كليه الطب
قسم طب وجراحة العين

عنوان الرسالة باللغة العربية

"التخثر البطيء عبر الصلبة للتخثير الضوئي للجسم الهدبي مقابل استئصال الشبكة التربيقية في حالات المياه الزرقاء مفتوحة الزاوية غير المتحكم فيها علاجياً لدى المرضى الذين خضعوا لزرع عدسة إصطناعية بعد إزالة عدسة العين"

Title of the study

"Slow Coagulation Trans-Scleral Cyclophotocoagulation versus Trabeculectomy in Medically Uncontrolled Open-Angle Glaucoma in Pseudophakic Patients"

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Introduction

Glaucoma is an optic neuropathy that is characterized by progressive structural and functional neuropathy.(1) It is a leading cause of irreversible blindness worldwide.(2)

Open angle glaucoma (OAG) is the commonest subtype of glaucoma. The number of patients diagnosed with POAG was estimated 52.68 million in 2020 and expected to be 79.76 million in 2040.(3)

The management of OAG in patients with pseudophakia aims to lower intraocular pressure (IOP), which is the major modifiable risk factor for glaucoma progression.(4) This can be achieved by different modalities including medical, laser or surgical methods.(5)

In many cases medical therapy can provide an effective IOP control, while surgery and laser are still indicated when the medical treatment fails to lower IOP sufficiently, or if the patient is not compliant with treatment.(6)

Trabeculectomy with mitomycin C (MMC) is a filtration procedure that reduces IOP by creating a connection between the anterior chamber and the sub-conjunctival space after excision of a part of the trabecular meshwork. Pseudophakic eyes with OAG have a higher risk for surgical failure of trabeculectomy with MMC than the phakic eyes.(7) Also it is associated with a higher incidence of complications as hypotony, lost anterior chamber or supra-choroidal effusion.(8)

Laser therapy, as a cyclodestructive procedure, lowers IOP by reducing aqueous humor production. This is achieved through the application of diode laser energy to the sclera, which is absorbed by the melanin pigment in the ciliary processes, resulting in coagulative necrosis of the ciliary body. Historically, this treatment was regarded as a last-resort option for eyes with very limited visual potential due to the significant risks of uncontrolled inflammation and phthisis bulbi.(9)

Now, with recent advances in laser probes and laser settings, the safety of trans-scleral cyclo-destruction has improved, rendering it a viable non-invasive option for a broader spectrum of patients including those with good visual acuity (VA) and as a primary procedure in management of OAG with pseudophakia.(10)

Two approaches are commonly used to deliver laser energy using continuous wave trans-scleral cyclo-photocoagulation (CW-TSCPC): the conventional "pop" technique, where laser energy is initially increased until an audible, explosive, cavitating tissue-derived "pop" is heard. The laser power is then reduced until these pops are no longer audible. This method typically

begins with a laser energy setting of approximately 1750–2000 mW, applied for a short duration of 2 seconds,(11) and the treatment is delivered circumferentially along the limbus. In contrast, slow coagulation (SC) CW-TSCPC utilizes a lower amount of diode laser energy over an extended period, approximately 1250 mW over 4 seconds.(11, 12)

Previous results comparing the outcomes of the slow coagulation approach with the conventional high-energy pop approach found a lower incidence of postoperative complications in the slow coagulation group and comparable IOP- lowering effects between both groups.(11) Although conventional CPC may have previously been reserved for blind painful eyes or eyes which have already failed prior glaucoma surgery, recent literature supports slow coagulation TSCPC (SC-TSCPC) as a reasonable primary option to lower IOP in eyes without prior incisional glaucoma surgery.(13, 14)

There have been few reports of SC-TSCPC being used as a primary surgical treatment in patients with glaucoma,(15, 16) and few studies published in the literature documenting the effect of SC-TSCPC in patients with good VA.(17)

Aim of the study

- This study aims to evaluate and compare the safety and efficacy (IOP control) of SC-TSCPC versus trabeculectomy with MMC in the management of medically uncontrolled OAG in pseudophakic eyes.

Patients and methods

- **Study design:**

The current study is a prospective, comparative, interventional, randomized clinical study.

- **Study Population:**

Study participants:

Will be 50 eyes of 50 patients with medically uncontrolled POAG, 25 patients will be subjected to SC-TSCPC (group A), while the other 25 patients will undergo trabeculectomy with MMC (group B).

