• Clinical Research •

Staged surgical treatment of complicated initial cataract in patients with advanced proliferative diabetic retinopathy

Karina I. Konovalova, Michael M. Shishkin, Rinat R. Faizrakhmanov, Dilara B. Babaeva

Department of Ophthalmology, N.I. Pirogov National Medical-Surgical Center, Ministry of Health of the Russian Federation, Moscow 105203, Russia

Correspondence to: Karina I. Konovalova. Department of Ophthalmology, N.I. Pirogov National Medical-Surgical Center, Ministry of Health of the Russian Federation, 70 Nizhnyaya Pervomaiskaya St., Moscow 105203, Russia. Kaleria1992@yandex.ru

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Abstract

• **AIM:** To evaluate the efficacy of second-stage phacoemulsification (PE) of complicated initial cataract after vitreoretinal surgery (VRS) in patients with advanced proliferative diabetic retinopathy (PDR).

• **METHODS:** Totally 216 patients with PDR and complicated initial cataract who underwent surgery were included. These patients were divided into four groups according to their management. In the 1st group patients were subjected to a two-step surgical procedure: VRS with silicone oil tamponade was performed as the first step, followed by the second step, PE+intraocular lens (IOL) implantation+silicone oil removal. In the 2nd group PE was performed simultaneously with VRS and silicone oil tamponade. The second step differed in the removal of silicone oil from the vitreous cavity. Patients Ia (*n*=17) and IIa (*n*=17) subgroups had their tear liquid samples being examined before surgery and on the 2nd day after the 1st phase. In subgroups Ib and IIb, an angiogenesis inhibitor was implanted 10-14d before VRS at a dose of 0.5 mg once. In the 3rd group patients were subjected to a two-step surgical procedure: VRS with gas tamponade performed as the 1st step in their treatment; followed by the 2nd step, PE and the IOL implantation. In the 4th group PE performed simultaneously with VRS with gas tamponade.

• **RESULTS:** Patients in subgroup Ia and group III had better functional results than those in subgroup IIa and group IV, respectively (*P*<0.001). More marked inflammatory response (2-3 points) was statistically significant in patients of the IIa subgroup (*P*<0.001) and group IV (*P*<0.001) in comparison with the patients in the Ia and group III respectively. The IIa subgroup (*n*=9; 14.5%) showed higher incidence of neovascular glaucoma (NVG) than the Ia (*n*=2; 3.2%), *P*=0.027. There also was a higher rate of NVG in group IV (*n*=6; 19.3%) compared to group III (*n*=1; 3.1%), *P*=0.04. Subgroup IIa revealed a 2 to 2.5 times higher concentration of interleukin 8 (IL-8), monocyte chemoattractant protein 1 (MCP-1), and inter-cellular adhesion molecule 1 (ICAM-1) compared to subgroup Ia.

• **CONCLUSION:** PE of initial cataract at the second stage after VRS in patients with advanced PDR provides a sparing approach to surgical treatment in this category of patients and allows to improve anatomical and functional results of VRS. In addition, it contributes to reduction of number and severity of postoperative complications.

• **KEYWORDS:** proliferative diabetic retinopathy; vitreoretinal surgery; phacoemulsification

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INTRODUCTION

Diabetic retinopathy (DR) is one of the most severe complications of diabetes mellitus (DM) and is the primary cause of vision loss and disability in this category of patients[1-2]. In addition, it is known that clinical manifestations of proliferative diabetic retinopathy (PDR) that require vitreoretinal surgery (VRS) are often combined with the presence of cataract[3]. In this case, specialists argue that VRS and the use of silicone oil (SO) or air-gas mixture as tamponade of the vitreous cavity further contribute to the progression of existing lens opacities[4]. And if the necessity of VRS in patients with advanced PDR is currently beyond doubt, the problem of planning the phacoemulsification (PE) of initial cataract, when they plan to undergo VRS, remains open to this

day. Thus, many authors claim that PE should be performed simultaneously with VRS and justify it by better visualization of the fundus during surgical procedure, reduction of the patient's rehabilitation period, decrease of the total number of surgeries, as well as by technical issues in cataract extraction in a vitrectomized eye and an increased risk of intraoperative complications[5-7]. At the same time, according to a number of researchers, there is a preexisting initial blood-ocular barrier damage in patients with DM, and this volume of surgical treatment is accompanied by a high risk of postoperative complications such as secondary neovascular glaucoma (NVG), recurrence of vitreous hemorrhage, uveitis, cystoid macular edema[8-10].

