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Efficacy and Safety of Intradermal Bleomycin Injection for Xanthelasma Palpebrarum: A Clinical Study

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Abstract

Purpose

To evaluate the efficacy and safety of intradermal bleomycin injection in patients with xanthelasma palpebrarum

Methods

This retrospective study included 41 patients with xanthelasma palpebrarum who received intradermal bleomycin injections (3 U/mL) and were followed for 6 months. Lesion area was measured using standardized digital photographs analyzed with ImageJ software. Safety was assessed at each visit.

Results

At 6 months, complete resolution was achieved in 26.8% of patients, while 63.4% showed partial response. The median lesion area decreased significantly from 30.9 × 10^3 mm^2 to 10.1 × 10^3 mm^2 ($p < 0.001$). Mild transient eyelid edema and erythema were observed in all patients, and postinflammatory hyperpigmentation occurred in 30%, resolving spontaneously within 6 months. No systemic adverse events were reported.

Conclusions

Intradermal bleomycin injection is a safe, effective, and minimally invasive treatment for xanthelasma palpebrarum. As one of the first systematic evaluations of this approach in ophthalmology, it highlights a valuable alternative to conventional surgical or laser-based methods.

İntroduction

Xanthelasma palpebrarum (XP) is the most common form of cutaneous xanthoma, typically presenting as yellowish plaques on the eyelids, particularly near the medial canthus of the upper lid. These lesions are usually symmetrically distributed and may vary in number and morphology, appearing as single or multiple, nodular or flat, soft, and either semisolid or calcified in consistency.[1] Although XP is a benign condition that does not present a significant health risk, its appearance often causes cosmetic dissatisfaction.[2] The reported prevalence of XP is approximately 1.1% in women and 0.3% in men, with the condition most commonly seen in individuals over the age of 50.[3] Nearly half of the affected patients have underlying dyslipidemia.[4]

While the exact pathogenesis of XP remains unclear, it is histologically marked by foam cells—lipid-laden histiocytes—accumulating in the superficial to mid-dermis around blood vessels and adnexal structures, often accompanied by varying degrees of fibrosis and inflammation.[5]

Various treatment modalities have been proposed for XP; however, none have demonstrated consistently satisfactory or long-term results. Medical management primarily involves lifestyle modifications—such as

regular physical activity and a low-fat diet—combined with lipid-lowering agents. Although these interventions are essential for controlling dyslipidemia, their direct impact on XP lesions is limited. Surgical treatment options include simple excision, laser therapy, chemical cauterization using trichloroacetic acid (TCA), radiofrequency ablation, and cryotherapy.[1,5]

Recent clinical studies have shown that intralesional injection of pingyangmycin, also known as bleomycin A5, is effective in the treatment of XP, producing satisfactory therapeutic outcomes.[6] More recently, intralesional application of bleomycin itself has emerged as a potential treatment option for XP.[7]

Bleomycin is an antineoplastic antibiotic with multiple subtypes, of which A2 and B2 are most commonly used; these forms are hydrophilic and possess a metal-binding core essential for their cytotoxic activity.[8,9] Bleomycin sulfate is an FDA-approved chemotherapeutic agent used in the treatment of several malignancies, including squamous cell carcinoma, germ cell tumors, and lymphomas.[10] Beyond oncology, it has also shown efficacy in managing various dermatologic conditions such as warts, keloids, hemangiomas, and Kaposi's sarcoma.[11,13] This retrospective study aims to evaluate the clinical efficacy and safety of intradermal bleomycin injection for the treatment of xanthelasma palpebrarum, presenting one of the first ophthalmology-based series exploring this minimally invasive therapeutic approach.

Materials and Methods

This study was designed as a retrospective medical chart review conducted at Başakşehir Çam and Sakura City Hospital, Istanbul, Turkey, between November 2024 and May 2025. Patients diagnosed with XP who underwent intradermal 3 units/mL bleomycin sulfate injection (Hisun Pfizer Pharmaceutical Co., Ltd., 15-unit vial) during this period were included. The treatment was performed in the oculoplastic outpatient clinic by a single surgeon using standardized injection protocols.

