Long-Term Results of Nonpenetrating Deep Sclerectomy: Seven Years and 70 Eyes Later

Resultados a Longo-Prazo da Esclerectomia Profunda Não-Perfurante: Sete Anos e 70 Olhos Depois

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ABSTRACT

INTRODUCTION: Deep sclerectomy is a nonpenetrating glaucoma surgery that presents as an effective option for open angle glaucoma treatment, with an enhanced safety profile than trabeculectomy. In this study, we present the long-term outcomes of deep sclerectomy in open angle glaucoma patients.

METHODS: Retrospective analysis of patients with open angle glaucoma submitted to nonpenetrating deep sclerectomy (NPDS) between 2011 and 2017, at Hospital Pedro Hispano. A minimum of 2 years of follow-up was required. Absolute success was defined as postoperative intraocular pressure (IOP) ≤18 mmHg without additional treatment and qualified success as postoperative IOP ≤18 mmHg with or without additional treatment.

RESULTS: A total of 76 eyes with primary open angle glaucoma (56 eyes, 73.7%) or pseudoexfoliative glaucoma (20 eyes, 26.3%) were included in this study. IOP was significantly reduced after surgery (p<0.001), with mean IOP<18 mmHg in all the evaluated follow-up moments (until month 84). Therapeutic success was superior to 90% in in the first 24 months. Absolute success was achieved in 78.4%, 60.7% and 51.2% at 24, 36 and 60 months of follow-up. Qualified success was achieved in 91.6%, 86.9% and 90.2% (24, 36 and 60 months). Additional treatment was required in 33 eyes (43.4%). Postoperatively, the mean number of medications dropped from 2.4 to 0.8 (p<0.05). Postoperative complications were infrequent.

CONCLUSION: Nonpenetrating deep sclerectomy is a safe and effective surgical procedure in open angle glaucoma, allowing sustained IOP control over time, allied to a low rate of surgical complications.

KEYWORDS: Filtering Surgery; Glaucoma; Intraocular Pressure; Sclerostomy.

RESUMO

INTRODUÇÃO: A esclerectomia profunda é uma cirurgia não-penetrante e é uma opção eficaz no tratamento do glaucoma de ângulo aberto, com um melhor perfil de segurança relativamente à trabeculectomia. Neste trabalho, os autores apresentam os resultados a longo-prazo da esclerectomia profunda em pacientes com glaucoma de ângulo aberto.

MÉTODOS: Análise retrospetiva de pacientes com glaucoma de ângulo aberto submetidos a

esclerectomia profunda não-perfurante (EPNP) entre 2011 e 2017, no Hospital Pedro Hispano. Um *follow-up* mínimo de 2 anos foi necessário para a análise. Sucesso absoluto foi definido como pressão intraocular (PIO) pós-operatória ≤18 mmHg, sem necessidade de tratamento adicional, e o sucesso relativo foi definido como PIO pós-operatória ≤18 mmHg, com ou sem tratamento adicional.

RESULTADOS: Um total de 76 olhos foram incluídos neste estudo (56 olhos, 73,7%, com glaucoma primário de ângulo aberto e 20 olhos, 26,3%, com glaucoma pseudoesfoliativo). A PIO foi significativamente reduzida após a cirurgia (p<0,001), com PIO média<18 mmHg em todos os momentos de *follow-up* avaliados (até ao mês 84). O sucesso terapêutico foi superior a 90% nos primeiros 24 meses. Sucesso absoluto foi atingido em 78,4%, 60,7% e 51,2% aos meses 24, 36 e 60 de seguimento. Sucesso relativo foi atingido em 91,6%, 86,9% e 90,2% (aos 24,36 e 60 meses). Tratamento adicional foi necessário em 33 olhos (43,4%). No pós-operatório, o número médio de fármacos hipotensores diminuiu de 2,4 para 0,8 (p<0,05). Foram registadas escassas complicações pós-operatórias.