Therefore, the aim of this study was to evaluate the efficacy of second-stage PE of complicated initial cataract after VRS in patients with advanced PDR.

PARTICIPANTS AND METHODS

Ethical Approval The study protocol was approved by local ethics committee of National Medical and Surgical Center named after N.I. Pirogov of Ministry of Healthcare of Russian Federation (protocol 1 dates 22.01.2020). Written informed consent was obtained from the participants.

We analyzed the results of examination of 216 patients with advanced stage of PDR and complicated initial cataract who were treated in the ophthalmology center of N.I. Pirogov National Medical-Surgical Center of the Ministry of Health of Russia from 2016 to 2020. Inclusion criteria were advanced stage of PDR and complicated initial cataract; DM in compensation/subcompensation stage [target hemoglobin A1c (HbA1c) value <7.5%]; patients who received SO or 16% gas-air mixture (C_2F_6) injection during VRS. Exclusion criteria: decompensated DM (target HbA1c>7.5%); concomitant eye pathology: age-related macular degeneration, acute and chronic inflammatory eye diseases, corneal pathology, iris rubeosis, open or closed-angle glaucoma, previous eyeball trauma; decompensated arterial hypertension (AH; blood pressure >160/100 mm Hg); acute coronary insufficiency; phlebothrombosis; history of myocardial infarction or acute stroke less than 6mo ago. All patients underwent VRS. The indications for VRS were: retinal tractional detachment (*n*=85), 39.4%; hemophthalmos lasting 3-6mo (*n*=42), 19.4%; vitreopapillary traction syndrome (*n*=78), 36.1%, vitreomacular traction syndrome (*n*=11), 5.1%. Depending on the time of PE and type of vitreous tamponade, four groups were identified.

Group I (*n*=77) consisted of patients who underwent VRS and PE in 2 stages: first stage, VRS with SO tamponade (1300 mL); second stage, PE+intraocular lens (IOL) implantation and SO removal. Subgroup Ia (*n*=62), patients who underwent surgical treatment without prior intravitreal injection of angiogenesis inhibitor. Subgroup Ib (*n*=15), patients who received prior intravitreal injection of angiogenesis inhibitor 10-14d before VRS.

Group II (*n*=76) was represented by patients who underwent PE with IOL implantation+VRS with SO tamponade (1300 cc) in a single step. The second stage included removal of SO from the vitreal cavity. Subgroup IIa (*n*=62), patients who underwent surgical treatment without prior intravitreal injection of angiogenesis inhibitor. Subgroup IIb (*n*=14), patients who received prior intravitreal injection of angiogenesis inhibitor 10-14d before VRS.

Group III (*n*=32) consisted of patients who underwent staged VRS and PE: first stage, VRS with air-gas mixture (C_2F_6) tamponade; second stage, PE with IOL implantation.

Group IV (*n*=31) included patients who underwent PE with IOL implantation simultaneously with VRS, the operation was completed by gas-air tamponade of the vitreal cavity (C_2F_6). In subgroups Ib and IIb an angiogenesis inhibitor (ranibizumab) was implanted 10-14d before VRS at a dose of 0.5 mg (0.05 mL) once. The study groups were comparable in terms of duration and type of DM, its compensation, sex and age (P>0.05; Table 1).

Patients of all subgroups underwent standard ophthalmological examinations, as well as B-scan ultrasound and optical coherence tomography. The manifestation of inflammatory reaction was assessed 1-5d after VRS by mean total score which included assessment of bulbar conjunctiva hyperemia degree and anterior chamber humor opalescence[11-12]. Spectral optical coherence tomography to assess fovea thickness preoperatively, 1 and 3mo after surgery could be assessed only in 38 of 216 patients included in the study: group Ia (*n*=19) and group IIa (*n*=19). In the remaining cases, the presence of tractional retinal detachment in the macular area, premacular fibrosis, and hemophthalmos prevented this preoperative study.

