

## Original Article

# The efficacy of tobramycin dexamethasone combined with pranoprofen in middle-aged and elderly post-cataract patients and the value of improving inflammatory factor levels

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**Abstract:** Objective: To analyze the effect of tobramycin dexamethasone combined with pranoprofen on middle-aged and elderly patients after cataract surgery. Methods: In this retrospective study, the clinical data from 108 middle-aged and elderly patients who had cataract surgery in the Second Hospital of Longyan between January 2021 and December 2023 were collected. The patients were divided into two groups based on treatment methods, a control group (n=54) that received tobramycin dexamethasone treatment, and an observation group (n=54) that treated with additional pranoprofen. The treatment effects in the two groups were compared. Results: Significant differences were observed between the groups at 1 day, 1 week, 3 weeks, and 5 weeks post-treatment in terms of ocular symptom scores, signs scores, and intraocular pressure levels (all  $P < 0.05$ ). The observation group demonstrated lower levels of inflammatory markers post-treatment ( $P < 0.05$ ). Additionally, at 1 week, 3 weeks and 5 weeks after treatment, significant differences were noted in anterior chamber flare value, best-corrected visual acuity (BCVA), macular center thickness, degree of corneal edema, and posterior lens capsular opacity grading scores (all  $P < 0.05$ ). The incidence of increased intraocular pressure and conjunctival congestion was 3.7% in the observation group, slightly lower than 7.41% in the control group ( $P > 0.05$ ). Conclusion: The combination of pranoprofen and tobramycin dexamethasone can improve the inflammatory reaction, ocular symptoms, anterior chamber flare value, macular center thickness, corneal oedema, and clarity of the posterior lens capsule in middle-aged and elderly cataract patients. This regimen also helps restore intraocular pressure and visual acuity of the patients, with relatively low adverse reactions, indicating an ideal clinical outcome.

**Keywords:** Tobramycin dexamethasone, pranoprofen, middle-aged and elderly, cataract, inflammatory factor

## Introduction

Cataracts are a prevalent visual disorder, particularly marked by subtle early symptoms such as mild blurred vision, which can easily lead to missed diagnosis. As the condition progresses, symptoms such as worsening blurred vision, compound strabismus, nearsightedness, and glare, potentially culminating in severe cases of complete blindness [1, 2]. In addition, the risk of cataracts is higher in the elderly population due to aging, abnormal immune function and other factors. At present, cataracts are mainly treated by surgery, which can effectively clear lens opacity and restores vision, known for its

safety and minimal invasiveness. However, despite these benefits, surgery can still lead to inflammatory responses, adversely impacting patient prognosis [3, 4].

Managing postoperative complications in middle-aged and elderly cataract patients is a critical clinical challenge. Tobramycin dexamethasone, a widely used glucocorticoid, effectively suppresses inflammatory reaction and enhances infection resistance, making it valuable for managing post-surgical inflammation in cataract patients. However, tobramycin dexamethasone can increase intraocular pressure during postoperative ocular anti-inflammatory pro-

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**Table 1.** Comparison of clinical data between the two groups [n (%), ( $\bar{x}\pm s$ )]

	n	Gender		Age (year)	Course of disease (day)	Affected eye	
		Male	Female			Left (n)	Right (n)
Observation	54	29	25	58.78±6.33	5.36±0.87	21	33
Control	54	30	24	58.20±6.42	5.40±0.80	22	32
$\chi^2/t$		0.038		0.473	0.249	0.039	
P		0.847		0.637	0.804	0.844	

cess, leading to inflammatory reactions in the body, which affects the clinical effect. Pranopfen, a non-steroidal anti-inflammatory drug (NSAID), not only offers good anti-inflammatory effect, but also stabilizes the cell membrane and inhibits prostaglandins. When used in conjunction with glucocorticoids, pranopfen minimizes the risk of drug toxicity and enhances clinical outcomes.

In this study, we aim to analyze the combined effect of pranopfen and tobramycin dexamethasone on post-surgical recovery in middle-aged and elderly cataract patients.