CONCLUSÃO: A EPNP é um procedimento cirúrgico seguro e eficaz no glaucoma de ângulo aberto, permitindo um controlo sustentado da PIO ao longo do tempo, aliado a uma baixa taxa de complicações cirúrgicas.

PALAVRAS-CHAVE: Cirurgia Filtrante; Esclerectomia; Glaucoma; Pressão Intraocular.

INTRODUCTION

Glaucoma is an optic neuropathy characterized by structural changes with associated visual field defects. Glaucoma is still a major cause of irreversible visual loss worldwide.[1] Lowering intraocular pressure (IOP) remains the treatment of choice for disease control and the only proven intervention capable of reducing disease progression.[2]

Surgery is indicated for inadequate IOP control or disease progression despite medical or laser therapy. Cases of intolerance or non-compliance to medical treatment can also be considered for surgical management.[1]] Nonpenetrating glaucoma surgeries have evolved as safe and effective options in open angle glaucoma and present a much lower rate of complications than the classic trabeculectomy.[3] In nonpenetrating deep sclerectomy (NPDS), a thin trabeculodescemet's membrane (TDM) is created, that allows a controlled outflow of aqueous humor.[4,5] In most cases, the IOP lowering effect of nonpenetrating glaucoma surgeries is not as dramatic as trabeculectomy,[6,7] however, in selected patients and with experienced surgeons, the IOP lowering effect of NPDS can be compared to that of trabeculectomy.[8-10]

The aim of this study is to evaluate the long-term efficacy and safety of NPDS.

METHODS

We performed a retrospective study of patients with open angle glaucoma submitted to NPDS at the Department of Ophthalmology of Hospital Pedro Hispano (Matosinhos, Portugal) between January 2011 and April 2017. Patients with primary open angle glaucoma (POAG) or pseudoexfoliative glaucoma (PXG) were included and a minimum period of follow-up of 2 years after surgery was required for inclusion. Cases with perforation of TDM were excluded from analysis, for this would turn NPDS into a perforating filtration procedure. Patients with other ophthalmological comorbidities were excluded from the study.

Indications for surgery were insufficient IOP control, non-compliance to topical treatment or disease progression. Data recorded from each patient included age, sex, type and stage of glaucoma and number of IOP-lowering medications. For the preoperative evaluation, best corrected visual acuity (BCVA), anterior segment slit-lamp examination, Goldmann applanation tonometry, gonioscopy, fundoscopy, visual fields (Humphrey visual field analyzer) and optical coherence tomography of optic disc (Optovue RTVue OCT®) were also performed. All IOP measurements were performed with Goldmann applanation tonometry. Glaucoma type was defined by gonioscopy and slit-lamp examination, and advanced glaucoma was defined according to the Hodapp-Parrish-Anderson's criteria.[11]

Absolute success was defined as postoperative intraocular pressure (IOP) ≤18 mmHg without additional treatment and qualified success as postoperative IOP ≤18 mmHg with or without additional treatment (medical or laser/surgery). All surgeries were performed by only one surgeon (PT). Main outcome measures of this study are IOP (mmHg) and number of hypotensive medications. Additional outcomes include best corrected visual acuity and MD from visual fields. Postoperative complications were recorded in all patients.

SURGICAL TECHNIQUE

Surgery was performed with either local anesthesia with monitored anesthesia care or general anesthesia. An 8-0 nylon traction suture was placed in the cornea adjacent to the superior limbus. A fornix-based conjunctival flap

