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REVIEW

Outcomes of Trabeculectomy and Glaucoma Drainage Device Surgery in Congenital Aniridia-Associated Glaucoma: A Systematic Review and Meta-Analysis

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ABSTRACT

Introduction: This study aimed to compare the surgical outcomes of trabeculectomy and glaucoma drainage device (GDD) implantation in patients with congenital aniridia.

Methods: Eligible studies were retrieved from Embase, MEDLINE (via PubMed), and the Cochrane Central Register of Controlled Trials (CENTRAL) up to December 15, 2024. Studies were included if they reported clinical outcomes following trabeculectomy or GDD implantation in individuals with aniridic glaucoma. Outcomes of interest included success rates, best spectacle-corrected visual acuity (BSCVA), intraocular pressure (IOP), use of glaucoma medications, and postoperative complications.
Data extraction and synthesis were conducted according to the Cochrane Handbook. Meta-analyses were performed using a random-effects model. Heterogeneity among studies was evaluated using the *Q* test and I^2 statistic.

Results: Twenty-two of the 1039 screened studies were included in the meta-analysis. Pooled complete success rates were not significantly different between trabeculectomy and GDD treatments ($p=0.88$). However, the qualified success rate was significantly higher following GDDs compared to trabeculectomy ($p<0.001$) in patients with aniridia. Cox frailty regression analysis of individual success data showed similar results: the hazard ratio of failure was significantly higher after trabeculectomy than after GDD (HR 5.684 from 1.46 to 22.14, $p=0.012$). No significant differences were observed between the two procedures in terms of IOP reduction ($p=0.53$), percentage change in IOP ($p=0.24$), or reduction in glaucoma medications ($p=0.56$) at final follow-up. Additionally, there was no significant difference in the change in BSCVA between the two groups ($p=0.72$).

Conclusion: Regarding complete success rates, trabeculectomy does not seem to provide a

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significant benefit over GDDs in treating aniridic glaucoma. However, the qualified success rate is greater with GDD implantation than with trabeculectomy. Both surgical approaches show similar effectiveness in lowering intraocular pressure, reducing the need for glaucoma medications, and maintaining visual acuity.

Keywords: Aniridia; Glaucoma; Trabeculectomy; Glaucoma drainage device; Tube shunt

Key Summary Points

Why carry out this study?

Both trabeculectomy and glaucoma drainage device surgery (GDD) are feasible to manage secondary glaucoma in congenital aniridia, but no consensus on which technique is better has been reached.

This study aims to synthesize the available evidence and compare the efficacy and safety of trabeculectomy and GDD in patients with aniridic glaucoma.

What was learned from the study?

The qualified success rate was higher after GDD compared to trabeculectomy in people with aniridic glaucoma.

Both surgical techniques are comparably effective in terms of complete success rate, reducing intraocular pressure, decreasing reliance on glaucoma medications, and preserving visual acuity.

No significant differences in the rate of serious postoperative complications were observed between trabeculectomy and GDDs.

INTRODUCTION

Congenital aniridia (aniridia) is a rare panocular disorder with an estimated prevalence of 1 in 72,000 individuals [1]. It typically affects both eyes and is characterized by varying degrees of iris hypoplasia. Approximately two-thirds of cases are familial, most commonly inherited in an autosomal dominant manner, while the remaining third occur sporadically [2]. The condition is classically caused by mutations in the *PAX6* gene, a key regulator of ocular development [3]. Aniridia may be associated with keratopathy, cataract, optic nerve and foveal hypoplasia, nystagmus, as well as secondary glaucoma [4].

Secondary glaucoma in aniridia typically develops during adolescence or early adulthood, with reported prevalence ranging from 6% to 75% [5]. Aniridic glaucoma is most commonly attributed to progressive angle closure due to anterior rotation of the residual iris stumps, which tends to evolve throughout the teenage years. Other potential mechanisms include congenital or infantile forms associated with trabeculodysgenesis or an underdeveloped Schlemm's canal [2, 6]. Glaucoma represents one of the most challenging complications of aniridia. Surgical intervention is often required when medical therapy fails to adequately control intraocular pressure (IOP) [7].

A variety of surgical techniques have been employed in the management of aniridic glaucoma, including cyclodestructive procedures, trabeculotomy, trabeculectomy, goniotomy, glaucoma drainage devices (GDDs), and minimally invasive glaucoma surgery (MIGS) [8, 9]. Trabeculectomy is widely regarded as the gold standard surgical procedure for lowering elevated IOP in glaucoma. Both trabeculectomy and GDDs involve the formation of an ostium that diverts aqueous humor away from the conventional outflow pathway, facilitating drainage into the subconjunctival space [10, 11]. Currently, there is no clear consensus regarding the optimal surgical approach for glaucoma [6], especially associated with congenital aniridia.

This study aims to conduct a systematic review and meta-analysis comparing trabeculectomy and GDD implantation in patients with congenital aniridia, focusing on outcomes such as surgical success rates, visual acuity, intraocular pressure control, and procedure-related complications. The underlying hypothesis is that significant differences may exist in postoperative outcomes between surgical techniques, which could provide valuable insights to help guide clinical decision-making and improve management strategies for aniridic glaucoma.

METHODS

The systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines [12], and was pre-registered in the PROSPERO database (Registration Number CRD42024627078). The study methodology followed the recommendations outlined in the Cochrane Handbook for Systematic Reviews of Interventions [13].

Ethical Approval

No ethical approval was required for this systematic review with meta-analysis, as all data were already published in peer-reviewed journals. No patients were involved in the design, conduct, or interpretation of our study. The datasets used in this study can be found in the full-text articles included in the systematic review and meta-analysis.

Information Source and Search Strategy

The electronic databases Embase, MEDLINE (via PubMed), and the Cochrane Central Register of Controlled Trials (CENTRAL) were systematically searched for relevant studies published up to December 15, 2024, with no language restrictions applied. Following the screening of titles and abstracts, all non-English manuscripts were excluded. Since only English-language titles and abstracts were available, translation services were not necessary. The search strategy included the following keywords: ((aniridia) OR (aniridic) OR (PAX6)) AND ((glaucoma) OR (ocular hypertension) OR ((ocular OR intra-ocular) AND pressure)).

Not all PICO elements were included in the search terms to avoid unduly narrowing the scope of the literature search. This approach was chosen to reduce the risk of omitting relevant studies that, while potentially addressing different primary research questions, may still provide valuable data for our analysis. Given the rarity of this disease, a broader search strategy was deliberately employed to maximize the identification of pertinent literature and minimize the chance of missing important evidence. No search filters were used in order to maximize sensitivity (see Table S1 in the electronic supplementary material for more details).

Eligibility Criteria

The research question was developed using the Population-Intervention-Comparator-Outcomes (PICO) framework. Eligible studies included patients with aniridia-associated glaucoma (P) who underwent cyclodestructive procedures, argon laser trabeculoplasty, goniotomy, trabeculotomy, trabeculectomy, or glaucoma drainage device implantation (I and C). Included studies reported at least one of the following outcomes (O): surgical success rate, postoperative best spectacle-corrected visual acuity (BSCVA), postoperative intraocular pressure change, postoperative change in topical glaucoma medication use, intra- and postoperative complications, visual field progression, and optic nerve head changes.

