Intermediate results on the use of drainage devices for paediatric glaucoma

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Abstract

Purpose: To evaluate the results and long-term complications of glaucoma drainage devices (GDD) in pediatric patients (0-15 years).

Methods: Retrospective cohort study was conducted on 17 implanted glaucoma drainage devices from July 1994 to April 2007 in 14 patients (17 eyes). In two patients (3 eyes) a Molteno GDD (MGDD) was implanted, and in 12 patients (14 eyes) an Ahmed GDD (AGDD) was used. We studied the demographic and glaucoma related patient data, as well as the probability of surgical success. The time which intraocular pressure (IOP) was controlled and the postoperative complications were also studied.

Results: Of the fourteen patients, 9 (64.28%) showed congenital glaucoma, and 5 (35.71%) aphakic glaucoma. The pre-aqueous drainage device median IOP was 29.82 mmHg (SD: 6.98), and 14.05 mmHg (SD: 7.57) postoperative. The median follow-up was 3.14 years (3 months to 8.3 years). Success of aqueous drainage device was defined as an IOP less than 21 mmHg with or without medication on the last two follow-up visits, and without severe complications or further glaucoma surgery. Using a Kaplan–Meier analysis there was success in 76%, 63% and 55% at the six months, 1–3 years and 4–8 years, respectively. The GDD was a failure in 41.17%.

Conclusions: GDDs are a good surgery option for refractory pediatric glaucoma when other surgery procedures have failed or have bad prognosis.

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Resultados a medio plazo de dispositivos de drenaje para glaucoma en pacientes pediátricos

R E S U M E N

Propósito: Evaluar los resultados y complicaciones a largo plazo de los dispositivos de drenaje para glaucoma (DDG) en pacientes pediátricos (0-15 años).

Material y métodos: Estudio retrospectivo de cohortes de 17 DDG implantadas desde julio de 1994 hasta abril del año 2007 en 14 pacientes (17 ojos). En dos pacientes (3 ojos) se implantó un DDG de Molteno (DDGM) y en 12 pacientes (14 ojos) un DDG de Ahmed (DDGA). Se han recogido datos demográficos y relacionados con la afección glaucomatósa de cada paciente. Se ha estudiado el porcentaje de éxito de la cirugía, así como el tiempo durante el cual se ha mantenido controlada la tensión desde el implante del dispositivo y las complicaciones derivadas de este.

Resultados: De los 14 pacientes, nueve (64,28%) presentaban glaucoma congénito, y cinco (35,71%) glaucoma afáquico secundario a cirugía de catarata. La media de la presión intraocular (PIO) preoperatoria fue de 29,82 mmHg (DS: 6,98). La media de la PIO posquirúrgica fue de 14,05 mmHg (DS: 7,57). La media del seguimiento ha sido de 3,14 años (3 meses-3,8 años). Se ha considerado como éxito mantener, en las dos últimas revisiones, la PIO igual o por debajo de 21 mmHg sin signos de progresión de glaucoma con o sin uso de fármacos hipotensores tópicos, sin necesidad de cirugías de glaucoma adicionales y sin la aparición de complicaciones devastadoras para la visión. La probabilidad acumulada de éxito según el análisis de Kaplan Meier ha sido de 76, 63 y 55% a los 6 meses, 1-3 años y 4-8 años respectivamente. El 41,17% de los DDG fracasaron (7/17).

Conclusiones: Los DDG son una buena opción quirúrgica para los glaucomas refractarios pediátricos cuando otros procedimientos quirúrgicos han fracasado o tienen un mal pronóstico.

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Introduction

In addition to goniotomy and trabeculectomy, which are the first choice for treating congenital glaucoma, the surgical options for pediatric glaucoma are trabeculectomy with or without adjuvant anti-fibrotic therapy, glaucoma drainage devices (GDD) or cycloablation procedures. The selection of each technique depends on the patient characteristics and the preferences of the surgeon.1

When performed in the first year of life, trabeculectomy has a lower percentage of success in the pediatric population than in adults. The additional use of anti-fibrotic agents such as mitomycin C or 5-fluoracil (5-FU) improves the success rate. However, the lack of information about the complications derived from the use of these agents in the pediatric population as well as the described rate of blebitis and endophthalmitis (7–17%) have given rise to the rejection of this technique.2–5 The cyclodestruction procedures such as cyclophotocoagulation, even though it exhibits a lower rate of severe adverse effects than surgical modes, it is associated to a lower and temporary intraocular pressure reduction.6 For this reason it continues to be considered as an adjuvant treatment to surgery restricted to patients where surgery is not recommended or as palliative treatment in cases of absolute painful glaucoma.

