

Submacular hemorrhage: A study amongst Indian eyes

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Aim: To evaluate the management outcomes amongst various treatment modalities for submacular hemorrhage (SMH) in Indian subjects. **Settings and Design:** Retrospective, single-center study. **Materials and Methods:** Patients presenting with SMH between 1999 and 2006 were included. Treatment modalities included: vitrectomy with subretinal recombinant tissue plasminogen activator (r-tPA) assisted SMH evacuation (group 1, $n = 14$); pneumatic displacement with intravitreal r-tPA and gas (group 2, $n = 25$); and pneumatic displacement with intraocular gas (group 3, $n = 7$). Favorable anatomical outcome was defined as complete displacement of SMH from fovea and favorable functional outcome was defined as a gain of >2 Snellen lines from the baseline. Kruskal–Wallis, analysis of variance (ANOVA), and Chi-square tests were used to compare the three groups, while Mann–Whitney and independent t -test were used to evaluate the influence of duration and size of SMH on outcomes. **Results:** There was no difference amongst groups in terms of favorable anatomical ($P = 0.121$) or functional outcomes ($P = 0.611$). Eyes with median duration of SMH less than 7.5 days had a significantly higher probability of achieving favorable anatomical outcome compared to eyes with SMH >14.5 days ($P = 0.042$). However, duration of SMH did not influence functional outcome ($P = 0.595$). Similarly, size of SMH did not affect anatomical ($P = 0.578$) or functional ($P = 0.381$) outcome. Median follow-up was 31.5, 6.5, and 2.5 months in the three groups, respectively. **Conclusions:** Co-existing posterior segment conditions and duration of SMH may influence the choice of treatment modality and treatment outcomes. Pneumatic displacement with r-tPA and r-tPA assisted vitrectomy appear to be favorable options for the management of SMH.

Key words: Age-related macular degeneration, choroidal neovascularization, ocular trauma, polypoidal choroidal vasculopathy, retinal macroaneurysm, submacular hemorrhage, subretinal hemorrhage, tissue plasminogen activator, vitrectomy

Submacular hemorrhage (SMH) is defined as the presence of blood in the potential space between the retinal pigment epithelium (RPE) and the neurosensory retina at the macula. It most commonly results due to choroidal neovascularization (CNV), with age-related macular degeneration (AMD) being the leading cause.^[1-3] Other ocular diseases that may lead to CNV and subsequent SMH include pathological myopia, angioid streaks, trauma, post-inflammatory sequelae, and idiopathic polypoidal choroidal vasculopathy (PCV).^[4] The natural history and the visual outcomes of SMH resulting from AMD are typically poor.^[5,6] Degeneration of the outer retina occurs rapidly because of the diffusion disturbances between photoreceptors and RPE, fibrin contraction, iron toxicity from erythrocyte degeneration, and fibrocellular scar formation.^[3,4] Early removal of SMH from the macular area is thus recommended to restore useful vision.^[1,5,6] The treatment options are varied and have evolved over the years. These include vitrectomy with manual removal of the clot,^[7,8] vitrectomy with injection of subretinal recombinant tissue plasminogen activator (r-tPA) and intraocular gas^[9-16] with/without surgical removal of the subretinal neovascular membrane,^[17] injection of intravitreal gas with^[18-21] or without

r-tPA,^[3,22] and injection of subretinal r-tPA with displacement of SMH by perfluorocarbon liquid.^[23]

Hemorrhages of 2 weeks duration or less and eyes with a good visual acuity prior to the hemorrhage are known to have a good visual prognosis.^[6] Eyes with relatively thick hemorrhages at the fovea, extending larger than three or more disc areas in greatest linear dimension, and eyes with AMD are known to be associated with poorer visual outcomes.^[5] In our series, we have tried to evaluate the functional and anatomical outcomes of different treatment modalities for SMH of various etiologies in Indian subjects.

