Original Article

Safety and efficacy of dexamethasone implant along with phacoemulsification and intraocular lens implantation in children with juvenile idiopathic arthritis associated uveitis

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Purpose: To assess the safety and efficacy of intraoperative intravitreal dexamethasone implant in patients of juvenile idiopathic arthritis (JIA)-associated uveitis undergoing phacoemulsification with posterior chamber intraocular lens (PCIOL) implantation. **Methods:** Retrospectively, data of patients with JIA-associated uveitis undergoing phacoemulsification with PCIOL implantation with intraoperative dexamethasone implant injection were analyzed. Patients with a minimum follow-up of 6 months were included. Primary outcome measures were ocular inflammation, intraocular pressure (IOP), best-corrected visual acuity (BCVA), and worsening of uveitis. **Results:** 8 eyes of 6 patients were included. BCVA was significantly improved at 1, 3, and 6 months postoperatively 0.20 ± 0.09, P = 0.008; 0.18 ± 0.11, P = 0.008; and 0.24 ± 0.11, P = 0.01, respectively. No statistical difference noted in mean IOP at various follow-up visits. None developed worsening of uveitis or Cystoid macular edema. **Conclusion:** Intraoperative intravitreal dexamethasone implant is a safe and effective in preventing and managing the postoperative inflammation in children with JIA-associated uveitic cataract.

Key words: Children, cataract surgery, dexamethasone implant, JIA, juvenile idiopathic arthritis, phacoemulsification, uveitis

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Juvenile idiopathic arthritis (JIA) is one of the most common causes of uveitis in children and is associated with ocular inflammation in approximately 10–20% cases. Out of these, children with JIA-associated uveitis, 20–30% develop cataract.[1,2] Significant visual morbidity may be associated with cataract and uveitis in these children. Traditionally, cataract surgery performed after quiescence of inflammation for a period of at least 3 months is associated with favorable outcomes.[3-5] However, despite adequate preoperative control of inflammation, children may develop various postoperative sequelae due to recurrence of inflammation, macular edema, visual axis obscuration due to posterior capsular opacification (PCO), formation of cyclitic membrane, hypotony, and phthisisbulbi.[5-8]

Often, children with JIA require long-term therapy with systemic corticosteroids, greatly increasing the chances of corticosteroid related side-effects including growth retardation in children. Therefore, in cases with severe, persistent, or uncontrolled inflammation, systemic immunosuppressive therapy with agents such as methotrexate, mycophenolatemofetil, azathioprine, and biological agents may be needed. Cataract surgery poses an additional trigger for inflammatory cascade, and per-operative increase in corticosteroid dosages are often recommended.

Dexamethasone implant (Ozurdex®, Allergan Inc, Irvine, California) is a sustained release intravitreal implant containing 700 µg dexamethasone that can provide a source of prolonged but steady intraocular corticosteroid delivery.[9] Gupta *et al.* have previously observed the safety and efficacy of dexamethasone implant during cataract surgery in uveitis patients in controlling post-surgery inflammation in the adult population.[10]In this retrospective case series, we have assessed the safety and efficacy of intravitreal dexamethasone implant in children with JIA-associated uveitis undergoing phacoemulsification with posterior chamber intraocular lens (IOL) implantation. Literature search including Pubmed and Medline did not show any previous report of the use of combined approach of injecting intravitreal dexamethasone implantation simultaneously with phacoemulsification and IOL implantation in JIA-associated uveitis.

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Methods

In this retrospective case series, children with JIA-associated uveitis who underwent cataract surgery along with intraoperative intravitreal dexamethasone implant injection at our tertiary eye care center were studied. For the purpose of the study, medical records from January 2010 to December2017 were analyzed. The study adhered to the tenets of the Declaration of Helsinki and the rules laid down by Health Insurance Portability and Accountability Act of 1996 (HIPAA). Written informed consent was obtained from the parents/guardians of all the children included in the study.