Exclusion criteria comprised patients with incomplete follow-up data or those who declined follow-up visits.

Clinical data—including demographic information, lesion localization, lesion size, and lipid profiles—were extracted from medical records. Standardized eyelid photographs were taken under uniform lighting and at a fixed distance using the same digital camera for all patients. Each image was calibrated in ImageJ using a scale marker to ensure accurate measurement. Because xanthelasma lesions often have curved and irregular borders, the freehand selection tool was used to manually trace the lesion contour. ImageJ then automatically calculated the lesion area in mm^2. To improve measurement reliability, all photographs were independently evaluated by two oculoplastic specialists, and discrepancies were resolved by consensus. Follow-up assessments were routinely scheduled on postoperative day 1, week 1, and at months 1, 3, and 6. Outcome measures included changes in lesion area, complete or partial response rates, and reported side effects. Treatment response was categorized according to changes in lesion area as measured by ImageJ at 6 months of follow-up. Complete response was defined as complete resolution of the lesion without clinically visible residual plaque. Partial response was defined as clinically significant but not complete

resolution of lesion size compared to baseline measurements. Lesions showing no significant change in size were classified as non-responders.

Ethical approval for the study protocol was obtained from the institutional review board, and the. The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all patients. Patients whose photographs were used for publication provided additional written consent for image use.

Procedure

Bleomycin sulfate (15 U vial) was reconstituted with 5 mL sterile normal saline to obtain a concentration of 3 U/mL immediately before injection. After preparing the periocular skin with 10% povidone-iodine solution, intradermal injections were performed using a 30-gauge insulin syringe. The needle was introduced into the mid-dermal layer, and the drug was delivered at multiple evenly spaced sites covering the entire lesion, with the total injected volume adjusted according to plaque size. Care was taken to avoid intravascular administration and excessive spread beyond the lesion borders. The procedure was repeated after eight weeks. No local or systemic anesthesia was required. Patients were observed briefly for immediate adverse reactions and advised to apply topical antibiotic ointment twice daily for three days and to avoid sun exposure. Follow-up visits were scheduled at 1 week, 1 month, 3 months, and 6 months to document changes in lesion size, pigmentary alterations, and any adverse events.

Statistical Methods

Descriptive statistics are expressed as mean, standard deviation, median, minimum, maximum, frequency, and percentage values. The distribution of variables was assessed using the Kolmogorov–Smirnov and Shapiro–Wilk tests. For independent quantitative data with normal distribution, the independent samples t-test was applied, whereas the Mann–Whitney U test was used for non-normally distributed data. The Wilcoxon signed-rank test was used for repeated measurements. Qualitative variables were compared using the chi-squared test. Spearman correlation analysis was performed to evaluate the relationships between continuous variables. All statistical analyses were conducted using SPSS software (version 27.0; (IBM Corp., Armonk, NY, USA), and a p-value of < 0.05 was considered statistically significant.

Results

A total of 41 patients diagnosed with xanthelasma palpebrarum were included in this study. The mean age was 50.5 ± 8.8 years (range: 34–75). Of the participants, 31 (75.6%) were female and 10 (24.4%) were male. The lesions were located on the right eyelid in 19 patients (46.3%) and on the left eyelid in 22 patients (53.7%). In terms of anatomical localization, 21 lesions (51.2%) were located on the upper eyelid, and 20 (48.8%) on the lower eyelid. Serum lipid profiles were available for all the patients. The mean low-density lipoprotein (LDL) level was 134.1 ± 30.8 mg/dL (range: 81–182), and the mean total cholesterol level was 216.5 ± 35.6 mg/dL (range: 141–279). The mean triglyceride (TG) level was 164.5 ± 81.5 mg/dL (range: 60–362), while the mean high-density lipoprotein (HDL) level was 47.8 ± 11.7 mg/dL (range: 30–76) (Table 1).

