Prospective Multicenter Trial of a Compounded Fixed Combination of Timolol Maleate 0.5%, Brimonidine Tartrate 0.2%, Dorzolamide Hydrochloride 2%, Latanoprost 0.005%, for Glaucoma

Nathan M. Radcliffe, MD
Lauren Seo, BA
Damien F. Goldberg, MD

Method

- This was a Prospective, Randomized Multi-center, Observer Masked Investigation of Parallel-Group with primary open-angle glaucoma. Inclusion criterial required patients to be currently taking at least 3 IOP lowering medications
- Study Design: Randomized 1:1, investigator masked, prospective, multi-center study of 53 subjects with POAG

Combination Drop Group OMNI

1. Timolol maleate 0.5%, brimonidine tartrate 0.2%, dorzolamide hydrochloride 2%, with BAK 0.01% qAM
2. Timolol maleate 0.5%, brimonidine tartrate 0.2%, dorzolamide hydrochloride 2%, latanoprost 0.005%, with BAK 0.001% qhs

Multiple Drops Group

- Continue current multiple drop therapy of 3 medications (control)

- Subjects were seen for evaluation at Baseline and on Days 7±2, 30±7, 60±7, and 90±7 following the initial visit and randomization arm was masked

Method

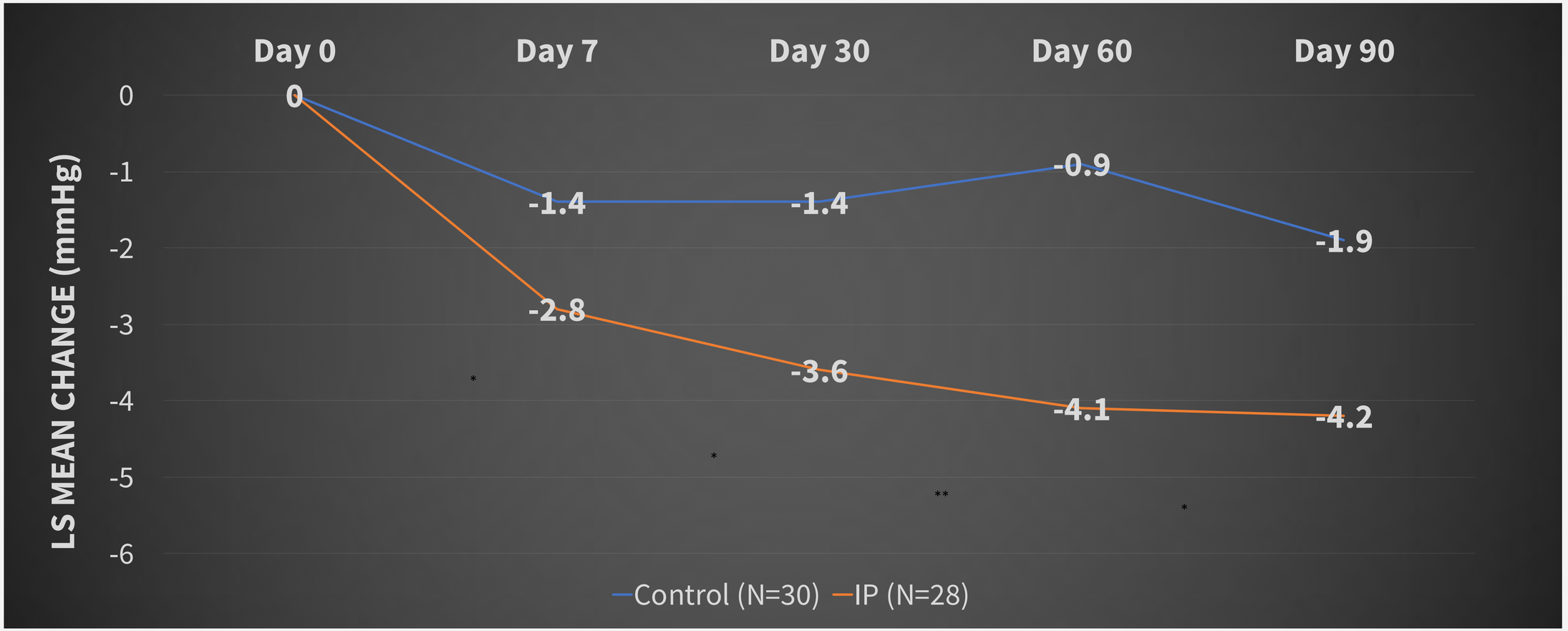
- The primary outcome measurement was IOP change, and secondary measurements included corneal staining, patient-reported symptoms, and visual acuity
- Study eye was defined as the eye with the highest morning IOP score at the screening visit (baseline) and was the primary eye used for analyses. Patients without baseline or any post baseline IOP data were excluded from analyses
- Primary Outcome: Non-inferiority as assessed by upper bound of 2-sided 95% confidence interval for the between-group difference in mean change from baseline at all time point
- Analysis of covariance, ANCOVA, was used to analyze continuous measures, with fixed effects for treatment and investigative site, and baseline as a continuous covariate

