# Primary trabeculectomy with mitomycin C in the treatment of medically uncontrolled inflammatory glaucoma and primary open-angle glaucoma: a comparative study

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**Purpose**
The aim of this study was to compare the outcomes of primary trabeculectomy (PT) with mitomycin C (MMC) in uveitic glaucoma (UG) and primary open-angle glaucoma (POAG).
**Design**
This is a retrospective, case–control study.
**Patients and methods**
We compared the outcomes of PT with 0.02% MMC for 2 min in 60 adult patients with POAG and 60 adult patients with UG, who underwent surgeries between January 2010 and January 2014 at two major hospitals in Birmingham, UK, and were followed up for 5 years. Trabeculectomy in both groups was performed by fornix-based conjunctival dissection.
**Results**
The patients' age was 53.6±5.4 years in POAG patients compared with 48.3±9.45 years in UG patients, with a statistically significant difference ($P$=0.046). The rates of qualified success, complete success, and failure at the first, third, and fifth year postoperatively did not differ significantly between the two groups ($P$=0.73, 0.71, and 0.37, respectively). The maximum postoperative intraocular pressure (IOP) reduction was observed in the first year, followed by a slow rise in IOP, and the number of antiglaucoma medications until the fifth year postoperatively. The 5-year postoperative IOP differed significantly between the two groups (18.33±2.98 vs. 19.88±3.41 mmHg in the POAG vs. UG, respectively, $P$=0.009).
**Conclusion**
The success rate of PT with MMC in UG was not inferior to that in POAG. One-year posttrabeculectomy with MMC, the qualified success rate mildly increased at the expense of the complete success rate while the failure rate remained largely constant, indicating a constant need for additional antiglaucoma medications.

**Keywords:**
antiglaucoma medications, intraocular pressure control, primary open-angle glaucoma, primary trabeculectomy with mitomycin C, uveitic glaucoma

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## Introduction

In a systematic review of population-based surveys, published by the WHO in 2002, which recorded the findings for ∼37 million individuals worldwide [1], 12.3% (4.4 million) of the patients were diagnosed with glaucoma, making it the second most common cause of blindness worldwide [2]. This finding illustrates the considerable global burden of glaucoma and the potential influence of adequate glaucoma prevention and treatment on the global rates of blindness [3].

A recent review estimated that the number of cases of primary open-angle glaucoma (POAG) worldwide was 44 million in 2013 and that this number rose to 53 million by 2020 due to population aging [4]. Despite its relative rarity, uveitis remains the fourth most common cause of blindness among the working-age population in developed countries [1,2]. The incidence of glaucoma in uveitic patients has been reported to be ∼20% with the use of maximum treatment to control the activity of uveitis [5–7], which increased to 35% in pediatric uveitis patients [8,9]. In terms of progression of ocular hypertension to glaucoma in uveitic patients, 24% of the eyes with an intraocular pressure (IOP) increase of more than or equal to 10 mmHg from baseline and 30% of eyes with an IOP increase of more than or equal to 30 mmHg from baseline developed glaucomatous optic neuropathy within 2 years [10].

Trabeculectomy is the standard surgical procedure for managing medically uncontrolled glaucoma. It involves removal of the trabecular meshwork sector to connect the aqueous layer in the anterior chamber to the subconjunctival space, enhancing the trabecular flow pathway, which is the major aqueous drainage route [11]. Many modifications have been attempted to improve the outcome of trabeculectomy, including the use of mitomycin C (MMC), 5-fluorouracil, subconjunctival bevacizumab, Ologen implants, amniotic membrane transplantation, polyvinylpyrrolidone collagen, or intracameral tissue plasminogen activator [12–16]. The outcome of fornix-based trabeculectomy did not differ significantly from that of limbal-based trabeculectomy; thus, the choice between the procedures depends on the surgeon's preference [17]. The efficacy and safety of different MMC concentrations in trabeculectomy have been evaluated, and some studies did not report a significant difference in IOP reduction between trabeculectomy with 0.2 and 0.4 mg/ml of MMC [18,19]. However, other studies have reported a higher rate of complications, such as prolonged hypotony with 0.4 mg/ml than with 0.2 mg/ml MMC [20,21]. Longer exposure to MMC during trabeculectomy may enhance the success rate, but not in every trabeculectomy case [22,23].