Studies were considered eligible if they evaluated at least one of the aforementioned treatment modalities in patients with aniridia and reported relevant outcome data. There was no distinction between specific GDD types, including Ahmed, Aurolab Aqueous Drainage Implant (AADI), Baerveldt, Molteno, and Schocket devices. Both retrospective and prospective studies, as well as case series and case reports, were included. Duplicates and non-human studies were excluded from the analysis.

Selection Process

All references were managed using EndNote 20 reference management software (Clarivate Analytics, Philadelphia, PA, USA). After automatic and manual removal of duplicates, the titles, abstracts, and full texts were independently screened by three reviewers (Li, Liu, and Tóth).

Any disagreements were resolved through discussion with a fourth reviewer (Szentmáry). The full texts of potentially eligible studies were subsequently assessed for final inclusion. One article was excluded because it reported on a combined trabeculectomy and trabeculotomy procedure, which did not allow for isolated analysis of surgical outcomes [6]. In cases of overlapping study populations, the publication with the larger sample size was selected to avoid duplication of data.

Data Collection Process and Items

Data from articles meeting the inclusion criteria were extracted into an Excel spreadsheet (Office 2016, Microsoft, Redmond, WA, USA). Extracted variables included general study information (author, publication year, study design), patient demographics (age, gender), number of subjects, and follow-up duration. For each study, both baseline (preoperative) and postoperative values were recorded, and outcomes were collected at multiple time points, where available.

Specifically, the extracted data included complete success rate, qualified success rate, BSCVA converted to logMAR, IOP, number of antiglaucoma medications, and postoperative complications. Additional variables such as prior glaucoma surgery, previous intraocular procedures, and the use of adjunctive agents (e.g., mitomycin C or 5-fluorouracil) were also documented. Complete success was defined as achieving a final IOP of 21 mmHg or less without the use of antiglaucoma medications. Qualified success was defined as a final IOP of 21 mmHg or less with the aid of antiglaucoma medications.

Where available, individual patient data (IPD) were collected directly from the included publications or through correspondence with study authors. Any disagreements during data extraction were resolved by team consensus following discussion.

Quality Assessment of Included Studies

The risk of bias was assessed using the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool [14] for non-randomized interventional studies and the Joanna Briggs Institute (JBI) Critical Appraisal Checklists [15] for observational studies, case series, and case reports. Any disagreements among the review authors regarding risk of bias assessments were resolved through discussion. In cases where consensus could not be reached, a third reviewer was consulted to make the final decision.

Statistical Methods and Data Synthesis

Statistical analyses were carried out using the meta and metafor packages of the R statistical software (version 4.4.2). The statistical analyses follow the advice of Harrer et al. [16]. For all statistical analyses, a p value of less than 0.05 was considered significant. All the performed analyses included random effect terms. Eyes were the base items in the analyses. In several studies, there were a few patients who underwent surgery on both eyes. It is a minor limitation that we could not account for this dependency because of lack of information.

We calculated pooled proportions using the generalized mixed-effect approach of Stijnen et al. [17]. This approach handles small studies well even those with zero event frequencies. Some studies contributed to both treatment subgroups. Although the results corresponded to different populations, the corresponding random effects are correlated in this case. For this reason, to get subgroup comparison p values, we logit-transformed the proportions and for the transformed data we fitted multivariable model using the rma.mv() function of the metafor R package. Since the populations behind the proportions were always different, the within-study covariance between any two logit transformed proportions is zero. As a continuity correction, in case of zero frequencies, we used 0.1 in the logit transformation. We also performed several study-level meta-regression analyses using the multivariate methodology on the logit-transformed proportions. When the meta-regression is based on aggregated variables, the results must be interpreted with caution due to the possibility of aggregation bias; see Sect. 7.6.2. of Schmid et al. [18] for details.

To pool within-group mean differences, classical inverse variance random-effect meta-analysis was applied with REML tau estimator and Hartung–Knapp adjustment. In several cases, the standard deviations of the pre- and post-treatment outcomes were available or could be estimated, but the standard deviation of the change was missing. Following the instructions in the Cochrane Handbook [13], we imputed several different correlations. In a few studies, as a result of the availability of IPD, we could calculate the correlation. On the basis of these available correlations we imputed correlations −0.4, 0, and 0.4. All correlations used provided similar results. The published results were obtained using a correlation of 0. It should be emphasized that although the pooled outcome and its confidence interval (CI) were roughly the same in all cases, the CIs of the individual study results naturally depended on the imputed correlation. We compared subgroups and generated subgroup difference p values using the classical mixed-effect approach implemented in the metagen() R function of the meta package.

We also collected failure time to event IPD data and calculated pooled HR using the mixed-effects (frailty) Cox proportional hazards model. In a few studies, we used the WebPlotDigitizer tool software (https://automeris.io/WebPlotDigitizer.html; accessed on February 25, 2025) to digitize Kaplan–Meier (KM) curves. We estimated individual patient data from the digitalized KM curves by direct calculation via inverting the construction of the KM curve, as similarly described in Guyot et al. [19].

We visualized the results on forest plots and bubble plots. Heterogeneity was assessed by calculating univariate I^2 measure and its CI.

We assessed publication bias separately in each subgroup, which had at least 10 studies. In the case of the mean difference, we created classical funnel plot and performed Egger's test. In the case of prevalence, the effect size and the standard error are dependent. For this reason, following the suggestion of Hunter et al. [20], we created a modified funnel plot to assess the publication bias visually: on the y-axis, we plotted the study size instead of the standard error. Moreover, instead of Egger's test, we used Peters' test [21] to check the presence of small-study bias.

Assessment of Grade of Evidence

As a result of the limited number of comparative studies, it was not possible to reliably determine the grade of evidence for the analyzed outcomes.

Protocol Amendment

As a result of the limited number of studies and insufficient reported data on the incidence of visual field changes and optic nerve head alterations, we deviated from the original protocol and did not include these outcomes in the final analysis.

RESULTS

Search and Selection

Our systematic search identified a total of 1039 articles. After removal of duplicates, 589 publications were screened by title and abstract. Ultimately, 22 studies met the inclusion criteria and were included in the quantitative synthesis (Fig. 1).

Basic Characteristics of Included Studies

Table 1 presents the baseline characteristics of the included studies. The analysis includes one comparative study involving 30 eyes with aniridic glaucoma, along with 16 case series and 5 case reports comprising a total of 147 eyes. Altogether, 177 eyes from patients with aniridic glaucoma were included in the meta-analysis. Trabeculectomy was performed with adjunctive agents in 64 eyes (83.1%), while adjunctive agents were used during GDD implantation in 4 eyes (3.8%).

