



One year efficiency and safety of ab interno trabeclectomy with Kahook Dual Blade in Japanese glaucoma patients.

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Purpose

Glaucoma is one of major causes of blindness and vision impairment worldwide,¹ and lowering of intraocular pressure (IOP) is essential to treat glaucoma patients with medications or by surgeries. While trabeculectomy and glaucoma drainage devices remain the gold standard for the surgical lowering of IOP, there has been a recent emergence of surgical techniques designed to lower IOP by re-establishing the natural aqueous humor outflow pathways.² Recently, ab interno trabeculectomy using small instruments of Kahook dual blade (KDB) (New World Medical, CA, USA) have been reported. However, only a few studies about clinical results of KDB are available.^{3, 4, 5}

Therefore, the aim of current study is to evaluate short-term surgical efficacy and safety of ab interno trabeculectomy with KDB surgery in Japanese glaucoma patients.

Methods

A retrospective chart review was performed on glaucoma patients who underwent standalone KDB surgery between February 2017 to October 2018 at University of Tokyo Hospital with 12 months of follow up. This observational study was approved by the institutional review boards of the University of Tokyo and conducted in accordance with the principles of the Declaration of Helsinki.

Changes of IOP and medication score over time were collected. IOP was measured using Goldmann applanation tonometry. IOP lowering medications were re-started based on surgeons' decision. Combination drug was counted as 2 and oral administration of acetazolamide was counted 1 medication in analysis of medication score. The extent of incision, and postoperative complications were analyzed.

The primary outcome of this study was the success rate of surgery. We defined four success definition (A, B and C). A, post operative IOP \leq 21mmHg and \geq 20% reduction from baseline; B, post operative IOP \leq 21mmHg; C, post operative \geq 20% reduction from baseline; all 3 definitions including criteria of additional glaucoma surgery.

All analyses were performed using JMP[®] version 14 software (SAS Institute Inc., Cary, NC, USA). Kaplan-Meier survival curves of this study were made and then compared using the long-rank test. Cox proportional hazard analysis was performed to determine factors associated with failure of ab interno trabeculectomy using the failure definition A.

Results

Thirty-seven eyes of 34 patients with 14 POAG, 1 NTG, 19 exfoliation glaucoma, 1 congenital glaucoma and 3 secondary glaucoma were included. The mean age was 69.8 ± 16.7 years old. The trabecular meshwork was incised in 105 ± 15.1 degrees.

The IOP and medication score significantly decreased from 25.8 ± 6.4 mmHg and 4.5 ± 1.1 at the baseline to 16.9 ± 5.6 mmHg and 2.0 ± 1.7 , 15.9 ± 4.3 mmHg and 2.9 ± 1.8 , 15.1 ± 4.3 mmHg and 2.8 ± 1.8 , and 18.5 ± 7.5 mmHg and 2.9 ± 1.5 at 1, 3, 6 and 12 months, respectively ($p < 0.05$, paired t-test with Bonferroni correction; Fig.1). VA in all visits was not significantly different.