centered at 12 o'clock was prepared, and the conjunctiva and Tenon's capsule were dissected. Light cautery was applied as needed. When mitomycin was used, sponges soaked in 0.2 mg/mL Mitomycin-C (MMC) were placed under the conjunctiva for about 2.5 minutes, and then the subconjunctival space was carefully washed with balanced salt solution. A 5 x 5 mm superficial (one-third thickness) scleral flap, with a limbus-based approach, was created and dissected anteriorly until clear cornea was reached. Then, a smaller (4 x 4 mm) deep scleral flap, with a limbus-based approach, was created, and dissection was continued anteriorly till the Schlemm's canal. After exposition, the inner wall of Schlemm's canal was carefully peeled off with forceps and the deep scleral flap excised. In cases were an implant was used, the implant (AquaFlow™ (STAAR Surgical, California) or Esnoper™ (AJL Ophthalmic, Spain)) was placed on the exposed scleral stroma bed and secured with one 10-0 nylon suture. The superficial scleral flap was sutured with interrupted 10-0 nylon suture and the conjunctival flap was also closed with 10-0 nylon suture. At the end of the procedure, the conjunctival closure was checked for watertightness. The surgery's last step consisted of subconjunctival injections of cefuroxime and metilpednisolone (administered in the inferior quadrants).

In cases combined with cataract surgery, phacoemulsification was performed first and NPDS followed as described.

Postoperatively, all patients received a standard regimen of topical antibiotic (quinolone), 5 times daily, discontinued after 2 weeks and topical corticosteroids (dexamethasone phosphate 1 mg/mL), 5 times daily during the first 4 to 6 weeks, tapered as needed. Topical nonsteroidal anti-inflammatory was administrated during the first month after combined surgery. Postoperative visits were generally scheduled at day 1, week 1, week 4, months 3, 6, 12, 18, and 24 and with a 6-12 months interval before month 24. Additional visits were scheduled according to the patients' clinical evolution.

STATISTICAL ANALYSIS

Statistical analysis was performed with SPSS, version 22. Descriptive statistics were presented as means (M) and standard deviations (SD) for quantitative variables and frequencies (n) and percentages (%) for categorical ones. RM ANOVAs were performed for comparing the several moments of assessment of IOP and visual acuity (VA), regarding a set of independent variables. Paired samples t-test was used to compare IOP after surgery, considering IOP before surgery (<21/ ≥21). Mcnemar paired test was used to compare medication, IOP≤18 and therapeutic success along the several moments of assessment. Significance level was 5%.

RESULTS

BASELINE SAMPLE CHARACTERISTICS

A total of 76 eyes (36 (47.4%) left and 40 (52.6%) right) from 72 patients were enrolled in this study. Mean patient's age was 71.1 years with age ranging from 47 to 85 years. Most of the individuals in our sample were females (n=43, 59.7%). Primary open angle glaucoma (POAG) was present in 56 eyes (73.7%) and the remaining 20 eyes (26.3%) presented pseudoexfoliative glaucoma (PXE). Most cases corresponded to advanced glaucoma (n=42, 55.3%), with moderate glaucoma present in 25 eyes (32.9%) and only 9 (11.8%) at an initial stage.

Before surgery, mean intraocular pressure (IOP) was 20.8±6.53 mmHg. Distribution of number of hypotensive medications was 0 (n=2; 2.6%), 1 (n=8; 10.5%), 2 (n=27; 35.5%) and 3 (n=39; 51.3%), with a mean number of 2.4 (±0.8) hypotensive drops per patient. Mean initial visual acuity (VA) was 0.66 (n=73) and mean initial mean deviation (MD) from visual fields was -14.43 (data available for 58 patients).

SURGICAL RESULTS

Combined phacoemulsification with NPDS was performed in 62 patients (81.6%), while 14 patients (18.4%) underwent NPDS alone. In 20 surgeries, mitomycin C (MMC) was used as an adjuvant. Implants were placed in 72 eyes – Esnoper in 40 eyes (52.6%) and Aquaflow in 32 (42.1%); in 4 eyes, no implant was placed. Mean follow-up time was 64 months.

IOP was evaluated throughout the whole follow-up period, as represented on Fig. 1. In the immediate postoperative period, mean IOP was significantly reduced (p<0.001), dropping to 10.3 mmHg (±4.79). This value gradually increased until the 24th month after surgery, achieving a mean of 15.1 mmHg and stabilizing after that time.

