Safety and Efficiency of Trabectome-mediated Trabecular Meshwork Ablation for Chinese Glaucoma Patients: A Two-year, Retrospective, Multicentre Study

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Abstract

Background: The aim of the study was to evaluate the long-term safety and efficacy of the Trabectome for Chinese glaucoma patients.

Methods: This was a multicenter, retrospective, observational study. Glaucoma patients, except those with neovascular glaucoma, with/without a visually significant cataract were enrolled. The patients received Trabectome or a combined surgery with phacoemulsification and intraocular lens implantation. The primary outcome evaluation was a reduction in intraocular pressure (IOP), and the secondary outcomes were a reduction in glaucoma medication, the 2-year success percentages, and complications. Success was defined as an IOP <21 mmHg and at least a 20% IOP reduction from baseline after 3 months for any two consecutive visits, without additional glaucoma surgery. The data were processed using the R Stats Package version 3.0.0. The Wilcoxon test was used to compare the postoperative IOP and the number of glaucoma medications with baselines. The Kaplan–Meier test was used to calculate the 2-year success percentage. The risk factors related to Trabectome failure were determined by logistic regression.

Results: A total of 120 glaucoma patients were enrolled. The Trabectome efficiently reduced the IOP from a baseline of 22.8 ± 1.34 mmHg to 17.6 ± 0.96 mmHg, and the use of glaucoma medications from 2.2 ± 0.17 mmHg to 1.4 ± 0.21 in a 2-year follow-up (both, \( P < 0.01 \)). The overall success percentage was 80%. No risk factor related to Trabectome failure was identified. No vision-threatening complication was observed. Ten patients, who required secondary glaucoma surgery, all reached the target IOP.

Conclusions: In a 2-year follow-up, Trabectome was an efficient and safe procedure for Chinese glaucoma patients.

Key words: Glaucoma; Intraocular Pressure; Minimally Invasive Surgical Procedures; Trabecular Meshwork

Introduction

Glaucoma is a degenerative disease of the optic nerve, affecting millions of people¹ and causing huge economic burdens worldwide.² Neuroprotection strategies (including gene therapy and medical therapy), which alleviate the deterioration of glaucomatous optic neuropathy, have shown promising effects in vitro and in glaucoma animal models but are still in preclinical stages.³⁻⁵ Currently, reducing intraocular pressure (IOP) is the only clinically proven treatment for glaucoma management.⁶⁻⁷ Conventional glaucoma surgeries such as trabeculectomy and tube shunt implantation can effectively reduce the IOP and the use of glaucoma medications but also have significant complications.⁷⁻⁸ In recent decades, minimally invasive glaucoma surgeries have shown comparable IOP-lowering effects when compared with conventional glaucoma surgeries, but with a better safety profile, thus becoming the first-line treatment for glaucoma patients with the maximum tolerance of medication.⁹⁻¹⁰ Invented and patented by George Baerveldt and Roy Chunk in 2002,¹⁰

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the Trabectome (NeoMedix, Tustin, CA, USA) is a United States Food and Drug Administration-approved minimally invasive glaucoma surgery designed to remove the trabecular meshwork (TM) using a high-frequency bipolar electrode.\[11\] With more than 5000 successful cases worldwide in the past decade, its safety and efficiency have been comprehensively investigated.\[12,13\]

Our team published the first clinical results of the Trabectome for Chinese open-angle glaucoma patients in a 12-month follow-up.\[14\] We found that the Trabectome sufficiently reduced the IOP from a baseline of 22.5 ± 8.1 mmHg to 17.6 ± 6.4 mmHg at 12 months without serious complications. The overall success was 85.0%. Only 9.8% of patients required a secondary glaucoma surgery. However, the long-term effects of the Trabectome for Chinese glaucoma patients remain unclear. In addition, the small sample size in the previous study also made it difficult to determine the risk factors related to Trabectome failures.

**METHODS**

**Ethical approval**

This was a multicenter, retrospective, observational study approved by the Institutional Review Board of Peking University Third Hospital in accordance with the 1964 Declaration of Helsinki. Due to the retrospective nature of the study design, no informed consent was required.

