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Intraocular Pressure During Short-Term Topical or Systemic Corticosteroid Treatment
Analysis of 3 Randomized Clinical Trials

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IMPORTANCE Increased intraocular pressure (IOP) is a known adverse effect of corticosteroid use and may lead to corticosteroid-induced glaucoma. However, clinical evidence on the impact of topical corticosteroids (TCS) on IOP is limited.

OBJECTIVE To evaluate changes in IOP during short-term treatment with periocular and whole-body TCS (studies 1 and 2) and systemic corticosteroids (study 3).

DESIGN, SETTING, AND PARTICIPANTS This report includes the findings of 3 randomized clinical trials (RCTs) conducted at Herlev-Gentofte Hospital, University of Copenhagen (Denmark). Study 1 was an open-label RCT of patients with periocular atopic dermatitis (AD) and healthy controls, conducted from October 2021 to August 2023. Study 2 was a double-blind active comparator RCT of patients with AD conducted from September 2019 to March 2021. Study 3 was a double-blind RCT of male individuals with overweight or obesity and without diabetes conducted from December 2019 to June 2021. Data were analyzed from October 2024 to April 2025.

INTERVENTIONS In study 1, patients with AD and healthy controls applied periocular hydrocortisone (1.0%) cream or hydrocortisone-17-butyrate (0.1%) cream for 4 weeks; another group of healthy controls received no treatment. In study 2, patients with AD completed 2 weeks of whole-body betamethasone 17-valerate (0.1%) plus placebo or tacrolimus (0.1%) twice daily, followed by 4 weeks of twice-weekly treatment. In study 3, patients with AD received 10 days of oral placebo or prednisolone (50 mg) or prednisolone (50 mg) plus curcumin (400 mg).

MAIN OUTCOME Change in IOP—the primary end point in study 1 and a predefined secondary end point in studies 2 and 3.

RESULTS Study 1 included 24 patients, 8 with periocular atopic dermatitis (AD) and 16 healthy controls; study 2 included 36 patients with AD; and study 3 included 24 male individuals with overweight or obesity and without diabetes. The analysis of the 3 studies included a total of 84 participants (34 female [40.5%] and 50 male [59.5%] patients) with comparable baseline characteristics (mean [SD] age, 32 [9], 28 [10], and 46 [14] years). In study 1, right eye IOP significantly decreased in patients with AD after treatment compared to untreated controls (−2.5 mm Hg; 95% CI, −3.9 to −1.1 mm Hg; P = .002). No significant changes were observed in the left eye or among treated healthy controls. In studies 2 and 3, IOP remained stable, with no significant changes.

CONCLUSIONS AND RELEVANCE In these 3 RCTs, short-term corticosteroid use, whether topical or systemic, did not appear to increase IOP. These findings support the ocular safety of short-term corticosteroid use.

TRIAL REGISTRATIONS EU Clinical Trials Register Identifier: 2020-000252-35; ClinicalTrials.gov Identifier: NCT04114097 and NCT04315350

Supplemental content

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Increased intraocular pressure (IOP) is a known adverse effect of corticosteroids and may lead to corticosteroid-induced glaucoma.[1] IOP typically normalizes after treatment cessation, but prolonged treatment can cause persistently increased IOP requiring antiglaucomatous treatment.[1] Atopic dermatitis (AD) is often treated with topical corticosteroids (TCS), yet concerns about ocular adverse effects limit their use on the face and contribute to undertreated facial AD. Evidence linking periocular TCS to increased IOP is primarily based on case reports and series and retrospective studies.[2] Long-term systemic corticosteroid (SC) treatment is associated with increased IOP.[1,3] However, clinical studies on the effects of short-term SC and TCS treatment on IOP are limited. The objective of this study was to evaluate IOP during short-term periocular treatment with hydrocortisone cream, 1%, or hydrocortisone-17-butyrate cream, 0.1%, whole-body treatment with betamethasone 17-valerate ointment, 0.1%,[4] or systemic treatment with prednisolone.[5]

Key Points

Question Does short-term use of a topical or systemic corticosteroid increase intraocular pressure (IOP) in adults with or without atopic dermatitis?