The use of GDD in the pediatric population has been on the increase since 1969, when it was first described by Molteno.7 To date, the described success rate ranges between 54% and 95%, depending on the follow-up period, the type of glaucoma being studied and the various success criteria applied.8 GDD are a good option in buphthalmic eyes with scleral thinning, even though in the majority of cases the implant is decided after the failure of other surgical options.

Ahmed’s GDD (DDGA), which started to be used in 1992,9 comprises a valve mechanism that establishes a restrictive one-way flow which, in contrast to the Molteno implant (DDGM) is able to prevent post-op hypotony by maintaining the IOP above 8 mmHg.7

This study presents our medium and long-term clinical experience with said GDDs (DDGA and DDGM) in pediatric patients.

Subjects, material and methods

A retrospective study was done of the GDDs implanted in pediatric patients in the Pediatric Ophthalmology Service of the 12 de Octubre Hospital of Madrid from July 1994 to April 2007. The study included only patients having over one year follow-up and, in the single case where more than one GDD was implanted in the same eye, the first was considered because the second GDD did not have over one year follow-up. Accordingly, 17 devices were selected that were implanted in 17 eyes of 14 patients. In 3 patients with bilateral glaucoma one device was implanted in each eye and in 2 of these cases the dual implant was made in the same surgical operation.
Two types of implants were analyzed: DDGA model S-2, S-3 and FP8 (New World Medical Inc., Rancho Cucamonga, CA, USA) which was utilized in 12 patients (10 implants model S-2, 1 implant model S-3 and 3 implants FP8) and DDGM (Ophthalmic Limited, Dunedin, New Zealand) utilized in the first 2 patients of the series (3 devices). The operation was performed by the same surgeons (two) in all cases and the surgical technique was the same in all cases, i.e., conjunctival dissection with fornix base and isolation of the rectum muscles of the quadrants corresponding to the reservoir implant site, which was stitched at 8–10 mm of the limbus and anchored to the sclera with two 5-0 polyester stitches and with 9-0 nylon in those operated from the year 2000 onwards. Of the 17 GDD implants, 88.23% were located in the upper temporal quadrant, 11.76% in the upper nasal quadrant and 5.88% in the lower temporal quadrant. The tunneling for the tube was made with a 23 G needle, locating the entrance at about 2 mm of the limbus for the tubes located in the anterior chamber and at 5 mm for those located in the vitreous cavity. For covering the extracocular path of the tube a fascia lata patch was applied (Pacific Coast Tissue Bank, Los Angeles, CA, USA) in the majority of cases, although in 5 cases other materials were applied such as autologous scleral flap (2, 1994), and dura mater patches (2, 1995–1996) or preserved sclera patches (1, 2001). The conjunctival closure was made with continuous stitching with 7-0 polyglycane 910. The post-op treatment consisted in antibiotics and topical corticoids. In the case of DDGA the tube was previously irrigated with saline solution to open the valve mechanism. In DDGMs a prolene 4-0 string was placed inside the tube to partially occlude its inner diameter in order to reduce postop hypotonia.

Demographic and presurgery data were obtained, including the patient age at surgery time, previous surgical procedures, number of hypotensor drugs, IOP and visual acuity (VA). IOP was measured with Goldmann’s applanation tonometer or with Perkins tonometer prior to surgery and in the 2 final assessments. The VA was measured with the Pigassou or Snellen optotypes provided that the patient age and cooperation made this measurement feasible. In each assessment slit lamp and indirect ophthalmoscopy were carried out. The post-surgery data were IOP in the 2 final assessments, the VA and the appearance of complications.

A complete success was established as an IOP value of 21 mmHg or less without glaucoma progression signs in the 2 final assessments (increase of the corneal size, the antero-posterior diameter of the ocular globe all the papillary cup), with or without the use of hypotensor drugs and without additional glaucoma surgery (excepting relocating or shortening the tube, or GDD revision surgeries such as cistiotomy or capsulectomy) or the appearance of complications with devastating consequences for vision such as endophthalmitis, retinal detachment or suprachoroidal hemorrhage.

All the analyses were carried out with the statistics application SPSS v.15.0 for Windows (SPSS Inc., Chicago, IL, USA).