Diagnosis of JIA-associated uveitis and patient enrolment

The diagnosis of JIA was made according to the International League of Associations for Rheumatology (ILAR) diagnostic criteria below 16 years of age.[11]All patients had been diagnosed with uveitis and were under follow-up in the Uveitis Services of the Hospital. Children who developed visually significant cataract and underwent phacoemulsification and IOL implantation along with intraoperative intravitreal injection of dexamethasone implant were enrolled in the study. All the children had a minimum follow-up of atleast 6 months. The decision to perform cataract surgery was made when the inflammation was under control (<1+ cells) for at least 3 consecutive months prior to surgery and corrected distance visual acuity <20/50 or less. Children in whom cataract surgery was performed without IOL implantation were excluded from the study. The other exclusion criteria were history of steroid responsiveness and follow-up of less than six months. All the children were diagnosed with JIA according to the ILAR criteria and were under treatment from pediatric rheumatologists.

Preoperative patient evaluation

Demographic details of all patients such as age and gender, clinical features including details of anterior and posterior segment inflammation, and laboratory details such as rheumatoid factor , anti-nuclear antibody, and anti-double stranded DNA, among others, were noted. At baseline, the patients underwent a complete ophthalmological examination, including best-corrected visual acuity (BCVA) evaluation, anterior segment slit-lamp biomicroscopy, cells and flare evaluation, and fundus examination. Standardization of Uveitis Nomenclature Working Group Grading was used for assessment of anterior chamber reaction. The intraocular pressure (IOP) was measured by Goldmann applanation tonometry. Fluorescein angiography and spectral-domain optical coherence tomography (SD-OCT) imaging with Spectralis® (Heidelberg Engineering, Germany) was done when required. Ultrasound B-scan was performed for posterior segment evaluation in patients with dense cataract.

Indications of dexamethasone implant

All the patients of JIA in our cohort had been on long-term follow-up prior to cataract surgery. These patients had developed various corticosteroid related side-effects such as moon facies, weight gain, and growth retardation. Thus, at the time of cataract surgery, the parents/guardians of the patients were given an option of use of intravitreal dexamethasone implant or preoperative increase in the dose of oral corticosteroids to counter the postoperative inflammation. They were explained the limited experience with the use of dexamethasone implant for this indication and the possible adverse events. Patients who consented for the implant were then included in the study. Patient having history of glaucoma or steroid responsiveness were excluded.

Surgical technique

Surgery was done on day care basis or on outpatient basis, or patients were admitted one day prior to surgery (if needed). Same surgeon (Jagat Ram) performed all the surgeries strictly adhering to principles of closed chamber technique. Written informed consent was taken from every patient before the surgery. All surgeries were performed under general anesthesia. Intravitreal 700 μg dexamethasone implant was given 3.5 mm away from the limbus temporally. Two side port incisions were created at 2 and 9 o'clock position, and main port was made using 2.2 mm disposable keratome. Trypan blue dye (0.06%) was used to stain the anterior lens capsule. The anterior chamber was formed using high viscosity viscoelastic (1.4% sodium hyaluronate). Small pupils were managed using Iris hooks or Malyugin's ring. Then, 5–5.5 mm capsulorrhexis were made using Uttrata's forceps. Standard steps of pediatric phacoaspiration were performed. Foldable hydrophobic acrylic IOL (SN60WF®, Alcon, Fort Worth, USA) were implanted in capsular bag in all cases.

Postoperative follow-up

Ophthalmic examination was performed at postoperative 1 day, 2 weeks, 1, 3, and 6 months. All the children received topical moxifloxacin 0.3% 6 times a day, topical atropine sulfate 1% 3 times a day, and topical betamethasone 0.1% with neomycin 0.5% 10–12 times per day initially, which was tapered according to the postoperative inflammatory response of the eye. At each visit, the patients underwent a complete ophthalmological examination, including BCVA evaluation, IOP assessment using Goldmann applanation tonometry, anterior segment slit-lamp biomicroscopy, cells and flare evaluation, and fundus examination. Additionally, the presence of synechiae formation, band-shaped keratopathy (BSK) formation, pigment deposits on the IOL, IOL decentration, visual axis obscuration, and macular edema were noted. SD-OCT was done to look for Cystoid macular edema as and when required.