Randomization:

Simple randomization will be done to get two equal groups. Cases will be randomly allocated to the groups through closed envelope system in which we will put 25 cards with symbol A and another 25 cards with symbol B in closed envelope. One card will be taken randomly and then will be allocated in the group according to the symbole in the card choosen.

- **Ethical approval**:

All patients included in this study will be verbally briefed about the details and the nature of the study & will sign a written consent according to the local Ethics Committee of Minia University Faculty of Medicine.

- **Place of the study:**

The study will be conducted in Ophthalmology department, Minia university Hospital, Egypt.

❖ **Inclusion criteria:**

1. Patients above 40 years old with POAG who underwent previous uncomplicated cataract surgery with intraocular lens implantation.
2. Pseudophakic patients with medically uncontrolled glaucoma in spite of the use of two anti-glaucoma medications or intolerance to medical therapy.
3. Glaucoma patients with the following characteristics:
    - Visual field testing with defects in both the superior and inferior hemi-fields outside the central 5 degrees of fixation.
    - Mean deviation (MD) on standard automated perimetry (SAP) ranges between -6 dB and -12 dB.

Exclusion criteria:

1. Patients with history of previous glaucoma surgery.
2. Patients who have used topical steroids within the last three months.
3. Patients with significant media opacity, such as corneal opacity, that obstructs fundoscopic examination.
4. Patients with ocular diseases as uveitis.
5. Patients with severe ocular surface disorders as ocular cicatricial pemphigoid.
6. Aphakic patients.
7. Ocular interventions apart from YAG posterior capsulotomy.

❖ Ophthalmic examination:

All patients will be subjected to the following:

(A)History:

❖ Complete medical history

❖ Family history of glaucoma.

- History of medications especially topical anti-glaucoma drugs (number of bottles, duration of treatment, & presence of any of side effects of these drops) also history of any systemic medications that may affect the IOP as systemic beta blockers for hypertension.

(B)pre-operative examination:

All patients will undergo a comprehensive ocular examination including:

- Uncorrected visual acuity (UCVA).
- Best corrected visual acuity (BCVA) by log MAR scale.
- Intraocular pressure by a calibrated Goldman-Applanation Tonometer.
- Anterior segment examination using slit-lamp bio-microscopy.
- Gonioscopic examination using Goldmann 3 mirror contact gonio lens.
- Fundus biomicroscopy using a +78 D condensing lens for assessment of optic disc changes.
- Measurement of central corneal thickness using Pentacam.
- Optical coherence tomography of the macula (OCT macula).
- Optical coherence tomography of the optic nerve head (OCT-ONH).
- Visual field examination with Humphrey visual field analyzer.

(C) Description of Surgical Procedure:

SC-TSCPC will be performed under local anaesthesia using topical 4% lidnocaine. All patients will receive 10 mg diazepam intramuscular half an hour before the procedure. A semiconductor diode laser system (wavelength 810 nm) will be used. A 600 μm-diameter laser delivery probe (G-probe) will be centered 1.5 mm behind the surgical limbus and orientated parallel to the visual axis.

The technique will be standardized (energy: 1250 mW; duration: 4 seconds; 24 applications). The applications will be divided into 2 arcs (upper and lower). For each arc, 12 spots will be applied over the ciliary body shadow sparing the 3 and 9 o'clock meridians.

Following SC-TSCPC, prednisolone 1% eye drops four times a day, and ciprofloxacin 0.3% drops four times a day for the prophylaxis of conjunctival infection due to any possible clinical or subclinical conjunctival burn. Antiglaucoma medications will be tapered according to measured IOP.

While trabeculectomy will be done according to Moorfields Safer Surgery System with MMC application with concentration 0.03.(18)

(D) post-operative examination:

1-IOP is measured by ICare tonometer.

- The schedule of IOP measurement will be done 2 weeks, 1 month, 3 months and then 6 months.

2-Postoperative assessment of the eye after the procedures:

- Slit lamp examination:
  - To assess the anterior chamber as regarding its depth (whether normal or shallow & if there is any irido-corneal touch) & its content to exclude hyphemia or reaction.
  - Also, to assess the morphology of the bleb after trabeculectomy whether it diffuse, thin & avascular or not.

3- Postoperative investigations:

- OCT macula at 1 month post-operatively with comparing its parameters to their values pre-operatively to detect macular edema.
- OCT-ONH after 6 months.
- Visual field examination after 6 months.

