Aim: The aim of this study is to assess the advantages and possible risks of single sitting bilateral cataract surgery over one eye at a time approach in children with developmental cataract. Settings and Design: Children (below 12 years) with bilateral developmental cataract with consenting parents were randomized to undergo either immediate sequential bilateral cataract (ISBC) surgery (both eyes at the same time) or delayed sequential bilateral cataract (DSBC) surgery (one eye at a time) over 4 years for logistics and complications. It was a prospective, randomized control trial.

Methods: Two groups of patients (below 12 years) undergoing bilateral cataract surgery were compared for number of visits, duration of hospital stay, cost of procedure, duration of operating room (OR) occupancy, and refractive outcome. The first group underwent ISBC and the second group underwent DSBC surgery. A note was also made of complications related to anesthesia and/or the surgery in both the groups. Time interval between two eye surgeries and patients not returning for second eye surgery in DSBC group were also noted. Central tendency and degree of dispersion of continuous variables were expressed as mean and standard deviation for both (ISBC and DSBC) groups. The difference between the two groups was analyzed with independent “t”-test and the level of significance taken as 95% or a P < 0.05. Results: Forty-seven patients (94 eyes) in the ISBC group and 41 (82 eyes) in the DSBC group were compared. ISBC group patients had 43.2% fewer hospital visits, 39.4% lesser duration of total hospital stay, spent 36.6% lesser, and occupied the OR for 39.0% lesser duration compared to DSBC patients. All these differences were statistically significant (P < 0.001). The refractive outcomes in both the groups were comparable (P = 0.916 for the eye operated first and P = 0.814 for the eye operated later). There were no major complications related to anesthesia or surgery in either group. The median interval between the surgeries of the two eyes in the DSBC group was 8 weeks (range: 4–73 weeks). Besides these, 11 patients (21.1%) in the DSBC group did not return for second eye surgery. Conclusions: Bilateral single sitting cataract surgery in children seems logical, patient-friendly, cost-effective, and without any significant disadvantages when performed with adequate precautions before, during, and after the procedure.

Key words: Children, immediate sequential bilateral cataract surgery, simultaneous bilateral cataract surgery

Immediate sequential bilateral cataract (ISBC) means performing bilateral cataract surgery in the same sitting whereas the usual practice of performing the second eye surgery a few days or weeks after the first is termed as delayed sequential bilateral cataract surgery (DSBC). The debate about performing ISBC surgery is not new.[1,2,3] However, publications related to this topic in children are not many and even fewer from developing countries where its implications would be significant.[4,5,6]

Logical advantages of this procedure would be both for the patient and the care providing system. For the patient, it would mean fewer visits and lesser stay in the hospital implying lesser work loss for parents. The cost of the procedure should be lower and the postoperative visual rehabilitation faster with avoidance of interprocedural anisometropia.[8] There would be possibly lesser complications related to repeat general anesthesia (GA) and the psychological impact on the caregivers.[9] There would also be lesser chances of the child being lost to follow-up and delaying the second eye surgery resulting in its amblyopia. Advantages for the hospital would be overall lesser cumulative time in operating room (OR), greater administrative, laboratory, and nursing efficiencies. In a government setup where waiting lists for GA run in several weeks, the decision could be crucial.

The possible disadvantages of ISBC would be potentially devastating complication of bilateral endophthalmitis, lesser than optimal refractive outcome, and financial loss for the profit-making hospitals.[1,9]

The present study was undertaken to assess some of these issues in Indian children with bilateral developmental cataract coming for treatment in a government medical university.
Methods

Incidence figures for anesthetic death in infants range from 0.2/10000 to 12.8/10000 and reports of endophthalmitis after cataract surgery in children from 7/10000 to 45/10000.\cite{11,13} Javitt indicated that for rare events such as endophthalmitis, one needs 10000 patients for a clinical trial to have meaningful power, and for drawing comparisons with anesthetic complications, a larger sample would be needed.\cite{10} As such, large sample sizes would make the study duration extremely long and delay the impact these observations might have. We, therefore, report results of our patients operated over 4 years.

After reading reports of favorable outcome of ISBC and analyzing our 2-year records of pediatric (<12 years) DSBC surgery, we decided to conduct this study from January 2012 to January 2016 after receiving clearance from the local ethics committee.\cite{4,6,7} After thorough systemic and local examination including a B scan, children of parents consenting to be included were randomized into the ISBC or the DSBC group. Simple randomization by computer-generated random numbers was done. Excluded were children with any other ocular abnormalities such as microphthalmia, retinal detachment, uveitis, blepharitis, and ocular surface disorders. All surgeries were conducted by a single surgeon.

