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Original Research Article

ASSESSMENT OF DRY EYE DISEASE PROGRESSION IN POSTMENOPAUSAL WOMEN: A PROSPECTIVE COHORT STUDY

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ABSTRACT

Background: This study aimed to assess the progression of dry eye disease (DED) in postmenopausal women and evaluate the effectiveness of therapeutic interventions on subjective and objective clinical outcomes over a 12-month follow-up period.

Materials and Methods: A prospective cohort study was conducted on 120 postmenopausal women aged 50 years and older with a confirmed diagnosis of DED. Baseline evaluations included demographic data, medical history, and DED assessments using the Ocular Surface Disease Index (OSDI), Tear Break-Up Time (TBUT), Schirmer Test I, and corneal and conjunctival staining. Meibomian Gland Dysfunction (MGD) was graded based on gland expression and morphology. Participants were followed for 12 months, with assessments at baseline, 3 months, 6 months, and 12 months. Statistical analyses were performed to evaluate changes in outcomes over time, with significance set at $p < 0.05$.

Results: The mean age of participants was 58.32 ± 5.45 years, with a mean BMI of 26.75 ± 3.21 kg/m². OSDI scores significantly decreased from 45.25 ± 4.21 at baseline to 28.12 ± 3.85 at 12 months ($p < 0.01$). TBUT improved from 5.32 ± 0.85 seconds to 8.34 ± 0.92 seconds ($p < 0.01$), and Schirmer test values increased from 6.42 ± 1.12 mm to 9.02 ± 1.02 mm ($p < 0.01$). Corneal and conjunctival staining scores decreased from 3.45 ± 0.45 to 1.76 ± 0.33 ($p < 0.01$). The prevalence of MGD decreased from 55.83 ± 5.12% to 35.83 ± 4.02% ($p < 0.01$).

Conclusion: Significant improvements were observed in both subjective and objective markers of DED in postmenopausal women over 12 months. These findings highlight the importance of comprehensive management strategies in mitigating DED progression and improving ocular surface health and quality of life in this population.

Keywords: Dry Eye Disease, Postmenopausal Women, Ocular Surface Disease Index, Tear Break-Up Time, Meibomian Gland Dysfunction.

INTRODUCTION

Dry eye disease (DED) is a multifactorial condition of the ocular surface characterized by the loss of tear film homeostasis and accompanied by symptoms such as ocular discomfort, dryness, and visual disturbance. It is a prevalent condition that significantly impacts the quality of life, particularly in specific populations, such as postmenopausal women. DED has both physical and psychological consequences, affecting daily activities, productivity, and emotional well-being. The condition results from a complex interplay of factors, including hormonal changes, inflammation, and environmental triggers, making it a challenging condition to manage effectively.[1] Postmenopausal women represent a significant demographic in the study of DED due to the hormonal changes that occur during and after menopause. The decline in estrogen and androgen levels during menopause has been linked to alterations in the ocular surface and

meibomian gland function, which contribute to the development and progression of DED. Hormonal changes lead to reduced lacrimal gland function, decreased tear production, and an increase in tear film instability, all of which exacerbate dry eye symptoms. Additionally, postmenopausal women are often more susceptible to systemic conditions, such as autoimmune diseases, that may further contribute to DED pathophysiology.[2] The tear film, which plays a critical role in maintaining ocular surface integrity, consists of three layers: the lipid, aqueous, and mucin layers. Each layer has a distinct function, and any disruption to this delicate structure can result in DED. The lipid layer, produced by the meibomian glands, reduces tear evaporation and maintains tear film stability. Dysfunction of the meibomian glands, commonly observed in postmenopausal women, leads to increased tear evaporation and evaporative DED. The aqueous layer, secreted by the lacrimal glands, provides hydration and nutrients to the cornea and conjunctiva. Reduced lacrimal gland secretion results in aqueous-deficient DED. The mucin layer, produced by goblet cells, aids in tear film adhesion to the ocular surface. A deficiency in mucin production can further contribute to tear film instability and epithelial damage.[3]

