Long-term follow-up of intravitreal bevacizumab for the treatment of pediatric retinal and choroidal diseases

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Long-term follow-up of intravitreal bevacizumab for the treatment of pediatric retinal and choroidal diseases

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PURPOSE To describe the long-term outcomes of intravitreal bevacizumab (IVB) for the treatment of pediatric retinal and choroidal diseases.

METHODS This was a multicenter, retrospective, consecutive case series of patients <18 years of age treated with IVB from 2005 to 2013. Primary outcome measures included visual acuity and central macular thickness at 12 months’ follow-up.

RESULTS A total of 95 eyes of 90 patients (average age, 8.7 years [range, 0.3-17 years]) were included, in which 352 injections (average, 3.7/eye) were administered for choroidal neovascular membrane (CNVM, n = 35), Coats disease (n = 35), familial exudative vitreoretinopathy (FEVR, n = 13), cystoid macular edema (CME, n = 6), and other (n = 6). Mean follow-up was 679 ± 581 days. IVB was used as monotherapy in 27 eyes and as part of combination therapy in 68. Mean Snellen equivalent visual acuity improved from 20/224 at baseline to 20/120 at 6 months (P = 0.034) and 20/108 at 12 months (P = 0.005). Mean central macular thickness improved from 426 µm to 349 µm at 6 months (P = 0.025) and 340 µm at 12 months (P = 0.002). Statistically significant visual acuity gains at 12 months were achieved in patients with CNVM (P = 0.009) but not in eyes with CME (P = 0.06), Coats disease (P = 0.15), or FEVR (P = 0.93). Adverse effects included ocular hypertension in 8 eyes and worsening tractional retinal detachment in 3 eyes.

CONCLUSIONS Patients receiving IVB as part of the treatment for pediatric retinal and choroidal diseases experienced significant visual acuity gains and reductions in central macular thickness. IVB was generally well tolerated, although safety concerns persist. (J AAPOS 2015;19:541-548)

Vascular endothelial growth factor (VEGF) is a key mediator of angiogenesis during normal fetal ocular development and also plays a critical role in retinal neovascularization and vascular permeability in a host of ocular diseases.1-6 Pathologic ocular neovascularization and vascular exudation are seen as part of many pediatric retinal and choroidal diseases, including retinopathy of prematurity (ROP), Coats disease, familial exudative vitreoretinopathy (FEVR), and choroidal neovascularization of various etiologies.1,2,7-32 Recent work has investigated the possible role of VEGF in the pathogenesis of these condition, and reports have demonstrated potential efficacy of anti-VEGF therapy.1,2,7-32 Limited data exists, however, regarding the long-term use of these agents for pediatric conditions other than ROP.2,7

Our group’s preliminary study of intravitreal bevacizumab (IVB) for pediatric retinal and choroidal diseases other than ROP found that IVB reduced vascular leakage and temporarily regressed pathologic neovascularization of the choroid, retina, and iris in conditions such as Coats disease, FEVR, and choroidal neovascularization.1 Here we present our long-term follow-up data, representing the largest series of children treated with IVB for pediatric retinal and choroidal conditions other than ROP.

Subjects and Methods

Institutional review board approval was obtained from the University of Miami Miller School of Medicine and University of Cincinnati College of Medicine. CPT code 67028 was used to identify patients under the age of 18 receiving an intravitreal injection between January 1, 2005, and January 1, 2013. The
medical records of consecutive patients who received off-label IVB for the treatment of retinal and choroidal diseases at the Bascom Palmer Eye Institute and Cincinnati Eye Institute were retrospectively reviewed. Inclusion criteria included administration of IVB, age <18 years, and an absence of a history of retinopathy of prematurity. Eyes presenting with visual acuity of light perception or worse were excluded. Of 95 eyes than ROP. Of these, 8 eyes with presenting visual acuity over the 8-year study period, 103 eyes of 98 patients were retrospectively reviewed. Inclusion criteria included Bascom Palmer Eye Institute and Cincinnati Eye Institute IVB for the treatment of retinal and choroidal diseases at the medical records of consecutive patients who received off-label, age

Patients generally received IVB during examination under anesthesia. Older, cooperative patients were offered IVB in an office-based setting. Following a povidone-iodine preparation, and using sterile technique, sterile gloves, and a lid speculum, 1.25 mg/0.05 mL of bevacizumab was administered by a vitreoretinal surgeon intravitreally via the pars plana using a 30- or 32-gauge half-inch needle. In one case, bevacizumab was administered intracameral.