All patients received intralesional bleomycin injections and were assessed at the 6-month follow-up, showing a statistically significant reduction in lesion area, with the mean area decreasing from $34.9 \times 10^3\,mm^2$ preoperatively to $16.8 \times 10^3\,mm^2$ postoperatively ($p < 0.001$) (Table 2).

There were no statistically significant differences between the superior and inferior eyelid lesion groups in terms of age, sex, or laterality ($P > 0.05$). However, pre-treatment triglyceride levels were significantly higher and HDL levels were significantly lower in the superior group ($p < 0.05$). Post-treatment, both groups showed a reduction in lesion size. (Table 3)

At the 6-month follow-up, a complete clinical response, defined as the total disappearance of the lesion (post-treatment area = 0), was observed in 11 patients (26.8%) (Photo 1). A partial response, characterized by a significant but incomplete reduction in lesion size, was seen in 28 patients (68.3%) (Photo 2), and only two patients (4.9%) showed no significant change in lesion area after treatment .

All patients reached the planned 6-month evaluation, allowing consistent assessment of treatment outcomes. However, all patients developed mild eyelid edema and erythema following intralesional injections, lasting approximately one week and subsiding spontaneously within 5–7 days. In 30% of patients, postinflammatory hyperpigmentation was observed during follow-up; however, this resolved completely by the 6-month visit. No serious or long-term complications were reported.

Discussion

Xanthelasma palpebrarum (XP) is the most frequent cutaneous xanthoma, typically presenting as slightly elevated yellowish plaques near the medial canthus, primarily on the upper eyelid but occasionally extending to the lower lid or lateral canthus.[14] Although benign, its visible nature often leads patients to seek treatment for cosmetic reasons rather than functional impairment.[2,14] XP predominantly affects individuals over 50 years of age and is commonly associated with dyslipidemia characterized by elevated LDL and triglyceride levels with reduced HDL.[4,15] In our series, the mean age and lipid profile closely mirrored previous reports, and XP was significantly more common in women, consistent with prior studies suggesting hormonal or cosmetic treatment–seeking differences.[1,4,16]

Various therapeutic approaches have been described, but no consensus exists regarding the optimal modality. Nonsurgical methods include chemical cauterization, cryotherapy, and laser ablation, while surgery remains the most definitive option for large or deep lesions.[1,5,17–20] Cryotherapy is inexpensive and effective for small lesions but is rarely used around the eyelids due to edema and risk of scarring.[17] Trichloroacetic acid (TCA) is also employed for superficial plaques but carries a notable risk of pigmentary alterations, particularly in periorbital skin.[21] Multiple laser systems—argon, CO_2, Er:YAG, Nd:YAG, and diode lasers—have demonstrated efficacy; however, most studies are small case series with heterogeneous outcomes and no standardized protocol.[18–23] Surgical excision, especially when combined with blepharoplasty, offers excellent cosmetic outcomes and low recurrence rates but entails risks such as scarring and ectropion and may be unsuitable for patients with lower eyelid lesions or systemic comorbidities.[24]

Intralesional pingyangmycin, a bleomycin derivative, has been reported as an effective alternative with minimal recurrence.[25] Bleomycin itself, widely used in dermatology for warts, keloids, hemangiomas, and Kaposi's sarcoma, exerts cytotoxic and sclerosing effects by inducing DNA strand breaks and fibrosis.[11–13,26] Despite its extensive dermatologic use, evidence regarding bleomycin for XP, particularly periocular lesions, remains scarce.[7] The proximity of these lesions to ocular structures raises concerns about safety and tissue reactivity, underscoring the need for clinical studies in ophthalmologic settings.