Materials and Methods

Case records of all the patients presenting with SMH between 1999 and 2006 were reviewed. Patient evaluation included a detailed history, best corrected visual acuity (BCVA), Goldmann applanation tonometry, biomicroscopic examination of the eyes (by slit-lamp examination and indirect ophthalmoscopy), and total duration of follow-up. The size of SMH in disc diameters (DD) was determined from the fundus photographs and the etiology was ascertained, wherever possible, with fundus digital fluorescein angiography, indocyanine green angiography, and optical coherence tomography (OCT) using the macular scan protocol.

Patients were managed by any one of the following treatment modalities: vitrectomy with 0.1–0.3 ml subretinal r-tPA (10 microgram/0.1 ml) assisted removal of the SMH (group 1); pneumatic displacement with 0.2–0.3 ml of 100% C3F8 gas

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combined with 0.1 ml intravitreal r-tPA (50 microgram/0.1 ml) (group 2); and pneumatic displacement with intravitreal gas alone (0.3 ml of 100% C₃F₈ without r-tPA) (group 3). In groups 2 and 3, patients were advised to maintain strict face down position for 12–14 h a day for at least 1 week. The choice of treatment was based on several factors including the availability of r-tPA and time period when the case was managed. Follow-up examinations were performed at periodic intervals using serial fundus photography.

The primary outcome measures included change in visual and anatomical status. Gain of visual acuity by >2 Snellen lines was considered as favorable functional outcome, whereas favorable anatomical outcome was defined as complete displacement of hemorrhage from the sub-foveal location.

All the continuous data were represented by mean ± standard deviation and median with interquartile range, and *t*-test, analysis of variance (ANOVA), and Mann–Whitney *U* test were used to evaluate differences between the three treatment groups. Categorical data were represented by frequency with percentages, and they were analyzed by Chi-square and Fisher's exact test. The analysis was done by using SPSS 14.0 version. A *P* value of less than 0.05 was considered statistically significant.

Results

Forty-six eyes of 46 patients were included in the study. Thirty-one (67%) were males and 15 (33%) were females. All the three treatment groups were comparable with respect to baseline demographics such as age, preoperative BCVA, duration and size of SMH [Table 1]. In terms of etiology, there was a significant difference, with group 3 having maximum cases attributable to PCV (57%) and only one case due to AMD (14%). The other two groups had similar number of cases of SMH due to AMD, ranging between 79% in group 1 and 60% in group 2. Fig. 1 shows preoperative and postoperative fundus findings in group 1. Figs. 2 and 3 show serial photographs of eyes treated with pneumatic displacement alone. Fig. 4 shows an eye with altered SMH, with fluorescein and indocyanine green angiography revealing focal hyperfluorescence suggestive of PCV.

There was no difference amongst groups in terms of favorable anatomical (*P* = 0.121) or functional outcomes

(*P* = 0.611). The number of eyes maintaining vision better than 20/80 was less than 50% overall with no statistical difference between the groups (*P* = 0.94). Eyes with median duration of SMH less than 7.5 days had a significantly higher probability of achieving favorable anatomical outcome compared to eyes with SMH >14.5 days (*P* = 0.042). However, duration of SMH did not influence functional outcome (*P* = 0.595). Similarly, size of SMH did not affect anatomical (*P* = 0.578) or functional outcome (*P* = 0.381). Median follow-up was 31.5, 6.5, and 2.5 months in the three groups, respectively. Table 2 shows a comparison of the outcomes in the three groups.

Discussion

SMH is catastrophic sequela of several disease processes and leads to considerable visual impairment. The management options for treating SMH have undergone paradigm shifts over the past decade from large retinotomies with manual clot evacuation toward more conservative approaches of combining pneumatic displacement of the hemorrhage assisted by r-tPA. These evolving practice patterns are depicted in our series in which several of the initial cases of SMH were treated with vitrectomy with subretinal r-tPA assisted clot lysis, followed by intravitreal r-tPA assisted pneumatic displacement using an expansile gas and postoperative positioning and finally pneumatic displacement alone, over the 7-year study period.