## Results

Fourteen patients under 15 years of age were included from July 1994 up to April 2007. Overall, the study comprises 17 devices, 3 DDGM implanted between 1994 and 1995 and 14 DDGA implanted between 1997 and 2007.

### Demographic data

Table 1 shows the demographic data of patients obtained before the surgery. The mean age at surgery time was of 3 years (15 days to 15 years). The type of glaucoma was congenital in 9 patients (9 eyes), and aphakic secondary to cataract surgery in 5 patients (8 eyes).

In 64.70% of cases (11/17 eyes) other glaucoma procedures had been performed, with trabeculectomy being the most frequent (Table 2). Within this group, 90.9% (10/11 eyes) has also undergone cataract surgery. In 17.64% of cases (3/17 eyes) only cataract surgery had been performed previously. In the remaining 23.52% of cases (4/17 eyes/3 patients) the GDD implant was the first surgery. This group comprised patients between 0.5 and 16 months with buphthalmic eyes with corneal edema, presurgery IOP between 34 and 41 mmHg.

### Table 1 – Pre-surgery demographic data.

<table>
<thead>
<tr>
<th>Pre-surgery demographic data</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of eyes (patients)</td>
<td>17 (14)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3</td>
</tr>
<tr>
<td>Range</td>
<td>15 days to 15 years</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male/female</td>
<td>9/5 (64.28/35.71)</td>
</tr>
<tr>
<td>Eye</td>
<td></td>
</tr>
<tr>
<td>Right/left</td>
<td>7/10 (41.17/58.82)</td>
</tr>
<tr>
<td>Diagnostic</td>
<td></td>
</tr>
<tr>
<td>Aphakic glaucoma</td>
<td>5 (35.71)</td>
</tr>
<tr>
<td>Congenital glaucoma</td>
<td>9 (64.28)</td>
</tr>
<tr>
<td>Pre-surgery IOP (mmHg)</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>29.82</td>
</tr>
<tr>
<td>SD</td>
<td>6.98</td>
</tr>
<tr>
<td>Range</td>
<td>(15–41)</td>
</tr>
<tr>
<td>Number of pre-surgery hypertensor drugs</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>1.94</td>
</tr>
<tr>
<td>Range</td>
<td>0–3</td>
</tr>
<tr>
<td>VA (logMar)</td>
<td></td>
</tr>
<tr>
<td>Mean ± DS</td>
<td>0.75</td>
</tr>
<tr>
<td>Range</td>
<td>0.30–1.30</td>
</tr>
</tbody>
</table>

VA: visual acuity; logMar: minimum resolution angle logarithm; IOP: intraocular pressure.

### Table 2 – Glaucoma surgery prior to implanting the drainage device for glaucoma.

<table>
<thead>
<tr>
<th>No. of glaucoma surgeries prior to GDD implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>One trabeculectomy</td>
</tr>
<tr>
<td>Two trabeculectomies</td>
</tr>
<tr>
<td>One goniotomy and one trabeculectomy</td>
</tr>
</tbody>
</table>

GDD: glaucoma drainage devices.
and malformation syndromes associated in 2 cases (Dandy-Walker syndrome and neurofibromatosis type 1).

**Intraocular pressure**

The mean pre-surgery IOP was of 29.82 mmHg (DS: 6.98) with a mean of 1.94 hypotensor drugs (0–3). The mean post-surgery IOP (considering the IOP of the last 2 measurements in GDD cases with positive progression and the IOP of the last assessment in failed cases) was of 14.05 mmHg (DS: 7.57) with a mean of 1.05 hypotensor drugs (0–3). The mean post-surgery IOP considering only the GDD with favorable evolution was of 11.90 mmHg (9–20) with a mean of 0.90 hypotensor drugs (0–3).

**Visual acuity**

Many of the patients were too small or exhibited associated pathologies which excluded sufficient cooperation to determine the VA. Accordingly, preop VA was assessed only in 6 patients (42.85%) (7 eyes) and post-surgery in 7 patients (50%) (9 eyes). The mean preop VA was of 0.75 logMar (minimum resolution angle logarithm) (1.30–0.30) and the mean post-surgery VA was of 0.71 logMar (0–1). These values remained stable in all cases except in one aphakic patient with bilateral glaucoma who exhibited bilateral retina detachment at month 3 and 10 after glaucoma surgery.