**Patients**

According to a previous study,\[15\] patients with primary or various secondary open-angle glaucomas as well as narrow angles were included, except neovascular glaucoma and those with postoperative follow-ups <3 months. All patients received either Trabectome alone or Trabectome with phacoemulsification/intraocular lens implantation. Trabectome was performed as previously described.\[16\] Briefly, a 1.6 mm iris, parallel, clear, corneal incision was made at the nasal insertion of the Trabectome tip into the anterior chamber, the eye was pressurized with active irrigation. The goniolens was then placed on the cornea, and the TM was engaged with the instrument at a 45° upward angle to facilitate the best visualization to the surgeon. A total of 120 patients from five glaucoma centers were enrolled in the study. The majority of patients were diagnosed with primary open-angle glaucoma (78%), followed by juvenile glaucoma (7%), angle closure glaucoma (2%), and other types of glaucoma. The mean age of these patients was 50 ± 19 years (range: 11–87 years) and 65% of them were male. Thirty of 84 phakic eyes with visually significant cataracts received combined surgery with phacoemulsification and intraocular lens implantation. Sixteen patients had previous glaucoma surgeries including 13 with trabeculectomy, 2 with Trabectome, 1 with selective laser trabeculoplasty, and 1 with tube shunt implantation [Table 1].

**Reductions in intraocular pressure and glaucoma medications**

The preoperative IOP was 22.8 ± 1.3 mmHg. It dramatically decreased to a maximum level of 16.4 ± 1.05 at the 1st postoperative day (P < 0.01, compared to the baseline). While a small IOP fluctuation was observed, the postoperative IOPs were all statistically lower than the baseline IOPs (all P < 0.01), with a range of 22.4–28.1% reduction [Figure 1 and Table 2]. Similar to the patterns of IOP reduction, Trabectome significantly reduced the number of glaucoma medications from 2.20 ± 0.17 at the baseline to a range of 1.20–1.40 during the 2-year follow-up (all P < 0.01) [Figure 2 and Table 3].

**Statistical analyses**

The quantitative data were presented as the mean ± standard error (SE) and analyzed using the R Stats Package software version 3.0.0 (Free Software Foundation, Boston, MA, USA). The Wilcoxon test was used to compare the postoperative IOP and number of glaucoma medications with the baselines. The Kaplan–Meier test was used to calculate the 2-year success percentage. The surgical success was defined as an IOP <21 mmHg and at least 20% of the IOP reduction from baseline after 3 months for any two consecutive visits with no additional glaucoma surgery required. The risk factors correlating with Trabectome failure were determined by logistic regression.

**RESULTS**

**Demographics**

A total of 120 patients from five glaucoma centers were enrolled in the study. The majority of patients were diagnosed with primary open-angle glaucoma (78%), followed by juvenile glaucoma (7%), angle closure glaucoma (2%), and other types of glaucoma. The mean age of these patients was 50 ± 19 years (range: 11–87 years) and 65% of them were male. Thirty of 84 phakic eyes with visually significant cataracts received combined surgery with phacoemulsification and intraocular lens implantation. Sixteen patients had previous glaucoma surgeries including 13 with trabeculectomy, 2 with Trabectome, 1 with selective laser trabeculoplasty, and 1 with tube shunt implantation [Table 1].

The primary outcome evaluation was the reduction in the IOP, and the secondary outcomes were reductions in glaucoma medications, 2-year success percentages, and surgical complications. The IOP was measured using Goldmann applanation tonometry. The target IOP was determined individually by the progression of the visual field loss and the preoperative IOP. The visual field was categorized as mild, moderate, or advanced according to a Humphrey visual field test. Slit lamp, Snellen best-corrected visual acuity, gonioscopy, and stereoscopic optic nerve photography were regularly performed during the follow-up.

**Two-year success**

Figure 3 shows that the surgery success declined at all times during the 2-year follow-up. Overall, 80% of the patients had a postoperative IOP <21 mmHg with over 20% of the patients showing an IOP reduction from the baseline and no secondary glaucoma surgery at any two consecutive visits [Figure 3a]. All patients (n = 30) who received combined surgery with phacoemulsification and intraocular...
who received Trabectome alone ($P = 0.264$) [Figure 3b]. In addition, patients with a history of trabeculectomy or tube shunt implantation ($n = 14$) had a similar success percentage, compared to those without such histories ($n = 106$) (79% vs. 82%; $P = 0.887$) [Figure 3c]. No risk factor including age, surgery type, or cup/disc ratio correlated with the surgical failure using univariate logistic regression [Table 4]. Due to the small sample size, multivariate logistic regression was not performed.

Complications and secondary glaucoma surgery

The only surgical complication identified in the study was transient blood reflux, which occurred in almost all cases but resolved spontaneously within a few days. No vision-threatening complication such as sustained hypotony defined as an IOP $<5$ mmHg, aqueous misdirection, endophthalmitis, wound leakage, or choroidal hemorrhage occurred. A total of ten patients required secondary glaucoma surgeries including four express shunt implantations, four trabeculectomies, and two Trabectomes at the opposite quadrant of the eye. All these cases reached the target IOP at the first follow-up.

