Intraocular inflammation after Ultrasound Cyclo Plasty for the treatment of glaucoma

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Abstract
• This is a prospective interventional clinical study evaluating intraocular inflammation developed after Ultrasound Cyclo Plasty (UCP) for the treatment of glaucoma. Eighteen eyes of 18 patients were treated with UCP second-generation probes (Eye OP1). After treatment, the mean intraocular pressure (IOP) significantly decreased from 26.8±7.2 to 18.8±6.1 mm Hg at day 1 and to 14.7±3.4 mm Hg at month 6 (all P<0.001). Mean laser flare-cell photometry value steeply increased after surgery from 12.1±7.5 to 64.1±53.9 ph/ms (P=0.001) at day 1, and then progressively decreased to respectively 60.6±49.7 at day 7, 43.5±38.5 at day 14 and 28.2±18.3 at month 1 (all P<0.05), returning at levels similar to baseline ones at month 3 and month 6 (respectively 16.7±6.2 and 12.8±10.2, both P>0.05). A significant negative correlation was found between postoperative increase of aqueous flare values and anterior chamber depth (R=-0.568, P=0.014). This timeframe may be considered reasonable for repeating UCP treatment, when required.
• KEYWORDS: Ultrasound Cyclo Plasty; glaucoma; intraocular pressure; ciliary body; intraocular inflammation; laser flare-cell photometry
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INTRODUCTION

Glaucoma represents one of the leading causes of visual impairment worldwide[11], and the reduction of intraocular pressure (IOP) represents the only treatment able to halt or slow the progression of visual field loss[12]. Many physical methods have been proposed in the past to partially destroy the ciliary body by means of diode and Nd:YAG laser, cryotherapy, and microwave heating[13-15]. However, cyclodestructive methods have two major drawbacks: they are non-selective for the ciliary body, potentially damaging also the adjacent structures; they have an unpredictable dose-effect relationship, with a high rate of complications.

Recently, a novel device using high-intensity focused ultrasound for the coagulation of the ciliary body, Ultrasound Cyclo Plasty (UCP), has been developed with the aim of achieving selective and controlled thermic effect on the ciliary body, thus limiting the damage to adjacent structures[6].

To date, there is no information available about the effects of UCP procedure on breakdown of blood-aqueous barrier, and thus on postoperative intraocular inflammation.

The purpose of the study was to assess the postoperative course of intraocular inflammation by laser flare-cell photometry in glaucoma patients undergone UCP.

SUBJECTS AND METHODS

Ethical Approval   This prospective interventional clinical study was conducted between January 2017 and June 2018 at S. Orsola-Malpighi University Hospital (Bologna, Italy). All participants provided both verbal and written informed consent before any study procedure. The study was approved by the local Institutional Review Board, and was carried out in accordance with the principles of the Declaration of Helsinki.

Methods Inclusion criteria were: age older than 18y; diagnosis of glaucoma with uncontrolled baseline IOP (≥ 21 mm Hg) under maximum treatment; intolerance to glaucoma medications despite well-controlled IOP. Exclusion criteria were: pregnancy; uveitic, traumatic or normal-tension glaucoma; history of laser or surgery within the previous 6mo; ocular surface disease; use of topical or systemic corticosteroid in the previous 3mo.

Patients were treated by UCP device (Eye OP1, Eye Tech Care, Rillieux-la-Pape, France). All of the procedures were performed under peribulbar anesthesia using the second-generation probes, as previously described[7]. After the procedure, patients were treated topically with tobramycin and dexamethasone combination eye drops (Tobradex, Alcon Inc., Fort Worth, TX, USA) 4 times daily for 4wk. Hypotensive medications were interrupted after surgery, and then prescribed again only if postoperative IOP was ≥ 21 mm Hg at any visit.
Baseline evaluation included best-corrected visual acuity (BCVA), slit lamp biomicroscopy examination, gonioscopy, fundus examination, IOP measurement by Goldmann applanation tonometry, optical biometry (Lenstar LS 900, Haag-Streit, Koeniz, Switzerland) and laser flare-cell photometry (FM-500, Kowa, Tokyo, Japan). Slit lamp biomicroscopy, BCVA, IOP measurements and laser flare-cell photometry were repeated postoperatively at 1, 7, and 14d, 1, 3 and 6mo.

Statistical Analysis The SPSS statistical software (SPSS Inc, Chicago, Illinois, USA) was used for data analysis. The homogeneity of variances was assessed by the Levene test. Variables following a normal distribution were presented as the mean±SD. Paired t tests were used to compare pre- and postoperative IOP and aqueous flare values. One-way ANOVA tests were conducted to assess the differences of aqueous flare values among glaucoma types and lens status. The associations of the aqueous flare values with the IOP and the biometric parameters were calculated using Pearson correlation analysis. A P<0.05 was considered statistically significant.

RESULTS Eighteen eyes of 18 consecutive patients undergone UCP procedure were included in the study. The baseline characteristics of patients are summarized in Table 1.

One day postoperatively, the mean IOP significantly decreased from 26.8±7.2 to 18.8±6.1 mm Hg (P<0.001). At 6mo postoperatively, the mean IOP was still significantly reduced compared to preoperative values (14.7±3.4 mm Hg; P<0.001). Figure 1 shows the reduction of IOP over the time, expressed as both mean value and percentage of reduction.