Environmental and lifestyle factors also play a role in the progression of DED. Prolonged screen time, exposure to air conditioning or heaters, and environmental pollutants can exacerbate dry eye symptoms by increasing tear evaporation and reducing blink rates. Furthermore, medications commonly used by postmenopausal women, such as antihistamines, diuretics, and antidepressants, may have side effects that contribute to dry eye by reducing tear production or altering tear film composition. The diagnosis of DED is complex and requires both subjective and objective assessments. Subjective evaluations include patient-reported symptoms such as dryness, irritation, and visual disturbances, often measured using validated questionnaires like the Ocular Surface Disease Index (OSDI). Objective assessments involve clinical tests such as tear break-up time (TBUT), Schirmer test, and corneal and conjunctival staining. These tests help quantify tear film stability, tear production, and ocular surface damage, providing a comprehensive understanding of the severity and underlying mechanisms of DED.[4] Management of DED in postmenopausal women involves a multifaceted approach that addresses the underlying causes and provides symptomatic relief. Artificial tears, anti-inflammatory therapies, and lipid-based eye drops are commonly used to restore tear film balance and alleviate symptoms. In addition, eyelid hygiene, warm compresses, and dietary modifications, such as increasing omega-3 fatty acid intake, are recommended to improve meibomian gland function and reduce inflammation. Advanced treatment options, including punctal plugs, intense pulsed light therapy, and biologic eye drops, may be considered for patients with severe or refractory DED. Hormone replacement therapy has also been investigated for its potential benefits in improving DED symptoms in postmenopausal women, though its use remains controversial due to potential systemic risks.[5] The progression of DED in postmenopausal women is influenced by the chronic nature of the condition and the interplay of hormonal, environmental, and systemic factors. Longitudinal studies have highlighted the importance of early detection and consistent management to prevent long-term complications, such as chronic inflammation, epithelial damage, and vision loss. Given the high prevalence of DED in postmenopausal women and its impact on quality of life, there is a need for tailored management strategies that address the unique challenges faced by this population.[6]

Research efforts in recent years have focused on understanding the pathophysiology of DED, identifying biomarkers for early diagnosis, and developing targeted therapies. The recognition of inflammation as a key contributor to DED has led to the development of anti-inflammatory treatments, such as cyclosporine and lifitegrast, which have shown promising results in reducing symptoms and improving ocular surface health. Advances in diagnostic technologies, including tear film imaging and ocular surface staining techniques, have enhanced our ability to accurately diagnose and monitor DED progression. Despite these advancements, significant gaps remain in the understanding of DED progression in postmenopausal women. The heterogeneity of the condition, combined with the variability in patient response to treatment, poses challenges in establishing standardized management protocols. Moreover, the impact of systemic conditions, comorbidities, and medication use on DED progression warrants further investigation to develop personalized treatment approaches.[7] DED is a prevalent and multifactorial condition that disproportionately affects postmenopausal women due to hormonal changes, systemic conditions, and environmental factors. The chronic and progressive nature of DED necessitates early diagnosis, comprehensive management, and regular follow-up to prevent complications and improve patient outcomes. Continued research into the pathophysiology, diagnostic techniques, and therapeutic options for DED is essential to address the unmet needs of this vulnerable population. By understanding the unique challenges faced by postmenopausal women with DED, clinicians can provide tailored care that enhances their quality of life and ocular health.[8]

MATERIALS AND METHODS

This prospective cohort study was conducted to assess the progression of dry eye disease (DED) in

postmenopausal women. A total of 120 postmenopausal women aged 50 years and older were recruited in this study at a tertiary care hospital. Inclusion criteria were a confirmed diagnosis of DED based on clinical criteria (as defined below) and postmenopausal status confirmed by medical history or laboratory evaluation. Exclusion criteria included any active ocular infection, history of ocular surgery within the past 6 months, current use of systemic immunosuppressive therapy, or other severe ocular or systemic conditions that could confound the study outcomes. The study was approved by the Institutional Review Board (IRB). Written informed consent was obtained from all participants before enrollment.

Methodology

At enrollment, participants underwent a comprehensive baseline evaluation, including the collection of demographic information, medical history, menopausal status, and details of previous or current treatments for dry eye disease (DED). Subjective symptoms were assessed using the Ocular Surface Disease Index (OSDI) questionnaire, followed by a comprehensive ocular examination using slit-lamp biomicroscopy to rule out other ocular surface conditions. Objective assessments included the measurement of tear film stability with Tear Break-Up Time (TBUT) using fluorescein strips, tear production using Schirmer Test I (without anesthesia), and ocular surface damage using corneal and conjunctival staining with fluorescein and lissamine green. Meibomian Gland Dysfunction (MGD) was graded based on gland expression and morphology. Participants were followed for 12 months, with evaluations conducted at baseline, 3 months, 6 months, and 12 months, during which the same assessments were repeated to monitor changes in symptoms and clinical signs. Primary outcomes included changes in OSDI scores and objective markers (TBUT, Schirmer test values, and corneal/conjunctival staining scores), while secondary outcomes examined the progression of MGD and the relationship between systemic factors, such as hormonal therapy, and DED progression.

Statistical Analysis

All data were analyzed using SPSS version 25.0. Descriptive statistics were used to summarize baseline characteristics. Paired t-tests or Wilcoxon signed-rank tests were used to compare changes in outcomes over time. A multivariate regression model was used to identify predictors of DED progression. Statistical significance was set at $p < 0.05$.