Other Antiglaucoma Surgical Procedures

As a result of small sample sizes, other interventions such as trabeculotomy, deep sclerectomy, minimal invasive glaucoma surgery cyclodestructive procedures and goniotomy (Table 2) could not be included in the

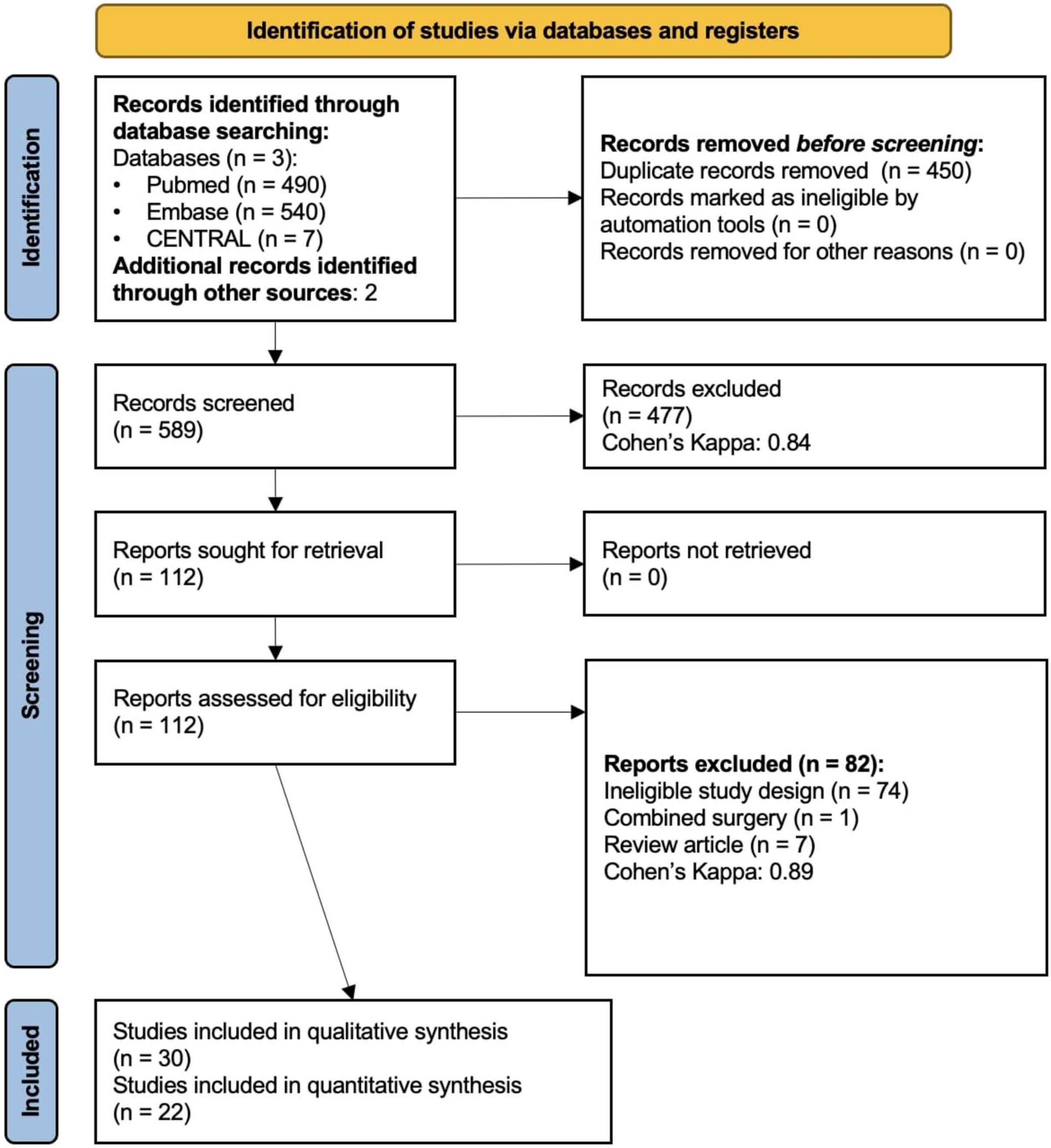

Fig. 1 Flowchart illustrating the study identification process

quantitative analysis. One case series was available on trabeculotomy, one on cyclodestructive surgery, and one on goniotomy. Other surgical procedures were reported only in case series.

Complete and Qualified Success Rates

Original data on complete and qualified success rates at last follow-up were extracted from all

Table 1 Basic characteristics of the included studies ($n = 22$)

First author (year)	Design	Country	Recruitment period	No. of included eyes (woman %)	Age (mean ± SD, years)	GR 1	GR 2	Type of the GDD	Mean follow-up (months)	Outcome
Adachi et al. (1997) [22]	RCS	USA	1958–1996	5 (NR)	NR	TE	–	–	NR	SR
Akagi et al. (2015) [23]	CR	Japan	NR	2 (0.0)	1.3	GDD	–	Baerveldt	24	SR, IOP, POC
Almousa et al. (2014) [24]	RCS	UK	2000–2009	8 (83.3)	Median: 49 (range, 12 to 60)	GDD	–	Ahmed	37.4	SR, BSCVA, IOP, AGM, POC
Arroyave et al. (2003) [25]	RCS	USA	1989–1999	8 (20.0)	14.7 ± 15.5	GDD	–	Baerveldt: 7 Molteno: 1	19	SR, BSCVA, IOP, AGM, POC
Barthakur et al. (2009) [26]	CR	Nepal	NR	2 (0.0)	9.0	TE	–	–	48	SR, BSCVA, IOP
Billson et al. (1989) [27]	RCS	Australia	NR	2 (NR)	13.0	GDD	–	Molteno	34.0	SR, BSCVA, IOP, POC
Bolek et al. (2023) [28]	RCS	Poland	2008–2019	7 (66.7)	45.7 ± 6.5	GDD	–	Ahmed	36	SR, BSCVA, IOP, AGM, POC
Cunliffe et al. (1998) [29]	RCS	New Zealand	NR	3 (NR)	18.0 ± 6.9	GDD	–	Molteno	100.0	SR, BSCVA, IOP, AGM
Demirok et al. (2019) [30]	RCS	Turkey	2001–2015	6 (16.7)	16.0 ± 12.3	GDD	–	Ahmed: 5 Molteno: 1	19.2	SR, BSCVA, IOP, AGM, POC

Table 1 continued

First author (year)	Design	Country	Recruitment period	No. of included eyes (woman %)	Age (mean ± SD, years)	GR 1	GR 2	Type of the GDD	Mean follow-up (months)	Outcome
Durai et al. (2021) [31]	Retrospective interventional comparative study	India	2005–2015	30 (26.7)	18.7	TE	GDD	Aurolab	48	SR, BSCVA, IOP, AGM, POC
Harvey et al. (2017) [32]	CR	USA	NR	1 (NR)	13.0	GDD	–	Ahmed	6	SR, BSCVA, IOP
Jacobson et al. (2022) [33]	RCS	USA	2012–2020	56 (NR)	28.2 ± 22.6	TE	GDD	Ahmed: 8 Baerveldt: 23 Other: 4	170.4	SR, POC
Magan et al. (2022) [34]	RCS	UK	1990–2021	4 (NR)	NR	TE	GDD	Baerveldt	NR	POC
Mandal et al. (1997) [35]	RCS	India	1992–1994	2 (100)	2.5	TE	–	–	23	SR, BSCVA, IOP, AGM,
Moreker et al. (2009) [36]	CR	India	NR	1 (NR)	35.0	TE	–	–	6.0	SR, BSCVA, IOP, AGM,
Omi et al. (1991) [37]	RCS	USA	NR	4 (NR)	NR	GDD	–	Schocket	11.5	SR, IOP
Pereira et al. (2002) [38]	RCS	USA	1990–1996	4 (100)	0.6 ± 0.2	GDD	–	Baerveldt: 3 Molteno: 1	NR	SR, IOP, POC
Sihota et al. (2021) [39]	RCS	India	NR	23 (40.0)	16.6 ± 9.8	TE	–	–	87.5	SR, BSCVA, IOP
Susanna et al. (1995) [40]	RCS	Brazil	1991–1993	1 (0.0)	0.5	TE	–	–	11.0	SR, IOP
Trigler et al. (2006) [41]	RCS	USA	1995–2004	1 (100)	0.09	GDD	–	Ahmed	6.0	SR, POC