Peyman *et al.*^[1] first reported visual outcomes of tPA assisted SMH removal in 1991. In their series, 60% patients achieved an improvement in BCVA of 2 or more lines. The results in our series were comparable with 64% of patients achieving a similar visual outcome. Kamei *et al.*^[23] have reported a favorable visual outcome in 86% of their patients. They recommended the use of intraoperative perfluorocarbon liquids (PFCL) to displace the SMH after subretinal injection of r-tPA through a smaller retinotomy, thus obviating major complications associated with a larger retinotomy. Lewis *et al.*^[21] reported good visual outcomes in 83% of their patients, with an underlying diagnosis of AMD, treated within 2 weeks of onset of SMH. It is proposed that subretinal injection of r-tPA may decrease the damage to the retina by diluting the concentration of toxins released by subretinal hemorrhage, decreasing the barrier effect of solid hemorrhage on the overlying neurosensory retina, and by

Table 1: Comparison of demographics in the three treatment groups

Category	Mean ± standard deviation/median [interquartile range]/n (%)			P value
	Vit + r-tPA + gas	Intravitreal r-tPA + gas	Only gas	
Number of eyes	14	25	7	
Age	55.57 ± 15.3	53.64 ± 15.8	53.14 ± 22.1	0.928 ⁺
Pre-op BCVA (logMAR)	1.5 ± 0.4	1.5 ± 0.5	1.7 ± 0.4	0.380 ⁺
Duration of SMH in days	8 [10]	10 [12]	8 [9]	0.866 [#]
Size of hemorrhage in DD	7.5 ± 3.4	5.6 ± 3.4	4.29 ± 1.3	0.077 ⁺
Etiology (as follows)				
AMD	11 (78.6%)	15 (60%)	1 (14.3%)	0.055 [*]
Trauma	2 (14.3%)	7 (28%)	1 (14.3%)	0.772 [*]
High myopia	1 (7.1%)	1 (4%)	0 (0%)	0.845 [*]
PCV	0 (0%)	1 (4%)	4 (57.1%)	<0.0001 [*]
RAM	0 (0%)	1 (4%)	1 (14.3%)	0.845 [*]

vit: vitrectomy, BCVA: Best corrected visual acuity, DD: Disc diameter, PCV: Polypoidal choroidal vasculopathy, RAM: Retinal artery macroaneurysm, *P* value is by +ANOVA, #Kruskal–Wallis, and *Chi-square test

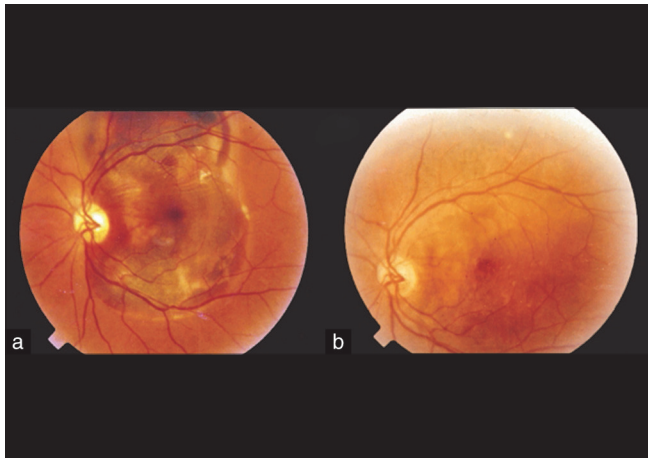


Figure 1: (a, b) Show preoperative and postoperative fundus findings, respectively, in an eye with SMH due to trauma that underwent vitrectomy with subretinal rt-PA and C3F8 gas

