

INTERMEDIATE-TERM OUTCOME OF GLAUCOMA DRAINAGE DEVICES

RESULTADOS A MEDIO PLAZO DE LOS DISPOSITIVOS DE DRENAJE PARA GLAUCOMA

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ABSTRACT

Objective: To study the intermediate-term results of glaucoma drainage devices (DDG) with respect to control of intraocular pressure (IOP), control of glaucoma, and maintenance of pre-operative visual acuity.

Methods: This was a retrospective cohort study of 86 eyes in 77 patients in whom a DDG was implanted, using descriptive statistics and survival analysis.

Results: Success was achieved in 53 eyes (61.6%), complete (without treatment) in 34 eyes (39.5%) and qualified (needing treatment) in 19 eyes (22.1%). In the 33 eyes where the DDG treatment was unsuccessful, poor IOP control occurred in 13 eyes - (15.1%), and complications occurred in 20 eyes (23.2%) resulting in a severe reduction or loss of visual acuity (plate exposure, suprachoroidal hemorrhage, retinal detachment). IOP control was obtained in 66 eyes (76.7%), 47 of them without treatment (54.6%), although on 13 occasions the overall treatment failed due to complications occurring. Despite IOP control, glaucoma progression occurred in 7 eyes (8.1%). Preoperative vision was maintained in 46 eyes (53.5%), but decreased by 3 or more lines in 20 eyes (46.5%); bullous keratopathy was the most frequent cause of the worse-

RESUMEN

Objetivos: Analizar los resultados a medio plazo de los dispositivos de drenaje para glaucoma (DDG) en cuanto a control de la presión intraocular (PIO), del glaucoma y del mantenimiento de la visión preoperatoria.

Métodos: Estudio de cohortes retrospectivo de 86 ojos de 77 pacientes en los que se ha implantado un DDG. Se ha empleado estadística descriptiva y análisis de supervivencia.

Resultados: Se han considerado como éxito 53 ojos (61,6%), completo (sin tratamiento) en 34 ojos (39,5%); y relativo (con tratamiento) en 19 ojos (22,1%). Las causas de fracaso han sido: mal control de la PIO en 13 ojos - (15,1%), y complicaciones en 20 ojos (23,2%) con reducción severa o pérdida de visión (extrusión del reservorio, hemorragia supracoroidea, desprendimiento de retina). Se ha obtenido control de la PIO en 66 ojos (76,7%), en 47 de ellos sin tratamiento (54,6%), aunque 13 de estos han sido fracasos por complicaciones. A pesar del control de la PIO, en siete ojos (8,1%) se ha observado progresión del glaucoma. En cuanto a la visión, en 46 ojos (53,5%) se ha mantenido estable y en 40 ha disminuido 3 o más líneas (46,5%), siendo la causa más frecuente la descompensación cor-

Received: Jan. 26, 2006. Accepted: Nov. 11, 2007.

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Paper presented at the LXXIX Congress of SEO (Valencia 2003).

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ning. Loss of light perception occurred in 21 eyes (24.4%) and 4 eyes (4.6%) were eviscerated.

Conclusions: DDG are an effective surgical option for control of IOP when conventional surgery has a poor prognosis, but they are associated with an increased risk of serious complications and loss of visual acuity in a significant proportion of cases (*Arch Soc Esp Oftalmol* 2008; 83: 15-22).

Key words: Glaucoma drainage device, tube aqueous-shunt, valve implant, Ahmed valve, Molteno implant.

neal. En 21 ojos (24,4%) se ha perdido la percepción de la luz, y cuatro ojos (4,6%) han sido eviscerados.

Discusión: Los DDG son una opción quirúrgica eficaz para el control de la PIO en ojos con mal pronóstico para la cirugía convencional de glaucoma, pero presentan complicaciones graves y deterioro visual en un porcentaje elevado de casos.

Palabras clave: Dispositivo drenaje glaucoma, implante drenaje, válvula Ahmed, implante Molteno.

INTRODUCTION

Glaucoma draining devices (GDD), particularly those fitted with valves, are a surgical alternative in cases of previous failed filtering surgery, important conjunctival alteration or a high risk of failure such as neovascular glaucoma or those secondary to iris-corneal syndromes (1,2).