In our study, intradermal bleomycin (3 U/mL) was administered twice at eight-week intervals. This conservative concentration was selected to optimize safety while maintaining therapeutic benefit, particularly in the delicate periocular skin. Prior dermatologic studies have demonstrated safe and effective use of intralesional bleomycin across a wide range of concentrations (1–7.5 U/mL).[13,26] Notably, Lin et al. compared 3.75 U/mL and 7.5 U/mL regimens and reported no significant difference in efficacy or adverse events between these higher doses,[7] suggesting that lower concentrations may be equally effective. Similarly, the systematic review by Bik et al. concluded that doses within the 1–3 U/mL range achieve substantial lesion reduction with minimal systemic toxicity,[13] and Saitta et al. emphasized that severe complications such as pulmonary fibrosis are associated with intravenous administration rather than intralesional use.[26] In our study, treatment was well tolerated, with only mild injection-site discomfort and transient eyelid edema and erythema resolving within 5–7 days, and postinflammatory hyperpigmentation in 30% of patients that resolved spontaneously within six months. No systemic adverse events were observed, further supporting the safety of this regimen in ophthalmic practice.Therapeutically, intradermal bleomycin produced a significant reduction in lesion area, with mean size decreasing from 34.9 mm² to 16.8 mm² at six months ($p < 0.001$). Mean lesion dimensions showed meaningful reduction. Complete clinical clearance was achieved in 26.8% of patients, while 68.3% demonstrated partial regression. Although partial responses do not eliminate the lesion entirely, they can still provide noticeable cosmetic improvement and may reduce the extent of tissue requiring removal if surgery is considered later. The overall response pattern in our cohort aligns with previously published nonsurgical XP treatment series, in which complete clearance rates are generally low.[17,23] In this context, even partial regression can represent a clinically meaningful outcome, particularly for lesions in cosmetically sensitive areas such as the lower eyelid, where minimizing surgical excision can translate into better aesthetic results.

Subgroup analysis revealed no significant differences between superior and inferior lesions regarding overall treatment response; however, superior eyelid lesions were associated with higher triglyceride and lower HDL levels, echoing previous findings of lipid profile variations by lesion location.[15,16] While dyslipidemia is implicated in XP pathogenesis, our data, in line with Kim et al. ,[31] suggest lipid parameters do not significantly influence therapeutic response to bleomycin. This highlights the importance of addressing systemic lipid abnormalities primarily for cardiovascular risk reduction rather than predicting local treatment outcomes.

Compared to lasers and surgery, intradermal bleomycin offers several advantages: it is minimally invasive, requires no specialized equipment, is cost-effective, and can be performed in an outpatient setting Importantly, it may be particularly beneficial for patients unsuitable for surgery or for lesions in

anatomically challenging areas, such as the lower eyelid, where surgical excision carries a higher risk of ectropion and contour deformities. This advantage is illustrated in Photo 3, which shows a representative example of lower eyelid plaques showing significant regression and excellent cosmetic results following intradermal bleomycin injection. However, limitations include the need for multiple sessions, potential for transient pigmentation, and the absence of long-term recurrence data.

This study is one of the first ophthalmology-based series to evaluate intradermal bleomycin for eyelid xanthelasma and suggests favorable clinical outcomes at a relatively low dose. However, the retrospective design, limited sample size, lack of a control group, and relatively short follow-up period limit the generalizability of the findings and prevent definitive conclusions regarding efficacy and long-term safety or direct comparison with established treatments such as surgical or laser methods. In this study treatment response should be interpreted as the presence of measurable lesion regression rather than complete resolution. In this benign and primarily cosmetic condition, lesions that do not show complete resolution but show significant improvement (characterized by significant size reduction along with visible cosmetic improvement) represent a clinically significant therapeutic outcome. Well-designed prospective controlled trials are needed in the future to confirm these preliminary findings and to determine optimal dosing strategies, treatment intervals, and long-term recurrence rates.

Conclusion

Intradermal bleomycin appears to be a promising minimally invasive option for reducing lesion size in patients with xanthelasma palpebrarum, and it was well tolerated with only mild, transient adverse effects in our cohort. However, the retrospective design, lack of a comparison group, and relatively short follow-up limit the strength of conclusions regarding true therapeutic efficacy and long-term recurrence. Further prospective controlled studies with longer follow-up and direct comparison with established treatments are needed to clarify the comparative effectiveness and optimal role of bleomycin in the management of xanthelasma palpebrarum.