### Information and methods

#### Clinical data

This study was approved by the Ethics Committee of the Second Hospital of Longyan. Sample size was calculated using PASS® version 15.0, determining that a sample of 66 would achieve a two-sided 95% confidence interval with a width of 0.050, assuming an incidence of cataract surgery in middle-aged and elderly patients of 2.89%. The clinical data from 108 middle-aged and elderly cataract patients who underwent surgery at the Second Hospital of Longyan from January 2021 to December 2023 were retrospectively analyzed. The patients were divided into two groups based on treatment methods: a control group (n=54) that was treated with tobramycin dexamethasone, and an observation group (n=54) that was treated with additional pranopfen on the basis of treatment in the control group.

Inclusion criteria: (1) Patients meeting the diagnostic criteria for cataracts as outlined in the *Cataract Grading Systems: A Review of Past and Present* [5]; (2) Patients aged over 45 years old; (3) Patients with no known allergies to the study medications, including Pranopfen; and (4) Patients who underwent surgical treatment

and developed inflammatory infections in the postoperative period. Exclusion criteria: (1) Patients with concurrent ocular diseases such as glaucoma and keratitis; (2) Patients with systemic conditions such as cardiac dysfunction, diabetes, or hypertension; (3) Patients with eyelids that could not partially or completely close; (4) Patients who received glucocorticoid treatment within the last 90 d; (5) Patients with a history of psychiatric diseases. There was no statistical difference in the baseline data between the two groups (all  $P > 0.05$ ), see **Table 1**.

#### Methods

The control group was given tobramycin dexamethasone eye drops (H20150119, S. a. AICONCOUVREUR n. V.) in the conjunctival sac at a dose of 1-2 drops, 3-4 times/d after the end of surgery.

In the observation group, pranopfen eye drops (Shandong Haisan Pharmaceuticals, H20093827) was additionally prescribed on the basis of the treatment in the control group. The dosage for pranopfen was 1-2 drops/times, administered 4 times per day.

All patients were continuously treated with anti-infection medication for 3 weeks.

#### Observation indicators

(1) Ocular symptoms and signs: The evaluation included assessments of conjunctival congestion and pain among six other aspects before the treatment, 1 d, 1 week, 3 weeks, and 5 weeks after the treatment. The assessment used a 4-grade scoring method (0-3 points), where higher scores indicate more severe symptoms. (2) Intraocular pressure (IOP): Changes in IOP were assessed at the same time points as above, using a tonometer. (3) Inflammatory factors: Before and after the treatment, venous blood was drawn from fast-

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**Table 2.** Comparison of ocular symptom and sign score between the two groups ( $\bar{x} \pm s$ , score)

	n	Before Treatment	1 Day After Treatment	1 Week After Treatment	3 Weeks After Treatment	5 Weeks After Treatment
Observation Group	54	9.14±0.77	5.86±0.62	4.50±0.59	3.20±0.51	1.11±0.16
Control Group	54	9.17±0.75	6.92±0.77	5.11±0.63	4.09±0.60	2.23±0.31
t		0.205	7.879	5.193	8.305	23.592
P		0.838	< 0.001	< 0.001	< 0.001	< 0.001

**Table 3.** Comparison of intraocular pressure between the two groups ( $\bar{x} \pm s$ , mmHg)

	n	Before Treatment	1 Day After Treatment	1 Week After Treatment	3 Weeks After Treatment	5 Weeks After Treatment
Observation Group	54	24.01±1.36	20.23±1.14	17.32±1.02	15.26±1.14	13.22±1.15
Control Group	54	24.06±1.22	21.63±1.20	19.11±1.07	17.41±1.30	15.78±1.26
t		0.201	6.216	8.898	9.138	11.028
P		0.841	< 0.001	< 0.001	< 0.001	< 0.001

