

Cataract Surgery Combined with Intravitreal Injection of Triamcinolone Acetonide for Diabetic Macular Edema

Cirurgia de Catarata Combinada com Injeção Intravítrea de Acetonido de Triamcinolona para Edema Macular Diabético

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Recebido/Received: 2023-10-05 | Aceite/Accepted: 2024-07-16 | Published online/Publicado online: 2024-10-23

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DOI: <https://doi.org/10.48560/rspo.33086>

ABSTRACT

INTRODUCTION: Diabetic macular edema (DME) is the main cause of visual impairment in diabetic patients. Further, cataract formation is known to be accelerated in these patients. DME exacerbation after cataract extraction surgery is common, leading to a poorer visual outcome. Intravitreal triamcinolone acetonide (IVTA) has been used to treat macular edema from a variety of causes and when used at time of phacoemulsification surgery may treat or prevent this complication.

This study aims to evaluate functional and anatomical outcomes of combined phacoemulsification and IVTA in eyes with concomitant or previous DME and cataract.

METHODS: Retrospective cohort study of the diabetic patients with cataract and concomitant DME or history of previous DME, undergoing phacoemulsification surgery combined with IVTA. The cases included were divided into two groups: group I, eyes with DME at surgery time; and group II, eyes without DME in the last 3 months before surgery, but with previous records of DME.

RESULTS: The mean age of our patients was 69.83 ± 6.99 years. 108 eyes of 98 patients (69 eyes in group I and 39 eyes in group II) were included in the study.

In group I, the mean best corrected visual acuity (BCVA), at baseline was 0.67 ± 0.33 logMAR and 1-month after the procedure was 0.41 ± 0.31 logMAR, a statistically significant increase ($p < 0.001$). Central macular thickness (CMT) decreased significantly in the first month ($p < 0.001$). A clinically significant increase ($\geq 20\%$) of CMT was verified in 6 cases (8.70%). Nine cases (13.04%) developed transient ocular hypertension.

In group II, the mean BCVA at baseline was 0.62 ± 0.34 logMAR and 1-month after the procedure was 0.32 ± 0.34 logMAR, with a statistically significant increase ($p < 0.001$). CMT decreased significantly in the first month ($p < 0.001$). A clinically significant increase ($\geq 20\%$) of CMT was verified in only 2 cases (5.13%). Six cases (15.38%) developed transient ocular hypertension.

CONCLUSION: Diabetic patients have an increased risk of developing central DME after phacoemulsification surgery, especially if previous DME history is present. Our study highlights IVTA in cataract surgery as a safe and effective tool to treat and prevent DME development.

KEYWORDS: Cataract Extraction; Diabetic Retinopathy; Glucocorticoids/therapeutic use; Intravitreal Injections; Macular Edema; Triamcinolone Acetonide/therapeutic use.

RESUMO

INTRODUÇÃO: O edema macular diabético (EMD) é a principal causa de déficit visual em pacientes diabéticos. Além disso, a formação de catarata é acelerada nestes pacientes. A exacerbação do EMD após a cirurgia de catarata é comum, com um pior resultado visual. Acetonido de triamcinolona intravítreo (IVTA) tem sido usado para tratar edema macular de diversas causas e quando usado aquando da cirurgia de facoemulsificação pode tratar ou prevenir esta complicação.

O objetivo deste estudo é avaliar os resultados funcionais e anatômicos da cirurgia de catarata combinada com IVTA em olhos com catarata e EMD prévio ou concomitante.

MÉTODOS: Estudo de coorte retrospectivo de pacientes diabéticos com catarata e EMD concomitante ou história prévia de EMD, submetidos a cirurgia de facoemulsificação combinada com IVTA. Os casos analisados foram divididos em grupo I, olhos com EMD no momento da cirurgia; e grupo II, olhos sem EMD nos últimos 3 meses antes da cirurgia, mas com registos prévios de EMD.