**Complications and aggregate success probability**

Half the cases (50%, seven patients) required subsequent interventions. In 3 patients (21.42%) a conjunctival stitch was required due to early dehiscence in 2 cases and amniotic membrane stitching due to extrusion of the reservoir in the third case, while in 2 patients (14.28%) capsulectomy associated to 5-FU injections were required due to early encapsulation, in 1 patient (7.14%) replacement of the tube due to retraction, in a further patient vitrectomy and cerclage due to retina detachment and in the remaining patient trans-scleral photocoagulation with diode laser due to poor pressure control.

The complications that arose throughout the follow-up in relation to the tube or the reservoir but without involving GDD failure were: (1) one early encapsulation case (one month after surgery) with good response after cistitomy and administration of 5-FU, (2) one case of early tube exposure with positive evolution after fascia lata suture, and (3) two motility alteration cases due to giant bleb around the reservoir starting one year after surgery. In one of the patients with type 1 neurofibromatosis this restriction could be also due to the presence of neurofibromatous tissue at the orbital level.

Seven surgeries in 5 patients (41.17%) were considered as a failure due to complications or poor pressure control. The complications derived from the tube or the reservoir and involving GDD failure were: (1) drainage tube retraction 4 years after placement in a patient with congenital microspherophakia, where the tube was lengthened and replaced without obtaining pressure control. In this case a second DDGA was implanted with favorable results after 2.58 years follow-up; (2) reservoir extrusion one month after surgery with posterior scleral necrosis in one patient with malformation syndrome (Dandy-Walker syndrome), buphthalmos and central descemetocele, where it was necessary to eviscerate the ocular globe 4 months after the valve implant; and (3) recurring conjunctival dehiscence with 2 secondary endophthalmitis episodes 5 months and one year after surgery. An additional complication that involved GDD failure which was not directly related to the presence of the tube or reservoir was bilateral retina detachment in one patient after 6 months and one year of the surgery. In one of the eyes (LE) an early encapsulation of the bleb occurred, resolved with cistitomy and 5 injections of 5-FU. Finally an additional case was considered to be a failure due to poor pressure control in which it was necessary to apply bilateral cyclodiode one year after surgery.

The Kaplan–Meier analysis gave an aggregate success probability of 76% at month 6, of 63% from year 1 to 3 and of 55% from year 4 to 8 at year one (Fig. 1).

**Discussion**

The GDD success rate described for the pediatric population is of 54–95% depending on patient age, success criteria applied, follow-up time and other factors. The additional use of hypotensor drugs or other non-filtrating surgeries such as bleb checkup are necessary for the majority of patients in order to control IOP after surgery. Accordingly, these are considered as relative success criteria.

The majority of GDD reviews in the pediatric population exhibit a short-term follow-up. It has been demonstrated that the success rate diminishes in proportion to the increase of said period. The Cunliffe and Molteno study has the longest follow-up period only with DDGM, with a mean of 11.2 years and a success rate of 85% despite the fact that 71% required subsequent surgery. Chen et al. published the longest follow-up period only with DDGA, with a mean of 2.2 ± 1.8 years (3 months to 7.5 years), a success rate of 85.1% in the first year and of 41.8% in the fourth year. There are virtually no studies including different implant types. O’Malley et al. presented a follow-up of DDGA and DDGM but differentiated in two groups according to the type of glaucoma (aphakic or congenital), with a mean of 3.5 and 5.5 years, respectively and a success rate of 90–92% in the first year and of 55–42% in the tenth year. Autrata et al. presented a study on DDGM and Baerveldt devices (DDGB) with a mean follow-up of 7.1 ± 6.5 years and a success rate of 91% in the first year and of 65% in the sixth year. In our study we have also considered 2 types of implants (DDGA and DDGM) with a mean follow-up of 3.14 years and a success rate of 63% in the first year and of 55% in year 8.

It is difficult to compare the success probabilities of the different GDDs in the pediatric population due to the lack of uniformity in criteria for selecting the implant. Beck et al. carried out the only study which compared DDGA and DDGB in the pediatric population and did not find significant differences between them. Even so, the choice of implant was not randomized.

The smaller age of the patients at surgery time has been considered as a poor prognosis factor. Most studies referred to children under 18 years of age at surgery time. O’Malley et al. and Coleman et al. included the patients under 15 years (mean ages of 0.75, 4.3 and 2.4 years, respectively).
Our study has also included only patients under 15 years of age, with a mean of 3 years.

Some studies have found a similar success rate between the 2 types of most frequent pediatric glaucoma, i.e. aphakic and congenital,\textsuperscript{12-14} while others describe the poorest prognosis in the congenital type\textsuperscript{11,15} even though this difference was only statistically significant in the study published by Djodeyre et al.\textsuperscript{16} In our paper we have found a failure rate of 50% in the aphakic glaucoma and 33% in the congenital glaucoma even though, due to the small number of cases, these values are not significant.