ing patients to measure levels of C-reactive protein (CRP), interleukin (IL)-6, and tumor necrosis factor (TNF)-alpha using an automatic biochemical analyzer. (4) Anterior chamber flare: The anterior chamber flare was measured using KowaFC-2000 laser flare cell detector at 1 d, 1 week, 3 weeks, and 5 weeks after treatment. (5) Visual acuity: Best corrected visual acuity (BCVA) was determined using optometry before treatment, 1 d, 1 week, 3 weeks, and 5 weeks after treatment. (6) Macular center thickness: The macular center thickness was measured using the iRrus HD-OCT imager before treatment, 1 week, 3 weeks, and 5 weeks after treatment. (7) Corneal oedema: Corneal edema was assessed concurrently with the macular center thickness measurements. It was graded on a scale from 0 to 4, where higher scores represent more severe edema [6]. (8) Posterior Lens Capsule Opacity: This was evaluated at the same times as the macular center thickness and graded according to the Posterior Capsular Opacification (PCO) scoring criteria, which include grades 0 through 5, with higher scores indicating greater turbidity [7]. (9) Adverse reactions: Adverse reactions including increased intraocular pressure, secondary infection, conjunctival congestion and others were monitored throughout the treatment course.

### Statistical analysis

SPSS 22.0 software was used for data analysis. Count data [n (%)] were compared using  $\chi^2$

test or corrected  $\chi^2$  test as appropriate. Measurement data ( $\bar{x} \pm s$ ) were analyzed using the t-test. A p-value of less than 0.05 was considered statistically significant.

### Results

#### *Comparison of ocular symptoms and signs between the two groups*

Before treatment, there was no significant differences in the scores of ocular symptoms and signs between the two groups ( $P > 0.05$ ). However, at 1 d, 1 week, 3 weeks and 5 weeks after treatment, patients in the observation group exhibited lower scores, indicating fewer symptoms and signs ( $P < 0.05$ ), see **Table 2**.

#### *Comparison of intraocular pressure changes between the two groups*

Prior to treatment, there were no significant differences in intraocular pressure (IOP) between the two groups. Post-treatment, significantly lower levels were noticed in the observation group at all subsequent time points (all  $P < 0.05$ ), see **Table 3**.

#### *Comparison of inflammatory factors between the two groups*

Before treatment, there was no significant difference in the inflammatory markers (CRP, IL-6, TNF- $\alpha$ ) between the two groups (all  $P > 0.05$ ). After treatment, compared with the control

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**Table 4.** Comparison of inflammatory marker levels between the two groups ( $\bar{x} \pm s$ )

	n	CRP (mg/L)		IL-6 (ng/L)		TNF- $\alpha$ (ng/ml)	
		Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
Observation	54	22.14 $\pm$ 2.37	8.95 $\pm$ 0.88	130.25 $\pm$ 10.11	85.67 $\pm$ 4.41	3.71 $\pm$ 0.62	1.12 $\pm$ 0.23
Control	54	22.50 $\pm$ 2.44	10.78 $\pm$ 0.95	130.78 $\pm$ 10.34	91.39 $\pm$ 4.20	3.78 $\pm$ 0.59	1.61 $\pm$ 0.30
t		0.778	10.385	0.269	6.902	0.601	9.525
P		0.438	< 0.001	0.788	< 0.001	0.549	< 0.001

**Table 5.** Comparison of anterior chamber flare values between the two groups ( $\bar{x} \pm s$ , p/msec)

	n	1 Day After Treatment	1 Week After Treatment	3 Weeks After Treatment	5 Weeks After Treatment
Observation Group	54	12.25 $\pm$ 1.22	8.23 $\pm$ 0.66	6.98 $\pm$ 0.65	6.20 $\pm$ 0.61
Control Group	54	12.36 $\pm$ 1.30	9.76 $\pm$ 0.75	8.55 $\pm$ 0.77	7.79 $\pm$ 0.50
t		0.453	11.254	11.449	14.814
P		0.651	< 0.001	< 0.001	< 0.001

**Table 6.** Comparison of visual acuity between the two groups ( $\bar{x} \pm s$ )

	n	BCVA				
		Before Treatment	After 1 Day	After 1 Week	After 3 Weeks	After 5 Weeks
Observation Group	54	0.15 $\pm$ 0.03	0.16 $\pm$ 0.04	0.59 $\pm$ 0.08	0.72 $\pm$ 0.09	0.83 $\pm$ 0.10
Control Group	54	0.16 $\pm$ 0.04	0.17 $\pm$ 0.05	0.50 $\pm$ 0.07	0.60 $\pm$ 0.10	0.71 $\pm$ 0.09
t		1.470	1.148	6.222	6.554	6.554
P		0.145	0.254	< 0.001	< 0.001	< 0.001

BCVA: best corrected visual acuity.

group, the observation group showed significantly lower levels of CRP, IL-6, and TNF- $\alpha$  (all  $P < 0.05$ ), as shown in **Table 4**.