Over the study period, time domain optical coherence tomography (OCT; Zeiss Stratus OCT 3; Carl Zeiss Meditec, Dublin, CA), spectral domain OCT (Cirrus OCT; Carl Zeiss Meditec, Dublin, CA) and spectral domain OCT (Heidelberg Spectralis, Heidelberg Engineering GmbH, Heidelberg, Germany) were used to measure central macular thickness using machine-specific proprietary software. Whenever possible, the same OCT machine was used for each individual patient to allow for proper comparison between visits. IOP recordings were measured using the Tonopen XL (Reichert Ophthalmic Instruments, Depew, NY).

Visual acuity was tested by age-appropriate measures, including Teller acuity cards, Allen picture cards, and Snellen visual acuity charts. For data analysis, Snellen results were converted to logarithm of the minimum angle of resolution (logMAR) equivalents. Visual acuities that were too poor or unable to be assessed using standard measures were converted using the following conventions: blinks to light in infants (20/200), fixes and follows in young children (20/200), hand motions (20/20000), no fix and follow (20/20000), and light perception (20/200000).

Statistical analyses were performed using SPSS Statistics for Windows, version 22 (IBM Corp, Armonk, NY). The paired \( t \) test was used to statistically evaluate changes in logMAR visual acuity, central macular thickness, intraocular pressure, number of glaucoma medications required to control intraocular pressure, systolic blood pressure, and diastolic blood pressure from baseline to 6 months, 12 months, and final follow-up. \( P \) values of <0.05 were considered statistically significant. Continuous variables are reported as mean and standard deviation.

**Results**

Over the 8-year study period, 103 eyes of 98 patients were treated for pediatric retinal and choroidal diseases other than ROP. Of these, 8 eyes with presenting visual acuity of light perception or worse were excluded. Of 95 eyes (51 right eyes [54%]) of 90 patients (54 males [60%]) included in the final analysis, average patient age was 8.7 years (range, 0.3-17 years). A total of 352 injections were administered (average, 3.7 per eye; range, 1-17). Average follow-up was 679 ± 581 days, with 81/95 eyes (85%) having at least 6 months’ follow-up and 60/95 eyes (63%) having at least 12 months’ follow-up (Table 1).

Clinical diagnoses included choroidal neovascular membrane (n = 35), Coats disease (n = 35), cystoid macular edema (n = 6), FEVR (n = 13), juvenile xanthogranuloma (n = 2), vitreous hemorrhage (n = 1), persistent fetal vasculature (n = 1), retinal capillary hemangioma (n = 1), and diffuse choroidal hemangioma (n = 1). In 78 eyes (82%) specific indications for IVB administration included intraretinal fluid/exudation or subretinal fluid/exudation; in 17 eyes (18%), neovascularization or hemorrhage (Table 2). At presentation, 89 eyes (94%) were phakic; 5 eyes (5%), pseudophakic; and 1 eye (1%), aphakic. IVB was used as monotherapy in 27 eyes (28%) and as part of combination therapy in 68 eyes (72%), which included sub-Tenon’s or intravitreal corticosteroid therapy (n = 29), diode laser ablative therapy (n = 52), or pars plana vitrectomy (PPV, n = 18).

As an entire group, mean Snellen equivalent visual acuity improved from 20/224 at baseline to 20/120 at 6 months \( (P = 0.034) \), 20/108 at 12 months \( (P = 0.005) \), and 20/156 at final follow-up \( (P = 0.096) \). As an entire group, mean central macular thickness improved from 426 \( \mu \)m at baseline to 349 \( \mu \)m at 6 months \( (P = 0.025) \), 340 \( \mu \)m at 12 months \( (P = 0.002) \), and 344 \( \mu \)m at final follow-up \( (P = 0.005) \). Visual acuity and central macular thickness outcomes are provided in Tables 3 and 4. No patients with CNVM, Coats disease, FEVR, or CME required enucleation or evisceration.