To quantitatively assess the severity of postoperative inflammatory response, immunological study of the tear samples was performed to study the concentration of cytokines [interleukin 1β (IL-1β), interleukin 8 (IL-8), interleukin 10 (IL-10), monocyte chemoattractant protein 1 (MCP-1)], intercellular adhesion factor-1 (ICAM-1), vascular endothelial growth factor (VEGF) before and on the second day after the first surgical treatment in Ia (*n*=17) and IIa (*n*=17) subgroups. The tear samples were collected using an automatic pipette dispenser Lenpipet LITE (10-100 μL) from the lower roof of the conjunctival cavity in an amount of 70-100 μL before treatment and on the second day after the first phase of surgical treatment in patients in both subgroups. The collected tear samples were placed in sterile Eppendorf tubes and frozen once at -70°C. The tear samples were examined by proteomic multiplex analysis. The levels of cytokines (IL-1β, IL-8, IL-10, MCP-1), ICAM-1 and VEGF were determined by flow

Table 1 Clinical and laboratory characteristics of the examined patients mean±SD, *n*=216

Parameters	Group I (*n*=77)	Group II (*n*=76)	Group III (*n*=32)	Group IV (*n*=31)	P^c	P^d
Age, y[a]	58.19±13.01	59.49±9.98	59.22±12.21	60.87±11.24	0.494	0.579
Gender[b], *n* (%)						
Male	31 (59.6)	21 (40.4)	12 (66.7)	6 (33.3)	0.125	0.164
Female	46 (45.5)	55 (54.5)	20 (44.4)	25 (55.6)		
History of DM, y[a]	15.47±6.98	16.78±6.35	15.31±8.9	17.65±8.8	0.227	0.301
Type of DM[b], *n* (%)						
Type I	12 (57.1)	9 (42.9)	8 (57.1)	6 (42.9)	0.639	0.763
Type II	65 (49.2)	67 (50.8)	24 (49.0)	25 (51.0)		
HbA1c, %[a]	6.84±0.65	6.9±0.7	6.9±0.51	6.97±0.45	0.575	0.581

[a]*t*-test for independent samples; [b]Fisher's exact test. [c]Significance value of differences between groups I and II; [d]Significance value of differences between groups III and IV. DM: Diabetic mellitus.

fluorimetry on a 2-beam laser automated analyzer (Bio-Plex Protein Assay System, Bio-Rad, USA) using commercial test systems Pro human Single-Plex set for each cytokine under study with prior mixing according to the manufacturer's instructions.

The results of surgical interventions performed by Shishkin MM were analyzed in the article. VRS included 3-port microinvasive vitrectomy 25G with segmentation and delamination of fibrovascular membranes, endolaser coagulation of retina, tamponade of vitreal cavity with SO or 16% C_2F_6 gas-air mixture. PE was performed according to the standard technique using the "phaco chop" technique. In groups I and II the second stage (removal of SO) was carried out using 2-port access with 25G instruments 2 to 6mo after VRS. After SO removal, revision of the vitreal cavity was performed using transscleral illumination with a 25G endo-illuminator and wide-angle BIOM system of the operating microscope. The surgical intervention was completed by replacing balanced salt solution (BSS) with sterile air. In group I the second stage of surgical treatment was started with PE and IOL implantation; a peculiarity of the operation was pre-installation of irrigation system port in the area of the lower external quadrant in 4 mm from limbus to prevent possible emptying of the anterior chamber and difficulties during sclerotomy in hypotensive eye.

Statistical Analysis Statistical processing of the obtained data was performed by the author independently and was carried out using IBM SPSS Statistics 27 (IBM) program. Significance of differences in mean values between the groups was assessed using the parametric Student's *t*-criterion and nonparametric Mann-Whitney test. Differences in time between two periods were evaluated using parametric Student's *t*-test for dependent samples and nonparametric Wilcoxon's sign criterion. Relationships between categorical variables were analyzed using nonparametric independence criterion χ^2-Pearson calculated on the basis of contingency tables, as well as Fisher's exact criterion for 2×2 contingency tables. The critical level of significance in hypothesis testing for acceptance of significant differences was accepted as $P<0.05$.

