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Research Article

Safety and Efficacy of Focused Ultrasound Cycloplasty in Glaucoma at the Central Military Hospital

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Abstract

Introduction: The ultrasound ciliary plasty has a mechanism of action comparable to other cyclodestructive procedures, as it lowers IOP by destruction of the ciliary processes and lowering the aqueous production. In this study we aim to analyse the safety and efficacy of this method and its associated complications, as well as the resulting need of hypotensive medication and percentage of IOP reduction.

Methods: This is a retrospective, transversal, analytic, observational study in which we analyzed the records of patients treated with UCP at the Central Military Hospital with a follow-up of 6 months, and the post operative findings on day 1, 7, 30, 3 months and 6 months, during the period from May 1st to November 30th 2022.

Results: Our sample had 31 eyes from 22 patients with an average of 3.31 hypotensive medication, which was lowered to 1.6. 59% of our patients had some kind of complication. The mean basal IOP was 19.19 mmHg, which lowered to 11.31 mmHg during the first week, 12.86 mmHg on the first month, 12.30 mmHg at the third month and 12.13 mmHg at the 6th month.

Conclusion: UCP is efficient as a method to lower IOP in patients who cannot achieve IOP goals even with maximum hypotensive therapy. It can be used as a first line surgical procedure and allows retreatment, as well as being useful as adjuvant therapy. Nevertheless, it is not exempt from complications although they are mild and temporary

Keywords: *Glaucoma; Intraocular Pressure; Ciliary Plasty; Ultrasound*

Introduction

Glaucoma is defined as a chronic and progressive optic neuropathy which presents as its main characteristic a loss of the nerve fiber layer of the retina, accompanied by defects in the visual field. In some cases, an increase in intraocular pressure (IOP) may occur and it is precisely this factor that is the only modifiable factor to control the disease [1].

Refractory glaucoma is diagnosed when it is hard to achieve adequate control of IOP despite medical treatment, and conventional filtering surgery has a poor curative effect, with a failure rate of up to 89%. For this reason, new alternatives have been sought to improve the effectiveness in controlling intraocular pressure. These alternatives target the ciliary body, since it is the responsible for the production of aqueous humor. Currently, methods for ciliary body destruction include trans-scleral ciliary body cryosurgery, trans-scleral ciliary body photocoagulation, and endoscopic ciliary body laser photocoagulation. However, these cycle destructive treatments have failed to achieve focused therapy, resulting in damage to surrounding tissues [1,2].

Focused ultrasound cycloplasty (UCP) is a procedure that uses high-intensity focused ultrasound with small transducers. This treatment focuses ultrasound energy on the ciliary process, causing irreversible coagulation necrosis and leaving no damage to surrounding tissues. Currently it is the only selective technology directed at the ciliary body [1,3]. Several clinical trials have shown that this device allows a significant and predictable reduction in intraocular pressure (IOP) with an acceptable safety profile [4-8].

Despite these advantages, focused ultrasound cycloplasty causes significant pain and inflammation, which limits its application. Coleman first published a report on focused ultrasound as glaucoma treatment in 1985 [7,8]. Since 1990, focused ultrasound technology was widely used in the treatment of refractory glaucoma in the United States and Europe, but due to the complexity of application by the limitation of the technology at that time, this technique was progressively abandoned. In 2011, Aptel., *et al*. described the Ultrasonic Cyclo Plasty (UCP) procedure, a new procedure that uses high-intensity focused ultrasound with miniaturized transducers, making treatment positioning more precise and the process simpler.

The main mechanisms of focused ultrasound in the treatment of glaucoma are as follows: (1) coagulation of ciliary epithelial cells and reduction of aqueous humor secretion; (2) contraction of the scleral tissue in the treatment area leading to traction and opening of the trabecular meshwork and eventually increasing the outflow of aqueous humor; (3) the scleral tissue in the treatment area is thinned and the aqueous humor flows from the thinned sclera to the subconjunctival area; and (4) reorganization of scleral tissue in the treatment area leads to separation of the sclera and ciliary body, thus increasing the outflow of aqueous humor from the suprachoroidal space [10-14].

Initial reports suggested that UCP (Focused Ultrasound Cycloplasty) has a comparable mechanism of action to other cyclodestructive procedures, such as transscleral diode photocoagulation, which lowers IOP by destroying ciliary processes and suppressing aqueous production.

Methodology

An observational, analytical, cross-sectional, retrospective study was carried out, in which records of patients with glaucoma who underwent cycloplasty by focused ultrasound at the Central Military Hospital were reviewed, who also had completed follow-up for 6 months and the findings of each visit were described in the Digital Health System in the period from May 1st, 2022 to November 30th, 2022. Postoperative findings were reported at day 1, 7, 30, 3 months and 6 months.