Outcome measures

Primary outcome measures in our study were safety measures including anterior chamber reaction (cells and flare), IOP and progression/worsening of uveitis, or development of endophthalmitis. Efficacy analysis included evaluation of BCVA during the follow-up visits. Secondary outcome measures included incidence of visual axis obscuration, posterior synechiae formation, pigment over IOL surface, BSK, IOL decentration, need of re-surgery, and any other complication related to surgery.

Statistical analysis

Statistical analysis was done using SPSS statistical software V.12.0.1(SPSS Inc.). Descriptive analysis was used for the evaluation of qualitative data. Normality of the data was checked by Shapiro-Wilk normality test. Quantitative data was analyzed for significance within groups using Wilcoxon signed rank test. Student's paired t test for intra-group comparison between two groups for parametric data analysis. Anova test was used for multiple group comparison. A P value of < 0.05 was considered to be statistically significant.

Results

After fulfilling the inclusion and exclusion criteria, 8 eyes of 6 patients who underwent phacoemulsification with posterior chamber IOL implantation with simultaneous dexamethasone implant injection were included in the study. Two patients underwent bilateral surgeries, one after another at an interval of approximately 4 months in both the patients. The mean age of the children was 7.16 ± 2.56 years (1 male).At the time of cataract surgery, all the children were on < 10 mg oral prednisone therapy. All children were on additional methotrexate therapy (range of 10–20 mg/week). Two children were also on additional immunosuppressive therapy with azathioprine (range of 50–100 mg/day), and two children were on mycophenolatemofetil therapy (range of 500–100 mg/day). None of the children had any other systemic illness. The demographic, clinical, and treatment details are listed in Tables 1 and 2. The mean follow-up of all the patients was 26.25 ± 24.85 months, with a median of 14.5 months.

Phacoemulsification and posterior chamber IOL implantation was uneventful in all the children[Fig. 1]. None of the children developed posterior capsular rupture at the time of surgery. Primary posterior capsulotomy was avoided in all eyes owing to the injection of dexamethasone implant.

Safety analyses

None of the eyes in our series developed any worsening of uveitis or endophthalmitis. The most common ocular side-effect was redness and pain postoperatively. The mean preoperative IOP in all the eyes was 15.37 ± 6.06 mm Hg. The IOP at day 1 postoperative was 16.12 ± 5.59 mm Hg (P = 0.13). The mean IOP at 1 month was 17.62 ± 5.45 mm Hg (P = 0.49) and 16.12 ± 4.15 mmHg (P = 0.99) at 3 months. The final IOP at 6 months was 15.75 ± 6.11 mm Hg (P = 0.92). One eye developed IOP of 27 mm Hg at 1 month and was started on a combination of topical dorzolamide and timolol. The change in IOP is depicted in Table 3 and Fig. 2. One eye of a patient developed vitritis/vitreous membranes at day 1 postoperatively that resolved by the next follow-up visit.

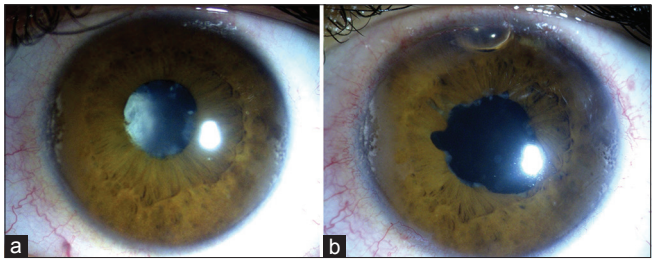

Figure 1: (a) Preoperative anterior segment photograph showing quiet eye with posterior synechiea and significant cataract (b) Postoperative anterior segment photograph at day 3 following phacoemulsification showing presence of intraocular lens with clear visual axis

Visual acuity outcomes

The mean preoperative BCVA was 0.73 ± 0.19 LogMAR units (20/100 Snellen equivalent). The BCVA improved to 0.20 ± 0.09 (P = 0.008) at 1 month (20/30 Snellen equivalent) and 0.24 ± 0.11 (P = 0.01) at 6 months (20/35 Snellen equivalent). The mean BCVA outcomes are reported in Table 3 and Fig. 3. The mean refractive spherical equivalent at six months was −0.89 ± 0.56 diopters. None of the eyes showed reduction in BCVA compared to preoperative visit during the 6 months of follow-up.