Abbreviations

LDL
low-density lipoprotein
HDL
high-density lipoprotein
TG
triglycerides
sd
standard deviation.

Declarations

Declaration of Interest:

The authors declare that they have no conflicts of interest related to this work.

Author Contribution

G O: conceptualization, data curation, investigation, formal analysis, writing —original draft, writing —review, and editing.MK, FS: Investigation, imaging review, data curation, writing —review, and editing.

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Tables

Table-1. Demographic, clinical, and laboratory characteristics of patients with xanthelasma palpebrarum

		Min-Max			Median	Mean±sd/n-%		
Age		34.0	-	75.0	51.0	50.5	±	8.8
Gender	Female					31		75.6%
	Male					10		24.4%
Side	Right					19		46.3%
	Left					22		53.7%
Localization	İnferior					20		48.8%
	Superior					21		51.2%
Area (x10³)		6.8	-	84.5	30.9	34.9	±	20.6
LDL		81.0	-	182.0	129.0	134.1	±	30.8
Total Cholesterol		141.0	-	279.0	212.0	216.5	±	35.6
TG		60.0	-	362.0	147.5	164.5	±	81.5
HDL		30.0	-	76.0	45.0	47.8	±	11.7

Abbreviations:

LDL, low-density lipoprotein; HDL, high-density lipoprotein; TG, triglycerides; sd, standard deviation.

Table-2

	Preop				Postop					
	Mean±sd			Median	Mean±sd			Median		
Area (x10³)	34.9	±	20.6	30.9	16.8	±	21.0	10.1	***0.000***	w

[w] Wilcoxon test

Table 3. Comparison of demographic characteristics, lesion area measurements, and lipid profile parameters between inferior and superior xanthelasma groups

		İnferior Group (n:20)			Superior Group (n:21)			p	
		Mean±sd/n-%		Median	Mean±sd/n-%		Median		
Age		51.4 ± 11.3		51.0	49.6 ± 5.7		49.0	0.628	m
Gender	Female	14	70.0%		17	81.0%		0.414	X^2
	Male	6	30.0%		4	19.0%			
Side	Right	8	40.0%		11	52.4%		0.427	X^2
	Left	12	60.0%		10	47.6%			
Area (x10³)									
Preop		46.2 ± 20.9		45.8	24.2 ± 13.8		20.1	***0.000***	m
Postop		19.2 ± 15.8		20.0	14.5 ± 25.2		6.9	***0.000***	m
Preop/ Postop Differance		27.0 ± 18.8		23.9	9.7 ± 25.0		7.7	***0.000***	m
Intragroup P Value		***0.000***		w	***0.001***		w		
LDL		130.8 ± 26.7		128.5	137.5 ± 34.9		148.0	0.424	m
Total Cholesterol		211.5 ± 36.3		208.0	221.5 ± 35.0		227.5	0.381	t
TG		131.8 ± 47.2		124.5	197.2 ± 95.7		187.0	***0.041***	m
HDL		50.9 ± 10.9		47.0	44.7 ± 11.9		43.5	***0.017***	m

Abbreviations:

[t] Independent Samples t test / [m] Mann-whitney u test / [w] Wilcoxon test/ [X^2] Chi-square test

LDL, low-density lipoprotein; HDL, high-density lipoprotein; TG, triglycerides; sd, standard deviation.

Figures



Figure 1

Upper: pretreatment; lower: 6-month follow-up. Marked regression of bilateral upper eyelid xanthelasma plaques.



Figure 2

Upper: pretreatment; lower: 6-month follow-up. Extensive upper and lower eyelid plaques showing substantial size reduction.



Figure 3

Upper: pretreatment; lower: 6-month follow-up. Inferior eyelid involvement with significant improvement following treatment.

Supplementary Files

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