Ultrasound Circular Cyclo Coagulation: a 12 months' follow-up pilot study

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PURPOSE
To evaluate the safety and efficacy of HIFU (high-intensity focused ultrasound) delivered by a miniaturized annular therapy probe in order to perform the new UC2 procedure (Ultrasound Circular Cyclo Coagulation) in patients with refractory glaucoma through 12 months' follow-up.

METHODS
HIFU device (EyeTechCare – France) : A ring shaped therapy probe containing six active piezoelectric elements was inserted in a coupling cone made of polymer. Each of the six transducers was a segment of a 10.2 mm radius cylinder with a 4.5 mm width and a 7 mm length (surface area of about 35 mm²). The focal volume of each transducer has approximately an elliptic cylinder geometric shape (axial length 1.2mm, transverse width 0.4 mm and the lateral width 3.5 mm).

The six transducers were placed at regular intervals on the circumference of the ring and oriented in order to create a focal zone consisting of 6 elliptic cylinders regularly disposed in a 11.7, 12.2 or 12.7 mm diameter circle superimposed on the ciliary body. The resonant frequency of the transducers was 7 MHz and we operated it at its third harmonic, i.e. 21 MHz.

CONCLUSIONS
Circular coagulation of the ciliary body using HIFU (high-intensity focused ultrasound) delivered by a ring shaped miniaturized therapy probe seems to be an effective and well-tolerated method to reduce intraocular pressure in patients with refractory glaucoma.

The single step procedure was short (less than 2 minutes), easy and accurate.

Results: IOP reduction

<table>
<thead>
<tr>
<th>Mean group IOP (mmHg)</th>
<th>5 days</th>
<th>5 weeks</th>
<th>1 month</th>
<th>6 months</th>
<th>12 months</th>
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</thead>
<tbody>
<tr>
<td>Preop (m=medications)</td>
<td>35.6 + 2.5 mmHg</td>
<td>40.5 + 13.6 mmHg</td>
<td>28.8 ± 7.9 mmHg</td>
<td>27.8 ± 9.0 mmHg</td>
<td>27.3 ± 3.2 mmHg</td>
</tr>
<tr>
<td>Postop (m=medications)</td>
<td>21.9 ± 19.1% (n=4)</td>
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Safety and tolerability
No major intra- or post-operative complications occurred. Trabeculectomy was performed in one patient (group 2) due to lack of efficacy at one month. Suprachoroidal punctate keratitis occurred in 4 patients. All of them presented a pre-operative pathologic condition of the comae. All were successfully treated with artificial tears and vitamin A. Visual acuity remained statistically unchanged.

Ultrasound Biomicroscopy
UBM showed cystic involution of the ciliary body in 9 of the 12 eyes, and a suprachoroidal fluid space in 8 of the 12 eyes.

Procedures: Prospective comparative interventional clinical study in 12 eyes of 12 patients with refractory glaucoma and uncontrolled intraocular pressure (IOP). UBM and a complete ophthalmic examination were performed before the procedure, and at 1 day, 1 week, 1, 3, 6 and 12 months after the procedure. The following parameters were used: acoustic power 2 W; duration of each shot 3 s (group 1: patients 1 to 4), 4 s (group 2: patients 5 to 12), time between each shot 20 s.


Reference:

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