### Comparison of anterior chamber flare between the two groups

Comparison of anterior chamber flare showed that except for the initial assessment at 1 d after treatment, the anterior chamber flare values were significantly lower in the observation group compared to the control group at 1 week, 3 weeks and 5 weeks after treatment (all  $P < 0.05$ ), see **Table 5**.

### Comparison of best corrected visual acuity (BCVA) between the two groups

Before treatment and 1 d after treatment, there was no significant difference in BCVA between the two groups ( $P > 0.05$ ). However, at 1 week, 3 weeks and 5 weeks after treatment, the BCVA in the observation group was relatively higher

( $P < 0.05$ ), indicating better visual outcomes, as shown in **Table 6**.

### Comparison of macular center thickness between the two groups

Initially, the difference in macular center thickness between the two groups was not significant ( $P > 0.05$ ). However, at 1, 3 and 5 weeks after treatment, the macular center thickness in the observation was significantly thinner than the control group ( $P < 0.05$ ), as shown in **Table 7**.

### Comparison of corneal oedema degree and posterior capsular opacification (PCO) between the two groups

Before treatment, there was no difference in the comparison of corneal oedema degree and PCO grading scores of all patients selected ( $P > 0.05$ ). Nevertheless, the corneal oedema degree and PCO of the observation group were

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**Table 7.** Comparison of macular center thickness between the two groups ( $\bar{x} \pm s$ ,  $\mu\text{m}$ )

	n	Macular center thickness			
		Before Treatment	1 Week After Treatment	3 Weeks After Treatment	5 Weeks After Treatment
Observation Group	54	176.52±10.11	166.55±10.23	156.33±10.29	142.25±9.78
Control Group	54	176.36±10.25	171.25±10.42	161.36±10.22	149.66±9.40
t		0.082	2.365	2.549	4.014
P		0.935	0.020	0.012	< 0.001

**Table 8.** Comparison of corneal oedema and posterior capsular opacification (PCO) between the two groups ( $\bar{x} \pm s$ , points)

Group	Cases	Degree of corneal oedema				PCO grading scores			
		Before Treatment	1 Week After Treatment	3 Weeks After Treatment	5 Weeks After Treatment	Before Treatment	1 Week After Treatment	3 Weeks After Treatment	5 Weeks After Treatment
Observation	54	2.46±0.36	1.72±0.25	1.55±0.24	1.21±0.22	2.98±0.32	2.46±0.29	2.11±0.32	1.52±0.23
Control	54	2.43±0.37	2.07±0.30	1.77±0.29	1.49±0.25	2.97±0.36	2.77±0.30	2.49±0.31	1.79±0.27
t		t-value	6.586	4.295	6.179	t-value	5.460	6.268	5.594
P		p-value	0.670	< 0.001	< 0.001	p-value	0.879	< 0.001	< 0.001

**Table 9.** Comparison of incidence of adverse reactions between the two groups [n (%)]

	n	Increased intraocular pressure	Secondary infection	Conjunctival congestion	Total incidence rate
Observation group	54	1 (1.85)	0 (0.00)	1 (1.85)	2 (3.70)
Control group	54	2 (3.70)	0 (0.00)	2 (3.70)	4 (7.41)
Correction $\chi^2$					0.176
P					0.674

significantly lower than the control group at 1, 3 and 5 weeks after treatment ( $P < 0.05$ ), as shown in **Table 8**.

### Comparison of the occurrence of adverse reactions in the two groups

There were no significant differences in the incidence of adverse reactions between the two groups (3.70% in the observation group vs 7.41% in the control group) ( $P > 0.05$ ), see **Table 9**.

