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Original Article

Immediate Sequential Bilateral Vitrectomy Surgery for Retinopathy of Prematurity: A Single Surgeon Experience

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Abstract

Objectives: We report the safety and efficacy of simultaneous bilateral vitrectomy for stage 4 and stage 5 retinopathy of prematurity (ROP).

Materials and Methods: Babies who had immediate sequential bilateral vitrectomy surgery for stage 4 or stage 5 ROP were included in this retrospective study. Clinical history, demographic characteristics of the patients, surgical procedure details, perioperative and postoperative ophthalmic and systemic complications, and postoperative anatomical success rates were evaluated. General anesthesia features were also recorded.

Results: Seventy eyes of 35 babies who had immediate sequential bilateral vitrectomy surgery for stage 4 or stage 5 ROP were reviewed. At the time of surgery, the mean age was 41.4±4.9 weeks. There was preoperative plus disease in 58.6% of the eyes. The mean surgery/eye ratio was 1.2. Mean anesthesia time was 95±64 minutes. The mean follow-up was 28.1 months (3 to 84 months). Anatomical success was 95.7% for stage 4A (44/46 eyes), 83.3% for stage 4B (15/18 eyes), and 50% for stage 5 (3/6 eyes) ROP. Patients with stage 5 ROP had significantly less anatomical success than stage 4A and 4B (p=0.004). None of the patients had endophthalmitis and anesthesia-related severe complications.

Conclusion: Immediate sequential bilateral vitrectomy surgery can be considered an option for patients with active bilateral stage 4 and stage 5 ROP. The risk of endophthalmitis should be weighed against the risks of disease progression and anesthesia-related complications.

Keywords: Retinopathy of prematurity, sequential bilateral surgery, vitrectomy

Introduction

The incidence of retinopathy of prematurity (ROP) is increasing with advances in neonatal care.[1] Even with careful screening and treatment, ROP still progresses to stage 4 or 5 and needs surgery in 12% of eyes.[2] Treatment for stage 4 and stage 5 ROP includes scleral buckling and vitrectomy with or without lensectomy.[3,4,5,6,7] Lens-sparing vitrectomy (LSV) in stage 4 and 5 ROP offers the greatest hope for visual rehabilitation of the phakic eye, but the decision to proceed with surgery must be weighed against the risks of iatrogenic retinal breaks and surgical aphakia, complications that have more significant consequences for infants than for adults.[8,9]

The timing of surgery for ROP should be planned carefully. Early intervention when the eye is highly vascularized can have as devastating results as waiting too long for the eye to become quiet.[10,11,12,13,14] The ideal timing for vitrectomy is when vascular

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activity is reducing and retinal detachment is beginning.[11] When both eyes show similar findings and need immediate surgery, waiting for days or weeks between eyes might lead to blindness in the latter eye in high-risk ROP cases.[11,15,16] Furthermore, general anesthesia-related complications increase in preterm babies when anesthesia is repeated after a short interval. Both of these factors encourage performing bilateral surgery in the same session (i.e., immediate sequential bilateral vitrectomy surgery).[11,13,16,17,18,19,20,21,22]

Here, we present our experience with immediate sequential bilateral vitrectomy surgery (ISBVS) for stage 4 and 5 ROP cases.

Materials and Methods

Patient Selection

This study is a retrospective cohort study conducted in the Ophthalmology Department of Gazi University Medical School in Ankara, Turkey. Institutional Review Board approval was obtained. The study complied with the Health Insurance Portability and Accountability Act of 1996 and adhered to the tenets of the Declaration of Helsinki.

Charts from September 2010 to October 2019 were reviewed. Patients who underwent surgery for ROP and had surgery on both eyes on the same day were identified. The detailed risks of simultaneous surgery, such as the risk of bilateral endophthalmitis, were explained to the parents of babies who underwent simultaneous bilateral surgery and their informed consent was obtained. All of the patients presented with stage 4 or stage 5 ROP.