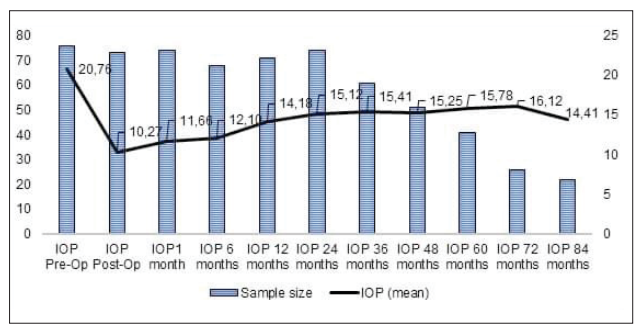

Figure 1. IOP evolution along follow-up time.

We evaluated interaction effects for stage, age and type of implant and no interaction was found for these variables (stage (p=0.096), age (p=0.452) and type of implant (p=0.431)). When evaluating the type of glaucoma, an interaction effect was found, with a higher decrease of IOP on the pseudoexfoliative glaucoma (PXG) group (p<0.001), even though these patients presented significantly higher IOP before surgery. Considering preoperative IOP (<21/ ≥21), no significant difference was found for IOP values after surgery. These results are shown in Table 1.

Regarding visual acuity, three moments of evaluation were considered: pre-operative (M=0.66; SD=0.25), 1 year after surgery (M=0.88, SD=0.18) and 2 years after surgery (M=0.85; SD=0.21), with a total of 64 patients. RM ANOVAs showed lin-

Table 1. Pre and post-op IOP comparisons

	IOP pre-op		IOP post-op		Global effect	Interaction effect
	M	SD	M	SD		
Type of glaucoma					***p*<0.001**	***p*<0.001**
POAG	19.04	5.03	10.60	5.04		
PXG	25.60	7.86	9.40	4.04		
Stage of glaucoma					***p*<0.001**	*p*=0.096
Non advanced glaucoma	19.62	4.67	10.70	4.38		
Advanced glaucoma	21.69	7.65	9.92	5.14		
Age					***p*<0.001**	*p*=0.452
< 60	18.75	4.10	10.71	4.61		
60 – 80	20.84	7.05	10.44	4.91		
> 80	21.82	5.02	9.18	4.58		
Type of implant					***p*<0.001**	*p*=0.431
Esnoper	21.47	7.84	10.69	5.57		
Aquaflow	20.59	4.53	9.69	3.81		
Pre-op IOP					*p*=0.149	-
< 21	-	-	9.22	3.62		
≥ 21	-	-	10.76	5.20		

ear significant improvement of the VA ($p<0.001$). This significant increase in VA can be explained by the high percentage of patients submitted to NPDS combined with phacoemulsification. No interaction was found with the independent variables studied, namely type of glaucoma ($p=0.186$), stage ($p=0.529$) and pre-operative IOP ($p=0.816$). A global linear effect was found for age, along with an interaction effect comparing age groups < 60 (n=7), 60-80 (n=35) and >80 (n=6) ($p=0.003$); this effect is explained by the fact that younger patients presented better initial VAs, and did not experience the same linear improvement as older patients ($p=0.003$). Mean MD from last evaluated visual fields was -13.8 (data available for 63 patients), with no statistically significant difference found between VF MD before and after surgery.

Surgical complications were observed in 11 patients (14.5%), the majority corresponding to immediate hypotony (defined as IOP < 5 mmHg; n=7; 63.6%) and the remaining cases due to late seidel. Complications were successfully managed with conservative treatment, except one eye that required a revision of conjunctival closure with 8-0 vicryl suture. No major complications, such as chronic hypotony, choroidal detachment or endophthalmitis were reported in these patients. Use of mitomycin was not associated with increased complications or increased success rates in our sample. No complications related to the phacoemulsification procedure were recorded.