### Discussion

The development of cataracts is closely linked to aging. As age increases, body functions begin to decline, including lens metabolism, which can become abnormal and lead to lens opacity, thereby triggering cataracts. In addition, factors such as ultraviolet radiation expo-

sure, underlying diseases like diabetes and hypertension, and long-term use of glucocorticosteroids or ethambutol can also increase the risk of developing cataracts. Currently, cataracts in the middle-aged and elderly are mainly controlled by surgery, such as ultrasonic emulsification cataract aspiration and artificial lens implan-

tation. The combination of the two approaches is often used in clinical practice, with less trauma and faster recovery speed. Post-surgical outcomes typically show a significant improvement in patients' visual acuity, enhancing their eyesight and thus substantially improving their quality of life. Despite these benefits, cataract surgery can still inflict some damage to the eyeball, potentially increasing the risk of inflammatory reactions. In addition, intraoperative residual lens and cortical debris during surgery may also trigger inflammatory reactions, affecting the prognosis of the patient. Therefore, these complications necessitate careful and effective management to optimize recovery and outcomes.

Tobramycin dexamethasone is a compound, primarily comprising the active ingredients dexamethasone and tobramycin, which deliver

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anti-inflammatory, anti-edema, and anti-allergic effects. Tobramycin is a widely used broad-spectrum antibiotic that can inhibit and kill a variety of bacteria, including Gram-positive and negative bacteria. Its mechanism of action involves disrupting bacterial protein synthesis, compromising the integrity of the bacterial cell wall and membrane, thereby exerting a sterilizing and anti-inflammatory impact. Dexamethasone, a type of glucocorticoid, is utilized in eye drops to relieve ocular inflammation and mitigate the symptoms of redness, swelling and pain caused by inflammation [8, 9]. In addition, dexamethasone can block the formation of inflammatory mediators, inhibit the activation of inflammatory cells, and play a protective role on the ocular surface. Therefore, tobramycin dexamethasone can be used for anti-infection treatment after cataract surgery in middle-aged and elderly people. However, clinical observations indicate that tobramycin dexamethasone may somewhat impair wound healing, potentially affecting its overall clinical efficacy.

This study found significantly lower scores of ocular symptoms and signs in the observation group at 1 day, 1 week, 3 weeks, and 5 weeks post-treatment, suggesting that tobramycin dexamethasone combined with pranoprofen can accelerate the speed of postoperative recovery in middle-aged and elderly patients after cataract surgery. Pranoprofen, by inhibiting the activity of cyclooxygenase-2, blocks the formation of inflammatory mediators, and alleviates symptoms such as ocular pain, redness and swelling caused by inflammatory reactions [10, 11]. Pranoprofen can also reduce the production of IL-1 to achieve an anti-inflammatory effect. CRP, as an acute-phase protein, activates complement system and enhances phagocytosis in response to inflammation. IL-6 is a pro-inflammatory factor, with elevated levels suggesting ongoing inflammation. TNF- $\alpha$  is another critical indicator of inflammation; its high level in the serum points to potential inflammatory and immune reactions within the body. In this study, significantly lower levels of CRP, IL-6, and TNF- $\alpha$ , were observed in patients receiving combined treatment, indicating that this drug combination is more effective in mitigating the inflammatory state following cataract surgery in middle-aged and elderly patients after cataract surgery. Tobramycin dexametha-

sone, known for its potent anti-inflammatory properties, also stimulates and enhances the activity of sensitive microorganisms [12, 13]. Pranoprofen, through its interaction with prostaglandins, complements the effects of tobramycin dexamethasone, resulting in a synergistic enhancement of the anti-inflammatory response.

The recovery of eye function after cataract surgery typically requires a period during which patients may experience elevated intraocular pressure, a generally normal phenomenon post-surgery. If an inflammatory reaction occurs, it can cause trabecular meshwork oedema, temporarily resulting intraocular pressure. Effective anti-inflammatory treatment is thus crucial for managing this condition. In this study, intraocular pressure was significantly lower in the observation group than that in the control group at various time points after treatment, indicating that the combination of tobramycin dexamethasone and pranoprofen can better improve the intraocular pressure of middle-aged and elderly cataract patients after surgery. Tobramycin dexamethasone eye drops serve as an anti-inflammatory agent, regulating the body's response to sensitive microbial activity and mitigating the negative impact of inflammation on postoperative intraocular pressure. This facilitates a quicker return to normal eye function. Pranoprofen can promote the dilation of arteries, and enhance the permeability of the patient's blood vessels, resisting the release of bradykinin. Its combination with tobramycin dexamethasone reduces the level of intraocular pressure in patients with cataract after surgery [14, 15]. In addition, postoperative inflammation in middle-aged and elderly cataract patients after surgery can damage the blood-aqueous barrier, allowing proteins to enter the aqueous fluid. This influx of proteins can cause anterior chamber flare.