Postoperative complications

None of the eyes in the cohort developed macular edema during the postoperative visits up to 6 months. Two eyes developed PCO at 3 months postoperatively (Patient #4 and 5). Two eyes showed presence of BSK that were pre-existing (prior to cataract surgery). Pigment deposition over the IOL was noted in 5 eyes. The pigment deposits were noted in the inferior part of the IOL but were not dense enough to obscure the visual axis. Although 7 out of 8 eyes had preoperative synechiae [Table 2], none of

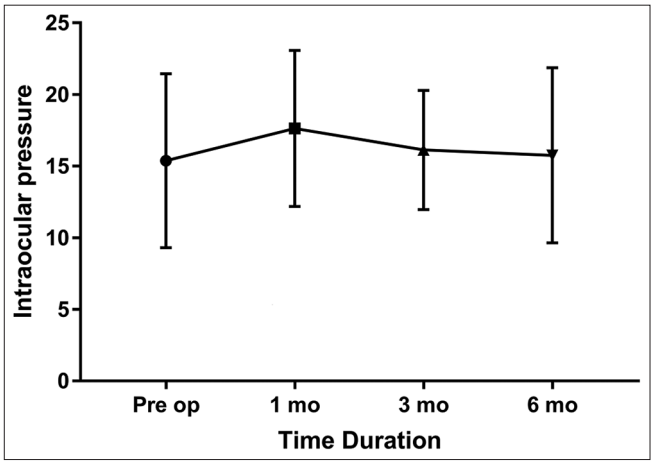

Figure 2: Graph showing trend of IOP on various follow-up visits

Table 1: Demographic, clinical, and treatment details of children with juvenile idiopathic arthritis included in the study

Patient No.	Age	Sex	Eye	Preoperative immunosuppressive therapy
1	6	F	OS	Oral prednisone (2.5 mg) + oral azathioprine (50 mg) + oral methotrexate (10 mg/week)
2	8	F	OD	Oral prednisone (10 mg) + oral methotrexate (12.5 mg/week)
3	5	M	OD	Subcutaneous methotrexate (15 mg/week)
4	10	F	OD	Oral prednisone (20 mg) + oral mycophenolatemofetil (500 mg/day) + subcutaneous methotrexate (20 mg/week)
5	10	F	OD OS	Oral prednisone (5 mg) + oral azathioprine (100 mg) + oral mycophenolatemofetil (1000 mg/day) + subcutaneous methotrexate (20 mg/week)
6	4	F	OD OS	Oral prednisone (10 mg) + subcutaneous methotrexate (15 mg/week)

F=Female, M=Male, OD=Right eye, OS=Left eye

Table 2: Clinical details of children with juvenile idiopathic arthritis included in the study

Patient No.	BCVA*	IOP mm Hg	Anterior chamber inflammation	Other Features
1	0.6	23	None	Posterior synechiae +
2	0.8	10	None	Posterior synechiae +
3	0.3	9	None	BSK +
4	0.8	16	None	Posterior synechiae +
5OD	0.8	19	Flare +	Posterior synechiae +
OS	0.8	22	Flare +	Posterior synechiae +
6OD	0.9	7	None	Posterior synechiae +
OS	0.8	17	None	BSK +, Posterior synechiae +

BCVA=Best-corrected visual acuity, BSK=band-shaped keratopathy, IOP=intraocular pressure, OD=right eye, OS=left eye. *BCVA is reported in LogMAR units

Table 3: Mean best-corrected visual acuity and intraocular pressure trends in children with juvenile idiopathic arthritis undergoing cataract surgery with intravitreal dexamethasone implant injection