Table 1 continued

First author (year)	Design	Country	Recruitment period	No. of included eyes (woman %)	Age (mean ± SD, years)	GR 1	GR 2	Type of the GDD	Mean follow-up (months)	Outcome
Ugalahi et al. (2020) [42]	RCS	Nigeria	2015–2019	6 (NR)	NR	TE	GDD	Other: 2	NR	SR, POC
Yalvac et al. (2004) [43]	CR	Turkey	NR	1 (0.0)	17.0	GDD	–	Ahmed	14.0	SR, BSCVA, IOP, AGM, POC

RCS retrospective case series, *CR* case report, *GR* group, *TE* trabeculectomy, *GDD* glaucoma drainage device, *SR* success rate, *NR* not reported, *BSCVA* best spectacle-corrected visual acuity, *IOP* intraocular pressure, *AGM* antiglaucoma medication, *POC* postoperative complications

included studies involving trabeculectomy and GDDs in patients with aniridic glaucoma, using deconstructed KM curves and pooled data. These results indicate that the complete success rate was comparable between trabeculectomy and GDDs ($p = 0.88$) (Fig. 2a), while the qualified success rate was significantly higher following GDDs compared to trabeculectomy ($p < 0.001$) (Fig. 2b). The pooled complete success rates were 0.48 [95% CI 0.06–0.93] for trabeculectomy and 0.39 [95% CI 0.05–0.87] for GDDs. The pooled qualified success rates were 0.56 [95% CI 0.13–0.91] for trabeculectomy and 0.84 [95% CI 0.69–0.92] for GDDs.

Failure event times and censored times are shown in Fig. S1 in the electronic supplementary material for the two treatment groups. According to the Cox frailty regression, the hazard ratio of failure is significantly higher in the trabeculectomy group than in the glaucoma drainage device treatment group (HR 5.684 from 1.46 to 22.14, $p = 0.012$).

After excluding case reports, similar results were observed (see Fig. S2A, B in the electronic supplementary material for more details). The pooled complete success rates were 0.23 [95% CI 0.01–0.92] for trabeculectomy and 0.44 [95% CI 0.03–0.95] for GDDs ($p = 0.56$). The pooled qualified success rates were 0.37 [95% CI 0.03–0.90] for trabeculectomy and 0.83 [95% CI 0.67–0.92] for GDDs ($p < 0.001$). Following excluding the study by Durai et al., similar results were observed. The pooled complete success rates were 0.64 [95% CI 0.02–0.99] for trabeculectomy and 0.29 [95% CI 0.02–0.89] for GDDs ($p = 0.11$). The pooled qualified success rates were 0.61 [95% CI 0.08–0.96] for trabeculectomy and 0.83 [95% CI 0.63–0.93] for GDDs ($p = 0.001$). See Fig. S3A, B in the electronic supplementary material for more details.

Meta-regression analyses assessing the effect of the covariates proportion of prior glaucoma surgery ($p = 0.74$ and $p = 0.06$), prior intraocular surgery ($p = 0.78$ and $p = 0.08$), or simultaneous adjunctive agents ($p = 0.69$ and $p = 0.20$) revealed no significant effect on complete and qualified success rates (see Figs. S4 and S5 in the electronic supplementary material for more details).

Table 2 Basic characteristics of reported data on other surgeries than trabeculectomy and glaucoma drainage devices in people with aniridic glaucoma

First author (year)	Design	Country	Recruitment period	No. of eyes	Age (mean ± SD, years)	Intervention	Mean follow-up (months)	Complete success (*n*, %)	Qualified success (*n*, %)
Adachi et al. (1997) [22]	RCS	USA	1958–1996	12	5.6 ± 8.1	Trabeculotomy	129.9	3 (25.0)	7 (58.3)
Aldarrab et al. (2018) [44]	CR	Saudi Arabia	NR	2	1.3 ± 0.1	Deep sclerectomy	6	0 (0.0)	2 (100)
Lindland et al. (2021) [45]	CR	Norway	NR	1	60	MIGS	24	0 (0.0)	1 (100)
Rawlyk at el. (2023) [46]	CR	Canada	NR	1	6	MIGS	18	1 (100)	1 (100)
Sbordone et al. (2013) [47]	CR	Italy	NR	1	18	Cyclodestructive surgery	60	0 (0.0)	1 (100)
Wagle et al. (1998) [48]	RCS	USA	1975–1996	8	NR	Cyclodestructive surgery	NR	NR	NR
Walton (1986) [49]	RCS	USA	NR	14	7	Goniotomy	NR	2 (14.2)	3 (21.3)
Wu et al. (2024) [50]	CR	China	NR	1	21	Trabeculotomy	12	0 (0.0)	1 (100)

RCS retrospective case series, *CR* case report, *MIGS* minimally invasive glaucoma surgery, *NR* not reported

The Peters' test for qualified success rate among GDDs did not reveal significant small-study effect ($p = 0.81$; see Fig. S6A in the electronic supplementary material for more details).