RESULTADOS: A média de idade dos nossos doentes foi de $69,83 \pm 6,99$ anos. 108 olhos de 98 pacientes (69 olhos no grupo I e 39 olhos no grupo II) foram incluídos no estudo.

No grupo I, a média da melhor acuidade visual corrigida no início do estudo foi de $0,67 \pm 0,33$ logMAR e após 1 mês era $0,41 \pm 0,31$ logMAR, um aumento estatisticamente significativo ($p < 0,001$). A espessura macular central (EMC) diminuiu significativamente no primeiro mês ($p < 0,001$). Foi verificado aumento clinicamente significativo ($\geq 20\%$) da EMC em 6 casos (8,70%). Nove casos (13,04%) desenvolveram hipertensão ocular transitória.

No grupo II, a acuidade visual média no início do estudo foi de $0,62 \pm 0,34$ logMAR e 1 mês depois $0,32 \pm 0,34$ logMAR, um aumento estatisticamente significativo ($p < 0,001$). A EMC diminuiu significativamente no primeiro mês ($p < 0,001$). Um aumento clinicamente significativo ($\geq 20\%$) foi verificado em apenas 2 casos (5,13%). Seis casos (15,38%) desenvolveram hipertensão ocular transitória.

CONCLUSÃO: Pacientes diabéticos têm um risco aumentado de desenvolver EMD após cirurgia de catarata, especialmente se houver história prévia. O nosso estudo destaca a IVTA na cirurgia de catarata como uma ferramenta importante para tratar ou prevenir o desenvolvimento de EMD.

PALAVRAS-CHAVE: Acetonido de Triamcinolona/uso terapêutico; Edema Macular; Extração de Cataratas; Glucocorticóides/uso terapêutico; Injeções Intravítreas; Retinopatia Diabética.

INTRODUCTION

Diabetic macular edema (DME) is the main cause of visual impairment in diabetic patients.¹ Progression of DME is commonly monitored by measuring the central macular thickness (CMT) in a safe and efficient method through optical coherence tomography (OCT). Thus, CMT has an inverse correlation with visual acuity (VA) in diabetic eyes.²

Further, cataract formation is known to be accelerated in diabetic patients, who represent 20% of all cataract surgeries.³ Although still controversial in the literature, it appears that uncomplicated cataract surgery is not directly responsible for diabetic retinopathy progression,⁴ as concluded by Protocol P of The Diabetes Retinopathy Clinical Research Network.⁵ This protocol supports uncomplicated cataract surgery can be safely performed in patients with diabetic retinopathy without increasing the risk of DR progression. Still, the presence of maculopathy at the time of surgery is seen as a bad prognostic factor to visual outcome. Eyes with diabetic retinopathy undergoing cataract surgery have a significant CMT increase compared with normal eyes.⁶ DME exacerbation after cataract extraction

surgery is common, leading to a poorer visual outcome. Macular edema development involves breakdown of the inner blood-retina barrier and release of endogenous permeability factors by an ischaemic retina.⁷

Several studies have supported the role of intravitreal and subconjunctival corticosteroids in reducing the severity of DME in diabetic patients. Likewise, intravitreal triamcinolone acetonide (IVTA), with a dosage ranging from 2 to 4 mg, has been used to treat macular edema from a variety of causes,⁸⁻¹¹ and when used at the time of phacoemulsification surgery may treat or prevent this complication. Nonetheless, it is important to consider the potential risks of IVTA, namely the transient rise in intraocular pressure, vitreous hemorrhage, retinal detachment and endophthalmitis.¹²⁻¹⁴

This study aims to evaluate functional and anatomical outcomes of combined phacoemulsification and IVTA in eyes with concomitant or previous DME and cataract.

METHODS

Retrospective cohort study of diabetic patients with cataract and concomitant DME or history of previous DME, un-

dergoing phacoemulsification surgery combined with IVTA in the last three years in our Department of Ophthalmology.