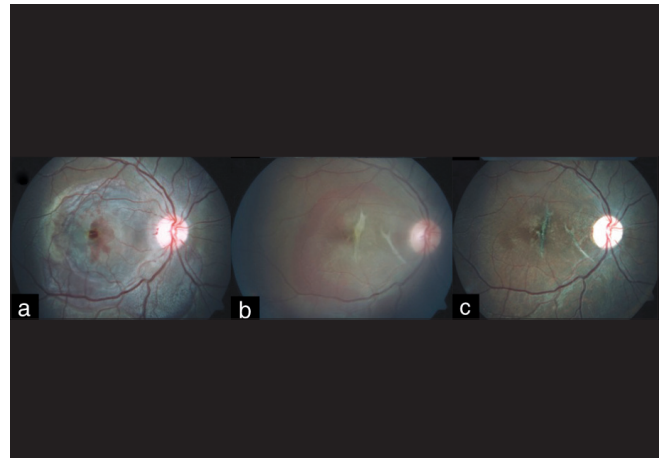


Figure 2: (a) Shows preoperative fundus in an eye with SMH due to trauma (b) shows pneumatic displacement of SMH at 1 week postoperative period (c) shows resolved SMH with scarring due to traumatic choroidal rupture

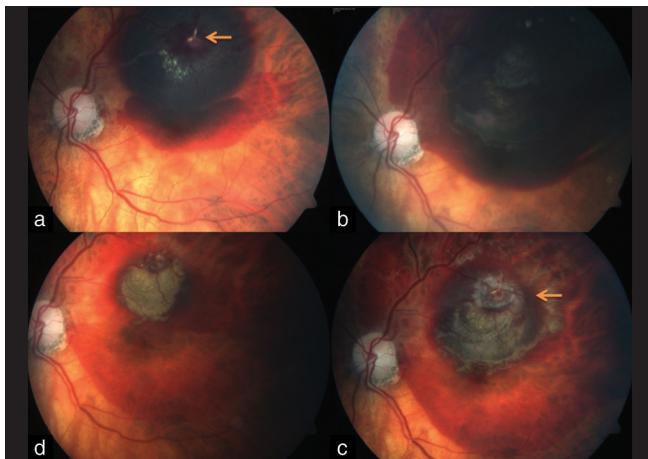


Figure 3: (a–d) Show SMH due to retinal artery macroaneurysm treated with laser photocoagulation to the macroaneurysm followed by pneumatic displacement of the SMH: (a) Preoperative (b) 2 days postoperative (c) 5 days postoperative, and (d) 2 weeks postoperative fundus picture

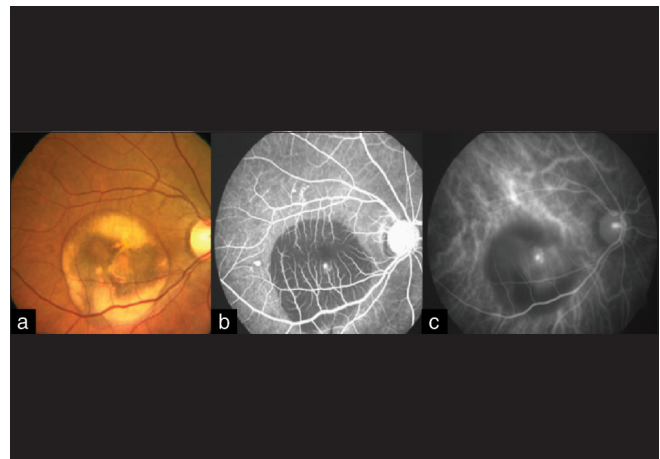


Figure 4: (a) Shows color fundus photograph of the right eye with altered submacular hemorrhage (b) fluorescein angiogram highlights a focal hyperfluorescent spot inferior to fovea (c) indocyanine green angiogram confirms the hyperfluorescence at the choroidal level, suggestive of polypoidal choroidal vasculopathy

Table 2: Comparison of outcomes in the three treatment groups

Category	Mean ± standard deviation/median [interquartile range]/n (%)			P value
	Vit + r-tPA + gas	Intravitreal r-tPA + gas	Only gas	
Number of eyes	14	25	7	
Follow-up in months	31.5 [43]	6.5 [23]	2.5 [22]	0.008*
No intraop complication	9 (64.3%)	19 (76%)	7 (100%)	0.029*
Iatrogenic retinal break	4 (28.6%)	6 (24%)	0 (0%)	0.527*
Incomplete clot lysis	1 (7.1%)	0 (0%)	0 (0%)	<0.0001*
Final BCVA (logMAR)	0.94 ± 0.52	0.94 ± 0.51	1.35 ± 0.72	0.237*
Final BCVA >20/80	5 (35.7%)	9 (36%)	3 (42.9%)	0.94^
Favorable anatomical outcome	13 (92.9%)	21 (84%)	4 (57.1%)	0.121^
Favorable functional outcome	9 (64.3%)	13 (52%)	3 (42.9%)	0.611^
Postoperative complications	Cataract (4), secondary glaucoma (2), RD (3)	Vitreous hemorrhage (1), RD (1)	Vitreous hemorrhage (1)	