Intraocular Pressure

No significant differences were observed between trabeculectomy and GDDs at the

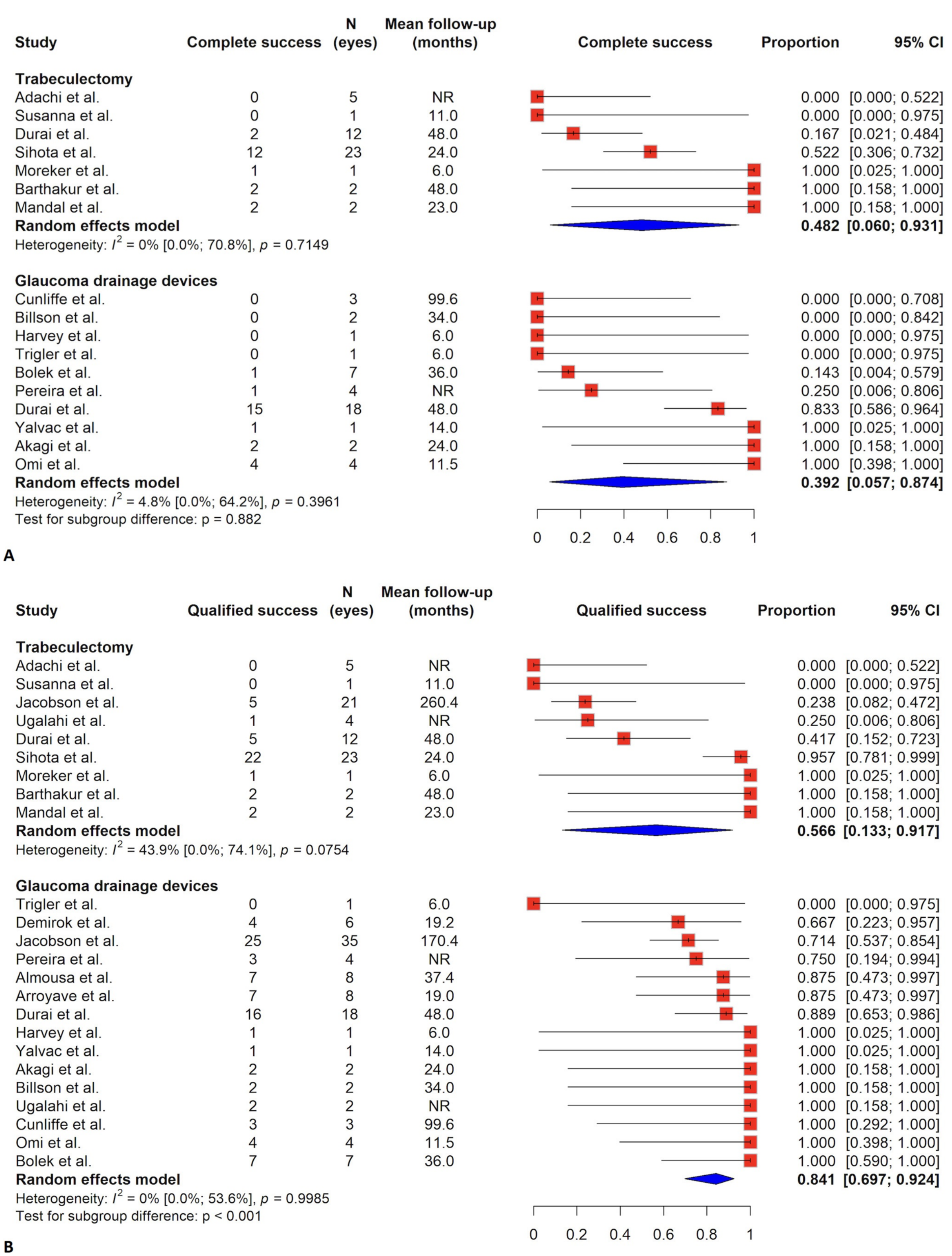

Fig. 2 Success rates of surgical interventions in aniridic glaucoma: complete success (**a**) and qualified success (**b**) for trabeculectomy and glaucoma drainage devices (GDDs). *CI* confidence interval, *NR* not reported

final follow-up in terms of IOP outcomes. The mean IOP change was – 17.82 mmHg [95% CI – 32.23 to – 3.41] for trabeculectomy and – 14.53 mmHg [95% CI – 16.88 to – 12.19] for GDDs ($p = 0.53$) (Fig. 3a). The Egger test for IOP change among GDDs did not reveal significant ($p = 0.09$) small-study effect (see Fig. S7 in the electronic supplementary material for more details). Similarly, the percentage change in IOP was – 62.92% [95% CI – 115.66

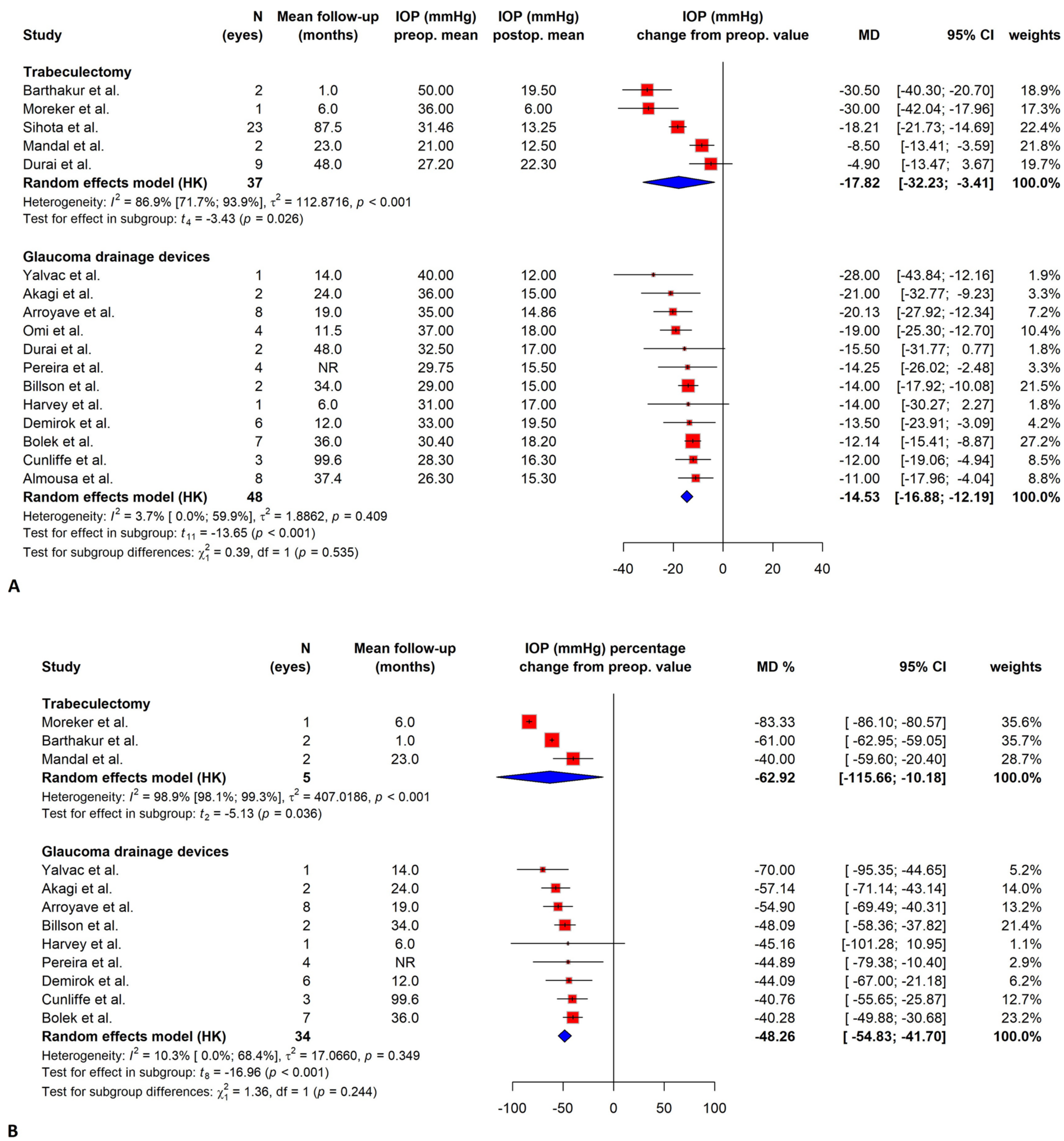

Fig. 3 Intraocular pressure outcomes at final follow-up in aniridic glaucoma: absolute intraocular pressure (**a**) and percentage reduction from baseline (**b**) following trabeculectomy and glaucoma drainage device (GDD) implantation. *IOP* intraocular pressure, *MD* mean difference, *CI* confidence interval, *preop* preoperative

to – 10.18] for trabeculectomy and – 48.26% [95% CI – 54.83 to – 41.70] for GDDs ($p = 0.24$) (Fig. 3b). Reduction in glaucoma medication use was also comparable between the two procedures, with a mean change of – 1.20 medications [95% CI – 5.59 to 3.19] for trabeculectomy and – 1.83 medications [95% CI – 2.82 to – 0.84] for GDDs ($p = 0.56$) (Fig. 4).