The choice between trabeculectomy with MMC and shunt operations, such as those with Ahmed valve or Molteno or Baerveldt implants, as the primary surgical intervention for medically uncontrolled uveitic glaucoma (UG), remains a topic of debate. This debate has been addressed in the literature by comparing the outcomes of primary trabeculectomy (PT) with MMC versus glaucoma drainage devices (GDD) and at a smaller level by comparing the outcomes of trabeculectomy with MMC in UG versus POAG to assess the success of the procedure. Although some surgeons recorded higher success rates for primary GDD [18,24], others did not report any difference in the success rates [25,26]. Some studies have aimed to identify the optimal primary surgical option for UG by comparing its outcome to that of POAG. Comparable outcomes would imply that trabeculectomy with MMC may avoid the higher complication rate associated with GDD. However, it is debatable whether the success rates of trabeculectomy with MMC in inflammatory glaucoma are significantly lower than those in POAG [23], or nearly similar [20,22].

Therefore, we aimed to compare the success and failure rates according to the American Academy of Glaucoma definition after PT with MMC in UG versus POAG.

## Patients and methods

We retrospectively collected the consecutive data to evaluate the outcomes of PT with 0.2 mg/ml MMC for 2 min in 60 POAG and 60 UG patients who underwent surgeries at the University Hospital of Birmingham and Birmingham Eye Center, Birmingham, UK as a collaborative project between January 2010 and January 2014. All patients have given a consnet that their data can be used anonymously for auditing aiming for better future service. Approval was obtained from the Ethics Review Committee of the Faculty of Medicine at Assiut University (approval number 17200695, dated 18/1/2015). In addition, approval was obtained from the Research Ethics Committee (REC) in UK (reference for correspondence 15/LO/0477, dated 12/3/2015, the clinical trial identification number is NCT03293251). Data collection was performed during an audit of services at both UK hospitals. We recorded the data for patients' age at the time of surgery, IOP level, and number of antiglaucoma medications used preoperatively and at 5 years postoperatively. The sample size was determined using the Open Epi Info program, Version 1.6, USA (7/26/2019, available at the website: www.cdc.gov/epiinfo) based on previous studies.

The study included patients with medically uncontrolled POAG or open-angle UG who underwent PT with 0.2 mg/ml MMC for 2 min, with patients' age of at least 18 years, as the outcomes of operations for juvenile glaucoma differ from those for adult patients, with data being available for follow-up assessments performed at our hospital.

Patients in whom phacosurgery was performed at the same time as trabeculectomy and patients with neovascular glaucoma associated with inflammatory glaucoma were excluded from the study.

### Outcomes recorded

(1) Success and failure rates according to the World Glaucoma Association definitions [27]:
   - (a) Complete success was defined as a postoperative IOP less than 21 mmHg without the use of any antiglaucoma medications.
   - (b) Qualified success was defined as a postoperative IOP less than 21 mmHg with the use of any antiglaucoma medications.

(c) Failure was defined as a postoperative IOP more than 21 mmHg with maximum antiglaucoma medications or by a postoperative IOP less than 5 mmHg.

(2) Mean IOP was measured preoperatively and at the first, third, and fifth years postoperatively.

(3) The mean±SD number of antiglaucoma medications, including oral cidamex or antiglaucoma eye drops, administered preoperatively and at the first, third, and fifth years postoperatively.

### Surgical technique

All surgeries were performed under general anesthesia. A corneal traction suture using 7-0 silk was placed superiorly for good exposure. A 10–13 mm wide fornix-based conjunctival flap was obtained with extradissection of the surrounding conjunctiva and the underlying Tenon's capsule. Light cauterization was applied to the area of partial thickness scleral incision. A sponge soaked in 0.02 mg/ml MMC (Vygoris Limited Pharmaceutical Company, London, UK) was applied for 2 min posteriorly over a wider area of the surrounding exposed sclera and covered with conjunctiva without touching the conjunctival edges to avoid impeding the conjunctival healing at the end of surgery. Subsequently, the surgical field was washed with 20 ml of saline. A 4×3 mm partial thickness rectangular scleral flap was raised. Subsequently, a paracentesis incision was made, and intracameral pilocarpine was injected. Scissors were used to cut a punch of the trabecular meshwork of ~1.5 mm width. A peripheral iridectomy was performed through this opening. The flap was closed using two 10/0 nylon sutures at the edges of the rectangle. Saline was injected through the side port to check for aqueous flow, wound integrity, and anterior chamber formation. Finally, the conjunctiva was closed watertight using 8-0 Vicryl sutures. Postoperatively, a combination of steroids and antibiotics for 4 weeks and atropine for 2 weeks were prescribed.

### Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) software (version 22.0; SPSS, Chicago, Illinois, USA). Descriptive statistics were used to evaluate the age and sex of patients. An independent sample $t$ test was used to compare the IOP and the number of antiglaucoma medications in both groups. The $\chi^2$ test was used to compare the success and failure rates between the two groups. We have used intention-to-treat analysis for these results. Kaplan–Meier curve was used to estimate the median survival time. The log-rank test was used to compare survival curves between the two groups. Statistical significance was set at $P$ value less than 0.05.

## Results

The study included data for 60 patients with medically uncontrolled POAG and 60 patients with medically uncontrolled open-angle UG, who underwent PT with MMC. We could not access the fifth year postoperative follow-up data of four patients. The mean age of the UG group at the time of surgery was 48.3±9.45 years (65% females and 35% males) compared with 53.6±5.4 years in the POAG group (58.33% females and 41.67% males), with a statistically significant difference between the two groups regarding age ($P$=0.046). Race was not available for many patients, so it was not counted in data collection. All uveitis cases showed disease inactivity for at least 3 months at the time of surgery. The preoperative use of steroids varied according to the previous recurrence rate of uveitis activity. Most uveitis cases were among the following causes: idiopathic disease (35%), HLA-B27 (27%), Vogt-Koyanagi-Harada disease (11%), and Behçet disease (8%).

The qualified success rate was higher than the complete success rate by 10% in the first year, 30% in the third year, and 36% in the fifth year in patients with POAG. Among patients with UG, the qualified success rate was higher than the complete success rate by 16.5% in the first[t] year, 37% in the third year, and more than 50% in the fifth year. The failure rate among patients with UG was higher than that among patients with POAG by ~3.5% over 5 years postoperatively. The success and failure rates did not differ significantly between the POAG and UG groups during the 5-year postoperative follow-up period (Table 1).

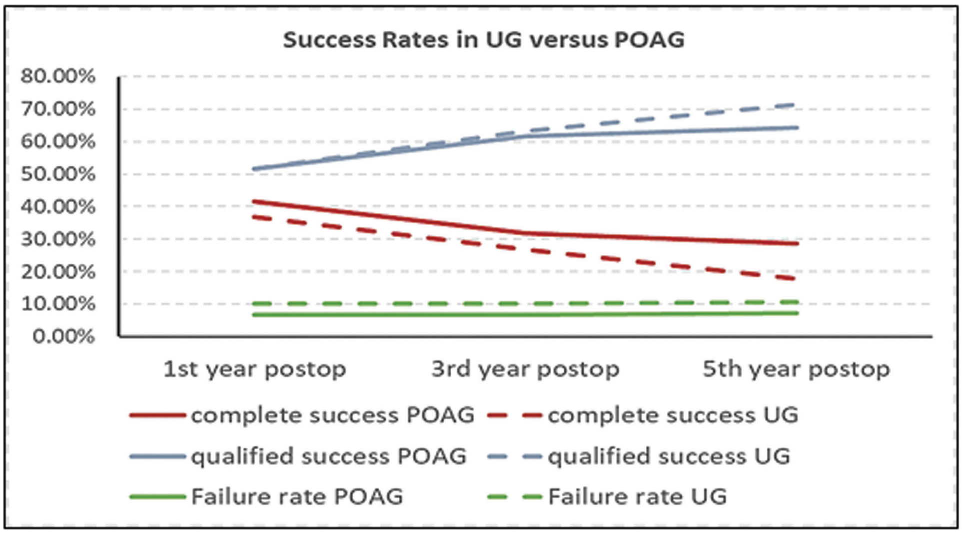
With time, the qualified success rate increased while the complete success rate decreased in both groups. The qualified success rate was higher than the complete success rate in both groups. From the first to the third year postoperatively, the qualified success rate was nearly the same (at ~50%) in both groups, but it started to rise subsequently, ending with ~7% higher in the UG group. However, the complete success rate was higher by ~5% in the POAG group since the first year postoperatively and remained higher for 5 years postoperatively, with the gap widening to 10% at 5 years postoperatively. The failure rate in both groups was nearly similar over 5 years postoperatively, with the