THERAPEUTIC SUCCESS ASSESSMENT

Therapeutic absolute success was defined as IOP≤18 mmHg, without additional treatment. Qualified success was defined as IOP≤18 mmHg with or without medication or additional treatment. Surgery failure/no success was defined as IOP>18 mmHg. Fig. 2 represents an evaluation of therapeutic success throughout the study.

In the first 12 months after surgery, absolute success was >90%. From that point and until the end of the follow-up period, we verified a decline in absolute success, while qualified success rates remained high. Consistent with these data, we verified a significant linear increase of the percentage of medicated patients along all considered periods ($p<0.001$). Surgery's failure rate was inferior to 10% throughout the follow-up, except at 36, 48 and 72 months.

Figure 2. Assessment of the therapeutic success.

Additional treatment was required in 33 eyes (43.4%), with 25 patients (32.9%) being treated only with hypotensive medication. Goniopuncture with ND:YAG laser was performed on 6 patients (7.9%) for IOP control, as well as selective laser trabeculoplasty (n=6, 7.9%). Two eyes (2.6%)

required surgical reintervention and were submitted to trabeculectomy (at 1 and 3 years after NPDS). At the end of follow-up, mean number of hypotensive medications per patient was 0.8 (p<0.05).

DISCUSSION

The juxtacanalicular (JXT) trabecular meshwork and the inner wall of Schlemm's canal (SC) present the highest resistance to aqueous humor (AH) outflow, both in heathy and in glaucomatous eyes.[12-14] In deep sclerectomy, the creation of a trabeculo-descemet's membrane (TDM) (by the excision of the SC's inner wall and the JXT meshwork) bypasses the outflow resistance and increases aqueous drainage.[4,12,14] Routes and mechanisms for IOP-lowering effect in NPDS include the subconjunctival filtering bleb and intrascleral lake, the suprachoroidal filtration route and the episcleral venous outflow.[12,15]

Deep sclerectomy, as a nonpenetrating procedure, presents several advantages over the traditional trabeculectomy, such as respecting the physiological outflow of aqueous humor, while providing a higher predictability of response and a reduced incidence of postoperative complications.[3,16] Maintaining the anatomical integrity of the anterior chamber reduces the likelihood of complications observed in trabeculectomy, such as excessive early filtration leading to hypotony, choroidal detachment or hyphema.[7,8,17,18] The long-term efficacy of deep sclerectomy on IOP control has been broadly reported.[19-22]

Surgical implants and antimetabolites have been used to increase success rates of NPDS. Spacer implants were proposed to increase filtration and avoid collapse of the intrascleral space. Several studies have confirmed increased NPDS efficacy with placement of implants.[9,15,19,23,24] Use of antimetabolites has also improved surgical success rates, without compromising the safety profile, by reducing scarring and fibrosis at the filtration site.[25,26]

NPDS can be safely combined with a phacoemulsification procedure in patients with medically uncontrolled open-angle glaucoma and cataract. Several studies have reported the efficacy of phaco-NPDS surgery, with combined surgery presenting similar results in IOP control and postoperative complications compared with NPDS alone, while providing significant visual gains.[10,27-29]

This study presents real-life and long-term data for NPDS in open-angle glaucoma. Success rates were notable throughout time, with an absolute success rate>90% in the first 12 months of follow-up and a substantial decrease in mean IOP. Visual acuity improved after surgery, as most patients were submitted to phaco-NPDS, and MD from visual fields remained stable.

Similar studies describing long-term success of nonpenetrating deep sclerectomy, with a minimum mean follow-up period of 24 months and including goniopuncture rates, were reviewed and are presented on Table 2. Comparisons should be read carefully, since methods, such as inclusion criteria and success outcomes, differ significantly among studies.