Surgical Procedures

All surgeries were performed by the same surgeon (S.O.). None of the patients received anti-VEGF or laser treatment to prepare for surgery in the preoperative period due to an increased risk of retinal traction. Before each surgery, a fundus examination was done with a binocular indirect ophthalmoscope to determine the sclerotomy sites. All sclerotomies were performed 1.5 mm from the limbus, after conjunctival peritomy, and all were sutured at the end of the surgery. Superior sclerotomies were 23 gauge (G), with or without (valved) cannulas, and the inferotemporal sclerotomy was made with a 23G 4-mm sutured infusion cannula. Following central core vitrectomy, detachment of the posterior hyaloid in the posterior pole was attempted with the help of diluted triamcinolone. If the posterior hyaloid did not detach easily, the vitreous was only trimmed for a more complete vitrectomy, leaving the posterior hyaloid attached. Even if the posterior hyaloid could be detached easily from the posterior pole, detachment beyond the arcuate was not attempted, and peripheral detachment was avoided to decrease the risk of retinal break and hemorrhage. LSV was intended for each case when possible; however, the lens was sacrificed when there was extensive anterior traction extending up to the posterior lens capsule or tractions extending to the far periphery. Fibrovascular membranes that caused retinal tractions were removed or trimmed as much as possible to relieve the retina. Endolaser was applied to the peripheral avascular retina intraoperatively as needed. At the end of the surgery, air or gas was used as a tamponade at the surgeon's discretion. At the end of each surgery, a subconjunctival antibiotic and steroid mixture was injected. Then the surgical team re-scrubbed, a new set of surgical instruments were used, and the fellow eye was prepared as a new patient.[12,14] All of the babies were examined on postoperative day 1, at week 2, month 1, 3, and 6, and every 6 months thereafter.

General Anesthesia

General anesthesia was induced with sevorane, combined with O_2 and air, and analgesia was achieved with remifentanil infusion during the operation in all patients. Laryngeal mask or endotracheal intubation was selected according to the anesthesia teams' experience. Postoperatively, the patients were transferred to the neonatal ward or neonatal intensive care unit (NICU), with incubators with 2 l/min O_2.

Chart Reviews

From the patient charts, gestational age, birth weight, sex, stage of ROP and presence of plus disease at the time of surgery, previous treatments, age at the time of surgery, intraoperative procedures, complications (vitreous hemorrhages necessitating secondary surgery, iatrogenic break, lensectomy need, and glaucoma), postoperative results including anatomical outcome and visual acuity results (Lea, tumbling E, and ETDRS charts were used according to patient cooperation), and follow-up time were collected. Additionally, regarding general anesthesia, duration of anesthesia, induction technique, airway management (endotracheal intubation or laryngeal mask), analgesia modalities, perioperative adverse events, and need for postoperative monitoring or ventilation in a post-anesthesia care unit and/or NICU were recorded.

Outcomes

Anatomical success was defined as complete retinal reattachment with undistorted or minimally distorted macula for stage 4A, complete retinal attachment or partial residual peripheral retinal detachment not involving the macular region for stage 4B, and attachment of any part of posterior pole for stage 5.

Statistical Analysis

Statistical analysis was performed with SPSS version 20.0 software (IBM Corp, Armonk, NY, USA). Continuous data were expressed as mean ± standard deviation and qualitative data were expressed as frequency and percent. The distribution of the data was analyzed using Shapiro-Wilk test. Differences between groups were analyzed with Mann-Whitney U (for two groups with continuous variables) and the Kruskal-Wallis test with Conover test as post-hoc analysis (for more than two groups with continuous variables). For categorical data, the Pearson χ^2 test was used with Bonferroni correction. A p value less than 0.05 was considered statistically significant.

Results

Patients

Seventy eyes of 35 patients who underwent surgery on both eyes simultaneously were included in the study. Mean gestational age at birth was 28.6±2.9 weeks (range: 23 to 35 weeks), mean birth weight was 1284.7±463.2 g (range: 670 to 2500 g). Eighteen of 35 patients were male (51.4%). The mean gestational age at surgery was 41.4±4.9 weeks (range: 33 to 58 weeks). Forty-six eyes were stage 4A, 18 eyes were stage 4B, and 6 eyes were stage 5. Patients were followed-up for 28.1±19.9 months (range: 3 to 84 months). The ROP staging and preoperative characteristics are summarized in Table 1. There was plus disease in 41 eyes (58.6%) preoperatively. Patients with stage 4A and 5 ROP had statistically significantly more plus disease than those with stage 4B (p=0.002, Pearson χ^2 test). Sixty eyes had received preoperative laser treatment (85.7%). Eight eyes did not receive any treatment before surgery (11.4%). Of the 60 eyes that received preoperative laser treatment, 24 (34.3%) had also received anti-VEGF (0.625 mg bevacizumab) treatment before surgery. Laser and anti-VEGF treatments had been performed elsewhere before referral of the babies to our center for surgery. The mean interval between initial laser treatment and surgery was 29.7±22 days and the mean interval between anti-VEGF treatment and surgery was 14.4±7.2 days. The mean post-conceptional age at surgery was statistically significantly lower in stage 5 eyes than in stage 4A and 4B eyes (p=0.03, Kruskal-Wallis test).