Morning IOP Change from Baseline

		Control	IP	IP minus Control	P-value*
Day 7	N LS Mean (SE) 95% CI LS Mean (95% CI)	30 -1.4 (0.55) (-2.5, -0.3)	28 -2.8 (0.53) (-3.9, -1.8)	-1.4 (-2.8, 0.0)	0.049
Day 30	N LS Mean (SE) 95% CI LS Mean (95% CI)	29 -1.4 (0.62) (-2.7, -0.2)	28 -3.6 (0.59) (-4.8, -2.4)	-2.1 (-3.7, -0.6)	0.009
Day 60	N LS Mean (SE) 95% CI LS Mean (95% CI)	28 -0.9 (0.57) (-2.0, 0.3)	28 -4.1 (0.52) (-5.1, -3.1)	-3.2 (-4.6, -1.8)	<0.001
Day 90	N LS Mean (SE) 95% CI LS Mean (95% CI)	26 -1.9 (0.71) (-3.4, -0.5)	28 -4.2 (0.58) (-5.4, -3.1)	-2.3 (-3.9, -0.7)	0.006

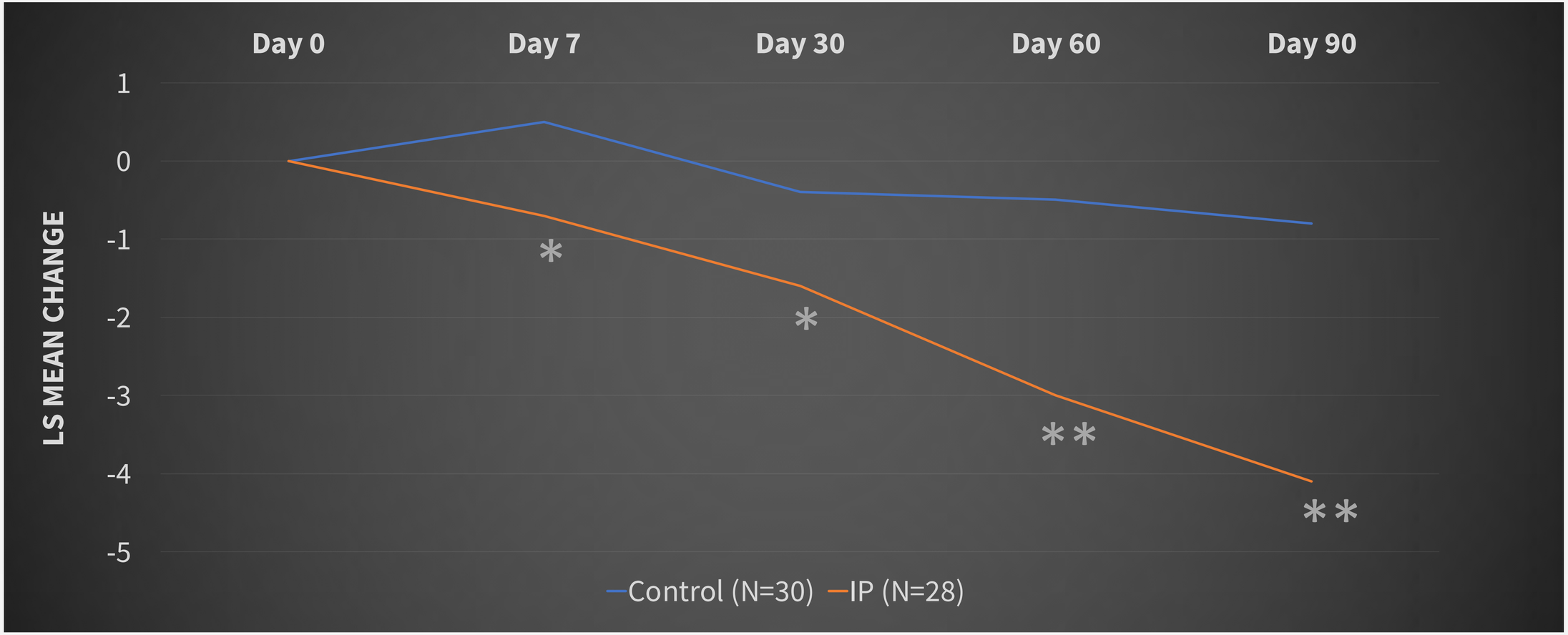
*ANCOVA

Mean (SE) Change from Baseline in IOP Over Time



* p<0.05 and **p<0.001, ANCOVA

Mean (SE) Change from Baseline in CFS Over Time



* p<0.05 and **p<0.001, ANCOVA

Conclusions

- **OMNI** for postoperative care and glaucoma is safe and therapeutically equivalent to conventional multiple medication therapy.
- **OMNI** postoperative care and glaucoma therapy helps reduce the burden of corneal toxicity, cost to the patient and compliance.
- The potential benefits of compounded medications warrant further investigation.

Timolol, Brimonidine Tartrate & Dorzolamide
0.5% / 0.2% / 2%

Timolol, Brimonidine Tartrate, Dorzolamide & Latanoprost
0.5% / 0.2% / 2% / 0.005%

Compounded medications are generally not reviewed by the FDA for safety or efficacy. OSRX does not compound copies of commercially available products. References available upon request. **View potential contraindications at: www.osrxpharmaceuticals.com/osrx-api-aecontraindication**