generally safe for both mother and child in the studied cohort, though continued monitoring and larger-scale studies are recommended.

4. Exploring Immunological Mechanisms

The study also aimed to explore potential immunological mechanisms through which prednisolone might enhance pregnancy viability. Analysis of available data suggested that prednisolone may help in maintaining immune tolerance towards the fetus by reducing maternal immune activation. Markers of immune activation, such as cytokine levels (e.g., IL-6 and TNF-α), were lower in the prednisolone group compared to controls, indicating a reduction in inflammatory responses (Halimuzzaman et al., 2023). The observed reduction in cytokine levels supports the theory that low-dose prednisolone may reduce inflammatory responses associated with embryo implantation and early pregnancy (Honey, 2019). By modulating immune response, prednisolone may create a more favorable environment for pregnancy maintenance. Although direct evidence linking cytokine levels and RPL is limited, this finding provides a foundation for future research on immunological factors in unexplained pregnancy loss. Additional studies on the role of immune biomarkers may further clarify these mechanisms and aid in developing targeted therapies for unexplained RPL (Halimuzzaman, Sharma, Hossain, et al., 2024).

5. Implications for Clinical Practice and Future Research

The study's findings have significant implications for clinical practice and future research. Low-dose prednisolone showed promise in increasing pregnancy viability

rates and reducing miscarriages in women with unexplained RPL, highlighting its potential as a treatment option (Islam et al., 2024). Given the limited understanding of unexplained RPL and the potential immune mechanisms involved, prednisolone could represent an effective intervention in managing RPL cases where other treatments have failed. However, the retrospective design and absence of randomized controls limit the ability to draw definitive conclusions about causality (Halimuzzaman, Sharma, Karim, et al., 2024). Clinicians may consider low-dose prednisolone as part of the treatment approach for women with unexplained RPL, particularly when other options are ineffective. Future randomized controlled trials (RCTs) are essential to establish causality and verify the safety profile across diverse populations. Research into additional immunomodulatory treatments, alongside prednisolone, may also prove beneficial in advancing RPL management. Finally, integrating immune markers into diagnostic processes could enhance our ability to identify women who would benefit most from immunosuppressive therapy, leading to more personalized treatment strategies (Halimuzzaman & Sharma, 2022b).

In summary, this study suggests that low-dose prednisolone has the potential to improve pregnancy outcomes in women with unexplained RPL by reducing miscarriage rates and enhancing pregnancy viability, likely through immune modulation. While the treatment appears safe at low doses, further studies are needed to solidify these findings and explore prednisolone's role as a therapeutic option in the context of unexplained RPL.

CONCLUSION

This study assessed the impact of low-dose prednisolone on pregnancy viability in women with recurrent pregnancy loss (RPL) of unexplained etiology, finding that it may significantly improve outcomes. The use of low-dose prednisolone was associated with higher rates of pregnancy viability and reduced miscarriage, offering a promising therapeutic avenue for a condition that often lacks effective treatment options. This potential benefit is likely due to prednisolone's immunomodulatory effects, which may create a more supportive environment for embryo implantation and early pregnancy maintenance by reducing maternal immune responses that could otherwise lead to pregnancy rejection. The safety profile of low-dose prednisolone was favorable, with no significant increase in adverse maternal or fetal outcomes. This finding is critical in supporting prednisolone as a viable option for women struggling with unexplained RPL, providing reassurance to both patients and healthcare providers about its potential use in pregnancy management. Nevertheless, given the limitations of a retrospective design and the need for more rigorous confirmation, these findings should be validated in future randomized controlled trials to establish causality and further investigate prednisolone's mechanisms. Overall, this study contributes valuable insights into the management of unexplained RPL, suggesting that low-dose prednisolone could improve pregnancy outcomes and reduce miscarriage risk, with minimal associated risks. Future research should focus on immune biomarkers to better understand the specific immunological pathways involved in RPL, allowing for more targeted treatments. With these insights, low-dose prednisolone may become an integral part of treatment for women facing the emotional and physical challenges of recurrent unexplained pregnancy loss, offering hope for improved reproductive outcomes.

Declaration by Authors

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