RESULTS

Before surgical treatment best corrected visual acuity (BCVA) was 0.05±0.02 in Ia subgroup, 0.05±0.03 in IIa subgroup ($P=0.974$), it was 0.05±0.03 and 0.05±0.02 in groups III and IV ($P=0.314$), respectively (Table 2). There were no statistical differences in initial functional characteristics and intraocular pressure level in the investigation subgroups ($P>0.05$). Initial intraocular pressure level in all patients in the study was within normal values before surgical treatment ($P>0.05$).

The study of visual functions revealed statistically significant improvement of BCVA in the long-term period at all follow-up periods in patients of all subgroups ($P<0.001$). However, when comparing subgroups by analysis of variance with repeated measurements, it was noted that patients in subgroup Ia and group III had better functional results than patients in subgroup IIa and group IV, respectively ($P<0.001$; Table 2).

The development of early postoperative period complications was assessed 1-14d after VRS. There were no statistically significant differences in the incidence of such complications as hemophthalmic recurrence, preretinal hemorrhages, hypotension and ophthalmohypertension in the early postoperative period in patients of Ia and IIa subgroups, III and IV groups ($P>0.05$).

The manifestation of inflammatory reaction was assessed on the 1st-5th day after the first stage of the surgical treatment. Signs of pronounced inflammatory response in early postoperative period after VRS were found only in 1.6% of patients in subgroup Ia, while in patients with simultaneous VRS and PE in subgroup IIa 14.5% ($P=0.008$) and in group IV 16.1% ($P=0.018$). An increase of inflammatory response was seen in patients in all subgroups by the second day, more marked inflammatory response (2-3 points) was statistically significant in the patients of the IIa subgroup ($P<0.001$) and IV group ($P<0.001$) in comparison with the patients in the Ia and III groups respectively. Gradual decay of the inflammatory reaction against the background of conservative anti-inflammatory therapy was registered on the 3rd-5th day.

Table 2 Time course of best corrected visual acuity in analyzed subgroups mean±SD

Groups	Before surgical treatment	1mo	6mo	1y	2y
Ia subgroup (*n*=62)	0.05±0.02	0.15±0.05[c]	0.21±0.06[c]	0.28±0.06[c]	0.36±0.07[c]
IIa subgroup (*n*=62)	0.05±0.03	0.09±0.05[c]	0.11±0.05[c]	0.14±0.06[c]	0.18±0.08[c]
III group (*n*=32)	0.05±0.03	0.24±0.06[c]	0.31±0.07[c]	0.33±0.07[c]	0.38±0.07[c]
IV group (*n*=31)	0.05±0.02	0.12±0.05[c]	0.15±0.05[c]	0.16±0.06[c]	0.21±0.08[c]

[c]*P*<0.001 compared with preoperative data.

The development of complications in the long-term postoperative period was observed 1-6mo after VRS, their surgical treatment was carried out at the same time. There was no statistically significant difference in the incidence of complications such as recurrence of hemophthalmos (*P*=0.769), retinal detachment (*P*=0.094), slow uveitis (*P*=0.052), ophthalmic hypertension (*P*=0.299) and SO emulsification (*P*=0.559) in Ia and IIa subgroups patients. The significant values of the differences between retinal detachment and flaccid uveitis were interpreted as a trend that required a larger sample size of patients to prove. When comparing the results obtained in group III and IV patients, no statistically significant differences were found in the frequency of recurrent hemophthalmos (*P*=0.663), retinal detachment (*P*=0.368), sluggish uveitis (*P*=0.535) and ophthalmohypertension (*P*=0.668).

The incidence of NVG was significantly higher in patients of subgroup IIa (*n*=9; 14.5%) than in patients of subgroup Ia (*n*=2; 3.2%), *P*=0.027. In comparison of groups with gas-air tamponade of vitreal cavity, there was also statistically significant increase of NVG development after phacovitrectomy in group IV patients (*n*=6; 19.3%), in comparison with group III patients (*n*=1; 3.1%), *P*=0,04. Repeat surgery (anti-glaucoma surgery with Ahmed valve implantation) for NVG was required in subgroup IIa (*n*=8; 12.9%), compared with subgroup Ia (*n*=2; 3.2%; *P*=0.048). In groups III and IV, surgical treatment was required only in the phacovitrectomy group, fistulizing surgery with Ahmed valve implantation in 16.1% (*P*=0.018).