DME was defined as retinal thickening within 1 disc diameter (about 1.5 mm) from the macula's center, of at least 250 μm , as shown by OCT. This definition followed the ETDRS criteria.¹⁵

Exclusion criteria include patients under 18 years old, follow-up for other serious eye diseases such as glaucoma, uveitis or age-related macular degeneration, amblyopia, previous vitrectomy surgery and ophthalmological follow-up less than one month after surgery. The cases included in the study were divided into two groups for analysis: group I, eyes with DME at surgery time; and group II, eyes without DME in the last 3 months before surgery, but with previous records of DME.

Best-correct visual acuity (BCVA), CMT on spectral-domain OCT (Spectralis, Heidelberg Engineering, Heidelberg, Germany), and intraocular pressure were assessed at baseline and one month postoperatively. The BCVA was assessed by a Snellen visual acuity chart and was converted to a logarithm of the minimum angle of resolution (logMAR) for analysis. CMT increases were considered clinically significant when greater or equal than 20%. Informed consent was obtained for each case prior to surgery.

All cataract surgery was carried out in an operating room setting using standard phacoemulsification and intracapsular intraocular lens implantation techniques. The procedure was performed under intracameral anesthesia with 2% lidocaine. Upon completion of the cataract extraction, 4 mg of triamcinolone acetonide, diluted in 0.1 mL of balanced salt solution (BSS[®]), was administered with a 27-gauge needle at a point 3.5 mm posterior to the inferotemporal limbus. Postoperatively, 1 mg/mL dexamethasone phosphate, 5 mg/mL levofloxacin and bromfenac 0.9 mg/mL eye drops were applied four times daily for 3 weeks.

After surgery, patients were followed up on day 1, week 1, and month 1. Minimal follow-up was 1 month. At each postoperative visit, IOP was measured using a non-contact tonometer, taken as a mean of three readings. If the IOP was greater than 20 mmHg, it was verified with a Goldmann applanation tonometer. Statistical analysis was performed using SPSS v27.0. A multilevel regression model was used for statistical analysis of data. A difference was considered statistically significant if $p \leq 0.05$.

RESULTS

The mean age of our patients was 69.83 ± 6.99 years, with 51.9% men ($n=56$) and 48.1% women ($n=52$). The dose of triamcinolone injected was 4 mg in all eyes. No intraoperative major complications were reported.

One hundred and eight eyes of 98 patients (69 eyes with DME at the time of surgery, group I; 39 eyes without DME in the last 3 months before surgery, but previous records of DME, group II) were included in the study.

In group I, the median age was 69.59 years and 52.2% ($n=36$) of patients were male. The median glycosylated hemoglobin (HbA1c) level was $7.65 \pm 1.51\%$ (36.8% with less

than 7). In the study, 84.1% ($n=58$) of cases had received previous retinal laser treatment in the form of panretinal photocoagulation. Mean BCVA, at baseline, before surgery, was 0.67 ± 0.33 logMAR and 1 month after the procedure was 0.41 ± 0.31 logMAR, a statistically significant increase ($p<0.001$). Baseline CMT (before surgery) was 435.57 ± 169.51 μm . CMT decreased significantly in the first month ($p<0.001$), with a mean variation of -88.70 ± 184.33 (-13.53%). Moreover, in 78.70% of the patients the CMT remained the same or decreased. A clinically significant increase ($\geq 20\%$) of CMT was verified in 6 cases (8.70%). Nine cases (13.04%) developed transient ocular hypertension, all of them completely reversed within a few days with antihypertensive eye drops. The mean intraocular pressure before surgery was 19.92 ± 3.52 mmHg. Mean intraocular pressure variation one-month after surgery was -0.67 ± 3.35 mmHg ($p=0.07$, no statistical significance).

