

# Trabeculectomy as a Gold Standard Initial Surgical Procedure for Non High Risk Glaucomas is Still Shimmering

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## Mini Review

Volume 2 Issue 2

Received Date: July 12, 2017

Published Date: July 18, 2017

## Introduction

On a previous editorial of mine in OAJO, which was published in May 2016 with the title "Is it time to overthrow trabeculectomy as an initial surgical procedure for non high risk Open Angle Glaucomas?", as my closing statement I had the following: "In conclusion, since we still do not know if trabeculectomy has better or same efficacy with a tube insertion in a non high risk eye. Trabeculectomy has to be the initial procedure in a 'virgin' non high risk eye. Otherwise, we risk eliminating from our armamentarium the 'gold standard' operation for COAG" [1].

Indeed, at that time we did not know if trabeculectomy or a tube insertion has better or same efficacy in a non high risk eye. That was because all relevant papers deal with trabeculectomy or a tube insertion, in eyes that were almost all in high risk. Specifically, concerning Ahmed Glaucoma Valve (AGV) vs Trabeculectomy, Tan Hai Bo, et al. [2] in a meta-analysis, reviewed two RCTs and four Non-RCT studies [3-8]. In all of these studies besides the Wilson's study, patients suffered from high risk glaucomas (COAG, CACG, NVG, PG, PEX, Aphacic). Wilson's study is actually the only study that deals with patients with low risk glaucomas (COAG, CACG) and patients without previous operation [8]. Also in all of these studies the IOP decrease, the number of antiglaucoma medication and the success rate were almost the same in both groups. However, there is still an urgent need for pragmatic RCT with long duration and a large sample size to further determine the efficacy and safety of AVG in the treatment of glaucoma.

Concerning Baerveldt Glaucoma Implant (BGI) vs Trabeculectomy, the most important information come from the Tube Versus Trabeculectomy (TVT) Study [9], in which 212 patients were randomized either to receive a 350-mm<sup>2</sup> BGI (Abbott Medical Optics, Inc., Santa Ana, CA) or trabeculectomy with MMC. Although In TVT study, tube shunts have a higher success rate, the majority of patients participating in the study, (174/212 or 82%) had some sort of previous conjunctival surgery (trabeculectomy, intracapsular or extracapsular cataract surgery, or scleral tunnel phacoemulsification) [10].

The results of the TVT Study suggest the need to extend the comparison of safety and efficacy between tube shunt surgery and trabeculectomy with MMC in patients at low risk of surgical failure, but without previous ocular surgery.

The Primary Tube Versus Trabeculectomy (PTVT) Study is a multicenter (15 clinical centers) randomized clinical trial that is similar in design to the TVT Study. The 242 enrolled patients are randomized to undergo placement of a 350mm<sup>2</sup> Baerveldt glaucoma implant or trabeculectomy with MMC (0.4 mg/mL for 2 minutes) and the purpose of this study is to compare the long-term safety and efficacy of these two operations in eyes that have not had previous ocular surgery [11]. As in TVT study patients in the PTVT study will be followed up to 5 years.

At the American Academy of Ophthalmology meeting last October in Chicago, Study Chair Steven Gedde MD, presented the 1-year results of the PTVT Study [12]. In the study, 117 patients in the tube group, and 108 patients in the trabeculectomy group completed their 1-

year of follow-up visits. Demographically, about 90% of the patients suffered from COAG, the mean preoperated IOP was around 23,5 mm Hg on approximately three medications and the mean IOP at baseline was close to 23 mm Hg in both groups.

In the trabeculectomy group lower pressures were observed compared with the tube group during the first year of the study (Trabeculectomy: 1st month:  $13.1 \pm 6.3$ , 3rd month:  $12.5 \pm 4.9$ , 6th month:  $12.8 \pm 4.8$ , 12th month:  $12.4 \pm 4.4$  vs BGI:  $19.7 \pm 7.3$ ,  $18.0 \pm 5.9$ ,  $14.7 \pm 4.4$  and  $13.8 \pm 4.1$  respectively). Even more, the greater degree of pressure reduction was achieved with fewer glaucoma medications in the Trabeculectomy group. (12<sup>th</sup> month Trabeculectomy group:  $0.9 \pm 1.4$  meds vs BGI group:  $2.1 \pm 1.4$  meds). ( $P < .001$  at 1 week, 1 month, 3 months, 6 months and 1 year for both measures).

Complete Success (which was defined as  $IOP \leq 21$  and  $\geq 6$  mmHg or 20% decrease from baseline) was achieved in 64 (59%) of trabeculectomy patients and 16 (14%) of tube patients. Failure (which was defined as  $IOP > 21$  mmHg, or no 20% decrease from baseline, or  $IOP \leq 5$  mmHg after 3 months, or additional glaucoma surgery, or loss of light perception) noticed in 9 (8%) and 23 (20%) respectively. The most common cause of failure was inadequate IOP decrease (44% in trabeculectomy patients, vs 57% in tube patients).

Surgical complications were common in the PTVT study, but most were transient and self-limited and the total numbers of patients with interventions were similar, fellow study author Sheng Lim, MD, reported in a subsequent presentation [13]. There was a similar loss  $\geq 2$  Snellen lines in both groups [trabeculectomy 28 (24%) and tube 32 (26%)] with cataract being the most common cause of visual loss in both groups.

## Conclusions

Although there are a lot of similarities between the two studies, the major difference was that all the patients in the TVT study did have prior ocular surgery whereas people in the PTVT had no previous ocular surgery. Finally, the biggest difference is in success rates. In TVT, tube shunts have a higher success rate and in the Primary TVT study, trabeculectomy had a higher success rate. The results are encouraging and we have to wait for the second year results. Meanwhile, I think that trabeculectomy, is still the operation of choice in eyes that suffer from medically uncontrolled glaucoma and have never being operated in the past.

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