The incidence of development and progression of macular edema after VRS in combination with PE was registered more frequently (*n*=9; 47.4%) in patients of IIa subgroup than in patients of Ia subgroup when FEC was performed in the second stage with simultaneous removal of SO after VRS (*n*=3; 15.8%; *P*=0.036).

The peculiarities of Ib and IIb subgroups patients' management were preoperative intravitreal injection of angiogenesis inhibitor 10-14d prior to VRS for DME and pronounced neovascularization of fibrovascular membranes. Before surgical treatment BCVA in Ib and IIb subgroups was 0.04±0.02. In the later period visual functions in both subgroups improved and reached 0.27±0.07 in Ib subgroup and 0.15±0.06 in IIb subgroup (*P*<0.001). As the results of our studies show, the incidence of fibrovascular membranes dissection hemorrhages during VRS, which were the main cause of preretinal hemorrhages in the early postoperative period, was registered more frequently in subgroups Ia (*n*=22; 35.5%) and IIa (*n*=19; 30.6%), whereas in the subgroups with prior intravitreal injection of angiogenesis inhibitor, this complication was recorded only in subgroup Ib (*n*=1; 6.7%) (*P*=0.031 and *P*=0.016, respectively). Iatrogenic ruptures were registered in 3.2% (*n*=2) of observations in Ia subgroup and in 4.8% (*n*=3) in IIa subgroup; this complication was not detected in Ib and IIb subgroup patients. The use of angiogenesis inhibitors before VRS not only reduces the risk of intraoperative bleeding but also reduces the damaging effect of vitreal surgery itself by reducing the need for intraocular diathermy in subgroups Ib and IIb and periodic IOP elevation by lifting the irrigation solution bottle for hemostasis.

Analysis of cytokines (IL-1β, IL-8, IL-10, MCP-1), VEGF, and ICAM-1 in the tear samples in patients with advanced PDR revealed that IL-1β and IL-10 concentrations were below threshold levels. IL-8, MCP-1, ICAM-1, and VEGF were used for further comparative analysis in this work. No statistically significant difference in the concentration of the studied cytokines (IL-8, MCP-1) and ICAM-1 before surgical treatment was found in patients of both subgroups (*P*>0.05). Comparative analysis of cytokine and intercellular adhesion factor-1 levels revealed statistically significant increase of IL-8, MCP-1 and ICAM-1 concentration in the tear samples on the second day after VRS surgery in both subgroups (*P*<0.001), with their levels after surgery being statistically significantly higher in the phacovitrectomy subgroup (*P*<0.001; Table 3).

Concentration of IL-8, a potent inflammatory mediator, in the tear samples of patients in subgroup IIa on the 2nd day after combined VRS and PE was statistically significantly (*P*<0.001), more than 4 times higher than in patients in subgroup Ia after VRS.

Level of MCP-1 which possesses prominent proinflammatory properties was 2.5 times higher in patients of IIa subgroup than in patients of Ia subgroup after the first stage of surgical treatment (*P*<0.001).

Concentration of ICAM-1 playing an important role in blood-ocular barrier damage disorder was 5-fold increased in patients after simultaneous VRS and PE compared to patients in Ia

Table 3 Concentrations of cytokines and intercellular adhesion factor-1 in the tear samples before surgical treatment and on the 2nd day after the first stage of surgical treatment

mean±SD, pg/mL

Parameters	Subgroup Ia (*n*=17) before surgical treatment	Subgroup Ia (*n*=17) on the 2nd day after VRS	Subgroup IIa (*n*=17) before surgical treatment	Subgroup IIa (*n*=17) on the 2nd day after phacovitrectomy
IL-8	23.59±9.21	118.86±19.76[c]	24.89±10.00	481.35±71.71[c,e]
MCP-1	91.29±20.51	161.68±34.95[c]	94.16±22.46	398.84±64.09[c,e]
ICAM-1	1834.74±348.08	9210.76±2945.35[c]	1845.5±340.09	48723.8±9702.27[c,e]

[c]*P*<0.001 compared with preoperative data; [e]*P*<0.001 compared to the data of subgroup Ia on the 2nd day after VRS. VRS: Vitreoretinal surgery; IL-8: Interleukin 8; MCP-1: Monocyte chemoattractant protein 1; ICAM-1: Inter-cellular adhesion molecule 1.

subgroup who underwent simple VRS (*P*<0.001).