Discussion

TM is a filter-like structure, accounting for 90% of the aqueous outflow resistance. Diseased TM is present in almost all types of glaucoma including primary open-angle glaucoma, primary angle-closure glaucoma, and congenital glaucoma. Ablation of this tissue either by surgery or other methods increases outflow facility and decreases the IOP. In the present study, the results showed that Trabectome-mediated TM ablation efficiently reduced the IOP from a baseline of $22.8 \pm 1.3$ mmHg to $17.6 \pm 1.0$ mmHg and decreased the use of glaucoma medications from $2.20 \pm 0.17$ to $1.40 \pm 0.21$ with an 80% overall success percentage after 2 years of follow-up. No vision-threatening complication occurred. These results were consistent with our previous findings and this study described the long-term results of Trabectome for Chinese glaucoma patients.
IOP reduction was the major goal of this surgery, although it varied depending on the glaucoma type and preoperative IOP. Steroid-induced glaucoma and pseudoexfoliation glaucoma, which are usually disorders primarily affecting the TM, have a higher IOP reduction than primary open-angle glaucoma, which has a more complicated mechanism involving ocular hypertension. Patients with a higher preoperative IOP and glaucoma severity are also likely to achieve a greater IOP reduction. However, it needs to be noted that the expected postoperative IOP should not be lower than 10 mmHg, which is the estimated pressure of the episcleral vein, indicating outflow resistance also exists in the downstream outflow tracts.

Reducing the use of glaucoma medication is another benefit of the Trabectome, especially for those with intolerable glaucoma medication. An average of 0.3 to 1.2 less medication can be achieved by different patient populations. Patients with refractory glaucoma have less medication reduction. In the present study, glaucoma medications were reduced from a baseline of 2.20 ± 0.17 to 1.40 ± 0.21 at the end of the 2-year follow-up, which was comparable to our previously reported results.

In a similar manner as other minimally invasive glaucoma surgeries, Trabectome may be performed with phacoemulsification/intraocular lens implantation, and the combined surgery usually is more successful than the Trabectome alone. In the present study, all thirty patients who received combined surgery were successfully treated when compared with only 77% of the patients in the Trabectome alone group. These results were consistent with a recent meta-analysis by Okeke et al., showing that combined surgery had a 78% lower risk of surgical failure. However, it is important to note that patients with the combined surgery usually had lower baseline IOPs, so the absolute IOP reduction might be lower than with Trabectome.

### Table 2: Reduction of intraocular pressure (mmHg)

| IOP     | Mean ± SE | P     |
|---------|-----------|-------|
| Baseline| 22.8 ± 1.34| –     |
| 1 day   | 16.4 ± 1.05| <0.01*|
| 1 month | 18.0 ± 0.90| <0.01*|
| 3 months| 18.2 ± 0.95| <0.01*|
| 6 months| 17.7 ± 0.80| <0.01*|
| 12 months| 16.9 ± 0.85| <0.01*|
| 18 months| 17.5 ± 0.94| <0.01*|
| 24 months| 17.6 ± 0.96| <0.01*|

Wilcoxon test were applied by comparing with baseline IOP or number of medications. *Significant level is 0.05. IOP: Intraocular pressure; SE: Standard error.

### Table 3: Reduction of glaucoma medication

| Numbers of medication | Mean ± SE | P     |
|-----------------------|-----------|-------|
| Baseline              | 2.2 ± 0.17| –     |
| 1 day                 | 1.2 ± 0.19| <0.01*|
| 1 month               | 1.4 ± 0.18| <0.01*|
| 3 months              | 1.3 ± 0.25| <0.01*|
| 6 months              | 1.4 ± 0.24| <0.01*|
| 12 months             | 1.4 ± 0.21| <0.01*|
| 18 months             | 1.4 ± 0.26| <0.01*|
| 24 months             | 1.4 ± 0.21| <0.01*|

Wilcoxon test were applied by comparing with baseline IOP or number of medications. *Significant level is 0.05. IOP: Intraocular pressure; SE: Standard error.

Figure 2: Reduction of glaucoma medication. Patients had an average of 2.20 ± 0.17 glaucoma eye drops before surgery. Trabectome significantly decreased the use of glaucoma medication throughout the study (all P < 0.01, compared to the baseline). The Wilcoxon test was used for statistical analyses. *Indicates a statistical difference with P < 0.01.