Our study presents a much lower rate of YAG laser goniopuncture than other published studies and this should

Table 2. Similar studies evaluating long-term success of nonpenetrating deep sclerectomy

Authors	Eyes (n)	Mean follow-up (months)	Mitomycin (%)	Goniopuncture (%)	Success rate
N Anand, R Pilling[30]	258	40±11	Yes (74.4%)	67%	No success rates described for NPDS alone
N Anand, A Kumar, A Gupta[31]	194	48±15	Yes (100%)	63%	IOP<19, 16 and 13 mmHg without medications or needle revision:
Bettin *et al*[32]	96	28.6±20	Yes (100%)	56%	At 36 months: IOP≤21 mmHg with medication was 92% and without 89% IOP≤15 mmHg with medication was 59% and without 58%
Romera-Romero *et al*[24]	41	24	Yes (100%)	66.8%	IOP≤18 mmHg and ≥20% of IOP reduction at 24 months: 61% without medication and 71% with medication
Bissig *et al*[19]	105	101.5±43.1	No (100%)	59.8%	IOP≤21 mmHg without medication 47.7% and in 89% with or without treatment
K Mercieca, L Steeples, N Anand[22]	43	68.5±33.5	Yes (81%)	62.8%	Probability of IOP<22 and <19 mmHg was 69% and 62% at 3 years and 60 and 51% at 5 years
K Mercieca, B Shevade, N Anand[29]	296	63.5±35.3	Yes (49%)	54.4%	IOP<19 mmHg and/or 20% decrease – 89% and 80% at 2 and 5 years IOP<16 mmHg and/or 30% drop – 81% and 68% at 2 and 5 years
A Elhofi, HA Helaly[33]	60	48	Yes (100%)	8.3%	At 48 months: IOP ≤ 21 mmHg without medication in 56.7% and with medication in 70%
Sharaawy *et al*[20]	105	43.2±14.3	No (100%)	45.7%	At 60 months: IOP<21 mmHg without medication 62% and 95% with or without medication

be analyzed according to the great success rate of NPDS presented in the first 12 months, where goniopuncture is most effective. Most published studies performed laser goniopuncture during the first 12 months of follow-up. Additionally, goniopuncture is associated with potentially significant complications, such as iris synechiae and incarceration and hypotony or acute IOP rise.[30-33]

Nonetheless, the authors preferred hypotensive medication as a strategy for IOP control and additional treatment was needed in a significant number of patients. However, our sample included mainly advanced glaucomas, which resulted in a lower IOP target. Over time, IOP control was achieved in virtually all eyes.

In our series, rate of postoperative complications was low and no major complications were observed. For patients, this reflects in a rapid visual recovery and maintenance of visual function, less postoperative visits with a faster return to active life and an increase in quality of life related measures.[34,35] For health services, this favorable safety profile of NPDS can reduce the burden of care and, possibly, reduce health costs. The patients' related quality of life, as well as individual and social costs must be considered when choosing glaucoma treatment.[36] Long-term follow-up is required, as some patients will need additional treatment. When necessary, treatment can be added in the form of hypotensive drugs, laser or a new surgery.

Our study presents limitations inherent to retrospective analysis. Other limitations include the nonuniformity in the application of antimetabolites and in the choice of the implant used. This can be explained by hospital and clinical procedural changes in the past years (currently, use of MMC is routine in all NPDS performed at our hospital). Strong points from our study include sample size and the lack of interphysician variability (by only including surgeries performed by one experienced surgeon).

CONCLUSION

Our results confirm the long-term efficacy and safety of nonpenetrating deep sclerectomy, alone or combined with phacoemulsification, in the treatment of open-angle glaucoma. NPDS, performed by experienced surgeons, provides a favorable IOP control over time, allied to a great safety profile.

PRESENTATIONS/APRESENTAÇÕES:

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CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO:

SP and RG - data collection, analysis and interpretation of results, drafting of the article and approval of the final version.

RCB - bibliographical search and approval of the final version.

PT and RB - analysis and interpretation of results, article review and approval of the final version.

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