Best Spectacle-Corrected Visual Acuity

No significant difference was observed in BSCVA change at the final follow-up between trabeculectomy [– 0.11, 95% CI – 0.44 to 0.22] and GDDs [– 0.07, 95% CI – 0.13 to 0.00] ($p = 0.72$) (Fig. 5). Similarly, there was no significant difference in the short-term follow-up [trabeculectomy: – 0.25 [95% CI – 0.98 to 0.47]; GDDs: – 0.07 [95% CI – 0.13 to – 0.01]; $p = 0.27$] (see Fig. S8A in the electronic supplementary material for more details) or in the long-term follow-up [trabeculectomy: – 0.08 [95% CI – 0.72 to 0.56]; GDDs: – 0.07 [95% CI – 0.13 to 0.00]; $p = 0.93$] (see Fig. S8B in the electronic supplementary material for more details).

Postoperative Complications

The most frequent complication following GDD implantation was tube exposure or blockage ($n = 12$; 6.9%), while bleb failure was most common after trabeculectomy ($n = 9$; 13.2%) (Table 3). No significant differences in the rate of serious postoperative complications were observed between trabeculectomy and GDDs [Fig. 6 ($p = 0.25$); see Fig. S9 in the electronic supplementary material for more details ($p = 0.45$)]. The study-level linear meta-regression did not identify a significant association between the proportion of prior intraocular surgery and the rate of serious complications ($p = 0.48$), nor between the use of simultaneous adjunctive agents and the rate of serious complications ($p = 0.15$). However, the effect of the proportion of prior glaucoma surgery on the serious complication rate was significant ($p = 0.029$); specifically, studies with a higher proportion of prior glaucoma surgery demonstrated a lower complication rate (see Fig. S10 in the electronic supplementary material for more details). In addition, the Peters' test for postoperative serious complication rates among GDDs did not reveal a significant small-study effect ($p = 0.13$; see Fig. S6B in the electronic supplementary material for more details).

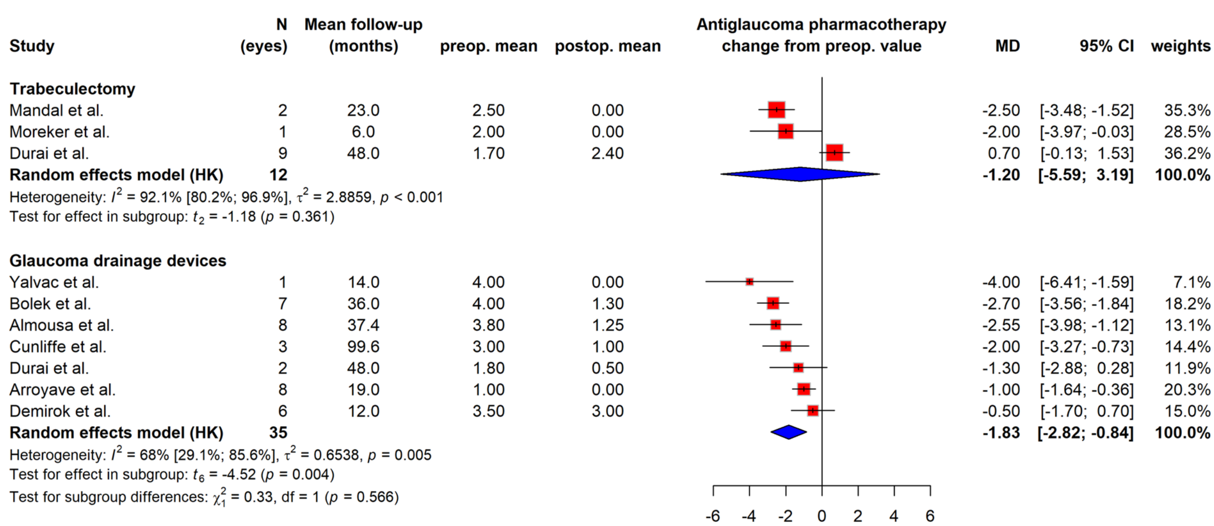

Fig. 4 Reduction in glaucoma medication use at final follow-up following trabeculectomy and glaucoma drainage device (GDD) implantation in aniridic glaucoma. *CI* confidence interval, *preop* preoperative

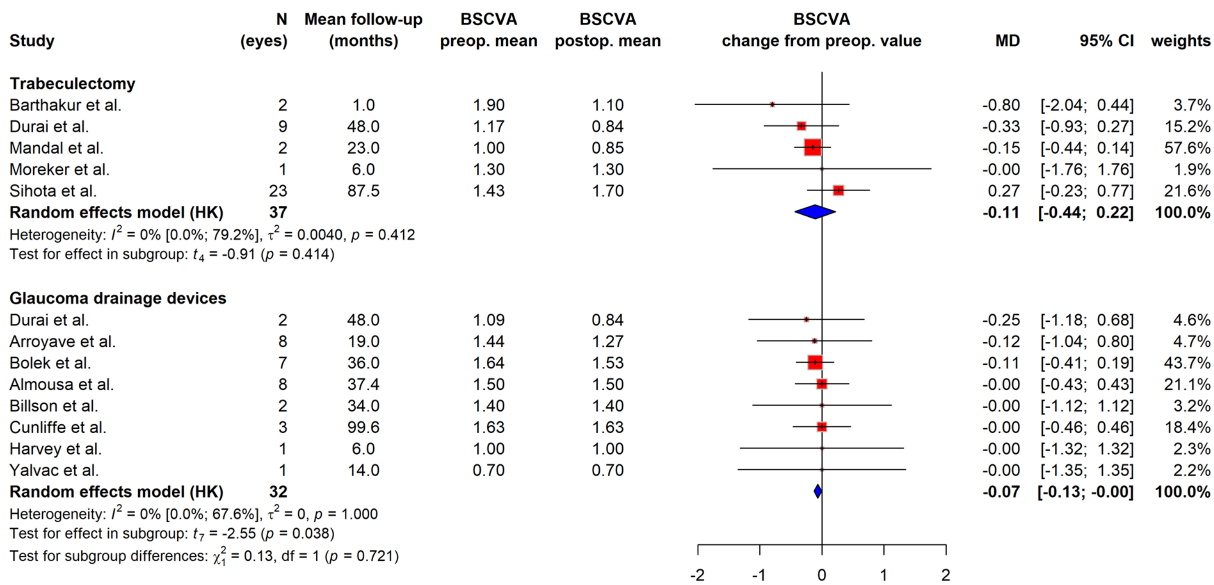

Fig. 5 Change in best spectacle-corrected visual acuity (BSCVA) at final follow-up after trabeculectomy and glaucoma drainage device (GDD) implantation in aniridic glaucoma. *CI* confidence interval, *MD* mean difference

