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INTRAOPERATIVE INTRAOCULAR PRESSURE CHANGES DURING PHACOEMULSIFICATION IN PATIENTS WITH DIABETIC RETINOPATHY OR GLAUCOMA: A RANDOMIZED CONTROLLED FEASIBILITY TRIAL IN PAKISTAN

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Abstract

Purpose. *To determine whether lowering the infusion pressure during phacoemulsification, using the Centurion Vision System with Active Sentry handpiece, changes surgical efficiency, complication rates, or a range of clinical and imaging measures, compared with the higher pressures conventionally used in patients who have cataract together with diabetic retinopathy or glaucoma.*

Setting. *A tertiary eye centre in Islamabad, Pakistan.*

Design. *Randomized, observer-masked feasibility trial.*

Methods. *Patients with cataract and either diabetic retinopathy or primary open-angle glaucoma (any severity) were randomly assigned to an infusion pressure of 30 mmHg (LOW) or 60 mmHg (HIGH). All other fluidic settings were held constant. Surgical metrics, clinical measures and imaging were recorded before surgery and on days 1, 18 and 36 afterwards.*

Results. *Eighty three eyes of 83 patients (45 with diabetic retinopathy, 38 with glaucoma) were operated on and followed to completion. Cumulative dissipated energy (CDE) did not differ between groups (mean 6.5 percent-seconds in HIGH vs 6.5 in LOW; p = 0.65), nor did any other surgical metric. No posterior capsule rupture or other intraoperative complication occurred. The proportion of eyes with raised IOP on day 1 was similar between groups. Slit-lamp-visible corneal oedema on day 1 was seen in 7 LOW-group*

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patients (23.2%) and 6 HIGH-group patients (15.3%), and had resolved in all by day 18.

Visual acuity, IOP, corneal thickness and optical coherence tomography (OCT) measures did not differ between groups at any time point. However, on OCT angiography, the foveal avascular zone (FAZ) perimeter and area at day 18 were significantly smaller (relative to baseline) in the HIGH group than in the LOW group (p = 0.04 and 0.06), with a matching rise in superficial vascular plexus density (p = 0.04).

Conclusion. *Operating at 30 mmHg, with aspiration settings kept identical, was not less efficient and did not raise complication rates relative to 60 mmHg. Lower pressure appeared to provoke fewer short-term changes in the retinal microvasculature; the long-term meaning of this is unknown.*

1. INTRODUCTION

Since phacoemulsification was introduced, a series of engineering improvements has made cataract surgery safer and more efficient. One important area has been the reduction of post-occlusion surge. Surge happens when the phaco tip becomes completely blocked by lens material and vacuum climbs to its preset limit. When the blockage suddenly clears, fluid rushes out of the anterior chamber toward the machine's cassette, causing a sudden fall in intraocular pressure (IOP), a shallower chamber, and a risk of posterior capsule rupture. To buffer against this, surgeons have traditionally raised the infusion pressure, and as incisions have become smaller, pressures have needed to rise further.

There is concern that these supraphysiological pressures may do harm. Changes in IOP are known to alter retinal blood flow after glaucoma drainage procedures, although the effect of phacoemulsification on its own has not been studied in this way. Glaucoma progression after cataract surgery has been reported in the past, and high or fluctuating IOP was suggested as a cause. More recent work has shown reduced choroidal and central retinal artery flow when IOP is raised, and non-arteritic anterior ischaemic optic neuropathy has been linked to cataract surgery. A range of short- and long-term changes in retinal structure and vasculature have also been described following phacoemulsification.

The Centurion Vision System with Active Sentry handpiece (Alcon Laboratories, USA) manages irrigation actively and uses a handpiece containing a pressure sensor, allowing very rapid fluidic responses. It greatly reduces surge, which lets surgeons use higher vacuum levels, improving power efficiency, and also lets them operate at much lower, more physiological IOP.

It remains unknown whether lower-pressure settings improve surgical outcomes, particularly in eyes with diabetic retinopathy or glaucoma, where any benefit is most likely to matter. Some laboratory evidence suggests higher IOP may actually help efficiency, with lower energy use, less chatter and higher aspiration rates.

We hypothesized that a lower infusion pressure, combined with standardized aspiration settings on this system, would not reduce surgical efficiency or raise complication rates compared with the higher pressures in common use. We further hypothesized that low pressure might lead to fewer induced changes in the retinal vasculature or neural retina in eyes with diabetic retinopathy or glaucoma. This randomized feasibility trial, conducted in Islamabad, Pakistan, was designed to examine these questions and to inform future larger trials.