No statistically significant difference in the concentration of endothelial vascular growth factor (VEGF) was found in the studied groups (*P*>0.05). In addition, the mean values of vasoproliferative factor were 117.8±24.43 pg/mL and 116.61±25.21 pg/mL before surgical treatment (*P*=0.889), 149.91±33.82 pg/mL and 148.34±31.96 pg/mL after surgery (*P*=0.887) in patients in Ia and IIa subgroups, respectively.

DISCUSSION

NVG is one of the most severe complications that could lead to irreversible vision loss. Our study is additionally supported by other authors' research, which reveals that simultaneous accomplishment of VRS and PE increases the risk of NVG in PDR patients[13-14]. It is believed that neovascularization of the iris and anterior chamber angle develops in response to retinal ischemia, trauma, or the inflammatory process[15]. The mechanisms of NVG development after simultaneous VRS and PE include the destruction of the barrier between the anterior and posterior segments of the eye, which leads to anterior diffusion of vasoproliferative substances, such as VEGF and inflammatory cytokines[16-17].

Frequency of development and progression of macular edema after VRS combined with PE was registered more often (*n*=9; 47.4%) than PE was performed as a second stage in combination with simultaneous removal of SO removal after VRS (*n*=3; 15.8%; *P*=0.036). From our point of view this can be explained by the fact that PE, as a component of VRS, is accompanied by a more profound inflammatory response. This is confirmed both by our observations and the works of other authors. Lahey *et al*[9] with co-authors has informed, that post-operational exudative-inflammatory response was more pronounced after combined surgery, compared to just VRS. It is especially valid for patients with DM, which have a risk of developing and inflammatory response after cataract surgery, even with execution of VRS, it is increased by 30% compared to patients without DM[18]. Using PE as a second stage on a background of a silicone tamponade is accompanied by less mechanical impact from ultrasound, which according to experts, can also be a trigger point of macular edema development[19].

Statistically significant increase of MCP-1 and IL-8 concentration in the tear samples after phacovitrectomy versus simple VRS reflects more pronounced postoperative inflammatory response with increased angiogenesis and fibrous proliferation in the eye cavity in patients of the IIa subgroup[17,20-21]. It should also be noted that patients in both subgroups showed no statistically significant increase in VEGF concentration on day 2 after VRS (*P*>0.05). Our results are in agreement with the data presented by other authors, who indicate a significant increase in VEGF concentration in the tear samples in patients with PDR[22-23]. For example, studies by Eriksson *et al*[18] showed that mean VEGF concentrations in the tear samples were significantly higher in the NPDR and PDR groups (114.9±8.6 pg/mL and 149.5±10.4 pg/mL, respectively) compared to the group without DR (41.2±11.3 pg/mL, *P*<0.001) in patients with type 2 DM, indicating a significant association with DR severity. Yoshida *et al*[23], in a study of proinflammatory cytokine concentrations in the tear samples during primary vitrectomy and repeated VRS complications, noted that MCP-1, IL-6, and IL-8 concentrations in the tear samples were significantly higher in eyes in repeated vitrectomy postoperative complications than in primary VRS in patients with DR, whereas VEGF levels in the tear samples were not significantly changed.

Thus, based on the data obtained, we can conclude that performing PE of initial cataract as a second stage after VRS is a reasonable and effective approach to surgical treatment of patients with a far advanced PDR. The tendency of surgeons to perform PE and VRS at the same time in patients with PDR who have initial blood-ocular barrier damage and elevated levels of proinflammatory cytokines in the eye cavity is accompanied by a more pronounced postoperative inflammatory response and a higher risk of developing postoperative complications. This, in turn, not only contributes to irreversible loss of visual function in this category of patients, but also leads to the need for additional surgical intervention. In patients with long-term DM and cardiovascular changes, it increases the risk of life-threatening complications. Based on the above, we can conclude that PE of initial cataract in the second stage after VRS in patients with far advanced

PDR provides a sparing approach to surgical treatment of this category of patients and allows to improve anatomical and functional results of VRS, contributes to reduction of number and severity of postoperative complications.

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