**Choroidal Neovascular Membrane**

A total of 35 eyes of 32 patients were treated for CNVM, etiologies of which included choroidal rupture (n = 6), idiopathic (n = 5), Best disease (n = 4), combined hamartoma of the retina and retinal pigment epithelium (RPE, n = 4), noninfectious posterior uveitis (n = 4), optic nerve head drusen (n = 3), choroidal osteoma (n = 2), toxoplasmosis (n = 2), Aicardi syndrome (n = 1), astrocytic hamartoma (n = 1), congenital hypertrophy of the RPE (n = 1),

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Baseline (n)</th>
<th>6 months (n)</th>
<th>12 months (n)</th>
<th>Average, months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNVM</td>
<td>35</td>
<td>27</td>
<td>21</td>
<td>19.9</td>
</tr>
<tr>
<td>Coats disease</td>
<td>35</td>
<td>30</td>
<td>20</td>
<td>23.4</td>
</tr>
<tr>
<td>FEVR</td>
<td>13</td>
<td>13</td>
<td>9</td>
<td>29.4</td>
</tr>
<tr>
<td>CME</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>30.6</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>26.7</td>
</tr>
<tr>
<td>All eyes</td>
<td>95</td>
<td>81</td>
<td>60</td>
<td>22.9</td>
</tr>
</tbody>
</table>

*CNME, cystoid macular edema; CNVM, choroidal neovascular membrane; FEVR, familial exudative vitreoretinopathy.*
Table 2. Primary indication for treatment with intravitreal bevacizumab

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Intraretinal or subretinal fluid/exudation</th>
<th>Neovascularization or vitreous hemorrhage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNVM</td>
<td>33</td>
<td>2</td>
</tr>
<tr>
<td>Coats disease</td>
<td>35</td>
<td>0</td>
</tr>
<tr>
<td>FEVR</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>CME</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>All eyes</td>
<td>78</td>
<td>17</td>
</tr>
</tbody>
</table>

CME, cystoid macular edema; CNVM, choroidal neovascular membrane; FEVR, familial exudative vitreoretinopathy.

Table 3. Mean Snellen equivalent best-corrected visual acuity by age-appropriate measures at baseline, 6 months, and 12 months

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Mean Snellen equivalent best-corrected visual acuity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>CNVM</td>
<td>20/145</td>
</tr>
<tr>
<td>Coats disease</td>
<td>20/390</td>
</tr>
<tr>
<td>FEVR</td>
<td>20/200</td>
</tr>
<tr>
<td>CME</td>
<td>20/448</td>
</tr>
<tr>
<td>All patients</td>
<td>20/224</td>
</tr>
</tbody>
</table>

CME, cystoid macular edema; CNVM, choroidal neovascular membrane; FEVR, familial exudative vitreoretinopathy.

Table 4. Mean central macular thickness at baseline, 6 months, and 12 months

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Mean central macular thickness, μm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>CNVM</td>
<td>393</td>
</tr>
<tr>
<td>Coats disease</td>
<td>499</td>
</tr>
<tr>
<td>FEVR</td>
<td>356</td>
</tr>
<tr>
<td>CME</td>
<td>492</td>
</tr>
<tr>
<td>All patients</td>
<td>426</td>
</tr>
</tbody>
</table>

CME, cystoid macular edema; CNVM, choroidal neovascular membrane; FEVR, familial exudative vitreoretinopathy.

treatment (n = 1) triamcinolone acetonide were used in an additional 3 eyes. In the remaining 27 eyes, the disease course was completely stabilized with laser and IVB alone. An example of a patient with Coats disease treated with laser ablation and IVB is shown in Figure 2.

Final visual acuity improved or was stable in 27 eyes and worse in 8 eyes. Foveal exudation (presence of subretinal lipid exudation at the fovea on fundus photography or OCT) was present in 30 eyes at baseline and was significantly correlated with worse mean visual acuity outcomes at 12 months (20/372 vs 20/30, P = 0.004) and final follow-up (20/364 vs 20/20, P = 0.001).