The study variables were number of hospital visits, duration of hospitalization, cost of the procedure (excluding implant), duration in OR, minor or major anesthesia complications, severe postoperative inflammation or endophthalmitis, and refractive outcome at 6 weeks. Visits, stay, cost (including admission, intraoperative consumable items, OR, and GA charges), and time in OR (measured from the entry of the patient in the OR to exit) were taken collectively for both the eyes. Minor anesthesia complications implied any additional drug or procedure requirement, and major complication implied a permanent disability or death. A note was also made of the interval between two eye surgeries and failure to return for second eye surgery in the DSBC group. Assessment of refractive error was made by dilated retinoscopy at 6 weeks, and spherical equivalent was calculated.

Management protocol followed for both the groups included intraocular lens (IOLs) power calculation by SRK II formula as it has been shown to be relatively accurate in children.\cite{11,13} We perform a 10% reduction in the calculated IOL power for children below 2 years and no reduction in children above this age as we believe like other researchers that emmetropic vision during the development phase is more important than emmetropia later in life.\cite{14} Furthermore, the predictability of myopic shift is not established.\cite{15,16} This observation carries more weight in developing countries where follow-ups are often irregular and delayed.

All children received topical 0.3% tobramycin 4 times a day for 3 days preoperatively and 1 drop of 5% betadine solution immediately preoperatively. Standard temporal clear corneal incision with anterior capsulorrhexis under sodium hyaluronate 1.4%, followed by hydrodissection and phacoaspiration, was performed.\cite{37} Posterior capsulotomy with anterior vitrectomy was performed for patients younger than 6 years. IOL implantation was done in children above 6 months of age. In-the-bag implantation was attempted, but when technically not possible, sulcus implantation was done. Intracameral 0.1 ml 0.5% moxifloxacin was injected in anterior chamber along with 0.3 ml sterile air. Single 10-0 nylon suture was applied to close the incision in all children below 2 years. In older children the incisions were sutured if wound integrity was doubtful. Subconjunctival depot of 0.25 ml 0.4% dexamethasone and 0.25 ml 4% gentamicin was given. The eyes were bandaged for 24 h, and 0.3% gatifloxacin + 1% prednisolone acetate 6 t/d, 0.3% tobramycin 4 t/d, and 1% cyclopentolate 2t/d was given for 4 weeks in tapering doses. The children also received oral amoxicillin (40 mg/kg/day) + clavulanic acid (10 mg/kg/day) in divided doses for 1 day preoperatively and 4 days after surgery along with prednisolone 1.5 mg/kg for 3 days preoperatively and 2 weeks postoperatively with 1 week taper. This is our standard regimen in pediatric cataract surgery.

Additional precautions in ISBC were separate trolley, instruments, and viscoelastic and irrigating solutions for both the eyes along with repeat scrubbing and gowning by surgeon and assistants.

The patients were admitted 12 h prior to surgery. Postoperatively, the patients were admitted for 3–4 days in DSBC and 4–5 days in ISBC. Follow-up was done every day for 3 days, at 2 weeks, and at 6 weeks. Refractive assessment was done at 6 weeks. Children planned for DSBC were given a 4-week appointment for the second eye surgery.

Central tendency and degree of dispersion of continuous variables were expressed as mean and standard deviation for both the groups (ISBC and DSBC). The difference between the two groups was analyzed with independent t-test and the level of significance was taken as 95% or $P < 0.05$. The Statistical Package for the Social Sciences (SPSS) Version 17.0 (IBM, New York, NY, USA) was used for statistical analysis.

Results

The results are summarized in Table 1. A total of 47 patients (94 eyes) were included in the ISBC group and 52 patients to the DSBC group. Eleven patients (21.1%) in the DSBC group did not return for the second eye surgery and also could not be contacted. They probably did not get the second eye operated or got operated elsewhere. Thus, 47 patients (94 eyes) in the ISBC group and 41 (82 eyes) in the DSBC group were taken up for comparison. The median age of patients in the ISBC group was 4 years (range: 3 months–12 years) and in the DSBC group was 3 years (range: 3 months–12 years). The median interval between the surgeries of the two eyes in the DSBC group was 8 weeks (range: 4–73 weeks).

The age of children in the two groups was similar ($P = 0.445$). ISBC group patients had 43.2% fewer hospital visits, 39.4% lesser duration of hospital stay, spent 36.6% lesser (excluding
the cost of implants), and occupied the OR for 39.0% lesser duration compared to DSBC patients. All these differences were statistically significant ($P < 0.001$). Eight eyes in both the groups were left aphakic as they were below 6 months of age which is our cut off for the implant. They were not included in the calculation of refractive outcome. Heparin-surface-modified hydrophilic acrylic IOL was our first choice.\cite{18,19} Those unable to afford this were implanted hydrophobic acrylic lens with square edge. The refractive outcomes in both the groups were comparable at 6 weeks ($P = 0.916$ for the eye operated first and $P = 0.814$ for the eye operated later).