In group II, median age was 70.23 years and 51% ($n=20$) of patients were male. The median HbA1c level was $7.59 \pm 1.47\%$ (40.5% with less than 7). Seventy-one-point eight percent ($n=28$) of cases had received retinal laser treatment, in the form of panretinal photocoagulation. Forty-six-point two percent ($n=18$) of these patients have never received anti-angiogenic intravitreal injections. Among the remaining 21 participants, the median number of injections received was 6.76 ± 4.69 . The average time interval between cataract surgery and last macular edema treatment in the form of intravitreal injection of anti-angiogenic was 19.29 ± 18.82 months. None had received treatment in the form of intravitreal corticosteroid therapy. The mean BCVA at baseline was 0.62 ± 0.34 logMAR and 1 month after the procedure was 0.32 ± 0.34 logMAR, a statistically significant increase ($p<0.001$). Baseline CMT (before surgery) was 295.03 ± 47.91 μm . CMT decreased in the first month ($p<0.001$), with a mean variation of -0.35 ± 48.71 (-1.7%). Moreover, in 70.60% of the patients the CMT remained the same or decreased. A clinically significant increase ($\geq 20\%$) of CMT was verified in only 2 cases (5.13%). Six cases (15.38%) developed transient ocular hypertension, completely reversed within a few days with antihypertensive eye drops, and no cases needed to maintain this medication after the 1-month reassessment. The mean intraocular pressure before surgery was 16.92 ± 3.13 mmHg. The mean intraocular pressure variation one month after surgery was -0.32 ± 5.02 mmHg ($p=0.48$, no statistical significance).

The key results are summarised in Table 1.

DISCUSSION

Despite multiple studies in the literature on the efficacy and safety of intravitreal corticosteroids in macular edema,^{8,11,15,16} the literature is still scarce with studies exclusively looking at the effect and approach of intraoperative IVTA along with cataract surgery in patients with DME or previous history of DME. In our study, there was significant improvement in BCVA and the majority of eyes had DME resolved, if previously present, or it was effectively prevented, if absent before, in the post-surgical period. No serious ocular compli-

Table 1. Comparison of Clinical Characteristics and Outcomes Between Group I and Group II Patients.

CHARACTERISTIC	GROUP I VALUE	GROUP II VALUE
Median age (years)	69.59	70.23
Male (%)	52 (n=36)	51 (n=20)
Median HbA1C level	7.65 ± 1.51	7.59 ± 1.47
Previous retinal laser treatment (%)	84.1 (n=58)	71.8 (n=28)
Median number of injections received	-	6.76 ± 4.69
Mean BCVA at baseline (logMAR)		0.62 ± 0.34
Mean BCVA 1-month post-op (logMAR)	0.41 ± 0.31	0.32 ± 0.34
Baseline CMT (µm)	435.57 ± 169.51	295.03 ± 47.91
Mean CMT variation	-88.70 ± 184.33	-0.35 ± 48.71
Mean IOP before surgery (mmHg)	19.92 ± 3.52	16.92 ± 3.13
Mean IOP variation 1-month post-op (mmHg)	-0.67 ± 3.35	-0.32 ± 5.02

BCVA best corrected visual acuity; CMT central macular thickness; IOP intraocular pressure.

cations occurred intraoperatively or postoperatively.

The more significant alternative treatment for DME is intravitreal injections of anti-vascular endothelial growth factor (anti-VEGF) agents. However, the most frequently utilized drugs are ranibizumab and bevacizumab, with ranibizumab noted for its considerable cost and bevacizumab employed off-label for DME. The comparative efficacy of IVTA and intravitreal bevacizumab in managing DME remains a topic of ongoing debate in the literature.¹⁷⁻²⁰

The DRRCR Retina Network Protocol Q study reported that patients with diabetic retinopathy had an increased risk of developing central DME if they had either preoperative noncentral DME or previous DME treatment.²¹ This suggests a possible benefit of additional therapy (i.e. intravitreal corticoid injection) in cataract surgery in eyes with preexisting DME or previous DME treatment. In our study, the addition of IVTA to cataract surgery resolved or prevented DME in most eyes, with beneficial results in both groups. The vast majority of cases of either of these categories showed a decrease or stabilization of CMT (78.70% and 70.60% of cases in group I and II, respectively). A clinically significant (>20%) CMT increase was verified in less than 10% of cases in both groups (8.70% and 5.13%, respectively).