Previous glaucoma filtering surgery (not cataract) has been considered by Souza et al.\textsuperscript{17} as a risk factor for GDD failure, although we must take into account that the study of these authors also includes adult implants. However, other authors such as Austrata et al. and Djodeyre et al. do not consider this as a failure.\textsuperscript{13,16} In our study, 71.14% of failed GDDs had been implanted in eyes with previous glaucoma surgery.

In our series, 52.94% of cases required hypotensive drugs for pressure control after the DDD implant. This percentage is similar to the rest of published series, where the percentage ranges between 54 and 55.6%.\textsuperscript{11,14}

In what concerns vision, other series describe VA improvements between 60% and 93.3% of at least one line in the Snellen scale.\textsuperscript{14} In our study, 83.34% of patients did not exhibit VA alterations although we must consider that the sample is small and VA could only be assessed before and after surgery in only 6 patients.

One of the most common complications after a GDD implant in the pediatric population is the poor pressure control due to obstruction of the tube or encapsulation of the bleb. The obstruction can be due to blood, fibrin, iris or vitreous. In the different series, the IOP increase due to this complication has an incidence rate of between 6% and 20%.\textsuperscript{8} Surgical repair of the obstruction usually gives good results. In the case of encapsulation adjuvant anti-fibrotic therapy is applied (5-FU), associated or not to bleb revision techniques or capsulotomy. If these procedures do not diminish the IOP, additional actions could be considered such as cyclophotocoagulation or the implant of another GDD in a different quadrant. In our series we have found 4 cases, 23.52% (4/17 eyes) of bleb encapsulation. Two of these (2 patients) were resolved with cistitomies and anti-fibrotic therapy (5-FU). The other two eyes (one patient) required an additional procedure for glaucoma (cycloidiode) due to poor pressure control.

A further post-surgery complication which is quite frequent in the pediatric population is the migration of the drainage tube which frequently makes contact with the endothelium. This is more frequent in buphthalmic eyes. The published series and considering different GDD types described rates between 5.7% and 26.2%.\textsuperscript{5} In our study we only found one case (5.8%) of tube retraction in an eye with buphthalmos which did not make contact with the endothelium.

The incidence of tube or reservoir erosion or extrusion has been described between 0 and 13%, with 0–5% of cases being associated to secondary endophthalmitis. In our series we have found 3 cases of extrusion (21.14%). In one, the reservoir was extruded one month after surgery with necrosis of the underlying sclera. In the other 2, the tube was exposed due to early conjunctival dehiscence, one of which had associated endophthalmitis due to Propionibacterium.\textsuperscript{25}

In our review we have not found any episode of post-surgery hypotonia or suprachoroidal hemorrhage despite the literature describing an incidence of 0–25 and 0–22%.\textsuperscript{8}

Finally, persistent extraocular motility alterations can also occur, with the literature describing a rate between 0 and 11%\textsuperscript{5} although in the latest article published by O’Malley et al. this percentage rises to 37%.\textsuperscript{19} Said alterations can be due to the mass effect produced by the filtration bleb or the implant dish, due to adhesion or scarring of the extrinsic muscles (Faden effect) or due to adherence syndrome. In our series we found 2 cases (14.28%) with endotropia and motility
restriction secondary to the formation of a giant bleb in the superior temporal quadrant.

In our series, even though the overall failure rate is of 41.17%, similar or even higher than others referred in the literature, the majority of said failures occurred during the first year, after which the evolution was highly favorable with a very low rate of failures in the mid- and long-term. On the other hand, most of said failures were due to complications in some cases unrelated to the GDD such as retina detachment. Only one case failed due to poor pressure control, requiring an additional glaucoma surgery. Accordingly, in our experience GDD have turned out to be an effective and lasting procedure for controlling IOP.

GDD has become a sound surgical option for pediatric resistant glaucoma. When other surgical procedures have failed or have a poor prognosis, or in cases of buphthalmos or cicatricial conjunctiva due to previous filtering surgery, we could consider GDD a good option for controlling IOP. Even though the complications derived from its use are numerous, most of them are reversible and are not sufficiently severe to cause loss of eyesight. Even so, randomized prospective studies are required to provide more information about long-term results.

Conflict of interests

No conflict of interests has been declared by the authors.

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