Table 3 Incidence of complications following trabeculectomy and glaucoma drainage device (GDD) implantation

	Total ($N=177$) *n* (%)	Trabeculectomy ($N=73$) *n* (%)	GDD ($N=104$) *n* (%)
Severe complications			
Tube exposure/blockage	12 (6.8)	0 (0.0)	12 (11.5)
Bleb failure	9 (5.1)	9 (12.3)	0 (0.0)
Retinal detachment	5 (2.8)	1 (1.4)	4 (3.8)
Decompression retinopathy	2 (1.1)	0 (0.0)	2 (1.9)
Corneal decompensation	2 (1.1)	0 (0.0)	2 (1.9)
Phthisis bulbi	2 (1.1)	1 (1.4)	1 (1.0)
Endophthalmitis	1 (0.6)	0 (0.0)	1 (1.0)
Limbal stem cell deficiency	1 (0.6)	0 (0.0)	1 (1.0)
Ciliary staphyloma	1 (0.6)	1 (1.4)	0 (0.0)
Mild complications			
Cataract	7 (4.0)	5 (6.8)	2 (1.9)
Vitreous hemorrhage	2 (1.1)	0 (0.0)	2 (1.9)
Tube touched the cornea	1 (0.6)	0 (0.0)	1 (1.0)
Hyphema	1 (0.6)	0 (0.0)	1 (1.0)
Shallow anterior chamber	1 (0.6)	0 (0.0)	1 (1.0)

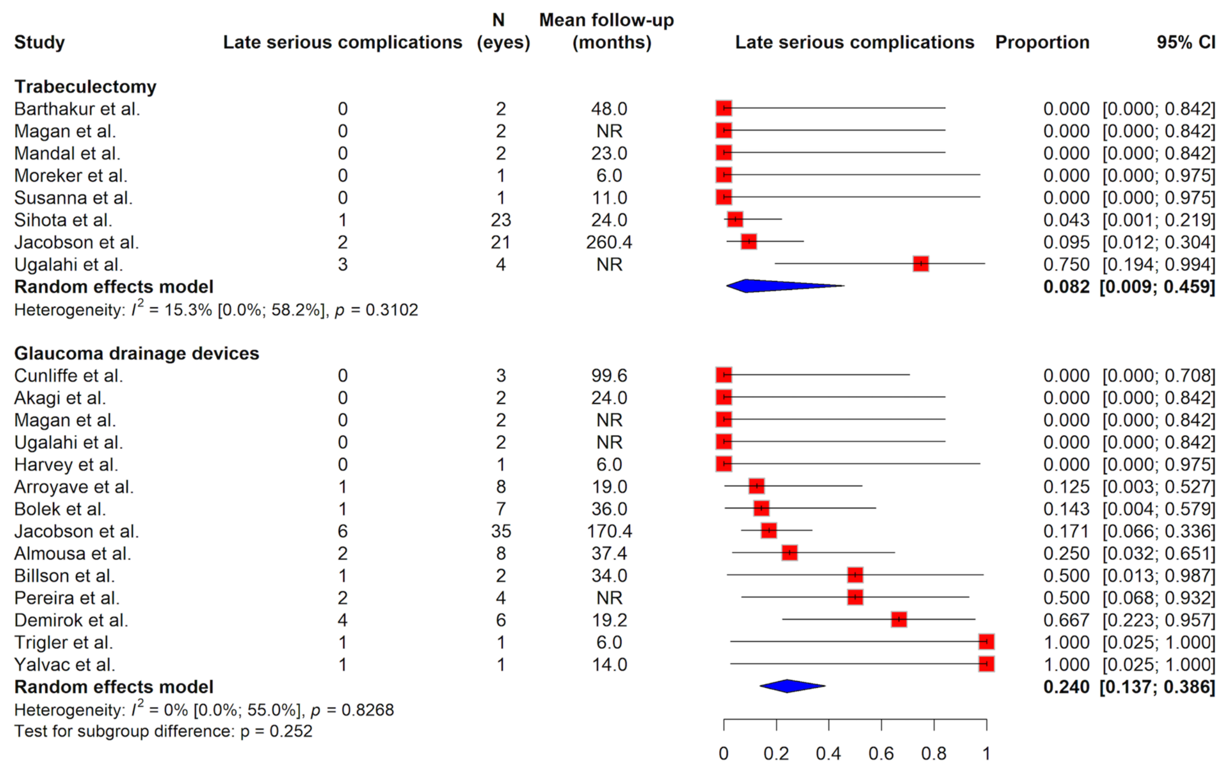

Fig. 6 Serious postoperative complications following trabeculectomy and glaucoma drainage device (GDD) implantation in aniridic glaucoma. *CI* confidence interval, *NR* not reported

Risk of Bias

The risk of bias varied moderately across the included studies, as assessed using the JBI Critical Appraisal Tool and the ROBINS-I instrument (see Tables S2–S4 in the electronic supplementary material for more details).

DISCUSSION

In this meta-analysis, we compared the success rates, visual acuity, and IOP change, as well as the influence of prior glaucoma surgery on success rates following glaucoma surgery in individuals with aniridia-associated glaucoma.

Although several surgical techniques are available, there is currently no consensus on the most appropriate method. Existing literature reports variable outcomes for cyclodestructive procedures [48], goniotomy [49], trabeculotomy [22], MIGS [45], and deep sclerectomy [44] in the context of aniridic glaucoma. Among these, trabeculectomy and GDDs are the most frequently performed procedures [31]. However, the choice between these two approaches remains controversial. Trabeculectomy is generally considered the preferred initial surgical approach, whereas GDDs are typically reserved for patients with higher risk profiles or those who have failed prior interventions [51].

In previous meta-analyses, HaiBo et al. [52] and Luo et al. [10] reported no significant differences in complete and qualified success rates between trabeculectomy and Ahmed valve implantation in low-risk eyes, based on analyses of eyes without congenital aniridia. While Luo et al. [10] found comparable complete success rates between trabeculectomy and Baerveldt shunt implantation, the qualified success rate was significantly higher with Baerveldt shunts. This may be attributed to the potential of the

Baerveldt shunt, in combination with postoperative antiglaucoma medications, to achieve more effective and sustained IOP reduction [53].

Furthermore, the fibrotic nature of the ocular tissues in aniridia—resulting from abnormal wound healing—is believed to contribute to a higher risk of surgical failure in aniridic glaucoma compared to primary glaucomas, both after trabeculectomy and GDD implantation [30]. While adjuvant antifibrotic agents such as mitomycin C (MMC) and 5-fluorouracil (5FU) are commonly used to enhance surgical success in trabeculectomy, their effectiveness in the aniridic population remains controversial [54]. Additionally, limbal pannus and aniridia-associated keratopathy may further contribute to reduced intra- and postoperative surgical success in this patient group [55].