This study found that, except for the first day after treatment, BCVA was significantly better while anterior chamber flare value was significantly lower in patients of the observation group at 1, 3, and 5 weeks after treatment, underscoring the superior efficacy of the combination treatment in enhancing visual outcomes and reducing anterior chamber flare. Pranoprofen, through its modulation of prosta-

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glandins, enhances the vascular permeability and arterial dilation while reducing bradykinin levels. This pharmacodynamic profile not only lays the groundwork for its anti-inflammatory effects but also avoids common glucocorticoid drawbacks such as increased intraocular pressure and delayed wound healing, consequently accelerating postoperative recovery [16, 17]. In addition, the longer half-life of tobramycin dexamethasone, when used in conjunction with pranoprofen, leverages the distinct anti-inflammatory properties of both drugs. This coordinated approach helps patients recover normal eye function more rapidly, thereby improving both visual acuity and anterior chamber flare values [18, 19].

For middle-aged and elderly cataract patients, ultrasonic emulsification and other surgical procedures are commonly used to treat cataracts. While these methods have proven effective, they can still compromise the cornea, triggering inflammatory responses that lead to corneal edema and potentially affect the patient's prognosis [20]. This study showed significantly lower corneal oedema degree at post-operative 1 week, 3 weeks and 5 weeks in the observation group. Administered within 30 minutes, Pranoprofen eye drops achieve high concentrations in the corneal and conjunctival tissues, where they non-selectively inhibit cyclooxygenase and block the production of inflammatory mediators. This action significantly mitigates ocular inflammatory symptoms and helps alleviate corneal edema resulting from surgical interventions [21]. In addition, Tobramycin Dexamethasone can also block the transformation of arachidonic acid to inflammatory factors. When combined with Pranoprofen, it enhances the therapeutic response, leading to improved management of corneal edema.

During cataract surgery, the surgical manipulation can inadvertently damage the pupil and induce macular phenomena, which typically resolve independently. However, if anti-inflammatory treatment is not administered after the operation, an inflammatory reaction can exacerbate the production of macular edema. In addition, post-surgical inflammation can impair corneal recovery and precipitate turbidity in the posterior lens capsule, complicating patient recovery. The data of this study showed that at post-operative 1 week, 3 weeks and 5 weeks,

the observation group reported significantly lower scores for macular edema and posterior lens capsule turbidity. Tobramycin dexamethasone reduces the risk of proliferative vitreoretinopathy and inhibits the proliferation and secretion of retinal pigment epithelial cells, as well as block the production of lens PCO. Pranoprofen, on the other hand, reduces damage to ocular tissues and decreases the adverse effects of both surgery and disease. When combined with tobramycin dexamethasone, it further improves the patient's PCO status. The synergistic effect of these drugs not only enhances the anti-inflammatory response but also effectively reduces macular edema. Besides, there was no statistical difference in the incidence of adverse reactions between the two groups, underscoring the high safety of the combination regimen of tobramycin dexamethasone and pranoprofen.

### Conclusion

Tobramycin dexamethasone combined with pranoprofen can improve the inflammatory reaction of middle-aged and elderly patients after cataract surgery, promote the recovery of intraocular pressure and visual acuity, and improve the thickness of the macular center, reduce corneal oedema and mitigate posterior lens capsule opacity, with reasonable safety. Thus, the regimen is worthy of promotion in the clinical practice.

However, there are limitations in this study. Firstly, the sample size was relatively small, and thus the representativeness is relatively low. Secondly, this study was conducted exclusively in one geographic region, limiting its applicability to a broader demographic. Patients from different regions might exhibit variations in response due to cultural, geographic, and individual factors, which could influence the study's conclusions. Therefore, further in-depth research involving a larger, more diverse population is necessary to substantiate these results and enhance their scientific validity.

### Disclosure of conflict of interest

None.

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