This paper shows the results obtained in the mid-term with GDDs, with its main objective being to analyze the control of intra-ocular pressure (IOP) as well as preservation of pre-op vision, progression of the globe, and the prevalence of complications.

SUBJECTS, MATERIAL AND METHODS

A retrospective cohort study analyzing the mid term results of 86 implants in 77 patients, operated between January 1992 and December 2002, of which 46 are women and 31 men having a mean age of 57 years (range, 0.05-85.7). The mean follow-up time was of 35 months (range, 1-130), and of at least 3 years in 35 eyes (40.7%), 2 years in 48 cases (55.8%) and 1 year in 64 cases (74.4%). In eight cases, the follow-up was less than 6 months, of which five were short term failures and three incomplete follow ups, one of them due to demise of the patient.

The types implants were Ahmed valve in 45 cases (52.3%), one of them pediatric, and Molteno device in 41 cases (47.7%). The surgical technique consisted in a limbus base conjunctival flap, reservoir suture at 8-10 mm of the limbus, preferably in the superior temporal quadrant, introduction of the tube in anterior chamber through a scleral tunnel made with a 23G syringe, placement of a fascia lata

patch over the extraocular portion of the tube and continuous conjunctival suture.

The type of glaucoma was aphakic-pseudophakic in 22 eyes (25.6%), open angle primary in 20 eyes (23.3%), neovascular in 20 eyes (23.3%), closed angle in 7 eyes (8.1%), congenital in 7 eyes (8.1%), traumatic in 3 eyes (3.5%), uveitic in 3 eyes and of other types in 3 eyes (one hemorrhagic, one juvenile and one Cogan-Reese syndrome).

The mean preop IOP was of 33.7 mmHg (range, 10-70), measured with Goldmann tonometer, and the number of drugs utilized prior to surgery was of 2.26 SD 0.91 (range 0-4). In seven eyes the pre-op IOP ranged between 16 and 21 mmHg, with maximum medical treatment and poor tolerance. Another case, with an IOP of 10 mmHg, required a substitution of a previous implant due to a recurring conjunctival dehiscence.

Three eyes had a previous drainage implant which was substituted during surgery, and in 19 eyes other surgery procedures were associated, such as retinal cryotherapy in 10 cases, extraction of cataracts in 3 cases, vitrectomy in four cases (anterior in 3 and posterior in 1), strabismus surgery in one case and intra-ocular lens extraction in one case.

In what concerns post-op IOP control, an IOP between 5 and 21 mmHg was considered to be successful, and total success was defined as the absence of pressure reducing medical treatment, with relative success when it was necessary to add a pressure reducing drug to maintain said limits. In turn, a failure was considered to be an IOP below 5 or above 21 mmHg in three consecutive checkups, taking the first of said checkups as the failure date, or the execution of an additional antiglaucoma surgery. In addition, the appearance of severe complications with severe visual reduction or loss were considered to be a cause of failure, even when the

IOP was adequately controlled together with pthisis bulbi and evisceration or enucleation.

The statistical analysis was carried out utilizing the statistical package SPSS 8.0. SPSS Inc., (Chicago, Illinois, USA) and Kaplan-Meyer curves were utilized for the survival analysis.

RESULTS

Success was obtained in 53 eyes (61.6%), of which 34 cases (39.5%) were complete success and 19 (22.1%) were a relative success. Of these, in 16 cases treatment for IOP above 21 mmHg was established, and in a further 3 for IOP below 21, but above the objective pressure for the corresponding eye. In 33 eyes (38.4%) the procedure was considered a failure due to severe complications in 20 cases (23.2%), of which 16 were devastating, and an IOP which could not be controlled with medical treatment in 13 cases (15.1%). The complications which caused the failure of the procedure were: Extrusion of GDD elements in six cases, retinal detachment in three, two each of suprachoroidal hemorrhage, vitreous-ciliary blockage and evolution to pthisis bulbi, and one each of corneal decompensation due to contact between the tube and the cornea, endophthalmitis and bullous keratopathy without tube-cornea contact.

Table I specifies the results according to the type of implant, while table II classifies results according to the type of glaucoma.