**Table 1 Success rates**

| Outcome of trabeculectomy with MMC | 1st year [*n* (%)] | 3rd year [*n* (%)] | 5th year [*n* (%)] |
|---|---|---|---|
| Complete success | | | |
| POAG | 25 (41.7) | 19 (31.7) | 16 (28.6) |
| UG | 22 (36.7) | 16 (26.7) | 10 (17.9) |
| Qualified success | | | |
| POAG | 31 (51.7) | 37 (61.7) | 36 (64.3) |
| UG | 32 (53.3) | 38 (63.3) | 40 (71.4) |
| Failure | | | |
| POAG | 4 (6.7) | 4 (6.7) | 4 (7.1) |
| UG | 6 (10.0) | 6 (10) | 6 (10.7) |
| $\chi^2$ | 0.607 | 0.670 | 1.99 |
| *P* | 0.738 | 0.715 | 0.368 |

MMC, mitomycin C; POAG, primary open-angle glaucoma; UG, uveitic glaucoma.

**Figure 1**




Success and failure rates in uveitic glaucoma (UG) versus primary open-angle glaucoma (POAG). Postop, postoperatively.

level in the UG group being higher than that in the POAG group by ~3% (Fig. 1).

The 1-, 3-, and 5-year cumulative success probabilities were constant at 96.4% in the POAG patients compared with 94.2% in the UG patients. Moreover, the median success time was estimated at 1 year for both groups. The log-rank test provided a *P* value of 0.551, indicating that the difference in success between the two groups was statistically insignificant (Fig. 2).

In both UG and POAG groups, the IOP decreased in the first year postoperatively and continued to increase slightly afterwards (Table 2). The preoperative IOP differed significantly between the POAG and UG groups (*P*=0.00). However, the IOP did not differ significantly between the two groups in the first and third postoperative years (*P*=0.079 and 0.48, respectively). Nevertheless, in the fifth postoperative year, a highly significant difference in IOP reappeared between the two groups (*P*=0.009, Table 2).

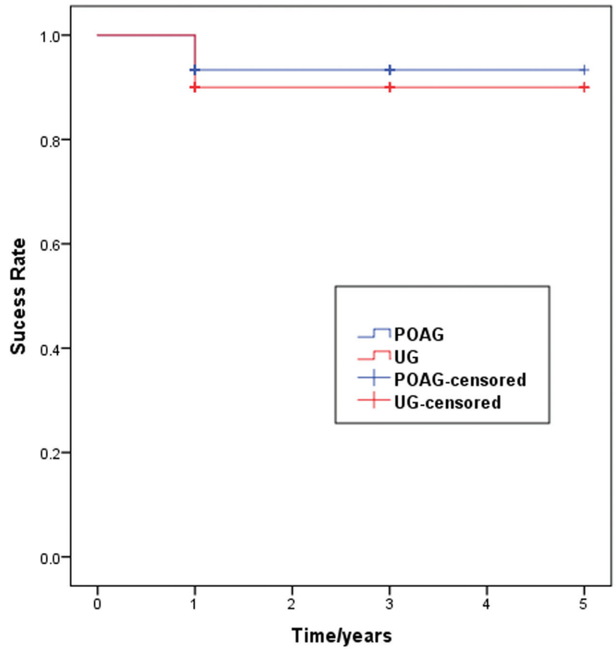
There was also a similar trend for the mean number of antiglaucoma medications in both UG and POAG groups, with the number decreasing immediately after surgery and then increasing gradually in both groups (Fig. 3). There was a statistically significant difference in the mean number of antiglaucoma medications preoperatively and at 1 and 3 years postoperatively, while there was no statistically significant difference between the two groups at the fifth year postoperatively (Table 3).