Mean BCVA remained statistically unchanged (1.54±1.18 vs 1.59±1.31 logMAR; P=0.234), and no major intraoperative or postoperative complications occurred. Before surgery, the mean laser flare-cell photometry value was 12.1±7.5 ph/ms. After surgery, flare values steeply increased to 64.1±53.9 ph/ms (P=0.001) at day 1, and then progressively decreased to respectively 60.6±49.7 at day 7, 43.5±38.5 at day 14 and 28.2±18.3 at month 1 (all P<0.05). ACG: Age-closure glaucoma; BCVA: Best-corrected visual acuity; IOP: Intraocular pressure; OAG: Open angle glaucoma; SD: Standard deviation; XFG: Exfoliative glaucoma.

DISCUSSION The present study confirms existing data about the safety and efficacy of UCP procedure, with no major complications and an IOP reduction of almost fifty percent after 6mo of follow-up.
Intraocular inflammation after Ultrasound Cyclo Plasty

Despite previous studies have shown increased flare values after various surgical procedures, including phacoemulsification, penetrating keratoplasty, refractive surgery, trabeculectomy and deep sclerectomy, poor information are available regarding postoperative inflammation in patients undergone cyclodestructive procedures. To the best of our knowledge, no research has yet addressed the post-operative inflammation following UCP. In fact, despite advances in ocular surgical techniques, some amount of post-operative intraocular inflammation is unavoidable, even after uneventful minimally invasive surgery, like UCP. Traditionally, inflammation in the anterior chamber is evaluated with the slit-lamp in a semi-quantitative method; conversely, laser flare-cell photometry provides an objective, non-invasive and quantitative method for measuring the aqueous flare.

In the present study, flare photometry values showed a significant increase at day 1 postoperatively, with one third of the patients having a flare higher than 100 ph/ms in the first post-operative week. Then, flare values gradually decreased, and recovered to preoperative levels by 3mo after surgery. The increase of flare values after UCP appears lower compared to values recorded after traditional cyclophotocoagulation in the only paper available in the literature. Postoperative inflammatory reaction may be secondary to the direct damage of the ciliary epithelium, which is a key component of the blood-aqueous barrier. Postoperative inflammation has major implications in daily clinical practice. It has been hypothesized that intraocular inflammation may be related, at least in part, to IOP-lowering effect of cyclodestructive procedures that intraocular inflammation may be related, at least in part, to IOP-lowering effect of cyclodestructive procedures. It has been hypothesized that intraocular inflammation may be related, at least in part, to IOP-lowering effect of cyclodestructive procedures. To the best of our knowledge, no research has yet addressed the post-operative inflammation following UCP. In fact, despite advances in ocular surgical techniques, some amount of post-operative intraocular inflammation is unavoidable, even after uneventful minimally invasive surgery, like UCP. Traditionally, inflammation in the anterior chamber is evaluated with the slit-lamp in a semi-quantitative method; conversely, laser flare-cell photometry provides an objective, non-invasive and quantitative method for measuring the aqueous flare. Postoperative inflammation in patients undergone cyclodestructive procedures. To the best of our knowledge, no research has yet addressed the post-operative inflammation following UCP. In fact, despite advances in ocular surgical techniques, some amount of post-operative intraocular inflammation is unavoidable, even after uneventful minimally invasive surgery, like UCP. Traditionally, inflammation in the anterior chamber is evaluated with the slit-lamp in a semi-quantitative method; conversely, laser flare-cell photometry provides an objective, non-invasive and quantitative method for measuring the aqueous flare.

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Additionally, intraocular inflammation is considered a major risk factor for developing post-surgical cystoid macular edema, a possible complication of various ocular surgeries, including cyclodestructive procedures. This matter is relevant since UCP is addressed also to eyes with good visual potential and in less advanced stage of disease, being an early option in glaucoma management. The lower increase of intraocular inflammation after UCP compared to traditional cyclodestructive techniques may provide an additional advantage of the former technique. In this study, a shallow anterior chamber was associated with a higher intraocular inflammation rise after UCP. A similar association was observed in a previous study evaluating the postoperative aqueous flare after trabeculectomy. Two main explanations could be proposed: firstly, leaked proteins may be diluted in a smaller aqueous volume in eyes with shallow anterior chamber; secondly, a better targeting of the ciliary body may occur in these eyes. Previous studies reported a significant higher flare in eyes with pseudoexfoliation syndrome, as well as a higher increase in flare after trabeculectomy in eyes with exfoliative glaucoma compared to those with primary open angle glaucoma. However, in the present study flare values were similar both before and after surgery among the different types of glaucoma.

Repeated treatment with UCP have been proposed in case of partial or insufficient IOP reduction, but the proper timeframe has yet to be defined. Our study showed that inflammation returned to baseline values three months after surgery, because of the gradual recovery of blood-aqueous barrier. This timeframe may be considered reasonable for repeating UCP treatment, when required.

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Conflicts of Interest: Pellegrini M, None; Sebastiani S, None; Giannaccare G, None; Campos EC, None.

REFERENCES