RESULTS

Baseline Demographic and Clinical Characteristics

The baseline characteristics of the 120 postmenopausal women enrolled in this study indicate a mean age of 58.32 ± 5.45 years, highlighting the inclusion of a representative population of postmenopausal women in the typical age range for menopause-related changes. The mean duration of menopause was 8.56 ± 3.22 years, reflecting a population with established postmenopausal status. The mean body mass index (BMI) was 26.75 ± 3.21 kg/m², indicating that the participants were, on average, slightly overweight. These baseline values provide essential context for interpreting the progression of dry eye disease (DED) in this cohort.

Ocular Surface Disease Index (OSDI) Scores Over Time

The mean OSDI scores, which assess subjective dry eye symptoms, showed significant improvement over the 12-month follow-up period. At baseline, the mean OSDI score was 45.25 ± 4.21, indicating moderate to severe symptoms of dry eye. Over time, the OSDI score significantly decreased to 38.74 ± 3.95 at 3 months, 32.45 ± 4.02 at 6 months, and 28.12 ± 3.85 at 12 months ($p < 0.01$ for all time points). These results suggest a steady and statistically significant improvement in the subjective symptoms of DED, likely attributable to the interventions and management strategies employed during the study.

Tear Break-Up Time (TBUT) Over Time

Objective measurements of tear film stability, assessed by TBUT, demonstrated a significant increase over the study period. The mean TBUT improved from 5.32 ± 0.85 seconds at baseline to 6.85 ± 0.91 seconds at 3 months, 7.92 ± 0.87 seconds at 6 months, and 8.34 ± 0.92 seconds at 12 months ($p < 0.01$ for all time points). This improvement in tear film stability reflects an enhancement in the functional quality of the tear film, which is critical for maintaining ocular surface health.

Schirmer Test I Results Over Time

The Schirmer test, which measures tear production, also showed significant improvement during the study. The mean Schirmer test values increased from 6.42 ± 1.12 mm at baseline to 7.65 ± 1.05 mm at 3 months, 8.45 ± 1.08 mm at 6 months, and 9.02 ± 1.02 mm at 12 months ($p < 0.01$ for all time points). These findings suggest enhanced lacrimal gland function or reduced tear evaporation due to improved ocular surface conditions.

Corneal and Conjunctival Staining Scores Over Time

Corneal and conjunctival staining scores, which indicate ocular surface damage, significantly decreased over the study period. At baseline, the mean staining score was 3.45 ± 0.45, which reduced to 2.89 ± 0.42 at 3 months, 2.12 ± 0.38 at 6 months, and 1.76 ± 0.33 at 12 months ($p < 0.01$ for all time points). This significant reduction indicates a marked improvement in the health of the ocular surface and decreased epithelial damage.

Prevalence of Meibomian Gland Dysfunction (MGD) Over Time

The prevalence of MGD decreased significantly over the course of the study. At baseline, 55.83 ± 5.12% of participants showed MGD, which declined to 48.33 ± 4.85% at 3 months, 41.67 ± 4.45% at 6 months, and 35.83 ± 4.02% at 12 months ($p < 0.01$ for all time points). This reduction indicates effective management of MGD, which likely contributed to the overall improvement in dry eye symptoms and objective measures.

Table 1: Baseline Demographic and Clinical Characteristics

Characteristics	Mean ± SD
Age (years)	58.32 ± 5.45
Duration of Menopause (years)	8.56 ± 3.22
BMI (kg/m²)	26.75 ± 3.21

Table 2: OSDI Scores Over Time

Time Point	Mean OSDI Score (± SD)	P-value
Baseline	45.25 ± 4.21	-
3 Months	38.74 ± 3.95	<0.01
6 Months	32.45 ± 4.02	<0.01
12 Months	28.12 ± 3.85	<0.01

Table 3: Tear Break-Up Time (TBUT) Over Time

Time Point	Mean TBUT (seconds ± SD)	P-value
Baseline	5.32 ± 0.85	-
3 Months	6.85 ± 0.91	<0.01
6 Months	7.92 ± 0.87	<0.01
12 Months	8.34 ± 0.92	<0.01

Table 4: Schirmer Test I Results Over Time

Time Point	Mean Schirmer Test I (mm ± SD)	P-value
Baseline	6.42 ± 1.12	-
3 Months	7.65 ± 1.05	<0.01
6 Months	8.45 ± 1.08	<0.01
12 Months	9.02 ± 1.02	<0.01

Table 5: Corneal and Conjunctival Staining Scores Over Time

Time Point	Mean Staining Score (± SD)	P-value
Baseline	3.45 ± 0.45	-
3 Months	2.89 ± 0.42	<0.01
6 Months	2.12 ± 0.38	<0.01
12 Months	1.76 ± 0.33	<0.01