Surgery

LSV could be performed in most cases, and lensectomy-vitrectomy was done in 13 eyes (18.6%) due to extensive anterior fibrovascular proliferation (Table 2). Subjects with stage 4B ROP had more lensectomy than stage 4A and 5 (p=0.03, Pearson χ^2 test). Posterior hyaloid detachment (PHD) could be performed in 34 eyes (48.6%). Air was the tamponade of choice in the majority of the eyes (75.7%). Sixteen eyes (22.9%) needed additional surgery due to vitreous hemorrhage, residual traction, or cataract (mean interval between surgeries, 11.6±14.9 weeks). The mean surgery/eye ratio was 1.2. Secondary surgery need was significantly more likely in stage 5 eyes (p=0.02, Pearson χ^2 test) (Table 2). Postoperative vitreous hemorrhage was observed in a total of 8 eyes (11.4%), 7 of which had a preoperative plus disease. The rate of postoperative vitreous hemorrhage was statistically significantly higher in eyes with preoperative plus disease than those without (p=0.04, Pearson χ^2 test). However, this rate did not differ significantly between eyes that received preoperative anti-VEGF treatment (2/26 eyes) and those that did not (6/44 eyes, p=0.36, Pearson χ^2 test).

Postoperative Outcomes

Overall anatomical success was achieved in 62 eyes (88.6%), being highest in eyes with stage 4A (95.7%) and lowest in eyes with stage 5 (50%). Stage 5 eyes had significantly less anatomical success than stage 4A and 4B (p=0.004, Pearson χ^2 test).

Thirty-four patients finished their first year follow-up. Fifty-nine of the eyes were able to follow small objects at 1 year. Forty-three eyes had refraction recorded in their charts in the first year. The refractive status of the phakic eyes and aphakic eyes were -6.51±4.92 and 16.21±7.6, respectively (p<0.001, Mann-Whitney U test). Among patients with longer follow-up, the mean LogMAR acuity was 1.1±0.27 (range: 0.5-1.5, 16 eyes) at 3 years and 0.76±0.31 (range: 0.5-1.5, 9 eyes) at 4 years.

Success rates tended to be lower in the presence of preoperative plus disease (85.4% vs. 93.1%) and postoperative vitreous hemorrhage (75% vs. 90.3%), but the difference was not statistically significant (p=0.45 and p=0.22, Pearson χ^2 test for all, respectively). Anatomical success was achieved in 14 of the 16 reoperated eyes.

Twelve patients had esotropia, three of which underwent strabismus surgery, and one of the patients had exotropia. Seven eyes had glaucoma; five were controlled with topical

Table 1. Demographics and baseline characteristics of patients who had immediate sequential bilateral vitrectomy surgery for stage 4 or 5 retinopathy of prematurity

Demographics and baseline characteristics	All eyes (n=70)	Stage 4A (n=46)	Stage 4B (n=18)	Stage 5 (n=6)	p value*
Gestational age (weeks), mean ± SD	28.6±2.9	28.7±3.1	29.1±2.8	26.8±1.3	0.15
Birth weight (g), mean ± SD	1284.7±463.2	1306.5±467.9	1330.0±483.8	981.7±268.9	0.20
Sex (male/female), n	36/34	25/21	10/8	1/5	0.20
Plus disease, n (%)	41 (58.6)	30 (65.2)	5 (27.8)	6 (100)	**0.002**
Preoperative treatment, n (%)					
None	8 (11.4)	4 (8.7)	4 (22.2)	0 (0)	0.43
Laser only	36 (51.4)	23 (50)	8 (44.4)	5 (83.3)	0.43
Anti-VEGF only	2 (2.9)	2 (4.3)	0 (0)	0 (0)	0.43
Laser and anti-VEGF	24 (34.3)	17 (37)	6 (33.3)	1 (16.7)	0.43
Postconceptional age at surgery (weeks), mean ± SD	41.4±4.9	41.2±4.6	43.2±5.8	37.5±2.7	**0.03**