Figure 3: Two-year success percentage. Overall success rate during 2-year follow-up (a). The combined surgery versus Trabectome alone (b). Patients with history of glaucoma surgery versus patients without history of glaucoma surgery (c).
Table 4: Risk factor with trabectome failure

| Variables                      | OR  | P   |
|--------------------------------|-----|-----|
| Age (years)                    |     |     |
| 30< age ≤50 (reference 10< age ≤30) | 0.285 | 0.12 |
| 50< age ≤90 (reference 10< age ≤30) | 0.167 | 0.06 |
| Surgery                        |     |     |
| Combined surgery with phaco    | <0.01 | 0.99 |
| C/D >0.8                       | 4.66 | 0.06 |
| Preoperative visual acuity     |     |     |
| 20/50 or worse                 | 3.12 | 0.06 |
| Prior surgery                  |     |     |
| Prior glaucoma surgery history | 0.600 | 0.56 |

OR: Odds ratio.

In our recent study, we found that combined surgery had 1.29 ± 0.39 mmHg less IOP reduction than that of Trabectome alone.[24] A meta-analysis by Kaplowitz et al. also reported similar results.[13]

A relatively safe profile is a significant feature of Trabectome surgery.[13,14,16,29,34] In the present study, no vision-threatening complication was observed, including sustained hypotony and bleb-related complications, which are common in conventional glaucoma filtering surgeries. Transient blood reflux was reported in all cases, indicating the opening of Schlemm’s canal.[35] Temporary hypotony occurred in two of 101 pigmentary glaucoma patients.[36] Peripheral anterior synechiae were reported in 24% of open-angle glaucoma patients[37] but not in the present study. Secondary glaucoma surgery might be needed for 10.5–34.9% of open-angle glaucoma patients.[23,29,31] Patients who received the combined surgery with phacoemulsification and intraocular implantation were likely to have a lower percentage of secondary procedures.[23]

This study had some limitations. First, no risk factors related to Trabectome failure were found possibly because of the small sample size. We have found P = 0.06 in terms of age >50 years, high cup/disk ratio, and worse preoperative best-corrected visual acuity using univariate logistic regression, suggesting a high risk of Trabectome failure. A future study enrolling more patients should, therefore, be conducted. Second, recent studies suggested that advanced and refractory glaucoma may also be indications of Trabectome surgery.[25,26,28] so studies investigating the effect of Trabectome for these patients are necessary.

In summary, Trabectome was an efficient and safe procedure for Chinese glaucoma patients in a 2-year follow-up study.

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Conflicts of interest

There are no conflicts of interest.

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微创小梁消融术对中国青光眼患者安全性及有效性的多中心、回顾性研究

目的: 探讨微创小梁消融术对中国青光眼患者的长期安全性及有效性。

方法: 多中心、回顾性队列研究。采集北京大学第三医院、北京同仁医院等国内六家眼科中心自2013年12月至2017年5月接受微创小梁消融术并随访超过2年的青光眼患者120例。合并白内障的患者同时接受超声乳化及人工晶状体植入术。手术效果评价的主要标准是眼压的下降。次要评价标准包括: 青光眼用药的减少、2年的手术成功率及并发症。手术成功的判定标准: (1) 术前后的任意连续2次随访的眼压低于21mmHg; (2) 与术前眼压相比, 20%的眼压下降; (3) 无二次青光眼手术。手术成功的判定标准: (1) 术后3个月后的任意连续2次随访的眼压低于21mmHg; (2) 与术前眼压相比, 20%的眼压下降; (3) 无二次青光眼手术。术前与术

手术效果评价的主要标准是眼压的下降。次要评价标准包括: 青光眼用药的减少、2年的手术成功率及并发症。手术成功的判定标准: (1) 术前与术后的任意连续2次随访的眼压低于21mmHg; (2) 与术前眼压相比, 20%的眼压下降; (3) 无二次青光眼手术。术前与术后眼压和青光眼用药数量的比较采用Wilcoxon检验, 术后2年成功率分析采用Kaplan Meier检验。我们还尝试使用回归分析寻找手术失败的危险因素。

结果: 经过2年随访, 接受微创小梁消融术的青光眼患者的眼压从术前的22.8 ± 1.34 mmHg下降到17.6 ± 0.96 mmHg (P < 0.01)。青光眼用药数量也从术前的2.2 ± 0.17降低到1.4 ± 0.21 (P < 0.01)。小梁消融术的2年总体成功率为80%，合并白内障手术的小梁消融术患者手术成功率高于单独接受小梁消融术的患者(100% vs. 77%)。由于样本量有限, 导致小梁消融术失败的危险因素未被找到。在安全性方面, 未发现术中及术后威胁视力的并发症,10例患者接受了二次青光眼手术, 术后眼压均控制良好。

结论: 微创小梁消融术能够长期、安全、显著地降低青光眼患者的眼压和用药数量, 因此是一种有效的青光眼手术方法。