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Cost of Intraocular Lens versus Contact Lens Treatment after Unilateral Congenital Cataract Surgery in the Infant Aphakia Treatment Study at Age 5 Years

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Purpose: To analyze differences in the cost of treatment for infants randomized to primary intraocular lens (IOL) implantation versus optical correction with a contact lens (CL) after unilateral cataract surgery in the Infant Aphakia Treatment Study (IATS).

Design: Retrospective cost analysis of a prospective, randomized clinical trial based on Georgia Medicaid reimbursement data as well as actual costs of supplies used during the study, adjusted for inflation.

Participants: The IATS is a multicenter (n = 12), randomized clinical trial comparing the optical treatment of aphakia with either primary IOL implantation (n = 57) or CL correction (n = 57) in 114 infants with unilateral congenital cataract.

Intervention: One hundred fourteen infants underwent unilateral cataract surgery and were either corrected optically by primary IOL implantation at the time of surgery or were corrected with a CL after surgery.

Main Outcome Measures: The mean cost of cataract surgery and all additional surgeries, examinations, and supplies used up to 5 years of age.

Results: The 5-year treatment cost of an infant with a unilateral congenital cataract corrected optically with an IOL was $27 090 versus $25 331 for a patient treated with a CL after initial cataract surgery. The total cost of supplies was $3204 in the IOL group versus $7728 in the CL group.

Conclusions: Unilateral cataract surgery in infancy coupled with primary IOL implantation is approximately 7% more expensive than aphakia and CL correction. Patient costs are more than double with CL versus IOL treatment. *Ophthalmology 2014;■:1–5 © 2014 by the American Academy of Ophthalmology.*

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The Infant Aphakia Treatment Study (IATS) was a multicenter, longitudinal, randomized clinical trial that evaluated the visual outcomes of 2 treatments for infants that underwent unilateral cataract surgery between 28 days and 7 months of age. All infants enrolled (n = 114) underwent unilateral cataract surgery and were assigned randomly to 1 of 2 treatment groups. In one treatment group (n = 57), the infants were corrected optically by primary intraocular lens (IOL) implantation at the time of cataract surgery. In the second group (n = 57), they were corrected optically by an aphakic contact lens (CL) within the first postoperative week. At 1 year of age, the infants had their vision tested by a travelling examiner via grating acuity. The vision was assessed again at 4.5 years of age by a traveling, masked examiner using the Ambylopia Treatment Study (ATS)-HOTV algorithm.[1] At both points, the cumulative data revealed no significant difference in the median visual acuity in the treated eyes between the 2 groups.[2,3]

Although there was no clear advantage to either treatment arm when comparing final visual outcomes, it is important to assess the financial impact of each treatment as well. This was carried out previously in a study using data of all patients at 12 months. At that time, primary IOL implantation was 37.5% (approximately $4000) more expensive per patient than treatment with CL. The increased cost in the IOL treatment group was attributed primarily to the higher cost associated with the patient's initial cataract surgery, as well as the higher frequency of additional surgeries. It was also noted that the average cost of supplies was 3 times higher in the CL group ($1600 per patient) versus the IOL group ($535 per patient).[4]

Despite the difficulties in analyzing data of this type because of differing billing codes used by physicians and institutions as well as a wide range of payments for the same services depending on the insurance carrier and the state

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where the service was rendered, important economic data can be gleaned from a large clinical trial in which the same cohort of patients are followed up longitudinally. In this study, patient retention was nearly 100%, with only 1 patient not undergoing vision assessment at 4.5 years of age. Because vision in the IOL group was not better than that in the CL group, it is important to determine if the cost advantage found at 1 year of age persisted at 5 years of age. As a result, we retrospectively estimated the costs incurred by the IATS at 5 years of age based on the payment structure of the same third-party payer (Georgia Medicaid) used in the 1-year study. All office-based care and all additional surgical services performed in the subsequent 4 years were included. In addition, supply costs based on actual invoiced expenditures were included in the total and were evaluated as a subset of data, because these are costs typically borne by the patients and their families. Supply costs are of particular interest because, although the cost of a particular treatment to a third-party payer may be more favorable, that same treatment may not be more cost effective to the patient and his or her family because of the extra out-of-pocket costs they incur.