❖ **Statistical Analysis:**

- Data obtained will be compared for each group.
- Results will be analysed using IBM SPSS.
- P value < 0.05 will be considered significant.

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الملخص العربي

الجلوكوما هو اعتلال العصب البصري الذي يتميز بالتدهور الهيكلي والوظيفي التدريجي للعصب البصري. إنه أحد الأسباب الرئيسية للعمي الغير قابل للعلاج في جميع أنحاء العالم.

الجلوكوما ذات الزاوية المفتوحة هي النوع الفرعي الأكثر شيوعًا من الجلوكوما. وقدر عدد الأشخاص الذين تم تشخيص إصابتهم بالجلوكوما ذات الزاوية المفتوحة بنحو 52.68 مليونًا في عام 2020 ومن المتوقع أن يصل إلى 79.76 مليونًا في عام 2040.

في الجلوكوما ذات الزاوية المفتوحة ، يظل الحفاظ على الرؤية هو هدف العلاج من خلال تصحيح عامل الخطر الوحيد القابل للعلاج في الجلوكوما وهو ضغط العين. يمكن تحقيق ذلك من خلال طرق مختلفة بما في ذلك الطرق الطبية أو الليزر أو الجراحية. ففي كثير من الحالات، يمكن أن توفر العلاجات الطبية والليزر تحكمًا فعالًا في ضغط العين، بينما لا تزال الجراحة ضرورية عندما تفشل الاولي في خفض ضغط العين بشكل كافٍ، أو إذا لم يكن المريض ملتزما بتلك الطرق العلاجية

إن استئصال التربيق مع اضافة مادة ال ميتوميسين هو إجراء ترشيح يقلل من ضغط العين عن طريق إنشاء اتصال بين الغرفة الأمامية والحيز تحت الملتحمة بعد استئصال جزء من الشبكة التربيقية. لسوء الحظ، على الرغم من أنه يقلل من ضغط العين بشكل فعال، إلا أنه يرتبط بارتفاع معدل حدوث المضاعفات مثل انخفاض ضغط العين، أو فقدان الغرفة الأمامية أو الارتشاح فوق المشيمية.

إن العلاج بالليزر كإجراء مدمر يخفض ضغط العين عن طريق تقليل إنتاج السائل المائي حيث يتم إمتصاص الليزر المطبق علي الصلبة بواسطة صبغة الميلانين في الجسم الهدبي مما يؤدي إلي تخثر الجسم الهدبي وكان يعتبر ذات يوم هو الخيار الأخير في العيون ذات الإمكانيات البصرية المنخفضة للغاية بسبب المخاطر المرتبطة بشدة الإلتهاب وضمور العين.

الان ومع التطورات الأخيرة في إعدادات الليزر تحسنت سلامة تدمير الجسم الهدبي عبر الصلبة مما يجعله خيارا غير جراحي قابل للتطبيق لمجموعة أوسع من المرضي بما في ذلك مرضي الزاوية المفتوحة مع وجود عدسة إصطناعية داخل العين.

تستخدم طريقتان بشكل شائع لتوصيل طاقة الليزر بإستخدام التخثر الضوئي المستمر عبر الصلبة: تقنية "الفرقعة" التقليدية حيث يتم زيادة طاقة الليزر حتي يتم سماع فرقعة مشتقة من الأنسجة ثم يتم تقليل الطاقة حتي لا يتم سماعها بعد. لذا بدءا بقوة طاقة الليزر حوالي 1750-2000 مللي واط لفترة زمنية قصيرة 2 ثانية.علي النقيض من ذلك يستخدم التخثر الضوئي البطئ والذي يستخدم كمية أقل من الطاقة علي مدي فترة ممتدة حوالي 1250 مللي واط علي مدي 4 ثوان.

أظهرت النتائج الحديثة التي قارنت بين نتائج نهج التخثر البطئ والنهج التقليدي انخفاض معدل حدوث المضاعفات بعد الجراحة في مجموعة التخثر البطئ. التخثر التقليدي كان يستخدم سابقا في العيون المؤلمة العمياء والعيون التي فشلت فيها جراحات الجلوكوما السابقة إلا أن التخثر البطئ أصبح خيار معقول لخفض ضغط العين دون اللجوء إلي الجراحة في المرضي الذين لديهم حدة إبصار جيدة.