CO2 Laser Assisted Sclerectomy Surgery(CLASS)

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INTRODUCTION

•In a manual non-penetrating deep sclerectomy (NPDS) procedure, a deep scleral flap is first dissected and then a second scleral layer is cut out, leaving an exposed thin layer of trabecular meshwork and Descemet's membrane. Fluid percolation through the remaining tissue is the desired outcome of the procedure.

•Inadvertent perforation of the thin trabecular membrane is a relatively frequent complication, occurring in about 30% of the cases in the early stages of the learning curve of this procedure. The procedure is very demanding and requires significant skills and expertise. Achieving a deep tissue ablation with minimal risk of perforation is therefore desirable.1

•The System (IOPtiMate) being proposed for evaluation is a Beam Manipulating System combined with an 'off the shelf' medical grade CO2 laser intended to enable the use of a CO2 laser, designed for soft tissue procedures, instead of a mechanical knife for the non-penetrating deep sclerectomy (NPDS) procedure. The system is indicated for patients with open angle or pseudo-exfoliative glaucoma.

AIM

The current study describes a prospective, single arm, multi center evaluation of the safety and performance of the CLASS procedure .

PATIENTS & METHODS

•27 eyes of 27 consecutive adult patients (aged 18 years or above) of both sexes, with primary open-angle glaucoma or pseudoexfoliative glaucoma in the eye scheduled for surgery were enrolled in the study.

•Mean age was 71.3±12.1. 12 Male Patients (44.4%), 20 POAG - (74%) & 7 PEX- (26%).

•The procedures were accomplished under topical and subconjunctival anesthesia. A superior fornix-based conjunctival incision was performed . MMC 0.02 % was applied on the bare sclera for 2 minutes. A rectangular limbal-based 5x5mm superior scleral flap of partial thickness (one-third to one-half) was dissected extending 1 mm into clear cornea. Setting of the desired scanning area and its shape was performed, followed by focusing of the laser beam. Visual verification of the area to be treated was done using a red laser aiming beam. The scleral bed was formed by the application of the CO2 laser beam over an area including the Schlemm's canal (Fig. 4).The residual charred tissue resulting from the laser application was removed with a sponge (Fig.5) and until sufficient percolation was achieved, ablation was continued. Once percolation is achieved, fluid absorbs laser energy and thus preventing further ablation (Fig.6). The CO2 laser beam was applied over the canal until percolation started (Fig.6).The scleral flap was repositioned, and 2 interrupted 10/0 Nylon sutures were used for the closure (Fig.7). A high-molecular weight ophthalmic viscosurgical material (Healon 5®) was then applied beneath the flap. The conjunctiva was sutured with 8/0 Vicryl continuous suture, and the eye was patched.

•The patients underwent a baseline examination within 2 weeks before surgery, and 1 day, 1, 2, 4, and 6 weeks, and 3, 6, and 12 months after surgery.

RESULTS

Figure 1

Figure 2

Figure 3

•Transitory complications were recorded. One case suffered malignant glaucoma and was treated with pars plana vitrectomy (3.7%). One case of wound leak (seidel positive) (3.7%) was recovered 1 day later. Six cases of iris incarceration (22.2%) developed in the post-operative period at different times and all recovered after YAG laser goniosynechiolysis and pilocarpine eye drops, one of them also developed macular edema (3.7%) that was treated medically with oral acetazolamide and non-steroidal antinflammatory drugs and resolved (Fig.1).

•At 6 months the preoperative IOP of 26.0mm Hg ± 4.3 (mean ±SD) dropped to 13.0 ± 3.4mm Hg and at 12 months postoperatively it was 13.1 ± 4.8 mm Hg , yielding average IOP reductions at 6 and 12 months of 51% in both time point (P<0.001). The preoperative use of hypotensive medications per patient dropped from an average of 3.11 ±1.05 to 0.22 ±0.52 at 6 months and 0.35 ± 0.65 at 12 months (P<0.001) yielding average IOP reductions of 87% in both time points (Fig.2). The best corrected visual acuity (BCVA) of 0.6±0.2 remained fairly stable at around 0.6±0.2 at 6 and 12 month yielding average changes in BCVA at 6 and 12 month of less than 10%.

•The complete success rate at 12 month is defined as the proportion of patients with IOP <21 mmHg without the use of glaucoma medications with or without goniopuncture or needling. The qualified success is the same; it also includes patients who require hypotensive medications postoperatively. At 12 months the complete success rate was 67% and the qualified success rate was 88%, respectively (Fig.3).

Figure 4:
CO2 laser beam over sclera including Schlemm's canal

Figure 5:
Shared tissue whipped off

Figure 6:
Starting percolation

Figure 7:
Closure of superior scleral flap

Figure 8:
Histological slide post CO2 laser (in animal)

CONCLUSION

•Results of NPGS with MMC show similarity with the results of our study in terms of complete and qualified success rate and in term of IOP reduction percentage at 12 month follow up period.

•The high rate of iris incarceration in the current study (22%) may be as a result of the large area of dissection/ablation that was performed in these cases, leading to a very thin membrane, excessive filtration and probable micro-perforations, resulting in a consequent iris incarceration postoperatively at different intervals. All the cases were treated with laser goniosynechiolysis; none of them required surgical intervention.

•The limited follow-up period (12 months) and the absence of a control group limit this study. To further evaluate and justify the efficacy and safety of the procedure on long-term, and to determine if it could be used in further indications, long term follow-up is required. Although there are some limitations, the results that were found are promising and suggest that the CLASS is a simple surgical procedure to perform, and it seems to be relatively safe and effective in the short and intermediate term. Randomized control trials comparing CLASS to manual technique will give better idea on safety and efficacy of the procedure.

REFERENCES

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