Familial Exudative Vitreoretinopathy

Thirteen eyes of 11 patients were treated with IVB for FEVR. Patients were staged, using the Pendergast and Trese classification, as follows: 2 (n = 4), 3A (n = 3), 3B (n = 5), and 4B (n = 1). An average number of 3.5 IVB injections per eye were performed (median, 3; range, 1-9).

All 7 eyes with stage 2 and 3A disease were treated with diode-laser ablative therapy in addition to IVB. In addition, 4/7 of these eyes received sub-Tenon’s triamcinolone acetonide injections: each eye achieved stabilization without need for scleral buckle surgery or PPV.

All 6 eyes with stage 3B and 4B disease received IVB as an adjunct to retinal detachment repair with scleral buckle (n = 5) and/or PPV with membrane peeling using silicone oil (n = 5) or gas tamponade (n = 1). Three of these eyes achieved stabilization of disease. However, in 3 eyes there was progression of tractional retinal detachment shortly after the administration of IVB as an adjunct to scleral buckling and indirect diode laser (2 eyes) or PPV with membrane peeling and endolaser (1 eye). The retina was successfully reattached in one of these eyes with subsequent surgery, but 2 eyes progressed to total retinal detachment and visual acuity of light perception despite further attempts at surgical intervention. An example of a patient with progression of tractional detachment after administration of IVB is shown in Figure 3. Final visual acuity was improved or stable in 9 eyes and was worse in 4 eyes.
Cystoid Macular Edema

Six eyes of 6 patients were treated for CME, etiologies of which included pars planitis (n = 2), radiation retinopathy (n = 2), central retinal vein occlusion (n = 1), and postoperative CME after glaucoma surgery (n = 1).

An average of 3.8 injections per eye (median, 1; range, 1-16) were administered. Concomitant treatment with topical corticosteroid drops (n = 4) and/or intravitreal triamcinolone acetonide (n = 3) was common. The 2 patients with pars planitis presented with neovascularization and hemorrhage for which they underwent PPV with endolaser and IVB as adjunctive therapy. Final visual acuity was improved or stable in 5 eyes and was worse in 1 eye.

Intraocular Pressure, Systemic Blood Pressure, and Adverse Events

Mean IOP at baseline was 16.0 mm Hg. Among all patients, there was no significant change in mean IOP, which at 6 months was 15.8 mm Hg (P = 0.94) and at 12 months was 15.8 mm Hg (P = 0.86). The mean number of separate glaucoma medications required by patients to control IOP at baseline was 0.063 compared to 0.137 at last follow-up visit (P = 0.034). Eight patients developed ocular hypertension (defined as IOP >30 or a need to add glaucoma drops to control IOP). Among these, 5 patients were treated with concomitant topical or local corticosteroid therapy. No patients required glaucoma surgery.

Eight eyes required surgery for visually significant cataract, either phacoemulsification with intraocular lens implantation (n = 5) or pars plana lensectomy (n = 3) during the course of treatment. Five eyes developed a cataract following PPV; the other 3 eyes had concomitant treatment with sub-Tenon’s triamcinolone acetonide injection. In no case was the cataract felt to be directly attributable to administration of IVB.

Blood pressure data was available for 18 patients at 6 months’ follow-up and 13 patients at 12 months’ follow-up. Among these patients, mean systolic blood pressure at baseline was 106 ± 16 mm Hg. Mean systolic blood pressure did not change significantly over time: 102 ± 14 mm Hg at 6 months (P = 0.22); 109 ± 13 mm Hg at 12 months (P = 0.26). Mean diastolic blood pressure was 56 ± 12 mm Hg at baseline and 59 ± 9 mm Hg at 6 months (P = 0.38). Mean diastolic blood pressure was 64 ± 9 mm Hg at 12 months (P = 0.010), which was statistically significantly higher than baseline measurements. Through 12 months’ follow-up, 1 child was measured to have a systolic blood pressure >120 mm Hg and no patients were measured to have a diastolic blood pressure >80 mm Hg.