Findings In 3 randomized clinical trials including 84 adults treated with periocular, whole-body, or systemic corticosteroids, short-term corticosteroid use did not increase IOP. A significant decrease of −2.5 mm Hg in IOP was observed in patients with periocular atopic dermatitis, with no significant increases in any group.

Meaning These findings suggest that short-term use of a topical or systemic corticosteroid does not increase IOP, supporting its ocular safety for short-term treatment courses.

Methods

This report and the included randomized clinical trials were reviewed and approved by the Research Ethics Committee of the Capital Region of Denmark, the Danish Data Protection Agency, and the Danish Medicines Agency. Informed consent was obtained from all participants prior to enrollment. The trials were conducted in accordance with the Declaration of Helsinki, the International Conference on Harmonization Good Clinical Practice guideline, and the Consolidated Standards of Reporting Trials (CONSORT).

The 3 randomized clinical trials included were The Risk of an Elevated Intraocular Pressure After Treatment With Topical Corticosteroids in the Periocular Region study (hereafter, study 1); The Effects of Topical Corticosteroid Use on Insulin Sensitivity and Bone Turnover study (hereafter, study 2); and The Effect of Curcumin on the Development of Prednisolone-induced Hepatic Insulin Resistance study (hereafter, study 3). The trial protocol for study 1 is available in Supplement 1; for study 2, in Supplement 2; and for study 3 in Supplement 3. An overview of all 3 studies is presented in eFigure 1 in Supplement 4.

Study 1: Periocular TCS

This randomized open-label trial included 3 groups: patients with AD (n = 8), healthy treated controls (n = 8), and healthy untreated controls (n = 8). Inclusion criteria were periocular AD, age 18 to 75 years, and body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) less than 30. Exclusion criteria for all 3 studies are provided in the eMethods in Supplement 4. The primary end point was change in IOP measured with iCare ic100 tonometer (Icare Finland Oy; additional details are available in the eMethods in Supplement 4).

At baseline, IOP was measured and AD severity was assessed with the Eczema Area and Severity Index (EASI) and Target Lesion Severity Score (TLSS). Patients with AD and healthy treated controls applied one-third of an index fingertip unit[6] of either hydrocortisone cream, 1% (n = 7), or hydrocortisone-17-butyrate cream, 0.1% (n = 9), around the eyes once daily for 4 weeks. IOP was measured at week 2, 3, and 4. Compliance was monitored by weighing the tubes. Details on randomization, protocol approval and registration are provided in eMethods in Supplement 4.

Study 2: Whole-Body TCS

In this randomized double-blinded trial, 36 patients with AD were allocated to either daily betamethasone 17-valerate ointment, 0.1% plus placebo (n = 18) or twice-daily tacrolimus ointment, 0.1% (n = 18). Inclusion criteria were age 18 to 75 years, BMI less than 30, and AD duration greater than 3 years. The primary outcome was insulin sensitivity, published elsewhere.[4] IOP was a secondary end point and measured at baseline, after 2 weeks of daily treatment and after an additional 4 weeks of twice-weekly treatment.

Study 3: Systemic Corticosteroids

In this randomized double-blinded trial, 24 male individuals with overweight or obesity and without diabetes were allocated to either prednisolone placebo and curcumin placebo (n = 8), 50-mg prednisolone and curcumin placebo (n = 8) or 50-mg prednisolone and 400-mg curcumin (n = 8). Inclusion criteria were male, age 18 to 59 years, and BMI of 24.9 to 32.0. The primary outcome was the effect of curcumin on prednisolone-induced insulin resistance, published elsewhere.[5] IOP was a secondary end point measured before and after 10 days of treatment.