Table I. Results According to the Type of Implant

Implant	Total		Moltene (n=41)		Ahmed (n=45)	
	n	%	n	%	n	%
Success total	53	61.6	24	58.53	29	64.44
complete	34	39.5	15	36.58	19	42.22
relative	19	22.1	9	21.95	10	22.22
Failure	33	38.4	17	41.46	16	35.55

Table II. Results According to the Type of Glaucoma p=0.07)

Type of glaucoma	N	Success		Complete success		Relative success		Failure	
		N	%	N	%	N	%	N	%
G. Aphakic	22	16	72.7	13	59.1	3	13.6	6	27.3
G. Open Angle	20	13	65.0	4	20.0	9	45.0	7	35.0
G. Neovascular	20	10	50.0	8	40.0	2	10.0	10	50.0
G. Closed Angle	7	3	42.9	1	14.3	2	28.6	4	57.1
G. Congenital	7	4	57.1	4	57.1	0	-	3	42.9

In what concerns IOP control, the following results were obtained: in 47 eyes (54.6%) IOP was under control (between 5 and 21 mmHg) without additional medical treatment and in 19 eyes (22.1%) with pressure reducing treatment (one drug in 14 eyes and two drugs in 5 eyes). Accordingly, IOP was controlled with or without treatment in 66 eyes (76.7% of cases) even though 13 of said eyes (nine with IOP under control without treatment) were considered to be a failure due to complications or vision reduction. Of the eyes which were not controlled, in 13 (15.1%) IOP was above 21 mmHg and in 7 eyes (8.1%) it was below 5 mmHg. Table 3 illustrates the pre-op IOP values and medical treatment as well as the post-op IOP in each follow-up year. Figure 1 shows the evolution of the mean IOP throughout the study.

Additional procedures were carried out in 12 eyes to maintain the functionality of the implant (revision with needle in four eyes, resection of the filtration bleb in two eyes, application of YAG laser in three eyes and anterior vitrectomy in a further three eyes due to obstruction of the intraocular portion of the tube). In six cases it was necessary to perform an additional antiglaucoma procedure (cyclodiode in 4 cases, substitution of implant in one case and implant of a second GDD

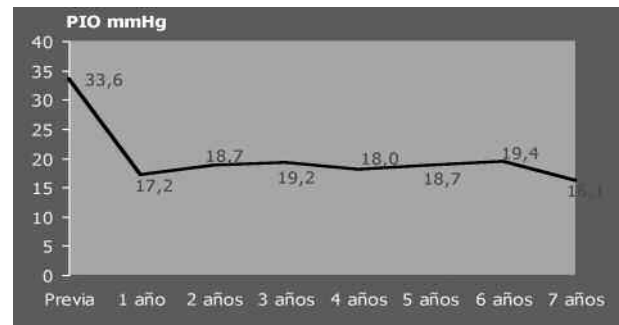


Fig. 1: Mean IOP value prior to surgery and throughout the follow-up.

Table III. Preop and Postop minimum, maximum and mean IOP values in yearly periods. Number of pressure reducing drugs prior to the GDD implant

	n	Minimum	Maximum	Mean	Standard Deviation
Previous # of drugs	86	0	4	2.26	0.91
IOP previou	86	10	70	33.74	12.09
IOP 1 years	60	0	40	17.17	6.84
IOP 2 years	46	10	40	18.72	5.86
IOP 3 years	32	10	45	19.22	7.29
IOP 4 years	25	10	40	18.00	6.25
IOP 5 years	18	10	40	18.72	6.85
IOP 6 years	15	11	44	19.40	7.80
IOP 7 years	9	11	26	16.11	4.65

IOP = intra-ocular pressure; GDD = glaucoma drainage device.

in a further case). These six cases were considered as failures.

The glaucoma progression cases and their relationship with IOP control are shown in Table 4. In 18 cases, the glaucoma remained stable (20.9%) and in 11 cases it progressed (12.8%), seven of which exhibited progression even though the IOP was under 21 mmHg. In the rest of cases (57 eyes - 66.3%) it was not possible to assess the progress of the glaucoma due to the impossibility of carrying out a visual field study or means opacity mainly because these were very advanced and neovascular cases.