	Mean Best-Corrected Visual Acuity (BCVA) LogMAR±SD	Mean Intraocular pressure (IOP) IOP±SD
Preoperative	0.73±0.19	15.37±6.06
Postoperative 1 Month	0.20±0.09	17.62±5.45
P	*P*=0.0078	*P*=0.49
Postoperative 3 Months	0.18±0.11	16.12±4.15
P	*P*=0.0078	*P*=0.99
Postoperative 6 Months	0.24±0.11	15.75±6.11
P	*P*=0.01	*P*=0.92
P (ANOVA)	*P*<0.0001	*P*=0.41

the eyes developed synechiae in the postoperative period. One patient developed severe anterior segment reaction with 3+ flare and 2+ cells, at 3 months postoperatively in both the eyes (Patient #5, Table 2). Her oral mycophenolatemofetil was increased from 1000 mg per day to 1500 mg per day in addition to oral prednisone (10 mg/day) and oral azathioprine 100 mg/day. One patient required surgical membranectomy at 8 months after cataract surgery owing to visual axis obscuration under the cover of intravenous methylprednisolone (Patient #3). None developed postoperative hypotony or papilloedema.

Bilateral injections

Two patients received bilateral intravitreal dexamethasone implant along with phacoemulsification and IOL implantation. The surgeries were performed with a minimum interval of 2 weeks. None of the eyes developed any complication related to the procedure during the follow-up. Only 1 eye required initiation of anti-glaucoma medicines as described earlier.

Discussion

Intravitreal injection of dexamethasone implant has a number of uses in various ocular inflammatory conditions such as non-infectious intermediate, posterior and panuveitis,[12-17]

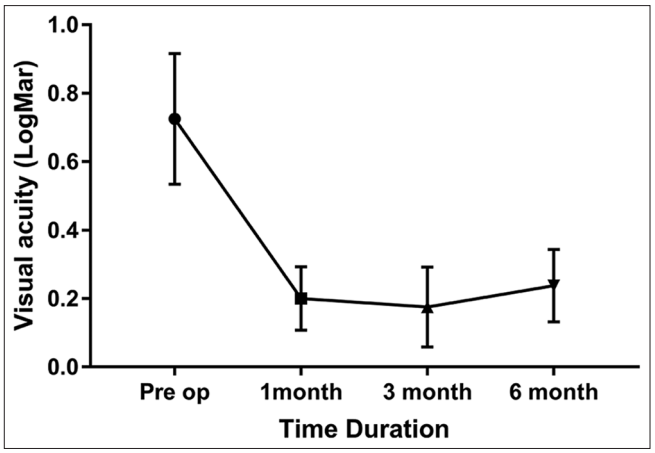

Figure 3: Graph showing trend of visual acuity (LogMar) on various follow-up visits

as well as certain infectious conditions such as intraocular tuberculosis.[18-20] Various multicenter international clinical studies have shown acceptable safety and efficacy of dexamethasone implant in other conditions such as diabetic macular edema and retinal vein occlusions.[21-25] Sustained improvement in BCVA and ocular inflammation has been noted with the use of dexamethasone implant in eyes with uveitis. However, thus far, there are a few studies that describe the safety and efficacy of this agent in children, especially in one of the most common childhood uveitis, JIA.[12,26-31]

A few studies have described the use of dexamethasone implant simultaneously with cataract surgery in eyes with diabetic macular edema, as well as uveitis.[10,32] The main concern with cataract surgery in uveitis is the exacerbation of inflammation in the postoperative period that can lead to permanent visual loss.[33-35] To prevent and treat postoperative spike in inflammation, perioperative increase in corticosteroids is often advocated. In pediatric eyes with uveitis, the risk of postoperative inflammation is much higher compared to adults, leading to further challenges.[36-38] Complications such as irido-IOL adhesions, PCO, IOL tilt and decentration, secondary glaucoma, and visual axis obscuration can occur if the inflammation is not adequately controlled. Children with JIA often require prolonged oral corticosteroid therapy leading to various systemic side-effects such as moon facies, bone weaknesses, growth retardation, hyperglycemia, secondary infections, and endocrinological abnormalities. Therefore, it is undesirable to increase the dosage of oral corticosteroid therapy in these children with JIA in whom cataract surgery is planned.

The results of our study showed that in all 6 children who underwent phacoemulsification with IOL implantation, there was no need to increase oral corticosteroids in the preoperative or immediate postoperative period. None of the eyes in our series developed worsening of inflammation in the postoperative period. The systemic immunomodulatory therapy was maintained in all the patients. Only one patient required increase in systemic mycophenolatemofetil dose 3 months after cataract surgery. In addition, there was no significant rise in IOP among the study eyes (except 1 eye in which topical anti-glaucoma therapy was needed) [Table 3].