Table 6: Prevalence of MGD Over Time

Time Point	Prevalence of MGD (%) ± SD	P-value
Baseline	55.83 ± 5.12	-
3 Months	48.33 ± 4.85	<0.01
6 Months	41.67 ± 4.45	<0.01
12 Months	35.83 ± 4.02	<0.01

DISCUSSION

This prospective cohort study evaluated the progression and management of dry eye disease (DED) in 120 postmenopausal women over a 12-month period. The findings highlight significant improvements in subjective symptoms, as measured by the Ocular Surface Disease Index (OSDI), and objective markers, such as Tear Break-Up Time (TBUT), Schirmer test, corneal/conjunctival staining, and the prevalence of Meibomian Gland Dysfunction (MGD).

The mean age of participants in this study (58.32 ± 5.45 years) aligns with the typical age range of postmenopausal women, making it comparable to other studies on postmenopausal DED. For instance, a study by Yildiz et al. (2021) reported a similar mean age of 57.80 ± 4.10 years among 102 postmenopausal women with DED.[9] The mean duration of menopause in this cohort (8.56 ± 3.22 years) is consistent with findings by Na et al. (2015), who reported a mean duration of 9.2 ± 3.5 years.[10] The BMI of participants (26.75 ± 3.21 kg/m²) indicates a population that is, on average, slightly overweight, which is a known risk factor for DED as supported by Sullivan et al. (2017), who noted that obesity may contribute to meibomian gland dysfunction.[11] The mean OSDI scores significantly decreased from 45.25 ± 4.21 at baseline to 28.12 ± 3.85 at 12 months ($p < 0.01$). This 37.87% reduction in OSDI scores reflects substantial alleviation of subjective dry eye symptoms, likely due to improved management strategies. A comparable study by Wolffsohn et al. (2017) showed a 30% reduction in OSDI scores in postmenopausal women receiving artificial tear

therapy and omega-3 supplementation. Our study observed a greater reduction, which may be attributable to a combination of personalized treatment approaches and consistent follow-up.[12] TBUT significantly improved from 5.32 ± 0.85 seconds at baseline to 8.34 ± 0.92 seconds at 12 months ($p < 0.01$). This 56.77% increase suggests improved tear film stability, which is crucial in reducing ocular surface damage. A study by Zhao et al. (2020) found similar improvements, reporting a 45% increase in TBUT after six months of DED management using eyelid hygiene and lipid-based artificial tears. The greater improvement observed in our study may result from a longer follow-up period and comprehensive therapeutic approaches.[13] Tear production, as measured by the Schirmer test, increased significantly from 6.42 ± 1.12 mm at baseline to 9.02 ± 1.02 mm at 12 months ($p < 0.01$). This 40.50% improvement suggests enhanced lacrimal gland function or reduced tear evaporation. Comparatively, a study by Yamaguchi et al. (2016) reported a 35% increase in Schirmer test values in postmenopausal women treated with hormone replacement therapy (HRT). While our study did not specifically evaluate the effects of HRT, the results underscore the importance of addressing systemic and ocular factors in managing DED.[14] Corneal and conjunctival staining scores significantly decreased from 3.45 ± 0.45 at baseline to 1.76 ± 0.33 at 12 months ($p < 0.01$), indicating a 49.00% reduction in ocular surface damage. A study by Craig et al. (2018) similarly reported a 40% reduction in staining scores after six months of treatment with warm compresses and anti-inflammatory eye drops. The greater reduction in our study highlights the benefits of sustained and multifaceted management.[15] The prevalence of MGD decreased from 55.83 ± 5.12% at baseline to 35.83 ± 4.02% at 12 months ($p < 0.01$). This 35.82% reduction suggests effective management of MGD, which is critical in improving tear film quality and reducing evaporative DED. In comparison, a study by Finis et al. (2015) observed a 30% reduction in MGD prevalence after 12 months of using eyelid hygiene protocols and meibomian gland expression. The slightly better outcomes in our study may be due to more rigorous follow-up and individualized interventions.[16]

CONCLUSION

This study demonstrates significant improvements in both subjective symptoms and objective markers of dry eye disease (DED) in postmenopausal women over a 12-month follow-up period. The consistent reduction in OSDI scores and corneal/conjunctival staining, along with improved Tear Break-Up Time (TBUT) and Schirmer test values, highlights the effectiveness of comprehensive management strategies. The decline in Meibomian Gland Dysfunction (MGD) prevalence further underscores the importance of addressing evaporative components in DED treatment. These findings emphasize the need for tailored, long-term therapeutic approaches to improve ocular surface health and quality of life in postmenopausal women.

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