Biodegradable Valve Ring Favorable in Short Term

BY DAMIAN McNAMARA
Miami Bureau

FORT LAUDERDALE, FLA. — Lower short-term morbidity and more favorable long-term outcomes are among the advantages of a biodegradable ring used for mitral valve repair in children with rheumatic disease, compared with a traditional rigid ring, according to a study.

Rheumatic mitral valve disease in children is progressive and surgery is the treatment of choice, Dr. Afksendiyos Kalangos said at the annual meeting of the Society of Thoracic Surgeons. To gauge the impact of a biodegradable ring on short- and long-term outcomes for these children, Dr. Kalangos and his associates assessed 220 valve repairs at the University Hospital of Geneva.

The single surgical team's experience included 143 girls and 77 boys with a mean age of 12 years (and a range of 2-16 years). The valve repairs were performed from January 1994 to March 2007. The majority of patients—198, or 90%—had predominant mitral valve deficiency.

"Mitral valve repair can be performed in a significant number of young rheumatic patients, depending on surgical expertise," said Dr. Kalangos, chairman of the division of cardiovascular surgery and the unit of pediatric cardiology, University Hospital of Geneva.

The surgeons also simultaneously addressed aortic valve insufficiency in 57 patients and tricuspid valve insufficiency in 51 patients.

Echocardiography was performed at 1 week, 3 months, and 6 months postoperatively, and then annually. Complete data were available for 213 participants.

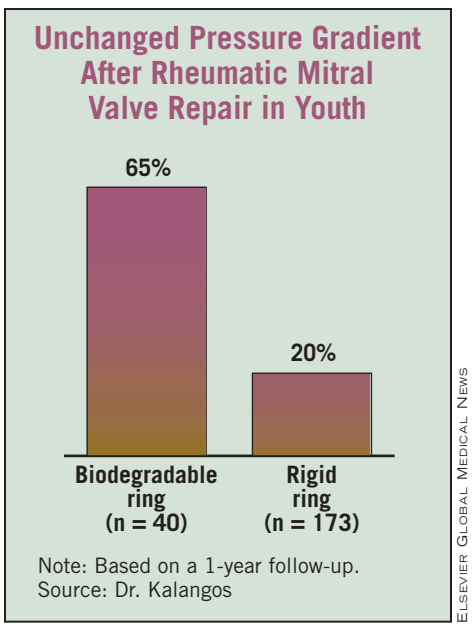
A total of 173 participants received a rigid annuoplasty ring (the Carpentier-Edwards ring, manufactured by Edwards Lifesciences LLC), until 2003. Thereafter, another 40 children received a biodegradable annuoplasty ring (manufactured by Bioring SA). The biodegradable ring has an investigational status with the Food and Drug Administration.

One immediate mitral valve repair failure led to a reoperation, Dr. Kalangos said. There was one late death from septicemia at 9 months. There were no hospital deaths or major postoperative morbidities.

There have been five reoperations during a mean follow-up of 76 months. "All reoperations so far were in the Carpentier-Edwards group," Dr. Kalangos said. Dr. Kalangos and his colleagues are royalty holders and consultants for Bioring SA.

The mean gradient was significantly lower for the biodegradable ring, compared with the rigid ring, at follow-up: 5.2 mm Hg versus 2.8 mm Hg at 7 days, 6.2 mm Hg versus 3.1 mm Hg at 6 months, and 7.0 mm Hg versus 3.3 mm Hg at 1 year after the procedure.

The researchers also found a statistically significant difference in the percentage of patients who had an unchanged gradient during the first year: 26 of 40 (65%) biodegradable ring patients and 35 of 173 (20%) of the rigid ring participants.



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Ask the Expert

Managing Arthritis-Associated Uveitis in Children

Chronic anterior uveitis is a serious extra-articular manifestation of juvenile idiopathic arthritis. The inflammatory eye disease is associated with progressive ophthalmologic morbidity, including vision-threatening complications such as cataract, band keratopathy, hypotony, and glaucoma.


C. ELGA RABINOVICH, M.D.

The diagnosis and treatment of chronic uveitis presents a significant clinical challenge to both pediatric rheumatologists and ophthalmologists. As with the articular symptoms of juvenile idiopathic arthritis (JIA), the course of the inflammatory eye disease is often persistent, with periods of improvement and flares. Symptoms are often nonspecific—such as pain, light sensitivity, and blurred vision—and they only present once vision complications have already occurred. Additionally, chronic uveitis can be refractory to topical and systemic anti-inflammatory therapies.

There is a dearth of controlled clinical trials in the pediatric uveitis literature, which is attributable in part to the historical lack of standardization of disease and outcome measures, according to Dr. C. Elga Rabinovich, cochief of pediatric rheumatology at Duke University Medical Center, Durham, N.C.

Fortunately, the 2005 publication of the Standardization of Uveitis Nomenclature (SUN) working group consensus statement for reporting clinical data has paved the way for more robust, informative investigations, she said (Am. J. Ophthalmol. 2005;140:509-16).