## Discussion

POAG and UG groups showed a significant difference in the patients' age at the time of surgery. However, the two groups showed no significant differences in the qualified success rate, complete success rate, and failure rate after reporting the 5-year postoperative outcome. Over the 5-year postoperative period, some patients shifted from complete success to qualified success, although the failure rate was nearly similar in both groups throughout the follow-up period. This explains the slow rise in the number of antiglaucoma medications used and IOP after the first year postoperatively in both groups. In addition, the significance in IOP difference between the two groups had *P* values of 0.079, 0.048, and 0.009 during the first, third, and fifth year postoperatively, respectively. Also, the IOP remained higher in the UG group even with a higher number of antiglaucoma medications than in the POAG group, both preoperatively and postoperatively.

The current study reported no significant differences in the success and failure rates of trabeculectomy with MMC over 5 years postoperatively in UG and POAG groups. This is one of the reasons some studies have recommended trabeculectomy with MMC as the primary external filtering surgery before considering

**Figure 2**



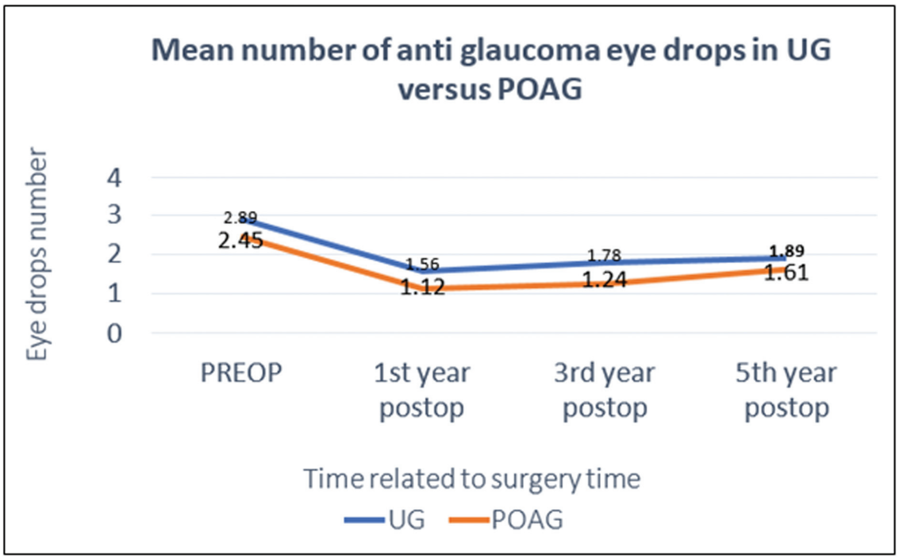

Kaplan–Meier curve for the success rate of the two groups. POAG, primary open-angle glaucoma and UG, uveitic glaucoma.

**Table 2 Intraocular pressure values preoperatively and at 1, 3, and 5 years postoperatively**

| IOP | Group | Mean±SD | SEM | *t* test for equality of means | |
|---|---|---|---|---|---|
| | | | | *t* | *P* |
| Preop | POAG | 29.08±3.055 | 0.394 | −3.714 | 0.000* |
| | UG | 31.30±3.470 | 0.448 | | |
| Postop | | | | | |
| 1st year | POAG | 16.88±2.662 | 0.344 | −1.772 | 0.079 |
| | UG | 17.95±3.829 | 0.494 | | |
| 3rd year | POAG | 18.03±2.899 | 0.374 | −1.998 | 0.048* |
| | UG | 19.15±3.215 | 0.415 | | |
| 5th year | POAG | 18.33±2.978 | 0.384 | −2.654 | 0.009* |
| | UG | 19.88±3.405 | 0.440 | | |

IOP, intraocular pressure; POAG, primary open-angle glaucoma; Postop, postoperative; Preop, preoperative; *t*, *t* value; UG, uveitic glaucoma. *Statistically significant. SEM: standard error of mean.

**Figure 3**




Mean number of antiglaucoma medications in uveitic glaucoma and primary open-angle glaucoma (POAG) groups before and after trabeculectomy with mitomycin C. Preop, preoperative; Postop, in uveitic glaucoma (UG) and postoperative.