Patients were monitored for systemic side effects and no cases of myocardial infarction, angina,
cerebrovascular accident, transient ischemic attack, or deep vein thrombosis were identified. One overweight 16-year-old girl with FEVR developed idiopathic intracranial hypertension. Magnetic resonance imaging and magnetic resonance venography revealed no evidence of venous sinus thrombosis and the patient was treated with weight loss and oral acetazolamide therapy. She did not develop visual field loss and visual acuity improved from 20/100 to 20/40 at follow-up of 5 years.

Discussion

In the current study, children receiving IVB as part of the management of pediatric retinal and choroidal conditions other than ROP achieved statistically significant visual gains and reductions in central macular thickness through 12 months’ follow-up. Choroidal neovascularization in children can arise from a wide variety of etiologies, including infection, inflammatory causes, optic nerve head anomalies, retinal dystrophies, or trauma.34,35 In many cases the cause of CNVM in children is unknown.34,35 Previous case reports and series have demonstrated the efficacy of intravitreal bevacizumab and intravitreal ranibizumab in...
the management of children with CNVM associated with toxoplasmosis, noninfectious uveitis, optic nerve coloboma, optic nerve head drusen, Best disease, choroidal rupture, and various other etiologies. In the current study, intravitreal bevacizumab was found to be beneficial in the management children with CNVM related to a wide range of ocular conditions. The majority of these patients were successfully managed with bevacizumab as single agent for treatment. In general, relatively few injections (mean, 3.6 per eye; median, 2) were required in this subset of patients, and recurrent, ongoing need for treatment was uncommon.

In some instances, CNVM in children improves with spontaneous involution; however, outcomes with observation are guarded in children presenting with visual acuity of 20/200 or worse. Laser photocoagulation and photodynamic therapy can be technically difficult to perform in children and are associated with RPE alterations and atrophy. Submacular surgery has been effective in select children with severe vision loss from subfoveal neovascularization; Sears and colleagues reported improved vision in 10 of 12 children, and Uemura and Thomas reported improved vision after surgery in 15 of 17 children. Recurrence of CNVM in both of these series, however, was common, occurring in 25%-35% of children. More recently, Kozak and colleagues retrospectively analyzed the results of 45 eyes of 39 children treated with IVB or ranibizumab for CNVM over a mean follow-up period of 12.8 months. A mean of 2.2 injections per eye were required for treatment. An improvement in visual acuity of >3 lines was seen in 22 eyes (49%), and only 1 eye had worsening of vision after treatment. In the current study, 86% of children treated with IVB for CNVM had improvement or stabilization of their vision.

Intravitreal bevacizumab is being used with increased frequency as an adjunct in the management of Coats disease. Patients in the current series presented with a wide range of ocular conditions. The majority of these patients were successfully managed with bevacizumab as single agent for treatment. In general, relatively few injections (mean, 3.6 per eye; median, 2) were required in this subset of patients, and recurrent, ongoing need for treatment was uncommon.

More recent studies have evaluated the use of IVB as an adjunct in the management of advanced Coats disease. In a case-control series in which children with stage 2B-3B Coats disease treated with IVB and ablative therapy (laser and/or cryotherapy) were matched to children treated with ablative therapy alone, Ray and colleagues found that 10 of 10 eyes treated with IVB and ablative therapy achieved full control of disease versus only 8 of 10 eyes undergoing ablative therapy alone. Zheng and Jiang retrospectively reviewed the use of IVB as initial treatment in 14 children with Coats disease (stage 2 in 1 eye, stage 3A in 9 eyes, and stage 3B in 4 eyes). All children in their series achieved full control of disease, with resolution of subretinal fluid and exudation. Patients were treated with a mean number of 2.9 IVB injections, in combination with laser, surgery, or cryotherapy, and statistically significant visual acuity gains were seen through follow-up of 24 weeks (logMAR best-corrected visual acuity of 1.50 ± 0.55 at baseline vs 1.13 ± 0.43 at 24 weeks’ follow-up [P = 0.005]). Villegas and colleagues recently demonstrated that repetitive IVB therapy in conjunction with laser ablative therapy was able to resolve exudative retinal detachments in 24 of 24 (100%) children with advanced Coats disease.