In what concerns post-op vision, in 46 cases (53.5%) the pre-op VA was maintained, although seven were terminal glaucoma cases with very low vision, and in 40 cases (46.5%) it was reduced. Of these, in 19 cases (22.1%) the vision reduction was moderate (loss of 2 or more lines in Snellen optotype) and 21 cases (24.4%) lost perception of light. The most frequent cause for vision reduction was corneal decompensation, which appeared or became more severe in 25.5% of eyes in long-term post-op (over six months). Other causes for vision reduction were glaucoma progression (seven cases), diabetic retinopathy or neovascular glaucoma progression (five cases), cataracts (five cases), evolution to

pthisis bulbi (five cases), vitreous ciliary blockage (two cases), retinal detachment (two cases), suprachoroidal hemorrhage (two cases) and endophthalmitis (one case).

Intra-op complications comprised two cases of conjunctival retraction, which did not allow direct suture and made it necessary to associate a conjunctival graft, 4 hemorrhages in the anterior chamber and one case of sclera perforation when suturing the reservoir which required cryotherapy on the perforation. This case did not exhibit post-op retinal complications.

Table 5 illustrates the post-op complications, classified as early (during the first six months) and late. Sixteen eyes (18.6%) exhibited devastating complications or evolution towards pthysis bulbi (massive suprachoroidal hemorrhage, retinal detachment and endophthalmitis) with loss of light perception, and in four eyes it was necessary to eviscerate the ocular globe. In addition, a further four eyes were considered as failures because their vision worsened.

Survival curves related to failure were drawn up, particularly to the high ocular pressure failure and to the appearance of complications or loss of vision. Figure 2 shows the global survival curve, the mean

Table IV. Progression of Glaucoma in relationship to IOP value control

		Progression of Glaucoma			
		n	Stable %	n	Progression %
IOP	Controlled without Treatment	9	75%	3	25%
	Controlled with Treatment	8	67%	4	33%
	Not controlled	1	20%	4	80%
Total		18		11	

IOP: intra-ocular pressure.

Table V. Early and late postop complications

Early post-op complications (n=86)		Late post-op complications (n= 51)	
Hyphema	28	Bullous keratopathy	13
Encapsulated blebs	18	Exposure or extrusion of GDD elements	12
Anterior chamber flattening	16	Encapsulated blebs	11
Intra-ocular tube obstructions	14	Cataracts	6
Uveitis	13	Glaucoma progression	5
Conjunctival dehiscence	11	Pthisis Bulbi	5
Exposure or extrusion of GDD elements	5	IOP increase	4
Choroidal detachments	5	Dehiscencias conjuntivales	4
Cataracts	4	Uveitis	4
Others: diplopia, HOP, bullous keratopathy, vitreous-ciliary blockage, suprachoroidal hemorrhage, endothelial contact, hemovitreous		Others: Retina detachment, tube obstructions, endothelial contact, endophthalmitis, hyphema, diplopia, hemovitreous, choroidal detachment, epiretinal membrane, tube retraction	

GDD= glaucoma drainage devices; HOP: High Ocular Pressure; IOP= intraocular pressure.

survival time being of fifteen months and the aggregate probability of success after 24, 48, 72 and 96 months of 70%, 63%, 41% and 23% respectively. Figure 3 shows the survival curve up to high ocular pressure failure, with the mean survival time being of 21 months and the aggregate success probability after 24, 48, 72 and 96 months of 87%, 81%, 61% and 34% respectively. In turn, figure 4 shows the survival curve up to failure due to complications. The mean survival time is of 14 months and the aggregate success probability after 24, 48, 72 and 96 months is of 85%, 81%, 67% and 67% respectively. Table 6 shows the mean survival times up to failure in each case.

DISCUSSION

This study shows the effectiveness of glaucoma drainage devices for reducing IOP in the mid-term in glaucoma cases which are resistant to other types of treatment. In our series, IOP was controlled in 76.8% of eyes, without treatment in 54.6%. Starting with a mean pre-op IOP value of 33.7 mmHg, after one year of evolution we have obtained an IOP of 17.2 mmHg and between 18 and 19 mmHg from the second year onwards, down to 16 mmHg in the seventh year of evolution. The obtained results are illustrated jointly for the Molteno and Ahmed