Statistical Analysis

In study 1, a 20% increase in IOP compared to baseline was considered clinically relevant. To detect this with 80% power at a 5% significance level, 16 patients with AD, 16 healthy treated controls, and 10 healthy untreated controls were required, leading to a total of 42 participants. In studies 2 and 3, sample sizes were based on power calculations for the primary outcomes, described elsewhere.[4,5] In all 3 studies, change from baseline and estimated treatment difference were analyzed using a constrained linear mixed model with inherent baseline adjustment and unstructured covariance.[7] Additional details are available in the eMethods in Supplement 4. Statistical tests

Table 1. Baseline Characteristics of Participants in 3 Studies of Intraocular Pressure (IOP) and Corticosteroids Use

Study and group	Intervention	No.			Mean (SD)		AD severity, mean (SD)	
		Total	Female	Male	Age, y	BMI	EASI	TLSS
Study 1								
Patients with AD	Hydrocortisone, 1%	4	2	2	31.0 (12.1)	23.8 (1.5)	12.8 (11.0)	6.9 (1.4)
	Hydrocortisone-17-butyrate, 0.1%	4	3	1	30.0 (8.7)	23.6 (4.0	8.9 (6.1)	6.1 (2.5)
Healthy treated controls	Hydrocortisone, 1%	3	2	1	25.3 (3.5)	22.8 (4.4)	NA	NA
	Hydrocortisone-17-butyrate, 0.1%	5	3	2	30.6 (10.1)	22.1 (5.8)	NA	NA
Healthy untreated controls	NA	8	5	3	33.5 (8.2)	24.0 (3.0)	NA	NA
Study 2								
Patients with AD	Betamethasone 17-valerate ointment, 0.1%	18	9	9	Median, (IQR), 26 (23-37)	23.0 (3.0)	16.5 (13.7)	NA
	Tacrolimus ointment, 0.1%	18	10	8	Median, (IQR), 23 (22-28)	23.7 (2.2)	16.3 (10.0)	NA
Study 3								
Male individuals with overweight or obesity and without diabetes	Prednisolone placebo + curcumin placebo	8	0	8	41.6 (9.8)	30.4 (4.3)	NA	NA
	Prednisolone (50 mg/d) + curcumin placebo	8	0	8	44.0 (13.5)	30.3 (3.3)	NA	NA
	Prednisolone (50 mg/d) + curcumin (400 mg/d)	8	0	8	47.0 (17.8)	29.3 (3.2)	NA	NA

Abbreviations: AD, atopic dermatitis; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); EASI, Eczema Area and Severity Index; NA, not applicable; TLSS, Target Lesion Severity Score.

were 2-tailed and $P < .05$ was considered to be statistically significant. Data were analyzed from October 2024 to April 2025 using SAS Enterprise Guide, version 8.3 (SAS Institute Inc).

RESULTS

Study 1 screened 46 adults and enrolled 24 (8 patients with periocular AD and 16 healthy controls); study 2 screened 49 adults and enrolled 36; and study 3 screened 30 adults and enrolled 24. The analysis included a total of 84 participants (34 female [40.5%] and 50 male [59.5%] patients); baseline characteristics including age, sex, and BMI, were comparable across groups (**Table 1**). CONSORT flow diagrams, treatment exposure, and study dropout rates are detailed in the eResults and eFigures 2 and 3 in Supplement 4.

Decreased IOP After Periocular TCS

Baseline IOP and changes are shown in **Table 2** and the **Figure**. In the AD group (n = 8), IOP decreased significantly. Right eye IOP decreased by −2.62 (95% CI, −3.64 to −1.60; $P < .001$) and left eye decreased by −2.38 (95% CI, −3.66 to −1.10; $P < .001$) after 4 weeks compared to baseline. In the healthy treated controls (n = 8), left eye IOP decreased significantly at week 4 (−1.37 mm Hg; 95% CI, −2.65 to −0.09; $P = .04$) compared to baseline, and no significant difference was found in right eye IOP. In the healthy untreated controls (n = 8), IOP remained stable in both eyes. Additional findings are available in the eResults in Supplement 4.