Inclusion criteria:

- Records of patients aged between 18 and 90 years.
- Diagnosis of glaucoma or ocular hypertension (OHT) with suboptimal IOP control despite maximum medical treatment.
- Patients who have undergone cycloplasty by focused ultrasound and who have completed 6 months of follow-up.

Exclusion criteria:

- Previous intraocular surgeries, including iridotomies < 3 months.
- Pregnancy.
- Systemic medications that could affect IOP.
- Incomplete files.

Results

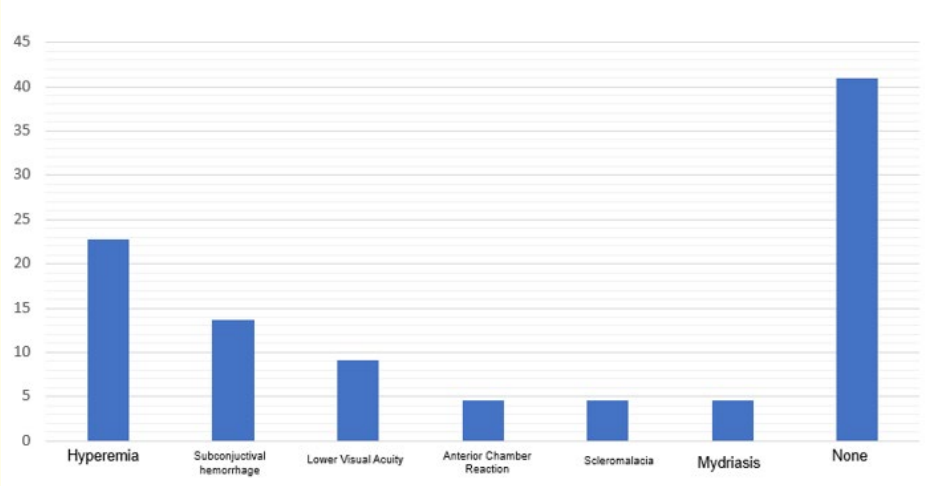
A total of 31 eyes of 22 patients were included in the study, mostly people over 65 years of age (64%), 55% (n = 12) of the population were men and 45% (n = 10) women. 82% of the population had a previous diagnosis of primary open-angle glaucoma, while 9% presented

Neovascular Glaucoma and the remaining 9% had other types of glaucoma. 55% (n = 12) of the population had received previous surgeries. Likewise, we observed that the average number of medications used by the patients was 3.31 before the Focused Ultrasound Cycloplasty, decreasing to 1.6% 6 months after the treatment (Table 1).

Classification by age	**Frequency (#)**	**(%)**
18 - 35 years	2	9
35 - 65 years	6	27
65 years and onwards	14	64
Gender	**Frequency (#)**	**(%)**
Female	10	45
Male	12	55
Glaucoma Classification	**Frequency (#)**	**(%)**
Primary Open Angle Glaucoma	18	82
Neovascular Glaucoma	2	9
Other	2	9
	Frequency (#)	**(%)**
Previous surgery	12	55
No surgery	10	45
Average amount of medications prior to the procedure	3.31	
Average amount of medications after the procedure	1.6	

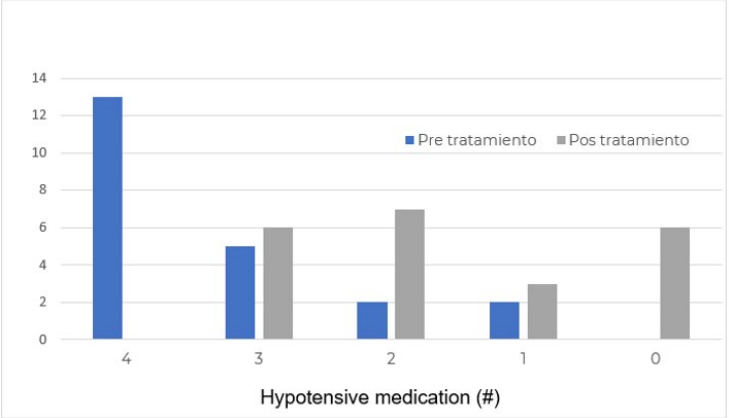
Table 1: *Patients characteristics.*

The results of this study show that 59% (n = 13) of the sample presented some complication. Hyperemia predominated with 23% (n = 5), hyposphagma with 14% (n = 3), decreased transient visual acuity with 9% (n = 2), and the remaining 15% presented other complications such as inflammation of the anterior chamber 5% (n = 1), scleral imprinting 5% (n = 1) and mydriasis 5% (n = 1). The patients who did not present any complications were 41% (n = 9). This is made evident on graph 1.