There were no major complications related to anesthesia in either group. Four patients (8.5%) in the ISBC group and 5 patients (12.1%) in the DSBC group had minor complications (such as delayed recovery time), and these were comparable in both the groups.

**Discussion**

The fewer visits and smaller duration of stay are obvious in the ISBC group; however, they were not 50% of the DSBC group as some of visits for both the eyes overlapped in the latter group. Furthermore, being extra cautious, the children were kept for at least 1 extra day in the hospital in the ISBC than when a single eye had been operated upon. These observations not only meant lesser financial burden for the family but also lesser days off from workplace for the working parents.

While calculating the costs, we excluded the cost of the IOL as its choice depended on the patient and introducing it in the calculations would unnecessarily make the groups heterogeneous. However, the other expenses including the cost of GA remain constant. Our facility has fixed operation and anesthesia charges irrespective of the one eye or both eyes being operated. It is not inclusive of intraoperative consumable items. It is obvious that the DSBC children spent significantly more than ISBC ones. Similar results are reported by other researchers.\cite{1,4,5}

The significant difference in time spent in the OR is because the majority time is spent in induction and recovery from GA. Lesser overall duration in the OR means significantly better utilization of our limited resources where GA waiting lists run in several weeks. This is also reflected in the observation that the time interval between the two eye surgeries (in DSBC group) though intended to be 4 weeks but was actually about 8 weeks with a large variability (range 4-73 weeks). We attributed this to delayed follow-ups due to ignorance and financial limitations of the parents. Some children received delayed GA fitness for the second surgery. Eleven out of 52 (21.1%) did not turn up for the second eye surgery after the first procedure. The mean age of these patients who did not return was 4.20 ± 2.54 years. These unnecessary delays at this critical age would be responsible for significant interprocedural anisometropia, amblyopia, and compromised binocular development of these children. This problem can be considered unique to illiterate in the developing world. Days away from work for the parents and from school for the children, though not calculated, are expected to be fewer in case of ISBC. These issues and the parent’s anxiety associated with the dual procedure may be overcome by ISBC. The issue of direct and indirect benefits associated with shorter stay in the hospital has been studied in detail in relation to several other diseases. It has been shown that there are lesser financial burden, better health-related quality of life, and no adverse effects of shorter hospital stay.\cite{30,32} It would, however, be interesting to study these on a larger scale in children (and their families) undergoing intraocular surgeries.

The minor complications related to GA were comparable in the two groups. Although the sample size is too small to draw farfetched conclusions, dual anesthesia disadvantage in DSBC is probably offset by the longer duration of anesthesia in ISBC.

Previous studies have talked about better refractive and visual outcome in deferred procedures.\cite{3} We have shown by our results that, by the current IOL calculation methods, the refractive outcome is comparable in both the groups and one does not need to defer the second eye surgery for this reason.

This is the first such comparative study from the Indian Subcontinent and the largest in terms of number of eyes recruited (PubMed search). It is also the first such report from a government medical university of a developing country. These observations could have significant implications for a developing country and more so for the patients coming to a government medical facility who are primarily from the economically weaker section of the society.

The reluctance for ISBC among the treating surgeons is probably because of lack of confidence in sterilization procedures and fear of the devastating complication of bilateral endophthalmitis.\cite{2,22} The fear is real, but with modern operating procedures and effective antibacterial drugs can be gradually overcome, especially since the financial and clinical implications are significant.\cite{5} Treating the two eyes as separate, observing stricter asepsis, and being extra vigilant in the postoperative period are essential for this switchover.
An additional day in the hospital postoperatively may also be recommended.

The study has some limitations; the sample size is much smaller than would be required to draw conclusions about the rare events being considered. The assessment of refractive outcome is less than ideal. A comparison of interocular difference in the two groups would be more logical as an attempt is usually made to increase the accuracy of IOL power calculation in the second eye in DSBC. Considering the 6-week follow-up as the last for this study, we are likely to have missed the delayed complications related to the interventions. The choice of IOL is unlikely to affect the short-come outcomes being studied; however, it may be a confounding factor for analysis postoperative inflammation.

However, the issues of hospital visits, duration of stay, and cost of procedure and OR efficiency have been adequately addressed. Refractive outcome, anesthesia-related issues, and possible psychological advantage to the parents have also been addressed to some degree.

Conclusion

It is concluded that bilateral single sitting cataract surgery in children seems logical, cost-effective, and without any significant disadvantages when performed with adequate precautions before, during, and after the procedure.

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Conflicts of interest
There are no conflicts of interest.

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