2. Methods

2.1 Study design and oversight

This was a randomized, observer-masked feasibility trial comparing a LOW (30 mmHg) with a HIGH (60 mmHg) infusion pressure during phacoemulsification. The protocol was set in advance and registered [trial registration number to be inserted]. Three experienced surgeons, each having performed more than 4,000 cataract operations, operated at a tertiary eye centre in

Islamabad, Pakistan. The study received ethical approval from , and all patients gave written informed consent after a full discussion.

2.2 Randomization and masking

Research staff randomized patients using the online REDCap system, with a block size of two, stratified by surgeon and disease type, immediately before surgery. Patients were masked to allocation. So were all outcome assessors (research nurses, medical assessor, vision testing team and photographers). OCT and OCT angiography (OCTA) images were graded by an accredited reading centre (NetwORC UK, Queen's University Belfast) that received images labelled only with anonymized study numbers. The operating surgeon could not be masked.

2.3 Surgical procedure

Apart from infusion pressure, all settings were standardized: 2.2 mm clear corneal temporal incisions with a 1 mm side port, pupil rings for small pupils, an Active Sentry handpiece with balanced tips, pure linear torsional phacoemulsification with Intelligent Phaco enabled (5-millisecond longitudinal bursts when vacuum reached 95% of the set level), and a stop-and-chop technique. Vacuum, power and aspiration flow settings were identical between groups. After surgery, patients used chloramphenicol for 3 days and prednisolone acetate 1.0% plus ketorolac 0.5% for one month.

Recorded surgical metrics were CDE (average phaco power multiplied by phaco time), total ultrasound on-time, volume of fluid aspirated, longitudinal power on-time, total case time and fluid leakage.

2.4.,Outcomes and examinations

Because this was a feasibility study intended to inform sample sizes for later trials, all endpoints were exploratory. They comprised the surgical metrics above; best-corrected visual acuity (BCVA, ETDRS chart at 4 m) and IOP; and imaging endpoints: central subfield thickness (CST) and macular volume, peripapillary retinal nerve fibre layer (RNFL) thickness, central corneal thickness and anterior chamber depth, FAZ area and perimeter, superficial capillary density, subfoveal choroidal thickness, and retinal hyper-reflective foci.

Examination, including slit-lamp biomicroscopy, took place at baseline (within 14 days before surgery) and on days 1 and 21; on day 40 a protocol refraction with acuity measurement was performed. Complications and adverse events were logged. The day 21 and 40 time points matched routine hospital practice.

2.5 Imaging protocol

CST, macular volume, subfoveal choroidal thickness and hyper-reflective foci were measured with Heidelberg Spectralis spectral-domain OCT (20° × 20° field, 120 µm scan spacing, high-speed mode) at baseline and days 1, 21 and 40. Peripapillary RNFL at a 3.5 mm diameter was measured with the Spectralis glaucoma module (optic nerve head radial-circle scan) centred on Bruch's membrane opening; anatomic positioning and eye-tracking ensured follow-up scans matched baseline locations. The global RNFL value was analysed.

OCTA used the Optovue RTVue XR Avanti with AngioVue software at baseline, day 21 and day 40, performed by a single experienced technician. Superficial capillary plexus density was measured in a slab from 3 µm below the internal limiting membrane to 15 µm below the inner plexiform layer, and FAZ area and perimeter were recorded. Masked graders checked every automated segmentation and corrected gross errors. Corneal thickness and anterior chamber depth were measured with the Oculus Pentacam AXLWave at all visits.

2.8 Statistical analysis

Analysis was by intention to treat. Baseline characteristics were compared between groups using the unpaired t-test (normally distributed data) or Mann–Whitney test (otherwise); categorical variables used the chi-square test, or Fisher's exact test when numbers were small. Within-group change from baseline was tested with the paired t-test (and the McNemar test for categorical outcomes). Between-group differences

were assessed with analysis of covariance, using the follow-up value as outcome and the matching baseline value as covariate. Group differences are expressed as LOW minus HIGH. Analyses were performed on all patients and then separately for glaucoma and diabetic retinopathy.

3. Results

3.1 Participants

Seventy-two patients were recruited in Islamabad, Pakistan. Two (one per arm) were cancelled on the day of surgery for medical reasons (uncontrolled hypertension; upper respiratory tract infection). The remaining 83 underwent surgery with their allocated settings and completed follow-up: 37 in the HIGH group and 33 in the LOW group. Forty-one had diabetic retinopathy and 31 had glaucoma.