Difference in changes from baseline in the AD group and healthy treated controls compared to the healthy untreated controls is presented in Table 2. Compared to untreated controls, patients with AD had significantly greater IOP reduction in the right eye across all weeks (95% CI, −3.94 to −1.05; $P = .002$). No differences were observed between healthy treated and untreated controls.

Stable IOP After Whole-Body TCS

In the TCS group (n = 18) and TCI group (n = 18), IOP remained stable after 2 weeks of daily treatment and further 4 weeks of twice-weekly treatment. No between-group differences were observed.

Stable IOP After Systemic Corticosteroids

Pooling the prednisolone-treated participants (n = 15), IOP remained stable after 10 days of daily treatment. No differences were observed compared to placebo.

DISCUSSION

Across 3 clinical trials, we found that short-term periocular TCS reduced IOP, while whole-body TCS and high-dose SC had no effect on IOP. The IOP decrease may reflect reduced eye rubbing following alleviation of itching. Chronic eye rubbing can affect corneal properties and rebound tonometry measurements.[8] Additionally, applying cream may involve gentle ocular massage, which can transiently lower IOP.[9] Thus, the decrease is likely incidental rather than treatment-related.

Our findings align with those of previous retrospective studies. Kim et al[10] reported no association between increased IOP and periocular treatment with moderately potent TCS twice daily for 4 to 10 months. Likewise, Tamagawa-Mineoka et al[11] and Haeck et al[12] reported stable IOP in patients with AD treated with daily periocular or whole-body mild, moderate or potent TCS for 2 weeks to 4 months. However, several case reports and series describe

Table 2. Change in Intraocular Pressure (IOP) From Baseline After Corticosteroid Use

Group	Intervention	IOP, mm Hg (95% CI)									
		Left eye						Right eye			
		Baseline, estimate (95% CI)	Change from baseline (95% CI)	*P* value	Treatment difference (95% CI)	*P* value		Baseline, estimate (95% CI)	Change from baseline (95% CI)	*P* value	Treatment difference (95% CI)	*P* value
Study 1												
Patients with AD	Hydrocortisone, 1%, or hydrocortisone-17-butyrate, 0.1%	14.4 (11.45 to 17.31)	−2.38 (−3.66 to −1.10)[a]	<.001	−1.72 (−3.52 to 0.09)[a]	.06		15.0 (12.3 to 17.7)	−2.62 (−3.64 to −1.60)[a]	<.001	−2.50 (−3.94 to 1.05)[a]	.002
Healthy treated controls	Hydrocortisone, 1%, or hydrocortisone-17-butyrate, 0.1%	13.5 (10.61 to 16.46)	−1.37 (−2.65 to −0.09)[a]	.04	−0.71 (−2.51 to 1.10)[a]	.43		13.7 (11.0 to 16.3)	−0.70 (−1.72 to 0.32)[a]	.17	−0.58 (−2.02 to 0.86)[a]	.41
Healthy untreated controls	NA	14.2 (11.28 to 17.13)	−0.66 (−1.94 to 0.61)[a]	.29	0 [Reference][a]	NA		14.2 (11.5 to 16.9)	−0.12 (−1.14 to 0.90)[a]	.81	0 [Reference][a]	NA
Study 2												
Patients with AD	Betamethasone, 0.1%, ointment	13.0 (11.9 to 14.0)	−0.33 (−1.13 to 0.47)[b]	.41	0 (−1.12 to 1.13)[b]	.99		13.8 (13.9 to 14.7)	−0.12 (−1.12 to 0.89)[b]	.81	0.12 (−1.31 to 1.54)[b]	.87
	Tacrolimus, 0.1%		−0.34 (−1.14 to 0.47)[b]	.40					−0.23 (−1.24 to 0.77)[b]	.64		
Patients with AD	Betamethasone, 0.1%, ointment	13.0 (11.9 to 14.0)	−0.15 (−1.27 to 0.96)[c]	.78	0.20 (−1.38 to 1.78)[c]	.80		13.8 (13.9 to 14.7)	0.80 (−0.59 to 2.18)[c]	.95	0.80 (−0.59 to 2.18)[c]	.25
	Tacrolimus, 0.1%		−0.35 (−1.48 to 0.78)[c]	.53					−0.76 (−1.76 to 0.23)[c]	.13		
Study 3												
Male individuals with overweight or obesity and without diabetes	Prednisolone (50 mg/d) + curcumin placebo	13.2 (11.8 to 14.6)	−0.37 (−1.43 to 0.68)[d]	.47	0.56 (−1.22 to 0.68)[d]	.52		13.7 (12.2 to 15.3)	−0.92 (−2.11 to 0.27)[d]	.12	0.02 (−2.00 to 2.04)[d]	.98
	Prednisolone (50 mg/d) + curcumin (400 mg/d)											
	Prednisolone placebo + curcumin placebo	NA	−0.93 (−2.37 to 0.51)[d]	.19	NA	NA		NA	−0.94 (−2.57 to 0.69)[d]	.25	NA	NA