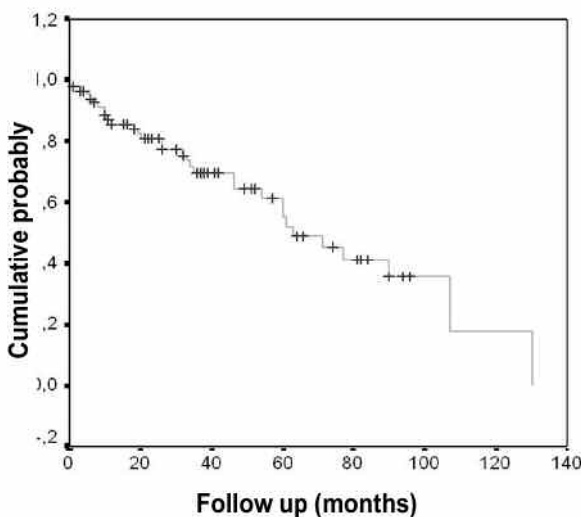


Fig. 2: Implant survival curve in relation to global failure.

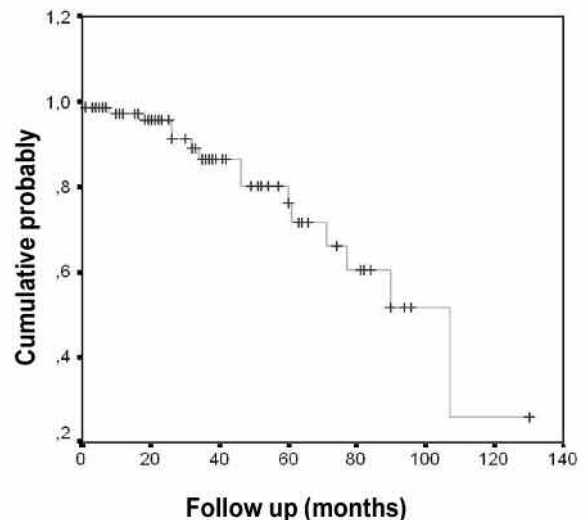


Fig. 3: Implant survival curve in relation to high ocular pressure failure.

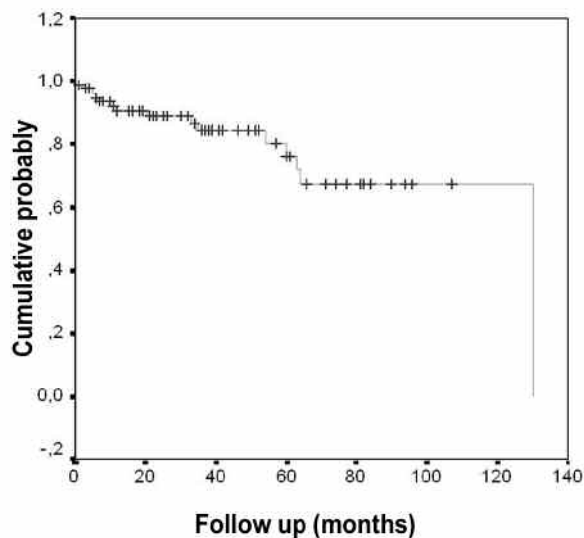


Fig. 4: Implant survival curve in relation to failure due to severe complications.

implants because, in our experience, there are no statistically significant differences between both types («Molteno versus Ahmed». Izquierdo Rodríguez C, Gutiérrez Díaz E, Montero Rodríguez M, Mencía Gutiérrez E, Reinoso Montalvo C, Ramos Castrillo A. 80th Congress of the Spanish Ophthalmological Society. Córdoba, Sept. 29 to Oct. 2, 2004; and «Long term results of Ahmed valve versus Molteno glaucoma drainage device». Gutiérrez Díaz E, Izquierdo Rodríguez C, Montero Rodríguez M, Mencía Gutiérrez E. 5th International Glaucoma Symposium – IGS. Cape Town (South Africa), March 30 to April 2, 2005).

The factors which determine results are the pre-op conditions of the eye and particularly the type of glaucoma rather than the type of implant. Although the differences are not statistically significant, the percentage of failures is greater in closed angle glaucoma (57%), neovascular (50%) and congenital (42.9%) and lower in the aphakic glaucoma (27.3%).