These data are consistent with the results found in the literature. Lam D *et al* (2005) has indicated before that diabetic patients with clinically significant macular edema who undergo combined phacoemulsification and IVTA can have statistically significant improvement in BCVA, maintained at 6 months postoperatively, with no significant adverse events.²² Other studies presented similar effective results in subjects who are unresponsive to conventional therapies like laser photocoagulation.²³⁻²⁵ In addition, the European PREMED study 2 found reduction of CMT with subconjunctival triamcinolone at the end of cataract surgery in diabetic patients. Even if the administration was different and not intravitreal, it provides support for the corticosteroids role in preventing and reducing the amount of macular edema in diabetic patients after cataract surgery.²⁶

Regarding functional improvement, mean BCVA increased significantly ($p < 0.001$) in both groups. The mean variation of VA in group I was -0.28 ± 0.25 logMAR, slightly lower than the -0.30 ± 0.29 logMAR variation of the group without DME at surgery time (group II). It represents an improvement of about three lines of visual acuity in both groups. However, a large contribution of this positive variation is likely attributable to the removal of the cataract.

Several previous studies have shown that IVTA is a safe procedure.¹²⁻¹⁴ Complications encountered can be drug-related, as elevation of intraocular pressure. Incidence of IOP elevation has been reported to vary from 25 to 70%.^{12,13,27} In this study, there was no significant increase of intraocular pressure after IVTA in most eyes, and even the few cases in which was verified an increased beyond normal pressure values (13% and 15% in group I and II, respectively), all of them completely reversed with few days with eye drops. Although no serious intraoperative or postoperative complications occurred, the effect of intraocular steroids on ocular hypertension is still of concern and it should be cautiously used in patients with history of glaucoma or ocular hypertension.

Complications may also be related with the procedure of injection, such as retinal or choroidal detachment, vitreous hemorrhage or even endophthalmitis.^{14,28} No acute complications of this kind were verified in the current study.

Limitations of this study include the retrospective design. The lack of a control group, which did not receive IVTA, hamper the understanding of the exact visual improvement attributed to intravitreal corticosteroid.

Nevertheless, our data suggest that our patients benefited in visual function and macular anatomy. Furthermore, IVTA is a choice with low economic cost, with the additional benefit of having an anti-inflammatory role, which might lead to a better and faster recovery from the cataract surgery itself. Intraoperative IVTA should be considered in diabetic population with concomitant cataract and DME or history of previous DME.

CONCLUSION

Diabetic patients have an increased risk of developing central DME after phacoemulsification surgery, especially if previous DME history is present. Our study highlights IVTA in cataract surgery as an important tool to prevent DME development. Furthermore, if DME is already present at time of surgery, concomitant IVTA is a safe and effective option, with good visual and anatomic outcomes.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO

ST: Desenho do estudo e escrita.

PM: Escrita e revisão.

FSN: Desenho do estudo e revisão.

Todos os autores aprovaram a versão a ser publicada.

ST: Study design and writing.

PM: Writing and review.

FSN: Study design and revision.

All authors have approved the version to be published.

RESPONSABILIDADES ÉTICAS

Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.

Fontes de Financiamento: Não existiram fontes externas de financiamento para a realização deste artigo.

Confidencialidade dos Dados: Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.

Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2013 e da Associação Médica Mundial.

Proveniência e Revisão por Pares: Não comissionado; revisão externa por pares.

ETHICAL DISCLOSURES

Conflicts of Interest: The authors have no conflicts of interest to declare.

Financing Support: This work has not received any contribution, grant or scholarship

Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of data from patients.

Protection of Human and Animal Subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of

the World Medical Association (Declaration of Helsinki as revised in 2013).

Provenance and Peer Review: Not commissioned; externally peer reviewed.

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