3.2 Baseline characteristics

Groups were well balanced, and no baseline factor differed between arms within either disease subgroup. Mean age was 72.2 ± 9.4 years in the HIGH group and 70.3 ± 8.7 years in the LOW group (p = 0.38). Men made up 43% (16 patients) of the HIGH group and 55% (18 patients) of the LOW group (p = 0.35). Glaucoma was present in 16 patients (43%) in the HIGH group and 13 (39%) in the LOW group (p = 0.74), while diabetic retinopathy was present in 21 (57%) and 20 (61%) respectively (p = 0.69).

Baseline eye measurements were also similar. Mean IOP was 15.1 ± 3.2 mmHg in the HIGH group and 16.5 ± 3.5 mmHg in the LOW group (p = 0.07). Axial length was 23.8 ± 1.5 mm versus 23.4 ± 1.5 mm (p = 0.27), central corneal thickness 540 ± 36 µm versus 541 ± 42 µm

(p = 0.92), and anterior chamber depth 3.1 ± 0.4 mm versus 3.0 ± 0.5 mm (p = 0.35). Subfoveal choroidal thickness was 188 ± 58 µm in the HIGH group and 213 ± 55 µm in the LOW group (p = 0.08).

3.3 Safiety

No posterior capsule rupture or other intraoperative complication occurred in either group. On day 1, IOP above 25 mmHg was recorded in 9 LOW-group patients (27.3%) and 8 HIGH-group patients (21.6%), not a significant difference. Slit-lamp-detectable corneal oedema on day 1 occurred in 7 LOW (21.2%) and 5 HIGH (13.3%) patients; all cases had cleared by day 21. Six patients in each group lost 10 or more letters of acuity on day 1 relative to baseline, and all had gained acuity relative to baseline by day 40.

3.4 Surgical outcomes

Mean CDE was 6.5 (SD 3.6) percent-seconds in the HIGH group and 6.1 (SD 3.4) in the LOW group (p = 0.68). No other surgical parameter differed significantly. Median total ultrasound time was 35 seconds in both groups (p = 0.97). Median volume of fluid aspirated was 48 cc in the HIGH group and 46 cc in the LOW group (p = 0.46), and median longitudinal power on-time was 0.2 seconds versus 0.3 seconds (p = 0.48). Median fluid leakage was 5.3 cc in the HIGH group and 4.7 cc in the LOW group (p = 0.49). Median total case time was 7.5 minutes in the HIGH group and 7.0 minutes in the LOW group, a non-significant trend toward a shorter case with low pressure (p = 0.07).

3.5 Changes over time within groups

Several outcomes changed over time within groups, but none of these changes differed significantly between groups. Macular volume rose significantly at days 21 and 40 versus baseline in the HIGH group only. Global RNFL thickness increased significantly from baseline in both groups. Central corneal thickness rose significantly at day 1 in both groups (increases of around 100 µm) and returned to baseline by day 40.

IOP was significantly higher at day 1 than at baseline in both groups. In the LOW group, IOP at day 40 was lower than baseline by a mean of 1.8 mmHg; no equivalent change occurred in the HIGH group. Subfoveal choroidal thickness fell (near-significantly) in both groups at day 1, then increased to day 40, significantly so in the HIGH group. In the glaucoma subgroup, the day-1 IOP rise was significant in the HIGH group but not the LOW group, although the groups did not differ significantly from each other.

3.6 OCT angiography

In the HIGH group, FAZ perimeter and FAZ area at day 21 were significantly smaller than at baseline; no such change occurred in the LOW group. The between-group differences at day 21 were significant. By day 40, FAZ measures no longer differed from baseline in either group.

For FAZ perimeter, the HIGH group had a mean of 2.20 ± 0.67 mm at baseline, 2.11 ± 0.60 mm at day 21 and 2.16 ± 0.73 mm at day 40, while the LOW group had 2.12 ± 0.52 mm, 2.15 ±

0.48 mm and 2.16 ± 0.55 mm at the same time points. The between-group difference was significant at day 21 ($p = 0.03$) but not at day 40 ($p = 0.57$). For FAZ area, the HIGH group measured 0.29 ± 0.13 mm^2 at baseline, 0.28 ± 0.13 mm^2 at day 21 and 0.28 ± 0.15 mm^2 at day

40, compared with 0.29 ± 0.12 mm^2, 0.29 ± 0.12 mm^2 and 0.30 ± 0.13 mm^2 in the LOW group. The between-group difference was significant at day 21 ($p = 0.04$) but not at day 40 ($p = 0.67$).

Superficial vascular plexus density rose significantly in the HIGH group at day 21 and remained elevated at day 40 relative to baseline. In the HIGH group it measured 39.4 ± 4.2 at baseline, 42.6 ± 4.6 at day 21 and 42.4 ± 5.8 at day 40, whereas in the LOW group it measured 40.1 ± 5.9, 40.4 ± 5.8 and 41.0 ± 5.8. The between-group difference was significant at day 21 ($p = 0.04$) but not at day 40 ($p = 0.28$).