*Pearson χ^2 test was used for categorical variables and Kruskal-Wallis test was used for numeric variables. Boldface values indicate statistical significance (p<0.05).
SD: Standard deviation, n: Number, VEGF: Vascular endothelial growth factor

Table 2. Surgical procedures and outcomes of patients who had immediate sequential bilateral vitrectomy surgery for ROP					
Surgical procedures and outcomes	**All eyes (n=70)**	**Stage 4A (n=46)**	**Stage 4B (n=18)**	**Stage 5 (n=6)**	**p value***
Lens sparing vitrectomy, n (%)	57 (81.4)	41 (89)	11 (61)	5 (83)	**0.03****
Lensectomy and vitrectomy, n (%)	13 (18.6)	5 (11)	7 (39)	1 (17)	
Tamponade, n (%)					
Air	53 (75.7)	35 (76)	12 (66.7)	6 (100)	0.32
Gas	3 (4.2)	1 (2.2)	2 (11)	0	
Induction posterior hyaloid detachment, n (%)	34 (48.6)	20 (43)	10 (55.5)	4 (66.7)	0.83
Postoperative vitreous hemorrhage, n (%)	8 (11.4)	5 (11)	1 (5.6)	2 (33.3)	0.36
Secondary surgery, n (%)	16 (22.9)	9 (19.4)	4 (22.2)	3 (50)	**0.02**
Anatomical success, n (%)	62 (88.6)	44 (95.7)	15 (83.3)	3 (50)	**0.004**

*Pearson χ^2 test was used for categorical variables. Boldface values indicate statistical significance ($p<0.05$)
ROP: Retinopathy of prematurity

medical treatment, while two eyes of one patient needed glaucoma surgery (right eye: Ahmed glaucoma valve and left eye: Harms trabeculotomy). Five eyes that developed glaucoma were phakic, and there was no statistically significant difference between phakic and aphakic eyes in terms of glaucoma development (p=0.95, Pearson χ^2 test). None of the patients had endophthalmitis. Ocular and systemic complications are summarized in Table 3.

General Anesthesia

The mean duration of general anesthesia was 95±64 minutes. There was no difference between the anatomical success group and non-success group (p=0.82, Mann-Whitney U test). The laryngeal mask was used in 8 patients (22.8%). Two patients were admitted to the NICU, one due to the need for mechanical ventilation and the other because of hydrocephalus. The patient who needed mechanical ventilation had longer general anesthesia duration (205 minutes) and was extubated 2 hours after surgery. There were no severe anesthesia-related complications such as requirement for re-intubation, desaturation, apneic episodes, seizures, cyanosis, cardiac arrest, aspiration pneumonia, embolism, malignant hyperthermia, sepsis, or death (Table 3).

Table 3. Ocular and systemic complications	
Complications	**n (%)**
Ocular	
Choroidal hemorrhage	0
Hypotony	0
Endophthalmitis	0
Cataract	2 (2.8)
Iatrogenic retinal tear†	1 (1.4)
Vitreous hemorrhage	8 (11.4)
Glaucoma	7 (10)
Strabismus (esotropia)	12 patients (34)
Nystagmus	14 (20)
Phthisis	3 (4.3)
Systemic	
Postoperative need for NICU	2 patients (5.7)
Postoperative mechanical ventilation	1 patient (2.8)

†Peripheral superior iatrogenic retinal tear treated with laser and gas tamponade. Retina remained attached during 44 months of follow-up.
NICU: Neonatal intensive care unit

Discussion

ISBVS in ROP can be rationalized in many ways. The patients are infants with many comorbidities, including bronchopulmonary dysplasia (BPD), which increases the risk of anesthesia administration and sometimes makes it impossible to repeat anesthesia.[17,18,19,22] Infants with BPD have especially high risk of developing respiratory problems such as bronchospasm and atelectasis in the perioperative period.[23] Additionally, when there is active ROP in both eyes, delaying surgery in the second eye may not be feasible.[15]