**Table 3 Antiglaucoma eye drops in primary open-angle glaucoma versus uveitic glaucoma**

| Antiglaucoma medications | Group | Mean | *t* | DF | SED | *P* |
|---|---|---|---|---|---|---|
| Preop | UG | 2.89 | 2.35 | 118 | 0.186 | 0.02* |
| | POAG | 2.45 | | | | |
| Postop | | | | | | |
| 1st year | UG | 1.56 | 2.69 | 118 | 0.189 | 0.008* |
| | POAG | 1.12 | | | | |
| 3rd year | UG | 1.78 | 2.69 | 118 | 0.201 | 0.008* |
| | POAG | 1.24 | | | | |
| 5th year | UG | 1.89 | 1.43 | 110 | 0.195 | 0.15 |
| | POAG | 1.61 | | | | |

DF, degree of freedom; POAG, primary open-angle glaucoma; Postop, postoperative; Preop, preoperative; *t*, *t* value; UG, uveitic glaucoma.
*Statistically significant. SED: standard error of difference.

shunt surgery for medically uncontrolled UG. In agreement with this study, Lee *et al.* [28], Kaburaki *et al.* [29], and Kanaya *et al.* [30] recorded nonsignificant differences in the success rates between UG and POAG eyes, from retrospective reviews of patients' data, despite using different definitions of success rates and considering the cutoff IOP for success as either 15 or 18 mmHg with or without antiglaucoma medications. However, Iwao *et al.* [31] reported a significantly lower success rate and a significantly higher failure rate in the UG group during 3 years of follow-up after trabeculectomy with MMC, which is also consistent with the findings reported by Muñoz-Negrete *et al.* [32].

In this study, the complete success rate declined over time postoperatively at the expense of an increase in the qualified success rate and the number of antiglaucoma medications, while the failure rate was nearly the same. In contrast, some studies have shown a decline in the cumulative probability of success at the expense of an increase in failure rates after trabeculectomy with MMC for managing UG [25,33]. However, a direct comparison of the absolute success rates of trabeculectomy with MMC in various studies is difficult because each study uses a different cutoff IOP level to define treatment success (21, 18, or 15 mmHg), and some studies heve mentioned only one type of success (complete, qualified, or cumulative). However, the American Academy of Glaucoma has defined 21 mmHg as a cutoff point for reporting postoperative outcomes in patients with glaucoma.

Bouhenni *et al.* [34] reported a nonsignificant difference in success rates between primary and secondary Baerveldt implants after reviewing 117 eyes with different etiologies for ∼5 years postoperatively, suggesting that GDD can serve as a worthwhile secondary surgical option to avoid the higher rate of complications, especially endophthalmitis, hypotony, and corneal endothelial damage. The results of using an Ahmed valve as a primary surgical option in inflammatory glaucoma were contradicting between the study by Bettis *et al.* [35], who reported a higher success rate with a primary Ahmed valve compared with trabeculectomy with MMC, and Kwon *et al.* [25] who found no difference in the outcome. The European Glaucoma Society in 2017 published its recommendations for the possible choice of shunt operations as a primary surgical option in a number of cases but did not mention UG in its list that included previously failed trabeculectomy with antimetabolites, excessive conjunctival scarring due to previous ocular surgery or cicatrizing ocular surface disease, neovascular glaucoma, pediatric, aphakia, or technical difficulties in performing trabeculectomy [36].

The retrospective nature of the current study imposed several limitations. First, we could not determine the best-corrected visual acuity, visual field data, or the cup to disk ratio for each patient at the follow-up points. Second, we could not study the effect of postoperative cataract surgery or activation of uveitis on the control of IOP after trabeculectomy. We hope to evaluate these prognostic factors in future prospective studies. Other study limitations are significant age difference and significant preoperative IOP difference between the two groups.

## Conclusion

Although UG is a refractory type of glaucoma, patients could still be treated using trabeculectomy with MMC as the primary external filtering surgery if medical control does not result in successful IOP reduction. Shunt operations could be performed in cases involving failure of trabeculectomy with MMC.

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**Conflicts of interest**
There are no conflicts of interest.

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