Abbreviations: AD, atopic dermatitis; NA, not applicable.

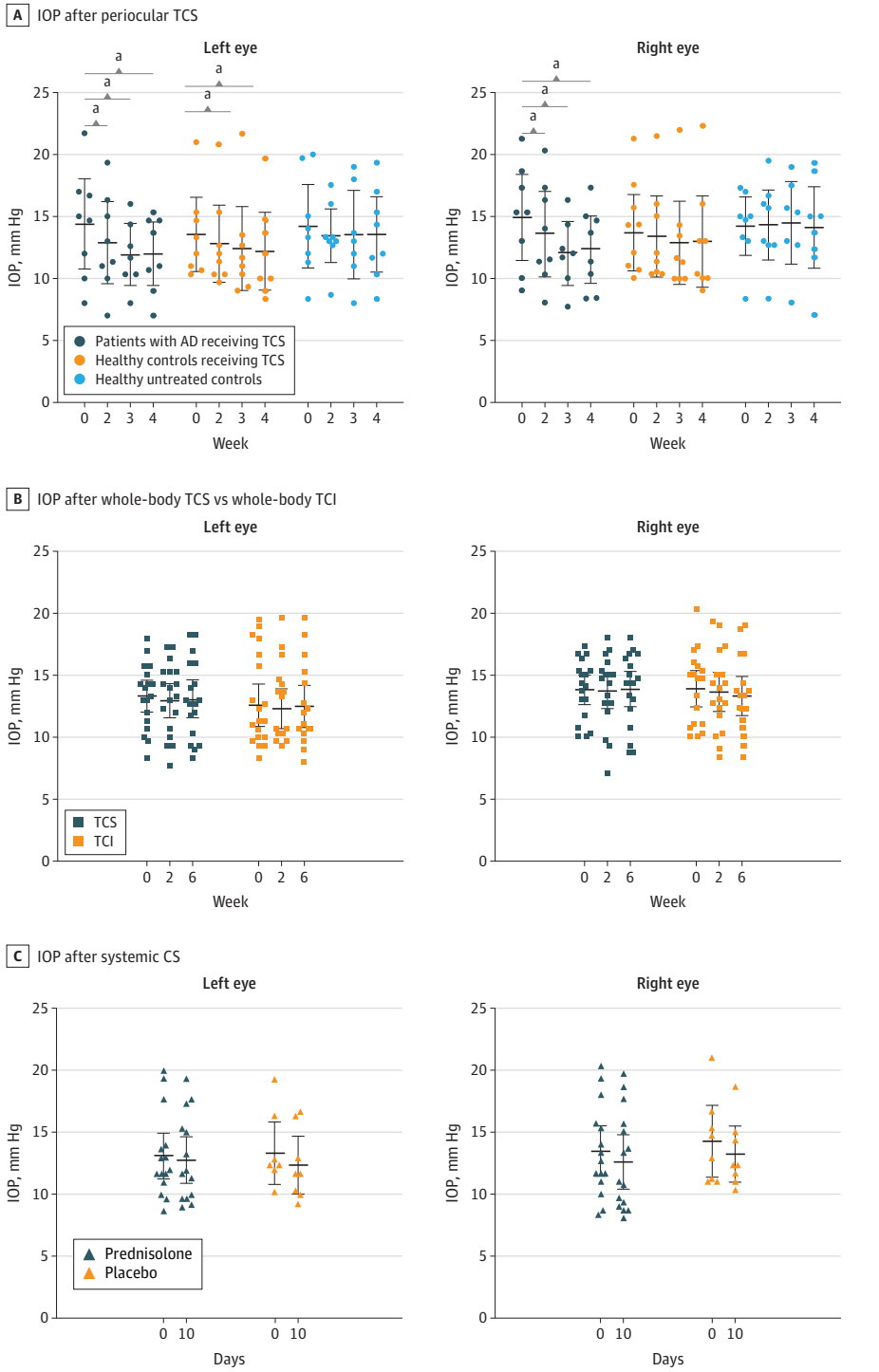
[a] Compared with week 4.