Graph 1: *Post operative complications (n = 31).*

Graph 2 shows the use of medications before and after focused ultrasound cycloplasty (UCP) treatment, in which it can be seen that prior to treatment, 59% (n = 13) of population used 4 medications, with an average of 3.31, however, after treatment it was reported an average of 1.6, in addition to the fact that 27% (n = 6) of the patients no longer required hypotensive medications, which means a decrease in the amount of medication used (Table 1).



Graph 2: *Pre and post operative hypotensive medication.*

Table 2 shows the results where the decrease in IOP can be observed in relation to time. The average basal intraocular pressure was 19.19 mmHg, and during the first week visitation, the relative reduction was 11.31 mmHg (41%); at the first month visitation, the average IOP was 12.86 mmHg (33%), and on the third and sixth month visitation the average IOP remained between 12.30 mmHg (36%) and 12.13 mmHg (37%), respectively.

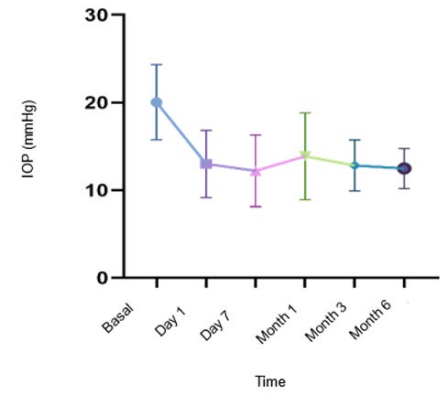
Time	Mean IOP (mmHg)	Relative reduction IOP (%)
Basal	19.19	-
1 day	11.93	38
1 week	11.31	41
1 month	12.86	33
3 months	12.30	36
6 months	12.13	37

Table 2: *Average intraocular pressure (IOP) at baseline and after focused ultrasound cycloplasty treatment.*

On graph 3 is shown that there is a significant decrease in IOP on the first postoperative day, which continues to decrease towards the first week, then increases slightly towards the first month of treatment and finally maintains a stability tending to decrease towards 6 months after treatment.

Discussion

Focused ultrasound cycloplasty (UCP) in patients with glaucoma demonstrated adequate efficacy and an acceptable safety profile at a 6-month follow-up. On average, a 37% decrease in IOP was obtained without serious or irreversible complications.



Graph 3: *Post operative IOP.*

The results of our study evaluated the reduction of IOP after treatment in terms of efficacy, as well as the decrease in the amount of medications required for IOP control. They are consistent with what is reported in the international literature, since in our population, the baseline IOP was 19.19 mmHg, and at the last visit recorded in the study was 12.13 mmHg. Literature published in France in 2014, by Denis., *et al*. [16] reports a 32% - 35% decrease within the first 6 months, while studies published in 2018, by Nardi., *et al*. [3] found a 30 - 35% reduction in IOP at 12-month follow-up. However, there is a significant difference with what was reported in 2018 by Alaghband., *et al*. [15] whose result is a 20% decrease in a 3-month follow-up. In our study, the decrease in maximum IOP was found in the first week, increasing towards 4 weeks and then stabilizing until 6 months of follow-up. Regarding the decrease in hypotensive medications required by the patient, this was proportional to the reduction in IOP. The initial average number of medications was 3.31, which decreased to 1.6, in addition to 27% of our sample terminating hypotensive treatment.

In our study we found 59% of complications, which were transient and mostly mild. Those reported were conjunctival hyperemia, scleral imprinting, anterior chamber inflammation, and hyposphagma. All of these events resolved spontaneously within the first 2 months of the study. Two patients presented decreased vision: in one patient it was accompanied by mydriasis secondary to injury to the nerve roots during the procedure, which resolved spontaneously after 2 months; the second patient presented central retinal vein occlusion, unrelated to the procedure. We found that there were no patients with hypotonia, corneal edema, choroidal detachment or phthisis bulbi. These findings are in line with what was reported by Alaghband., *et al*. (2018) [15] in the United Kingdom and Figus., *et al*. (2021) [7], where they observed adequate tolerance to the intervention.

The limitations our study finds are the relatively small sample and the short follow-up of the patients.

Conclusion

According to our findings, we conclude that UCP is efficient in reducing IOP in patients with suboptimal control despite maximum treatment. This therapy can be used as a first line of surgical treatment in patients with glaucoma and with the possibility of retreatment or as an alternative in patients with previous filtering surgeries. However, it is not free of complications, although these are mild and temporary in nature. Therefore, the safety profile of UCP is high and is well tolerated by patients.

Conflict of Interests

All authors declare no conflict of interests.

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