Hemostasis with Fibrin Glue in Surgery for PDR: Preliminary findings of a randomized controlled trial

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Introduction

- Vitreous surgery for proliferative diabetic retinopathy (PDR) is challenging.
- Recurrent bleeding is a notorious complication, affecting a third of the eyes.
- Our group has shown fibrin glue (FG) to be safe when used over the retina.
- Current study evaluated role of FG to attain hemostasis in surgery for PDR

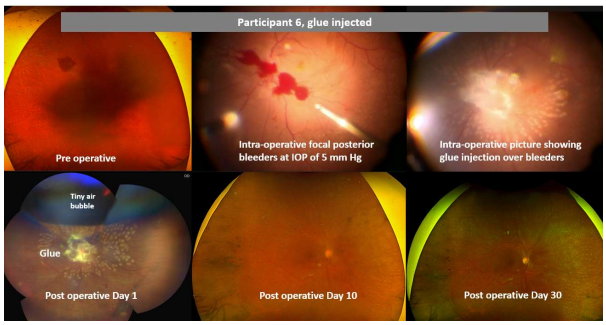
Methods

- Open label randomized controlled trial with double masking.
- Vitreous surgery-naïve eyes being operated for PDR using a single vitrectomy setup. Patients with preoperative or unintended iatrogenic retinal breaks and/or extramacular retinal detachment > 5DD were excluded.
- Procedure: Application of FG on posterior bleeders, where endo-cautery is not possible, detected at infusion pressure of 5 mm Hg at end of surgery.
- Main outcome measure: Media clarity and amount of recurrent bleed in post-operative period on day 7 and 30. Total follow up of 3 months planned.
- Preliminary descriptive analysis of first 10 participants is presented. Randomization order: (N/Y/N/N/N/Y/N/Y/Y/Y).

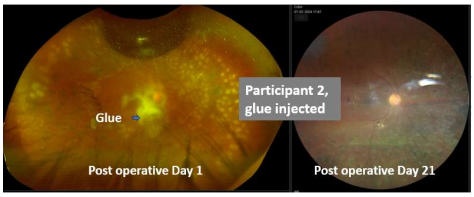
Results

- 10 participants included in current analysis.
- Mean age: 58.4 ±10.4 years for controls, 55.2 ± 9.5 yrs for cases

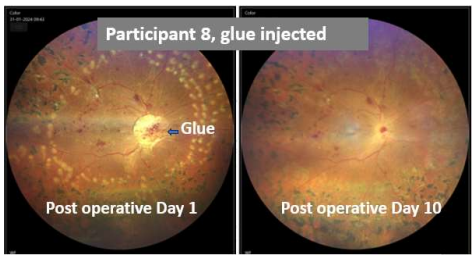
Pre-operative characteristics	Glue injected (n=5)	Controls (n=5)
Mean visual acuity (LogMAR)	1.40	1.54
Mean Media Haze	Grade 1.4	Grade 3.2
Fibrovascular proliferation > 2-disc diameters	4	4
Fibrovascular proliferation centred on pole	4	4
Frank macular detachment	2	0
Preparatory anti-VEGF	3	1
History of laser	5	5
Anti-platelets used	3	4
Mean systolic BP on day of surgery (mm Hg)	158.4	148
Mean Diastolic BP on day of surgery (mm Hg)	87.8	84.4

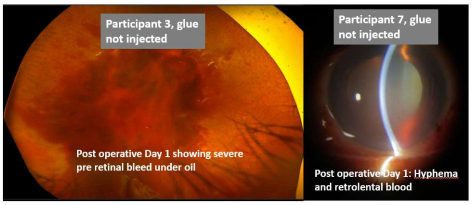


Surgical characteristics	Glue injected (n=5)	Controls (n=5)
Mean surgical time (minutes)	54	60
Surgical manoeuvres for membrane peeling		
a) Only cutter	0	2
b) Cutter with forceps	4	2
c) Cutter with forceps and scissors	0	1
d) Chandelier-based bimanual dissection	1	0
Tamponade used		
a) Fluid	4	0
b) Air	0	2
c) Gas/Oil	1	3
Mean number of bleeders identified at low IOP	1.6	1.6



Post-operative characteristics	Glue injected	Controls
1 week follow up completed	5	5
1 month follow up completed	2	3
Mean visual acuity (LogMAR) on day 1	1.39	2.28
Mean visual acuity (LogMAR) on day 7-10	1.28	1.88
Mean visual acuity (LogMAR) on day 30-45	0.38	2.28
Mean Media Haze on day 1	Grade 0.2	Grade 3
Mean Media Haze on day 7-10	Grade 0.6	Grade 3
Mean Media Haze on day 30-45	Grade 0	Grade 3.6
Post operative bleed at 1 week more than left on table and or day 1	1	4
Repeat surgery till follow up	0	1
Complications till follow up	0	0





Discussion

- Bleeding points at macula and optic nerve can not be cured with endo-cautery during surgery.
- FG seems to be efficacious and safe for handling such posterior bleeders in surgery for PDR.
- The additional step does not seem to incur significantly additional surgical time.

Conclusions

- The preliminary results of this randomized control trial are encouraging. FG must be considered for a complete and thorough utility as an adjunctive hemostasis agent during surgery for PDR.
- The 3-month results of the trial will help identify any possible long-term complications of FG over retina during such a surgery.

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References

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