[b] Compared with week 2.

[c] Compared with week 6.

[d] Compared with day 10.

Figure. Changes in Intraocular Pressure (IOP) During Treatment With Corticosteroids in 3 Randomized Clinical Trials



A, Study 1 findings of IOP after treatment with or without periocular TCS measured at baseline, after 2, 3, and 4 weeks in 3 groups. B, Study 2 findings of IOP measured in patients with AD treated with whole-body TCS or with whole-body TCI. C, Study 3 findings of IOP after treatment with CS or placebo in male individuals with overweight or obesity. Data are presented as a mean (95% CI). AD indicates atopic dermatitis; CS, corticosteroid; TCI, whole-body topical calcineurin inhibitors; TCS, topical corticosteroid.

[a]Significant difference.

cases in which periocular TCS use was associated with increased IOP and/or glaucoma in patients with AD.[2] These patients had severe, recurrent periocular AD and had used TCS for several years. Percutaneous absorption is greater through eyelid skin and an impaired skin barrier.[13] While AD severity and TCS potency can affect absorption, the increased IOP reported is more likely due to prolonged use of TCS. Furthermore, 4% to 5% of healthy adults are steroid-responders, meaning IOP responsiveness to corticosteroids depends on genetic and risk factors, including primary open-angle glaucoma.[1] Identifying steroid-responders before initiating TCS is difficult; therefore, IOP monitoring is

advisable in patients at high risk and those receiving long-term treatment.

Systemic prednisolone did not change IOP. Increased IOP is less common with SC treatment than with TCS treatment,[1,14] suggesting lower ocular exposure. Periocular TCS may reach the eye through percutaneous absorption or by ocular contamination from cream on the hands, potentially explaining the difference between the administration routes.

Strengths and Limitations

Strengths of this study include evaluation of 3 different corticosteroid administration routes, IOP measurement by a single trained examiner and consistent timing to reduce diurnal variability. Limitations include underpowered sample size in study 1 due to patient and dermatologist reluctance to use periocular TCS, and generalizability limited to short-term treatment. Long-term clinical trials with larger sample sizes are warranted.

CONCLUSIONS

This analysis of 3 randomized clinical trials found that short-term corticosteroid treatment, whether periocular, whole-body, or systemic, did not increase IOP. While these findings support short-term safety of periocular TCS, intolerance in patients with corticosteroid responsiveness cannot be excluded.

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Author Contributions: Drs Gether and Amiri had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Amiri, Thyssen, Skov, Kolko, Gether.
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