However, complications have been an important cause of failure (23.2%), leading to a reduction of the global success of the procedure to 61.6%. This implies that GDDs, even after successive modifications and improvements both of implants and surgical techniques, continue to be a complex and meticulous procedure which requires a personal risk-benefit assessment for each patient and, generally, it is considered that it should be performed only in eyes having possibilities of maintaining vision, leaving cycle-destructive procedures only for amaurotic eyes or for those having a minimum visual function (1,2).

The comparison with results of other series is difficult in this type of procedure. Success rates between 30% and 90% have been described according to the type of glaucoma and the criteria for measuring success, which are considerably variable. In this study we have selected relatively strict success criteria, including preservation of pre-op vision.

Studies with results exceeding 5 years follow-up are very scarce. Of note are the papers published by the group of Molteno et al (3) on ten year results of the Molteno implants in different types of glaucoma. These results are very good, reaching 100% success after ten years in the series on primary glaucoma surgery with risk factor or the series comparing the Molteno implant versus trabeculectomy in which both procedures are associated to cataract removal (4). However, it must be emphasized that these series include eyes with limited risk factors. Accordingly, in the latter series the Molteno implants have a greater frequency of prior glaucoma and cornea guttata surgery, but the remaining risk factors are similar in both groups (4), while the primary surgery series considers the presence of pseudophakia without other systemic alterations or diseases such as vascular pathology (infarct, heart insufficiency or ictus) or respiratory insufficiency (3) to be risk factors. In other types of glaucoma the results are slightly worse, such as in the series on traumatic glaucoma in which the possibility of con-

Table VI. Mean survival times to failure

	n	Minimum	Maximum	Mean	Standard Deviation
Follow up (months)	86	1	130	35.10	30.01
Mean time to failure	33	0.07	91.00	15.38	22.09
Mean time to severe complication	18	0.07	63.43	14.26	20.86
Mean time to HOP failure	15	1.80	91.00	20.73	26.57

HOP= High Ocular Pressure.

control is of 0.80 at 5 years and 0.72 at 10 years (5). In glaucoma secondary to uveitis, the probability of control is of 0.87 at 1 year, and 0.77 at 5 and 10 years (6). And in patients under 50, the success rate is of 73% with a control probability of 0.89 at 1 year, 0.85 at 2 years and 0.78 at 10 years (7). However, even in glaucoma cases with very bad prognosis such as neovascular types, the control probability of IOP is of 0.72 at 1 year and 0.40 at 5 years, with failure being related to a persistence of iris neovascularization. In this series, pre-op vision was maintained only in 39% of eyes (8).

In our series, we have obtained 76.8% of pressure control with or without treatment and the aggregate success probability at 1, 2, 3 and 4 years is of 81%, 70%, 66% and 63% respectively. Other studies also illustrate long-term data and their results are consistent with our study. The series of Topouzis et al (9) with Ahmed implants had an aggregate success probability of 0.76 at 1 year and 0.45 at 4 years. Broadway et al (10) presented a survival analysis with Molteno implants with a mean follow up of 43 months in which the global success rate was of 60.5%, and IOP control without treatment in 33.6%. In turn, the series of Mills et al (11), also with Molteno implants and a mean follow up of 44 months, obtained IOP control in 57% of cases, in 23% without treatment, and pre-op vision was maintained in 66% of eyes. Eid et al (12) presented a series of eighteen eyes of children treated with Molteno, Schocket and Baerveldt implants with a mean follow up of 47 months, in which 72.2% of eyes were controlled at 6 months, but only 44.4% at 2 years after surgery.

The use of mitomycin C does not seem to improve the success rate. The series of Irak et al (13) on 64 eyes in which a Baerveldt device was implanted with the application of mitomycin C (0.4 mg/cc for 2-3 minutes), the 1-year success probability was of 0.77 and 0.59 at 5 years. In this series, 15% of cases exhibited a corneal decompensation.

In the light of the mid- and long-term results of glaucoma drainage devices, it can be concluded that it is an efficient surgery for reducing IOP and a good option in glaucoma cases with bad prognosis, particularly in neovascular glaucoma. However, the risk of failure due to complications is relatively high in the early postoperative period and in the

long term due to corneal decompensation. Accordingly, the indication for this surgery must be assessed individually for each patient.

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