In our analysis, we found no significant effects of the proportion of prior glaucoma surgery, prior intraocular surgery, or use of MMC/5FU during trabeculectomy on complete and qualified success rates. These factors therefore appear to have no significant impact on surgical success in aniridia-associated glaucoma. However, long-term surgical outcomes may still be influenced by subsequent procedures, such as cataract surgery, keratoplasty, or keratoprosthesis implantation [39]. The only available comparative study assessing outcomes of trabeculectomy versus GDD, specifically in aniridic glaucoma, conducted by Durai et al. [31], reported higher complete and qualified success rates following GDD implantation. The definitions of complete and qualified success did not differ significantly among the included studies, including the study by Durai (see Table S5 in the electronic supplementary material for more details). Notably, the study by Durai et al. contributed the largest number of eyes to the analysis. In this study, the difference in effectiveness between trabeculectomy and GDD was substantial, favoring GDD. Therefore, we performed sensitivity analyses by repeating the meta-analyses for complete and qualified success after excluding this study. These sensitivity analyses yielded similar results for both complete and qualified success (see Fig. S3A, B in the electronic supplementary material for more details). Nonetheless, this study—as well as other included case series—must be interpreted with caution due to small sample sizes and limited generalizability.

In addition, comparisons of success rates across studies may be misleading because of inconsistencies in success criteria. To address this limitation, we focused on evaluating IOP reduction and changes in glaucoma medication use, which are more objective and quantifiable outcome measures. Our analysis revealed no significant difference between trabeculectomy and GDDs in terms of IOP reduction or reduction in glaucoma medications, suggesting that both surgical approaches offer comparable efficacy in managing aniridic glaucoma. To account for variations in follow-up duration among the included studies, IOP data were analyzed on the basis of the final reported follow-up visit.

These findings are consistent with results from previous meta-analyses by Abu Serhan et al. [56], Luo et al. [10], and HaiBo et al. [52], all of which reported no significant differences in IOP or medication reduction between trabeculectomy and GDDs. Similarly, large-scale studies conducted in low-risk glaucoma populations, such as the Tube Versus Trabeculectomy (TVT) study at 5 years of follow-up [57] and the Helwe et al. study [58], also did not demonstrate significant differences in IOP reduction between these two surgical modalities. In contrast, Durai et al. [31] reported a greater reduction in IOP following GDD implantation compared to trabeculectomy in patients with aniridic glaucoma, although the change in glaucoma medication use remained similar between the two groups.

Visual prognosis in aniridia is generally poor because of the high burden of associated ocular comorbidities [59]. The prevalence of bilateral blindness has been reported to be as high as 69.8% at 5 years and 97.6% at 10 years [39]. In the TVT study, although a decline in visual acuity was noted after 1 year [60], there was no significant difference in visual acuity change between trabeculectomy and GDD after 5 years of follow-up [57]. Similarly, Tokumo et al. [61] found no difference in visual acuity outcomes between the two procedures in patients with neovascular glaucoma. Our study also did not demonstrate a significant difference in BSCVA at final follow-up between trabeculectomy and GDD implantation. Subtle changes in visual acuity may occur after both trabeculectomy and GDD implantation, as both procedures can contribute to corneal astigmatism. Additionally, trabeculectomy may induce hyperopic shift due to a shortening of the axial length by approximately 0.1–0.9 mm postoperatively [62]. Furthermore, glaucoma surgery is known to increase the incidence and progression of cataract formation [63].

In terms of safety, similar rates of serious complications were observed following both procedures. The most common complications included tube exposure or blockage in the GDD group, and bleb failure in the trabeculectomy group. However, most reported complications were transient and well manageable, highlighting the overall acceptable safety profiles of both surgical options.

Strengths and Limitations

Strengths: (1) This is the first meta-analysis to directly compare the surgical outcomes of trabeculectomy and GDDs, specifically in patients with aniridia-associated glaucoma. (2) The use of IPD for data synthesis improves the accuracy, granularity, and reliability of the findings compared to traditional aggregate-level analyses.

Limitations: (1) A primary limitation is the relatively small number of patients included in the analysis, which may limit the generalizability of the findings. (2) The absence of prospective, interventional studies among the included literature reduces the overall strength of evidence. (3) The lack of standardized guidelines for the surgical management of glaucoma in patients with aniridia introduces potential selection and reporting bias. (4) Heterogeneity in study design, patient selection criteria, baseline characteristics, implant types, definitions of success rates (see Table S5 in the electronic supplementary material for more details), and inconsistently reported outcome measures may have influenced the pooled results. (5) Patient-level analysis was not feasible, since in several cases both eyes were included in the dataset. (6) Possible aggregation bias in meta-regression analysis of effects of glaucoma surgery history or previous intraocular procedures.

Implication for Practice, Research, and Policymakers

This meta-analysis underscores the need for individualized, patient-centered approaches to the surgical management of aniridic glaucoma, taking into account patient-specific risk factors and ocular comorbidities. Clinicians should carefully weigh the risks and benefits of each surgical technique and place particular emphasis on effective postoperative monitoring and care.

Future research should prioritize large-scale, prospective studies to directly compare the long-term outcomes of different surgical strategies in this rare patient population. The development of standardized treatment protocols, along with a deeper understanding of the underlying pathophysiology of aniridia-associated glaucoma, could lead to improved therapeutic strategies and preventive measures.

Furthermore, policymakers and funding bodies can play a critical role by supporting research on rare diseases, facilitating multicenter collaborations, and developing uniform clinical guidelines, all of which are essential to improving outcomes and quality of care for individuals living with aniridia [64, 65].

CONCLUSION

With respect to complete success rates, trabeculectomy does not appear to offer a significant advantage over GDDs in the management of aniridic glaucoma. In contrast, the qualified success rate is higher following GDD implantation compared to trabeculectomy. Both procedures demonstrate comparable efficacy in terms of IOP reduction, decrease in glaucoma medication burden, and visual preservation.

Author Contribution. Gábor Tóth planned and designed the survey and wrote the manuscript. Shanhe Liu and Shuailin Li designed and conducted the survey. Péter Hegyi planned the survey and reviewed the manuscript. Szilárd Váncsa, Mátyás Paczkó, Tamás Kói, and Nóra Szentmáry planned and designed the survey, and edited and reviewed the manuscript. All

authors approve the final version of the manuscript and agree to be accountable for all aspects of the work.

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Data Availability. All data generated or analyzed during this study are included in this published article/as supplementary information files.

Declarations

Conflict of Interest. The work of Gábor Tóth, Shanhe Liu, Shuailin Li and Nóra Szentmáry at the Dr. Rolf M. Schwiete Center has been supported by the Dr. Rolf M. Schwiete Foundation. The work of Shanhe Liu and Shuailin Li has been supported by the China Scholarship Council. Szilárd Váncsa, Mátyás Paczkó, Tamás Kói and Péter Hegyi have no competing interests. Nóra Szentmáry is an Editorial Board member of *Ophthalmology and Therapy*. She was not involved in the selection of peer reviewers for this manuscript or in any subsequent editorial decisions. Szilárd Váncsa, Mátyás Paczkó, Tamás Kói, and Péter Hegyi have nothing to disclose.

Ethical Approval. No ethical approval was required for this systematic review with meta-analysis, as all data were already published in peer-reviewed journals. No patients were involved in the design, conduct or interpretation of our study. The datasets used in this study can be found in the full-text articles included in the systematic review and meta-analysis.

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