Figure.1 Change of IOP and medication score over time

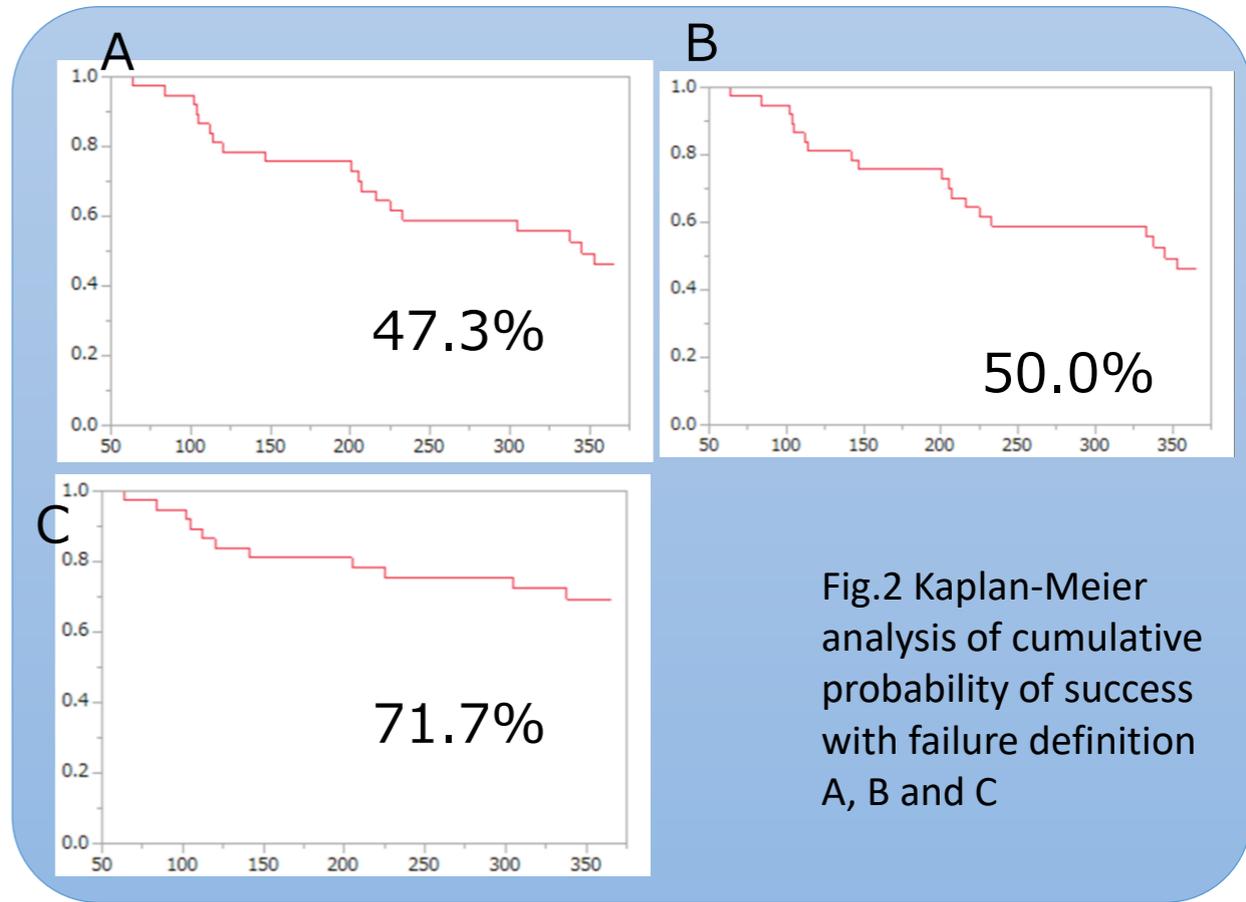
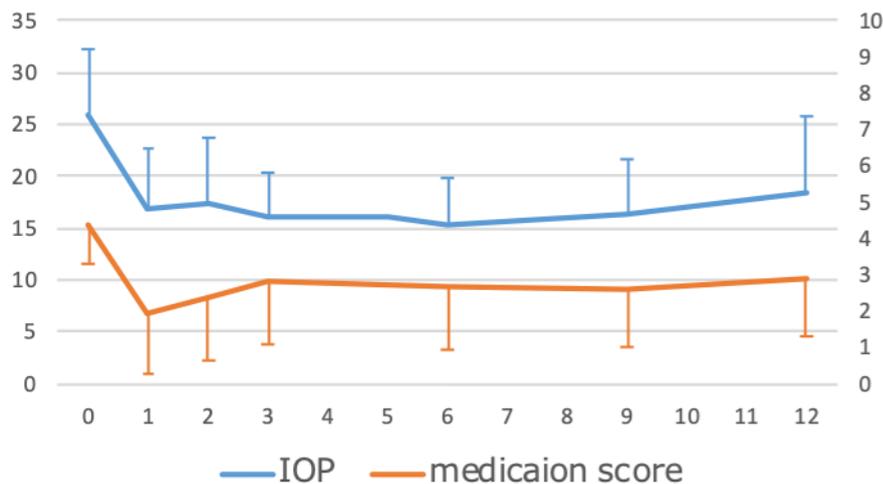


Fig.2 Kaplan-Meier analysis of cumulative probability of success with failure definition A, B and C

Kaplan-Meier cumulative survival analyses are shown in Fig.2. At 12-months postoperatively, success rates in the 47.3% using definition A, 50% using criteria B, 71.1% using criteria C.

In the univariate cox proportional hazard analysis, baseline IOP and type of glaucoma showed a P value less than 0.05 (table 1)

Hypheema was seen in 7 eyes (18.9%) on the first postoperative day. Additional surgery was needed in 9 eyes (24.3%) because of insufficient IOP reduction after the operation. Other complications were not occurred in this study.

Discussion

KDB is a single-use ophthalmic knife designed to perform a goniotomy through precise excision of a strip of TM via an ab interno approach through a clear corneal incision.⁶

A recent study including 53 eyes of combined surgeries of ab interno trabeculectomy with KDB showed decreased IOP from 23.5 mmHg at baseline to 10.3 mmHg at 6 months (43.8% reduction) with significantly reduced IOP lowering medications from 2.5 to 1.5.⁷

Another study including 102 eyes of combined surgeries of ab interno trabeclectomy with KDB showed risk factors for failure in the multivariate analyses.⁸

In current study, we showed our short-term clinical results of ab interno trabeculectomy with KDB. The baseline IOP significantly decreased from 26.0 mmHg to 18.5 mmHg (28.8% reduction) with significantly decreased IOP lowering medications (from 4.4 to 2.9) at 12 months. In our study, baseline IOP and type of glaucoma is risk factor for postoperative IOP control using the univariate analysis and Cox regression model.

Reference

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Table1. Multivariate Cox Proportional Hazard Analysis for the Study Group

	HR	95% CI	P value
Base line IOP(mmHg)	1.74	-0.23 to -0.02	0.029
Type of glaucoma	1.54	1.24 to 6.71	0.018
Age	0.13	-0.06 to 0.04	0.74
Phakia/pesudophakia	0.026	-1.17 to 1.39	0.94

Conclusion

KDB surgery was safe and effective on IOP reduction and medication score reduction during 12 months.

Baseline IOP and type of glaucoma were associated with ab interno trabeclectomy failure in the present study.

Howeber, in this study, the observation period was short and the number of cases was small.

Further study is required to determine the long-term efficacy and safety.