P value is by *ANOVA, #Kruskal–Wallis, *Chi-square test, ^Fisher's exact test

lysing inter-photoreceptor fibrin.^[6,18] Ibanez *et al.*^[24] did not observe any significant difference in the visual outcomes in patients undergoing mechanical clot extraction to those in patients undergoing r-tPA assisted drainage of thick SMH. The authors also concluded that SMH secondary to AMD had a poor visual prognosis, with or without surgical drainage. The addition of tPA assisted clot lysis did not appear to significantly improve the visual outcome following surgery in their series. The anatomical results in our study were significantly better in terms of complete resolution of SMH, seen in nearly 93% of our patients undergoing this procedure. Also, we found visual improvement (greater than 2 line improvement in BCVA) to be more in non-AMD patients (100%) as compared to AMD patients (64%). Similar results have been documented in the other studies.^[1,5,11,19]

Median follow-up in our series in eyes undergoing vitrectomy with subretinal r-tPA was 31.5 months (range 3–113 months), which was longer as compared to other major studies. Postoperative complications seen in this subgroup were retinal detachment (RD) with proliferative vitreoretinopathy (PVR), secondary cataract, and glaucoma. Other reported complications are epiretinal membrane formation and a recurrence of the SMH.^[7,8] This technique decreases the retinal manipulation and iatrogenic damage caused due to manual clot extraction through a large retinotomy while facilitating the direct evacuation of subretinal hemorrhage through a small retinal opening. Tissue plasminogen activator liquefies subretinal clots and hastens resorption of pre-existing subretinal hemorrhage, thereby facilitating drainage.

The minimally invasive technique of displacing SMH with a combination of intravitreal r-tPA and intraocular gas was first described by Wilson Herriot.^[18] This technique utilizes the enzymatic clot lysing properties of r-tPA and the mechanical effect of gas bubble to displace the liquefied blood. Diffusion of intravitreal r-tPA into the subretinal space is controversial; studies in rabbits show that molecules as large as r-tPA (70 kDa) do not penetrate the internal limiting membrane (ILM), whereas others suggest that mechanically induced microlesions of the retina and focal breaks in ILM facilitate diffusion of r-tPA in both directions.^[25] The largest retrospective case series by Hattenbach *et al.*^[20] reported complete displacement of blood from the fovea in 81% of the eyes and final visual improvement by 2 lines in 30% with 50 mg/0.1 ml of r-tPA and 0.5 ml of 100% SF₆. The results obtained by us are similar; there was complete disappearance of the SMH in 84% eyes after a median follow-up of 6.5 months (range 1–73 months). Also, a favorable functional outcome was noted with 52% of eyes. The most common complication reported in literature for this technique is breakthrough vitreous hemorrhage reported in up to 20% of published cases, more so in eyes with retinal artery macroaneurysm.^[15] Only one eye (4%) in our series undergoing this procedure developed vitreous hemorrhage. We found intravitreal injection of r-tPA and gas, followed by prone positioning to be a relatively safe and effective technique in displacement of SMH.

Ohji *et al.* were the first to report success with intravitreal gas alone in the treatment of SMH.^[3] Five eyes treated by this procedure showed visual improvement (four eyes had ARMD and one eye had retinal artery macroaneurysm). Other studies of pneumatic displacement for large, thick SMH in ARMD have failed to demonstrate such promising visual outcomes.