Of note in our study was the rapid progression of tractional retinal detachment seen in 3 eyes of patients with stage 3B FEVR, who were treated with IVB as an adjunct to surgery with scleral buckling and indirect diode laser (2 eyes) or PPV with membrane peeling and endolaser (1 eye). In contrast, all 7 eyes with stage 2 or 3A FEVR in our series achieved stabilization of disease with laser and IVB alone and did not develop progressive tractional retinal detachment.

Worsening of tractional retinal detachment by acute contraction of fibrovascular membranes have been reported in other pediatric retinal conditions following IVB injections. Quriam and colleagues reported the results of intravitreal pegaptanib treatment in 4 eyes with vascularly active FEVR, stage 3 or worse, despite previous treatment with laser ablative therapy and intravitreal triamcinolone acetonide. All 4 patients in this series demonstrated a rapid reduction in retinal exudation and reduced leakage on fluorescein angiography; however, 2 patients in their series developed a progression of tractional retinal detachment and associated vitreous hemorrhage within 2 months of pegaptanib injection.

Honda and colleagues reported a girl born at 23 weeks’ gestation who developed a rapid progression of tractional retinal detachment following IVB for ROP. She underwent laser ablative therapy at 10 weeks of age.
for stage 3, zone 1 ROP with plus disease but nevertheless progressed to stage 4A disease and was offered IVB as a possible alternative to PPV. The patient developed centripetal contraction of a fibrovascular membrane within 1 day of injection, which progressed to a funnel tractional detachment over a 7-day period.

Ramunasramanian and Shields reported progressive tractional retinal detachment in 3 of 8 eyes of children with advanced Coats disease treated with IVB and cryotherapy, with or without adjunctive laser. Similar phenomena have been reported in adults with severe proliferative diabetic retinopathy treated with IVB as an adjuvant to PPV.

IVB was administered for several CME-related conditions and was felt to be helpful in each, but too few eyes were treated to draw meaningful conclusions regarding efficacy.

The long-term safety of IVB is an important consideration when treating children. All children treated in this series presented with potentially blinding ocular conditions, and families were consented appropriately that the systemic effects of IVB in children are not well known. Children in this series received a full 1.25mg/0.05 mL dose of bevacizumab. Other series have used lower doses of IVB, either 0.625 mg or 0.3125 mg, with reported efficacy for ROP.

Children have physically smaller eyes than adults, but children with Coats disease and ROP also present with very high intraocular VEGF levels prior to treatment. He and colleagues reported a mean intraocular VEGF level of 2394.5 pg/mL in children with Coats disease and Sonmez and colleagues reported a median intraocular VEGF level of 3454 pg/mL in infants with actively vascular ROP. In contrast, Roh and colleagues reported a mean intraocular VEGF level of 66.8 pg/mL in adults with naive neovascular age-related macular degeneration and Park and colleagues reported a mean intraocular VEGF level of 328 pg/mL in adults with cystoid macular edema from branch retinal vein occlusion. At this time, the ideal dosing or specific intravitreal anti-VEGF agent are not known in regards to the treatment of children with pediatric retinal and choroidal diseases.

In general IVB was well tolerated with minimal side effects; however, the current study is retrospective in design and was not sufficiently powered to assess the safety profile of IVB in this patient population. In terms of ocular side effects, 3 eyes developed ocular hypertension that was felt to be attributable to IVB, and no eyes developed cataract that was felt to be attributable to IVB. No serious systemic adverse events were identified. The wide variability in the ages of children in our series made comparison of blood pressure measurements difficult. Additionally, blood pressure measurements were made in a perioperative setting, which may not be an accurate reflection of a child’s mean blood pressure over time. Nevertheless, a potentially concerning finding from the current study was that a statistically significant increase in mean diastolic blood pressure was seen at 12 months. Further prospective studies are required to elucidate if this is a valid finding.

Acknowledgments

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