It may be argued that intravitreal triamcinolone may be used in patients with JIA undergoing cataract surgery because it can permit primary posterior capsulotomy and is a cheaper option. However, the major limitation with triamcinolone is its short duration of action (half life of 18 days) and high risk of increased IOP in the postoperative period. For a chronic disease such as JIA, long-term agents such as depot injections may be preferable. Moreover, unlike dexamethasone implant, intravitreal triamcinolone is not a preferred approach in the management of chronic non-infectious uveitis. Miguel Cordero-Coma performed primary posterior capsulotomyin patients of JIA undergoing cataract surgery and administered intravitreal dexamethasone implant one month prior to the surgery.[30] This is another possible approach that can be used by surgeons who prefer primary posterior capsulotomy. Two eyes in our series developed PCO (25%), and pigment deposition over the IOL was seen in 5 eyes. However, surgical membranectomy was required in only 1 eye owing to visual axis obscuration at 8 months. Due to lack of a comparative group, it may not be possible to assess the difference in the postoperative complication rates in our series caused by administration of dexamethasone implant. Development of PCO is a well-known complication of pediatric cataract even in eyes without uveitis.[39-43] However, none of the children required rescue therapy with intravenous or oral corticosteroids in our series, nor did any child require a major shift in the immunomodulatory therapy. None of the children developed postoperative synechiae during the follow-up period. All children in our series received standardized topical anti-inflammatory therapy avoiding treatment bias. Thus, dexamethasone implant injection along with cataract surgery may play a role in suppressing local ocular inflammation that can occur in eyes with JIA-associated uveitis undergoing phacoemulsification, *without the need for hiking of systemic corticosteroids, avoiding their undesirable adverse effects*. Its effect lasts for 3 to 6 months duration.

All eyes in our series demonstrated improvement in BCVA from 20/100 Snellen equivalent at baseline to 20/30 Snellen equivalent at 6 months. None of the eyes showed reduction in BCVA compared to baseline. All the eyes in our series that received bilateral injections tolerated them well.

In children with JIA-associated uveitis undergoing phacoemulsification, a number of studies have recently shown the safety of foldable hydrophobic acrylic IOLs, permitting their use in expert hands.[44-46] There are several challenges in the surgical technique of phacoemulsification in these eyes owing to small pupils, synechiae, difficulty in performing capsulorhexis, and most importantly, the postoperative management. Addition of intraoperative dexamethasone implant may help the pediatric ophthalmologist in managing the postoperative inflammation well, in conjunction with the uveitis specialist as well as the rheumatologist.

There are a number of limitations of the index study, including the modest sample size. However, this is the first pilot data on the safety of intravitreal dexamethasone implant injection along with phacoemulsification and IOL implantation in these eyes. Encouraging data from this study may help in enrolling additional patients to understand its efficacy better. Another limitation of the study is the lack of a comparative group, i.e., children with JIA-uveitis who underwent phacoemulsification and IOL implantation with standard of care therapy (oral corticosteroids). Prospective studies need to be planned in the future to overcome this limitation. Children in our series were on varying immunomodulatory drugs that may have an impact on the postoperative course of the disease. Because of the simultaneous use of immunomodulatory agents, it may not be possible to determine the efficacy of intravitreal dexamethasone implant. However, this pilot investigation provides safety data and suggests a possible approach in the management of JIA-associated cataract. As our center holds special interest in pediatric cataract surgery as well as uveitis, meticulous follow-up and documentation are the strengths of this study.

Conclusion

In summary, the use of intravitreal injection of dexamethasone implant along with phacoemulsification and IOL implantation is a safe and viable option to avoid perioperative increase in systemic corticosteroids in children with JIA-associated uveitis. Although its cost can be of concern in developing countries, careful patient selection and monitoring of systemic immunomodulatory therapy over 6 months following cataract surgery can help in satisfactory control of inflammation. Close follow-up and monitoring of postoperative complications including PCO is necessary. Future studies with larger sample size may help in the understanding of differences in the rates of complications in these eyes between dexamethasone implant versus systemic corticosteroids.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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