Bilateral simultaneous cataract surgeries in pediatric patients have been previously reported.[20,21,24,25] Postoperative endophthalmitis is the most frightening complication after bilateral simultaneous intraocular surgeries. Previous studies reported endophthalmitis rates in pediatric and adult cataract surgery between 0.15 and 1.1%.[25] The endophthalmitis risk after adult vitreoretinal surgery is reported to be between 0.03% and 0.08%.[26,27,28] Although pediatric vitrectomy surgeries might not have similar endophthalmitis rates and it is not certain that each eye has independent endophthalmitis risk[29], it has been calculated that the risk for bilateral endophthalmitis after ISBVS would be 1 case in 150,000 to 1,000,000.[13] This rate is much lower than the general anesthesia-related mortality rate in the pediatric population. To reduce the risk of bilateral endophthalmitis, we treated each eye as a new patient, as described in the methods.[11,13] None of our patients had endophthalmitis.

The mortality rate for pediatric patients subjected to general anesthesia ranges between 0.2 and 12.8 per 10,000.[21,30] It is estimated that simultaneous bilateral surgery reduces anesthesia-

related complications by 50% for sequential surgery, especially in high-risk patients such as premature infants.[20] For preterm neonates, the risks of general anesthesia, such as intracranial hemorrhage, hypoxia, oxygen toxicity, postoperative apnea, bradycardia, and hypothermia, are greater than for term infants.[22] Subjecting the infant to this risk for a second time in a short period might increase the risk of anesthesia-related complications. Besides, deterioration of the infant's general status after the first surgery may delay the surgery of the contralateral eye. None of our patients had serious complications related to general anesthesia.

We performed ISBVS when both eyes had active stage 4 and 5 ROP disease, and delaying a second surgery would lead to disease progression in the latter eye. Most of these bilateral surgeries were done on stage 4A ROP because of the relatively short surgical time and less general anesthesia time. This complies with a previous international multicenter study, which suggests performing ISBVS for patients in whom the surgical intervention would be relatively short.[13]

Shah et al.[11] reported favorable results in their cases of simultaneous bilateral surgeries only in stage 4A ROP. Although most of our cases were also stage 4, we had 6 eyes with stage 5 ROP in our series, though the fellow eyes were stage 4 in all of these cases. Additionally, all of the stage 5 eyes were recent stage 5 cases who had been lasered before, which fixed the peripheral retina and prevented anterior closed-funnel retinal detachment.

Our results imply that preoperative plus disease is a good predictor of postoperative vitreous hemorrhage. PHD could be easily achieved in almost half of the eyes (48.6%) in the present series, contrary to the usual expectations in pediatric eyes. The anatomical success rate in our cases was 95.7% for stage 4A, 83.3% for stage 4B, and 50% for stage 5 eyes, similar to previous reports.[11,12,14,31,32,33]

A large international multicentric retrospective study on ISBVS for pediatric retinal disorders reported ISBVS to be a feasible and safe treatment paradigm for pediatric patients with bilateral vitreoretinal pathological features when repeated general anesthesia is undesirable or impractical.[13] These findings are supported by another recent study from India.[16]

Study Limitation

The drawbacks of this study are that it is retrospective and has a relatively small sample size because it is a single surgeon experience. However, there are only a few papers on this subject and it needs to be clarified with more experiences.

Conclusion

In conclusion, as ROP is usually a rapidly progressive disease when untreated during the active stage, ISBVS should be considered in bilateral cases when there is a risk of rapid progression in both eyes and when comorbidities of the infant make a second general anesthesia undesirable. All precautions should be taken to reduce the risk of endophthalmitis. The risk of endophthalmitis should be weighed over the risk of anesthesia-related complications and disease progression.

Ethics

Ethics Committee Approval: Gazi University Faculty of Medicine Clinical Research Ethics Committee (date: 19.06.2017, decision no: 312).

Informed Consent: Written consent was obtained from the legal guardian of all patients.

Peer-review: Internally and externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: Ş.Ö., Concept: Ş.Ö., M.C.Ö., Design: Ş.Ö., M.C.Ö., Data Collection or Processing: Ş.Ö., M.C.Ö., D.Y., H.T.A., D.C., Analysis or Interpretation: Ş.Ö., M.C.Ö., Literature Search: M.C.Ö., D.Y., H.T.A., Writing: M.C.Ö., D.Y.

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