In this month's column, Dr. Rabinovich discusses the prevalence, risk factors, and management of JIA-associated uveitis, as well as recent research considerations.

Rheumatology News: How common is uveitis among children with JIA?

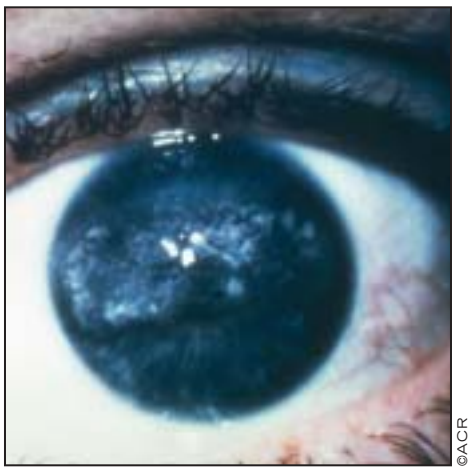
Dr. Rabinovich: Firm numbers are hard to come by as population-based studies are few. In addition, the change of nomenclature in the late 1990s—juvenile idiopathic arthritis (JIA) vs. juvenile rheumatoid arthritis (JRA)—with the inclusion of a larger number of chronic childhood arthritis subtypes, makes comparison of prevalence numbers difficult. For example, one population study of 88 children with JRA from Olmsted County, Minn., estimated an incidence of 3.4% (Graefes Arch. Clin. Exp. Ophthalmol. 2005;243:217-21), which is a much lower figure than reported by others. In a recent study out of the United Kingdom, 24 out of 130 (18%) children with JIA developed uveitis (Br. J. Ophthalmol. 2006;90:1549-50), and in an Australian study, 27 out of 71 (38%) children with JRA developed the condition (Can. J. Ophthalmol. 2004;39:614-20). A meta-analysis of the literature examining prevalence among children with JRA that included predominantly non–population-based retrospective reports between 1980 and 2004 found a cumulative incidence of 8.3% (Graefes Arch. Clin. Exp. Ophthalmol. 2006;244:281-90). A search of a database in Toronto yielded 1,081 children with JIA with an incidence of uveitis of 13.1% (Arthritis Rheum. 2007;56:647-57). Thus, incidence is difficult to estimate, but it is somewhere between 8% and 30%.

RN: Is there an increased risk associated with any specific type of JIA?

Dr. Rabinovich: Having pauciarticular or polyarticular JIA, a positive antinuclear antibody (ANA), and age of JIA onset younger than 6 years are the widely recognized risk factors for development of uveitis. Additionally, female gender has been identified as a risk factor for children with pauciarticular JIA.

RN: When, how frequently, and by what means should JIA patients be screened?

Dr. Rabinovich: Guidelines for screening were published by the American Academy of Pediatrics (Pediatrics, 2006;117:1843-5).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The eye of a child with JIA uveitis shows degenerative band keratopathy.

For children with pauciarticular or polyarticular JIA who are 6 years old or younger at diagnosis and ANA-positive, screening is recommended every 3 months for the first 4 years of disease. If they do not develop uveitis in this time frame, then they can be screened every 6 months for the next 3 years, followed then by yearly eye exams. For children who are 6 years or older at time of diagnosis and ANA-positive, the screening recommendations are every 6 months for the first 4 years, then yearly. Children younger than 6 years at diagnosis who are ANA-negative should be screened every 6 months for the first 4 years, then annually thereafter, and ANA-negative children older than 6 years at diagnosis should be screened annually. Finally, the guidelines recommend yearly ophthalmologic exams for children with systemic onset JIA.

RN: What is the current standard of care?

Dr. Rabinovich: Topical steroid drops and mydriatics are recognized as first-line therapies. For persistent uveitis (defined as uveitis present longer than 3 months), most experts advocate systemic therapy. In times of severe acute inflammation, systemic steroid therapy or periocular steroid injections may be needed. The most common systemic therapy used for treatment of uveitis is weekly methotrexate. Other medications such as mycophenolate mofetil, cyclosporin A, or chlorambucil also have been used. For methotrexate-resistant uveitis, many physicians are now using anti–tumor necrosis factor–α (anti-TNF-α) therapy. The most common anti-TNF-α agent reported in the literature for treatment of persistent uveitis is infliximab, although there are now some case series of successful treatment with adalimumab. The studies on the use of anti-TNF-α therapies in JIA-associated uveitis to date are mainly uncontrolled retrospective case series, and there are many unanswered questions, including optimal dosing regimen and long-term efficacy. Prospective controlled studies are needed to define better the role of TNF-α blockade in the treatment of pediatric uveitis. In this regard, the Childhood Arthritis and Rheumatology Research Alliance has funded a prospective registry of infliximab use in pediatric uveitis, using the SUN definitions for uveitis disease activity, for which I am the primary investigator. The trial is currently enrolling patients.

By Diana Mahoney, New England Bureau

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