The authors believe that the etiology plays a major role in this group of patients, but the duration of SMH and the size of hemorrhage were not significant risk factors for their group of patients. In our study, a favorable functional and anatomical outcome was seen in 43% and 57% of the eyes, respectively, treated by this procedure. A small, yet dense SMH may be resistant to pneumatic displacement contributing to relatively poor functional and anatomical outcomes. These results may prompt treating physicians to consider combining pneumatic displacement with anti-vascular endothelial growth factor (anti-VEGF) agents in eyes with PCV in the hope of obtaining better outcomes. This was demonstrated by Chawla *et al.* in four cases where they injected intravitreal bevacizumab, 0.05 ml, along with 0.5 ml of SF₆ through the pars plana into the vitreous cavity for SMH secondary to choroidal neovascularisation (CNV).^[26]

The final structural and functional outcome following treatment presumably depends upon the underlying etiology causing the SMH, as well as the duration, size, and density of the SMH. In our study, we found no influence of size of SMH on anatomical and functional outcomes. Though there was no association between the duration of SMH and the functional outcome, there was a significant association between duration of SMH and favorable anatomical outcome. Avery *et al.*^[5] and Scupola *et al.*^[6] reported an inverse correlation between the area of retinal hemorrhage and the final visual acuity. Many others, however, have not found a definite correlation between the area of subretinal hemorrhage as well as duration of hemorrhage and the final visual acuity. This may be related to the location and the shape of the hemorrhages with respect to the fovea. A small hemorrhage centered at the fovea may be associated with a worse visual outcome than a larger one that is thin and eccentric to the fovea. Another factor that may influence visual outcome is the histologic location of the hemorrhage. Subretinal hemorrhages are amenable to pneumatic displacement or surgical evacuation, but sub-RPE hemorrhages are not. These entities can be differentiated clinically and using OCT. Fig. 5 shows the role of OCT in demarcating the extent of subretinal hemorrhage from sub-RPE location of the blood. Sub-RPE hemorrhage at the fovea heralds a poor visual prognosis irrespective of the etiology that caused it.

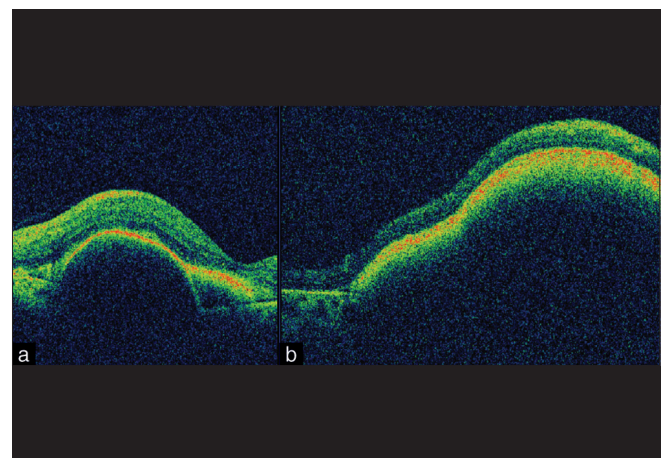


Figure 5: (a) Linear OCT scan reveals location of submacular hemorrhage, predominantly in the subretinal pigment epithelial space. However, a pocket of subfoveal hemorrhage can be made out (b) Linear OCT scan reveals a large subretinal hemorrhage with shadowing, obscuring the underlying RPE

To the best of our knowledge, this is the first study comparing long-term anatomical and functional outcomes of three different treatment modalities for a variety of causes of SMH from a single center. The drawbacks of this series are its retrospective design, relatively small size with unequal distribution between groups, and selection bias of one modality, i.e. pneumatic displacement for PCV. However, the heterogeneous etiologies of this potentially vision-threatening entity make direct comparisons difficult.

In conclusion, both “subretinal r-tPA assisted vitrectomy” and “pneumatic displacement with r-tPA” appear to be effective in the management of SMH. Although we found excellent anatomical outcomes with subretinal r-tPA assisted vitrectomy, it did not amount to equivalent visual improvement. Pneumatic displacement with r-tPA, being safer of the two, may be the preferred modality in managing eyes with SMH that have characteristics similar to those described in our series. Combining pneumatic displacement and r-tPA with anti-VEGF agents for SMH is a proposition that requires further study.

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