Methods

The IATS was a National Eye Institute (National Institutes of Health)−sponsored, multicenter clinical trial that was approved by the respective institutional review boards at all sites. In addition, this study was performed in accordance with the Health Insurance Portability and Accountability Act. The IATS is registered with clinicaltrials.gov (NCT 00212134) and this research adhered to the tenets of the Declaration of Helsinki. The off-label research use of the AcrySof SN60AT and MA60AC IOL (Alcon Laboratories, Fort Worth, TX) is covered by United States Food and Drug Administration investigational device exemption G020021. Inclusion criteria of the IATS were the following: the presence of a visually significant cataract in 1 eye and an age at surgery of 28 days to younger than 7 months. A complete list of other inclusion and exclusion criteria can be found in previously published IATS articles.[5] Data in this analysis included costs incurred at up to 5 years of age.

Financial data were collected from all 12 sites involved in the IATS. However, because of the diverse nature of payer coverage, and to maintain consistency with data reported at an earlier end point, we applied the costs of a single payer, Georgia Medicaid, to the office visits, procedures performed, and treatments rendered. Supply expenses included the costs of CLs, spectacles, and occlusive patches. The cost for CLs is based on a the annual mean number of Silsoft (Valeant Pharmaceuticals, Lynchberg, VA) CLs used per study year, which were all invoiced and paid for through the clinical coordinating center (Emory University). Our data were collected and broken down into 3 groups for ease of comparison and interpretation: office visits, surgeries, and supplies. Surgical procedures of all types and for all indications were included together, regardless of indication and procedure performed. More detailed data on additional surgeries and adverse events can be found in other publications.[3] The cost of office visits was based on the number and type of visits mandated by the study protocol, not by actual visit number. The cost of supplies is the total cost of CLs, glasses, and patches for each treatment group. Finally, all data were adjusted based on the Consumer Price Index (CPI) and were adjusted per study year accordingly. Our data are reported in 2013 dollars.[6]

Surgery

The cost of surgical procedures was based on Georgia Medicaid payments for each current procedural terminology code from the July 2009 Georgia Medicaid fee schedule, and these were adjusted based on the CPI for the year in which the procedure was performed. A discount for multiple procedures performed on the same day was not taken into account, and we assumed a 100% reimbursement rate as allowed by Georgia Medicaid for all procedures included. Surgical procedures performed in years 2 through 5 included membranectomy (66830), glaucoma surgery (65850, 66625, 65865), IOL exchange (66986), and strabismus surgery (67312). There were 3 secondary IOLs placed (66985) in 3 patients from the CL group in years 2 through 5 as well. Costs are based on the absolute number of procedures and not per patient, because some patients had the same surgery more than once. The cost of postoperative medication was not factored into our calculations.

Office Visits

In years 2 through 4, the study protocol called for patients to be seen 4 times in each year, with 1 of those visits requiring a comprehensive examination with pupil dilation and cycloplegic refraction. We used the office based eye code 92012 for follow-up examinations and 92014 for comprehensive examinations. In addition, the code 92060 (sensory motor examination) was included based on the rates of strabismus in each arm at the conclusion of the study.[3] In year 5, there were 3 required visits as the study protocol changed from evaluation at certain postoperative dates to a chronological age basis. Beginning after age 4 years, the patients were seen at ages 4.25, 4.5, and 5.0 years. All of these were comprehensive examinations, and the code 92014 with the corresponding rate of 92060 was used for calculation in this year.

Supplies

Contact lens cost data were tabulated at the clinical coordinating center. All CL invoicing was carried out through this center because the majority of patients in the CL arm (n = 46) were treated with Silsoft CLs (Valeant Pharmaceuticals, Lynchberg, VA). Eleven patients were treated with rigid gas permeable lenses, and because these data were not readily available, they were excluded. The average number of Silsoft lenses then was extrapolated to all patients in the CL arm for that study year less any patient(s) that underwent secondary IOL placement.

The cost of glasses across the 12 sites was somewhat more variable. In addition, detailed paperwork was not necessarily submitted to the data coordinating center or even to the provider because glasses prescriptions were not required to be filled at 1 specific optical shop. As such, our data were averaged from the data sets of 4 sites where it was readily attainable because all patients used the same optical shop for the entire duration of the study (Miami, Florida; Atlanta, Georgia; Nashville, Tennessee; Portland, Oregon); these data then were averaged and extrapolated for the total number of patients in that arm for that study year (n = 57 in each IOL and CL arm). There was an equal amount of data in the IOL arm (n = 17) and CL arm (n = 17) obtained.

The cost of a box of patches is also variable, but to a lesser degree. The price per box was based on invoicing from the manufacturer for one brand (Ortopad; Eye Care and Cure, Tucson, AZ) to a physician's office (Stacey J. Kruger, Miami, FL). The total number of patches dispensed was calculated based on 1 patch for each day between study-mandated follow-up visits plus 1 extra box, to account for loss and use of more than 1 patch in the course of a day. The number of boxes distributed to the patient was based on 50 patches per box.