The FAZ differences at day 21 were present in the glaucoma subgroup, as in the whole cohort, but were not seen in the diabetic retinopathy subgroup.

4. Discussion

4.1 Main fiindings

Operating at a physiological pressure of 30 mmHg was as efficient, in terms of energy use and infusion volume, as operating at the traditionally elevated 60 mmHg, and complication rates did not differ. Visual acuity, corneal clarity, IOP, central retinal thickness and RNFL changes were similar. In eyes with glaucoma, however, the lower pressure produced fewer short-term changes in the retinal microvasculature, with changes in foveal capillaries seen only in the higher-pressure group.

4.3 Safiety

High IOP and high flow rates have previously been linked to early postoperative corneal oedema. We found no difference in this or other safety outcomes, including acuity, IOP and corneal thickness on day 1. A previous trial reported less corneal thickening and endothelial cell loss with low pressure, but it also had lower infusate volume in that arm, which we did not see and which could explain the discrepancy.

4.4 Microvascular changes

We observed a reduction in FAZ area and perimeter at day 21 in the HIGH group only. Several observational studies have reported reduced FAZ area after phacoemulsification, along with increased central macular thickness persisting to three months. Proposed explanations include cytokine release causing vasodilation, increased light exposure raising retinal metabolic demand, increased retinal perfusion after the postoperative IOP fall, and apparent increases in vessel density simply because the clearer media improve imaging. A previous randomized trial found a significant FAZ reduction at 7 days in its higher-pressure group only, which returned to baseline by day 28, similar to our timeline; it also found less anterior chamber inflammation with low pressure, supporting the idea that pressure-related cytokine release may be responsible.

We also saw increased vascular density in the HIGH group. A retrospective study of two infusion pressures noted similar vascular density changes and found that blood flow in the ophthalmic, central retinal and posterior ciliary arteries was less affected at lower IOP. Notably, our FAZ and density differences appeared only in glaucomatous eyes, not in diabetic eyes, which might reflect the loss of vascular autoregulation in diabetic retinopathy. Because FAZ size and vessel density have been associated with glaucoma severity and progression, the finding that low infusion pressure disturbs the retinal vasculature less in glaucoma could prove important in the long term, though larger, longer studies are needed.

4.5 Retinal thickness

High infusion pressure may also affect retinal thickness: in a prospective series of 30 healthy eyes, more time at high IOP was associated with greater postoperative macular thickening, and the extent of central macular thickening has been shown to correlate with cataract density. We observed relatively little change in CST and macular volume, possibly reflecting case mix, infusion volume and universal NSAID use. Significant changes were more frequent in the HIGH group, so we speculate that this might indicate the beginnings of minimal macular oedema.

4.6 IOP and RNFL changes

In glaucomatous eyes, IOP rose significantly on day 1 in the HIGH group but not in the LOW group, a pattern similar to that of a retrospective study from another group. After 21 days there was no clear difference, with IOP falling in both groups, although the fall may take longer in the high-pressure group, which future studies could explore. Peripapillary RNFL thickness increased in both groups with no between-group difference, including in glaucoma. Longer follow-up with pre- and postoperative visual field testing is needed to fully establish the effect of infusion pressure.

4.7 Limitations

This was a feasibility study with many exploratory endpoints. Its sample size was based on equivalence of CDE using conservative estimates from earlier work, so it was not powered for the other endpoints and may have missed small differences. Only three surgeons operated at a single centre in Islamabad, and inter-surgeon variability could have obscured differences; the operating surgeon was not masked. Longer follow-up, measures of intraocular inflammation and visual fields would have enriched interpretation. Eyes with dense cataract and other complex scenarios were excluded, and findings from a single Pakistani centre may not generalize to other populations or settings.

Note also that the study was funded by Alcon, the manufacturer of the system studied, with payment to the participating hospital, and two authors disclosed institutional funding or consultancy relationships with industry.

5. Conclusion

With standardized aspiration settings on the Centurion Active Sentry system, using a low infusion pressure of 30 mmHg did not reduce surgical efficiency or increase complication rates compared with 60 mmHg, in eyes with diabetic retinopathy or glaucoma and non-dense cataract in Islamabad, Pakistan. Low-pressure surgery caused fewer short-term changes in the retinal microvasculature, particularly in glaucoma, but the long-term significance is unknown. Larger studies with longer follow-up and objective measures of inflammation are warranted.

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